Dossier zur Nutzenbewertung gemäß § 35a SGB V

Zolbetuximab (VYLOY™)

Astellas Pharma GmbH

Modul 4 A, Anhang 4-G1

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 GLOW

Primärer Datenschnitt vom 07.10.2022

Finaler Datenschnitt vom 12.01.2024

Stand: 30.10.2024

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Anhang 4-G1 Baseline Charakteristika

Table 302.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Sex		
Male	159 (62.6%)	156 (61.7%)
Female	95 (37.4%)	97 (38.3%)
Unknown	0	0
Age (years)		
n	254	253
Mean (SD)	58.56 (12.09)	56.67 (13.04)
Median	61.0	59.0
Range	22.0 - 82.0	21.0 - 83.0
Age (years)		
>=18 to <=64	167 (65.7%)	173 (68.4%)
>=65 to <85	87 (34.3%)	80 (31.6%)
Age Group 1 (years)		
<=65	176 (69.3%)	180 (71.1%)
>65	78 (30.7%)	73 (28.9%)
Age Group 2 (years)		
<=75	242 (95.3%)	239 (94.5%)
>75	12 (4.7%)	14 (5.5%)
Race		
White	94 (37.3%)	90 (36.3%)
Black or African American	0	0
Asian	158 (62.7%)	158 (63.7%)
American Indian or Alaska Native	0	0
Native Hawaiian or Other Pacific Islander	0	0
Other	0	0
Missing	2	5

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: 07OCT22

Table 302.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Ethnicity		
Hispanic or Latino	10 (4.0%)	7 (2.8%)
Not Hispanic or Latino	242 (96.0%)	241 (97.2%)
Missing	2	5
Country 1		
Japan	24 (9.4%)	27 (10.7%)
Non-Japan	230 (90.6%)	226 (89.3%)
Country 2		
China	76 (29.9%)	69 (27.3%)
Non-China	178 (70.1%)	184 (72.7%)
Height (cm)		
n	253	250
Mean (SD)	164.66 (8.68)	165.11 (8.52)
Median	165.0	165.0
Range	145.0 - 189.0	141.5 - 189.0
Weight (kg)		
n	253	250
Mean (SD)	61.60 (13.60)	60.17 (12.73)
Median	60.5	59.6
Range	35.5 - 111.2	29.1 - 100.0
BMI (kg/m^2)		
<18.5	38 (15.0%)	42 (16.8%)
>=18.5 to <25	145 (57.3%)	154 (61.6%)
>=25 to <30	59 (23.3%)	49 (19.6%)
>=30	11 (4.3%)	5 (2.0%)
Missing	1	3

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: 07OCT22

Table 302.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
BSA (m^2)		
n	253	250
Mean (SD)	1.67 (0.20)	1.65 (0.20)
Median	1.7	1.6
Range	1.2 - 2.3	1.1 - 2.3
BSA (m^2)		
<1.7	134 (53.0%)	146 (58.4%)
>=1.7	119 (47.0%)	104 (41.6%)
Missing	1	3
Tobacco History		
Never	128 (51.2%)	132 (53.0%)
Current	32 (12.8%)	33 (13.3%)
Former	90 (36.0%)	84 (33.7%)
Missing	4	4
Baseline ECOG Status		
0	108 (42.7%)	108 (43.2%)
>=1	145 (57.3%)	142 (56.8%)
Missing	1	3
Region (IRT)		
Asia	157 (61.8%)	158 (62.5%)
Non-Asia	97 (38.2%)	95 (37.5%)
Region (eCRF)		
Asia	157 (61.8%)	158 (62.5%)
Non-Asia	97 (38.2%)	95 (37.5%)
Number of Organs with Metastatic Sites (IRT)		
0-2	189 (74.4%)	188 (74.3%)

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: 07OCT22

Table 302.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
>=3	65 (25.6%)	65 (25.7%)
Number of Organs with Metastatic Sites (eCRF)		
0-2	186 (73.2%)	186 (73.5%)
>=3	68 (26.8%)	67 (26.5%)
Prior Gastrectomy (IRT)		
Yes	75 (29.5%)	75 (29.6%)
No	179 (70.5%)	178 (70.4%)
Prior Gastrectomy (eCRF)		
Yes	73 (28.7%)	66 (26.1%)
No	181 (71.3%)	187 (73.9%)
CPS Status		
<5	129 (50.8%)	128 (50.6%)
>=5	35 (13.8%)	40 (15.8%)
Unknown	90 (35.4%)	85 (33.6%)

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: 07OCT22

Table 302.1.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Medical Condition	Gastric Adenocarcinoma	219 (86.2%)	209 (82.6%)
	Gastro-Esophageal Junction Adenocarcinoma	35 (13.8%)	44 (17.4%)
Duration Since Initial Diagnosis (days)	n	242	246
	Mean (SD)	230.17 (461.97)	243.02 (609.48)
	Median	44.0	43.5
	Range	12 - 2396	2 - 6010
Tumor Location			
All	Proximal	88 (34.6%)	94 (37.2%)
	Distal	100 (39.4%)	96 (37.9%)
	Unknown	66 (26.0%)	63 (24.9%)
Gastric	n	219	209
	Proximal	73 (33.3%)	73 (34.9%)
	Distal	90 (41.1%)	83 (39.7%)
	Unknown	56 (25.6%)	53 (25.4%)
GEJ	n	35	44
	Proximal	15 (42.9%)	21 (47.7%)
	Distal	10 (28.6%)	13 (29.5%)
	Unknown	10 (28.6%)	10 (22.7%)
Tumor Type	Diffuse	87 (34.4%)	100 (39.5%)
	Intestinal	36 (14.2%)	41 (16.2%)
	Mixed	20 (7.9%)	21 (8.3%)
	Other	34 (13.4%)	27 (10.7%)
	Unknown	76 (30.0%)	64 (25.3%)
	Missing	1	0
Primary Tumor	TX	65 (25.6%)	47 (18.6%)
	T0	1 (0.4%)	0
	Tis	0	0
	T1	1 (0.4%)	1 (0.4%)
	T1a	0	2 (0.8%)
	T1b	1 (0.4%)	2 (0.8%)
	T2	20 (7.9%)	12 (4.7%)

Parameter	Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
	T3	63 (24.8%)	63 (24.9%)
	T4	36 (14.2%)	44 (17.4%)
	T4a	47 (18.5%)	62 (24.5%)
	T4b	20 (7.9%)	20 (7.9%)
Regional Lymph Nodes	NX	82 (32.3%)	64 (25.3%)
	N0	23 (9.1%)	25 (9.9%)
	N1	48 (18.9%)	39 (15.4%)
	N2	45 (17.7%)	51 (20.2%)
	N3	31 (12.2%)	47 (18.6%)
	N3a	15 (5.9%)	14 (5.5%)
	N3b	10 (3.9%)	13 (5.1%)
Distant Metastasis [1]	M0	59 (23.3%)	56 (22.1%)
	M1	194 (76.7%)	197 (77.9%)
	Missing	1	0
Tumor Metastatic [1]	Yes	222 (87.4%)	222 (87.7%)
	No	32 (12.6%)	31 (12.3%)
Metastasis Location	Abdominal Cavity	16 (6.3%)	9 (3.6%)
	Adrenal Gland	12 (4.7%)	10 (4.0%)
	Bile Duct	0	1 (0.4%)
	Bladder	2 (0.8%)	0
	Bone	18 (7.1%)	26 (10.3%)
	Colon	7 (2.8%)	4 (1.6%)
	Esophagus	0	1 (0.4%)
	Kidney	0	1 (0.4%)
	Liver	73 (28.7%)	57 (22.5%)
	Lung	18 (7.1%)	21 (8.3%)
	Lymph Node	131 (51.6%)	119 (47.0%)
	Mediastinum	3 (1.2%)	3 (1.2%)
	Neck	0	1 (0.4%)
	Omentum	10 (3.9%)	10 (4.0%)
	Other	11 (4.3%)	19 (7.5%)
	Ovary	21 (8.3%)	21 (8.3%)
	Pancreas	0	5 (2.0%)
	Pelvis	7 (2.8%)	2 (0.8%)
	Pericardium	2 (0.8%)	1 (0.4%)
	Peritoneum	83 (32.7%)	91 (36.0%)
	Pleura	8 (3.1%)	4 (1.6%)
	Rectum	0	2 (0.8%)

Parameter	Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
	Retroperitoneum	3 (1.2%)	3 (1.2%)
	Skin	0	1 (0.4%)
	Small Intestine	3 (1.2%)	1 (0.4%)
	Spleen	1 (0.4%)	3 (1.2%)
	Stomach	5 (2.0%)	4 (1.6%)
	Testis	1 (0.4%)	0
History of Helicobacter pylori Infection	Yes	44 (17.3%)	35 (13.8%)
	No	102 (40.2%)	114 (45.1%)
	Unknown	108 (42.5%)	104 (41.1%)
Barrett's Esophagus Diagnosed	Yes	4 (1.6%)	3 (1.2%)
	No	150 (59.1%)	163 (64.4%)
	Unknown	100 (39.4%)	87 (34.4%)
CLDN18.2 Testing Result	<75%	0	0
	>=75%	254 (100.0%)	253 (100.0%)
	Not Applicable	0	0
HER2 Status	Positive	0	0
	Negative	254 (100.0%)	253 (100.0%)
	Not Applicable	0	0
Measurable Disease based on Central	Yes	195 (76.8%)	205 (81.0%)
	No	59 (23.2%)	48 (19.0%)
Measurable Disease based on Local	Yes	206 (81.1%)	209 (82.6%)
	No	48 (18.9%)	44 (17.4%)

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Overall	214 (84.3%)	214 (84.6%)	428 (84.4%)
Blood And Lymphatic System Disorders	44 (17.3%)	56 (22.1%)	100 (19.7%)
Anaemia	36 (14.2%)	54 (21.3%)	90 (17.8%)
Iron Deficiency Anaemia	3 (1.2%)	2 (0.8%)	5 (1.0%)
Hypocoagulable State	0	3 (1.2%)	3 (0.6%)
Thrombocytopenia	3 (1.2%)	0	3 (0.6%)
Lymphadenopathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Splenomegaly	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal Lymphadenopathy	0	1 (0.4%)	1 (0.2%)
Coagulopathy	0	1 (0.4%)	1 (0.2%)
Hilar Lymphadenopathy	1 (0.4%)	0	1 (0.2%)
Lymphadenopathy Mediastinal	1 (0.4%)	0	1 (0.2%)
Mastocytosis	1 (0.4%)	0	1 (0.2%)
Pernicious Anaemia	1 (0.4%)	0	1 (0.2%)
Thrombocytosis	1 (0.4%)	0	1 (0.2%)
Cardiac Disorders	27 (10.6%)	22 (8.7%)	49 (9.7%)
Coronary Artery Disease	8 (3.1%)	2 (0.8%)	10 (2.0%)
Sinus Bradycardia	6 (2.4%)	3 (1.2%)	9 (1.8%)
Atrial Fibrillation	2 (0.8%)	3 (1.2%)	5 (1.0%)
Myocardial Ischaemia	3 (1.2%)	2 (0.8%)	5 (1.0%)
Angina Pectoris	1 (0.4%)	3 (1.2%)	4 (0.8%)
Arrhythmia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Supraventricular Extrasystoles	1 (0.4%)	3 (1.2%)	4 (0.8%)
Cardiac Failure Chronic	1 (0.4%)	2 (0.8%)	3 (0.6%)
Tachycardia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Arteriosclerosis Coronary Artery	2 (0.8%)	0	2 (0.4%)
Pericardial Effusion	2 (0.8%)	0	2 (0.4%)
Aortic Valve Stenosis	0	1 (0.4%)	1 (0.2%)
Atrioventricular Block First Degree	0	1 (0.4%)	1 (0.2%)
Bradycardia	0	1 (0.4%)	1 (0.2%)
Bundle Branch Block Right	0	1 (0.4%)	1 (0.2%)
Cardiac Failure Congestive	1 (0.4%)	0	1 (0.2%)
Cardiomyopathy	1 (0.4%)	0	1 (0.2%)
Coronary Artery Occlusion	1 (0.4%)	0	1 (0.2%)
Defect Conduction Intraventricular	1 (0.4%)	0	1 (0.2%)
Left Ventricular Hypertrophy	1 (0.4%)	0	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Myocardial Hypoxia	1 (0.4%)	0	1 (0.2%)
Myocardial Injury	0	1 (0.4%)	1 (0.2%)
Prinzmetal Angina	1 (0.4%)	0	1 (0.2%)
Sinus Tachycardia	0	1 (0.4%)	1 (0.2%)
Ventricular Arrhythmia	0	1 (0.4%)	1 (0.2%)
Congenital, Familial And Genetic Disorders	7 (2.8%)	2 (0.8%)	9 (1.8%)
Thalassaemia Minor	2 (0.8%)	0	2 (0.4%)
Adrenogenital Syndrome	1 (0.4%)	0	1 (0.2%)
Albinism	1 (0.4%)	0	1 (0.2%)
Cataract Congenital	0	1 (0.4%)	1 (0.2%)
Hydrocele	1 (0.4%)	0	1 (0.2%)
Oesophageal Atresia	0	1 (0.4%)	1 (0.2%)
Polycystic Liver Disease	1 (0.4%)	0	1 (0.2%)
Retinitis Pigmentosa	1 (0.4%)	0	1 (0.2%)
Ear And Labyrinth Disorders	3 (1.2%)	1 (0.4%)	4 (0.8%)
Vertigo	2 (0.8%)	0	2 (0.4%)
Deafness	0	1 (0.4%)	1 (0.2%)
Deafness Unilateral	1 (0.4%)	0	1 (0.2%)
Endocrine Disorders	14 (5.5%)	9 (3.6%)	23 (4.5%)
Hypothyroidism	8 (3.1%)	4 (1.6%)	12 (2.4%)
Hyperthyroidism	2 (0.8%)	1 (0.4%)	3 (0.6%)
Goitre	1 (0.4%)	1 (0.4%)	2 (0.4%)
Thyroid Mass	1 (0.4%)	1 (0.4%)	2 (0.4%)
Autoimmune Thyroiditis	0	1 (0.4%)	1 (0.2%)
Hyperplasia Adrenal	1 (0.4%)	0	1 (0.2%)
Primary Hypothyroidism	1 (0.4%)	0	1 (0.2%)
Thyroid Disorder	0	1 (0.4%)	1 (0.2%)
Eye Disorders	5 (2.0%)	9 (3.6%)	14 (2.8%)
Cataract	2 (0.8%)	3 (1.2%)	5 (1.0%)
Glaucoma	2 (0.8%)	3 (1.2%)	5 (1.0%)
Age-Related Macular Degeneration	0	1 (0.4%)	1 (0.2%)
Lacrimation Increased	1 (0.4%)	0	1 (0.2%)
Narrow Anterior Chamber Angle	0	1 (0.4%)	1 (0.2%)
Optic Atrophy	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Disorders	111 (43.7%)	107 (42.3%)	218 (43.0%)
Abdominal Pain	29 (11.4%)	28 (11.1%)	57 (11.2%)
Constipation	27 (10.6%)	25 (9.9%)	52 (10.3%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Abdominal Pain Upper	21 (8.3%)	15 (5.9%)	36 (7.1%)
Abdominal Distension	15 (5.9%)	15 (5.9%)	30 (5.9%)
Gastrooesophageal Reflux Disease	12 (4.7%)	11 (4.3%)	23 (4.5%)
Nausea	9 (3.5%)	13 (5.1%)	22 (4.3%)
Dyspepsia	8 (3.1%)	9 (3.6%)	17 (3.4%)
Chronic Gastritis	8 (3.1%)	8 (3.2%)	16 (3.2%)
Dysphagia	7 (2.8%)	7 (2.8%)	14 (2.8%)
Gastric Ulcer	7 (2.8%)	6 (2.4%)	13 (2.6%)
Vomiting	5 (2.0%)	6 (2.4%)	11 (2.2%)
Ascites	5 (2.0%)	5 (2.0%)	10 (2.0%)
Haemorrhoids	4 (1.6%)	5 (2.0%)	9 (1.8%)
Diarrhoea	5 (2.0%)	1 (0.4%)	6 (1.2%)
Eructation	4 (1.6%)	2 (0.8%)	6 (1.2%)
Duodenal Ulcer	1 (0.4%)	4 (1.6%)	5 (1.0%)
Flatulence	3 (1.2%)	2 (0.8%)	5 (1.0%)
Gastritis	2 (0.8%)	3 (1.2%)	5 (1.0%)
Inguinal Hernia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Abdominal Discomfort	3 (1.2%)	0	3 (0.6%)
Abdominal Pain Lower	2 (0.8%)	1 (0.4%)	3 (0.6%)
Barrett's Oesophagus	2 (0.8%)	1 (0.4%)	3 (0.6%)
Large Intestine Polyp	2 (0.8%)	1 (0.4%)	3 (0.6%)
Regurgitation	0	3 (1.2%)	3 (0.6%)
Diverticulum Intestinal	2 (0.8%)	0	2 (0.4%)
Functional Gastrointestinal Disorder	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gastritis Erosive	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hiatus Hernia	2 (0.8%)	0	2 (0.4%)
Intestinal Obstruction	0	2 (0.8%)	2 (0.4%)
Obstruction Gastric	1 (0.4%)	1 (0.4%)	2 (0.4%)
Peptic Ulcer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Upper Gastrointestinal Haemorrhage	2 (0.8%)	0	2 (0.4%)
Abdominal Wall Mass	0	1 (0.4%)	1 (0.2%)
Bezoar	0	1 (0.4%)	1 (0.2%)
Breath Odour	1 (0.4%)	0	1 (0.2%)
Diverticulum	0	1 (0.4%)	1 (0.2%)
Dry Mouth	0	1 (0.4%)	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Dyschezia	1 (0.4%)	0	1 (0.2%)
Epigastric Discomfort	1 (0.4%)	0	1 (0.2%)
Gastric Perforation	1 (0.4%)	0	1 (0.2%)
Gastric Polyps	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Disorder	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Haemorrhage	1 (0.4%)	0	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Gastrointestinal Stenosis	0	1 (0.4%)	1 (0.2%)
Large Intestinal Obstruction	0	1 (0.4%)	1 (0.2%)
Large Intestinal Stenosis	0	1 (0.4%)	1 (0.2%)
Mallory-Weiss Syndrome	0	1 (0.4%)	1 (0.2%)
Pancreatitis Acute	0	1 (0.4%)	1 (0.2%)
Pancreatitis Chronic	0	1 (0.4%)	1 (0.2%)
Periodontal Disease	0	1 (0.4%)	1 (0.2%)
Proctalgia	1 (0.4%)	0	1 (0.2%)
Rectal Prolapse	0	1 (0.4%)	1 (0.2%)
General Disorders And Administration Site Conditions	31 (12.2%)	13 (5.1%)	44 (8.7%)
Asthenia	14 (5.5%)	3 (1.2%)	17 (3.4%)
Pain	5 (2.0%)	3 (1.2%)	8 (1.6%)
Fatigue	3 (1.2%)	3 (1.2%)	6 (1.2%)
Oedema Peripheral	4 (1.6%)	0	4 (0.8%)
Chest Pain	2 (0.8%)	1 (0.4%)	3 (0.6%)
Early Satiety	3 (1.2%)	0	3 (0.6%)
Drug Intolerance	1 (0.4%)	1 (0.4%)	2 (0.4%)
Malaise	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gait Disturbance	0	1 (0.4%)	1 (0.2%)
Mucosal Inflammation	1 (0.4%)	0	1 (0.2%)
Non-Cardiac Chest Pain	1 (0.4%)	0	1 (0.2%)
Peripheral Swelling	0	1 (0.4%)	1 (0.2%)
Hepatobiliary Disorders	20 (7.9%)	19 (7.5%)	39 (7.7%)
Hepatic Cyst	9 (3.5%)	3 (1.2%)	12 (2.4%)
Cholelithiasis	5 (2.0%)	3 (1.2%)	8 (1.6%)
Cholecystitis	1 (0.4%)	3 (1.2%)	4 (0.8%)
Gallbladder Polyp	1 (0.4%)	3 (1.2%)	4 (0.8%)
Hepatic Function Abnormal	3 (1.2%)	1 (0.4%)	4 (0.8%)
Biliary Obstruction	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hepatic Steatosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Biliary Dilatation	0	1 (0.4%)	1 (0.2%)
Hepatic Calcification	1 (0.4%)	0	1 (0.2%)
Hepatic Cirrhosis	0	1 (0.4%)	1 (0.2%)
Hepatic Cytolysis	0	1 (0.4%)	1 (0.2%)
Hepatic Failure	0	1 (0.4%)	1 (0.2%)
Hepatitis	0	1 (0.4%)	1 (0.2%)
Jaundice	0	1 (0.4%)	1 (0.2%)
Jaundice Cholestatic	0	1 (0.4%)	1 (0.2%)
Portal Vein Thrombosis	0	1 (0.4%)	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Immune System Disorders	7 (2.8%)	5 (2.0%)	12 (2.4%)
Seasonal Allergy	1 (0.4%)	4 (1.6%)	5 (1.0%)
Drug Hypersensitivity	3 (1.2%)	1 (0.4%)	4 (0.8%)
Allergy To Plants	1 (0.4%)	0	1 (0.2%)
Hypersensitivity	1 (0.4%)	0	1 (0.2%)
Sarcoidosis	1 (0.4%)	0	1 (0.2%)
Infections And Infestations	29 (11.4%)	23 (9.1%)	52 (10.3%)
Appendicitis	3 (1.2%)	4 (1.6%)	7 (1.4%)
Pneumonia	4 (1.6%)	2 (0.8%)	6 (1.2%)
Helicobacter Infection	3 (1.2%)	2 (0.8%)	5 (1.0%)
Hepatitis B	2 (0.8%)	3 (1.2%)	5 (1.0%)
Bronchitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Biliary Tract Infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Covid-19	2 (0.8%)	0	2 (0.4%)
Fungal Oesophagitis	2 (0.8%)	0	2 (0.4%)
Hepatitis A	0	2 (0.8%)	2 (0.4%)
Oral Herpes	1 (0.4%)	1 (0.4%)	2 (0.4%)
Periodontitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pulmonary Tuberculosis	2 (0.8%)	0	2 (0.4%)
Bronchiolitis	1 (0.4%)	0	1 (0.2%)
Chronic Hepatitis B	1 (0.4%)	0	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Helicobacter Gastritis	0	1 (0.4%)	1 (0.2%)
Hepatitis C	0	1 (0.4%)	1 (0.2%)
Hepatitis Viral	0	1 (0.4%)	1 (0.2%)
Myelitis	0	1 (0.4%)	1 (0.2%)
Papilloma Viral Infection	0	1 (0.4%)	1 (0.2%)
Pneumonia Legionella	0	1 (0.4%)	1 (0.2%)
Poliomyelitis	1 (0.4%)	0	1 (0.2%)
Pyelonephritis Acute	1 (0.4%)	0	1 (0.2%)
Skin Infection	1 (0.4%)	0	1 (0.2%)
Syphilis	0	1 (0.4%)	1 (0.2%)
Viral Hepatitis Carrier	0	1 (0.4%)	1 (0.2%)
Injury, Poisoning And Procedural Complications	3 (1.2%)	5 (2.0%)	8 (1.6%)
Lower Limb Fracture	0	2 (0.8%)	2 (0.4%)
Chest Injury	1 (0.4%)	0	1 (0.2%)
Fall	1 (0.4%)	0	1 (0.2%)
Head Injury	1 (0.4%)	0	1 (0.2%)
Limb Injury	0	1 (0.4%)	1 (0.2%)
Meniscus Injury	1 (0.4%)	0	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Procedural Pain	1 (0.4%)	0	1 (0.2%)
Radiation Injury	0	1 (0.4%)	1 (0.2%)
Stoma Site Pain	0	1 (0.4%)	1 (0.2%)
Upper Limb Fracture	1 (0.4%)	0	1 (0.2%)
Wrist Fracture	1 (0.4%)	0	1 (0.2%)
Investigations	24 (9.4%)	30 (11.9%)	54 (10.7%)
Weight Decreased	10 (3.9%)	8 (3.2%)	18 (3.6%)
Aspartate Aminotransferase Increased	1 (0.4%)	5 (2.0%)	6 (1.2%)
Blood Alkaline Phosphatase Increased	0	6 (2.4%)	6 (1.2%)
Blood Cholesterol Increased	4 (1.6%)	2 (0.8%)	6 (1.2%)
Blood Creatinine Increased	0	4 (1.6%)	4 (0.8%)
Alanine Aminotransferase Increased	1 (0.4%)	2 (0.8%)	3 (0.6%)
Gamma-Glutamyltransferase Increased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lymphocyte Count Decreased	1 (0.4%)	2 (0.8%)	3 (0.6%)
Arthroscopy	1 (0.4%)	0	1 (0.2%)
Blood Bilirubin Increased	1 (0.4%)	0	1 (0.2%)
Blood Fibrinogen Increased	0	1 (0.4%)	1 (0.2%)
Blood Glucose Increased	1 (0.4%)	0	1 (0.2%)
Blood Thyroid Stimulating Hormone Increased	0	1 (0.4%)	1 (0.2%)
Blood Urea Increased	0	1 (0.4%)	1 (0.2%)
Carbohydrate Antigen 19-9 Increased	1 (0.4%)	0	1 (0.2%)
Electrocardiogram Abnormal	1 (0.4%)	0	1 (0.2%)
Electrocardiogram St-T Change	1 (0.4%)	0	1 (0.2%)
Electrocardiogram T Wave Abnormal	0	1 (0.4%)	1 (0.2%)
Fibrin D Dimer Increased	0	1 (0.4%)	1 (0.2%)
Gastric Ph Decreased	0	1 (0.4%)	1 (0.2%)
Lipoprotein Increased	0	1 (0.4%)	1 (0.2%)
Neutrophil Count Decreased	1 (0.4%)	0	1 (0.2%)
Paracentesis	1 (0.4%)	0	1 (0.2%)
Platelet Count Decreased	0	1 (0.4%)	1 (0.2%)
Sars-Cov-2 Test Positive	0	1 (0.4%)	1 (0.2%)
Vitamin B12 Decreased	0	1 (0.4%)	1 (0.2%)
Vitamin D Decreased	1 (0.4%)	0	1 (0.2%)
White Blood Cell Count	0	1 (0.4%)	1 (0.2%)
Metabolism And Nutrition Disorders	78 (30.7%)	78 (30.8%)	156 (30.8%)
Decreased Appetite	24 (9.4%)	22 (8.7%)	46 (9.1%)
Diabetes Mellitus	18 (7.1%)	17 (6.7%)	35 (6.9%)
Dyslipidaemia	17 (6.7%)	16 (6.3%)	33 (6.5%)
Type 2 Diabetes Mellitus	14 (5.5%)	11 (4.3%)	25 (4.9%)
Hyperuricaemia	4 (1.6%)	6 (2.4%)	10 (2.0%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Hypoalbuminaemia	6 (2.4%)	4 (1.6%)	10 (2.0%)
Gout	2 (0.8%)	7 (2.8%)	9 (1.8%)
Hyperlipidaemia	6 (2.4%)	1 (0.4%)	7 (1.4%)
Hypoproteinaemia	3 (1.2%)	4 (1.6%)	7 (1.4%)
Malnutrition	4 (1.6%)	2 (0.8%)	6 (1.2%)
Hypercholesterolaemia	1 (0.4%)	3 (1.2%)	4 (0.8%)
Hyponatraemia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Hyperglycaemia	1 (0.4%)	2 (0.8%)	3 (0.6%)
Vitamin B12 Deficiency	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hypocalcaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Iron Deficiency	0	2 (0.8%)	2 (0.4%)
Type 1 Diabetes Mellitus	1 (0.4%)	1 (0.4%)	2 (0.4%)
Feeding Disorder	1 (0.4%)	0	1 (0.2%)
Hypertriglyceridaemia	1 (0.4%)	0	1 (0.2%)
Hypoglycaemia	1 (0.4%)	0	1 (0.2%)
Hypokalaemia	1 (0.4%)	0	1 (0.2%)
Hypouricaemia	1 (0.4%)	0	1 (0.2%)
Obesity	1 (0.4%)	0	1 (0.2%)
Vitamin D Deficiency	0	1 (0.4%)	1 (0.2%)
Musculoskeletal And Connective Tissue Disorders	31 (12.2%)	29 (11.5%)	60 (11.8%)
Back Pain	13 (5.1%)	14 (5.5%)	27 (5.3%)
Osteoarthritis	6 (2.4%)	1 (0.4%)	7 (1.4%)
Arthralgia	2 (0.8%)	4 (1.6%)	6 (1.2%)
Intervertebral Disc Protrusion	1 (0.4%)	2 (0.8%)	3 (0.6%)
Musculoskeletal Chest Pain	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pain In Extremity	0	3 (1.2%)	3 (0.6%)
Spinal Stenosis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bone Pain	2 (0.8%)	0	2 (0.4%)
Osteopenia	2 (0.8%)	0	2 (0.4%)
Rheumatoid Arthritis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dupuytren's Contracture	0	1 (0.4%)	1 (0.2%)
Fibromyalgia	1 (0.4%)	0	1 (0.2%)
Gouty Arthritis	0	1 (0.4%)	1 (0.2%)
Intervertebral Disc Degeneration	1 (0.4%)	0	1 (0.2%)
Musculoskeletal Disorder	0	1 (0.4%)	1 (0.2%)
Neck Mass	1 (0.4%)	0	1 (0.2%)
Neck Pain	0	1 (0.4%)	1 (0.2%)
Osteoporosis	0	1 (0.4%)	1 (0.2%)
Periarthritis	1 (0.4%)	0	1 (0.2%)
Psoriatic Arthropathy	0	1 (0.4%)	1 (0.2%)
Rotator Cuff Syndrome	1 (0.4%)	0	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Spinal Osteoarthritis	0	1 (0.4%)	1 (0.2%)
Spinal Pain	0	1 (0.4%)	1 (0.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	31 (12.2%)	33 (13.0%)	64 (12.6%)
Cancer Pain	5 (2.0%)	12 (4.7%)	17 (3.4%)
Uterine Leiomyoma	6 (2.4%)	4 (1.6%)	10 (2.0%)
Prostate Cancer	3 (1.2%)	1 (0.4%)	4 (0.8%)
Benign Neoplasm Of Thyroid Gland	1 (0.4%)	2 (0.8%)	3 (0.6%)
Breast Cancer	3 (1.2%)	0	3 (0.6%)
Haemangioma Of Liver	2 (0.8%)	1 (0.4%)	3 (0.6%)
Metastases To Bone	3 (1.2%)	0	3 (0.6%)
Tumour Pain	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bladder Cancer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Colorectal Adenoma	2 (0.8%)	0	2 (0.4%)
Gastric Cancer	0	2 (0.8%)	2 (0.4%)
Haemangioma	1 (0.4%)	1 (0.4%)	2 (0.4%)
Adrenal Adenoma	0	1 (0.4%)	1 (0.2%)
Adrenal Neoplasm	1 (0.4%)	0	1 (0.2%)
Benign Lung Neoplasm	1 (0.4%)	0	1 (0.2%)
Bowen's Disease	0	1 (0.4%)	1 (0.2%)
Breast Cancer In Situ	1 (0.4%)	0	1 (0.2%)
Essential Thrombocythaemia	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Tract Adenoma	1 (0.4%)	0	1 (0.2%)
Intraductal Papillary Mucinous Neoplasm	1 (0.4%)	0	1 (0.2%)
Leser-Trelat Sign	0	1 (0.4%)	1 (0.2%)
Lipoma	0	1 (0.4%)	1 (0.2%)
Lymphoma	0	1 (0.4%)	1 (0.2%)
Metastases To Peritoneum	1 (0.4%)	0	1 (0.2%)
Non-Hodgkin's Lymphoma	0	1 (0.4%)	1 (0.2%)
Oesophageal Carcinoma	0	1 (0.4%)	1 (0.2%)
Oesophageal Neoplasm	1 (0.4%)	0	1 (0.2%)
Oropharyngeal Neoplasm	1 (0.4%)	0	1 (0.2%)
Ovarian Cancer	1 (0.4%)	0	1 (0.2%)
Ovarian Epithelial Cancer	1 (0.4%)	0	1 (0.2%)
Pyogenic Granuloma	0	1 (0.4%)	1 (0.2%)
Renal Cancer	1 (0.4%)	0	1 (0.2%)
Tongue Neoplasm Benign	0	1 (0.4%)	1 (0.2%)
Nervous System Disorders	17 (6.7%)	13 (5.1%)	30 (5.9%)
Migraine	1 (0.4%)	2 (0.8%)	3 (0.6%)
Hypoaesthesia	2 (0.8%)	0	2 (0.4%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Intracranial Aneurysm	2 (0.8%)	0	2 (0.4%)
Lethargy	0	2 (0.8%)	2 (0.4%)
Neuropathy Peripheral	2 (0.8%)	0	2 (0.4%)
Restless Legs Syndrome	1 (0.4%)	1 (0.4%)	2 (0.4%)
Anosmia	1 (0.4%)	0	1 (0.2%)
Carotid Arteriosclerosis	1 (0.4%)	0	1 (0.2%)
Carotid Artery Stenosis	1 (0.4%)	0	1 (0.2%)
Cerebellar Haemorrhage	1 (0.4%)	0	1 (0.2%)
Cerebellar Stroke	0	1 (0.4%)	1 (0.2%)
Cerebral Infarction	1 (0.4%)	0	1 (0.2%)
Cerebrovascular Accident	1 (0.4%)	0	1 (0.2%)
Diabetic Neuropathy	0	1 (0.4%)	1 (0.2%)
Dizziness	1 (0.4%)	0	1 (0.2%)
Dysgeusia	1 (0.4%)	0	1 (0.2%)
Essential Tremor	1 (0.4%)	0	1 (0.2%)
Intention Tremor	0	1 (0.4%)	1 (0.2%)
Occipital Neuralgia	0	1 (0.4%)	1 (0.2%)
Optic Neuritis	0	1 (0.4%)	1 (0.2%)
Parkinson's Disease	0	1 (0.4%)	1 (0.2%)
Peripheral Sensorimotor Neuropathy	0	1 (0.4%)	1 (0.2%)
Sensory Disturbance	1 (0.4%)	0	1 (0.2%)
Subarachnoid Haemorrhage	0	1 (0.4%)	1 (0.2%)
Transient Ischaemic Attack	0	1 (0.4%)	1 (0.2%)
Vascular Headache	1 (0.4%)	0	1 (0.2%)
Pregnancy, Puerperium And Perinatal Conditions	1 (0.4%)	0	1 (0.2%)
Gestational Diabetes	1 (0.4%)	0	1 (0.2%)
Psychiatric Disorders	18 (7.1%)	23 (9.1%)	41 (8.1%)
Insomnia	8 (3.1%)	13 (5.1%)	21 (4.1%)
Anxiety	4 (1.6%)	5 (2.0%)	9 (1.8%)
Depression	4 (1.6%)	3 (1.2%)	7 (1.4%)
Sleep Disorder	1 (0.4%)	2 (0.8%)	3 (0.6%)
Adjustment Disorder	0	1 (0.4%)	1 (0.2%)
Anxiety Disorder	1 (0.4%)	0	1 (0.2%)
Bipolar Disorder	0	1 (0.4%)	1 (0.2%)
Stress	0	1 (0.4%)	1 (0.2%)
Renal And Urinary Disorders	25 (9.8%)	17 (6.7%)	42 (8.3%)
Renal Cyst	10 (3.9%)	4 (1.6%)	14 (2.8%)
Nephrolithiasis	8 (3.1%)	3 (1.2%)	11 (2.2%)
Chronic Kidney Disease	2 (0.8%)	2 (0.8%)	4 (0.8%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Hydronephrosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Renal Colic	2 (0.8%)	1 (0.4%)	3 (0.6%)
Nocturia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ureteric Dilatation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acute Kidney Injury	0	1 (0.4%)	1 (0.2%)
Bladder Hypertrophy	1 (0.4%)	0	1 (0.2%)
Calculus Bladder	1 (0.4%)	0	1 (0.2%)
Glomerulonephritis Chronic	1 (0.4%)	0	1 (0.2%)
Hypercalciuria	1 (0.4%)	0	1 (0.2%)
Hypertonic Bladder	0	1 (0.4%)	1 (0.2%)
Lower Urinary Tract Symptoms	0	1 (0.4%)	1 (0.2%)
Micturition Urgency	0	1 (0.4%)	1 (0.2%)
Pollakiuria	0	1 (0.4%)	1 (0.2%)
Pyelocaliectasis	0	1 (0.4%)	1 (0.2%)
Renal Atrophy	0	1 (0.4%)	1 (0.2%)
Renal Failure	0	1 (0.4%)	1 (0.2%)
Renal Impairment	0	1 (0.4%)	1 (0.2%)
Ureteral Wall Thickening	1 (0.4%)	0	1 (0.2%)
Reproductive System And Breast Disorders	20 (7.9%)	20 (7.9%)	40 (7.9%)
Benign Prostatic Hyperplasia	13 (5.1%)	11 (4.3%)	24 (4.7%)
Ovarian Cyst	0	4 (1.6%)	4 (0.8%)
Prostatic Calcification	2 (0.8%)	1 (0.4%)	3 (0.6%)
Prostatomegaly	1 (0.4%)	2 (0.8%)	3 (0.6%)
Breast Fibrosis	0	1 (0.4%)	1 (0.2%)
Genital Haemorrhage	1 (0.4%)	0	1 (0.2%)
Menstruation Irregular	0	1 (0.4%)	1 (0.2%)
Ovarian Mass	1 (0.4%)	0	1 (0.2%)
Ovarian Vein Thrombosis	1 (0.4%)	0	1 (0.2%)
Premature Menopause	0	1 (0.4%)	1 (0.2%)
Prostatitis	0	1 (0.4%)	1 (0.2%)
Uterine Polyp	1 (0.4%)	0	1 (0.2%)
Uterine Prolapse	1 (0.4%)	0	1 (0.2%)
Respiratory, Thoracic And Mediastinal Disorders	31 (12.2%)	28 (11.1%)	59 (11.6%)
Emphysema	6 (2.4%)	4 (1.6%)	10 (2.0%)
Asthma	5 (2.0%)	2 (0.8%)	7 (1.4%)
Chronic Obstructive Pulmonary Disease	3 (1.2%)	4 (1.6%)	7 (1.4%)
Hiccups	3 (1.2%)	4 (1.6%)	7 (1.4%)
Cough	2 (0.8%)	2 (0.8%)	4 (0.8%)
Pulmonary Mass	3 (1.2%)	1 (0.4%)	4 (0.8%)
Dyspnoea	2 (0.8%)	1 (0.4%)	3 (0.6%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Pleural Effusion	1 (0.4%)	2 (0.8%)	3 (0.6%)
Sleep Apnoea Syndrome	2 (0.8%)	1 (0.4%)	3 (0.6%)
Atelectasis	0	2 (0.8%)	2 (0.4%)
Bronchiectasis	0	2 (0.8%)	2 (0.4%)
Bronchitis Chronic	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dysphonia	2 (0.8%)	0	2 (0.4%)
Pneumothorax Spontaneous	0	2 (0.8%)	2 (0.4%)
Rhinitis Allergic	1 (0.4%)	1 (0.4%)	2 (0.4%)
Apnoea	1 (0.4%)	0	1 (0.2%)
Cystic Lung Disease	1 (0.4%)	0	1 (0.2%)
Diffuse Panbronchiolitis	1 (0.4%)	0	1 (0.2%)
Obstructive Airways Disorder	0	1 (0.4%)	1 (0.2%)
Oropharyngeal Pain	1 (0.4%)	0	1 (0.2%)
Pneumonitis	0	1 (0.4%)	1 (0.2%)
Productive Cough	1 (0.4%)	0	1 (0.2%)
Pulmonary Artery Thrombosis	0	1 (0.4%)	1 (0.2%)
Pulmonary Embolism	0	1 (0.4%)	1 (0.2%)
Skin And Subcutaneous Tissue Disorders	3 (1.2%)	11 (4.3%)	14 (2.8%)
Eczema	0	2 (0.8%)	2 (0.4%)
Eczema Asteatotic	0	2 (0.8%)	2 (0.4%)
Chronic Spontaneous Urticaria	0	1 (0.4%)	1 (0.2%)
Dermal Cyst	0	1 (0.4%)	1 (0.2%)
Dermatitis	0	1 (0.4%)	1 (0.2%)
Dermatosis	1 (0.4%)	0	1 (0.2%)
Dry Skin	1 (0.4%)	0	1 (0.2%)
Hyperhidrosis	0	1 (0.4%)	1 (0.2%)
Leukoderma	0	1 (0.4%)	1 (0.2%)
Pruritus	1 (0.4%)	0	1 (0.2%)
Seborrhoeic Dermatitis	0	1 (0.4%)	1 (0.2%)
Skin Oedema	0	1 (0.4%)	1 (0.2%)
Social Circumstances	1 (0.4%)	0	1 (0.2%)
Ex-Tobacco User	1 (0.4%)	0	1 (0.2%)
Surgical And Medical Procedures	27 (10.6%)	33 (13.0%)	60 (11.8%)
Cholecystectomy	6 (2.4%)	4 (1.6%)	10 (2.0%)
Appendicectomy	3 (1.2%)	3 (1.2%)	6 (1.2%)
Caesarean Section	0	4 (1.6%)	4 (0.8%)
Coronary Arterial Stent Insertion	2 (0.8%)	2 (0.8%)	4 (0.8%)
Gastrectomy	2 (0.8%)	2 (0.8%)	4 (0.8%)
Cataract Operation	3 (1.2%)	0	3 (0.6%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Inguinal Hernia Repair	0	3 (1.2%)	3 (0.6%)
Thyroidectomy	2 (0.8%)	1 (0.4%)	3 (0.6%)
Adenoidectomy	0	2 (0.8%)	2 (0.4%)
Amygdalotomy	0	2 (0.8%)	2 (0.4%)
Endometriosis Ablation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Knee Arthroplasty	2 (0.8%)	0	2 (0.4%)
Papilloma Excision	1 (0.4%)	1 (0.4%)	2 (0.4%)
Radical Prostatectomy	0	2 (0.8%)	2 (0.4%)
Salpingo-Oophorectomy Bilateral	2 (0.8%)	0	2 (0.4%)
Spinal Operation	0	2 (0.8%)	2 (0.4%)
Splenectomy	0	2 (0.8%)	2 (0.4%)
Tonsillectomy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Varicose Vein Operation	0	2 (0.8%)	2 (0.4%)
Abdominoplasty	1 (0.4%)	0	1 (0.2%)
Anal Fistula Repair	0	1 (0.4%)	1 (0.2%)
Ankle Operation	1 (0.4%)	0	1 (0.2%)
Bladder Neoplasm Surgery	0	1 (0.4%)	1 (0.2%)
Bone Operation	0	1 (0.4%)	1 (0.2%)
Breast Conserving Surgery	0	1 (0.4%)	1 (0.2%)
Breast Operation	1 (0.4%)	0	1 (0.2%)
Bunion Operation	1 (0.4%)	0	1 (0.2%)
Cardiac Ablation	1 (0.4%)	0	1 (0.2%)
Central Venous Catheterisation	1 (0.4%)	0	1 (0.2%)
Cyst Removal	1 (0.4%)	0	1 (0.2%)
Dermatofibroma Removal	1 (0.4%)	0	1 (0.2%)
Enterostomy	1 (0.4%)	0	1 (0.2%)
Female Sterilisation	0	1 (0.4%)	1 (0.2%)
Gastric Stent Insertion	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Tube Insertion	0	1 (0.4%)	1 (0.2%)
Hepatectomy	1 (0.4%)	0	1 (0.2%)
Hernia Repair	0	1 (0.4%)	1 (0.2%)
Hip Surgery	0	1 (0.4%)	1 (0.2%)
Intestinal Adhesion Lysis	0	1 (0.4%)	1 (0.2%)
Jejunostomy	1 (0.4%)	0	1 (0.2%)
Knee Operation	1 (0.4%)	0	1 (0.2%)
Ligament Operation	1 (0.4%)	0	1 (0.2%)
Mastectomy	1 (0.4%)	0	1 (0.2%)
Meniscus Operation	0	1 (0.4%)	1 (0.2%)
Meniscus Removal	1 (0.4%)	0	1 (0.2%)
Nephrostomy	1 (0.4%)	0	1 (0.2%)
Oesophageal Fistula Repair	0	1 (0.4%)	1 (0.2%)
Oesophagogastric Fundoplasty	0	1 (0.4%)	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Omentectomy	1 (0.4%)	0	1 (0.2%)
Orchidectomy	0	1 (0.4%)	1 (0.2%)
Peritoneal Lavage	1 (0.4%)	0	1 (0.2%)
Peritonectomy	1 (0.4%)	0	1 (0.2%)
Prophylaxis Of Nausea And Vomiting	0	1 (0.4%)	1 (0.2%)
Prostatectomy	1 (0.4%)	0	1 (0.2%)
Prostatic Operation	0	1 (0.4%)	1 (0.2%)
Renal Stone Removal	1 (0.4%)	0	1 (0.2%)
Rhinoplasty	1 (0.4%)	0	1 (0.2%)
Salpingo-Oophorectomy Unilateral	1 (0.4%)	0	1 (0.2%)
Sinus Operation	0	1 (0.4%)	1 (0.2%)
Stent Placement	1 (0.4%)	0	1 (0.2%)
Umbilical Hernia Repair	0	1 (0.4%)	1 (0.2%)
Urinary Incontinence Surgery	1 (0.4%)	0	1 (0.2%)
Vascular Disorders	77 (30.3%)	58 (22.9%)	135 (26.6%)
Hypertension	68 (26.8%)	55 (21.7%)	123 (24.3%)
Aortic Arteriosclerosis	4 (1.6%)	0	4 (0.8%)
Varicose Vein	3 (1.2%)	0	3 (0.6%)
Peripheral Venous Disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Angiopathy	1 (0.4%)	0	1 (0.2%)
Deep Vein Thrombosis	1 (0.4%)	0	1 (0.2%)
Essential Hypertension	1 (0.4%)	0	1 (0.2%)
Hypotension	1 (0.4%)	0	1 (0.2%)
Leriche Syndrome	0	1 (0.4%)	1 (0.2%)
Subclavian Vein Thrombosis	1 (0.4%)	0	1 (0.2%)
Thrombosis	0	1 (0.4%)	1 (0.2%)
Venous Thrombosis	1 (0.4%)	0	1 (0.2%)
Venous Thrombosis Limb	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
ASTELLAS Data Cutoff Date: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022

Anhang 4-G1 Gesamtüberleben und Progressionsfreies Überleben

Anhang 4-G1 Gesamtüberleben

1. Time-to-Event-Analyse

Table 302.1.1002.1.1: Summary of Overall Survival - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	144 (56.7%)	174 (68.8%)	
Number of patients censored	110 (43.3%)	79 (31.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	14.4 [12.3, 16.5]	12.2 [10.3, 13.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.771 [0.615, 0.965]
Log-rank test			
Two-sided stratified log-rank p-value			0.0236

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: 07OCT22

Table 302.1.1002.1.2: Type of Events and Censoring of Overall Survival - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Number of patients at risk	254 (100.0%)	253 (100.0%)
Number of patients with events	144 (56.7%)	174 (68.8%)
Death Before Analysis Cutoff Date	144 (56.7%)	174 (68.8%)
Number of patients censored	110 (43.3%)	79 (31.2%)
Last Known Alive Date Is Before Cutoff Date	94 (37.0%)	68 (26.9%)
Censored At Cutoff Date	16 (6.3%)	11 (4.3%)

Abbreviations: N=number of patients.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.1002.1.3: Summary of Overall Survival by Subgroups - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	92 (52.3)	14.5 [12.4, 17.6]	180	127 (70.6)	11.8 [9.3, 13.2]	0.664 [0.507, 0.869]	0.0027	0.1110
>65 years	78	52 (66.7)	14.4 [9.1, 17.4]	73	47 (64.4)	12.9 [9.8, 16.6]	0.951 [0.637, 1.420]	0.8107	
Age Group 2									
<=75 years	242	137 (56.6)	14.3 [12.0, 16.4]	239	164 (68.6)	12.1 [9.9, 13.2]	0.755 [0.602, 0.948]	0.0153	0.8839
>75 years	12	7 (58.3)	16.5 [2.7, 30.1]	14	10 (71.4)	17.4 [5.1, 17.7]	0.544 [0.183, 1.617]	0.2802	
Sex									
Male	159	94 (59.1)	13.1 [10.3, 16.4]	156	114 (73.1)	11.5 [8.9, 13.2]	0.779 [0.593, 1.025]	0.0731	0.7683
Female	95	50 (52.6)	16.5 [13.1, 19.4]	97	60 (61.9)	13.2 [9.9, 15.4]	0.722 [0.494, 1.054]	0.0914	
Race									
White	94	53 (56.4)	13.3 [10.8, 18.2]	90	60 (66.7)	13.7 [11.0, 17.4]	0.891 [0.615, 1.291]	0.5439	0.2603
Asian	158	89 (56.3)	15.5 [12.4, 17.6]	158	110 (69.6)	11.2 [9.3, 13.2]	0.678 [0.512, 0.898]	0.0065	
Tobacco History									
Current	32	20 (62.5)	12.3 [9.3, 21.7]	33	21 (63.6)	15.0 [9.3, 19.4]	1.006 [0.541, 1.873]	0.9848	0.4323
Former	90	52 (57.8)	14.3 [10.8, 17.8]	84	59 (70.2)	11.9 [9.7, 14.5]	0.793 [0.545, 1.154]	0.2281	
Never	128	71 (55.5)	14.5 [12.1, 18.4]	132	93 (70.5)	11.2 [8.7, 13.9]	0.656 [0.481, 0.895]	0.0074	
Region									
Asia	157	88 (56.1)	15.5 [12.5, 17.8]	158	110 (69.6)	11.2 [9.3, 13.2]	0.674 [0.508, 0.893]	0.0058	0.2247
Non-Asia	97	56 (57.7)	12.6 [10.3, 17.2]	95	64 (67.4)	13.3 [9.2, 16.0]	0.903 [0.630, 1.294]	0.5794	
Number of Organs with Metastatic Sites									
0-2	189	100 (52.9)	16.4 [13.6, 18.4]	188	126 (67.0)	12.9 [11.0, 14.8]	0.708 [0.544, 0.922]	0.0099	0.3577
>=3	65	44 (67.7)	11.1 [8.1, 12.6]	65	48 (73.8)	9.9 [7.5, 13.2]	0.903 [0.598, 1.362]	0.6275	
Prior Gastrectomy (total or partial)									
Yes	75	35 (46.7)	18.8 [11.4, 29.3]	75	49 (65.3)	12.6 [9.1, 17.3]	0.632 [0.408, 0.982]	0.0394	0.3938
No	179	109 (60.9)	13.6 [11.9, 15.7]	178	125 (70.2)	11.9 [9.8, 13.9]	0.804 [0.622, 1.040]	0.0968	

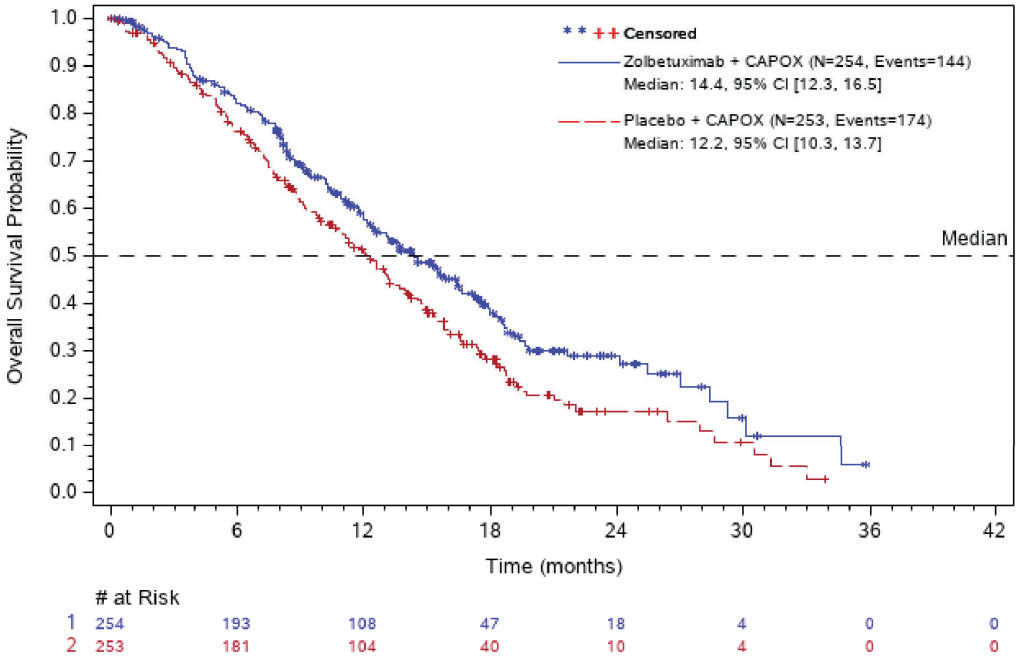
	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Histology (Tumor Type)									
Diffuse	87	44 (50.6)	14.3 [12.0, 18.6]	100	63 (63.0)	12.6 [9.1, 15.4]	0.726 [0.493, 1.069]	0.1047	0.5833
Intestinal	36	23 (63.9)	17.8 [12.3, 25.5]	41	30 (73.2)	12.6 [8.3, 17.3]	0.702 [0.403, 1.222]	0.2111	
Mixed/Other	54	36 (66.7)	11.7 [8.7, 17.4]	48	37 (77.1)	13.3 [11.5, 16.0]	0.945 [0.594, 1.502]	0.8078	
Tumor Location 1									
Gastric	219	124 (56.6)	14.5 [12.3, 17.2]	209	146 (69.9)	12.1 [9.9, 13.7]	0.718 [0.565, 0.913]	0.0066	0.2839
GEJ	35	20 (57.1)	13.1 [9.4, 17.9]	44	28 (63.6)	12.3 [9.2, 16.6]	1.013 [0.563, 1.823]	0.9627	
Tumor Location 2									
Gastric Proximal	73	42 (57.5)	15.2 [12.0, 17.8]	73	51 (69.9)	10.9 [8.3, 14.7]	0.680 [0.450, 1.025]	0.0647	0.5455
Gastric Distal	90	51 (56.7)	13.6 [10.1, 16.5]	83	56 (67.5)	12.9 [9.9, 15.0]	0.819 [0.560, 1.198]	0.3046	
Tumor Location 3									
GEJ Proximal	15	7 (46.7)	17.9 [8.3, 34.6]	21	13 (61.9)	11.9 [6.8, 18.7]	0.575 [0.216, 1.531]	0.2623	0.1506
GEJ Distal	10	6 (60.0)	13.1 [3.6, NC]	13	8 (61.5)	15.3 [8.9, NC]	1.663 [0.565, 4.897]	0.3516	

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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G1 Gesamtüberleben

2. Kaplan-Meier-Plots

Figure 302.1.1002.1: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G1 Progressionsfreies Überleben (IRC und INV)

1. Time-to-Event-Analysen

Table 302.1.1002.2.1: Summary of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	137 (53.9%)	172 (68.0%)	
Number of patients censored	117 (46.1%)	81 (32.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.2 [7.5, 8.8]	6.8 [6.1, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.687 [0.544, 0.866]
Log-rank test			
Two-sided stratified log-rank p-value			0.0014

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: 07OCT22

Table 302.1.1002.2.2: Type of Events and Censoring of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Number of patients at risk	254 (100.0%)	253 (100.0%)
Number of patients with events	137 (53.9%)	172 (68.0%)
rPD	77 (30.3%)	103 (40.7%)
No rPD, but death recorded on eCRF	60 (23.6%)	69 (27.3%)
Number of patients censored	117 (46.1%)	81 (32.0%)

Abbreviations: eCRF=electronic case report form; IRC=independent review committee; N=number of patients; rPD=radiological progressive disease.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.1002.2.3: Summary of Progression-Free Survival (IRC) by Subgroups - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	92 (52.3)	8.3 [7.9, 10.3]	180	130 (72.2)	6.4 [6.1, 8.1]	0.606 [0.463, 0.794]	0.0002	0.0561
>65 years	78	45 (57.7)	7.1 [6.1, 9.2]	73	42 (57.5)	8.2 [6.0, 10.3]	0.917 [0.596, 1.410]	0.6945	
Age Group 2									
<=75 years	242	134 (55.4)	8.2 [7.1, 8.5]	239	165 (69.0)	6.5 [6.1, 8.1]	0.698 [0.554, 0.879]	0.0021	0.6602
>75 years	12	3 (25.0)	NC [1.1, NC]	14	7 (50.0)	10.3 [4.1, 14.2]	0.435 [0.111, 1.713]	0.2242	
Sex									
Male	159	92 (57.9)	8.2 [7.1, 8.8]	156	110 (70.5)	6.3 [6.0, 7.7]	0.679 [0.513, 0.898]	0.0064	0.8822
Female	95	45 (47.4)	8.3 [6.4, 12.7]	97	62 (63.9)	8.1 [6.5, 8.5]	0.700 [0.474, 1.035]	0.0729	
Race									
White	94	52 (55.3)	8.0 [6.4, 8.4]	90	58 (64.4)	8.1 [6.3, 8.7]	0.918 [0.629, 1.339]	0.6571	0.0681
Asian	158	83 (52.5)	8.4 [7.3, 10.4]	158	109 (69.0)	6.3 [6.0, 8.0]	0.587 [0.440, 0.785]	0.0003	
Tobacco History									
Current	32	20 (62.5)	8.1 [6.1, 9.3]	33	24 (72.7)	8.0 [4.3, 8.4]	0.742 [0.404, 1.362]	0.3380	0.8903
Former	90	43 (47.8)	8.5 [6.5, 12.0]	84	61 (72.6)	6.5 [6.1, 8.2]	0.622 [0.418, 0.927]	0.0193	
Never	128	73 (57.0)	8.3 [6.4, 9.2]	132	87 (65.9)	6.5 [5.3, 8.3]	0.684 [0.499, 0.938]	0.0171	
Region									
Asia	157	82 (52.2)	8.5 [7.3, 10.4]	158	109 (69.0)	6.3 [6.0, 8.0]	0.583 [0.436, 0.781]	0.0002	0.0526
Non-Asia	97	55 (56.7)	8.0 [6.2, 8.4]	95	63 (66.3)	8.1 [6.3, 8.7]	0.928 [0.645, 1.336]	0.6892	
Number of Organs with Metastatic Sites									
0-2	189	97 (51.3)	8.3 [7.8, 10.4]	188	125 (66.5)	7.7 [6.3, 8.2]	0.691 [0.529, 0.904]	0.0066	0.9765
>=3	65	40 (61.5)	7.9 [6.1, 8.8]	65	47 (72.3)	6.0 [4.1, 8.0]	0.682 [0.445, 1.045]	0.0779	
Prior Gastrectomy (total or partial)									
Yes	75	40 (53.3)	8.3 [6.2, 15.5]	75	47 (62.7)	7.8 [6.0, 8.3]	0.726 [0.472, 1.114]	0.1394	0.9539
No	179	97 (54.2)	8.2 [7.3, 8.8]	178	125 (70.2)	6.5 [6.0, 8.1]	0.696 [0.533, 0.909]	0.0075	

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [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	87	38 (43.7)	10.4 [7.9, 15.2]	100	60 (60.0)	8.1 [6.4, 8.8]	0.620 [0.411, 0.936]	0.0217	0.8622
Intestinal	36	21 (58.3)	8.1 [6.1, 17.8]	41	26 (63.4)	6.1 [5.8, 8.3]	0.675 [0.375, 1.217]	0.1932	
Mixed/Other	54	28 (51.9)	7.5 [4.2, 8.8]	48	36 (75.0)	6.4 [5.3, 8.5]	0.824 [0.499, 1.358]	0.4477	
Tumor Location 1									
Gastric	219	116 (53.0)	8.3 [7.9, 9.4]	209	149 (71.3)	6.4 [6.0, 8.1]	0.619 [0.484, 0.791]	0.0001	0.0094
GEJ	35	21 (60.0)	6.2 [4.2, 8.4]	44	23 (52.3)	9.2 [6.4, 10.4]	1.351 [0.731, 2.496]	0.3414	
Tumor Location 2									
Gastric Proximal	73	40 (54.8)	9.1 [7.9, 12.1]	73	53 (72.6)	6.5 [4.4, 8.3]	0.561 [0.370, 0.850]	0.0058	0.3075
Gastric Distal	90	46 (51.1)	7.5 [6.1, 9.4]	83	55 (66.3)	6.3 [5.2, 8.3]	0.805 [0.542, 1.194]	0.2801	
Tumor Location 3									
GEJ Proximal	15	9 (60.0)	6.2 [4.2, 23.3]	21	11 (52.4)	6.2 [4.3, 10.2]	0.867 [0.345, 2.182]	0.7584	0.2051
GEJ Distal	10	4 (40.0)	8.1 [2.2, NC]	13	9 (69.2)	10.4 [6.4, 15.8]	2.614 [0.632, 10.816]	0.1699	

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.
[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: 07OCT22

Table 302.1.1002.3.1: Summary of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	158 (62.2%)	200 (79.1%)	
Number of patients censored	96 (37.8%)	53 (20.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.8 [6.3, 8.3]	6.1 [5.4, 6.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.678 [0.546, 0.841]
Log-rank test			
Two-sided stratified log-rank p-value			0.0004

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: 07OCT22

Table 302.1.1002.3.2: Type of Events and Censoring of Progression-Free Survival (INV) - Full Analysis Set

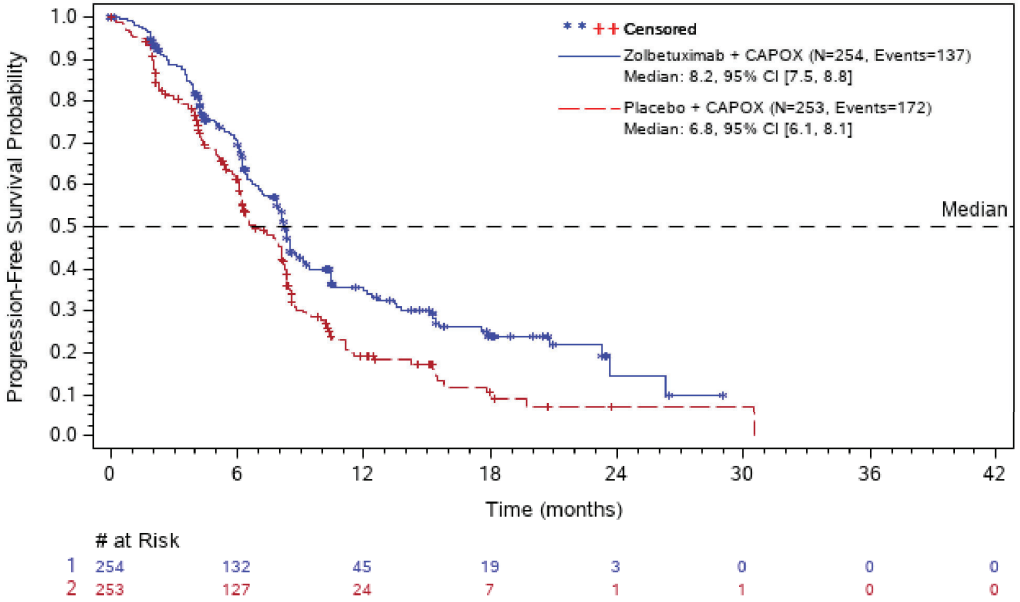
	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Number of patients at risk	254 (100.0%)	253 (100.0%)
Number of patients with events	158 (62.2%)	200 (79.1%)
rPD	113 (44.5%)	163 (64.4%)
No rPD, but death recorded on eCRF	45 (17.7%)	37 (14.6%)
Number of patients censored	96 (37.8%)	53 (20.9%)

Abbreviations: eCRF= electronic case report form; INV=investigator; N=number of patients; rPD=radiological progressive disease.
ASTELLAS Data Cutoff Date: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G1 Progressionsfreies Überleben (IRC und INV)

2. Kaplan-Meier-Plots

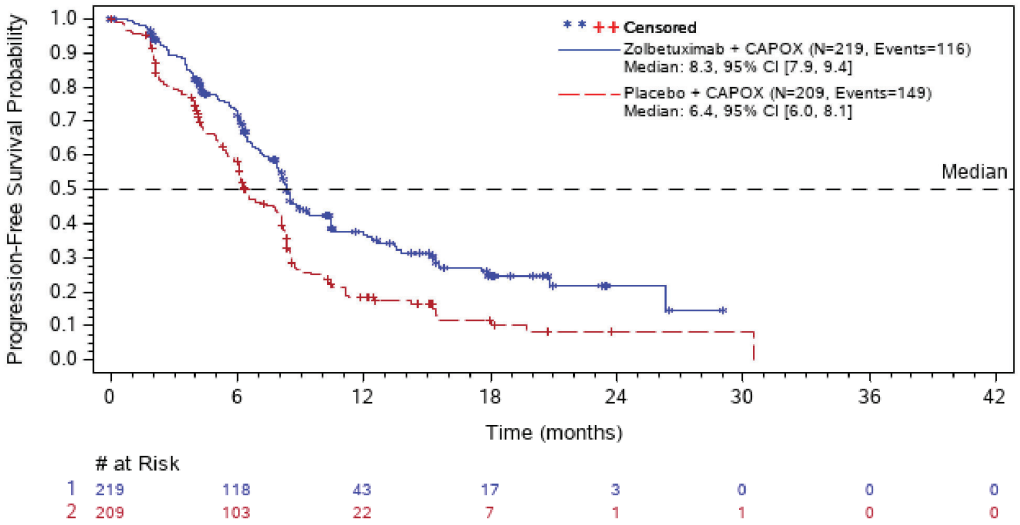
Figure 302.1.1002.2: Kaplan-Meier Plot of Progression-Free Survival (IRC) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; IRC=independent review committee; N=number of patients.
ASTELLAS Data Cutoff Date: 07OCT22

Figure 302.1.1002.2.10: Kaplan-Meier Plot of Progression-Free Survival (IRC) by Tumor Location 1 - Full Analysis Set

Tumor Location 1: Gastric



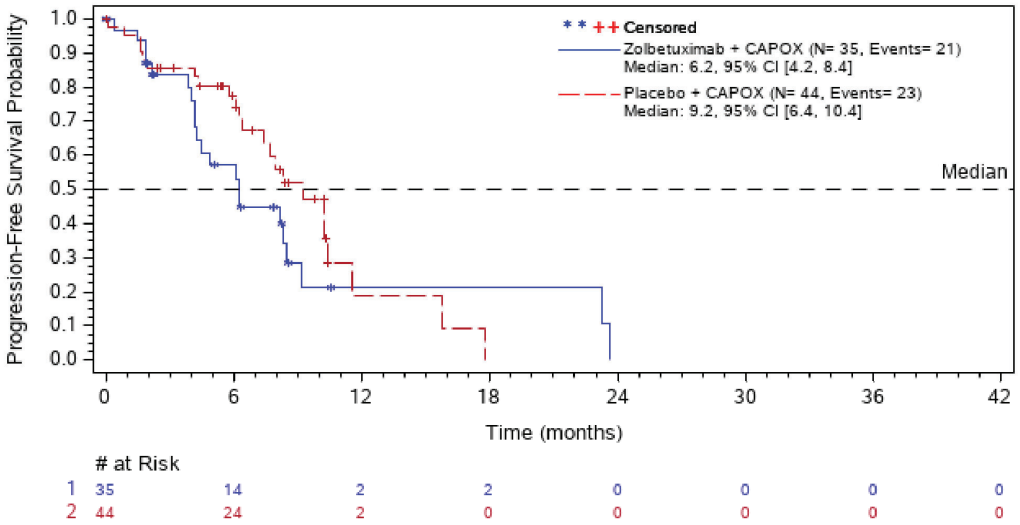
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; GEJ=gastro-esophageal junction; IRC=independent review committee; N=number of patients.

Figure was provided if interaction p-value of subgroup from corresponding summary of time to Progression Free Survival (IRC) was significant (p<0.05).

ASTELLAS Data Cutoff Date: 07OCT22

Figure 302.1.1002.2.10: Kaplan-Meier Plot of Progression-Free Survival (IRC) by Tumor Location 1 - Full Analysis Set

Tumor Location 1: GEJ

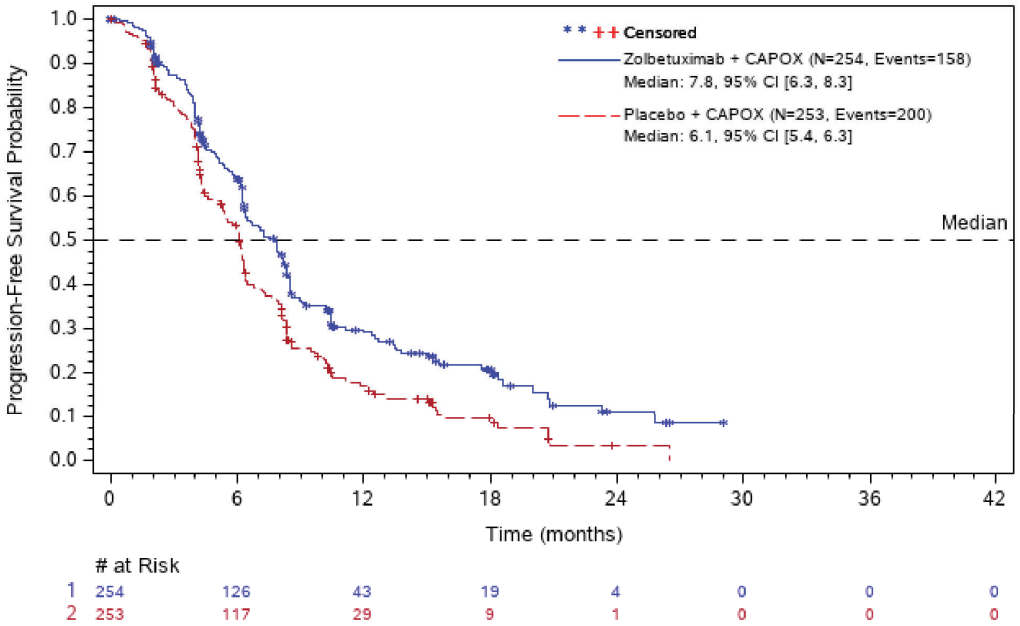


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; GEJ=gastro-esophageal junction; IRC=independent review committee; N=number of patients.

Figure was provided if interaction p-value of subgroup from corresponding summary of time to Progression Free Survival (IRC) was significant (p<0.05).

ASTELLAS Data Cutoff Date: 07OCT22

Figure 302.1.1002.3: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022

Anhang 4-G1 Patientenberichtete Endpunkte

Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

1. Rücklaufquoten

Table 302.1.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/223 (83.4%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/202 (60.4%)	122/254 (48.0%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	155/213 (72.8%)	155/231 (67.1%)	155/253 (61.3%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

Table 302.1.3002.5: 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 + CAPOX (N=254)												
Baseline	242	68.84	18.98	0.0	66.67	100.0						
Cycle 2 Day 1	209	69.06	17.50	0.0	66.67	100.0	208	0.04	17.35	-83.3	0.00	58.3
Cycle 3 Day 1	187	70.99	17.18	0.0	66.67	100.0	182	1.47	17.15	-66.7	0.00	58.3
Cycle 4 Day 1	172	72.14	17.44	8.3	79.17	100.0	169	2.61	18.79	-50.0	0.00	75.0
Cycle 5 Day 1	162	70.42	20.48	0.0	75.00	100.0	159	0.89	20.96	-91.7	0.00	75.0
Cycle 6 Day 1	151	71.08	19.93	0.0	75.00	100.0	149	0.84	19.32	-83.3	0.00	58.3
Cycle 7 Day 1	122	73.22	16.29	16.7	83.33	100.0	120	1.94	18.29	-50.0	0.00	66.7
Cycle 8 Day 1	114	73.17	18.14	0.0	79.17	100.0	108	0.77	16.96	-50.0	0.00	50.0
Cycle 9 Day 1	107	72.98	17.16	16.7	75.00	100.0	102	1.88	20.91	-50.0	0.00	83.3
Cycle 10 Day 1	88	74.15	18.00	25.0	83.33	100.0	85	2.65	20.38	-41.7	0.00	75.0
Cycle 11 Day 1	83	74.60	16.04	41.7	83.33	100.0	80	1.25	22.03	-41.7	0.00	75.0
Cycle 12 Day 1	76	75.88	18.79	0.0	83.33	100.0	74	2.48	23.60	-83.3	0.00	75.0
Cycle 13 Day 1	62	77.02	16.37	41.7	83.33	100.0	60	3.47	24.22	-41.7	0.00	91.7
Cycle 14 Day 1	56	76.93	14.91	41.7	83.33	100.0	54	1.54	18.25	-33.3	0.00	50.0
Cycle 15 Day 1	51	77.61	16.37	33.3	83.33	100.0	49	3.06	22.99	-33.3	0.00	91.7
Cycle 16 Day 1	46	76.63	15.87	33.3	83.33	100.0	44	3.22	23.52	-41.7	0.00	75.0
Cycle 17 Day 1	41	79.67	13.70	50.0	83.33	100.0	39	6.20	20.12	-33.3	0.00	58.3
Cycle 18 Day 1	37	79.05	13.41	50.0	83.33	100.0	35	4.76	22.44	-33.3	0.00	75.0
Cycle 19 Day 1	37	80.18	14.21	50.0	83.33	100.0	35	4.76	17.88	-33.3	0.00	41.7
Cycle 20 Day 1	35	77.38	15.86	25.0	83.33	100.0	33	1.77	18.37	-25.0	0.00	41.7
Cycle 21 Day 1	32	79.17	14.82	41.7	83.33	100.0	30	3.89	19.54	-25.0	0.00	50.0
Cycle 22 Day 1	30	80.00	16.61	50.0	83.33	100.0	28	4.17	20.48	-33.3	0.00	50.0
Cycle 23 Day 1	28	81.25	14.98	50.0	83.33	100.0	26	4.49	17.83	-25.0	0.00	50.0
Cycle 24 Day 1	25	79.00	14.26	50.0	83.33	100.0	23	2.17	20.75	-33.3	0.00	50.0
Cycle 25 Day 1	23	78.99	15.26	50.0	83.33	100.0	21	1.98	20.73	-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: 07OCT22

Table 302.1.3002.5: 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 26 Day 1	22	81.06	12.91	50.0	83.33	100.0	20	4.17	16.99	-16.7	0.00	33.3
Cycle 27 Day 1	20	80.00	18.42	50.0	83.33	100.0	18	4.63	19.64	-16.7	0.00	50.0
Cycle 28 Day 1	11	86.36	12.51	66.7	83.33	100.0	9	1.85	17.57	-16.7	0.00	33.3
Cycle 29 Day 1	12	84.72	11.14	66.7	83.33	100.0	10	3.33	15.32	-16.7	0.00	33.3
Study Disc 1	124	62.50	22.75	0.0	66.67	100.0	122	-8.74	24.45	-100.0	0.00	50.0
30 D SFU Z/P	52	65.87	24.32	0.0	66.67	100.0	51	-7.35	25.09	-75.0	0.00	50.0
90 D SFU Z/P	48	71.53	19.66	0.0	66.67	100.0	47	-5.67	22.66	-83.3	0.00	50.0
Placebo + CAPOX (N=253)												
Baseline	242	66.15	19.40	0.0	66.67	100.0						
Cycle 2 Day 1	222	69.71	17.70	0.0	66.67	100.0	217	2.96	18.89	-100.0	0.00	50.0
Cycle 3 Day 1	200	70.12	18.96	8.3	66.67	100.0	197	3.68	20.69	-83.3	0.00	58.3
Cycle 4 Day 1	171	71.54	17.02	8.3	66.67	100.0	169	4.54	20.59	-58.3	0.00	58.3
Cycle 5 Day 1	166	70.48	18.18	0.0	70.83	100.0	165	3.48	19.57	-50.0	0.00	58.3
Cycle 6 Day 1	147	71.83	17.83	0.0	75.00	100.0	146	3.94	20.51	-58.3	0.00	58.3
Cycle 7 Day 1	127	69.69	17.62	33.3	66.67	100.0	126	2.12	19.69	-50.0	0.00	58.3
Cycle 8 Day 1	111	71.10	18.83	0.0	75.00	100.0	110	4.32	20.31	-50.0	0.00	66.7
Cycle 9 Day 1	104	72.04	16.74	33.3	66.67	100.0	103	3.32	20.89	-50.0	0.00	66.7
Cycle 10 Day 1	81	73.15	16.56	33.3	66.67	100.0	79	3.48	22.23	-50.0	0.00	66.7
Cycle 11 Day 1	72	72.57	17.72	25.0	75.00	100.0	71	3.99	23.18	-50.0	0.00	75.0
Cycle 12 Day 1	59	73.45	18.60	33.3	75.00	100.0	57	2.63	22.06	-50.0	0.00	75.0
Cycle 13 Day 1	47	72.16	17.83	25.0	75.00	100.0	45	2.59	21.01	-41.7	0.00	58.3
Cycle 14 Day 1	44	75.38	20.57	16.7	83.33	100.0	42	3.37	21.55	-66.7	0.00	50.0
Cycle 15 Day 1	36	74.77	22.76	8.3	83.33	100.0	34	1.96	21.42	-66.7	0.00	58.3
Cycle 16 Day 1	32	76.82	21.14	0.0	83.33	100.0	30	4.72	16.91	-25.0	0.00	41.7
Cycle 17 Day 1	26	75.96	18.76	33.3	83.33	100.0	24	2.08	19.85	-33.3	0.00	58.3
Cycle 18 Day 1	21	77.78	22.87	0.0	83.33	100.0	20	2.92	31.79	-100.0	4.17	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: 07OCT22

Table 302.1.3002.5: 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 19 Day 1	20	85.83	13.27	50.0	83.33	100.0	19	8.33	13.32	-8.3	0.00	41.7
Cycle 20 Day 1	17	79.41	15.62	50.0	83.33	100.0	16	3.12	19.45	-33.3	0.00	58.3
Cycle 21 Day 1	18	79.63	18.35	50.0	83.33	100.0	17	2.94	19.75	-16.7	0.00	66.7
Cycle 22 Day 1	15	81.11	14.25	50.0	83.33	100.0	14	8.33	21.68	-16.7	0.00	58.3
Cycle 23 Day 1	12	80.56	13.91	50.0	83.33	100.0	11	10.61	23.30	-16.7	0.00	66.7
Study Disc 1	150	53.78	23.58	0.0	50.00	100.0	145	-13.05	22.46	-83.3	-8.33	41.7
30 D SFU Z/P	76	57.02	22.36	0.0	50.00	100.0	74	-11.15	24.88	-83.3	-8.33	41.7
90 D SFU Z/P	70	61.67	22.45	0.0	66.67	100.0	68	-4.53	23.24	-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: 07OCT22

Table 302.1.3002.6: 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 + CAPOX (N=254)												
Baseline	242	83.72	16.85	13.3	86.67	100.0						
Cycle 2 Day 1	209	83.09	17.53	0.0	86.67	100.0	208	-0.93	14.62	-60.0	0.00	40.0
Cycle 3 Day 1	187	82.50	17.93	0.0	86.67	100.0	182	-1.76	14.13	-66.7	0.00	40.0
Cycle 4 Day 1	172	84.07	17.08	13.3	86.67	100.0	169	-0.16	14.25	-53.3	0.00	33.3
Cycle 5 Day 1	162	83.54	16.90	6.7	86.67	100.0	159	-0.67	15.32	-46.7	0.00	46.7
Cycle 6 Day 1	151	83.00	18.68	6.7	86.67	100.0	149	-0.89	15.47	-53.3	0.00	40.0
Cycle 7 Day 1	122	82.46	18.78	6.7	86.67	100.0	120	-1.78	16.05	-80.0	0.00	46.7
Cycle 8 Day 1	114	82.40	17.09	13.3	86.67	100.0	108	-3.27	15.51	-33.3	0.00	60.0
Cycle 9 Day 1	107	81.81	19.42	0.0	86.67	100.0	102	-3.20	17.84	-66.7	0.00	46.7
Cycle 10 Day 1	88	82.58	19.51	0.0	86.67	100.0	85	-2.75	17.13	-66.7	0.00	46.7
Cycle 11 Day 1	83	86.27	12.94	40.0	86.67	100.0	80	-0.83	15.09	-33.3	0.00	46.7
Cycle 12 Day 1	76	86.32	12.55	46.7	86.67	100.0	74	-0.90	17.42	-26.7	0.00	46.7
Cycle 13 Day 1	62	85.81	11.03	60.0	86.67	100.0	60	-0.56	18.59	-33.3	0.00	60.0
Cycle 14 Day 1	56	86.90	12.19	60.0	86.67	100.0	54	0.12	16.10	-26.7	0.00	46.7
Cycle 15 Day 1	51	87.58	12.93	60.0	93.33	100.0	49	0.41	14.49	-20.0	0.00	40.0
Cycle 16 Day 1	46	85.94	11.78	53.3	86.67	100.0	44	-0.76	15.37	-26.7	0.00	40.0
Cycle 17 Day 1	41	89.59	12.48	53.3	93.33	100.0	39	1.54	14.94	-26.7	0.00	53.3
Cycle 18 Day 1	37	85.95	12.15	60.0	86.67	100.0	35	-2.10	13.79	-20.0	0.00	33.3
Cycle 19 Day 1	37	88.29	12.51	53.3	93.33	100.0	35	0.57	10.77	-13.3	0.00	33.3
Cycle 20 Day 1	35	86.86	12.78	53.3	86.67	100.0	33	-1.82	12.50	-20.0	0.00	33.3
Cycle 21 Day 1	32	87.71	12.11	60.0	86.67	100.0	30	-1.78	12.62	-26.7	0.00	33.3
Cycle 22 Day 1	30	89.33	13.52	53.3	93.33	100.0	28	-0.48	12.16	-20.0	0.00	26.7
Cycle 23 Day 1	28	90.95	10.77	60.0	96.67	100.0	26	0.00	15.43	-20.0	0.00	53.3
Cycle 24 Day 1	25	91.47	9.91	66.7	93.33	100.0	23	1.45	15.69	-20.0	0.00	53.3
Cycle 25 Day 1	23	90.14	13.01	60.0	100.00	100.0	21	0.00	19.66	-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: 07OCT22

Table 302.1.3002.6: 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 26 Day 1	22	91.82	10.48	66.7	96.67	100.0	20	1.33	19.30	-26.7	0.00	66.7
Cycle 27 Day 1	20	90.33	11.54	66.7	93.33	100.0	18	0.74	18.42	-26.7	0.00	60.0
Cycle 28 Day 1	11	89.09	14.69	60.0	100.00	100.0	9	-0.74	22.72	-26.7	0.00	46.7
Cycle 29 Day 1	12	93.33	10.64	66.7	100.00	100.0	10	3.33	23.99	-33.3	3.33	60.0
Study Disc 1	124	75.05	24.94	0.0	83.33	100.0	122	-10.66	22.98	-100.0	-6.67	46.7
30 D SFU Z/P	52	78.59	20.80	6.7	80.00	100.0	51	-7.06	22.21	-66.7	0.00	46.7
90 D SFU Z/P	48	79.86	20.09	6.7	80.00	100.0	47	-9.36	21.20	-86.7	-6.67	33.3
Placebo + CAPOX (N=253)												
Baseline	242	83.55	17.22	0.0	86.67	100.0						
Cycle 2 Day 1	222	83.27	17.17	0.0	86.67	100.0	217	-0.77	13.70	-73.3	0.00	33.3
Cycle 3 Day 1	200	84.43	17.96	13.3	86.67	100.0	197	-0.07	14.94	-80.0	0.00	46.7
Cycle 4 Day 1	171	85.11	16.35	6.7	86.67	100.0	169	1.07	15.38	-93.3	0.00	46.7
Cycle 5 Day 1	166	84.82	17.50	13.3	86.67	100.0	165	0.24	16.29	-66.7	0.00	53.3
Cycle 6 Day 1	147	83.90	19.64	0.0	86.67	100.0	146	-0.96	17.94	-86.7	0.00	53.3
Cycle 7 Day 1	127	85.51	17.03	6.7	86.67	100.0	126	0.21	17.69	-93.3	0.00	46.7
Cycle 8 Day 1	111	83.78	19.36	6.7	86.67	100.0	110	-1.33	17.08	-93.3	0.00	33.3
Cycle 9 Day 1	104	84.94	18.83	6.7	86.67	100.0	103	-0.84	18.26	-93.3	0.00	46.7
Cycle 10 Day 1	81	85.02	17.78	13.3	86.67	100.0	79	-2.28	18.76	-86.7	0.00	40.0
Cycle 11 Day 1	72	86.76	15.76	20.0	93.33	100.0	71	-0.09	17.11	-80.0	0.00	33.3
Cycle 12 Day 1	59	87.34	16.92	20.0	93.33	100.0	57	-0.70	19.18	-80.0	0.00	46.7
Cycle 13 Day 1	47	88.23	13.35	33.3	86.67	100.0	45	1.04	13.85	-46.7	0.00	40.0
Cycle 14 Day 1	44	88.64	15.26	6.7	86.67	100.0	42	1.43	12.80	-26.7	0.00	33.3
Cycle 15 Day 1	36	86.30	17.74	6.7	86.67	100.0	34	-0.20	13.78	-40.0	0.00	33.3
Cycle 16 Day 1	32	87.50	17.00	13.3	90.00	100.0	30	0.67	12.30	-20.0	0.00	33.3
Cycle 17 Day 1	26	87.95	16.00	40.0	93.33	100.0	24	1.94	17.08	-40.0	0.00	33.3
Cycle 18 Day 1	21	91.75	11.14	60.0	93.33	100.0	20	3.33	15.82	-40.0	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: 07OCT22

Table 302.1.3002.6: 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 19 Day 1	20	94.00	7.14	80.0	96.67	100.0	19	3.86	13.76	-20.0	0.00	46.7
Cycle 20 Day 1	17	92.16	9.79	66.7	93.33	100.0	16	5.42	14.24	-13.3	0.00	46.7
Cycle 21 Day 1	18	92.96	8.08	73.3	93.33	100.0	17	5.49	12.30	-6.7	0.00	40.0
Cycle 22 Day 1	15	94.22	6.60	80.0	93.33	100.0	14	9.05	14.23	0.0	3.33	46.7
Cycle 23 Day 1	12	93.89	11.18	60.0	96.67	100.0	11	8.48	21.72	-33.3	0.00	46.7
Study Disc 1	150	69.38	29.18	0.0	80.00	100.0	145	-14.85	26.36	-100.0	-6.67	33.3
30 D SFU Z/P	76	76.75	22.06	0.0	80.00	100.0	74	-9.10	20.03	-66.7	-6.67	26.7
90 D SFU Z/P	70	76.10	25.19	0.0	80.00	100.0	68	-11.37	22.78	-86.7	-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: 07OCT22

Table 302.1.3002.7: 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 + CAPOX (N=254)												
Baseline	242	83.13	22.54	0.0	100.00	100.0						
Cycle 2 Day 1	209	80.78	24.16	0.0	83.33	100.0	208	-2.64	20.52	-66.7	0.00	66.7
Cycle 3 Day 1	187	81.28	23.19	0.0	100.00	100.0	182	-2.38	21.82	-83.3	0.00	50.0
Cycle 4 Day 1	172	80.81	23.91	0.0	100.00	100.0	169	-2.37	20.36	-66.7	0.00	33.3
Cycle 5 Day 1	162	82.72	22.05	0.0	100.00	100.0	159	-0.94	20.73	-66.7	0.00	66.7
Cycle 6 Day 1	151	79.25	25.96	0.0	83.33	100.0	149	-3.69	22.91	-100.0	0.00	66.7
Cycle 7 Day 1	122	82.24	22.03	0.0	83.33	100.0	120	-2.08	20.68	-66.7	0.00	50.0
Cycle 8 Day 1	114	78.22	24.50	0.0	83.33	100.0	108	-5.25	21.57	-66.7	0.00	66.7
Cycle 9 Day 1	107	77.88	25.78	0.0	83.33	100.0	102	-5.39	23.71	-83.3	0.00	66.7
Cycle 10 Day 1	88	81.63	25.78	0.0	100.00	100.0	85	-3.92	24.89	-83.3	0.00	50.0
Cycle 11 Day 1	83	84.34	16.33	50.0	83.33	100.0	80	-3.54	19.43	-33.3	0.00	66.7
Cycle 12 Day 1	76	85.09	17.76	33.3	100.00	100.0	74	-3.38	24.05	-66.7	0.00	66.7
Cycle 13 Day 1	62	87.10	16.64	50.0	100.00	100.0	60	-0.83	24.44	-50.0	0.00	66.7
Cycle 14 Day 1	56	86.01	17.05	50.0	100.00	100.0	54	-1.23	21.68	-50.0	0.00	66.7
Cycle 15 Day 1	51	87.91	17.02	33.3	100.00	100.0	49	-0.34	21.38	-33.3	0.00	66.7
Cycle 16 Day 1	46	86.96	15.68	66.7	100.00	100.0	44	1.52	24.06	-33.3	0.00	66.7
Cycle 17 Day 1	41	89.02	16.08	50.0	100.00	100.0	39	2.14	23.00	-33.3	0.00	66.7
Cycle 18 Day 1	37	83.33	16.20	66.7	83.33	100.0	35	-4.29	21.14	-33.3	0.00	33.3
Cycle 19 Day 1	37	85.59	18.07	33.3	100.00	100.0	35	-1.43	21.15	-33.3	0.00	33.3
Cycle 20 Day 1	35	87.14	17.66	33.3	100.00	100.0	33	0.00	21.25	-33.3	0.00	33.3
Cycle 21 Day 1	32	85.94	15.90	66.7	100.00	100.0	30	-1.67	20.22	-33.3	0.00	33.3
Cycle 22 Day 1	30	87.78	18.01	33.3	100.00	100.0	28	-1.19	19.21	-33.3	0.00	33.3
Cycle 23 Day 1	28	88.69	15.75	66.7	100.00	100.0	26	-1.92	19.05	-33.3	0.00	33.3
Cycle 24 Day 1	25	88.67	14.21	66.7	100.00	100.0	23	-0.72	20.40	-33.3	0.00	33.3
Cycle 25 Day 1	23	90.58	14.93	66.7	100.00	100.0	21	0.79	23.26	-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: 07OCT22

Table 302.1.3002.7: 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 26 Day 1	22	88.64	15.76	66.7	100.00	100.0	20	-0.83	21.27	-33.3	0.00	33.3
Cycle 27 Day 1	20	88.33	15.39	66.7	100.00	100.0	18	0.00	17.15	-33.3	0.00	33.3
Cycle 28 Day 1	11	93.94	11.24	66.7	100.00	100.0	9	3.70	21.70	-33.3	0.00	33.3
Cycle 29 Day 1	12	93.06	13.22	66.7	100.00	100.0	10	1.67	25.40	-33.3	0.00	50.0
Study Disc 1	124	72.04	30.69	0.0	75.00	100.0	122	-14.48	27.44	-100.0	0.00	66.7
30 D SFU Z/P	52	74.36	25.02	0.0	66.67	100.0	51	-13.07	27.75	-100.0	0.00	33.3
90 D SFU Z/P	48	79.51	25.09	0.0	83.33	100.0	47	-11.70	27.35	-100.0	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	242	82.23	23.59	0.0	100.00	100.0						
Cycle 2 Day 1	222	80.71	23.98	0.0	83.33	100.0	217	-1.92	19.97	-83.3	0.00	66.7
Cycle 3 Day 1	200	80.92	25.31	0.0	100.00	100.0	197	-2.28	24.38	-100.0	0.00	66.7
Cycle 4 Day 1	171	81.77	25.32	0.0	100.00	100.0	169	-0.79	24.65	-100.0	0.00	66.7
Cycle 5 Day 1	166	82.73	23.42	0.0	100.00	100.0	165	-0.40	25.03	-83.3	0.00	83.3
Cycle 6 Day 1	147	80.39	24.50	0.0	83.33	100.0	146	-3.08	24.68	-100.0	0.00	66.7
Cycle 7 Day 1	127	83.33	22.12	0.0	100.00	100.0	126	-0.79	23.74	-100.0	0.00	66.7
Cycle 8 Day 1	111	78.68	27.36	0.0	100.00	100.0	110	-5.61	26.16	-100.0	0.00	33.3
Cycle 9 Day 1	104	81.57	23.45	0.0	83.33	100.0	103	-2.59	23.89	-100.0	0.00	50.0
Cycle 10 Day 1	81	82.10	24.83	0.0	100.00	100.0	79	-3.59	26.91	-100.0	0.00	50.0
Cycle 11 Day 1	72	81.94	25.45	0.0	100.00	100.0	71	-3.29	28.40	-100.0	0.00	66.7
Cycle 12 Day 1	59	84.18	23.86	0.0	100.00	100.0	57	-2.63	26.69	-100.0	0.00	33.3
Cycle 13 Day 1	47	85.11	22.58	0.0	100.00	100.0	45	0.37	25.99	-66.7	0.00	66.7
Cycle 14 Day 1	44	84.47	21.08	0.0	100.00	100.0	42	0.00	21.15	-50.0	0.00	66.7
Cycle 15 Day 1	36	84.26	23.89	0.0	100.00	100.0	34	-0.49	25.45	-100.0	0.00	50.0
Cycle 16 Day 1	32	82.81	22.59	0.0	91.67	100.0	30	-1.11	20.50	-33.3	0.00	50.0
Cycle 17 Day 1	26	83.97	22.35	33.3	100.00	100.0	24	1.39	28.62	-66.7	0.00	66.7
Cycle 18 Day 1	21	88.10	18.37	33.3	100.00	100.0	20	5.00	21.01	-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: 07OCT22

Table 302.1.3002.7: 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 19 Day 1	20	92.50	12.65	66.7	100.00	100.0	19	5.26	16.72	-16.7	0.00	33.3
Cycle 20 Day 1	17	93.14	11.87	66.7	100.00	100.0	16	11.46	22.54	-16.7	0.00	66.7
Cycle 21 Day 1	18	92.59	14.26	66.7	100.00	100.0	17	7.84	25.08	-33.3	0.00	66.7
Cycle 22 Day 1	15	90.00	15.17	66.7	100.00	100.0	14	8.33	25.11	-33.3	0.00	66.7
Cycle 23 Day 1	12	91.67	13.30	66.7	100.00	100.0	11	9.09	34.45	-33.3	0.00	83.3
Study Disc 1	150	65.78	32.30	0.0	66.67	100.0	145	-15.86	32.17	-100.0	0.00	66.7
30 D SFU Z/P	76	68.20	29.08	0.0	66.67	100.0	74	-15.32	29.55	-100.0	-16.67	50.0
90 D SFU Z/P	70	74.05	28.18	0.0	83.33	100.0	68	-11.03	29.87	-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: 07OCT22

Table 302.1.3002.8: 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 + CAPOX (N=254)												
Baseline	242	80.37	19.16	8.3	83.33	100.0						
Cycle 2 Day 1	209	82.22	19.08	16.7	83.33	100.0	208	1.32	15.92	-50.0	0.00	58.3
Cycle 3 Day 1	187	82.13	18.36	0.0	83.33	100.0	182	0.05	16.21	-91.7	0.00	66.7
Cycle 4 Day 1	172	83.62	17.45	8.3	91.67	100.0	169	2.42	15.52	-50.0	0.00	58.3
Cycle 5 Day 1	162	83.74	17.59	0.0	91.67	100.0	159	2.46	17.35	-100.0	0.00	58.3
Cycle 6 Day 1	151	83.00	18.25	8.3	83.33	100.0	149	1.79	15.96	-58.3	0.00	50.0
Cycle 7 Day 1	122	84.63	16.18	33.3	91.67	100.0	120	3.54	17.90	-50.0	0.00	91.7
Cycle 8 Day 1	114	80.70	21.71	8.3	83.33	100.0	108	0.77	19.15	-50.0	0.00	91.7
Cycle 9 Day 1	107	80.84	19.06	0.0	83.33	100.0	102	2.53	19.19	-58.3	0.00	91.7
Cycle 10 Day 1	88	83.52	19.24	0.0	91.67	100.0	85	5.20	21.13	-41.7	0.00	91.7
Cycle 11 Day 1	83	84.64	16.02	41.7	91.67	100.0	80	5.52	20.54	-33.3	4.17	91.7
Cycle 12 Day 1	76	87.06	14.30	41.7	91.67	100.0	74	6.53	20.05	-33.3	0.00	91.7
Cycle 13 Day 1	62	86.69	16.35	41.7	91.67	100.0	60	6.11	20.40	-33.3	0.00	91.7
Cycle 14 Day 1	56	85.42	16.61	33.3	91.67	100.0	54	4.17	20.07	-41.7	0.00	91.7
Cycle 15 Day 1	51	86.27	15.88	41.7	91.67	100.0	49	4.76	16.67	-33.3	8.33	41.7
Cycle 16 Day 1	46	85.14	16.00	41.7	91.67	100.0	44	3.41	16.11	-33.3	0.00	41.7
Cycle 17 Day 1	41	87.80	15.60	41.7	91.67	100.0	39	7.05	15.00	-25.0	8.33	41.7
Cycle 18 Day 1	37	83.56	16.25	41.7	91.67	100.0	35	3.33	15.68	-25.0	0.00	41.7
Cycle 19 Day 1	37	86.49	15.38	41.7	91.67	100.0	35	5.48	15.91	-33.3	8.33	41.7
Cycle 20 Day 1	35	85.48	16.46	33.3	91.67	100.0	33	4.80	16.14	-41.7	8.33	41.7
Cycle 21 Day 1	32	86.20	18.41	25.0	91.67	100.0	30	5.00	18.77	-50.0	4.17	41.7
Cycle 22 Day 1	30	86.11	16.43	41.7	91.67	100.0	28	3.87	14.96	-25.0	0.00	33.3
Cycle 23 Day 1	28	86.90	16.27	41.7	91.67	100.0	26	2.56	12.19	-25.0	0.00	33.3
Cycle 24 Day 1	25	84.67	17.79	41.7	91.67	100.0	23	1.45	16.02	-33.3	0.00	41.7
Cycle 25 Day 1	23	87.32	18.95	25.0	100.00	100.0	21	3.57	17.39	-50.0	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: 07OCT22

Table 302.1.3002.8: 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 26 Day 1	22	85.61	18.75	33.3	95.83	100.0	20	4.17	17.83	-41.7	0.00	41.7
Cycle 27 Day 1	20	84.58	22.01	25.0	91.67	100.0	18	2.31	20.97	-50.0	0.00	41.7
Cycle 28 Day 1	11	81.82	23.52	25.0	91.67	100.0	9	-1.85	23.12	-50.0	0.00	25.0
Cycle 29 Day 1	12	83.33	15.89	50.0	87.50	100.0	10	-0.83	17.76	-25.0	0.00	25.0
Study Disc 1	124	75.74	24.39	0.0	83.33	100.0	122	-6.63	23.47	-100.0	0.00	91.7
30 D SFU Z/P	52	77.24	23.29	0.0	83.33	100.0	51	-5.07	26.09	-75.0	-8.33	91.7
90 D SFU Z/P	48	82.99	19.06	33.3	91.67	100.0	47	-3.55	15.32	-50.0	0.00	41.7
Placebo + CAPOX (N=253)												
Baseline	242	78.79	19.41	0.0	83.33	100.0						
Cycle 2 Day 1	222	82.96	18.47	0.0	83.33	100.0	217	4.42	16.49	-58.3	0.00	58.3
Cycle 3 Day 1	200	81.46	19.35	0.0	83.33	100.0	197	3.00	18.84	-66.7	0.00	66.7
Cycle 4 Day 1	171	81.63	18.70	0.0	83.33	100.0	169	2.51	19.52	-50.0	0.00	66.7
Cycle 5 Day 1	166	83.23	17.31	33.3	83.33	100.0	165	3.69	17.81	-58.3	0.00	50.0
Cycle 6 Day 1	147	82.60	19.43	0.0	91.67	100.0	146	3.77	19.18	-58.3	0.00	66.7
Cycle 7 Day 1	127	81.50	20.27	0.0	83.33	100.0	126	2.12	21.24	-66.7	0.00	58.3
Cycle 8 Day 1	111	80.93	20.46	0.0	83.33	100.0	110	2.20	18.08	-50.0	0.00	33.3
Cycle 9 Day 1	104	82.45	18.76	0.0	83.33	100.0	103	2.59	19.07	-50.0	0.00	41.7
Cycle 10 Day 1	81	81.38	20.04	8.3	83.33	100.0	79	1.79	20.62	-50.0	0.00	50.0
Cycle 11 Day 1	72	83.68	22.53	0.0	91.67	100.0	71	2.58	20.97	-50.0	0.00	58.3
Cycle 12 Day 1	59	83.05	22.05	8.3	91.67	100.0	57	2.05	21.49	-50.0	0.00	50.0
Cycle 13 Day 1	47	83.87	19.38	25.0	91.67	100.0	45	2.22	21.79	-50.0	0.00	50.0
Cycle 14 Day 1	44	82.58	19.34	25.0	87.50	100.0	42	-1.98	18.93	-50.0	0.00	41.7
Cycle 15 Day 1	36	84.26	20.87	25.0	91.67	100.0	34	-2.21	21.55	-50.0	0.00	50.0
Cycle 16 Day 1	32	85.94	19.79	33.3	95.83	100.0	30	-0.28	23.62	-58.3	0.00	50.0
Cycle 17 Day 1	26	92.31	10.78	66.7	100.00	100.0	24	5.56	16.42	-16.7	0.00	50.0
Cycle 18 Day 1	21	91.27	12.49	58.3	100.00	100.0	20	4.58	19.96	-33.3	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: 07OCT22

Table 302.1.3002.8: 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 19 Day 1	20	95.42	9.16	66.7	100.00	100.0	19	4.82	13.41	-25.0	0.00	33.3
Cycle 20 Day 1	17	91.67	11.41	66.7	100.00	100.0	16	4.17	20.86	-33.3	4.17	58.3
Cycle 21 Day 1	18	93.52	9.29	66.7	100.00	100.0	17	5.88	17.62	-33.3	0.00	50.0
Cycle 22 Day 1	15	91.67	9.45	75.0	91.67	100.0	14	5.95	18.32	-16.7	4.17	58.3
Cycle 23 Day 1	12	92.36	11.49	66.7	100.00	100.0	11	6.06	25.03	-25.0	0.00	58.3
Study Disc 1	150	69.72	24.68	0.0	66.67	100.0	145	-6.78	22.74	-66.7	0.00	41.7
30 D SFU Z/P	76	72.15	25.59	0.0	75.00	100.0	74	-4.73	24.41	-75.0	0.00	41.7
90 D SFU Z/P	70	75.00	24.45	0.0	83.33	100.0	68	-0.37	23.15	-58.3	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: 07OCT22

Table 302.1.3002.9: 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 + CAPOX (N=254)												
Baseline	242	90.91	14.88	33.3	100.00	100.0						
Cycle 2 Day 1	209	90.51	15.47	33.3	100.00	100.0	208	-0.24	13.36	-66.7	0.00	66.7
Cycle 3 Day 1	187	89.75	15.37	0.0	100.00	100.0	182	-1.47	14.90	-83.3	0.00	50.0
Cycle 4 Day 1	172	90.99	14.46	16.7	100.00	100.0	169	-0.59	13.47	-50.0	0.00	50.0
Cycle 5 Day 1	162	89.61	16.51	0.0	100.00	100.0	159	-1.89	15.80	-83.3	0.00	50.0
Cycle 6 Day 1	151	90.07	15.54	16.7	100.00	100.0	149	-1.45	14.87	-50.0	0.00	50.0
Cycle 7 Day 1	122	91.26	13.92	33.3	100.00	100.0	120	0.00	16.31	-66.7	0.00	66.7
Cycle 8 Day 1	114	88.45	15.85	16.7	100.00	100.0	108	-2.16	15.13	-50.0	0.00	50.0
Cycle 9 Day 1	107	88.47	16.73	16.7	100.00	100.0	102	-1.96	14.70	-50.0	0.00	33.3
Cycle 10 Day 1	88	89.96	14.85	33.3	100.00	100.0	85	-0.59	17.15	-50.0	0.00	66.7
Cycle 11 Day 1	83	90.36	14.05	50.0	100.00	100.0	80	-1.25	14.95	-33.3	0.00	50.0
Cycle 12 Day 1	76	91.23	12.31	66.7	100.00	100.0	74	-0.45	13.79	-33.3	0.00	50.0
Cycle 13 Day 1	62	90.59	13.02	66.7	100.00	100.0	60	-0.28	15.19	-33.3	0.00	66.7
Cycle 14 Day 1	56	92.56	11.86	66.7	100.00	100.0	54	0.31	15.69	-33.3	0.00	66.7
Cycle 15 Day 1	51	92.48	11.70	66.7	100.00	100.0	49	-0.34	15.02	-33.3	0.00	50.0
Cycle 16 Day 1	46	92.75	11.47	66.7	100.00	100.0	44	1.14	16.63	-16.7	0.00	66.7
Cycle 17 Day 1	41	93.09	11.77	66.7	100.00	100.0	39	1.28	12.90	-16.7	0.00	50.0
Cycle 18 Day 1	37	91.44	11.53	66.7	100.00	100.0	35	1.43	14.78	-16.7	0.00	50.0
Cycle 19 Day 1	37	90.54	12.13	66.7	100.00	100.0	35	0.95	17.59	-33.3	0.00	50.0
Cycle 20 Day 1	35	91.43	12.37	66.7	100.00	100.0	33	2.02	18.98	-33.3	0.00	66.7
Cycle 21 Day 1	32	92.71	11.93	66.7	100.00	100.0	30	2.78	19.12	-33.3	0.00	50.0
Cycle 22 Day 1	30	92.22	12.17	66.7	100.00	100.0	28	2.38	19.09	-33.3	0.00	50.0
Cycle 23 Day 1	28	92.86	12.36	66.7	100.00	100.0	26	1.28	19.39	-33.3	0.00	66.7
Cycle 24 Day 1	25	94.67	11.51	66.7	100.00	100.0	23	3.62	20.69	-33.3	0.00	66.7
Cycle 25 Day 1	23	94.93	9.31	66.7	100.00	100.0	21	4.76	20.51	-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: 07OCT22

Table 302.1.3002.9: 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 26 Day 1	22	94.70	13.00	50.0	100.00	100.0	20	4.17	20.86	-33.3	0.00	66.7
Cycle 27 Day 1	20	94.17	11.18	66.7	100.00	100.0	18	4.63	19.64	-16.7	0.00	66.7
Cycle 28 Day 1	11	96.97	10.05	66.7	100.00	100.0	9	11.11	25.00	-16.7	0.00	66.7
Cycle 29 Day 1	12	97.22	9.62	66.7	100.00	100.0	10	10.00	23.83	-16.7	0.00	66.7
Study Disc 1	124	84.95	19.29	0.0	91.67	100.0	122	-6.56	18.75	-100.0	0.00	50.0
30 D SFU Z/P	52	90.06	17.85	16.7	100.00	100.0	51	-2.29	18.57	-83.3	0.00	50.0
90 D SFU Z/P	48	87.50	16.67	33.3	100.00	100.0	47	-7.09	17.29	-66.7	0.00	16.7
Placebo + CAPOX (N=253)												
Baseline	242	87.81	18.01	0.0	100.00	100.0						
Cycle 2 Day 1	222	88.51	17.28	0.0	100.00	100.0	217	0.54	15.50	-50.0	0.00	66.7
Cycle 3 Day 1	200	88.75	16.79	0.0	100.00	100.0	197	0.51	15.51	-50.0	0.00	50.0
Cycle 4 Day 1	171	89.28	16.53	16.7	100.00	100.0	169	1.87	15.58	-50.0	0.00	50.0
Cycle 5 Day 1	166	90.16	15.25	16.7	100.00	100.0	165	2.22	15.13	-50.0	0.00	50.0
Cycle 6 Day 1	147	88.66	17.12	0.0	100.00	100.0	146	0.91	16.81	-66.7	0.00	66.7
Cycle 7 Day 1	127	86.48	17.91	33.3	100.00	100.0	126	-1.19	17.02	-66.7	0.00	50.0
Cycle 8 Day 1	111	87.24	18.66	16.7	100.00	100.0	110	0.15	18.27	-83.3	0.00	33.3
Cycle 9 Day 1	104	88.14	17.94	0.0	100.00	100.0	103	0.97	18.05	-100.0	0.00	33.3
Cycle 10 Day 1	81	87.24	18.12	16.7	100.00	100.0	79	-0.42	19.61	-83.3	0.00	50.0
Cycle 11 Day 1	72	86.81	16.77	33.3	100.00	100.0	71	-1.41	18.42	-66.7	0.00	50.0
Cycle 12 Day 1	59	88.42	16.74	16.7	100.00	100.0	57	1.17	16.62	-50.0	0.00	33.3
Cycle 13 Day 1	47	87.59	17.88	16.7	100.00	100.0	45	0.37	22.61	-50.0	0.00	83.3
Cycle 14 Day 1	44	87.50	19.40	16.7	100.00	100.0	42	-0.79	19.11	-66.7	0.00	50.0
Cycle 15 Day 1	36	86.57	16.82	33.3	91.67	100.0	34	-2.45	19.73	-50.0	0.00	66.7
Cycle 16 Day 1	32	83.85	20.52	16.7	100.00	100.0	30	-3.33	20.72	-50.0	0.00	50.0
Cycle 17 Day 1	26	87.82	18.59	33.3	100.00	100.0	24	2.08	15.00	-33.3	0.00	50.0
Cycle 18 Day 1	21	90.48	13.51	66.7	100.00	100.0	20	1.67	16.13	-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: 07OCT22

Table 302.1.3002.9: 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 19 Day 1	20	94.17	12.42	66.7	100.00	100.0	19	2.63	11.47	-33.3	0.00	16.7
Cycle 20 Day 1	17	89.22	13.10	66.7	100.00	100.0	16	3.13	22.13	-33.3	0.00	66.7
Cycle 21 Day 1	18	92.59	13.06	66.7	100.00	100.0	17	5.88	19.49	-33.3	0.00	66.7
Cycle 22 Day 1	15	91.11	13.90	66.7	100.00	100.0	14	5.95	21.29	-33.3	0.00	66.7
Cycle 23 Day 1	12	94.44	10.86	66.7	100.00	100.0	11	7.58	15.57	0.0	0.00	50.0
Study Disc 1	150	80.11	24.33	0.0	83.33	100.0	145	-6.09	20.86	-83.3	0.00	66.7
30 D SFU Z/P	76	81.80	24.22	0.0	91.67	100.0	74	-3.83	20.37	-100.0	0.00	50.0
90 D SFU Z/P	70	82.86	21.97	0.0	83.33	100.0	68	-3.19	20.41	-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: 07OCT22

Table 302.1.3002.10: 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 + CAPOX (N=254)												
Baseline	242	79.34	22.16	0.0	83.33	100.0						
Cycle 2 Day 1	209	80.70	20.99	16.7	83.33	100.0	208	0.88	21.31	-66.7	0.00	66.7
Cycle 3 Day 1	187	77.63	22.73	0.0	83.33	100.0	182	-1.47	23.65	-66.7	0.00	66.7
Cycle 4 Day 1	172	80.33	21.15	0.0	83.33	100.0	169	0.79	23.77	-66.7	0.00	66.7
Cycle 5 Day 1	162	80.97	21.97	0.0	83.33	100.0	159	2.20	25.58	-100.0	0.00	66.7
Cycle 6 Day 1	151	78.70	22.78	0.0	83.33	100.0	149	-0.78	25.29	-83.3	0.00	66.7
Cycle 7 Day 1	122	78.96	22.45	0.0	83.33	100.0	120	-0.97	26.22	-100.0	0.00	66.7
Cycle 8 Day 1	114	78.80	23.18	0.0	83.33	100.0	108	-0.93	27.33	-100.0	0.00	66.7
Cycle 9 Day 1	107	77.26	22.94	0.0	83.33	100.0	102	-0.98	24.01	-66.7	0.00	66.7
Cycle 10 Day 1	88	81.06	23.19	0.0	83.33	100.0	85	2.55	25.39	-66.7	0.00	66.7
Cycle 11 Day 1	83	83.73	17.65	33.3	83.33	100.0	80	3.33	23.33	-66.7	0.00	66.7
Cycle 12 Day 1	76	84.21	18.24	33.3	91.67	100.0	74	3.60	23.13	-66.7	0.00	66.7
Cycle 13 Day 1	62	84.14	18.46	33.3	100.00	100.0	60	3.89	24.43	-66.7	0.00	66.7
Cycle 14 Day 1	56	83.63	16.66	50.0	83.33	100.0	54	2.16	20.99	-33.3	0.00	66.7
Cycle 15 Day 1	51	84.64	17.90	33.3	100.00	100.0	49	2.04	22.21	-66.7	0.00	66.7
Cycle 16 Day 1	46	85.14	19.00	16.7	100.00	100.0	44	4.92	20.83	-50.0	0.00	50.0
Cycle 17 Day 1	41	86.59	16.76	50.0	100.00	100.0	39	5.56	18.86	-33.3	0.00	66.7
Cycle 18 Day 1	37	82.43	18.40	33.3	83.33	100.0	35	2.38	24.30	-66.7	0.00	66.7
Cycle 19 Day 1	37	85.59	16.27	50.0	100.00	100.0	35	7.14	18.65	-33.3	0.00	66.7
Cycle 20 Day 1	35	81.43	18.42	50.0	83.33	100.0	33	2.53	23.24	-50.0	0.00	66.7
Cycle 21 Day 1	32	82.81	21.79	33.3	100.00	100.0	30	2.22	23.46	-33.3	0.00	66.7
Cycle 22 Day 1	30	88.33	17.04	33.3	100.00	100.0	28	6.55	21.91	-33.3	0.00	66.7
Cycle 23 Day 1	28	88.69	17.60	33.3	100.00	100.0	26	5.77	25.80	-66.7	0.00	66.7
Cycle 24 Day 1	25	88.00	15.61	66.7	100.00	100.0	23	5.07	26.32	-33.3	0.00	66.7
Cycle 25 Day 1	23	89.13	14.74	66.7	100.00	100.0	21	6.35	23.85	-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: 07OCT22

Table 302.1.3002.10: 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 26 Day 1	22	91.67	13.36	66.7	100.00	100.0	20	8.33	23.88	-33.3	0.00	66.7
Cycle 27 Day 1	20	90.83	18.32	33.3	100.00	100.0	18	9.26	27.55	-66.7	0.00	66.7
Cycle 28 Day 1	11	90.91	17.26	50.0	100.00	100.0	9	12.96	33.10	-50.0	0.00	66.7
Cycle 29 Day 1	12	91.67	13.30	66.7	100.00	100.0	10	11.67	24.91	-16.7	0.00	66.7
Study Disc 1	124	73.52	27.55	0.0	66.67	100.0	122	-7.51	29.62	-100.0	0.00	66.7
30 D SFU Z/P	52	78.53	24.77	0.0	75.00	100.0	51	-3.92	27.61	-100.0	0.00	66.7
90 D SFU Z/P	48	83.33	20.05	33.3	91.67	100.0	47	1.06	24.43	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	79.55	23.48	0.0	83.33	100.0						
Cycle 2 Day 1	222	78.45	24.87	0.0	83.33	100.0	217	-1.61	20.88	-100.0	0.00	50.0
Cycle 3 Day 1	200	79.00	22.24	0.0	83.33	100.0	197	-1.44	22.70	-83.3	0.00	66.7
Cycle 4 Day 1	171	82.55	21.83	0.0	83.33	100.0	169	1.97	21.73	-100.0	0.00	66.7
Cycle 5 Day 1	166	81.43	21.27	0.0	83.33	100.0	165	0.20	22.31	-66.7	0.00	83.3
Cycle 6 Day 1	147	79.82	23.10	0.0	83.33	100.0	146	-1.37	22.53	-100.0	0.00	66.7
Cycle 7 Day 1	127	80.31	22.16	0.0	83.33	100.0	126	-0.66	24.71	-100.0	0.00	66.7
Cycle 8 Day 1	111	77.93	24.53	0.0	83.33	100.0	110	-2.12	23.58	-100.0	0.00	66.7
Cycle 9 Day 1	104	80.13	23.00	0.0	83.33	100.0	103	-0.32	24.47	-100.0	0.00	66.7
Cycle 10 Day 1	81	81.48	24.72	0.0	100.00	100.0	79	-0.84	27.20	-100.0	0.00	66.7
Cycle 11 Day 1	72	79.40	24.94	0.0	83.33	100.0	71	-2.58	25.14	-100.0	0.00	33.3
Cycle 12 Day 1	59	80.79	26.77	0.0	100.00	100.0	57	-1.75	28.12	-100.0	0.00	66.7
Cycle 13 Day 1	47	84.40	23.67	0.0	100.00	100.0	45	0.37	23.70	-100.0	0.00	33.3
Cycle 14 Day 1	44	85.23	23.63	0.0	100.00	100.0	42	1.19	25.34	-100.0	0.00	66.7
Cycle 15 Day 1	36	82.87	24.07	0.0	100.00	100.0	34	-2.45	23.62	-100.0	0.00	33.3
Cycle 16 Day 1	32	85.94	20.35	16.7	100.00	100.0	30	1.67	19.25	-33.3	0.00	33.3
Cycle 17 Day 1	26	87.18	18.44	33.3	100.00	100.0	24	4.17	15.73	-33.3	0.00	33.3
Cycle 18 Day 1	21	90.48	13.51	66.7	100.00	100.0	20	3.33	16.75	-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: 07OCT22

Table 302.1.3002.10: 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 19 Day 1	20	94.17	11.18	66.7	100.00	100.0	19	7.89	21.06	-33.3	0.00	66.7
Cycle 20 Day 1	17	94.12	11.70	66.7	100.00	100.0	16	7.29	21.92	-33.3	0.00	66.7
Cycle 21 Day 1	18	93.52	11.63	66.7	100.00	100.0	17	3.92	17.21	-33.3	0.00	50.0
Cycle 22 Day 1	15	92.22	13.90	66.7	100.00	100.0	14	4.76	16.57	-16.7	0.00	33.3
Cycle 23 Day 1	12	97.22	9.62	66.7	100.00	100.0	11	6.06	13.48	0.0	0.00	33.3
Study Disc 1	150	65.78	31.77	0.0	66.67	100.0	145	-12.53	29.43	-100.0	0.00	66.7
30 D SFU Z/P	76	68.20	28.83	0.0	66.67	100.0	74	-12.61	26.43	-100.0	0.00	33.3
90 D SFU Z/P	70	72.14	27.91	0.0	66.67	100.0	68	-10.29	26.86	-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: 07OCT22

Table 302.1.3002.11: 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 + CAPOX (N=254)												
Baseline	242	26.31	22.04	0.0	22.22	100.0						
Cycle 2 Day 1	209	27.91	19.92	0.0	33.33	100.0	208	1.66	19.69	-66.7	0.00	66.7
Cycle 3 Day 1	187	29.41	21.04	0.0	33.33	100.0	182	3.17	21.71	-66.7	0.00	66.7
Cycle 4 Day 1	172	26.94	21.33	0.0	33.33	100.0	169	1.05	21.93	-77.8	0.00	55.6
Cycle 5 Day 1	162	26.95	21.87	0.0	33.33	100.0	159	1.40	23.21	-66.7	0.00	88.9
Cycle 6 Day 1	151	29.21	22.02	0.0	33.33	100.0	149	2.83	21.07	-55.6	0.00	55.6
Cycle 7 Day 1	122	26.41	20.57	0.0	22.22	100.0	120	1.11	20.99	-55.6	0.00	66.7
Cycle 8 Day 1	114	28.85	21.71	0.0	33.33	100.0	108	4.94	20.34	-66.7	0.00	55.6
Cycle 9 Day 1	107	28.25	25.82	0.0	33.33	100.0	102	1.96	24.94	-66.7	0.00	77.8
Cycle 10 Day 1	88	26.01	24.11	0.0	22.22	100.0	85	1.57	25.67	-77.8	0.00	66.7
Cycle 11 Day 1	83	21.95	16.64	0.0	22.22	66.7	80	-0.14	22.67	-66.7	0.00	44.4
Cycle 12 Day 1	76	20.18	18.83	0.0	22.22	66.7	74	-1.05	24.20	-66.7	0.00	66.7
Cycle 13 Day 1	62	18.46	16.46	0.0	16.67	44.4	60	-3.70	25.03	-77.8	0.00	33.3
Cycle 14 Day 1	56	18.06	16.76	0.0	11.11	66.7	54	-2.26	20.18	-66.7	0.00	33.3
Cycle 15 Day 1	51	16.99	16.53	0.0	11.11	55.6	49	-3.40	21.54	-66.7	0.00	44.4
Cycle 16 Day 1	46	17.39	15.83	0.0	22.22	55.6	44	-3.54	22.19	-66.7	0.00	33.3
Cycle 17 Day 1	41	18.43	17.85	0.0	11.11	55.6	39	-2.28	19.77	-55.6	0.00	33.3
Cycle 18 Day 1	37	21.92	16.46	0.0	22.22	55.6	35	0.32	17.97	-44.4	0.00	33.3
Cycle 19 Day 1	37	19.52	17.84	0.0	22.22	66.7	35	-0.95	19.13	-55.6	0.00	44.4
Cycle 20 Day 1	35	21.27	17.54	0.0	22.22	66.7	33	1.35	17.29	-22.2	0.00	33.3
Cycle 21 Day 1	32	19.79	17.11	0.0	22.22	66.7	30	1.11	17.10	-22.2	0.00	44.4
Cycle 22 Day 1	30	15.93	16.42	0.0	16.67	66.7	28	-2.38	19.91	-44.4	0.00	33.3
Cycle 23 Day 1	28	16.27	16.70	0.0	11.11	44.4	26	-0.43	18.72	-33.3	0.00	44.4
Cycle 24 Day 1	25	17.78	15.38	0.0	11.11	44.4	23	0.48	18.50	-33.3	0.00	33.3
Cycle 25 Day 1	23	13.53	16.40	0.0	0.00	44.4	21	-3.17	20.23	-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: 07OCT22

Table 302.1.3002.11: 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 26 Day 1	22	16.67	17.06	0.0	16.67	55.6	20	0.00	23.64	-44.4	0.00	44.4
Cycle 27 Day 1	20	16.11	16.71	0.0	16.67	44.4	18	-1.85	14.88	-22.2	0.00	22.2
Cycle 28 Day 1	11	13.13	13.89	0.0	11.11	33.3	9	-3.70	14.70	-22.2	0.00	22.2
Cycle 29 Day 1	12	16.67	14.60	0.0	16.67	33.3	10	-1.11	18.48	-22.2	-5.56	33.3
Study Disc 1	124	33.96	26.89	0.0	33.33	100.0	122	10.20	26.05	-66.7	5.56	100.0
30 D SFU Z/P	52	33.33	24.40	0.0	33.33	88.9	51	11.55	24.14	-44.4	0.00	66.7
90 D SFU Z/P	48	30.09	21.74	0.0	33.33	100.0	47	13.24	20.93	-22.2	11.11	77.8
Placebo + CAPOX (N=253)												
Baseline	242	27.55	22.43	0.0	22.22	100.0						
Cycle 2 Day 1	222	27.43	20.21	0.0	33.33	100.0	217	0.15	19.11	-77.8	0.00	44.4
Cycle 3 Day 1	200	27.28	22.90	0.0	33.33	100.0	197	0.96	21.26	-66.7	0.00	77.8
Cycle 4 Day 1	171	25.93	21.32	0.0	22.22	100.0	169	-0.46	22.03	-66.7	0.00	77.8
Cycle 5 Day 1	166	25.57	22.24	0.0	22.22	100.0	165	-0.81	23.52	-77.8	0.00	66.7
Cycle 6 Day 1	147	26.00	23.17	0.0	22.22	100.0	146	0.91	25.25	-77.8	0.00	77.8
Cycle 7 Day 1	127	24.23	20.74	0.0	22.22	100.0	126	-1.06	23.11	-66.7	0.00	66.7
Cycle 8 Day 1	111	25.83	22.33	0.0	22.22	100.0	110	0.10	23.05	-66.7	0.00	66.7
Cycle 9 Day 1	104	23.93	20.93	0.0	22.22	100.0	103	-0.86	23.06	-77.8	0.00	66.7
Cycle 10 Day 1	81	21.95	22.70	0.0	22.22	100.0	79	-0.42	24.81	-55.6	0.00	66.7
Cycle 11 Day 1	72	22.84	23.87	0.0	22.22	100.0	71	-0.31	24.34	-55.6	0.00	77.8
Cycle 12 Day 1	59	19.96	22.96	0.0	11.11	100.0	57	0.00	23.19	-44.4	0.00	66.7
Cycle 13 Day 1	47	21.04	19.83	0.0	22.22	88.9	45	-0.49	20.51	-44.4	0.00	44.4
Cycle 14 Day 1	44	20.45	22.21	0.0	16.67	100.0	42	-0.26	20.01	-44.4	0.00	66.7
Cycle 15 Day 1	36	20.68	21.44	0.0	22.22	100.0	34	0.00	17.30	-33.3	0.00	44.4
Cycle 16 Day 1	32	19.10	18.56	0.0	16.67	88.9	30	-1.11	16.85	-33.3	0.00	33.3
Cycle 17 Day 1	26	19.23	17.37	0.0	22.22	66.7	24	-1.39	18.91	-44.4	0.00	33.3
Cycle 18 Day 1	21	11.64	12.90	0.0	11.11	33.3	20	-7.78	17.70	-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.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3002.11: 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 19 Day 1	20	12.78	13.13	0.0	11.11	33.3	19	-4.68	15.85	-33.3	0.00	22.2
Cycle 20 Day 1	17	15.03	15.68	0.0	11.11	55.6	16	-6.25	19.86	-44.4	0.00	22.2
Cycle 21 Day 1	18	12.96	14.39	0.0	11.11	44.4	17	-3.92	20.39	-33.3	0.00	44.4
Cycle 22 Day 1	15	12.59	12.51	0.0	11.11	33.3	14	-5.56	18.36	-44.4	0.00	22.2
Cycle 23 Day 1	12	10.19	10.00	0.0	11.11	22.2	11	-10.10	21.35	-44.4	-11.11	22.2
Study Disc 1	150	40.59	29.35	0.0	33.33	100.0	145	12.72	26.29	-44.4	11.11	100.0
30 D SFU Z/P	76	35.53	24.95	0.0	33.33	100.0	74	11.41	24.33	-44.4	0.00	77.8
90 D SFU Z/P	70	32.22	25.11	0.0	33.33	100.0	68	7.84	22.14	-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: 07OCT22

Table 302.1.3002.12: 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 + CAPOX (N=254)												
Baseline	242	10.54	18.10	0.0	0.00	100.0						
Cycle 2 Day 1	209	16.03	19.67	0.0	0.00	83.3	208	6.41	19.77	-50.0	0.00	83.3
Cycle 3 Day 1	187	15.15	19.07	0.0	16.67	100.0	182	5.86	19.88	-50.0	0.00	83.3
Cycle 4 Day 1	172	13.76	17.88	0.0	0.00	66.7	169	4.73	20.67	-66.7	0.00	66.7
Cycle 5 Day 1	162	14.09	18.72	0.0	0.00	100.0	159	4.93	21.01	-66.7	0.00	66.7
Cycle 6 Day 1	151	15.01	20.71	0.0	0.00	100.0	149	6.04	20.25	-66.7	0.00	66.7
Cycle 7 Day 1	122	9.29	12.50	0.0	0.00	66.7	120	1.25	19.94	-83.3	0.00	50.0
Cycle 8 Day 1	114	11.26	15.44	0.0	0.00	66.7	108	3.09	20.14	-83.3	0.00	50.0
Cycle 9 Day 1	107	10.90	14.50	0.0	0.00	66.7	102	1.80	20.83	-83.3	0.00	50.0
Cycle 10 Day 1	88	7.20	12.58	0.0	0.00	50.0	85	0.39	20.25	-83.3	0.00	50.0
Cycle 11 Day 1	83	5.42	11.38	0.0	0.00	50.0	80	-1.67	19.77	-83.3	0.00	33.3
Cycle 12 Day 1	76	5.92	10.79	0.0	0.00	33.3	74	-1.13	19.96	-83.3	0.00	33.3
Cycle 13 Day 1	62	4.57	10.53	0.0	0.00	66.7	60	-3.33	20.54	-83.3	0.00	66.7
Cycle 14 Day 1	56	5.06	10.50	0.0	0.00	50.0	54	-1.23	19.92	-83.3	0.00	50.0
Cycle 15 Day 1	51	2.61	6.97	0.0	0.00	33.3	49	-3.74	17.76	-83.3	0.00	33.3
Cycle 16 Day 1	46	5.43	11.14	0.0	0.00	33.3	44	-1.14	19.82	-83.3	0.00	33.3
Cycle 17 Day 1	41	4.07	8.15	0.0	0.00	33.3	39	-2.99	19.07	-83.3	0.00	16.7
Cycle 18 Day 1	37	7.66	12.17	0.0	0.00	33.3	35	0.00	21.39	-83.3	0.00	33.3
Cycle 19 Day 1	37	6.76	10.73	0.0	0.00	33.3	35	-0.95	20.98	-83.3	0.00	33.3
Cycle 20 Day 1	35	6.19	9.97	0.0	0.00	33.3	33	-2.02	19.88	-83.3	0.00	33.3
Cycle 21 Day 1	32	5.73	10.03	0.0	0.00	33.3	30	-2.22	20.40	-83.3	0.00	33.3
Cycle 22 Day 1	30	4.44	8.68	0.0	0.00	33.3	28	-4.17	20.09	-83.3	0.00	16.7
Cycle 23 Day 1	28	2.38	7.47	0.0	0.00	33.3	26	-5.77	22.08	-83.3	0.00	16.7
Cycle 24 Day 1	25	4.00	7.26	0.0	0.00	16.7	23	-5.07	22.15	-83.3	0.00	16.7
Cycle 25 Day 1	23	2.17	5.74	0.0	0.00	16.7	21	-7.14	22.09	-83.3	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: 07OCT22

Table 302.1.3002.12: 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 26 Day 1	22	3.03	6.58	0.0	0.00	16.7	20	-6.67	23.20	-83.3	0.00	16.7
Cycle 27 Day 1	20	3.33	6.84	0.0	0.00	16.7	18	-7.41	23.02	-83.3	0.00	16.7
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	9	-12.96	27.36	-83.3	0.00	0.0
Cycle 29 Day 1	12	0.00	0.00	0.0	0.00	0.0	10	-11.67	26.12	-83.3	0.00	0.0
Study Disc 1	124	16.26	24.92	0.0	0.00	100.0	122	7.10	25.16	-50.0	0.00	100.0
30 D SFU Z/P	52	12.50	22.35	0.0	0.00	100.0	51	5.23	19.86	-50.0	0.00	50.0
90 D SFU Z/P	48	13.19	17.18	0.0	0.00	66.7	47	8.16	17.33	-33.3	0.00	50.0
Placebo + CAPOX (N=253)												
Baseline	242	15.08	23.20	0.0	0.00	100.0						
Cycle 2 Day 1	222	12.31	17.25	0.0	0.00	100.0	217	-0.92	20.77	-100.0	0.00	83.3
Cycle 3 Day 1	200	12.33	17.14	0.0	0.00	83.3	197	0.17	22.21	-100.0	0.00	83.3
Cycle 4 Day 1	171	9.94	15.82	0.0	0.00	100.0	169	-2.76	22.98	-100.0	0.00	100.0
Cycle 5 Day 1	166	9.54	14.49	0.0	0.00	66.7	165	-3.74	25.06	-100.0	0.00	50.0
Cycle 6 Day 1	147	12.02	17.20	0.0	0.00	66.7	146	-1.60	24.71	-100.0	0.00	66.7
Cycle 7 Day 1	127	10.24	16.27	0.0	0.00	100.0	126	-2.91	24.59	-100.0	0.00	100.0
Cycle 8 Day 1	111	6.31	12.32	0.0	0.00	66.7	110	-6.97	23.83	-100.0	0.00	33.3
Cycle 9 Day 1	104	7.21	12.46	0.0	0.00	50.0	103	-6.15	20.74	-100.0	0.00	50.0
Cycle 10 Day 1	81	5.97	14.75	0.0	0.00	83.3	79	-7.17	24.99	-100.0	0.00	50.0
Cycle 11 Day 1	72	6.25	12.33	0.0	0.00	50.0	71	-6.81	24.17	-100.0	0.00	33.3
Cycle 12 Day 1	59	7.91	17.60	0.0	0.00	66.7	57	-2.34	25.48	-100.0	0.00	66.7
Cycle 13 Day 1	47	4.61	10.82	0.0	0.00	50.0	45	-8.15	24.52	-100.0	0.00	33.3
Cycle 14 Day 1	44	7.95	17.05	0.0	0.00	66.7	42	-3.97	21.40	-66.7	0.00	33.3
Cycle 15 Day 1	36	6.94	20.46	0.0	0.00	100.0	34	-5.39	20.81	-50.0	0.00	66.7
Cycle 16 Day 1	32	4.17	10.37	0.0	0.00	33.3	30	-6.11	20.75	-66.7	0.00	33.3
Cycle 17 Day 1	26	7.05	13.48	0.0	0.00	33.3	24	2.78	13.61	-33.3	0.00	33.3
Cycle 18 Day 1	21	0.79	3.64	0.0	0.00	16.7	20	-5.00	12.21	-33.3	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: 07OCT22

Table 302.1.3002.12: 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 19 Day 1	20	1.67	5.13	0.0	0.00	16.7	19	-4.39	12.22	-33.3	0.00	16.7
Cycle 20 Day 1	17	0.98	4.04	0.0	0.00	16.7	16	-4.17	12.91	-33.3	0.00	16.7
Cycle 21 Day 1	18	0.93	3.93	0.0	0.00	16.7	17	-4.90	11.43	-33.3	0.00	0.0
Cycle 22 Day 1	15	1.11	4.30	0.0	0.00	16.7	14	-5.95	14.03	-33.3	0.00	16.7
Cycle 23 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-7.58	13.67	-33.3	0.00	0.0
Study Disc 1	150	19.22	26.95	0.0	0.00	100.0	145	6.21	29.00	-100.0	0.00	100.0
30 D SFU Z/P	76	12.72	21.06	0.0	0.00	100.0	74	-1.13	21.95	-83.3	0.00	66.7
90 D SFU Z/P	70	13.33	24.67	0.0	0.00	100.0	68	0.25	24.85	-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: 07OCT22

Table 302.1.3002.13: 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 + CAPOX (N=254)												
Baseline	242	21.63	22.17	0.0	16.67	100.0						
Cycle 2 Day 1	209	16.99	19.74	0.0	16.67	100.0	208	-4.17	22.43	-83.3	0.00	66.7
Cycle 3 Day 1	187	15.69	19.64	0.0	0.00	83.3	182	-5.40	21.16	-83.3	0.00	50.0
Cycle 4 Day 1	172	15.12	19.93	0.0	0.00	100.0	169	-7.10	21.18	-66.7	0.00	50.0
Cycle 5 Day 1	162	15.23	19.69	0.0	0.00	100.0	159	-4.82	22.06	-83.3	0.00	83.3
Cycle 6 Day 1	151	17.88	20.83	0.0	16.67	83.3	149	-3.13	19.79	-66.7	0.00	50.0
Cycle 7 Day 1	122	13.52	17.45	0.0	0.00	66.7	120	-6.39	22.16	-100.0	0.00	50.0
Cycle 8 Day 1	114	16.81	21.32	0.0	16.67	100.0	108	-4.17	22.22	-100.0	0.00	50.0
Cycle 9 Day 1	107	16.67	19.56	0.0	16.67	83.3	102	-5.07	21.72	-100.0	0.00	50.0
Cycle 10 Day 1	88	15.34	19.45	0.0	0.00	83.3	85	-4.12	22.11	-100.0	0.00	33.3
Cycle 11 Day 1	83	12.05	16.11	0.0	0.00	66.7	80	-6.25	21.11	-100.0	0.00	33.3
Cycle 12 Day 1	76	13.82	19.13	0.0	0.00	100.0	74	-4.28	22.59	-100.0	0.00	50.0
Cycle 13 Day 1	62	11.29	16.74	0.0	0.00	66.7	60	-6.39	23.98	-100.0	0.00	33.3
Cycle 14 Day 1	56	10.42	14.41	0.0	0.00	50.0	54	-5.56	22.43	-100.0	0.00	33.3
Cycle 15 Day 1	51	9.15	13.87	0.0	0.00	33.3	49	-6.12	19.45	-66.7	0.00	33.3
Cycle 16 Day 1	46	11.23	15.34	0.0	0.00	50.0	44	-5.30	19.94	-66.7	0.00	33.3
Cycle 17 Day 1	41	10.98	14.24	0.0	0.00	50.0	39	-5.56	19.99	-66.7	0.00	33.3
Cycle 18 Day 1	37	14.86	15.61	0.0	16.67	50.0	35	-1.90	19.29	-50.0	0.00	33.3
Cycle 19 Day 1	37	13.06	17.18	0.0	0.00	66.7	35	-2.38	19.02	-66.7	0.00	33.3
Cycle 20 Day 1	35	13.81	16.90	0.0	0.00	66.7	33	-1.01	17.65	-66.7	0.00	33.3
Cycle 21 Day 1	32	10.42	13.88	0.0	0.00	33.3	30	-2.78	20.57	-66.7	0.00	33.3
Cycle 22 Day 1	30	10.00	16.72	0.0	0.00	66.7	28	-2.98	18.73	-66.7	0.00	33.3
Cycle 23 Day 1	28	7.74	13.21	0.0	0.00	33.3	26	-3.21	19.45	-66.7	0.00	33.3
Cycle 24 Day 1	25	7.33	12.80	0.0	0.00	33.3	23	-4.35	20.24	-66.7	0.00	33.3
Cycle 25 Day 1	23	9.42	14.06	0.0	0.00	33.3	21	-2.38	22.54	-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: 07OCT22

Table 302.1.3002.13: 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 26 Day 1	22	7.58	12.31	0.0	0.00	33.3	20	-5.00	21.01	-66.7	0.00	33.3
Cycle 27 Day 1	20	7.50	12.65	0.0	0.00	33.3	18	-4.63	23.44	-66.7	0.00	33.3
Cycle 28 Day 1	11	7.58	8.70	0.0	0.00	16.7	9	-5.56	26.35	-66.7	0.00	16.7
Cycle 29 Day 1	12	5.56	10.86	0.0	0.00	33.3	10	-6.67	26.29	-66.7	0.00	33.3
Study Disc 1	124	27.28	27.24	0.0	25.00	100.0	122	7.10	25.62	-83.3	0.00	100.0
30 D SFU Z/P	52	22.76	24.92	0.0	16.67	100.0	51	3.27	26.88	-100.0	0.00	66.7
90 D SFU Z/P	48	19.10	21.19	0.0	16.67	66.7	47	4.26	22.91	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	24.10	23.71	0.0	16.67	100.0						
Cycle 2 Day 1	222	18.69	19.47	0.0	16.67	100.0	217	-4.61	20.08	-66.7	0.00	50.0
Cycle 3 Day 1	200	18.33	22.04	0.0	16.67	100.0	197	-3.38	22.77	-66.7	0.00	83.3
Cycle 4 Day 1	171	14.33	18.46	0.0	0.00	83.3	169	-7.40	22.41	-83.3	0.00	66.7
Cycle 5 Day 1	166	15.86	22.00	0.0	0.00	100.0	165	-6.26	26.05	-83.3	0.00	83.3
Cycle 6 Day 1	147	14.40	21.60	0.0	0.00	100.0	146	-6.85	26.09	-83.3	0.00	66.7
Cycle 7 Day 1	127	13.65	17.37	0.0	0.00	66.7	126	-7.67	22.57	-66.7	0.00	50.0
Cycle 8 Day 1	111	15.77	22.34	0.0	0.00	100.0	110	-5.61	24.96	-83.3	0.00	66.7
Cycle 9 Day 1	104	12.50	20.48	0.0	0.00	83.3	103	-8.09	24.46	-83.3	0.00	66.7
Cycle 10 Day 1	81	14.40	20.88	0.0	0.00	83.3	79	-6.33	25.50	-66.7	0.00	66.7
Cycle 11 Day 1	72	13.89	19.58	0.0	0.00	66.7	71	-6.34	26.78	-83.3	0.00	66.7
Cycle 12 Day 1	59	11.30	17.35	0.0	0.00	66.7	57	-7.02	24.99	-66.7	0.00	66.7
Cycle 13 Day 1	47	12.77	18.46	0.0	0.00	83.3	45	-6.67	24.72	-83.3	0.00	66.7
Cycle 14 Day 1	44	13.64	21.94	0.0	0.00	100.0	42	-5.95	24.09	-66.7	0.00	66.7
Cycle 15 Day 1	36	13.43	22.82	0.0	0.00	100.0	34	-6.86	21.37	-66.7	0.00	50.0
Cycle 16 Day 1	32	13.54	18.66	0.0	0.00	66.7	30	-5.56	22.88	-66.7	0.00	33.3
Cycle 17 Day 1	26	10.26	19.48	0.0	0.00	66.7	24	-7.64	26.46	-83.3	0.00	33.3
Cycle 18 Day 1	21	6.35	9.83	0.0	0.00	33.3	20	-10.83	28.24	-83.3	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: 07OCT22

Table 302.1.3002.13: 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 19 Day 1	20	5.83	15.56	0.0	0.00	66.7	19	-7.02	26.83	-66.7	0.00	66.7
Cycle 20 Day 1	17	9.80	17.74	0.0	0.00	66.7	16	-6.25	29.74	-83.3	0.00	50.0
Cycle 21 Day 1	18	5.56	16.17	0.0	0.00	66.7	17	-10.78	30.01	-83.3	0.00	66.7
Cycle 22 Day 1	15	6.67	10.54	0.0	0.00	33.3	14	-11.90	27.29	-83.3	-8.33	16.7
Cycle 23 Day 1	12	2.78	6.49	0.0	0.00	16.7	11	-15.15	28.34	-83.3	0.00	16.7
Study Disc 1	150	33.78	29.41	0.0	33.33	100.0	145	9.54	25.44	-50.0	0.00	83.3
30 D SFU Z/P	76	27.63	28.36	0.0	16.67	100.0	74	7.88	25.91	-66.7	0.00	100.0
90 D SFU Z/P	70	23.33	26.07	0.0	16.67	83.3	68	3.92	21.57	-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: 07OCT22

Table 302.1.3002.14: 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 + CAPOX (N=254)												
Baseline	242	9.64	17.93	0.0	0.00	100.0						
Cycle 2 Day 1	209	11.96	18.79	0.0	0.00	100.0	208	2.24	15.89	-33.3	0.00	66.7
Cycle 3 Day 1	187	9.09	17.81	0.0	0.00	100.0	182	-0.37	16.80	-66.7	0.00	66.7
Cycle 4 Day 1	172	8.72	16.37	0.0	0.00	100.0	169	0.00	16.67	-33.3	0.00	66.7
Cycle 5 Day 1	162	8.85	15.67	0.0	0.00	66.7	159	-0.42	19.48	-66.7	0.00	66.7
Cycle 6 Day 1	151	8.61	17.83	0.0	0.00	100.0	149	1.12	19.54	-33.3	0.00	100.0
Cycle 7 Day 1	122	9.02	16.06	0.0	0.00	66.7	120	1.67	20.20	-66.7	0.00	66.7
Cycle 8 Day 1	114	8.77	16.62	0.0	0.00	100.0	108	1.85	19.25	-66.7	0.00	100.0
Cycle 9 Day 1	107	7.48	14.70	0.0	0.00	66.7	102	0.65	18.15	-66.7	0.00	33.3
Cycle 10 Day 1	88	8.33	15.37	0.0	0.00	66.7	85	1.18	20.86	-66.7	0.00	66.7
Cycle 11 Day 1	83	7.63	15.90	0.0	0.00	66.7	80	0.42	20.19	-66.7	0.00	66.7
Cycle 12 Day 1	76	5.70	13.76	0.0	0.00	66.7	74	-1.35	20.23	-66.7	0.00	66.7
Cycle 13 Day 1	62	6.99	16.12	0.0	0.00	66.7	60	-0.56	23.36	-66.7	0.00	66.7
Cycle 14 Day 1	56	6.55	14.80	0.0	0.00	66.7	54	-0.62	20.97	-66.7	0.00	66.7
Cycle 15 Day 1	51	5.88	12.83	0.0	0.00	33.3	49	-1.36	16.61	-33.3	0.00	33.3
Cycle 16 Day 1	46	6.52	13.37	0.0	0.00	33.3	44	-0.76	16.84	-33.3	0.00	33.3
Cycle 17 Day 1	41	5.69	12.70	0.0	0.00	33.3	39	-0.85	16.20	-33.3	0.00	33.3
Cycle 18 Day 1	37	8.11	14.50	0.0	0.00	33.3	35	0.95	17.12	-33.3	0.00	33.3
Cycle 19 Day 1	37	6.31	13.24	0.0	0.00	33.3	35	-0.95	17.12	-33.3	0.00	33.3
Cycle 20 Day 1	35	8.57	14.78	0.0	0.00	33.3	33	1.01	19.52	-33.3	0.00	33.3
Cycle 21 Day 1	32	7.29	14.00	0.0	0.00	33.3	30	0.00	17.51	-33.3	0.00	33.3
Cycle 22 Day 1	30	6.67	13.56	0.0	0.00	33.3	28	-1.19	19.21	-33.3	0.00	33.3
Cycle 23 Day 1	28	7.14	13.93	0.0	0.00	33.3	26	-1.28	14.85	-33.3	0.00	33.3
Cycle 24 Day 1	25	6.67	13.61	0.0	0.00	33.3	23	-2.90	17.15	-33.3	0.00	33.3
Cycle 25 Day 1	23	7.25	14.06	0.0	0.00	33.3	21	-1.59	19.65	-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: 07OCT22

Table 302.1.3002.14: 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 26 Day 1	22	4.55	11.71	0.0	0.00	33.3	20	-5.00	16.31	-33.3	0.00	33.3
Cycle 27 Day 1	20	10.00	19.04	0.0	0.00	66.7	18	0.00	16.17	-33.3	0.00	33.3
Cycle 28 Day 1	11	6.06	13.48	0.0	0.00	33.3	9	-3.70	11.11	-33.3	0.00	0.0
Cycle 29 Day 1	12	5.56	12.97	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
Study Disc 1	124	11.56	19.96	0.0	0.00	100.0	122	4.37	20.97	-66.7	0.00	66.7
30 D SFU Z/P	52	8.33	16.00	0.0	0.00	66.7	51	3.27	16.67	-66.7	0.00	33.3
90 D SFU Z/P	48	6.25	13.15	0.0	0.00	33.3	47	2.84	15.27	-33.3	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	242	10.88	19.35	0.0	0.00	100.0						
Cycle 2 Day 1	222	10.36	19.23	0.0	0.00	100.0	217	-0.77	17.99	-66.7	0.00	66.7
Cycle 3 Day 1	200	10.67	18.83	0.0	0.00	100.0	197	0.51	22.20	-100.0	0.00	100.0
Cycle 4 Day 1	171	10.33	19.57	0.0	0.00	100.0	169	-0.39	23.28	-66.7	0.00	100.0
Cycle 5 Day 1	166	7.83	17.18	0.0	0.00	100.0	165	-2.22	23.03	-100.0	0.00	66.7
Cycle 6 Day 1	147	8.39	17.38	0.0	0.00	100.0	146	0.00	21.80	-66.7	0.00	100.0
Cycle 7 Day 1	127	9.45	17.26	0.0	0.00	100.0	126	-0.53	22.70	-66.7	0.00	100.0
Cycle 8 Day 1	111	11.71	22.31	0.0	0.00	100.0	110	2.12	23.58	-66.7	0.00	100.0
Cycle 9 Day 1	104	8.33	17.22	0.0	0.00	66.7	103	-2.27	20.49	-66.7	0.00	66.7
Cycle 10 Day 1	81	8.64	17.30	0.0	0.00	100.0	79	-0.42	24.16	-66.7	0.00	100.0
Cycle 11 Day 1	72	7.41	15.03	0.0	0.00	66.7	71	-3.29	21.20	-66.7	0.00	33.3
Cycle 12 Day 1	59	6.78	14.88	0.0	0.00	66.7	57	-2.92	19.19	-33.3	0.00	66.7
Cycle 13 Day 1	47	7.09	15.44	0.0	0.00	66.7	45	-2.96	22.27	-66.7	0.00	66.7
Cycle 14 Day 1	44	6.82	15.38	0.0	0.00	66.7	42	-4.76	20.26	-66.7	0.00	33.3
Cycle 15 Day 1	36	6.48	15.57	0.0	0.00	66.7	34	-5.88	15.29	-33.3	0.00	33.3
Cycle 16 Day 1	32	9.37	21.14	0.0	0.00	100.0	30	-3.33	22.06	-66.7	0.00	33.3
Cycle 17 Day 1	26	5.13	12.26	0.0	0.00	33.3	24	-6.94	21.93	-66.7	0.00	33.3
Cycle 18 Day 1	21	3.17	10.03	0.0	0.00	33.3	20	-10.00	19.04	-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: 07OCT22

Table 302.1.3002.14: 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 19 Day 1	20	0.00	0.00	0.0	0.00	0.0	19	-12.28	19.91	-66.7	0.00	0.0
Cycle 20 Day 1	17	0.00	0.00	0.0	0.00	0.0	16	-14.58	20.97	-66.7	0.00	0.0
Cycle 21 Day 1	18	1.85	7.86	0.0	0.00	33.3	17	-11.76	20.21	-66.7	0.00	0.0
Cycle 22 Day 1	15	0.00	0.00	0.0	0.00	0.0	14	-14.29	21.54	-66.7	0.00	0.0
Cycle 23 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-15.15	22.92	-66.7	0.00	0.0
Study Disc 1	150	20.89	27.18	0.0	0.00	100.0	145	9.66	27.75	-66.7	0.00	100.0
30 D SFU Z/P	76	13.16	21.14	0.0	0.00	100.0	74	3.60	23.13	-66.7	0.00	66.7
90 D SFU Z/P	70	14.29	23.79	0.0	0.00	100.0	68	3.43	25.85	-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: 07OCT22

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea 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 + CAPOX (N=176)												
	Baseline	169	9.07	17.34	0.0	0.00	100.0						
	Cycle 2 Day 1	147	12.02	19.87	0.0	0.00	100.0	147	2.72	17.23	-33.3	0.00	66.7
	Cycle 3 Day 1	136	8.09	16.48	0.0	0.00	100.0	133	-0.75	16.65	-66.7	0.00	66.7
	Cycle 4 Day 1	124	7.80	14.17	0.0	0.00	33.3	123	-0.54	15.96	-33.3	0.00	33.3
	Cycle 5 Day 1	117	7.12	13.72	0.0	0.00	33.3	116	-1.44	18.85	-66.7	0.00	33.3
	Cycle 6 Day 1	110	8.18	15.76	0.0	0.00	66.7	110	0.91	18.32	-33.3	0.00	66.7
	Cycle 7 Day 1	87	9.20	15.82	0.0	0.00	66.7	87	1.53	19.63	-66.7	0.00	66.7
	Cycle 8 Day 1	86	8.14	14.40	0.0	0.00	33.3	83	1.20	17.61	-66.7	0.00	33.3
	Cycle 9 Day 1	81	6.58	14.36	0.0	0.00	66.7	78	0.00	18.61	-66.7	0.00	33.3
	Cycle 10 Day 1	68	8.82	15.90	0.0	0.00	66.7	66	2.53	22.88	-66.7	0.00	66.7
	Cycle 11 Day 1	64	7.29	15.11	0.0	0.00	66.7	62	1.08	21.74	-66.7	0.00	66.7
	Cycle 12 Day 1	59	6.78	14.88	0.0	0.00	66.7	57	0.00	21.82	-66.7	0.00	66.7
	Cycle 13 Day 1	49	7.48	17.03	0.0	0.00	66.7	47	0.00	25.06	-66.7	0.00	66.7
	Cycle 14 Day 1	44	6.82	15.38	0.0	0.00	66.7	42	0.00	22.09	-66.7	0.00	66.7
	Cycle 15 Day 1	41	4.88	11.93	0.0	0.00	33.3	39	-1.71	17.01	-33.3	0.00	33.3
	Cycle 16 Day 1	37	6.31	13.24	0.0	0.00	33.3	35	0.00	16.17	-33.3	0.00	33.3
	Cycle 17 Day 1	33	6.06	13.06	0.0	0.00	33.3	31	0.00	17.21	-33.3	0.00	33.3
	Cycle 18 Day 1	29	9.20	15.16	0.0	0.00	33.3	27	2.47	18.32	-33.3	0.00	33.3
	Cycle 19 Day 1	29	6.90	13.74	0.0	0.00	33.3	27	0.00	18.49	-33.3	0.00	33.3
	Cycle 20 Day 1	27	8.64	14.89	0.0	0.00	33.3	25	1.33	22.53	-33.3	0.00	33.3
	Cycle 21 Day 1	24	6.94	13.83	0.0	0.00	33.3	22	0.00	17.82	-33.3	0.00	33.3
	Cycle 22 Day 1	24	5.56	12.69	0.0	0.00	33.3	22	-1.52	21.77	-33.3	0.00	33.3
	Cycle 23 Day 1	22	6.06	13.16	0.0	0.00	33.3	20	-1.67	17.01	-33.3	0.00	33.3
	Cycle 24 Day 1	20	5.00	12.21	0.0	0.00	33.3	18	-3.70	19.43	-33.3	0.00	33.3
	Cycle 25 Day 1	18	7.41	14.26	0.0	0.00	33.3	16	0.00	21.08	-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: 07OCT22

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea 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 26 Day 1	17	3.92	11.07	0.0	0.00	33.3	15	-4.44	17.21	-33.3	0.00	33.3
	Cycle 27 Day 1	15	8.89	19.79	0.0	0.00	66.7	13	0.00	19.25	-33.3	0.00	33.3
	Study Disc 1	88	13.26	21.17	0.0	0.00	100.0	87	5.36	23.22	-66.7	0.00	66.7
	30 D SFU Z/P	35	7.62	16.34	0.0	0.00	66.7	34	0.98	17.38	-66.7	0.00	33.3
	90 D SFU Z/P	33	6.06	13.06	0.0	0.00	33.3	32	3.12	13.01	-33.3	0.00	33.3
	Placebo + CAPOX (N=180)												
	Baseline	173	10.02	19.42	0.0	0.00	100.0						
	Cycle 2 Day 1	162	10.29	20.44	0.0	0.00	100.0	159	0.00	17.59	-66.7	0.00	66.7
	Cycle 3 Day 1	147	10.43	19.03	0.0	0.00	100.0	144	1.39	21.90	-100.0	0.00	100.0
	Cycle 4 Day 1	120	8.89	19.20	0.0	0.00	100.0	118	-0.85	23.66	-66.7	0.00	100.0
	Cycle 5 Day 1	119	7.56	17.05	0.0	0.00	100.0	118	-1.13	22.19	-66.7	0.00	66.7
	Cycle 6 Day 1	107	8.10	18.22	0.0	0.00	100.0	106	0.63	22.53	-66.7	0.00	100.0
	Cycle 7 Day 1	87	8.81	17.94	0.0	0.00	100.0	86	0.78	21.68	-66.7	0.00	100.0
	Cycle 8 Day 1	83	8.84	18.83	0.0	0.00	100.0	82	1.22	21.88	-66.7	0.00	100.0
	Cycle 9 Day 1	78	8.12	17.15	0.0	0.00	66.7	77	-0.87	19.48	-66.7	0.00	33.3
	Cycle 10 Day 1	59	9.04	18.39	0.0	0.00	100.0	58	0.57	24.58	-66.7	0.00	100.0
	Cycle 11 Day 1	54	6.79	15.02	0.0	0.00	66.7	53	-2.52	21.53	-66.7	0.00	33.3
	Cycle 12 Day 1	42	6.35	13.25	0.0	0.00	33.3	41	-2.44	17.30	-33.3	0.00	33.3
	Cycle 13 Day 1	34	6.86	13.68	0.0	0.00	33.3	33	-3.03	21.02	-66.7	0.00	33.3
	Cycle 14 Day 1	33	6.06	15.49	0.0	0.00	66.7	32	-4.17	20.30	-66.7	0.00	33.3
	Cycle 15 Day 1	27	6.17	16.11	0.0	0.00	66.7	26	-5.13	15.47	-33.3	0.00	33.3
	Cycle 16 Day 1	21	9.52	23.90	0.0	0.00	100.0	20	-1.67	25.31	-66.7	0.00	33.3
	Cycle 17 Day 1	16	2.08	8.33	0.0	0.00	33.3	15	-8.89	23.46	-66.7	0.00	33.3
	Cycle 18 Day 1	13	2.56	9.25	0.0	0.00	33.3	12	-11.11	16.41	-33.3	0.00	0.0
	Cycle 19 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-12.12	22.47	-66.7	0.00	0.0
	Cycle 20 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-15.15	22.92	-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.
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: 07OCT22

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea 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 21 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-13.89	22.29	-66.7	0.00	0.0
	Cycle 22 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	-16.67	23.57	-66.7	0.00	0.0
	Study Disc 1	109	22.32	27.98	0.0	0.00	100.0	106	11.64	29.11	-66.7	0.00	100.0
	30 D SFU Z/P	53	13.84	22.10	0.0	0.00	100.0	51	5.23	23.45	-66.7	0.00	66.7
	90 D SFU Z/P	46	13.77	23.91	0.0	0.00	100.0	44	2.27	27.28	-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.
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: 07OCT22

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea 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 + CAPOX (N= 78)												
	Baseline	73	10.96	19.29	0.0	0.00	100.0						
	Cycle 2 Day 1	62	11.83	16.08	0.0	0.00	33.3	61	1.09	12.12	-33.3	0.00	33.3
	Cycle 3 Day 1	51	11.76	20.90	0.0	0.00	100.0	49	0.68	17.33	-33.3	0.00	66.7
	Cycle 4 Day 1	48	11.11	21.01	0.0	0.00	100.0	46	1.45	18.53	-33.3	0.00	66.7
	Cycle 5 Day 1	45	13.33	19.33	0.0	0.00	66.7	43	2.33	21.08	-33.3	0.00	66.7
	Cycle 6 Day 1	41	9.76	22.66	0.0	0.00	100.0	39	1.71	22.88	-33.3	0.00	100.0
	Cycle 7 Day 1	35	8.57	16.85	0.0	0.00	66.7	33	2.02	21.95	-33.3	0.00	66.7
	Cycle 8 Day 1	28	10.71	22.32	0.0	0.00	100.0	25	4.00	24.19	-33.3	0.00	100.0
	Cycle 9 Day 1	26	10.26	15.69	0.0	0.00	33.3	24	2.78	16.79	-33.3	0.00	33.3
	Cycle 10 Day 1	20	6.67	13.68	0.0	0.00	33.3	19	-3.51	10.51	-33.3	0.00	0.0
	Cycle 11 Day 1	19	8.77	18.73	0.0	0.00	66.7	18	-1.85	13.87	-33.3	0.00	33.3
	Cycle 12 Day 1	17	1.96	8.08	0.0	0.00	33.3	17	-5.88	13.10	-33.3	0.00	0.0
	Cycle 13 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 14 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Cycle 15 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	36	7.41	16.16	0.0	0.00	66.7	35	1.90	13.87	-33.3	0.00	33.3
	30 D SFU Z/P	17	9.80	15.66	0.0	0.00	33.3	17	7.84	14.57	0.0	0.00	33.3
	90 D SFU Z/P	15	6.67	13.80	0.0	0.00	33.3	15	2.22	19.79	-33.3	0.00	33.3
	Placebo + CAPOX (N= 73)												
	Baseline	69	13.04	19.15	0.0	0.00	100.0						
	Cycle 2 Day 1	60	10.56	15.64	0.0	0.00	33.3	58	-2.87	19.03	-66.7	0.00	33.3
	Cycle 3 Day 1	53	11.32	18.42	0.0	0.00	66.7	53	-1.89	23.03	-66.7	0.00	66.7
	Cycle 4 Day 1	51	13.73	20.20	0.0	0.00	66.7	51	0.65	22.60	-66.7	0.00	66.7
	Cycle 5 Day 1	47	8.51	17.68	0.0	0.00	66.7	47	-4.96	25.04	-100.0	0.00	66.7
	Cycle 6 Day 1	40	9.17	15.07	0.0	0.00	33.3	40	-1.67	19.90	-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: 07OCT22

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea 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 7 Day 1	40	10.83	15.81	0.0	0.00	33.3	40	-3.33	24.81	-66.7	0.00	33.3
	Cycle 8 Day 1	28	20.24	29.17	0.0	0.00	100.0	28	4.76	28.28	-33.3	0.00	100.0
	Cycle 9 Day 1	26	8.97	17.78	0.0	0.00	66.7	26	-6.41	23.13	-33.3	0.00	66.7
	Cycle 10 Day 1	22	7.58	14.30	0.0	0.00	33.3	21	-3.17	23.34	-33.3	0.00	33.3
	Cycle 11 Day 1	18	9.26	15.36	0.0	0.00	33.3	18	-5.56	20.61	-33.3	0.00	33.3
	Cycle 12 Day 1	17	7.84	18.74	0.0	0.00	66.7	16	-4.17	23.96	-33.3	0.00	66.7
	Cycle 13 Day 1	13	7.69	19.97	0.0	0.00	66.7	12	-2.78	26.43	-33.3	0.00	66.7
	Cycle 14 Day 1	11	9.09	15.57	0.0	0.00	33.3	10	-6.67	21.08	-33.3	0.00	33.3
	Cycle 16 Day 1	11	9.09	15.57	0.0	0.00	33.3	10	-6.67	14.05	-33.3	0.00	0.0
	Cycle 17 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3
	Study Disc 1	41	17.07	24.86	0.0	0.00	100.0	39	4.27	23.17	-33.3	0.00	66.7
	30 D SFU Z/P	23	11.59	19.09	0.0	0.00	66.7	23	0.00	22.47	-33.3	0.00	33.3
	90 D SFU Z/P	24	15.28	24.04	0.0	0.00	100.0	24	5.56	23.40	-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: 07OCT22

Table 302.1.3002.15: 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 + CAPOX (N=254)												
Baseline	242	21.07	27.18	0.0	0.00	100.0						
Cycle 2 Day 1	209	19.94	26.58	0.0	0.00	100.0	208	-1.44	27.47	-100.0	0.00	100.0
Cycle 3 Day 1	187	18.72	23.45	0.0	0.00	100.0	182	-0.55	28.14	-100.0	0.00	100.0
Cycle 4 Day 1	172	15.12	21.72	0.0	0.00	100.0	169	-4.73	28.47	-66.7	0.00	66.7
Cycle 5 Day 1	162	16.05	22.36	0.0	0.00	100.0	159	-2.73	28.06	-100.0	0.00	66.7
Cycle 6 Day 1	151	15.01	22.99	0.0	0.00	100.0	149	-5.15	28.40	-66.7	0.00	100.0
Cycle 7 Day 1	122	13.93	20.48	0.0	0.00	100.0	120	-5.28	28.34	-100.0	0.00	66.7
Cycle 8 Day 1	114	18.13	21.79	0.0	0.00	100.0	108	0.31	29.00	-100.0	0.00	66.7
Cycle 9 Day 1	107	15.26	19.58	0.0	0.00	100.0	102	-4.90	29.44	-100.0	0.00	66.7
Cycle 10 Day 1	88	13.26	20.55	0.0	0.00	100.0	85	-5.49	29.48	-100.0	0.00	66.7
Cycle 11 Day 1	83	14.86	18.22	0.0	0.00	66.7	80	-2.50	29.90	-100.0	0.00	33.3
Cycle 12 Day 1	76	15.35	19.96	0.0	0.00	100.0	74	-0.90	27.57	-100.0	0.00	66.7
Cycle 13 Day 1	62	11.83	19.18	0.0	0.00	66.7	60	-3.33	24.32	-66.7	0.00	66.7
Cycle 14 Day 1	56	13.10	17.61	0.0	0.00	66.7	54	0.62	27.84	-100.0	0.00	33.3
Cycle 15 Day 1	51	15.03	18.03	0.0	0.00	66.7	49	4.76	23.57	-66.7	0.00	33.3
Cycle 16 Day 1	46	13.04	16.45	0.0	0.00	33.3	44	0.76	23.28	-66.7	0.00	33.3
Cycle 17 Day 1	41	10.57	15.70	0.0	0.00	33.3	39	0.00	22.94	-66.7	0.00	33.3
Cycle 18 Day 1	37	13.51	16.59	0.0	0.00	33.3	35	1.90	21.30	-33.3	0.00	33.3
Cycle 19 Day 1	37	9.91	15.45	0.0	0.00	33.3	35	0.00	18.08	-33.3	0.00	33.3
Cycle 20 Day 1	35	9.52	17.29	0.0	0.00	66.7	33	0.00	16.67	-33.3	0.00	33.3
Cycle 21 Day 1	32	10.42	15.70	0.0	0.00	33.3	30	1.11	20.50	-33.3	0.00	33.3
Cycle 22 Day 1	30	7.78	14.34	0.0	0.00	33.3	28	-2.38	15.53	-33.3	0.00	33.3
Cycle 23 Day 1	28	7.14	13.93	0.0	0.00	33.3	26	0.00	13.33	-33.3	0.00	33.3
Cycle 24 Day 1	25	9.33	15.28	0.0	0.00	33.3	23	1.45	18.74	-33.3	0.00	33.3
Cycle 25 Day 1	23	5.80	12.92	0.0	0.00	33.3	21	-1.59	19.65	-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: 07OCT22

Table 302.1.3002.15: 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 26 Day 1	22	9.09	15.19	0.0	0.00	33.3	20	0.00	18.73	-33.3	0.00	33.3
Cycle 27 Day 1	20	6.67	13.68	0.0	0.00	33.3	18	-1.85	17.98	-33.3	0.00	33.3
Cycle 28 Day 1	11	3.03	10.05	0.0	0.00	33.3	9	-7.41	14.70	-33.3	0.00	0.0
Cycle 29 Day 1	12	5.56	12.97	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Study Disc 1	124	24.46	28.23	0.0	33.33	100.0	122	6.83	34.80	-100.0	0.00	100.0
30 D SFU Z/P	52	21.15	24.72	0.0	0.00	66.7	51	7.19	30.78	-100.0	0.00	66.7
90 D SFU Z/P	48	18.06	19.40	0.0	16.67	66.7	47	6.38	24.71	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	24.79	26.66	0.0	33.33	100.0						
Cycle 2 Day 1	222	22.82	25.95	0.0	33.33	100.0	217	-1.54	27.55	-66.7	0.00	100.0
Cycle 3 Day 1	200	21.50	26.29	0.0	0.00	100.0	197	-2.54	28.56	-66.7	0.00	100.0
Cycle 4 Day 1	171	19.10	24.23	0.0	0.00	100.0	169	-5.13	27.94	-66.7	0.00	66.7
Cycle 5 Day 1	166	18.88	22.44	0.0	0.00	66.7	165	-4.44	28.16	-66.7	0.00	66.7
Cycle 6 Day 1	147	20.41	27.16	0.0	0.00	100.0	146	-2.51	30.35	-100.0	0.00	100.0
Cycle 7 Day 1	127	19.69	24.25	0.0	0.00	100.0	126	-2.91	31.28	-100.0	0.00	100.0
Cycle 8 Day 1	111	19.22	24.02	0.0	0.00	100.0	110	-4.85	25.48	-66.7	0.00	66.7
Cycle 9 Day 1	104	17.95	26.24	0.0	0.00	100.0	103	-4.21	27.88	-66.7	0.00	66.7
Cycle 10 Day 1	81	20.99	24.41	0.0	0.00	100.0	79	-0.42	28.49	-66.7	0.00	66.7
Cycle 11 Day 1	72	21.76	25.73	0.0	16.67	100.0	71	0.94	30.33	-66.7	0.00	100.0
Cycle 12 Day 1	59	18.64	23.38	0.0	0.00	100.0	57	-0.58	29.87	-66.7	0.00	66.7
Cycle 13 Day 1	47	19.15	24.81	0.0	0.00	100.0	45	-0.74	32.94	-66.7	0.00	66.7
Cycle 14 Day 1	44	15.91	22.14	0.0	0.00	66.7	42	-2.38	32.42	-66.7	0.00	66.7
Cycle 15 Day 1	36	17.59	18.66	0.0	16.67	66.7	34	0.00	29.59	-66.7	0.00	66.7
Cycle 16 Day 1	32	21.87	21.77	0.0	33.33	66.7	30	6.67	25.37	-33.3	0.00	66.7
Cycle 17 Day 1	26	24.36	30.63	0.0	0.00	100.0	24	12.50	32.32	-33.3	0.00	100.0
Cycle 18 Day 1	21	12.70	19.65	0.0	0.00	66.7	20	1.67	20.16	-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: 07OCT22

Table 302.1.3002.15: 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 19 Day 1	20	13.33	25.13	0.0	0.00	100.0	19	1.75	32.34	-33.3	0.00	100.0
Cycle 20 Day 1	17	17.65	23.91	0.0	0.00	66.7	16	6.25	21.84	-33.3	0.00	66.7
Cycle 21 Day 1	18	16.67	23.57	0.0	0.00	66.7	17	7.84	30.11	-33.3	0.00	66.7
Cycle 22 Day 1	15	20.00	30.34	0.0	0.00	100.0	14	9.52	35.63	-33.3	0.00	100.0
Cycle 23 Day 1	12	11.11	21.71	0.0	0.00	66.7	11	0.00	29.81	-33.3	0.00	66.7
Study Disc 1	150	33.11	30.77	0.0	33.33	100.0	145	8.97	34.75	-66.7	0.00	100.0
30 D SFU Z/P	76	27.19	28.13	0.0	33.33	100.0	74	6.76	35.32	-66.7	0.00	100.0
90 D SFU Z/P	70	24.76	27.62	0.0	33.33	100.0	68	0.00	29.37	-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: 07OCT22

Table 302.1.3002.16: 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 + CAPOX (N=254)												
Baseline	242	26.17	29.97	0.0	33.33	100.0						
Cycle 2 Day 1	209	28.23	28.97	0.0	33.33	100.0	208	3.69	31.97	-66.7	0.00	100.0
Cycle 3 Day 1	187	26.56	29.15	0.0	33.33	100.0	182	0.73	34.86	-100.0	0.00	100.0
Cycle 4 Day 1	172	22.09	26.79	0.0	0.00	100.0	169	-3.55	34.32	-100.0	0.00	100.0
Cycle 5 Day 1	162	22.84	28.41	0.0	0.00	100.0	159	-2.94	36.24	-100.0	0.00	100.0
Cycle 6 Day 1	151	26.71	29.32	0.0	33.33	100.0	149	-0.22	34.55	-66.7	0.00	100.0
Cycle 7 Day 1	122	19.95	24.11	0.0	0.00	100.0	120	-4.44	37.41	-100.0	0.00	100.0
Cycle 8 Day 1	114	23.10	26.28	0.0	33.33	100.0	108	-1.23	31.55	-100.0	0.00	66.7
Cycle 9 Day 1	107	20.87	30.55	0.0	0.00	100.0	102	-3.92	36.72	-100.0	0.00	100.0
Cycle 10 Day 1	88	18.94	26.65	0.0	0.00	100.0	85	-3.92	31.04	-100.0	0.00	66.7
Cycle 11 Day 1	83	13.25	21.43	0.0	0.00	100.0	80	-7.92	31.49	-100.0	0.00	66.7
Cycle 12 Day 1	76	14.04	21.27	0.0	0.00	100.0	74	-8.11	31.60	-100.0	0.00	66.7
Cycle 13 Day 1	62	14.52	23.08	0.0	0.00	100.0	60	-9.44	36.36	-100.0	0.00	66.7
Cycle 14 Day 1	56	10.12	18.98	0.0	0.00	100.0	54	-12.35	31.25	-100.0	0.00	66.7
Cycle 15 Day 1	51	12.42	19.96	0.0	0.00	100.0	49	-10.20	30.58	-100.0	0.00	66.7
Cycle 16 Day 1	46	13.77	19.34	0.0	0.00	66.7	44	-9.85	33.39	-100.0	0.00	66.7
Cycle 17 Day 1	41	15.45	23.68	0.0	0.00	100.0	39	-7.69	33.74	-100.0	0.00	100.0
Cycle 18 Day 1	37	14.41	21.57	0.0	0.00	100.0	35	-12.38	34.38	-100.0	0.00	100.0
Cycle 19 Day 1	37	11.71	17.94	0.0	0.00	66.7	35	-15.24	31.67	-100.0	0.00	66.7
Cycle 20 Day 1	35	15.24	24.71	0.0	0.00	100.0	33	-9.09	36.58	-100.0	0.00	100.0
Cycle 21 Day 1	32	18.75	20.63	0.0	16.67	66.7	30	-3.33	35.40	-100.0	0.00	66.7
Cycle 22 Day 1	30	10.00	17.83	0.0	0.00	66.7	28	-13.10	33.13	-100.0	0.00	33.3
Cycle 23 Day 1	28	10.71	24.09	0.0	0.00	100.0	26	-11.54	32.58	-100.0	0.00	33.3
Cycle 24 Day 1	25	8.00	17.43	0.0	0.00	66.7	23	-14.49	31.50	-100.0	0.00	33.3
Cycle 25 Day 1	23	10.14	18.63	0.0	0.00	66.7	21	-11.11	33.88	-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: 07OCT22

Table 302.1.3002.16: 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 26 Day 1	22	10.61	23.87	0.0	0.00	100.0	20	-11.67	37.89	-100.0	0.00	66.7
Cycle 27 Day 1	20	11.67	16.31	0.0	0.00	33.3	18	-11.11	34.30	-100.0	0.00	33.3
Cycle 28 Day 1	11	3.03	10.05	0.0	0.00	33.3	9	-18.52	41.20	-100.0	0.00	33.3
Cycle 29 Day 1	12	2.78	9.62	0.0	0.00	33.3	10	-16.67	39.28	-100.0	0.00	33.3
Study Disc 1	124	28.76	32.18	0.0	33.33	100.0	122	6.83	35.32	-100.0	0.00	100.0
30 D SFU Z/P	52	27.56	34.75	0.0	0.00	100.0	51	6.54	38.88	-100.0	0.00	100.0
90 D SFU Z/P	48	24.31	31.31	0.0	0.00	100.0	47	6.38	40.31	-66.7	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	242	24.66	29.17	0.0	33.33	100.0						
Cycle 2 Day 1	222	21.47	24.45	0.0	33.33	100.0	217	-2.61	27.37	-100.0	0.00	100.0
Cycle 3 Day 1	200	19.83	25.47	0.0	0.00	100.0	197	-2.71	27.43	-100.0	0.00	66.7
Cycle 4 Day 1	171	18.91	25.31	0.0	0.00	100.0	169	-5.13	33.13	-100.0	0.00	100.0
Cycle 5 Day 1	166	19.28	24.41	0.0	0.00	100.0	165	-4.44	33.03	-100.0	0.00	66.7
Cycle 6 Day 1	147	21.09	25.31	0.0	0.00	100.0	146	-2.51	33.47	-100.0	0.00	100.0
Cycle 7 Day 1	127	16.27	22.95	0.0	0.00	100.0	126	-6.88	31.36	-100.0	0.00	100.0
Cycle 8 Day 1	111	16.82	22.42	0.0	0.00	100.0	110	-6.36	32.71	-100.0	0.00	66.7
Cycle 9 Day 1	104	16.35	25.01	0.0	0.00	100.0	103	-7.12	34.51	-100.0	0.00	100.0
Cycle 10 Day 1	81	12.35	20.03	0.0	0.00	66.7	79	-10.13	32.62	-100.0	0.00	66.7
Cycle 11 Day 1	72	11.57	21.05	0.0	0.00	100.0	71	-12.21	33.92	-100.0	0.00	66.7
Cycle 12 Day 1	59	9.04	19.41	0.0	0.00	100.0	57	-11.11	30.43	-66.7	0.00	66.7
Cycle 13 Day 1	47	9.22	16.60	0.0	0.00	66.7	45	-12.59	31.21	-100.0	0.00	66.7
Cycle 14 Day 1	44	10.61	18.71	0.0	0.00	66.7	42	-10.32	30.79	-100.0	0.00	66.7
Cycle 15 Day 1	36	10.19	20.81	0.0	0.00	100.0	34	-10.78	30.40	-100.0	0.00	66.7
Cycle 16 Day 1	32	11.46	18.18	0.0	0.00	66.7	30	-7.78	32.38	-100.0	0.00	66.7
Cycle 17 Day 1	26	10.26	18.30	0.0	0.00	66.7	24	-8.33	35.78	-100.0	0.00	66.7
Cycle 18 Day 1	21	11.11	19.25	0.0	0.00	66.7	20	-10.00	36.03	-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: 07OCT22

Table 302.1.3002.16: 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 19 Day 1	20	3.33	10.26	0.0	0.00	33.3	19	-14.04	20.23	-66.7	0.00	0.0
Cycle 20 Day 1	17	7.84	14.57	0.0	0.00	33.3	16	-18.75	29.74	-100.0	0.00	0.0
Cycle 21 Day 1	18	11.11	19.80	0.0	0.00	66.7	17	-13.73	35.47	-66.7	0.00	66.7
Cycle 22 Day 1	15	8.89	19.79	0.0	0.00	66.7	14	-21.43	30.96	-100.0	0.00	0.0
Cycle 23 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-24.24	36.79	-100.0	-33.33	33.3
Study Disc 1	150	32.22	33.76	0.0	33.33	100.0	145	7.59	33.96	-100.0	0.00	100.0
30 D SFU Z/P	76	26.32	27.39	0.0	33.33	100.0	74	4.95	28.50	-66.7	0.00	66.7
90 D SFU Z/P	70	20.95	26.11	0.0	0.00	100.0	68	0.49	33.33	-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: 07OCT22

Table 302.1.3002.17: 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 + CAPOX (N=254)												
Baseline	242	18.04	26.13	0.0	0.00	100.0						
Cycle 2 Day 1	209	16.43	22.67	0.0	0.00	100.0	208	-0.64	24.94	-66.7	0.00	100.0
Cycle 3 Day 1	187	15.15	24.49	0.0	0.00	100.0	182	-2.38	26.23	-100.0	0.00	100.0
Cycle 4 Day 1	172	12.98	21.46	0.0	0.00	100.0	169	-4.73	26.30	-100.0	0.00	66.7
Cycle 5 Day 1	162	14.20	24.59	0.0	0.00	100.0	159	-2.73	25.97	-66.7	0.00	100.0
Cycle 6 Day 1	151	12.36	21.98	0.0	0.00	100.0	149	-5.82	26.77	-100.0	0.00	100.0
Cycle 7 Day 1	122	10.93	17.90	0.0	0.00	66.7	120	-7.78	26.19	-66.7	0.00	66.7
Cycle 8 Day 1	114	13.16	22.00	0.0	0.00	100.0	108	-4.63	27.14	-100.0	0.00	66.7
Cycle 9 Day 1	107	14.64	21.56	0.0	0.00	100.0	102	-4.25	22.82	-66.7	0.00	66.7
Cycle 10 Day 1	88	11.74	20.86	0.0	0.00	100.0	85	-6.27	26.97	-66.7	0.00	100.0
Cycle 11 Day 1	83	10.44	20.11	0.0	0.00	100.0	80	-5.00	28.61	-100.0	0.00	100.0
Cycle 12 Day 1	76	10.09	18.07	0.0	0.00	100.0	74	-6.76	25.27	-100.0	0.00	33.3
Cycle 13 Day 1	62	9.14	17.25	0.0	0.00	66.7	60	-7.78	25.58	-66.7	0.00	66.7
Cycle 14 Day 1	56	10.12	18.98	0.0	0.00	66.7	54	-6.79	25.39	-66.7	0.00	66.7
Cycle 15 Day 1	51	11.76	18.65	0.0	0.00	66.7	49	-5.44	27.51	-66.7	0.00	66.7
Cycle 16 Day 1	46	12.32	19.06	0.0	0.00	66.7	44	-3.03	26.72	-66.7	0.00	66.7
Cycle 17 Day 1	41	11.38	20.56	0.0	0.00	100.0	39	-4.27	27.76	-66.7	0.00	100.0
Cycle 18 Day 1	37	9.91	17.33	0.0	0.00	66.7	35	-6.67	26.57	-66.7	0.00	66.7
Cycle 19 Day 1	37	9.91	19.03	0.0	0.00	66.7	35	-6.67	23.98	-66.7	0.00	66.7
Cycle 20 Day 1	35	14.29	25.93	0.0	0.00	100.0	33	-1.01	32.79	-66.7	0.00	100.0
Cycle 21 Day 1	32	14.58	23.85	0.0	0.00	100.0	30	0.00	27.68	-33.3	0.00	100.0
Cycle 22 Day 1	30	12.22	23.95	0.0	0.00	100.0	28	-3.57	33.13	-66.7	0.00	100.0
Cycle 23 Day 1	28	9.52	21.96	0.0	0.00	100.0	26	-3.85	28.79	-66.7	0.00	100.0
Cycle 24 Day 1	25	10.67	18.56	0.0	0.00	66.7	23	-4.35	25.23	-66.7	0.00	33.3
Cycle 25 Day 1	23	11.59	19.09	0.0	0.00	66.7	21	-1.59	26.82	-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: 07OCT22

Table 302.1.3002.17: 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 26 Day 1	22	9.09	18.35	0.0	0.00	66.7	20	-5.00	29.17	-100.0	0.00	33.3
Cycle 27 Day 1	20	6.67	17.44	0.0	0.00	66.7	18	-7.41	29.27	-100.0	0.00	33.3
Cycle 28 Day 1	11	12.12	22.47	0.0	0.00	66.7	9	0.00	23.57	-33.3	0.00	33.3
Cycle 29 Day 1	12	11.11	21.71	0.0	0.00	66.7	10	0.00	27.22	-66.7	0.00	33.3
Study Disc 1	124	16.13	24.23	0.0	0.00	100.0	122	-1.37	27.57	-66.7	0.00	100.0
30 D SFU Z/P	52	16.67	26.81	0.0	0.00	100.0	51	-1.96	30.85	-66.7	0.00	100.0
90 D SFU Z/P	48	17.36	25.72	0.0	0.00	100.0	47	3.55	28.00	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	17.63	27.02	0.0	0.00	100.0						
Cycle 2 Day 1	222	14.56	22.93	0.0	0.00	100.0	217	-2.76	25.10	-100.0	0.00	66.7
Cycle 3 Day 1	200	11.17	20.13	0.0	0.00	100.0	197	-5.25	23.58	-100.0	0.00	66.7
Cycle 4 Day 1	171	10.33	20.86	0.0	0.00	100.0	169	-6.90	29.07	-100.0	0.00	100.0
Cycle 5 Day 1	166	11.85	19.77	0.0	0.00	100.0	165	-4.65	26.77	-100.0	0.00	66.7
Cycle 6 Day 1	147	13.15	22.26	0.0	0.00	100.0	146	-4.34	29.36	-100.0	0.00	100.0
Cycle 7 Day 1	127	14.70	24.00	0.0	0.00	100.0	126	-2.12	32.32	-100.0	0.00	100.0
Cycle 8 Day 1	111	13.81	23.12	0.0	0.00	100.0	110	-3.03	31.13	-100.0	0.00	100.0
Cycle 9 Day 1	104	10.90	21.00	0.0	0.00	100.0	103	-5.50	29.19	-100.0	0.00	66.7
Cycle 10 Day 1	81	8.64	20.26	0.0	0.00	100.0	79	-7.17	30.97	-100.0	0.00	100.0
Cycle 11 Day 1	72	12.50	24.67	0.0	0.00	100.0	71	-3.29	33.88	-100.0	0.00	100.0
Cycle 12 Day 1	59	11.86	23.78	0.0	0.00	100.0	57	-1.17	26.70	-66.7	0.00	100.0
Cycle 13 Day 1	47	10.64	22.10	0.0	0.00	100.0	45	-4.44	33.03	-100.0	0.00	100.0
Cycle 14 Day 1	44	13.64	23.09	0.0	0.00	100.0	42	-1.59	28.47	-100.0	0.00	66.7
Cycle 15 Day 1	36	11.11	19.52	0.0	0.00	66.7	34	-2.94	33.20	-100.0	0.00	66.7
Cycle 16 Day 1	32	11.46	24.84	0.0	0.00	100.0	30	-2.22	33.83	-66.7	0.00	66.7
Cycle 17 Day 1	26	7.69	21.72	0.0	0.00	100.0	24	-2.78	25.85	-66.7	0.00	66.7
Cycle 18 Day 1	21	4.76	11.95	0.0	0.00	33.3	20	-6.67	29.81	-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: 07OCT22

Table 302.1.3002.17: 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 19 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	-5.26	16.72	-66.7	0.00	0.0
Cycle 20 Day 1	17	5.88	13.10	0.0	0.00	33.3	16	-6.25	27.81	-66.7	0.00	33.3
Cycle 21 Day 1	18	3.70	10.78	0.0	0.00	33.3	17	-7.84	32.34	-100.0	0.00	33.3
Cycle 22 Day 1	15	11.11	16.27	0.0	0.00	33.3	14	0.00	26.15	-66.7	0.00	33.3
Cycle 23 Day 1	12	5.56	12.97	0.0	0.00	33.3	11	-6.06	32.72	-100.0	0.00	33.3
Study Disc 1	150	20.67	26.94	0.0	0.00	100.0	145	4.37	31.00	-100.0	0.00	66.7
30 D SFU Z/P	76	16.67	22.11	0.0	0.00	100.0	74	2.25	25.48	-66.7	0.00	66.7
90 D SFU Z/P	70	20.48	26.19	0.0	0.00	100.0	68	6.37	31.15	-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: 07OCT22

Table 302.1.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 + CAPOX (N=157)												
	Baseline	154	14.50	22.84	0.0	0.00	100.0						
	Cycle 2 Day 1	138	14.98	22.09	0.0	0.00	100.0	138	0.72	22.23	-66.7	0.00	66.7
	Cycle 3 Day 1	121	13.22	22.56	0.0	0.00	100.0	120	-1.11	21.14	-66.7	0.00	100.0
	Cycle 4 Day 1	110	13.03	19.73	0.0	0.00	66.7	110	-1.21	22.09	-100.0	0.00	66.7
	Cycle 5 Day 1	106	13.21	21.42	0.0	0.00	100.0	106	-0.94	21.31	-66.7	0.00	66.7
	Cycle 6 Day 1	95	10.88	19.11	0.0	0.00	66.7	95	-3.51	22.53	-100.0	0.00	33.3
	Cycle 7 Day 1	80	9.17	15.89	0.0	0.00	66.7	80	-7.50	22.49	-66.7	0.00	33.3
	Cycle 8 Day 1	70	12.86	20.69	0.0	0.00	100.0	69	-2.90	22.68	-100.0	0.00	33.3
	Cycle 9 Day 1	70	13.33	18.30	0.0	0.00	66.7	69	-2.42	20.06	-66.7	0.00	33.3
	Cycle 10 Day 1	55	10.91	19.30	0.0	0.00	100.0	54	-4.94	20.89	-66.7	0.00	33.3
	Cycle 11 Day 1	55	12.73	19.76	0.0	0.00	100.0	54	-1.85	22.82	-66.7	0.00	33.3
	Cycle 12 Day 1	52	12.18	19.83	0.0	0.00	100.0	51	-3.27	22.37	-66.7	0.00	33.3
	Cycle 13 Day 1	44	9.09	16.65	0.0	0.00	66.7	43	-6.98	20.00	-66.7	0.00	33.3
	Cycle 14 Day 1	39	10.26	17.36	0.0	0.00	66.7	38	-5.26	21.26	-66.7	0.00	33.3
	Cycle 15 Day 1	34	10.78	15.83	0.0	0.00	33.3	33	-5.05	22.24	-66.7	0.00	33.3
	Cycle 16 Day 1	32	11.46	16.09	0.0	0.00	33.3	31	-5.38	21.25	-66.7	0.00	33.3
	Cycle 17 Day 1	29	10.34	15.69	0.0	0.00	33.3	28	-5.95	20.39	-66.7	0.00	33.3
	Cycle 18 Day 1	26	8.97	15.08	0.0	0.00	33.3	25	-8.00	22.11	-66.7	0.00	33.3
	Cycle 19 Day 1	26	10.26	18.30	0.0	0.00	66.7	25	-6.67	19.25	-33.3	0.00	33.3
	Cycle 20 Day 1	26	8.97	15.08	0.0	0.00	33.3	25	-8.00	19.91	-66.7	0.00	33.3
	Cycle 21 Day 1	23	11.59	19.09	0.0	0.00	66.7	22	-4.55	18.67	-33.3	0.00	33.3
	Cycle 22 Day 1	21	12.70	19.65	0.0	0.00	66.7	20	-5.00	27.09	-66.7	0.00	33.3
	Cycle 23 Day 1	20	8.33	14.81	0.0	0.00	33.3	19	-8.77	21.78	-66.7	0.00	33.3
	Cycle 24 Day 1	19	12.28	19.91	0.0	0.00	66.7	18	-5.56	26.20	-66.7	0.00	33.3
	Cycle 25 Day 1	17	13.73	20.61	0.0	0.00	66.7	16	-2.08	28.46	-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: 07OCT22

Table 302.1.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 26 Day 1	16	10.42	20.07	0.0	0.00	66.7	15	-6.67	31.37	-100.0	0.00	33.3
	Cycle 27 Day 1	15	8.89	19.79	0.0	0.00	66.7	14	-7.14	32.50	-100.0	0.00	33.3
	Study Disc 1	82	15.45	24.68	0.0	0.00	100.0	82	-0.81	26.18	-66.7	0.00	100.0
	30 D SFU Z/P	36	15.74	27.01	0.0	0.00	100.0	36	0.00	23.90	-66.7	0.00	66.7
	90 D SFU Z/P	32	20.83	26.44	0.0	16.67	100.0	32	6.25	23.09	-33.3	0.00	66.7
	Placebo + CAPOX (N=158)												
	Baseline	155	16.34	23.53	0.0	0.00	100.0						
	Cycle 2 Day 1	140	12.38	20.52	0.0	0.00	100.0	139	-3.60	20.73	-100.0	0.00	66.7
	Cycle 3 Day 1	127	9.97	17.97	0.0	0.00	66.7	126	-4.76	20.96	-66.7	0.00	66.7
	Cycle 4 Day 1	108	8.64	18.44	0.0	0.00	100.0	107	-7.48	25.62	-100.0	0.00	100.0
	Cycle 5 Day 1	104	10.90	18.83	0.0	0.00	66.7	104	-4.81	25.62	-100.0	0.00	66.7
	Cycle 6 Day 1	88	11.36	19.50	0.0	0.00	66.7	88	-6.06	26.04	-100.0	0.00	66.7
	Cycle 7 Day 1	79	13.50	21.03	0.0	0.00	66.7	79	-2.95	24.57	-100.0	0.00	66.7
	Cycle 8 Day 1	68	13.24	20.88	0.0	0.00	66.7	68	-3.92	26.72	-100.0	0.00	66.7
	Cycle 9 Day 1	63	10.05	19.52	0.0	0.00	66.7	63	-5.82	26.46	-100.0	0.00	66.7
	Cycle 10 Day 1	47	5.67	14.44	0.0	0.00	66.7	47	-8.51	28.21	-100.0	0.00	66.7
	Cycle 11 Day 1	45	9.63	23.16	0.0	0.00	100.0	45	-2.96	29.15	-100.0	0.00	100.0
	Cycle 12 Day 1	34	7.84	18.46	0.0	0.00	66.7	34	-3.92	21.34	-66.7	0.00	66.7
	Cycle 13 Day 1	27	9.88	24.13	0.0	0.00	100.0	27	2.47	26.03	-66.7	0.00	100.0
	Cycle 14 Day 1	24	9.72	18.33	0.0	0.00	66.7	24	2.78	23.91	-66.7	0.00	66.7
	Cycle 15 Day 1	18	11.11	19.80	0.0	0.00	66.7	18	3.70	27.75	-66.7	0.00	66.7
	Cycle 16 Day 1	17	13.73	29.01	0.0	0.00	100.0	17	5.88	29.43	-66.7	0.00	66.7
	Cycle 17 Day 1	14	9.52	27.51	0.0	0.00	100.0	14	2.38	27.62	-66.7	0.00	66.7
	Cycle 18 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	-6.67	21.08	-66.7	0.00	0.0
	Cycle 19 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-6.06	20.10	-66.7	0.00	0.0
	Study Disc 1	98	19.05	25.33	0.0	0.00	66.7	97	3.78	30.76	-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.
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: 07OCT22

Table 302.1.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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
	30 D SFU Z/P	50	16.00	19.33	0.0	0.00	66.7	50	2.67	24.13	-66.7	0.00	66.7
	90 D SFU Z/P	44	18.94	26.31	0.0	0.00	100.0	44	6.82	28.38	-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: 07OCT22

Table 302.1.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 + CAPOX (N= 97)												
	Baseline	88	24.24	30.21	0.0	0.00	100.0						
	Cycle 2 Day 1	71	19.25	23.68	0.0	0.00	100.0	70	-3.33	29.57	-66.7	0.00	100.0
	Cycle 3 Day 1	66	18.69	27.51	0.0	0.00	100.0	62	-4.84	34.06	-100.0	0.00	100.0
	Cycle 4 Day 1	62	12.90	24.41	0.0	0.00	100.0	59	-11.30	31.93	-100.0	0.00	66.7
	Cycle 5 Day 1	56	16.07	29.81	0.0	0.00	100.0	53	-6.29	33.37	-66.7	0.00	100.0
	Cycle 6 Day 1	56	14.88	26.15	0.0	0.00	100.0	54	-9.88	32.78	-66.7	0.00	100.0
	Cycle 7 Day 1	42	14.29	21.01	0.0	0.00	66.7	40	-8.33	32.69	-66.7	0.00	66.7
	Cycle 8 Day 1	44	13.64	24.19	0.0	0.00	100.0	39	-7.69	33.74	-100.0	0.00	66.7
	Cycle 9 Day 1	37	17.12	26.78	0.0	0.00	100.0	33	-8.08	27.68	-66.7	0.00	66.7
	Cycle 10 Day 1	33	13.13	23.48	0.0	0.00	100.0	31	-8.60	35.45	-66.7	0.00	100.0
	Cycle 11 Day 1	28	5.95	20.39	0.0	0.00	100.0	26	-11.54	37.64	-100.0	0.00	100.0
	Cycle 12 Day 1	24	5.56	12.69	0.0	0.00	33.3	23	-14.49	29.86	-100.0	0.00	33.3
	Cycle 13 Day 1	18	9.26	19.15	0.0	0.00	66.7	17	-9.80	36.83	-66.7	0.00	66.7
	Cycle 14 Day 1	17	9.80	22.87	0.0	0.00	66.7	16	-10.42	33.82	-66.7	0.00	66.7
	Cycle 15 Day 1	17	13.73	23.74	0.0	0.00	66.7	16	-6.25	36.96	-66.7	0.00	66.7
	Cycle 16 Day 1	14	14.29	25.20	0.0	0.00	66.7	13	2.56	37.17	-66.7	0.00	66.7
	Cycle 17 Day 1	12	13.89	30.01	0.0	0.00	100.0	11	0.00	42.16	-66.7	0.00	100.0
	Cycle 18 Day 1	11	12.12	22.47	0.0	0.00	66.7	10	-3.33	36.68	-66.7	0.00	66.7
	Cycle 19 Day 1	11	9.09	21.56	0.0	0.00	66.7	10	-6.67	34.43	-66.7	0.00	66.7
	Study Disc 1	42	17.46	23.56	0.0	0.00	100.0	40	-2.50	30.56	-66.7	0.00	100.0
	30 D SFU Z/P	16	18.75	27.13	0.0	0.00	100.0	15	-6.67	44.01	-66.7	0.00	100.0
	90 D SFU Z/P	16	10.42	23.47	0.0	0.00	66.7	15	-2.22	36.66	-66.7	0.00	66.7
	Placebo + CAPOX (N= 95)												
	Baseline	87	19.92	32.33	0.0	0.00	100.0						
	Cycle 2 Day 1	82	18.29	26.27	0.0	0.00	100.0	78	-1.28	31.53	-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.
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: 07OCT22

Table 302.1.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 3 Day 1	73	13.24	23.40	0.0	0.00	100.0	71	-6.10	27.78	-100.0	0.00	66.7
	Cycle 4 Day 1	63	13.23	24.35	0.0	0.00	100.0	62	-5.91	34.42	-100.0	0.00	100.0
	Cycle 5 Day 1	62	13.44	21.31	0.0	0.00	100.0	61	-4.37	28.85	-100.0	0.00	33.3
	Cycle 6 Day 1	59	15.82	25.79	0.0	0.00	100.0	58	-1.72	33.87	-100.0	0.00	100.0
	Cycle 7 Day 1	48	16.67	28.35	0.0	0.00	100.0	47	-0.71	42.56	-100.0	0.00	100.0
	Cycle 8 Day 1	43	14.73	26.53	0.0	0.00	100.0	42	-1.59	37.51	-100.0	0.00	100.0
	Cycle 9 Day 1	41	12.20	23.28	0.0	0.00	100.0	40	-5.00	33.38	-100.0	0.00	66.7
	Cycle 10 Day 1	34	12.75	25.97	0.0	0.00	100.0	32	-5.21	35.02	-100.0	0.00	100.0
	Cycle 11 Day 1	27	17.28	26.75	0.0	0.00	100.0	26	-3.85	41.45	-100.0	0.00	100.0
	Cycle 12 Day 1	25	17.33	29.06	0.0	0.00	100.0	23	2.90	33.20	-33.3	0.00	100.0
	Cycle 13 Day 1	20	11.67	19.57	0.0	0.00	66.7	18	-14.81	39.97	-100.0	0.00	33.3
	Cycle 14 Day 1	20	18.33	27.52	0.0	0.00	100.0	18	-7.41	33.44	-100.0	0.00	33.3
	Cycle 15 Day 1	18	11.11	19.80	0.0	0.00	66.7	16	-10.42	37.94	-100.0	0.00	33.3
	Cycle 16 Day 1	15	8.89	19.79	0.0	0.00	66.7	13	-12.82	37.36	-66.7	0.00	66.7
	Cycle 17 Day 1	12	5.56	12.97	0.0	0.00	33.3	10	-10.00	22.50	-66.7	0.00	0.0
	Cycle 18 Day 1	11	9.09	15.57	0.0	0.00	33.3	10	-6.67	37.84	-100.0	0.00	33.3
	Study Disc 1	52	23.72	29.77	0.0	0.00	100.0	48	5.56	31.76	-100.0	0.00	66.7
	30 D SFU Z/P	26	17.95	27.05	0.0	0.00	100.0	24	1.39	28.62	-66.7	0.00	66.7
	90 D SFU Z/P	26	23.08	26.28	0.0	16.67	66.7	24	5.56	36.34	-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.
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: 07OCT22

Table 302.1.3002.18: 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 + CAPOX (N=254)												
Baseline	242	8.13	16.44	0.0	0.00	100.0						
Cycle 2 Day 1	209	10.37	18.60	0.0	0.00	100.0	208	2.56	20.56	-66.7	0.00	66.7
Cycle 3 Day 1	187	10.70	20.56	0.0	0.00	100.0	182	2.93	21.40	-66.7	0.00	66.7
Cycle 4 Day 1	172	9.30	17.77	0.0	0.00	66.7	169	1.38	21.00	-66.7	0.00	66.7
Cycle 5 Day 1	162	9.47	18.38	0.0	0.00	100.0	159	1.47	20.66	-66.7	0.00	66.7
Cycle 6 Day 1	151	11.04	21.68	0.0	0.00	100.0	149	2.91	24.79	-66.7	0.00	100.0
Cycle 7 Day 1	122	10.38	20.14	0.0	0.00	100.0	120	1.94	24.17	-33.3	0.00	100.0
Cycle 8 Day 1	114	9.94	18.78	0.0	0.00	100.0	108	1.23	21.82	-33.3	0.00	100.0
Cycle 9 Day 1	107	10.59	19.21	0.0	0.00	100.0	102	1.31	23.42	-66.7	0.00	100.0
Cycle 10 Day 1	88	8.33	18.40	0.0	0.00	100.0	85	1.18	19.55	-33.3	0.00	66.7
Cycle 11 Day 1	83	4.82	17.37	0.0	0.00	100.0	80	-3.33	21.61	-66.7	0.00	100.0
Cycle 12 Day 1	76	5.70	14.80	0.0	0.00	66.7	74	-1.35	17.83	-33.3	0.00	66.7
Cycle 13 Day 1	62	4.30	12.78	0.0	0.00	66.7	60	-3.89	16.34	-33.3	0.00	33.3
Cycle 14 Day 1	56	4.76	11.77	0.0	0.00	33.3	54	-3.09	17.46	-33.3	0.00	33.3
Cycle 15 Day 1	51	5.23	12.24	0.0	0.00	33.3	49	-2.04	19.73	-33.3	0.00	33.3
Cycle 16 Day 1	46	5.07	12.11	0.0	0.00	33.3	44	-1.52	16.00	-33.3	0.00	33.3
Cycle 17 Day 1	41	7.32	15.83	0.0	0.00	66.7	39	0.00	20.23	-33.3	0.00	66.7
Cycle 18 Day 1	37	4.50	11.55	0.0	0.00	33.3	35	-2.86	16.90	-33.3	0.00	33.3
Cycle 19 Day 1	37	4.50	11.55	0.0	0.00	33.3	35	-2.86	16.90	-33.3	0.00	33.3
Cycle 20 Day 1	35	5.71	15.09	0.0	0.00	66.7	33	-2.02	18.52	-33.3	0.00	33.3
Cycle 21 Day 1	32	5.21	12.30	0.0	0.00	33.3	30	-2.22	19.44	-33.3	0.00	33.3
Cycle 22 Day 1	30	4.44	14.47	0.0	0.00	66.7	28	-1.19	14.29	-33.3	0.00	33.3
Cycle 23 Day 1	28	4.76	11.88	0.0	0.00	33.3	26	0.00	16.33	-33.3	0.00	33.3
Cycle 24 Day 1	25	6.67	13.61	0.0	0.00	33.3	23	1.45	12.22	-33.3	0.00	33.3
Cycle 25 Day 1	23	4.35	11.48	0.0	0.00	33.3	21	-1.59	16.59	-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: 07OCT22

Table 302.1.3002.18: 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 26 Day 1	22	4.55	11.71	0.0	0.00	33.3	20	-1.67	13.13	-33.3	0.00	33.3
Cycle 27 Day 1	20	5.00	12.21	0.0	0.00	33.3	18	-1.85	13.87	-33.3	0.00	33.3
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	9	-3.70	11.11	-33.3	0.00	0.0
Cycle 29 Day 1	12	2.78	9.62	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
Study Disc 1	124	7.26	16.22	0.0	0.00	66.7	122	-1.91	19.31	-66.7	0.00	66.7
30 D SFU Z/P	52	6.41	14.82	0.0	0.00	66.7	51	-1.96	16.88	-33.3	0.00	33.3
90 D SFU Z/P	48	9.72	19.40	0.0	0.00	100.0	47	4.26	20.40	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	7.71	15.34	0.0	0.00	66.7						
Cycle 2 Day 1	222	12.76	22.47	0.0	0.00	100.0	217	5.68	22.98	-66.7	0.00	100.0
Cycle 3 Day 1	200	10.83	20.58	0.0	0.00	100.0	197	4.06	20.63	-66.7	0.00	100.0
Cycle 4 Day 1	171	10.92	21.03	0.0	0.00	100.0	169	3.94	22.07	-66.7	0.00	100.0
Cycle 5 Day 1	166	10.84	21.47	0.0	0.00	100.0	165	4.44	20.34	-33.3	0.00	100.0
Cycle 6 Day 1	147	9.75	20.35	0.0	0.00	100.0	146	3.65	21.49	-66.7	0.00	100.0
Cycle 7 Day 1	127	11.29	20.67	0.0	0.00	100.0	126	5.29	19.51	-33.3	0.00	66.7
Cycle 8 Day 1	111	8.71	18.37	0.0	0.00	100.0	110	2.12	18.77	-33.3	0.00	66.7
Cycle 9 Day 1	104	7.05	15.87	0.0	0.00	66.7	103	0.65	19.79	-66.7	0.00	66.7
Cycle 10 Day 1	81	4.53	14.68	0.0	0.00	100.0	79	-2.53	17.52	-66.7	0.00	66.7
Cycle 11 Day 1	72	5.56	15.82	0.0	0.00	100.0	71	-0.94	18.66	-66.7	0.00	66.7
Cycle 12 Day 1	59	5.65	14.05	0.0	0.00	66.7	57	-2.92	20.20	-66.7	0.00	66.7
Cycle 13 Day 1	47	4.26	11.24	0.0	0.00	33.3	45	-4.44	18.26	-66.7	0.00	33.3
Cycle 14 Day 1	44	6.06	13.01	0.0	0.00	33.3	42	-2.38	21.33	-66.7	0.00	33.3
Cycle 15 Day 1	36	5.56	14.91	0.0	0.00	66.7	34	-2.94	20.71	-66.7	0.00	66.7
Cycle 16 Day 1	32	5.21	12.30	0.0	0.00	33.3	30	-3.33	13.42	-33.3	0.00	33.3
Cycle 17 Day 1	26	6.41	13.40	0.0	0.00	33.3	24	-4.17	11.26	-33.3	0.00	0.0
Cycle 18 Day 1	21	4.76	11.95	0.0	0.00	33.3	20	-5.00	19.57	-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: 07OCT22

Table 302.1.3002.18: 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 19 Day 1	20	6.67	13.68	0.0	0.00	33.3	19	-3.51	15.29	-33.3	0.00	33.3
Cycle 20 Day 1	17	5.88	13.10	0.0	0.00	33.3	16	-4.17	16.67	-33.3	0.00	33.3
Cycle 21 Day 1	18	7.41	14.26	0.0	0.00	33.3	17	-3.92	16.17	-33.3	0.00	33.3
Cycle 22 Day 1	15	6.67	13.80	0.0	0.00	33.3	14	-7.14	23.31	-66.7	0.00	33.3
Cycle 23 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-9.09	15.57	-33.3	0.00	0.0
Study Disc 1	150	8.22	19.29	0.0	0.00	100.0	145	2.07	20.87	-66.7	0.00	100.0
30 D SFU Z/P	76	8.77	16.66	0.0	0.00	66.7	74	1.80	19.03	-33.3	0.00	66.7
90 D SFU Z/P	70	9.52	18.07	0.0	0.00	100.0	68	0.49	21.92	-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: 07OCT22

Table 302.1.3002.19: 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 + CAPOX (N=254)												
Baseline	242	20.80	26.01	0.0	0.00	100.0						
Cycle 2 Day 1	209	19.78	24.51	0.0	0.00	100.0	208	-0.64	25.58	-66.7	0.00	100.0
Cycle 3 Day 1	187	19.43	24.13	0.0	0.00	100.0	182	-0.92	25.13	-66.7	0.00	100.0
Cycle 4 Day 1	172	17.64	21.15	0.0	0.00	66.7	169	-2.17	23.33	-66.7	0.00	66.7
Cycle 5 Day 1	162	20.37	26.85	0.0	0.00	100.0	159	-0.63	28.92	-100.0	0.00	100.0
Cycle 6 Day 1	151	18.54	24.54	0.0	0.00	100.0	149	-0.89	27.66	-66.7	0.00	100.0
Cycle 7 Day 1	122	19.40	22.61	0.0	0.00	100.0	120	0.56	24.05	-66.7	0.00	66.7
Cycle 8 Day 1	114	19.59	23.80	0.0	0.00	100.0	108	-0.62	26.95	-66.7	0.00	100.0
Cycle 9 Day 1	107	21.81	25.12	0.0	33.33	100.0	102	2.29	24.94	-66.7	0.00	66.7
Cycle 10 Day 1	88	15.15	22.55	0.0	0.00	100.0	85	-2.75	27.80	-100.0	0.00	66.7
Cycle 11 Day 1	83	18.47	24.00	0.0	0.00	100.0	80	0.00	27.56	-66.7	0.00	66.7
Cycle 12 Day 1	76	17.54	24.02	0.0	0.00	100.0	74	-0.90	30.21	-66.7	0.00	100.0
Cycle 13 Day 1	62	16.67	23.18	0.0	0.00	100.0	60	-3.33	27.92	-66.7	0.00	100.0
Cycle 14 Day 1	56	17.86	22.89	0.0	0.00	100.0	54	-0.62	29.31	-66.7	0.00	66.7
Cycle 15 Day 1	51	18.30	25.22	0.0	0.00	100.0	49	0.68	29.26	-66.7	0.00	66.7
Cycle 16 Day 1	46	16.67	23.04	0.0	0.00	100.0	44	-1.52	25.87	-66.7	0.00	66.7
Cycle 17 Day 1	41	15.45	23.68	0.0	0.00	100.0	39	-1.71	20.16	-66.7	0.00	66.7
Cycle 18 Day 1	37	17.12	25.61	0.0	0.00	100.0	35	1.90	22.78	-33.3	0.00	66.7
Cycle 19 Day 1	37	13.51	21.46	0.0	0.00	100.0	35	-2.86	21.95	-66.7	0.00	33.3
Cycle 20 Day 1	35	15.24	21.91	0.0	0.00	100.0	33	-1.01	21.22	-33.3	0.00	33.3
Cycle 21 Day 1	32	14.58	20.63	0.0	0.00	66.7	30	2.22	23.05	-33.3	0.00	66.7
Cycle 22 Day 1	30	7.78	14.34	0.0	0.00	33.3	28	-3.57	20.96	-66.7	0.00	33.3
Cycle 23 Day 1	28	11.90	18.62	0.0	0.00	66.7	26	1.28	19.96	-33.3	0.00	33.3
Cycle 24 Day 1	25	9.33	15.28	0.0	0.00	33.3	23	-1.45	23.52	-66.7	0.00	33.3
Cycle 25 Day 1	23	7.25	14.06	0.0	0.00	33.3	21	-4.76	21.82	-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: 07OCT22

Table 302.1.3002.19: 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 26 Day 1	22	4.55	11.71	0.0	0.00	33.3	20	-5.00	22.36	-66.7	0.00	33.3
Cycle 27 Day 1	20	8.33	18.34	0.0	0.00	66.7	18	-1.85	17.98	-33.3	0.00	33.3
Cycle 28 Day 1	11	3.03	10.05	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
Cycle 29 Day 1	12	8.33	15.08	0.0	0.00	33.3	10	6.67	14.05	0.0	0.00	33.3
Study Disc 1	124	25.54	28.55	0.0	33.33	100.0	122	4.92	33.10	-66.7	0.00	100.0
30 D SFU Z/P	52	22.44	26.17	0.0	33.33	100.0	51	2.61	25.68	-66.7	0.00	66.7
90 D SFU Z/P	48	18.06	24.75	0.0	0.00	100.0	47	1.42	26.88	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	19.42	25.30	0.0	0.00	100.0						
Cycle 2 Day 1	222	18.02	24.88	0.0	0.00	100.0	217	-0.92	18.68	-66.7	0.00	100.0
Cycle 3 Day 1	200	20.50	25.82	0.0	0.00	100.0	197	1.18	22.43	-66.7	0.00	100.0
Cycle 4 Day 1	171	18.13	25.10	0.0	0.00	100.0	169	-1.58	22.07	-100.0	0.00	100.0
Cycle 5 Day 1	166	19.28	24.13	0.0	0.00	100.0	165	0.81	19.81	-66.7	0.00	66.7
Cycle 6 Day 1	147	20.18	25.45	0.0	0.00	100.0	146	0.00	21.80	-66.7	0.00	66.7
Cycle 7 Day 1	127	20.47	27.23	0.0	0.00	100.0	126	0.26	24.76	-100.0	0.00	66.7
Cycle 8 Day 1	111	23.12	28.35	0.0	0.00	100.0	110	3.33	23.87	-33.3	0.00	66.7
Cycle 9 Day 1	104	20.83	27.55	0.0	0.00	100.0	103	1.94	21.30	-33.3	0.00	66.7
Cycle 10 Day 1	81	19.34	28.80	0.0	0.00	100.0	79	1.27	24.13	-33.3	0.00	66.7
Cycle 11 Day 1	72	23.15	28.33	0.0	33.33	100.0	71	4.69	22.04	-33.3	0.00	66.7
Cycle 12 Day 1	59	20.90	28.97	0.0	0.00	100.0	57	3.51	22.44	-33.3	0.00	66.7
Cycle 13 Day 1	47	17.73	27.67	0.0	0.00	100.0	45	3.70	25.84	-33.3	0.00	66.7
Cycle 14 Day 1	44	13.64	23.09	0.0	0.00	100.0	42	0.79	23.84	-33.3	0.00	66.7
Cycle 15 Day 1	36	16.67	27.02	0.0	0.00	100.0	34	4.90	24.80	-33.3	0.00	66.7
Cycle 16 Day 1	32	17.71	23.92	0.0	0.00	66.7	30	6.67	26.84	-33.3	0.00	66.7
Cycle 17 Day 1	26	12.82	21.24	0.0	0.00	66.7	24	1.39	20.80	-33.3	0.00	66.7
Cycle 18 Day 1	21	12.70	22.30	0.0	0.00	66.7	20	5.00	24.84	-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: 07OCT22

Table 302.1.3002.19: 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 19 Day 1	20	6.67	13.68	0.0	0.00	33.3	19	-1.75	17.48	-33.3	0.00	33.3
Cycle 20 Day 1	17	7.84	18.74	0.0	0.00	66.7	16	0.00	21.08	-33.3	0.00	66.7
Cycle 21 Day 1	18	11.11	19.80	0.0	0.00	66.7	17	5.88	21.20	-33.3	0.00	66.7
Cycle 22 Day 1	15	13.33	24.56	0.0	0.00	66.7	14	7.14	26.73	-33.3	0.00	66.7
Cycle 23 Day 1	12	13.89	22.29	0.0	0.00	66.7	11	9.09	26.21	-33.3	0.00	66.7
Study Disc 1	150	29.56	30.78	0.0	33.33	100.0	145	9.43	27.70	-33.3	0.00	100.0
30 D SFU Z/P	76	25.88	30.60	0.0	33.33	100.0	74	8.56	24.09	-33.3	0.00	100.0
90 D SFU Z/P	70	21.90	26.55	0.0	0.00	100.0	68	5.39	20.45	-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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

Table 302.1.3004.5.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	125 (49.2%)	144 (56.9%)	
Number of patients censored	129 (50.8%)	109 (43.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.6 [3.7, 7.2]	4.4 [3.5, 5.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.956 [0.749, 1.221]
Log-rank test			
Two-sided stratified log-rank p-value			0.7126

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: 07OCT22

Table 302.1.3004.5.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	85 (48.3)	6.6 [4.0, 7.9]	180	99 (55.0)	4.6 [3.7, 6.8]	0.920 [0.688, 1.229]	0.5670	0.7892
>65 years	78	40 (51.3)	3.8 [2.6, 6.0]	73	45 (61.6)	3.8 [2.8, 5.1]	0.973 [0.634, 1.493]	0.8995	
Sex									
Male	159	76 (47.8)	6.0 [4.1, 9.2]	156	92 (59.0)	4.4 [3.0, 5.3]	0.810 [0.598, 1.099]	0.1772	0.1069
Female	95	49 (51.6)	3.5 [2.3, 6.7]	97	52 (53.6)	4.2 [3.0, 7.2]	1.214 [0.822, 1.795]	0.3334	
Region									
Asia	157	75 (47.8)	6.7 [3.7, 9.7]	158	93 (58.9)	4.4 [3.4, 5.3]	0.802 [0.591, 1.087]	0.1514	0.0927
Non-Asia	97	50 (51.5)	4.0 [2.6, 6.3]	95	51 (53.7)	4.4 [2.8, 8.5]	1.225 [0.827, 1.813]	0.3039	
Number of Organs with Metastatic Sites									
0-2	189	96 (50.8)	4.2 [3.3, 6.7]	188	107 (56.9)	4.2 [3.1, 5.3]	0.961 [0.729, 1.266]	0.7802	0.6811
>=3	65	29 (44.6)	7.2 [3.2, 10.6]	65	37 (56.9)	5.0 [3.0, 6.7]	0.816 [0.498, 1.336]	0.4089	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.6.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	134 (52.8%)	141 (55.7%)	
Number of patients censored	120 (47.2%)	112 (44.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.2 [3.2, 5.0]	4.9 [4.2, 6.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.088 [0.856, 1.383]
Log-rank test			
Two-sided stratified log-rank p-value			0.4906

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: 07OCT22

Table 302.1.3004.6.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	93 (52.8)	4.6 [3.2, 7.1]	180	101 (56.1)	5.6 [4.2, 6.9]	0.997 [0.752, 1.322]	0.9928	0.4054
>65 years	78	41 (52.6)	3.5 [1.9, 4.5]	73	40 (54.8)	4.8 [3.1, 6.2]	1.275 [0.823, 1.977]	0.2747	
Sex									
Male	159	86 (54.1)	4.2 [3.0, 5.0]	156	90 (57.7)	4.8 [3.4, 5.6]	0.989 [0.735, 1.329]	0.9425	0.4048
Female	95	48 (50.5)	4.0 [2.3, 6.7]	97	51 (52.6)	6.7 [4.1, 8.8]	1.199 [0.806, 1.783]	0.3640	
Region									
Asia	157	80 (51.0)	4.7 [3.3, 7.6]	158	87 (55.1)	5.2 [4.2, 6.7]	0.959 [0.707, 1.300]	0.7906	0.2358
Non-Asia	97	54 (55.7)	3.5 [1.9, 4.4]	95	54 (56.8)	4.8 [3.0, 7.7]	1.294 [0.885, 1.891]	0.1788	
Number of Organs with Metastatic Sites									
0-2	189	100 (52.9)	4.4 [3.2, 6.7]	188	104 (55.3)	4.9 [4.1, 6.7]	1.056 [0.802, 1.390]	0.6928	0.8605
>=3	65	34 (52.3)	4.0 [1.9, 5.1]	65	37 (56.9)	5.3 [2.3, 7.0]	1.116 [0.699, 1.781]	0.6456	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.7.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	142 (55.9%)	156 (61.7%)	
Number of patients censored	112 (44.1%)	97 (38.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.7 [2.3, 4.7]	2.9 [2.3, 4.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.890 [0.706, 1.121]
Log-rank test			
Two-sided stratified log-rank p-value			0.3299

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: 07OCT22

Table 302.1.3004.7.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	101 (57.4)	4.2 [2.3, 5.1]	180	114 (63.3)	2.8 [2.0, 4.4]	0.883 [0.675, 1.155]	0.3737	0.7610
>65 years	78	41 (52.6)	3.1 [1.6, 6.7]	73	42 (57.5)	3.2 [1.6, 4.9]	0.941 [0.610, 1.451]	0.7889	
Sex									
Male	159	90 (56.6)	4.0 [2.2, 5.6]	156	103 (66.0)	2.5 [1.6, 4.1]	0.813 [0.612, 1.080]	0.1553	0.2760
Female	95	52 (54.7)	3.3 [2.1, 4.8]	97	53 (54.6)	3.9 [2.3, 6.9]	1.061 [0.723, 1.559]	0.7516	
Region									
Asia	157	88 (56.1)	4.2 [3.1, 5.3]	158	97 (61.4)	3.1 [2.3, 4.9]	0.841 [0.629, 1.124]	0.2446	0.4930
Non-Asia	97	54 (55.7)	2.3 [1.7, 5.1]	95	59 (62.1)	2.8 [1.5, 4.8]	0.993 [0.685, 1.439]	0.9865	
Number of Organs with Metastatic Sites									
0-2	189	106 (56.1)	4.0 [2.3, 5.6]	188	120 (63.8)	3.3 [2.4, 4.8]	0.861 [0.662, 1.120]	0.2701	0.5249
>=3	65	36 (55.4)	3.0 [1.7, 4.4]	65	36 (55.4)	2.1 [1.4, 4.8]	1.008 [0.635, 1.600]	0.9592	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.8.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	112 (44.1%)	113 (44.7%)	
Number of patients censored	142 (55.9%)	140 (55.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.1 [5.5, 9.2]	6.7 [5.5, 8.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.038 [0.796, 1.354]
Log-rank test			
Two-sided stratified log-rank p-value			0.7736

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: 07OCT22

Table 302.1.3004.8.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	78 (44.3)	7.9 [5.7, 10.9]	180	85 (47.2)	6.4 [4.4, 8.8]	0.904 [0.664, 1.231]	0.5230	0.0968
>65 years	78	34 (43.6)	5.4 [3.1, 8.3]	73	28 (38.4)	7.9 [5.7, NC]	1.514 [0.912, 2.512]	0.1058	
Sex									
Male	159	70 (44.0)	7.2 [5.7, 10.0]	156	67 (42.9)	6.4 [4.5, 28.7]	1.002 [0.716, 1.402]	0.9791	0.6223
Female	95	42 (44.2)	5.5 [3.0, 22.9]	97	46 (47.4)	6.7 [5.0, 10.2]	1.127 [0.739, 1.718]	0.5791	
Region									
Asia	157	69 (43.9)	8.0 [5.4, 10.9]	158	70 (44.3)	6.7 [5.7, 8.8]	0.962 [0.689, 1.343]	0.8188	0.4234
Non-Asia	97	43 (44.3)	6.3 [3.3, 7.3]	95	43 (45.3)	6.3 [4.1, 28.7]	1.183 [0.772, 1.813]	0.4309	
Number of Organs with Metastatic Sites									
0-2	189	84 (44.4)	7.1 [5.5, 10.0]	188	79 (42.0)	7.2 [6.3, 11.6]	1.132 [0.832, 1.541]	0.4287	0.3730
>=3	65	28 (43.1)	6.3 [3.5, 10.9]	65	34 (52.3)	4.9 [3.1, 6.7]	0.867 [0.525, 1.432]	0.5776	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.9.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	131 (51.6%)	130 (51.4%)	
Number of patients censored	123 (48.4%)	123 (48.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.9 [3.4, 5.8]	5.0 [4.1, 7.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.107 [0.866, 1.415]
Log-rank test			
Two-sided stratified log-rank p-value			0.4095

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: 07OCT22

Table 302.1.3004.9.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	89 (50.6)	5.6 [4.1, 6.9]	180	96 (53.3)	4.7 [3.9, 7.7]	0.938 [0.703, 1.252]	0.6764	0.0518
>65 years	78	42 (53.8)	3.3 [1.6, 5.3]	73	34 (46.6)	6.0 [3.6, 10.8]	1.626 [1.031, 2.563]	0.0347	
Sex									
Male	159	81 (50.9)	5.2 [3.6, 7.6]	156	80 (51.3)	4.7 [3.3, 8.0]	1.023 [0.751, 1.394]	0.8805	0.4264
Female	95	50 (52.6)	4.3 [2.3, 5.8]	97	50 (51.5)	5.1 [3.9, 7.9]	1.258 [0.848, 1.867]	0.2475	
Region									
Asia	157	86 (54.8)	4.2 [3.0, 6.5]	158	84 (53.2)	4.4 [3.3, 7.8]	1.066 [0.789, 1.439]	0.6726	0.8161
Non-Asia	97	45 (46.4)	5.8 [3.4, 6.9]	95	46 (48.4)	6.5 [4.2, 8.9]	1.153 [0.763, 1.742]	0.5022	
Number of Organs with Metastatic Sites									
0-2	189	97 (51.3)	5.4 [3.7, 6.7]	188	95 (50.5)	5.1 [4.1, 8.0]	1.067 [0.804, 1.416]	0.6459	0.7137
>=3	65	34 (52.3)	3.6 [2.1, 5.6]	65	35 (53.8)	4.5 [2.8, 7.7]	1.241 [0.772, 1.994]	0.3734	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.10.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	130 (51.2%)	139 (54.9%)	
Number of patients censored	124 (48.8%)	114 (45.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.0 [2.8, 6.7]	4.2 [2.8, 5.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.966 [0.757, 1.232]
Log-rank test			
Two-sided stratified log-rank p-value			0.8016

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: 07OCT22

Table 302.1.3004.10.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	92 (52.3)	5.6 [2.8, 7.4]	180	105 (58.3)	4.2 [2.8, 5.1]	0.872 [0.658, 1.154]	0.3456	0.1593
>65 years	78	38 (48.7)	3.3 [1.6, 7.6]	73	34 (46.6)	5.8 [2.3, NC]	1.272 [0.800, 2.024]	0.3053	
Sex									
Male	159	83 (52.2)	4.4 [2.1, 7.6]	156	88 (56.4)	4.5 [2.7, 6.9]	0.947 [0.701, 1.280]	0.7389	0.8070
Female	95	47 (49.5)	5.6 [1.6, 8.1]	97	51 (52.6)	4.2 [2.3, 7.7]	1.009 [0.679, 1.501]	0.9568	
Region									
Asia	157	78 (49.7)	6.1 [2.8, 9.0]	158	77 (48.7)	6.9 [3.1, 10.2]	1.062 [0.774, 1.455]	0.7124	0.3639
Non-Asia	97	52 (53.6)	3.3 [1.6, 5.8]	95	62 (65.3)	2.8 [1.5, 4.4]	0.835 [0.577, 1.210]	0.3575	
Number of Organs with Metastatic Sites									
0-2	189	96 (50.8)	5.6 [2.9, 8.5]	188	103 (54.8)	4.2 [2.7, 6.9]	0.916 [0.693, 1.210]	0.5467	0.3546
>=3	65	34 (52.3)	2.8 [1.4, 5.8]	65	36 (55.4)	4.5 [2.4, 7.3]	1.195 [0.746, 1.913]	0.4487	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.11.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	167 (65.7%)	171 (67.6%)	
Number of patients censored	87 (34.3%)	82 (32.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.9 [1.5, 2.4]	2.6 [1.6, 3.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.077 [0.867, 1.338]
Log-rank test			
Two-sided stratified log-rank p-value			0.4890

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: 07OCT22

Table 302.1.3004.11.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	115 (65.3)	1.9 [1.4, 2.4]	180	124 (68.9)	2.5 [1.6, 3.4]	1.011 [0.783, 1.304]	0.9234	0.4134
>65 years	78	52 (66.7)	2.1 [1.5, 3.3]	73	47 (64.4)	2.6 [1.5, 3.7]	1.235 [0.828, 1.842]	0.2952	
Sex									
Male	159	106 (66.7)	1.7 [1.4, 3.3]	156	108 (69.2)	2.3 [1.5, 3.3]	0.976 [0.746, 1.276]	0.8707	0.1865
Female	95	61 (64.2)	1.9 [1.0, 2.4]	97	63 (64.9)	2.6 [1.4, 4.1]	1.319 [0.923, 1.883]	0.1198	
Region									
Asia	157	105 (66.9)	1.6 [1.4, 2.6]	158	105 (66.5)	3.0 [1.7, 4.2]	1.162 [0.886, 1.523]	0.2817	0.4259
Non-Asia	97	62 (63.9)	2.1 [1.5, 3.4]	95	66 (69.5)	1.6 [0.9, 2.9]	0.973 [0.687, 1.378]	0.9252	
Number of Organs with Metastatic Sites									
0-2	189	126 (66.7)	1.7 [1.5, 2.8]	188	131 (69.7)	2.3 [1.5, 3.0]	1.043 [0.816, 1.333]	0.7118	0.6122
>=3	65	41 (63.1)	1.9 [1.1, 3.7]	65	40 (61.5)	3.5 [1.4, 5.8]	1.193 [0.768, 1.853]	0.4476	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.12.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	163 (64.2%)	142 (56.1%)	
Number of patients censored	91 (35.8%)	111 (43.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.7 [1.5, 2.5]	3.9 [3.0, 4.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.589 [1.259, 2.005]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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: 07OCT22

Table 302.1.3004.12.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	119 (67.6)	1.6 [1.4, 2.3]	180	105 (58.3)	4.0 [2.8, 5.3]	1.604 [1.232, 2.088]	0.0004	0.4877
>65 years	78	44 (56.4)	3.0 [1.5, 3.8]	73	37 (50.7)	3.6 [2.3, 6.0]	1.338 [0.863, 2.074]	0.1903	
Sex									
Male	159	100 (62.9)	2.3 [1.5, 3.3]	156	90 (57.7)	3.7 [3.0, 4.5]	1.381 [1.038, 1.838]	0.0268	0.1979
Female	95	63 (66.3)	1.4 [0.9, 2.1]	97	52 (53.6)	3.9 [2.3, 6.0]	1.852 [1.276, 2.686]	0.0009	
Region									
Asia	157	100 (63.7)	2.2 [1.5, 3.0]	158	84 (53.2)	4.1 [2.8, 5.3]	1.446 [1.081, 1.934]	0.0135	0.4299
Non-Asia	97	63 (64.9)	1.5 [1.0, 2.3]	95	58 (61.1)	3.6 [2.8, 5.4]	1.900 [1.309, 2.759]	0.0005	
Number of Organs with Metastatic Sites									
0-2	189	123 (65.1)	1.7 [1.5, 2.4]	188	108 (57.4)	3.7 [2.8, 4.5]	1.484 [1.144, 1.923]	0.0025	0.7912
>=3	65	40 (61.5)	2.3 [1.0, 3.7]	65	34 (52.3)	4.3 [2.6, 7.0]	1.693 [1.069, 2.681]	0.0253	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.13.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	129 (50.8%)	148 (58.5%)	
Number of patients censored	125 (49.2%)	105 (41.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.3 [3.6, 5.7]	5.0 [3.6, 5.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.931 [0.732, 1.184]
Log-rank test			
Two-sided stratified log-rank p-value			0.5567

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: 07OCT22

Table 302.1.3004.13.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	90 (51.1)	4.4 [3.2, 7.9]	180	102 (56.7)	5.6 [4.2, 6.7]	0.975 [0.734, 1.295]	0.8626	0.4945
>65 years	78	39 (50.0)	4.2 [2.9, 7.0]	73	46 (63.0)	3.5 [2.1, 5.3]	0.829 [0.541, 1.271]	0.3881	
Sex									
Male	159	83 (52.2)	4.3 [3.4, 7.0]	156	95 (60.9)	5.0 [3.1, 6.0]	0.842 [0.627, 1.131]	0.2563	0.3026
Female	95	46 (48.4)	4.2 [2.7, 7.7]	97	53 (54.6)	5.6 [3.4, 7.7]	1.096 [0.737, 1.630]	0.6543	
Region									
Asia	157	80 (51.0)	4.6 [3.3, 8.8]	158	90 (57.0)	5.6 [3.8, 6.1]	0.897 [0.662, 1.215]	0.4749	0.7861
Non-Asia	97	49 (50.5)	4.1 [2.8, 5.6]	95	58 (61.1)	4.1 [2.1, 5.8]	0.963 [0.657, 1.412]	0.8531	
Number of Organs with Metastatic Sites									
0-2	189	97 (51.3)	4.2 [3.3, 7.5]	188	116 (61.7)	4.6 [3.1, 5.8]	0.872 [0.666, 1.143]	0.3213	0.3618
>=3	65	32 (49.2)	4.4 [3.0, 8.8]	65	32 (49.2)	5.3 [3.4, 7.9]	1.113 [0.681, 1.820]	0.6691	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.14.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	92 (36.2%)	107 (42.3%)	
Number of patients censored	162 (63.8%)	146 (57.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.4 [6.7, 23.0]	7.2 [6.0, 11.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.876 [0.660, 1.164]
Log-rank test			
Two-sided stratified log-rank p-value			0.3548

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: 07OCT22

Table 302.1.3004.14.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	63 (35.8)	10.9 [7.4, NC]	180	85 (47.2)	6.7 [5.0, 8.8]	0.743 [0.536, 1.031]	0.0740	0.0472
>65 years	78	29 (37.2)	6.2 [4.4, 23.0]	73	22 (30.1)	NC [5.8, NC]	1.392 [0.795, 2.436]	0.2432	
Sex									
Male	159	62 (39.0)	10.4 [5.3, 23.0]	156	64 (41.0)	6.8 [5.3, 28.7]	0.956 [0.673, 1.358]	0.7998	0.3795
Female	95	30 (31.6)	9.8 [6.7, NC]	97	43 (44.3)	7.2 [5.0, 9.2]	0.751 [0.471, 1.198]	0.2334	
Region									
Asia	157	63 (40.1)	8.5 [6.3, 23.0]	158	68 (43.0)	7.2 [5.3, 12.4]	0.925 [0.656, 1.304]	0.6531	0.5828
Non-Asia	97	29 (29.9)	10.4 [6.2, NC]	95	39 (41.1)	7.7 [5.0, 28.7]	0.781 [0.482, 1.267]	0.3205	
Number of Organs with Metastatic Sites									
0-2	189	68 (36.0)	10.9 [7.4, NC]	188	71 (37.8)	12.9 [6.0, 28.7]	0.971 [0.695, 1.356]	0.8692	0.3091
>=3	65	24 (36.9)	6.3 [3.9, 19.5]	65	36 (55.4)	5.1 [4.1, 7.2]	0.715 [0.426, 1.200]	0.2010	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.15.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	117 (46.1%)	121 (47.8%)	
Number of patients censored	137 (53.9%)	132 (52.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.4 [3.8, 7.6]	5.2 [4.0, 7.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.999 [0.772, 1.293]
Log-rank test			
Two-sided stratified log-rank p-value			0.9960

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: 07OCT22

Table 302.1.3004.15.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	83 (47.2)	5.4 [3.7, 7.9]	180	87 (48.3)	6.0 [4.0, 8.0]	0.998 [0.738, 1.348]	0.9968	0.9439
>65 years	78	34 (43.6)	6.1 [2.4, 10.8]	73	34 (46.6)	4.6 [2.3, 15.0]	1.037 [0.644, 1.670]	0.8856	
Sex									
Male	159	80 (50.3)	4.4 [3.7, 7.2]	156	79 (50.6)	5.1 [3.7, 6.5]	1.031 [0.754, 1.409]	0.8385	0.7117
Female	95	37 (38.9)	6.7 [2.9, NC]	97	42 (43.3)	7.3 [3.0, 11.6]	0.953 [0.612, 1.484]	0.8269	
Region									
Asia	157	77 (49.0)	6.1 [3.8, 7.9]	158	76 (48.1)	5.7 [4.2, 10.2]	1.079 [0.786, 1.482]	0.6374	0.4733
Non-Asia	97	40 (41.2)	4.4 [3.0, 21.0]	95	45 (47.4)	3.9 [2.3, 10.3]	0.878 [0.571, 1.349]	0.5589	
Number of Organs with Metastatic Sites									
0-2	189	88 (46.6)	5.4 [3.8, 7.7]	188	86 (45.7)	6.7 [4.2, 11.6]	1.104 [0.820, 1.488]	0.5077	0.2092
>=3	65	29 (44.6)	6.0 [1.6, 13.9]	65	35 (53.8)	2.8 [1.5, 5.3]	0.752 [0.456, 1.239]	0.2521	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.16.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	142 (55.9%)	136 (53.8%)	
Number of patients censored	112 (44.1%)	117 (46.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.8 [1.6, 3.5]	4.3 [3.0, 5.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.273 [1.003, 1.616]
Log-rank test			
Two-sided stratified log-rank p-value			0.0479

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: 07OCT22

Table 302.1.3004.16.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	98 (55.7)	3.3 [1.6, 4.2]	180	95 (52.8)	5.0 [3.0, 6.3]	1.208 [0.910, 1.605]	0.1921	0.8273
>65 years	78	44 (56.4)	2.0 [1.4, 3.3]	73	41 (56.2)	3.3 [2.1, 5.7]	1.307 [0.851, 2.005]	0.2214	
Sex									
Male	159	91 (57.2)	2.8 [1.6, 3.6]	156	87 (55.8)	3.5 [2.8, 5.4]	1.147 [0.854, 1.541]	0.3617	0.4230
Female	95	51 (53.7)	3.0 [1.0, 3.9]	97	49 (50.5)	5.3 [2.9, 7.8]	1.378 [0.930, 2.043]	0.1099	
Region									
Asia	157	102 (65.0)	2.3 [1.4, 3.3]	158	85 (53.8)	3.5 [2.8, 5.6]	1.401 [1.050, 1.870]	0.0218	0.1689
Non-Asia	97	40 (41.2)	4.1 [1.5, 7.9]	95	51 (53.7)	5.1 [2.8, 7.0]	0.968 [0.638, 1.469]	0.8854	
Number of Organs with Metastatic Sites									
0-2	189	113 (59.8)	2.3 [1.5, 3.4]	188	103 (54.8)	3.5 [2.9, 5.7]	1.284 [0.982, 1.678]	0.0657	0.4797
>=3	65	29 (44.6)	3.6 [1.4, NC]	65	33 (50.8)	5.0 [2.8, 7.0]	1.107 [0.672, 1.826]	0.6963	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.17.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	90 (35.4%)	101 (39.9%)	
Number of patients censored	164 (64.6%)	152 (60.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.3 [6.6, NC]	7.4 [5.3, 13.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.938 [0.703, 1.251]
Log-rank test			
Two-sided stratified log-rank p-value			0.6478

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: 07OCT22

Table 302.1.3004.17.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	68 (38.6)	8.5 [5.4, NC]	180	74 (41.1)	7.2 [4.9, 10.8]	0.943 [0.678, 1.311]	0.7131	0.9125
>65 years	78	22 (28.2)	9.6 [5.5, NC]	73	27 (37.0)	8.0 [4.5, NC]	0.935 [0.531, 1.647]	0.8143	
Sex									
Male	159	59 (37.1)	8.5 [5.5, NC]	156	65 (41.7)	6.5 [4.4, NC]	0.879 [0.617, 1.251]	0.4647	0.5704
Female	95	31 (32.6)	9.3 [5.5, NC]	97	36 (37.1)	8.6 [6.4, NC]	1.048 [0.648, 1.696]	0.8501	
Region									
Asia	157	62 (39.5)	8.5 [6.0, NC]	158	56 (35.4)	9.0 [6.4, NC]	1.188 [0.827, 1.705]	0.3566	0.0313
Non-Asia	97	28 (28.9)	NC [5.2, NC]	95	45 (47.4)	4.9 [2.9, 8.0]	0.615 [0.384, 0.986]	0.0412	
Number of Organs with Metastatic Sites									
0-2	189	69 (36.5)	9.6 [6.0, NC]	188	70 (37.2)	9.0 [6.4, NC]	1.017 [0.729, 1.418]	0.9236	0.3415
>=3	65	21 (32.3)	7.0 [3.5, NC]	65	31 (47.7)	4.9 [2.5, 8.3]	0.740 [0.425, 1.288]	0.2711	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.18.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhoea (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	95 (37.4%)	122 (48.2%)	
Number of patients censored	159 (62.6%)	131 (51.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.1 [5.3, NC]	5.0 [3.3, 8.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.760 [0.580, 0.997]
Log-rank test			
Two-sided stratified log-rank p-value			0.0481

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: 07OCT22

Table 302.1.3004.18.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhoea by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	67 (38.1)	13.4 [5.3, NC]	180	84 (46.7)	6.2 [3.1, 10.1]	0.762 [0.552, 1.050]	0.0984	0.9193
>65 years	78	28 (35.9)	9.1 [3.3, NC]	73	38 (52.1)	4.1 [2.9, 6.8]	0.751 [0.459, 1.231]	0.2549	
Sex									
Male	159	59 (37.1)	9.1 [5.3, NC]	156	74 (47.4)	4.9 [3.3, 9.0]	0.755 [0.536, 1.063]	0.1076	0.9442
Female	95	36 (37.9)	13.4 [4.0, 26.0]	97	48 (49.5)	5.0 [2.6, 10.7]	0.755 [0.488, 1.168]	0.2066	
Region									
Asia	157	61 (38.9)	26.0 [5.3, 26.0]	158	79 (50.0)	5.0 [3.5, 8.3]	0.730 [0.522, 1.022]	0.0654	0.7779
Non-Asia	97	34 (35.1)	6.9 [4.4, NC]	95	43 (45.3)	4.5 [2.8, NC]	0.805 [0.513, 1.263]	0.3592	
Number of Organs with Metastatic Sites									
0-2	189	73 (38.6)	9.1 [5.3, NC]	188	90 (47.9)	6.2 [3.7, 9.3]	0.779 [0.572, 1.063]	0.1165	0.6844
>=3	65	22 (33.8)	NC [3.5, NC]	65	32 (49.2)	3.7 [2.8, 8.3]	0.692 [0.402, 1.191]	0.1830	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3004.19.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	98 (38.6%)	96 (37.9%)	
Number of patients censored	156 (61.4%)	157 (62.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.0 [6.6, 12.7]	10.9 [5.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.055 [0.795, 1.401]
Log-rank test			
Two-sided stratified log-rank p-value			0.7108

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: 07OCT22

Table 302.1.3004.19.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	71 (40.3)	8.8 [6.0, 20.3]	180	67 (37.2)	10.9 [5.0, NC]	1.068 [0.765, 1.492]	0.6981	0.9656
>65 years	78	27 (34.6)	9.2 [3.3, NC]	73	29 (39.7)	7.6 [4.1, NC]	1.056 [0.621, 1.794]	0.8400	
Sex									
Male	159	63 (39.6)	9.2 [6.0, 20.3]	156	63 (40.4)	7.6 [4.5, NC]	0.963 [0.679, 1.366]	0.8270	0.3443
Female	95	35 (36.8)	8.8 [5.6, 26.0]	97	33 (34.0)	NC [5.0, NC]	1.265 [0.783, 2.044]	0.3369	
Region									
Asia	157	63 (40.1)	9.2 [6.2, 26.0]	158	60 (38.0)	10.9 [5.1, NC]	1.041 [0.730, 1.486]	0.8267	0.9093
Non-Asia	97	35 (36.1)	7.8 [4.4, 11.4]	95	36 (37.9)	NC [3.7, NC]	1.084 [0.681, 1.727]	0.7330	
Number of Organs with Metastatic Sites									
0-2	189	74 (39.2)	9.2 [6.7, 20.3]	188	64 (34.0)	NC [7.6, NC]	1.194 [0.854, 1.669]	0.3010	0.2260
>=3	65	24 (36.9)	6.0 [2.8, NC]	65	32 (49.2)	4.5 [3.3, 7.8]	0.817 [0.481, 1.388]	0.4529	

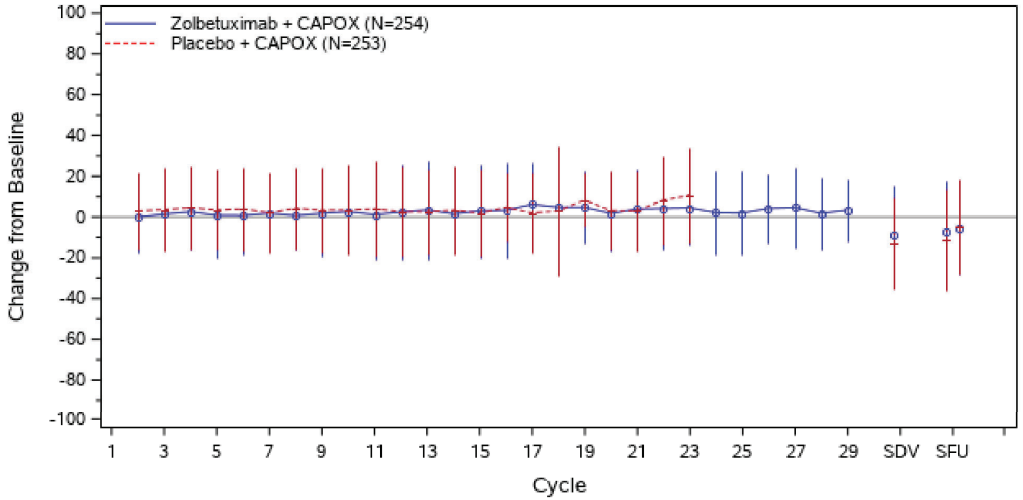
Abbreviations: CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; NC=not calculated.
Note: 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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

The SAS System

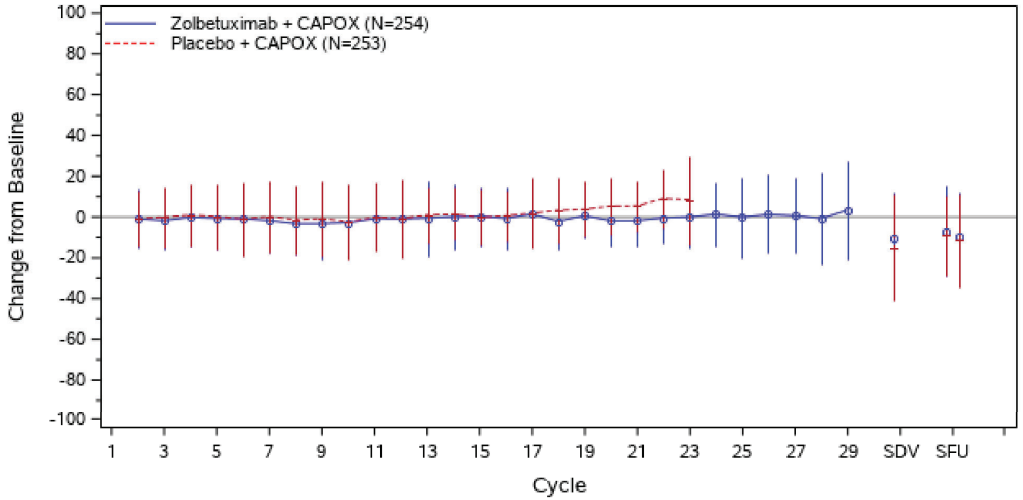
Figure 302.1.3002.5: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Global Health Status - Full Analysis Set



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: 07OCT22

The SAS System

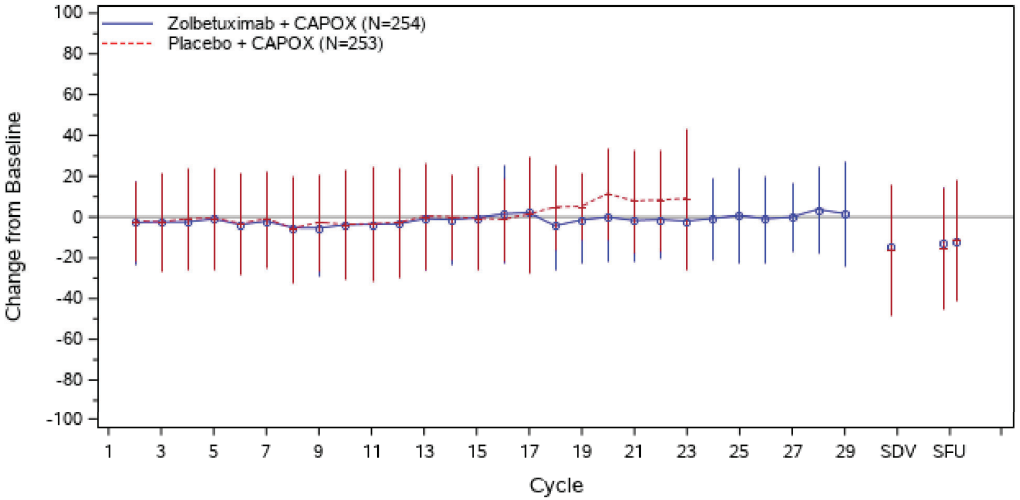
Figure 302.1.3002.6: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Physical Functioning - Full Analysis Set



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: 07OCT22

The SAS System

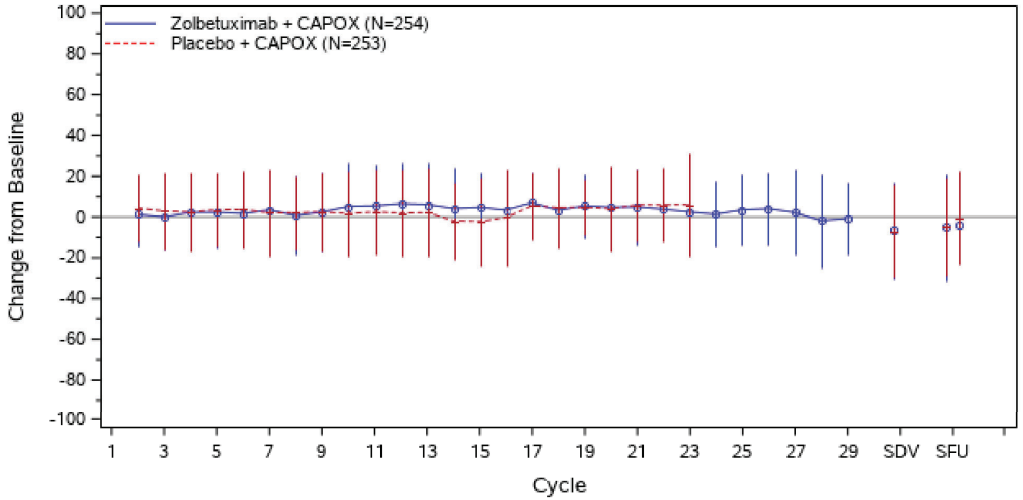
Figure 302.1.3002.7: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Role Functioning - Full Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.3002.8: 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: 07OCT22

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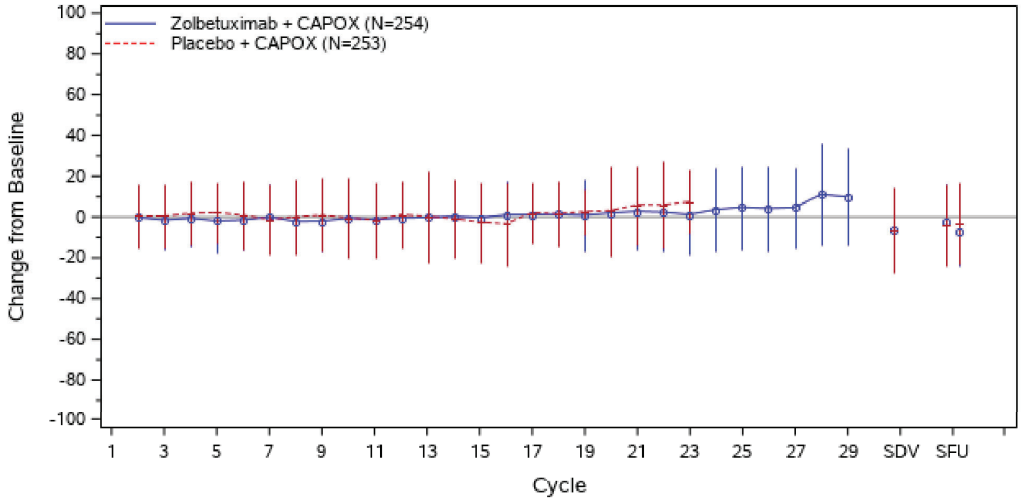
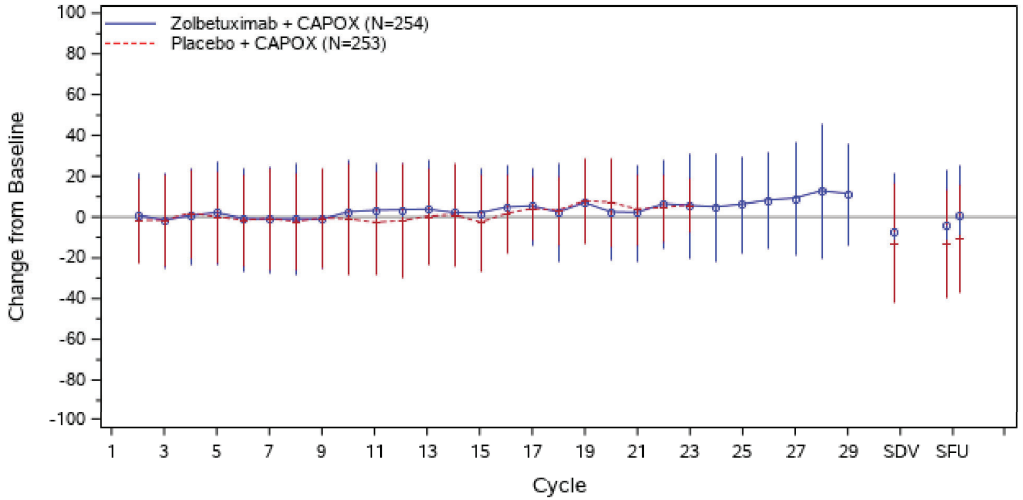
Figure 302.1.3002.9: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Cognitive Functioning - Full Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.3002.10: 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: 07OCT22

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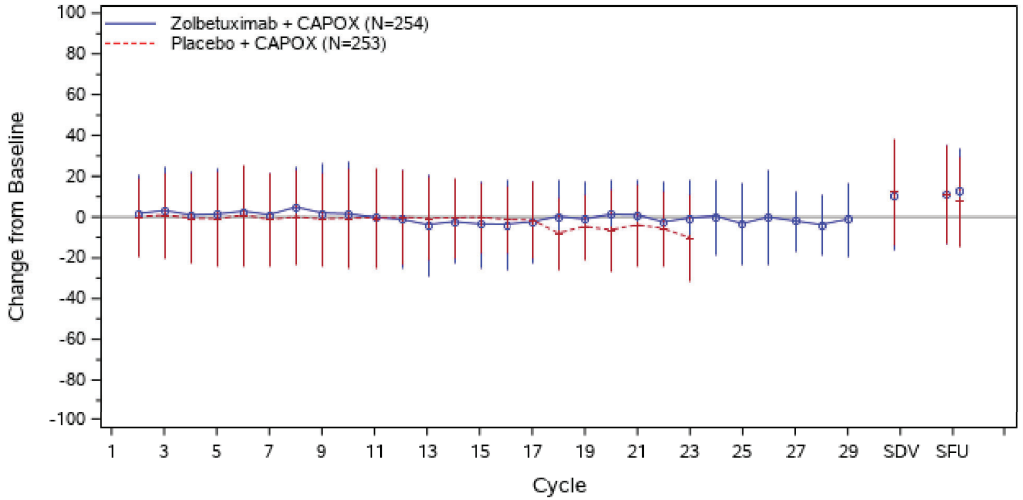
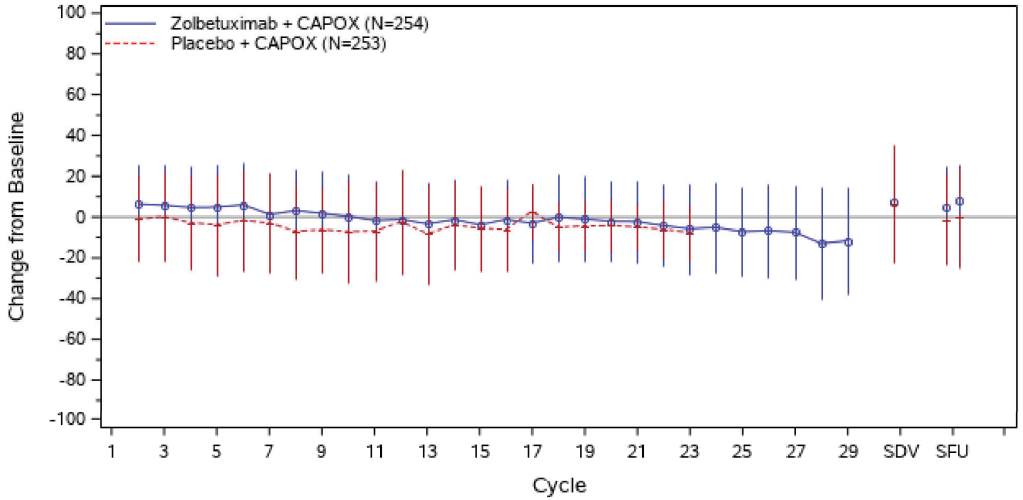
Figure 302.1.3002.11: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Fatigue - Full Analysis Set



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: 07OCT22

The SAS System

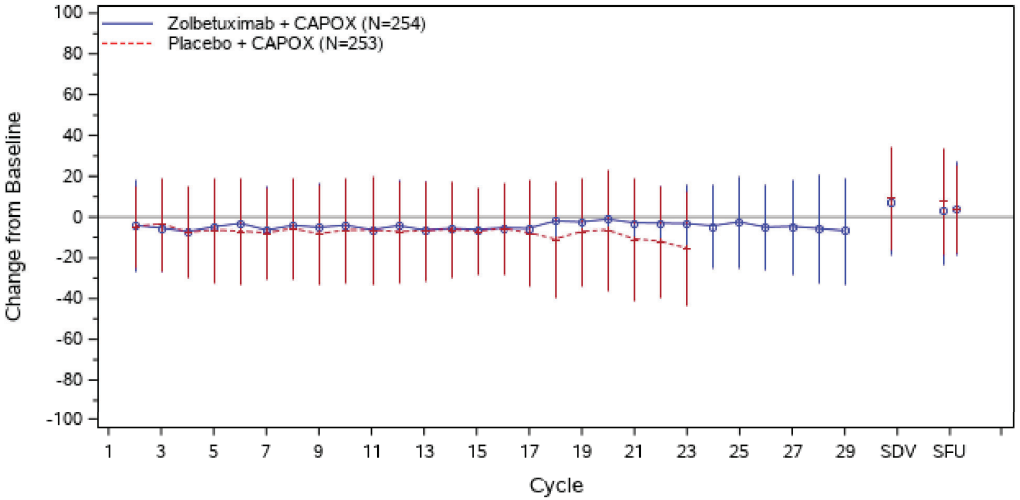
Figure 302.1.3002.12: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Nausea and Vomiting - Full Analysis Set



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: 07OCT22

The SAS System

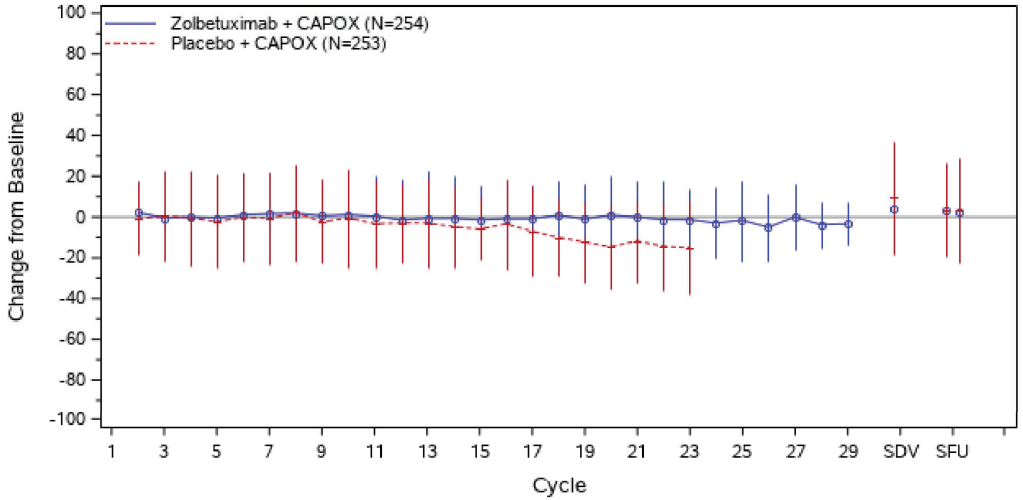
Figure 302.1.3002.13: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Pain - Full Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.3002.14: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Dyspnoea - Full Analysis Set

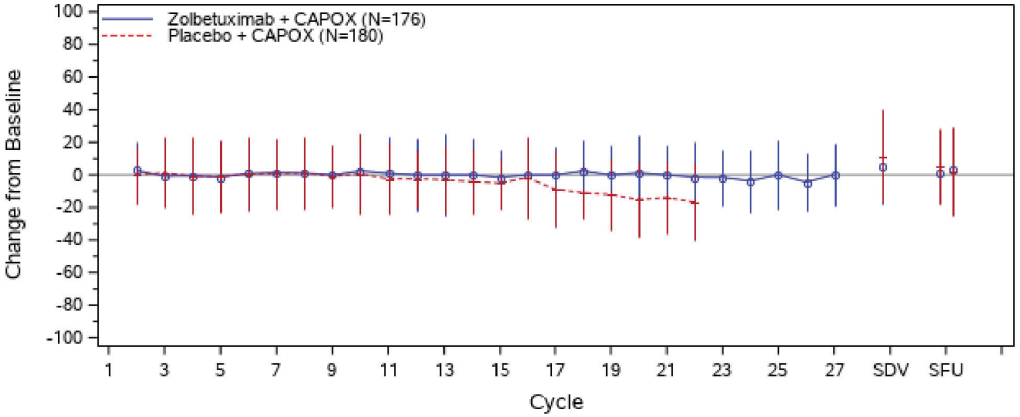


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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: 07OCT22

The SAS System

Figure 302.1.3002.14.1: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Dyspnoea 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: 07OCT22

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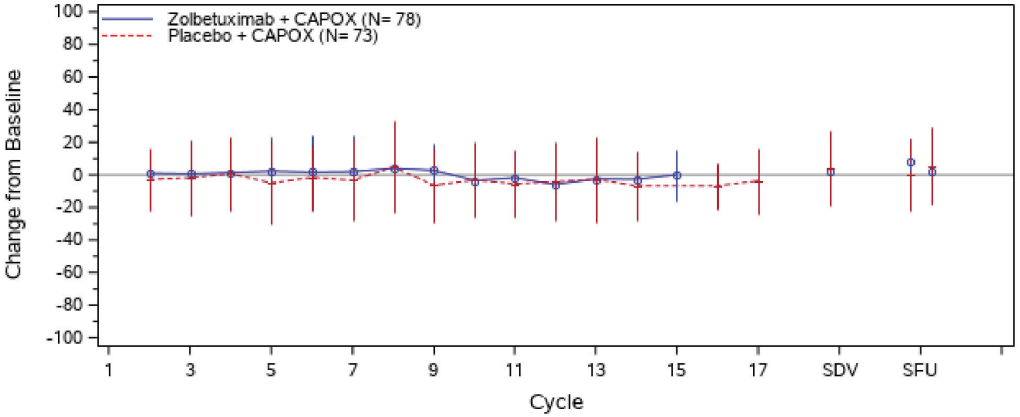
Figure 302.1.3002.14.1: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Dyspnoea by Age Group 1 - Full Analysis Set

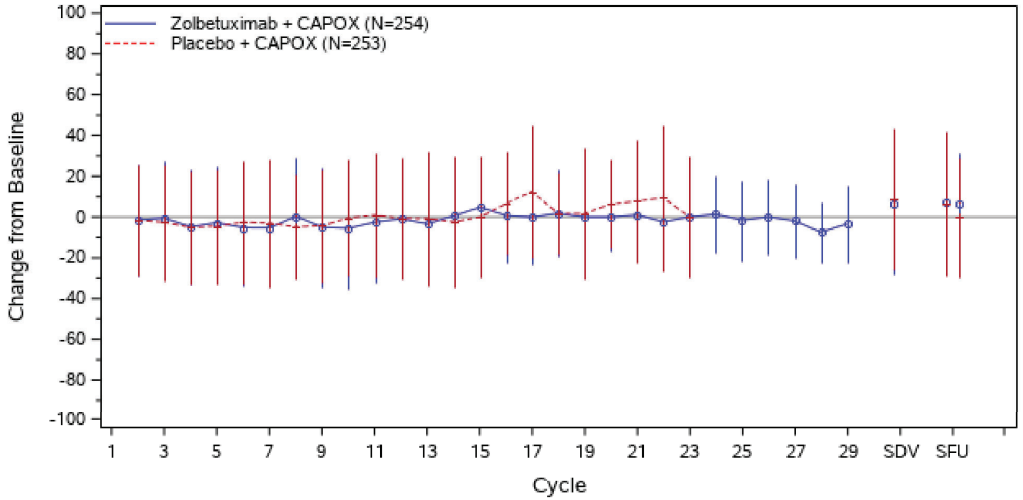
Age Group 1: >65 years



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: 07OCT22

The SAS System

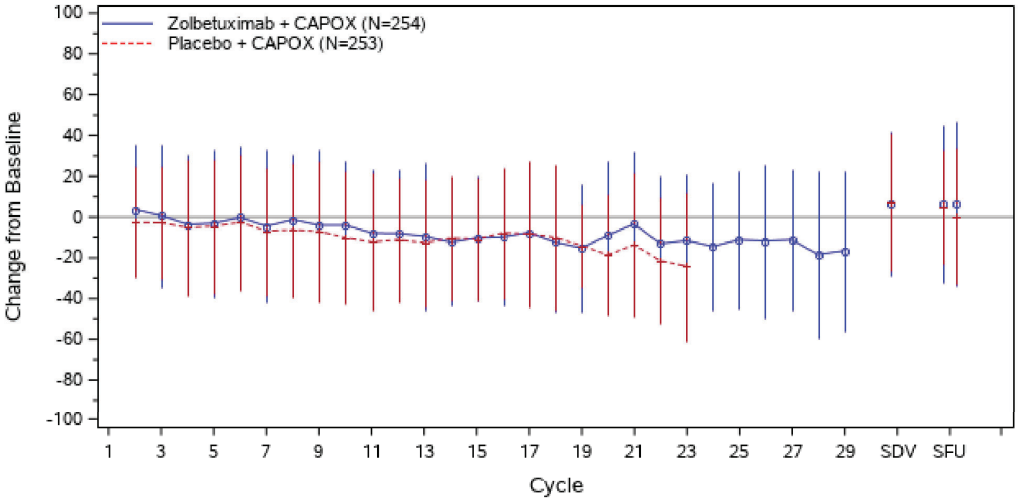
Figure 302.1.3002.15: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Insomnia - Full Analysis Set



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: 07OCT22

The SAS System

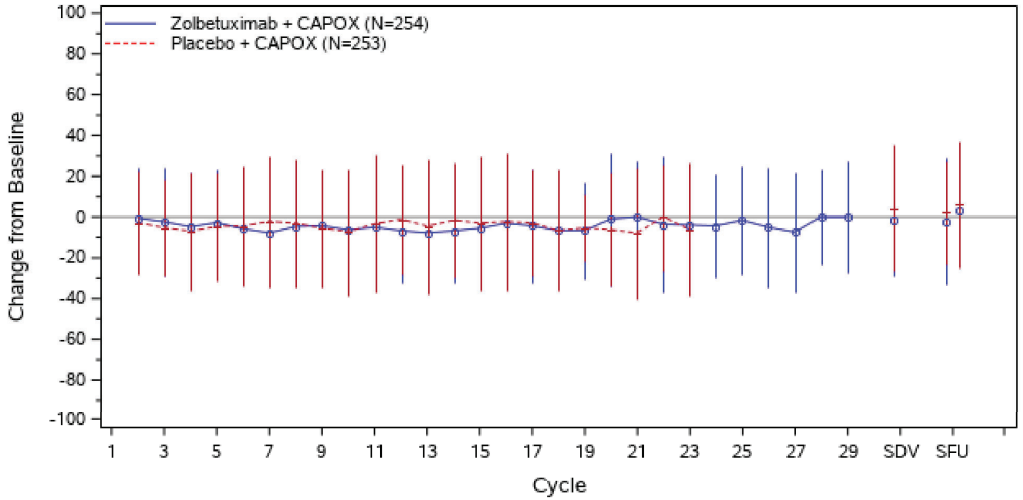
Figure 302.1.3002.16: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Appetite Loss - Full Analysis Set



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: 07OCT22

The SAS System

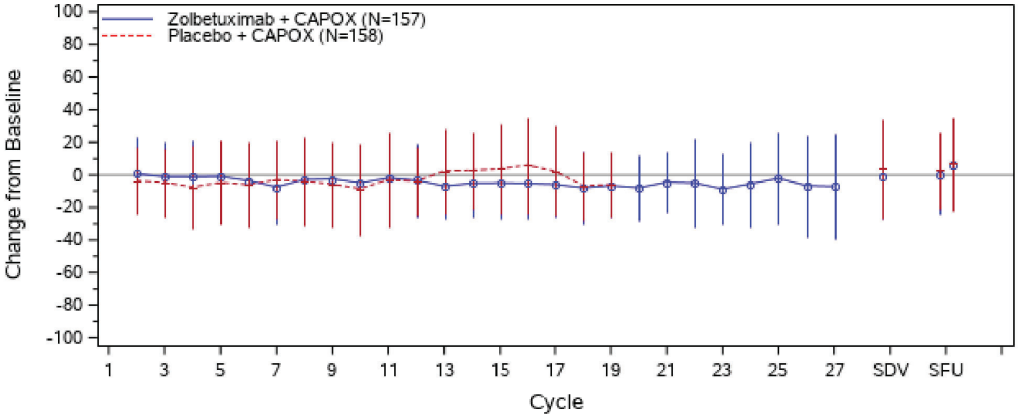
Figure 302.1.3002.17: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Constipation - Full Analysis Set



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: 07OCT22

The SAS System

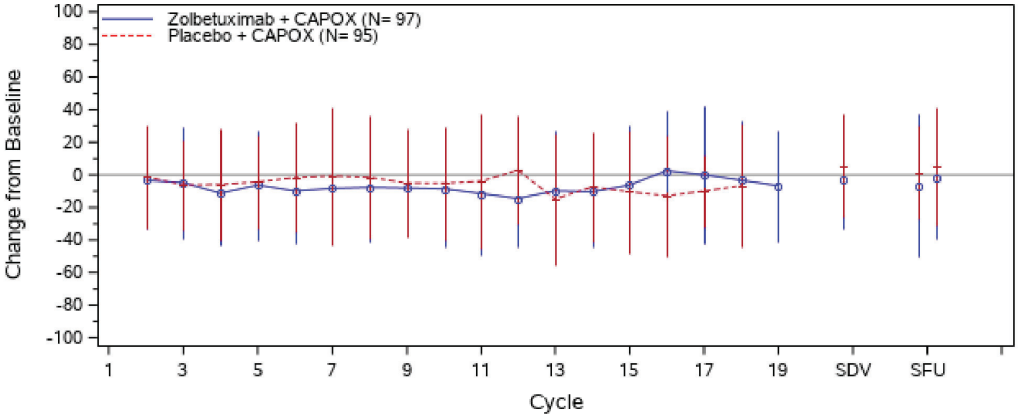
Figure 302.1.3002.17.3: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Constipation by Region - Full Analysis Set
Region: Asia



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: 07OCT22

The SAS System

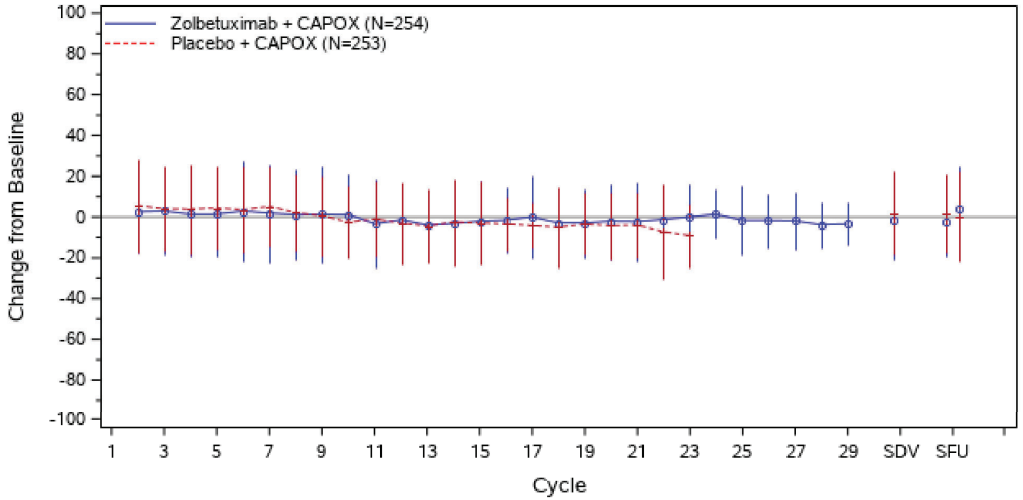
Figure 302.1.3002.17.3: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Constipation by Region - Full Analysis Set
Region: Non-Asia



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: 07OCT22

The SAS System

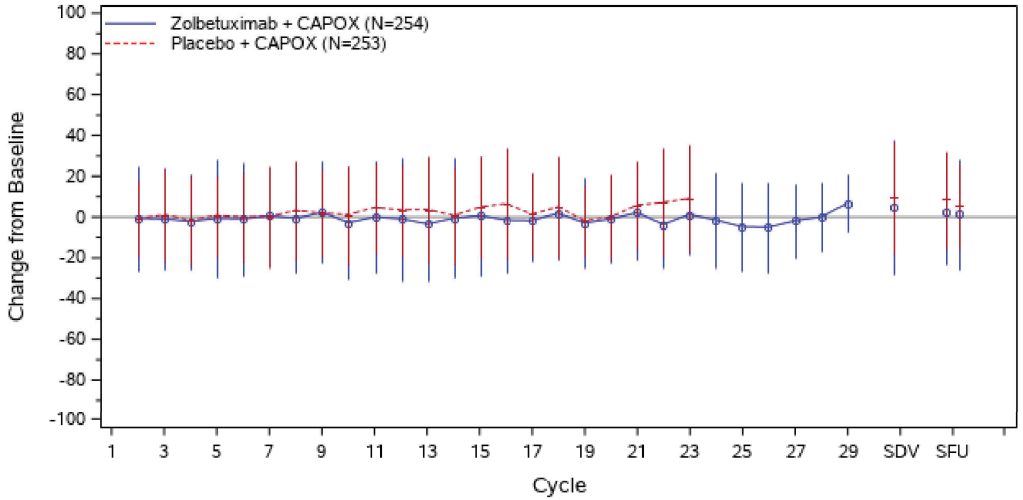
Figure 302.1.3002.18: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Diarrhoea - Full Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.3002.19: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Financial Difficulties - Full Analysis Set



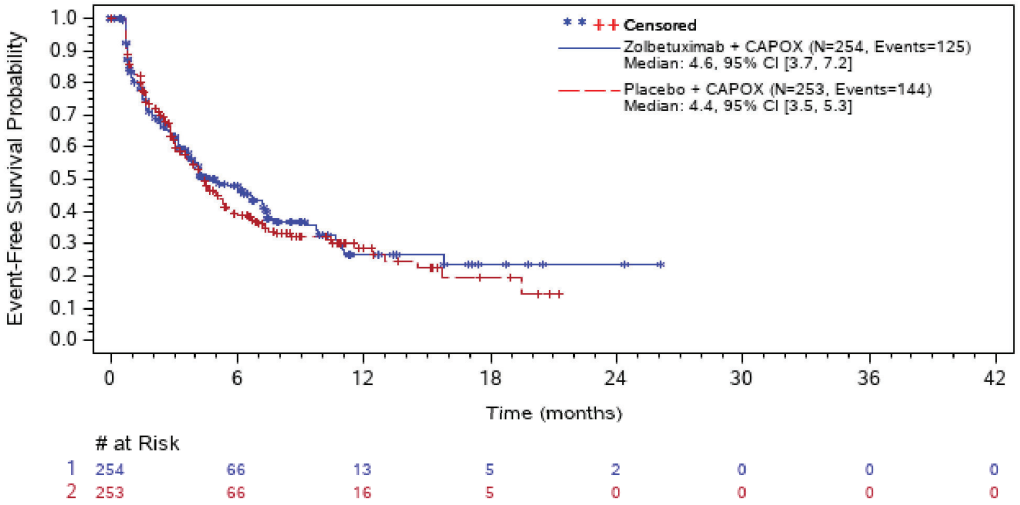
Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

5. Kaplan-Meier-Plots

The SAS System

Figure 302.1.3004.5: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Global Health Status (MID=10) - Full Analysis Set



# at Risk								
1	254	66	13	5	2	0	0	0
2	253	66	16	5	0	0	0	0

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.

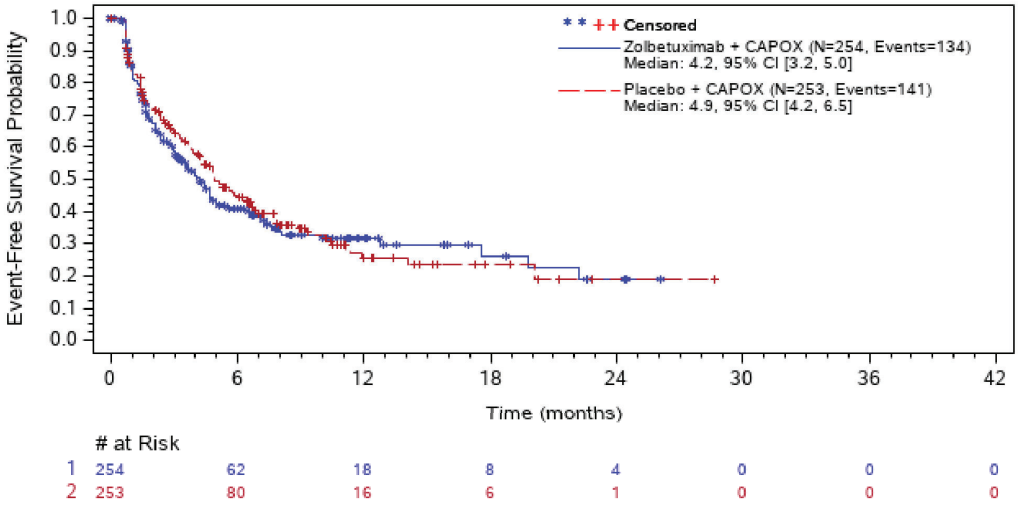
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.6: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Physical Functioning (MID=10) - Full Analysis Set



	# at Risk							
1	254	62	18	8	4	0	0	0
2	253	80	16	6	1	0	0	0

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.

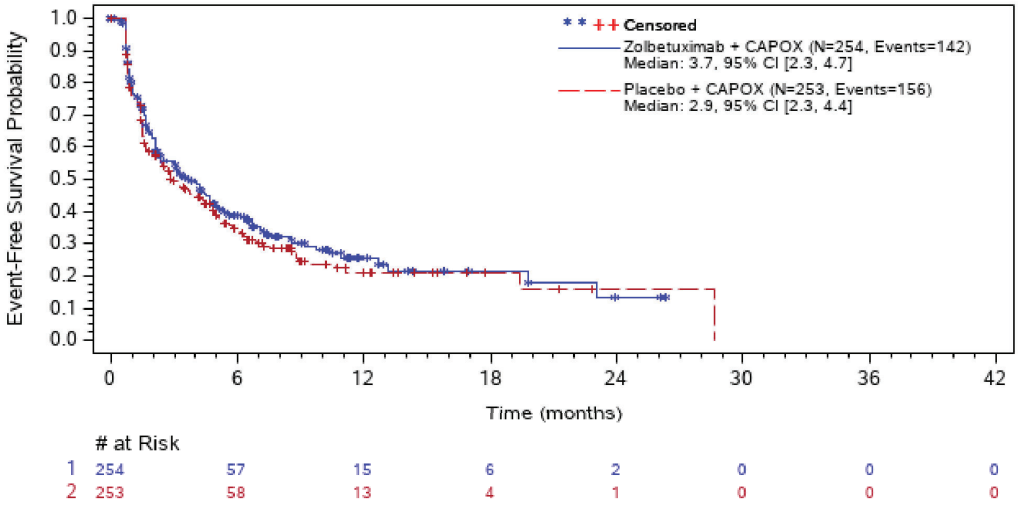
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.7: 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.

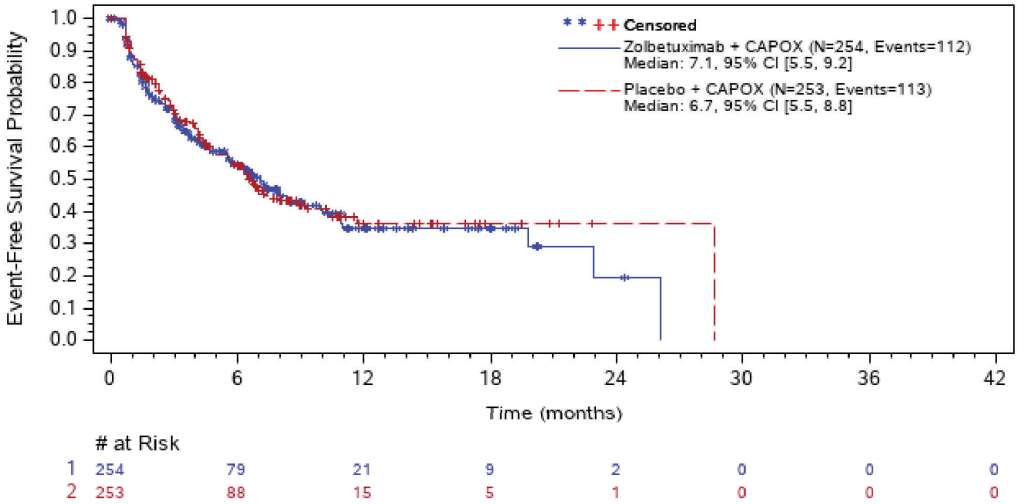
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.8: 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.

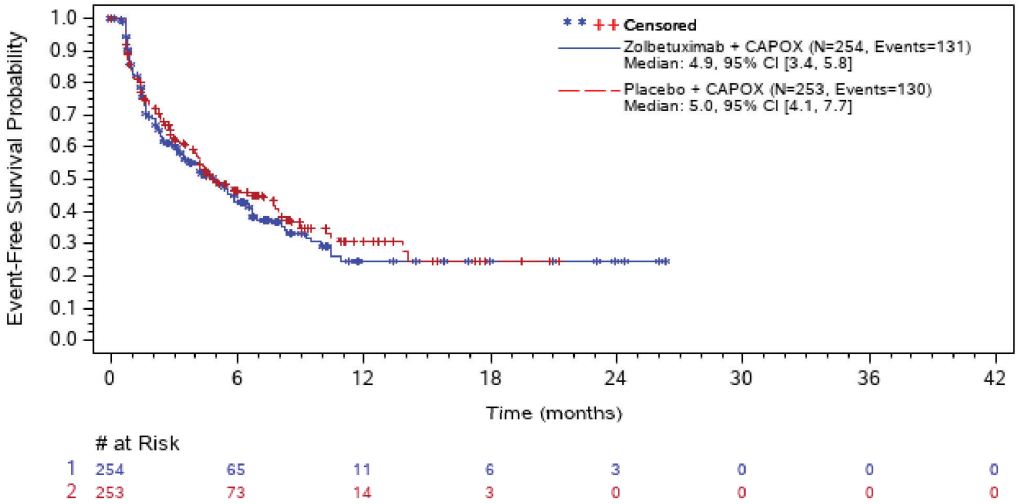
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.9: 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.

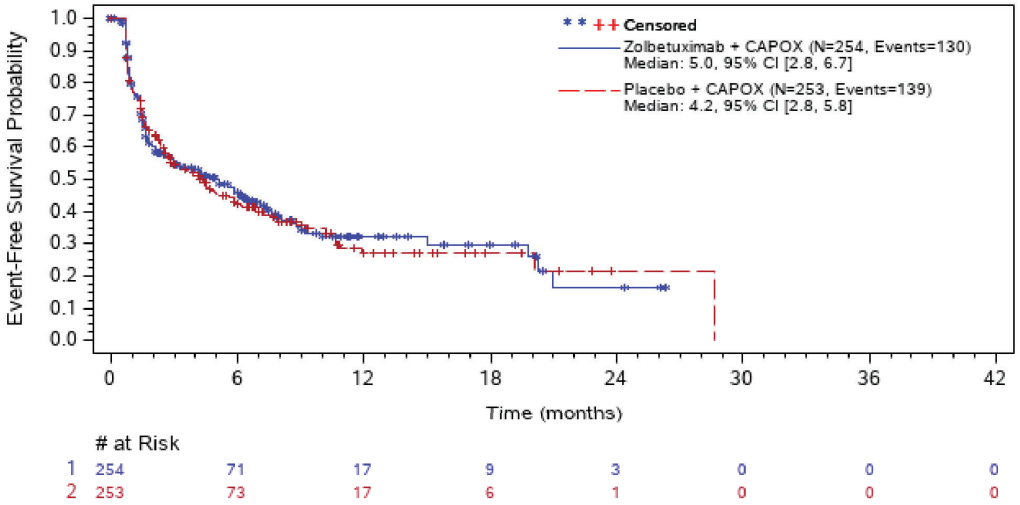
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.10: 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.

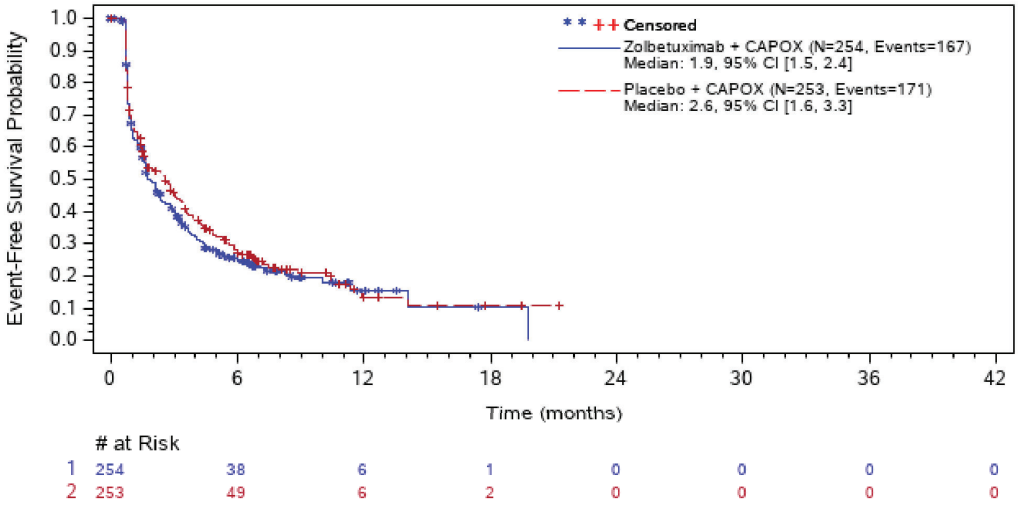
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.11: 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.

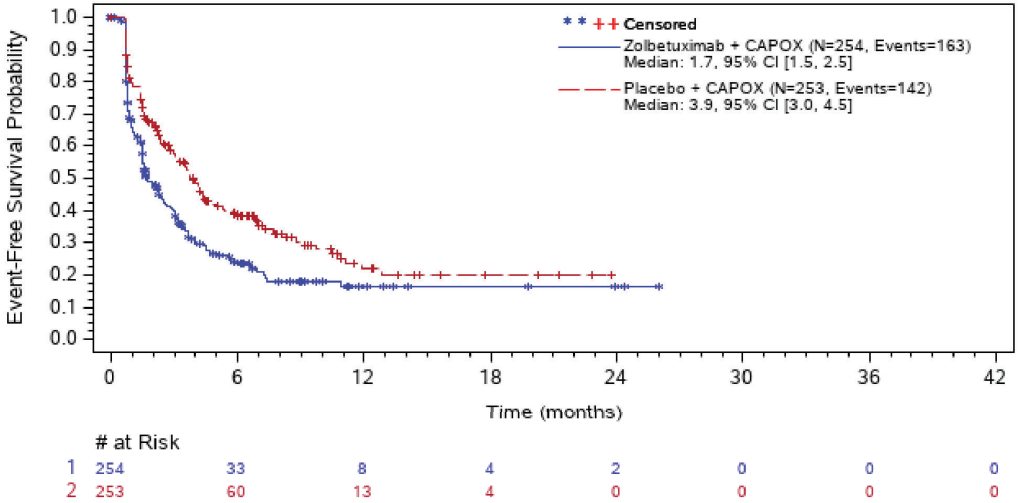
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.12: 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.

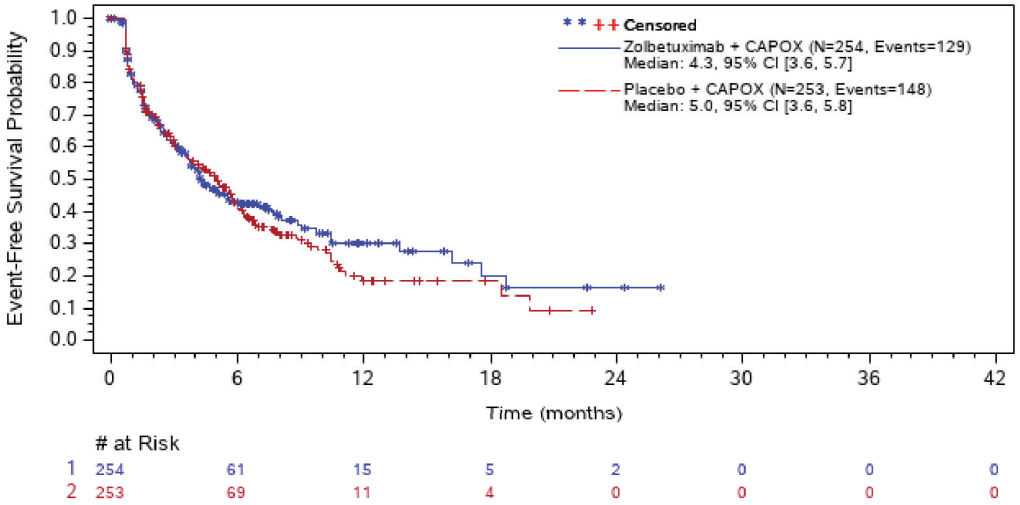
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.13: 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.

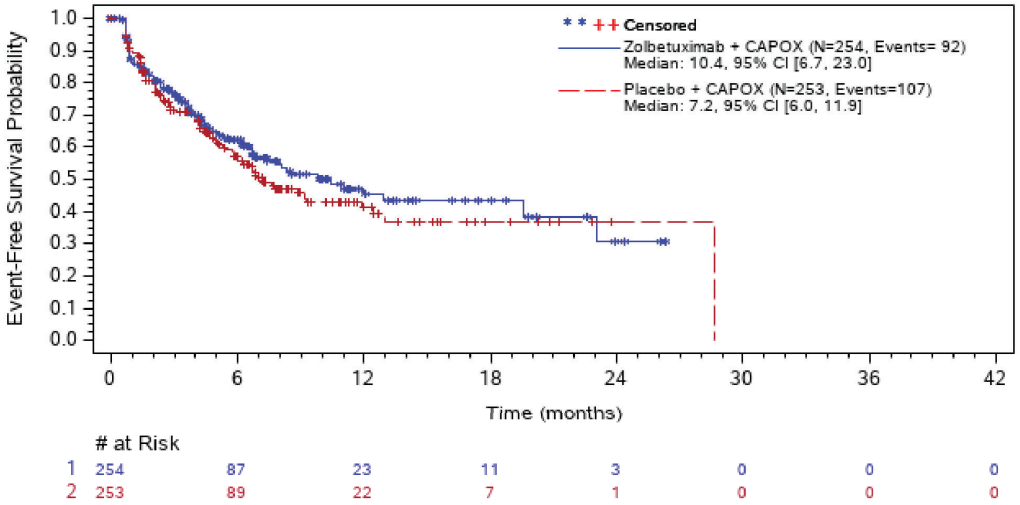
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.14: 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.

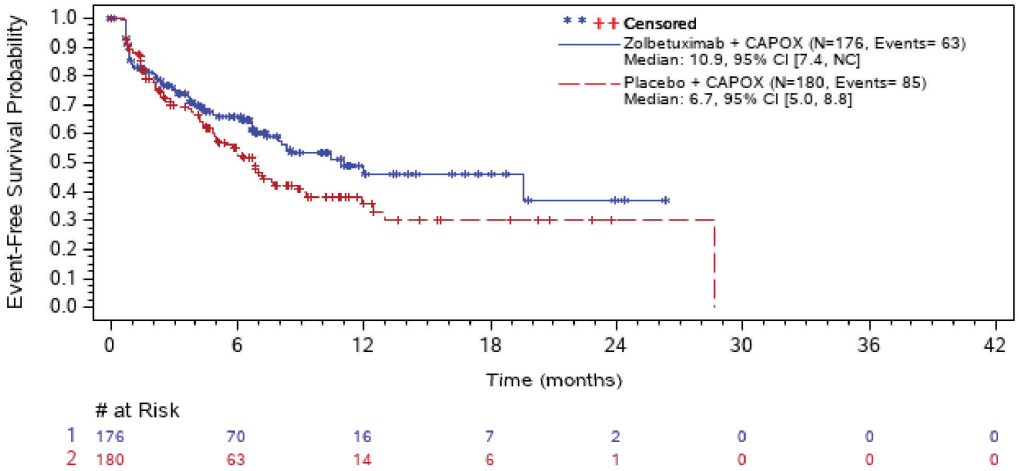
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.14.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Dyspnoea by Age Group 1 (MID=10) - Full Analysis Set
Age Group 1: <=65 years

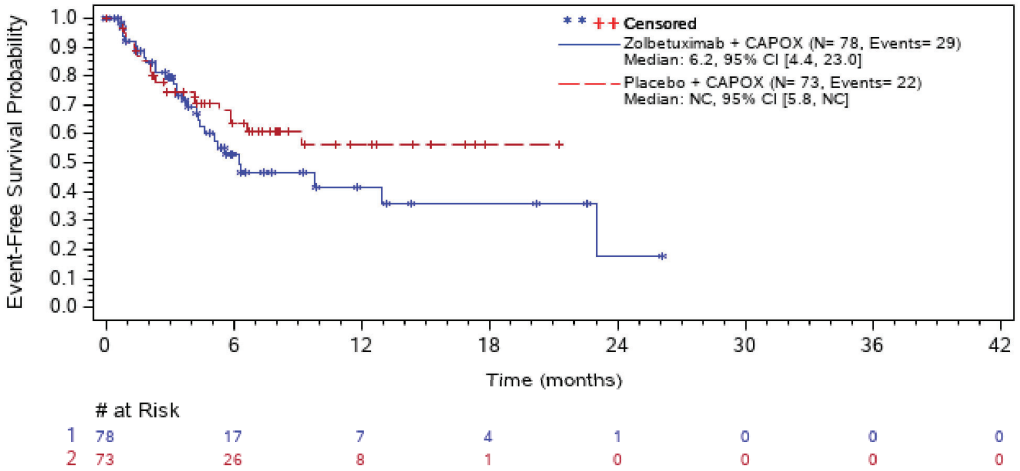


# at Risk								
1	176	70	16	7	2	0	0	0
2	180	63	14	6	1	0	0	0

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: 07OCT22

The SAS System

Figure 302.1.3004.14.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Dyspnoea by Age Group 1 (MID=10) - Full Analysis Set
Age Group 1: >65 years

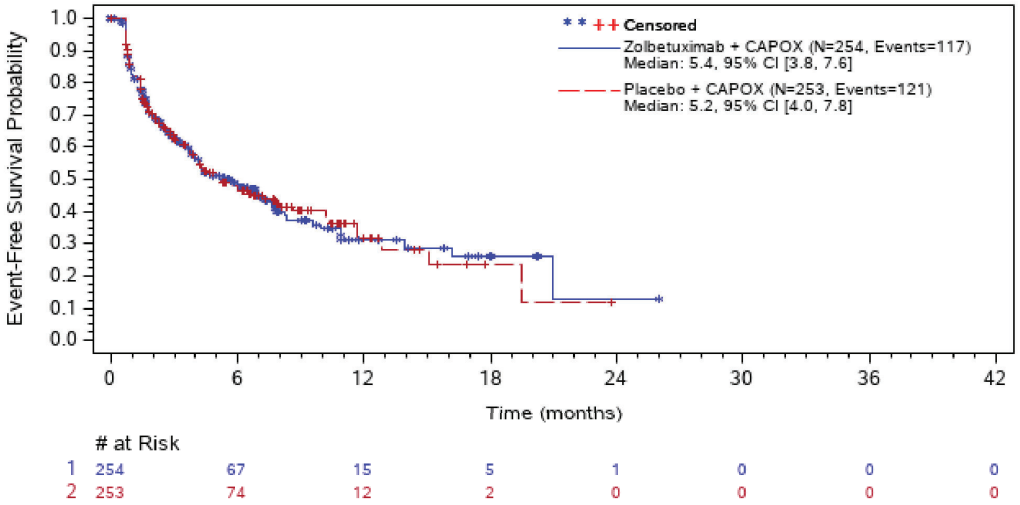


	# at Risk							
1	78	17	7	4	1	0	0	0
2	73	26	8	1	0	0	0	0

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: 07OCT22

The SAS System

Figure 302.1.3004.15: 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.

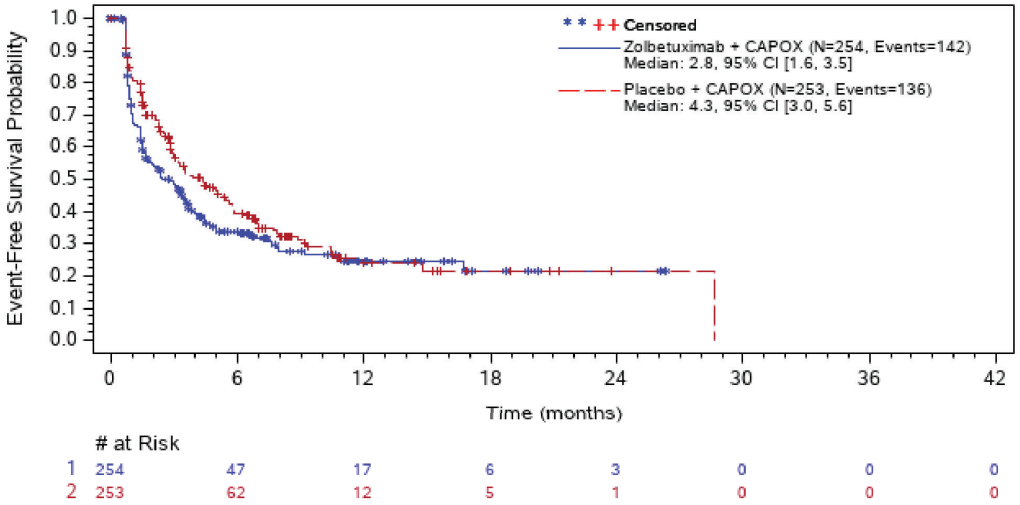
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.16: 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.

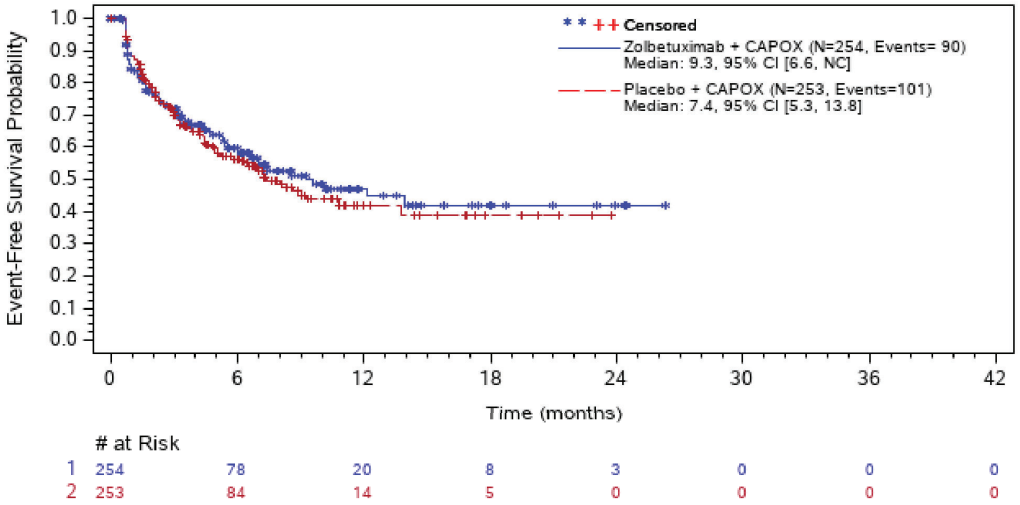
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.17: 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.

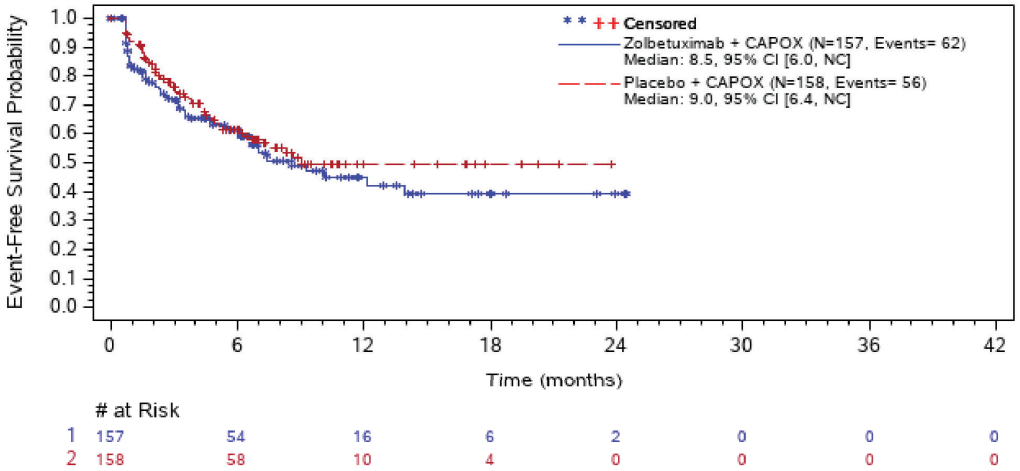
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

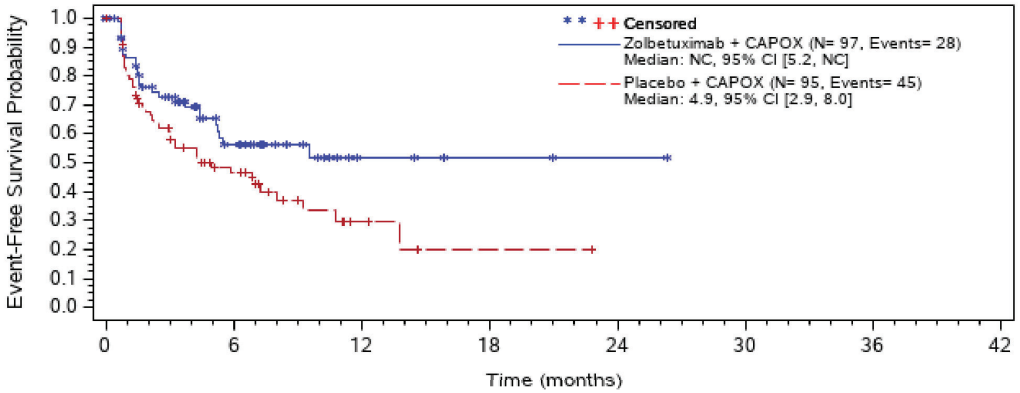
Figure 302.1.3004.17.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Constipation by Region (MID=10) - Full Analysis Set
Region: Asia



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: 07OCT22

The SAS System

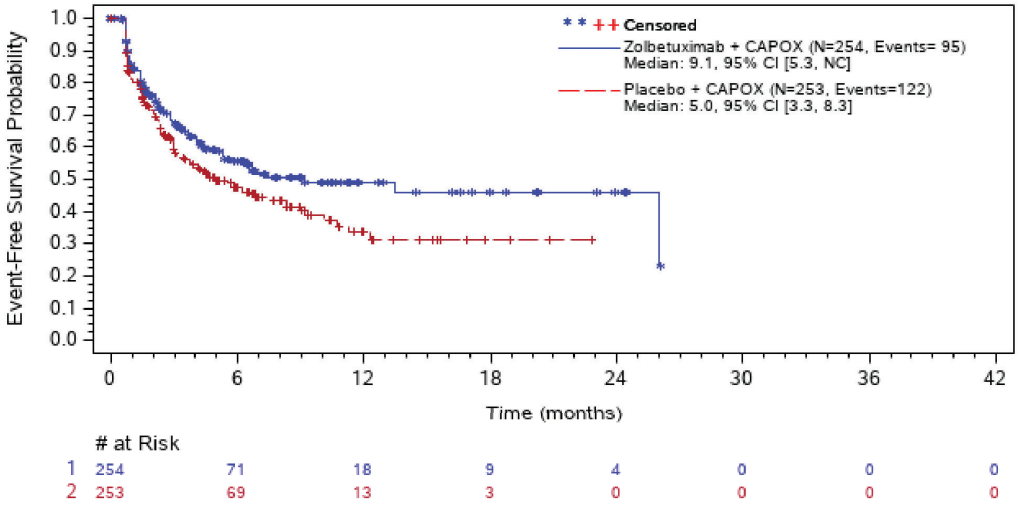
Figure 302.1.3004.17.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Constipation by Region (MID=10) - Full Analysis Set
Region: Non-Asia



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: 07OCT22

The SAS System

Figure 302.1.3004.18: 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.

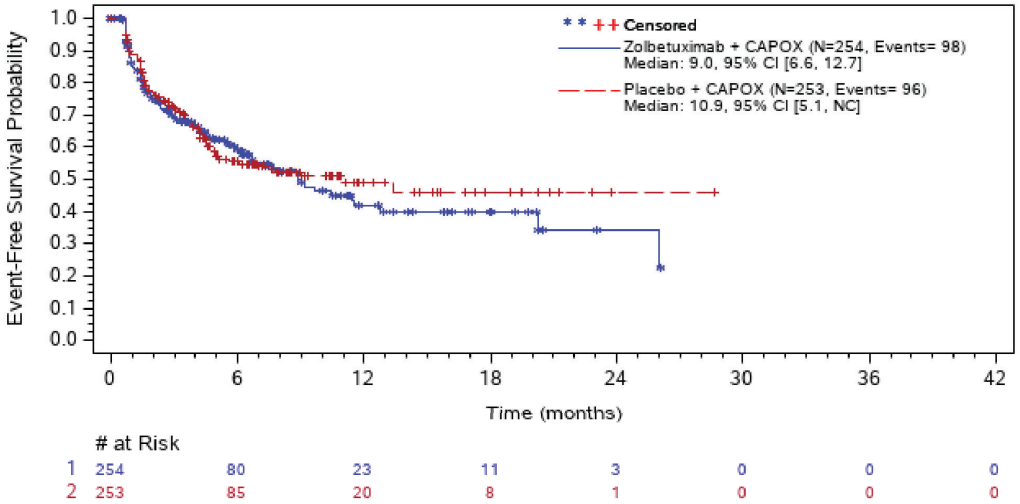
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.19: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Financial Difficulties (MID=10) - Full Analysis Set



	# at Risk							
1	254	80	23	11	3	0	0	0
2	253	85	20	8	1	0	0	0

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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

1. Rücklaufquoten

Table 302.1.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (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: 07OCT22

Table 302.1.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Table 302.1.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	91/253 (36.0%)	91/253 (36.0%)	91/254 (35.8%)	85/250 (34.0%)	85/252 (33.7%)	85/253 (33.6%)
Cycle 2 Day 1	100/224 (44.6%)	100/236 (42.4%)	100/254 (39.4%)	90/229 (39.3%)	91/237 (38.4%)	91/253 (36.0%)
Cycle 3 Day 1	102/197 (51.8%)	102/223 (45.7%)	103/254 (40.6%)	78/215 (36.3%)	78/232 (33.6%)	78/253 (30.8%)
Cycle 4 Day 1	90/182 (49.5%)	90/220 (40.9%)	90/254 (35.4%)	69/192 (35.9%)	70/229 (30.6%)	70/253 (27.7%)
Cycle 5 Day 1	71/172 (41.3%)	72/215 (33.5%)	74/254 (29.1%)	69/181 (38.1%)	69/228 (30.3%)	69/253 (27.3%)
Cycle 6 Day 1	68/155 (43.9%)	71/208 (34.1%)	72/254 (28.3%)	61/165 (37.0%)	61/222 (27.5%)	61/253 (24.1%)
Cycle 7 Day 1	52/128 (40.6%)	53/202 (26.2%)	53/254 (20.9%)	57/141 (40.4%)	57/220 (25.9%)	57/253 (22.5%)
Cycle 8 Day 1	52/119 (43.7%)	52/199 (26.1%)	53/254 (20.9%)	53/125 (42.4%)	53/220 (24.1%)	53/253 (20.9%)
Cycle 9 Day 1	52/108 (48.1%)	52/196 (26.5%)	52/254 (20.5%)	42/110 (38.2%)	44/217 (20.3%)	44/253 (17.4%)
Cycle 10 Day 1	35/ 89 (39.3%)	37/192 (19.3%)	37/254 (14.6%)	40/ 91 (44.0%)	40/216 (18.5%)	40/253 (15.8%)
Cycle 11 Day 1	36/ 83 (43.4%)	37/191 (19.4%)	37/254 (14.6%)	32/ 78 (41.0%)	32/215 (14.9%)	32/253 (12.6%)
Cycle 12 Day 1	36/ 76 (47.4%)	38/191 (19.9%)	38/254 (15.0%)	27/ 68 (39.7%)	28/214 (13.1%)	28/253 (11.1%)
Cycle 13 Day 1	30/ 66 (45.5%)	31/191 (16.2%)	31/254 (12.2%)	18/ 54 (33.3%)	18/213 (8.5%)	18/253 (7.1%)
Cycle 14 Day 1	22/ 58 (37.9%)	22/191 (11.5%)	22/254 (8.7%)	17/ 47 (36.2%)	17/213 (8.0%)	17/253 (6.7%)
Cycle 15 Day 1	18/ 52 (34.6%)	19/189 (10.1%)	20/254 (7.9%)	12/ 41 (29.3%)	12/211 (5.7%)	12/253 (4.7%)
Cycle 16 Day 1	20/ 45 (44.4%)	21/189 (11.1%)	21/254 (8.3%)	12/ 33 (36.4%)	12/211 (5.7%)	12/253 (4.7%)
Cycle 17 Day 1	20/ 42 (47.6%)	21/189 (11.1%)	21/254 (8.3%)	9/ 27 (33.3%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 18 Day 1	17/ 38 (44.7%)	18/189 (9.5%)	18/254 (7.1%)	8/ 22 (36.4%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 19 Day 1	15/ 38 (39.5%)	15/189 (7.9%)	15/254 (5.9%)	9/ 21 (42.9%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 20 Day 1	15/ 36 (41.7%)	15/188 (8.0%)	15/254 (5.9%)	9/ 19 (47.4%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 21 Day 1	12/ 33 (36.4%)	12/188 (6.4%)	12/254 (4.7%)	7/ 18 (38.9%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 22 Day 1	10/ 30 (33.3%)	10/187 (5.3%)	10/254 (3.9%)	6/ 16 (37.5%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 23 Day 1	9/ 29 (31.0%)	9/187 (4.8%)	9/254 (3.5%)	5/ 13 (38.5%)	5/210 (2.4%)	5/253 (2.0%)
Cycle 24 Day 1	9/ 25 (36.0%)	9/187 (4.8%)	9/254 (3.5%)	4/ 10 (40.0%)	4/210 (1.9%)	4/253 (1.6%)
Cycle 25 Day 1	7/ 24 (29.2%)	7/187 (3.7%)	7/254 (2.8%)	2/ 8 (25.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 26 Day 1	6/ 22 (27.3%)	6/187 (3.2%)	6/254 (2.4%)	2/ 7 (28.6%)	2/210 (1.0%)	2/253 (0.8%)

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: 07OCT22

Table 302.1.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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/ 18 (22.2%)	6/187 (3.2%)	6/254 (2.4%)	1/ 7 (14.3%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 28 Day 1	3/ 12 (25.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 7 (14.3%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 29 Day 1	3/ 12 (25.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 6 (16.7%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 30 Day 1	2/ 9 (22.2%)	2/187 (1.1%)	2/254 (0.8%)	2/ 3 (66.7%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 31 Day 1	2/ 9 (22.2%)	2/187 (1.1%)	2/254 (0.8%)	0/ 2 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 32 Day 1	2/ 8 (25.0%)	2/187 (1.1%)	2/254 (0.8%)	0/ 2 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 33 Day 1	2/ 8 (25.0%)	2/187 (1.1%)	2/254 (0.8%)	0/ 2 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 34 Day 1	1/ 6 (16.7%)	1/187 (0.5%)	1/254 (0.4%)	0/ 2 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 35 Day 1	0/ 5 (0.0%)	0/187 (0.0%)	0/254 (0.0%)	0/ 2 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 36 Day 1	0/ 3 (0.0%)	0/187 (0.0%)	0/254 (0.0%)	0/ 1 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 37 Day 1	0/ 3 (0.0%)	0/187 (0.0%)	0/254 (0.0%)	0/ 1 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 38 Day 1	0/ 1 (0.0%)	0/187 (0.0%)	0/254 (0.0%)	0/ 1 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 39 Day 1	0/ 1 (0.0%)	0/187 (0.0%)	0/254 (0.0%)	0/ 1 (0.0%)	0/210 (0.0%)	0/253 (0.0%)
Cycle 40 Day 1	0/ 1 (0.0%)	0/187 (0.0%)	0/254 (0.0%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	53/198 (26.8%)	53/228 (23.2%)	53/254 (20.9%)	61/213 (28.6%)	61/231 (26.4%)	61/253 (24.1%)
30 D SFU Z/P	20/187 (10.7%)	20/220 (9.1%)	20/254 (7.9%)	33/201 (16.4%)	33/219 (15.1%)	33/253 (13.0%)
90 D SFU Z/P	28/166 (16.9%)	28/205 (13.7%)	28/254 (11.0%)	52/160 (32.5%)	52/182 (28.6%)	52/253 (20.6%)

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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

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

Table 302.1.3002.20: 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 + CAPOX (N=254)												
Baseline	242	12.12	18.30	0.0	0.00	77.8						
Cycle 2 Day 1	209	11.38	17.41	0.0	0.00	88.9	208	-0.37	17.07	-55.6	0.00	66.7
Cycle 3 Day 1	186	10.22	16.17	0.0	0.00	88.9	182	-0.92	15.22	-55.6	0.00	66.7
Cycle 4 Day 1	169	8.02	14.34	0.0	0.00	88.9	166	-2.68	17.13	-77.8	0.00	66.7
Cycle 5 Day 1	162	9.60	16.31	0.0	0.00	100.0	159	-1.05	20.30	-77.8	0.00	100.0
Cycle 6 Day 1	151	9.49	15.47	0.0	0.00	77.8	149	-1.42	16.81	-66.7	0.00	66.7
Cycle 7 Day 1	121	6.61	11.53	0.0	0.00	55.6	119	-2.61	16.28	-55.6	0.00	55.6
Cycle 8 Day 1	114	7.89	14.84	0.0	0.00	66.7	108	-2.88	18.81	-77.8	0.00	55.6
Cycle 9 Day 1	107	8.62	14.90	0.0	0.00	77.8	102	-2.83	17.67	-55.6	0.00	44.4
Cycle 10 Day 1	88	6.69	13.64	0.0	0.00	77.8	85	-3.27	16.61	-55.6	0.00	44.4
Cycle 11 Day 1	82	6.10	11.99	0.0	0.00	44.4	79	-3.38	17.01	-66.7	0.00	44.4
Cycle 12 Day 1	76	5.70	12.50	0.0	0.00	77.8	74	-3.75	17.18	-66.7	0.00	33.3
Cycle 13 Day 1	62	3.58	8.48	0.0	0.00	33.3	60	-6.30	17.64	-66.7	0.00	33.3
Cycle 14 Day 1	56	4.37	9.40	0.0	0.00	44.4	54	-4.32	15.63	-55.6	0.00	44.4
Cycle 15 Day 1	51	5.01	10.73	0.0	0.00	44.4	49	-2.95	14.48	-44.4	0.00	33.3
Cycle 16 Day 1	46	7.49	11.49	0.0	0.00	33.3	44	-1.01	13.94	-44.4	0.00	33.3
Cycle 17 Day 1	41	5.69	11.42	0.0	0.00	44.4	39	-2.85	13.42	-44.4	0.00	33.3
Cycle 18 Day 1	37	5.71	10.35	0.0	0.00	33.3	35	-3.49	14.70	-44.4	0.00	33.3
Cycle 19 Day 1	37	5.41	9.30	0.0	0.00	33.3	35	-3.81	13.46	-44.4	0.00	33.3
Cycle 20 Day 1	35	5.08	10.21	0.0	0.00	44.4	33	-4.38	11.43	-44.4	0.00	11.1
Cycle 21 Day 1	32	5.56	10.56	0.0	0.00	33.3	30	-2.59	14.79	-44.4	0.00	33.3
Cycle 22 Day 1	30	4.44	8.56	0.0	0.00	33.3	28	-4.37	14.92	-44.4	0.00	33.3
Cycle 23 Day 1	28	3.57	8.03	0.0	0.00	33.3	26	-4.27	15.42	-44.4	0.00	33.3
Cycle 24 Day 1	25	2.67	7.37	0.0	0.00	33.3	23	-4.83	14.14	-44.4	0.00	33.3
Cycle 25 Day 1	23	3.86	8.61	0.0	0.00	33.3	21	-3.70	13.30	-44.4	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: 07OCT22

Table 302.1.3002.20: 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 26 Day 1	22	6.06	15.61	0.0	0.00	66.7	20	-1.11	19.38	-44.4	0.00	66.7
Cycle 27 Day 1	20	2.78	6.11	0.0	0.00	22.2	18	-5.56	13.34	-44.4	0.00	22.2
Cycle 28 Day 1	11	1.01	3.35	0.0	0.00	11.1	9	-8.64	14.46	-44.4	0.00	0.0
Cycle 29 Day 1	12	0.93	3.21	0.0	0.00	11.1	10	-7.78	13.91	-44.4	0.00	0.0
Study Disc 1	124	15.59	23.96	0.0	0.00	100.0	122	4.46	23.02	-55.6	0.00	88.9
30 D SFU Z/P	52	13.03	23.36	0.0	0.00	100.0	51	5.23	23.55	-44.4	0.00	100.0
90 D SFU Z/P	48	5.79	10.75	0.0	0.00	55.6	47	0.95	11.54	-44.4	0.00	22.2
Placebo + CAPOX (N=253)												
Baseline	241	12.59	19.27	0.0	0.00	100.0						
Cycle 2 Day 1	222	8.46	14.73	0.0	0.00	100.0	216	-3.86	15.69	-66.7	0.00	77.8
Cycle 3 Day 1	200	7.22	13.54	0.0	0.00	66.7	196	-4.59	16.22	-66.7	0.00	44.4
Cycle 4 Day 1	171	6.89	13.04	0.0	0.00	77.8	169	-5.00	17.23	-66.7	0.00	44.4
Cycle 5 Day 1	166	6.02	11.05	0.0	0.00	55.6	165	-5.66	17.07	-55.6	0.00	44.4
Cycle 6 Day 1	146	7.61	14.81	0.0	0.00	77.8	145	-3.45	19.00	-66.7	0.00	66.7
Cycle 7 Day 1	126	6.00	12.14	0.0	0.00	66.7	125	-5.16	17.02	-77.8	0.00	33.3
Cycle 8 Day 1	110	6.87	12.23	0.0	0.00	66.7	109	-4.28	17.88	-77.8	0.00	55.6
Cycle 9 Day 1	104	4.81	10.24	0.0	0.00	55.6	103	-5.93	17.17	-77.8	0.00	44.4
Cycle 10 Day 1	81	4.66	10.81	0.0	0.00	55.6	79	-6.75	18.70	-77.8	0.00	55.6
Cycle 11 Day 1	72	4.48	11.14	0.0	0.00	66.7	71	-5.95	19.41	-44.4	0.00	66.7
Cycle 12 Day 1	59	3.77	8.66	0.0	0.00	44.4	57	-5.65	16.15	-44.4	0.00	44.4
Cycle 13 Day 1	47	4.49	8.56	0.0	0.00	33.3	45	-3.95	15.01	-44.4	0.00	33.3
Cycle 14 Day 1	44	4.55	10.26	0.0	0.00	44.4	42	-2.38	14.21	-44.4	0.00	44.4
Cycle 15 Day 1	36	6.17	13.13	0.0	0.00	55.6	34	-0.98	17.38	-44.4	0.00	55.6
Cycle 16 Day 1	32	6.60	11.93	0.0	0.00	44.4	30	0.37	12.88	-33.3	0.00	33.3
Cycle 17 Day 1	26	4.27	9.98	0.0	0.00	33.3	24	-1.39	11.95	-33.3	0.00	22.2
Cycle 18 Day 1	21	2.12	7.55	0.0	0.00	33.3	20	-3.89	10.98	-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.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3002.20: 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 19 Day 1	20	2.22	4.56	0.0	0.00	11.1	19	-2.34	7.01	-22.2	0.00	11.1
Cycle 20 Day 1	17	3.92	9.58	0.0	0.00	33.3	16	-2.08	11.63	-33.3	0.00	22.2
Cycle 21 Day 1	18	3.09	6.38	0.0	0.00	22.2	17	-2.61	13.91	-33.3	0.00	22.2
Cycle 22 Day 1	15	2.22	6.23	0.0	0.00	22.2	14	-4.76	10.42	-33.3	0.00	0.0
Cycle 23 Day 1	12	0.93	3.21	0.0	0.00	11.1	11	-3.03	11.21	-33.3	0.00	11.1
Study Disc 1	149	16.85	25.59	0.0	0.00	100.0	144	4.32	26.09	-77.8	0.00	100.0
30 D SFU Z/P	74	12.46	21.83	0.0	0.00	100.0	72	-0.62	22.37	-55.6	0.00	66.7
90 D SFU Z/P	70	10.79	17.33	0.0	0.00	66.7	68	-2.12	19.70	-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: 07OCT22

Table 302.1.3002.21: 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 + CAPOX (N=254)												
Baseline	242	22.62	25.24	0.0	16.67	100.0						
Cycle 2 Day 1	209	20.41	21.59	0.0	16.67	100.0	208	-1.24	21.39	-66.7	0.00	83.3
Cycle 3 Day 1	186	17.11	20.86	0.0	8.33	100.0	182	-4.12	20.26	-83.3	0.00	66.7
Cycle 4 Day 1	169	15.29	20.04	0.0	8.33	100.0	166	-5.52	21.76	-75.0	0.00	75.0
Cycle 5 Day 1	162	16.05	19.85	0.0	8.33	100.0	159	-5.14	23.77	-83.3	0.00	100.0
Cycle 6 Day 1	151	17.49	21.75	0.0	8.33	100.0	149	-3.97	21.24	-75.0	0.00	66.7
Cycle 7 Day 1	121	14.60	18.17	0.0	8.33	100.0	119	-4.69	21.03	-66.7	0.00	66.7
Cycle 8 Day 1	114	16.37	21.00	0.0	8.33	100.0	108	-3.70	21.87	-100.0	0.00	66.7
Cycle 9 Day 1	107	17.37	20.06	0.0	8.33	91.7	102	-3.59	22.75	-100.0	0.00	58.3
Cycle 10 Day 1	88	15.44	20.82	0.0	8.33	100.0	85	-4.80	24.03	-100.0	0.00	66.7
Cycle 11 Day 1	82	12.09	19.47	0.0	0.00	100.0	79	-5.91	26.12	-100.0	0.00	66.7
Cycle 12 Day 1	76	11.73	19.96	0.0	0.00	100.0	74	-6.31	27.65	-100.0	0.00	66.7
Cycle 13 Day 1	62	10.75	17.23	0.0	0.00	91.7	60	-9.31	28.04	-100.0	0.00	58.3
Cycle 14 Day 1	56	11.46	17.66	0.0	0.00	100.0	54	-7.10	25.67	-100.0	0.00	66.7
Cycle 15 Day 1	51	11.44	17.79	0.0	0.00	100.0	49	-7.31	24.92	-75.0	0.00	66.7
Cycle 16 Day 1	46	11.59	13.89	0.0	8.33	41.7	44	-8.14	23.05	-75.0	-4.17	33.3
Cycle 17 Day 1	41	12.40	14.33	0.0	8.33	50.0	39	-8.12	23.76	-66.7	0.00	33.3
Cycle 18 Day 1	37	13.96	15.35	0.0	8.33	41.7	35	-7.62	25.52	-75.0	0.00	33.3
Cycle 19 Day 1	37	12.39	14.25	0.0	8.33	41.7	35	-8.10	21.34	-66.7	-8.33	33.3
Cycle 20 Day 1	35	14.05	18.39	0.0	8.33	58.3	33	-6.82	24.78	-66.7	0.00	50.0
Cycle 21 Day 1	32	13.28	16.38	0.0	8.33	58.3	30	-5.83	22.44	-66.7	0.00	41.7
Cycle 22 Day 1	30	10.83	16.40	0.0	0.00	66.7	28	-7.74	25.15	-66.7	0.00	50.0
Cycle 23 Day 1	28	11.01	16.98	0.0	0.00	66.7	26	-6.09	21.80	-66.7	0.00	50.0
Cycle 24 Day 1	25	10.67	14.74	0.0	8.33	50.0	23	-3.99	19.76	-58.3	0.00	25.0
Cycle 25 Day 1	23	9.06	14.41	0.0	0.00	58.3	21	-5.56	23.32	-66.7	0.00	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: 07OCT22

Table 302.1.3002.21: 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 26 Day 1	22	10.23	18.53	0.0	0.00	75.0	20	-4.58	24.40	-58.3	-4.17	58.3
Cycle 27 Day 1	20	7.08	13.32	0.0	0.00	41.7	18	-8.80	19.27	-66.7	-4.17	8.3
Cycle 28 Day 1	11	3.03	5.62	0.0	0.00	16.7	9	-12.04	23.24	-66.7	-8.33	8.3
Cycle 29 Day 1	12	3.47	7.50	0.0	0.00	25.0	10	-10.83	20.05	-58.3	-8.33	16.7
Study Disc 1	124	23.86	27.43	0.0	16.67	100.0	122	2.73	27.60	-100.0	0.00	75.0
30 D SFU Z/P	52	20.03	26.00	0.0	8.33	100.0	51	0.49	28.98	-100.0	0.00	58.3
90 D SFU Z/P	48	14.76	16.24	0.0	8.33	75.0	47	-1.95	21.01	-50.0	0.00	50.0
Placebo + CAPOX (N=253)												
Baseline	241	22.51	24.22	0.0	16.67	100.0						
Cycle 2 Day 1	222	18.02	21.01	0.0	8.33	100.0	216	-4.55	20.82	-83.3	0.00	83.3
Cycle 3 Day 1	200	15.25	19.33	0.0	8.33	91.7	196	-6.08	20.52	-100.0	0.00	58.3
Cycle 4 Day 1	171	14.23	18.41	0.0	8.33	83.3	169	-8.19	21.18	-91.7	0.00	58.3
Cycle 5 Day 1	166	14.41	17.99	0.0	8.33	75.0	165	-7.22	22.12	-91.7	0.00	50.0
Cycle 6 Day 1	146	15.30	19.35	0.0	8.33	75.0	145	-6.03	23.04	-83.3	0.00	58.3
Cycle 7 Day 1	126	14.09	18.87	0.0	4.17	75.0	125	-5.07	22.32	-91.7	0.00	58.3
Cycle 8 Day 1	110	14.39	19.09	0.0	8.33	91.7	109	-6.27	24.35	-91.7	0.00	66.7
Cycle 9 Day 1	104	12.42	17.18	0.0	0.00	83.3	103	-7.52	22.25	-91.7	0.00	58.3
Cycle 10 Day 1	81	12.14	18.45	0.0	0.00	75.0	79	-8.54	26.75	-91.7	0.00	75.0
Cycle 11 Day 1	72	10.42	16.65	0.0	0.00	66.7	71	-9.39	27.17	-91.7	0.00	66.7
Cycle 12 Day 1	59	9.75	16.61	0.0	0.00	83.3	57	-9.36	22.33	-75.0	0.00	50.0
Cycle 13 Day 1	47	8.87	14.27	0.0	0.00	58.3	45	-11.30	21.92	-75.0	0.00	25.0
Cycle 14 Day 1	44	11.93	21.22	0.0	0.00	100.0	42	-7.14	22.66	-66.7	0.00	58.3
Cycle 15 Day 1	36	13.19	21.02	0.0	0.00	91.7	34	-5.64	21.39	-58.3	0.00	50.0
Cycle 16 Day 1	32	12.24	16.12	0.0	4.17	66.7	30	-5.83	19.96	-66.7	0.00	25.0
Cycle 17 Day 1	26	12.18	16.71	0.0	4.17	66.7	24	-4.17	21.56	-66.7	0.00	25.0
Cycle 18 Day 1	21	7.54	13.15	0.0	0.00	50.0	20	-9.17	21.10	-66.7	0.00	25.0

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: 07OCT22

Table 302.1.3002.21: 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 19 Day 1	20	5.42	10.22	0.0	0.00	33.3	19	-8.33	13.89	-50.0	0.00	0.0
Cycle 20 Day 1	17	8.33	11.41	0.0	8.33	33.3	16	-8.85	20.29	-58.3	0.00	8.3
Cycle 21 Day 1	18	6.94	10.40	0.0	0.00	33.3	17	-9.31	20.81	-58.3	0.00	16.7
Cycle 22 Day 1	15	6.11	11.56	0.0	0.00	33.3	14	-13.10	21.11	-66.7	0.00	8.3
Cycle 23 Day 1	12	2.78	5.43	0.0	0.00	16.7	11	-12.12	21.20	-58.3	0.00	16.7
Study Disc 1	149	27.01	29.02	0.0	16.67	100.0	144	5.09	26.43	-83.3	0.00	100.0
30 D SFU Z/P	74	20.95	25.10	0.0	12.50	100.0	72	-0.46	22.24	-75.0	0.00	50.0
90 D SFU Z/P	70	19.29	22.94	0.0	8.33	75.0	68	0.12	22.28	-50.0	0.00	58.3

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: 07OCT22

Table 302.1.3002.22: 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 + CAPOX (N=254)												
Baseline	242	13.15	20.32	0.0	0.00	100.0						
Cycle 2 Day 1	209	12.12	18.47	0.0	0.00	100.0	208	-1.04	20.79	-66.7	0.00	100.0
Cycle 3 Day 1	186	12.19	19.70	0.0	0.00	100.0	182	-0.09	21.71	-66.7	0.00	66.7
Cycle 4 Day 1	169	12.03	18.63	0.0	0.00	100.0	166	-0.70	22.80	-66.7	0.00	100.0
Cycle 5 Day 1	162	11.42	15.70	0.0	0.00	66.7	159	-0.84	22.17	-83.3	0.00	50.0
Cycle 6 Day 1	151	12.25	18.83	0.0	0.00	100.0	149	-0.11	22.39	-66.7	0.00	100.0
Cycle 7 Day 1	121	9.37	15.65	0.0	0.00	100.0	119	-1.68	20.40	-66.7	0.00	50.0
Cycle 8 Day 1	114	10.82	18.68	0.0	0.00	100.0	108	-1.08	23.04	-83.3	0.00	66.7
Cycle 9 Day 1	107	12.62	20.96	0.0	0.00	100.0	102	-0.82	27.49	-83.3	0.00	100.0
Cycle 10 Day 1	88	9.85	20.32	0.0	0.00	100.0	85	-1.57	23.80	-83.3	0.00	66.7
Cycle 11 Day 1	82	7.11	15.50	0.0	0.00	100.0	79	-3.16	21.36	-83.3	0.00	66.7
Cycle 12 Day 1	76	6.58	12.79	0.0	0.00	50.0	74	-4.50	22.63	-83.3	0.00	33.3
Cycle 13 Day 1	62	8.87	16.45	0.0	0.00	83.3	60	-3.33	28.26	-83.3	0.00	83.3
Cycle 14 Day 1	56	8.33	13.85	0.0	0.00	50.0	54	-1.85	22.59	-83.3	0.00	50.0
Cycle 15 Day 1	51	5.23	10.80	0.0	0.00	33.3	49	-3.74	18.40	-66.7	0.00	33.3
Cycle 16 Day 1	46	8.70	13.49	0.0	0.00	33.3	44	-0.76	22.72	-66.7	0.00	33.3
Cycle 17 Day 1	41	5.69	12.14	0.0	0.00	33.3	39	-4.27	21.53	-66.7	0.00	33.3
Cycle 18 Day 1	37	7.66	14.48	0.0	0.00	50.0	35	-2.38	24.30	-66.7	0.00	50.0
Cycle 19 Day 1	37	7.21	14.46	0.0	0.00	66.7	35	-1.90	23.49	-66.7	0.00	66.7
Cycle 20 Day 1	35	9.52	13.58	0.0	0.00	50.0	33	1.01	21.63	-66.7	0.00	50.0
Cycle 21 Day 1	32	8.85	19.85	0.0	0.00	100.0	30	1.11	25.87	-50.0	0.00	100.0
Cycle 22 Day 1	30	3.89	8.40	0.0	0.00	33.3	28	-5.36	18.73	-66.7	0.00	33.3
Cycle 23 Day 1	28	3.57	6.96	0.0	0.00	16.7	26	-4.49	17.99	-66.7	0.00	16.7
Cycle 24 Day 1	25	4.00	8.71	0.0	0.00	33.3	23	-2.90	20.51	-66.7	0.00	33.3
Cycle 25 Day 1	23	4.35	9.01	0.0	0.00	33.3	21	-2.38	21.91	-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: 07OCT22

Table 302.1.3002.22: 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 26 Day 1	22	5.30	10.77	0.0	0.00	33.3	20	-2.50	17.33	-50.0	0.00	33.3
Cycle 27 Day 1	20	5.00	9.52	0.0	0.00	33.3	18	-2.78	17.39	-50.0	0.00	16.7
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	9	-7.41	16.90	-50.0	0.00	0.0
Cycle 29 Day 1	12	1.39	4.81	0.0	0.00	16.7	10	-5.00	17.66	-50.0	0.00	16.7
Study Disc 1	124	14.65	23.14	0.0	0.00	100.0	122	3.01	24.81	-83.3	0.00	100.0
30 D SFU Z/P	52	13.14	25.21	0.0	0.00	100.0	51	2.61	26.11	-83.3	0.00	100.0
90 D SFU Z/P	48	10.07	17.78	0.0	0.00	66.7	47	2.48	19.03	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	16.11	22.25	0.0	0.00	100.0						
Cycle 2 Day 1	222	10.74	18.38	0.0	0.00	100.0	216	-4.01	18.66	-83.3	0.00	66.7
Cycle 3 Day 1	200	10.08	17.19	0.0	0.00	100.0	196	-4.17	18.36	-66.7	0.00	50.0
Cycle 4 Day 1	171	8.48	15.59	0.0	0.00	66.7	169	-5.82	21.53	-83.3	0.00	50.0
Cycle 5 Day 1	166	6.93	13.12	0.0	0.00	66.7	165	-7.88	19.87	-83.3	0.00	33.3
Cycle 6 Day 1	146	8.45	15.19	0.0	0.00	66.7	145	-7.01	20.57	-83.3	0.00	33.3
Cycle 7 Day 1	126	8.60	13.78	0.0	0.00	66.7	125	-6.67	21.48	-83.3	0.00	33.3
Cycle 8 Day 1	110	6.97	15.21	0.0	0.00	66.7	109	-9.17	21.81	-83.3	0.00	33.3
Cycle 9 Day 1	104	5.45	11.48	0.0	0.00	66.7	103	-11.00	20.82	-83.3	0.00	33.3
Cycle 10 Day 1	81	7.20	13.16	0.0	0.00	50.0	79	-10.34	22.69	-83.3	0.00	33.3
Cycle 11 Day 1	72	5.32	11.47	0.0	0.00	33.3	71	-11.03	24.23	-83.3	0.00	33.3
Cycle 12 Day 1	59	6.50	13.14	0.0	0.00	50.0	57	-8.48	23.60	-100.0	0.00	33.3
Cycle 13 Day 1	47	7.80	14.27	0.0	0.00	50.0	45	-7.41	23.98	-83.3	0.00	50.0
Cycle 14 Day 1	44	5.30	11.80	0.0	0.00	33.3	42	-7.14	19.18	-83.3	0.00	33.3
Cycle 15 Day 1	36	6.02	13.31	0.0	0.00	50.0	34	-5.39	23.11	-83.3	0.00	33.3
Cycle 16 Day 1	32	6.25	14.51	0.0	0.00	50.0	30	-4.44	20.50	-66.7	0.00	50.0
Cycle 17 Day 1	26	5.13	11.32	0.0	0.00	33.3	24	-2.08	21.60	-83.3	0.00	33.3
Cycle 18 Day 1	21	6.35	13.41	0.0	0.00	50.0	20	-2.50	24.35	-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: 07OCT22

Table 302.1.3002.22: 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 19 Day 1	20	5.00	10.95	0.0	0.00	33.3	19	-0.88	13.00	-16.7	0.00	33.3
Cycle 20 Day 1	17	4.90	14.15	0.0	0.00	50.0	16	-4.17	26.18	-83.3	0.00	50.0
Cycle 21 Day 1	18	6.48	17.28	0.0	0.00	66.7	17	-1.96	29.39	-83.3	0.00	66.7
Cycle 22 Day 1	15	7.78	13.90	0.0	0.00	50.0	14	-1.19	28.84	-83.3	0.00	50.0
Cycle 23 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-6.06	28.16	-83.3	0.00	33.3
Study Disc 1	149	17.56	25.17	0.0	0.00	100.0	144	3.13	27.17	-66.7	0.00	100.0
30 D SFU Z/P	74	13.29	23.57	0.0	0.00	100.0	72	-1.39	23.69	-100.0	0.00	66.7
90 D SFU Z/P	70	9.76	20.16	0.0	0.00	100.0	68	-1.96	20.67	-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: 07OCT22

Table 302.1.3002.23: 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 + CAPOX (N=254)												
Baseline	242	15.70	22.80	0.0	0.00	100.0						
Cycle 2 Day 1	209	13.16	18.66	0.0	0.00	100.0	208	-2.80	21.46	-83.3	0.00	66.7
Cycle 3 Day 1	186	10.75	16.00	0.0	0.00	66.7	182	-3.94	19.38	-66.7	0.00	50.0
Cycle 4 Day 1	169	9.07	16.16	0.0	0.00	66.7	166	-5.22	21.93	-66.7	0.00	66.7
Cycle 5 Day 1	162	10.49	15.42	0.0	0.00	100.0	159	-4.19	22.58	-66.7	0.00	100.0
Cycle 6 Day 1	151	11.59	20.37	0.0	0.00	100.0	149	-2.80	20.54	-66.7	0.00	83.3
Cycle 7 Day 1	121	8.68	14.92	0.0	0.00	83.3	119	-3.92	19.73	-50.0	0.00	83.3
Cycle 8 Day 1	114	9.94	17.56	0.0	0.00	83.3	108	-4.32	21.54	-100.0	0.00	66.7
Cycle 9 Day 1	107	11.68	17.91	0.0	0.00	83.3	102	-2.94	22.30	-100.0	0.00	66.7
Cycle 10 Day 1	88	9.85	17.26	0.0	0.00	100.0	85	-5.10	24.26	-100.0	0.00	66.7
Cycle 11 Day 1	82	9.76	18.51	0.0	0.00	100.0	79	-4.22	25.94	-100.0	0.00	66.7
Cycle 12 Day 1	76	7.68	15.02	0.0	0.00	66.7	74	-6.76	25.87	-100.0	0.00	66.7
Cycle 13 Day 1	62	8.06	12.71	0.0	0.00	33.3	60	-8.06	26.66	-100.0	0.00	33.3
Cycle 14 Day 1	56	6.55	12.18	0.0	0.00	50.0	54	-7.72	24.38	-100.0	0.00	50.0
Cycle 15 Day 1	51	6.54	13.78	0.0	0.00	66.7	49	-7.48	23.34	-66.7	0.00	66.7
Cycle 16 Day 1	46	7.97	12.54	0.0	0.00	33.3	44	-7.58	22.00	-66.7	0.00	33.3
Cycle 17 Day 1	41	6.10	11.64	0.0	0.00	33.3	39	-11.11	21.74	-66.7	0.00	33.3
Cycle 18 Day 1	37	9.01	13.94	0.0	0.00	33.3	35	-9.05	23.69	-66.7	0.00	33.3
Cycle 19 Day 1	37	6.76	12.70	0.0	0.00	50.0	35	-10.00	19.05	-66.7	0.00	33.3
Cycle 20 Day 1	35	9.05	15.83	0.0	0.00	66.7	33	-6.06	22.37	-66.7	0.00	33.3
Cycle 21 Day 1	32	9.90	16.86	0.0	0.00	66.7	30	-3.33	19.28	-66.7	0.00	50.0
Cycle 22 Day 1	30	8.89	16.22	0.0	0.00	66.7	28	-5.36	20.31	-66.7	0.00	33.3
Cycle 23 Day 1	28	6.55	13.10	0.0	0.00	50.0	26	-5.77	21.57	-66.7	0.00	50.0
Cycle 24 Day 1	25	7.33	14.50	0.0	0.00	50.0	23	-3.62	18.77	-33.3	0.00	50.0
Cycle 25 Day 1	23	4.35	10.32	0.0	0.00	33.3	21	-7.14	18.69	-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: 07OCT22

Table 302.1.3002.23: 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 26 Day 1	22	6.82	15.14	0.0	0.00	50.0	20	-4.17	22.86	-50.0	0.00	50.0
Cycle 27 Day 1	20	6.67	11.34	0.0	0.00	33.3	18	-5.56	15.12	-33.3	0.00	16.7
Cycle 28 Day 1	11	3.03	6.74	0.0	0.00	16.7	9	-7.41	16.90	-33.3	0.00	16.7
Cycle 29 Day 1	12	4.17	7.54	0.0	0.00	16.7	10	-5.00	13.72	-33.3	0.00	16.7
Study Disc 1	124	15.99	25.27	0.0	0.00	100.0	122	2.19	25.62	-100.0	0.00	83.3
30 D SFU Z/P	52	14.10	25.86	0.0	0.00	100.0	51	1.31	30.52	-100.0	0.00	83.3
90 D SFU Z/P	48	9.38	17.83	0.0	0.00	100.0	47	2.48	17.37	-50.0	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	17.29	24.69	0.0	0.00	100.0						
Cycle 2 Day 1	222	12.61	19.12	0.0	0.00	100.0	216	-4.63	22.20	-83.3	0.00	66.7
Cycle 3 Day 1	200	10.17	18.74	0.0	0.00	100.0	196	-6.04	20.37	-83.3	0.00	66.7
Cycle 4 Day 1	171	8.87	15.79	0.0	0.00	100.0	169	-8.19	21.14	-100.0	0.00	33.3
Cycle 5 Day 1	166	8.73	15.32	0.0	0.00	83.3	165	-7.58	23.75	-100.0	0.00	50.0
Cycle 6 Day 1	146	10.27	17.75	0.0	0.00	83.3	145	-5.98	22.96	-100.0	0.00	66.7
Cycle 7 Day 1	126	10.19	15.49	0.0	0.00	66.7	125	-5.33	24.19	-100.0	0.00	50.0
Cycle 8 Day 1	110	9.55	16.04	0.0	0.00	66.7	109	-7.19	23.83	-100.0	0.00	50.0
Cycle 9 Day 1	104	8.01	14.68	0.0	0.00	83.3	103	-7.93	24.35	-100.0	0.00	50.0
Cycle 10 Day 1	81	8.85	17.89	0.0	0.00	100.0	79	-8.02	28.35	-100.0	0.00	100.0
Cycle 11 Day 1	72	6.48	14.14	0.0	0.00	66.7	71	-9.62	27.26	-100.0	0.00	66.7
Cycle 12 Day 1	59	6.21	12.34	0.0	0.00	50.0	57	-7.60	22.29	-83.3	0.00	50.0
Cycle 13 Day 1	47	7.80	14.27	0.0	0.00	50.0	45	-7.41	26.00	-100.0	0.00	50.0
Cycle 14 Day 1	44	8.71	17.79	0.0	0.00	66.7	42	-4.76	24.22	-100.0	0.00	33.3
Cycle 15 Day 1	36	10.65	20.76	0.0	0.00	100.0	34	-1.96	27.76	-100.0	0.00	66.7
Cycle 16 Day 1	32	9.90	17.38	0.0	0.00	66.7	30	0.00	23.57	-83.3	0.00	50.0
Cycle 17 Day 1	26	6.41	14.20	0.0	0.00	66.7	24	-3.47	24.56	-100.0	0.00	33.3
Cycle 18 Day 1	21	3.97	8.98	0.0	0.00	33.3	20	-6.67	23.82	-100.0	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.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3002.23: 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 19 Day 1	20	1.67	5.13	0.0	0.00	16.7	19	-4.39	10.89	-33.3	0.00	16.7
Cycle 20 Day 1	17	4.90	9.80	0.0	0.00	33.3	16	-7.29	27.87	-100.0	0.00	16.7
Cycle 21 Day 1	18	4.63	9.58	0.0	0.00	33.3	17	-6.86	24.34	-83.3	0.00	33.3
Cycle 22 Day 1	15	3.33	6.90	0.0	0.00	16.7	14	-10.71	27.43	-100.0	0.00	16.7
Cycle 23 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-13.64	29.64	-100.0	0.00	0.0
Study Disc 1	149	20.25	26.68	0.0	0.00	100.0	144	4.28	27.29	-100.0	0.00	83.3
30 D SFU Z/P	74	19.14	28.89	0.0	0.00	100.0	72	1.62	28.00	-100.0	0.00	66.7
90 D SFU Z/P	70	14.52	21.22	0.0	0.00	100.0	68	0.00	21.16	-66.7	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: 07OCT22

Table 302.1.3002.24: 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 + CAPOX (N=254)												
Baseline	242	23.48	23.92	0.0	16.67	100.0						
Cycle 2 Day 1	209	18.98	20.12	0.0	16.67	100.0	208	-4.25	23.38	-100.0	0.00	66.7
Cycle 3 Day 1	186	16.94	18.62	0.0	16.67	66.7	182	-6.59	22.14	-100.0	0.00	33.3
Cycle 4 Day 1	169	15.98	18.75	0.0	0.00	83.3	166	-7.33	24.99	-100.0	0.00	50.0
Cycle 5 Day 1	162	15.02	17.74	0.0	8.33	83.3	159	-7.44	20.43	-83.3	0.00	33.3
Cycle 6 Day 1	151	16.78	23.77	0.0	0.00	100.0	149	-5.82	25.48	-100.0	0.00	66.7
Cycle 7 Day 1	121	13.77	17.83	0.0	0.00	66.7	119	-8.54	23.95	-100.0	0.00	66.7
Cycle 8 Day 1	114	15.79	20.06	0.0	8.33	100.0	108	-7.10	23.04	-100.0	0.00	33.3
Cycle 9 Day 1	107	19.16	23.66	0.0	16.67	100.0	102	-5.07	24.57	-100.0	0.00	66.7
Cycle 10 Day 1	88	15.53	21.41	0.0	0.00	100.0	85	-8.24	26.80	-100.0	0.00	66.7
Cycle 11 Day 1	82	14.02	21.51	0.0	0.00	100.0	79	-7.81	30.17	-100.0	0.00	83.3
Cycle 12 Day 1	76	14.91	19.92	0.0	0.00	100.0	74	-6.53	27.70	-100.0	0.00	66.7
Cycle 13 Day 1	62	11.29	15.90	0.0	0.00	66.7	60	-11.39	27.19	-100.0	0.00	33.3
Cycle 14 Day 1	56	10.71	14.01	0.0	0.00	33.3	54	-9.57	25.41	-100.0	0.00	33.3
Cycle 15 Day 1	51	11.76	15.38	0.0	0.00	50.0	49	-8.84	24.08	-83.3	0.00	50.0
Cycle 16 Day 1	46	10.87	15.00	0.0	0.00	50.0	44	-10.23	24.96	-83.3	0.00	33.3
Cycle 17 Day 1	41	12.60	14.80	0.0	0.00	33.3	39	-9.40	25.88	-66.7	0.00	33.3
Cycle 18 Day 1	37	12.16	16.50	0.0	0.00	66.7	35	-10.95	23.55	-83.3	0.00	33.3
Cycle 19 Day 1	37	14.86	14.58	0.0	16.67	33.3	35	-5.71	24.23	-66.7	0.00	33.3
Cycle 20 Day 1	35	15.24	17.33	0.0	16.67	66.7	33	-4.55	20.95	-66.7	0.00	33.3
Cycle 21 Day 1	32	11.46	16.63	0.0	0.00	66.7	30	-7.22	21.30	-66.7	0.00	33.3
Cycle 22 Day 1	30	11.67	17.59	0.0	0.00	66.7	28	-8.33	21.03	-66.7	0.00	33.3
Cycle 23 Day 1	28	8.93	14.69	0.0	0.00	50.0	26	-8.97	20.67	-66.7	0.00	33.3
Cycle 24 Day 1	25	8.67	14.53	0.0	0.00	50.0	23	-7.25	18.69	-33.3	0.00	33.3
Cycle 25 Day 1	23	4.35	10.32	0.0	0.00	33.3	21	-13.49	20.83	-50.0	-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: 07OCT22

Table 302.1.3002.24: 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 26 Day 1	22	12.88	19.20	0.0	0.00	66.7	20	-3.33	26.27	-33.3	0.00	66.7
Cycle 27 Day 1	20	8.33	12.68	0.0	0.00	33.3	18	-9.26	20.79	-50.0	0.00	33.3
Cycle 28 Day 1	11	3.03	6.74	0.0	0.00	16.7	9	-11.11	11.79	-33.3	-16.67	0.0
Cycle 29 Day 1	12	6.94	13.22	0.0	0.00	33.3	10	-5.00	8.05	-16.7	0.00	0.0
Study Disc 1	124	24.87	27.91	0.0	16.67	100.0	122	3.96	25.90	-66.7	0.00	100.0
30 D SFU Z/P	52	18.59	26.74	0.0	0.00	100.0	51	0.00	30.18	-100.0	0.00	66.7
90 D SFU Z/P	48	14.58	23.22	0.0	0.00	100.0	47	-0.71	27.35	-66.7	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	241	25.38	25.42	0.0	33.33	100.0						
Cycle 2 Day 1	222	18.47	20.04	0.0	16.67	100.0	216	-6.94	24.18	-83.3	0.00	66.7
Cycle 3 Day 1	200	16.00	20.72	0.0	0.00	100.0	196	-8.25	21.97	-100.0	0.00	66.7
Cycle 4 Day 1	171	14.04	18.02	0.0	0.00	100.0	169	-11.34	24.08	-100.0	0.00	66.7
Cycle 5 Day 1	166	13.86	18.50	0.0	0.00	83.3	165	-11.41	26.21	-100.0	0.00	66.7
Cycle 6 Day 1	146	15.07	19.51	0.0	0.00	100.0	145	-9.31	27.28	-100.0	0.00	66.7
Cycle 7 Day 1	126	14.29	17.73	0.0	0.00	100.0	125	-9.20	24.54	-100.0	0.00	50.0
Cycle 8 Day 1	110	13.03	17.97	0.0	0.00	66.7	109	-9.94	25.87	-100.0	0.00	66.7
Cycle 9 Day 1	104	13.94	19.31	0.0	0.00	100.0	103	-8.09	26.08	-100.0	0.00	66.7
Cycle 10 Day 1	81	13.99	21.16	0.0	0.00	100.0	79	-8.23	28.48	-83.3	0.00	100.0
Cycle 11 Day 1	72	13.89	18.34	0.0	0.00	66.7	71	-8.22	28.99	-100.0	0.00	66.7
Cycle 12 Day 1	59	12.99	18.84	0.0	0.00	66.7	57	-5.85	25.49	-83.3	0.00	66.7
Cycle 13 Day 1	47	13.48	16.90	0.0	0.00	66.7	45	-7.41	30.48	-100.0	0.00	50.0
Cycle 14 Day 1	44	15.53	21.98	0.0	0.00	100.0	42	-2.38	27.69	-66.7	0.00	66.7
Cycle 15 Day 1	36	16.20	23.40	0.0	0.00	100.0	34	-2.45	29.05	-83.3	0.00	66.7
Cycle 16 Day 1	32	12.50	20.74	0.0	0.00	66.7	30	-4.44	28.34	-83.3	0.00	66.7
Cycle 17 Day 1	26	7.05	15.04	0.0	0.00	66.7	24	-6.25	29.00	-100.0	0.00	66.7
Cycle 18 Day 1	21	8.73	13.56	0.0	0.00	33.3	20	-6.67	29.32	-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: 07OCT22

Table 302.1.3002.24: 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 19 Day 1	20	4.17	10.64	0.0	0.00	33.3	19	-5.26	17.61	-33.3	0.00	33.3
Cycle 20 Day 1	17	7.84	13.33	0.0	0.00	33.3	16	-8.33	26.53	-83.3	0.00	33.3
Cycle 21 Day 1	18	4.63	11.15	0.0	0.00	33.3	17	-10.78	22.78	-66.7	0.00	33.3
Cycle 22 Day 1	15	5.56	10.29	0.0	0.00	33.3	14	-10.71	32.43	-100.0	0.00	33.3
Cycle 23 Day 1	12	5.56	10.86	0.0	0.00	33.3	11	-13.64	32.33	-100.0	0.00	16.7
Study Disc 1	149	26.85	28.06	0.0	33.33	100.0	144	1.16	31.14	-100.0	0.00	100.0
30 D SFU Z/P	74	23.87	27.60	0.0	16.67	100.0	72	-0.69	27.04	-66.7	0.00	66.7
90 D SFU Z/P	70	18.81	24.06	0.0	8.33	100.0	68	-4.17	22.19	-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: 07OCT22

Table 302.1.3002.25: 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 + CAPOX (N=254)												
Baseline	242	38.98	28.37	0.0	33.33	100.0						
Cycle 2 Day 1	209	34.21	28.18	0.0	33.33	100.0	208	-3.93	25.15	-66.7	0.00	83.3
Cycle 3 Day 1	186	35.04	25.79	0.0	33.33	100.0	182	-3.02	24.93	-66.7	0.00	66.7
Cycle 4 Day 1	169	33.14	25.72	0.0	33.33	100.0	166	-4.12	24.65	-83.3	0.00	83.3
Cycle 5 Day 1	162	34.57	28.75	0.0	33.33	100.0	159	-2.73	26.24	-83.3	0.00	83.3
Cycle 6 Day 1	151	31.35	24.94	0.0	33.33	100.0	149	-6.04	23.43	-100.0	0.00	66.7
Cycle 7 Day 1	121	31.54	27.37	0.0	33.33	100.0	119	-3.64	23.28	-66.7	0.00	66.7
Cycle 8 Day 1	114	33.19	28.18	0.0	33.33	100.0	108	-4.32	25.21	-83.3	0.00	66.7
Cycle 9 Day 1	107	32.71	28.50	0.0	33.33	100.0	102	-5.23	25.80	-100.0	0.00	66.7
Cycle 10 Day 1	88	30.11	26.24	0.0	33.33	100.0	85	-7.45	28.11	-100.0	0.00	66.7
Cycle 11 Day 1	82	28.46	23.79	0.0	33.33	100.0	79	-7.17	28.70	-100.0	0.00	66.7
Cycle 12 Day 1	76	26.54	23.12	0.0	33.33	100.0	74	-9.68	29.46	-100.0	0.00	66.7
Cycle 13 Day 1	62	28.23	25.17	0.0	33.33	100.0	60	-7.78	30.76	-100.0	0.00	66.7
Cycle 14 Day 1	56	26.79	25.16	0.0	33.33	100.0	54	-8.02	28.55	-100.0	0.00	66.7
Cycle 15 Day 1	51	27.45	21.30	0.0	33.33	100.0	49	-9.52	28.46	-83.3	0.00	66.7
Cycle 16 Day 1	46	21.74	21.62	0.0	33.33	100.0	44	-14.77	27.89	-83.3	-8.33	66.7
Cycle 17 Day 1	41	30.49	24.41	0.0	33.33	100.0	39	-6.84	24.99	-66.7	0.00	66.7
Cycle 18 Day 1	37	30.63	21.70	0.0	33.33	100.0	35	-8.10	28.11	-83.3	0.00	66.7
Cycle 19 Day 1	37	27.48	23.31	0.0	33.33	100.0	35	-10.00	25.95	-66.7	0.00	66.7
Cycle 20 Day 1	35	26.67	22.94	0.0	33.33	100.0	33	-10.61	26.29	-66.7	0.00	66.7
Cycle 21 Day 1	32	28.12	25.20	0.0	33.33	100.0	30	-9.44	32.07	-83.3	0.00	66.7
Cycle 22 Day 1	30	30.00	30.76	0.0	33.33	100.0	28	-5.95	27.67	-66.7	0.00	66.7
Cycle 23 Day 1	28	27.38	26.14	0.0	33.33	100.0	26	-7.69	27.17	-66.7	0.00	66.7
Cycle 24 Day 1	25	25.33	24.59	0.0	33.33	100.0	23	-7.97	30.51	-66.7	0.00	66.7
Cycle 25 Day 1	23	23.91	26.03	0.0	33.33	100.0	21	-9.52	27.17	-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: 07OCT22

Table 302.1.3002.25: 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 26 Day 1	22	27.27	26.50	0.0	33.33	100.0	20	-6.67	27.25	-66.7	0.00	66.7
Cycle 27 Day 1	20	28.33	31.58	0.0	33.33	100.0	18	-6.48	34.37	-66.7	0.00	66.7
Cycle 28 Day 1	11	31.82	30.23	0.0	33.33	100.0	9	-3.70	37.99	-50.0	0.00	66.7
Cycle 29 Day 1	12	34.72	22.98	0.0	33.33	100.0	10	3.33	33.15	-33.3	0.00	66.7
Study Disc 1	124	38.31	31.45	0.0	33.33	100.0	122	1.23	31.21	-100.0	0.00	100.0
30 D SFU Z/P	52	39.10	29.50	0.0	33.33	100.0	51	1.96	31.38	-100.0	0.00	83.3
90 D SFU Z/P	48	32.29	27.38	0.0	33.33	100.0	47	0.35	25.89	-66.7	0.00	83.3
Placebo + CAPOX (N=253)												
Baseline	241	42.05	28.30	0.0	33.33	100.0						
Cycle 2 Day 1	222	35.96	27.40	0.0	33.33	100.0	216	-7.02	25.23	-66.7	0.00	66.7
Cycle 3 Day 1	200	36.25	26.91	0.0	33.33	100.0	196	-6.04	25.63	-83.3	0.00	66.7
Cycle 4 Day 1	171	34.21	28.48	0.0	33.33	100.0	169	-7.20	26.96	-66.7	0.00	66.7
Cycle 5 Day 1	166	33.84	26.11	0.0	33.33	100.0	165	-6.77	27.66	-66.7	0.00	66.7
Cycle 6 Day 1	146	32.19	26.67	0.0	33.33	100.0	145	-8.51	29.14	-66.7	0.00	100.0
Cycle 7 Day 1	126	30.03	26.42	0.0	33.33	100.0	125	-8.80	26.23	-66.7	0.00	66.7
Cycle 8 Day 1	110	33.64	27.74	0.0	33.33	100.0	109	-8.87	29.79	-66.7	0.00	66.7
Cycle 9 Day 1	104	33.49	26.53	0.0	33.33	100.0	103	-6.96	26.04	-66.7	0.00	66.7
Cycle 10 Day 1	81	30.86	28.52	0.0	33.33	100.0	79	-11.60	32.40	-100.0	0.00	66.7
Cycle 11 Day 1	72	31.02	26.58	0.0	33.33	100.0	71	-8.69	31.35	-100.0	0.00	66.7
Cycle 12 Day 1	59	31.36	26.82	0.0	33.33	100.0	57	-8.19	31.67	-100.0	0.00	66.7
Cycle 13 Day 1	47	32.27	25.40	0.0	33.33	100.0	45	-6.30	31.84	-66.7	0.00	66.7
Cycle 14 Day 1	44	31.06	25.31	0.0	33.33	100.0	42	-4.37	31.68	-66.7	0.00	66.7
Cycle 15 Day 1	36	29.17	29.11	0.0	33.33	100.0	34	-5.39	33.77	-66.7	0.00	66.7
Cycle 16 Day 1	32	28.12	26.59	0.0	33.33	100.0	30	-3.33	38.01	-66.7	0.00	66.7
Cycle 17 Day 1	26	26.28	23.18	0.0	33.33	66.7	24	-6.94	35.41	-83.3	0.00	66.7
Cycle 18 Day 1	21	23.02	23.26	0.0	16.67	66.7	20	-10.83	37.96	-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: 07OCT22

Table 302.1.3002.25: 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 19 Day 1	20	25.83	23.24	0.0	33.33	66.7	19	-2.63	28.47	-66.7	0.00	66.7
Cycle 20 Day 1	17	20.59	20.86	0.0	16.67	66.7	16	-13.54	35.60	-83.3	0.00	66.7
Cycle 21 Day 1	18	16.67	18.96	0.0	16.67	66.7	17	-13.73	36.91	-83.3	0.00	66.7
Cycle 22 Day 1	15	22.22	18.54	0.0	16.67	66.7	14	-14.29	41.27	-83.3	0.00	66.7
Cycle 23 Day 1	12	15.28	21.86	0.0	0.00	66.7	11	-15.15	36.86	-66.7	-16.67	66.7
Study Disc 1	149	46.53	29.46	0.0	33.33	100.0	144	2.66	28.88	-66.7	0.00	83.3
30 D SFU Z/P	74	46.62	30.59	0.0	33.33	100.0	72	2.08	25.78	-50.0	0.00	66.7
90 D SFU Z/P	70	39.29	29.90	0.0	33.33	100.0	68	-5.64	30.96	-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: 07OCT22

Table 302.1.3002.26: 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 + CAPOX (N=254)												
Baseline	242	10.74	21.56	0.0	0.00	100.0						
Cycle 2 Day 1	209	7.18	15.56	0.0	0.00	66.7	208	-3.21	18.25	-100.0	0.00	66.7
Cycle 3 Day 1	186	6.27	13.95	0.0	0.00	66.7	182	-2.01	18.26	-100.0	0.00	66.7
Cycle 4 Day 1	169	5.92	14.70	0.0	0.00	100.0	166	-3.01	16.34	-66.7	0.00	33.3
Cycle 5 Day 1	162	7.20	15.64	0.0	0.00	100.0	159	-1.68	15.82	-66.7	0.00	33.3
Cycle 6 Day 1	151	8.61	18.24	0.0	0.00	100.0	149	-0.22	15.25	-33.3	0.00	33.3
Cycle 7 Day 1	121	6.89	14.86	0.0	0.00	66.7	119	-0.84	18.13	-66.7	0.00	66.7
Cycle 8 Day 1	114	7.60	15.38	0.0	0.00	66.7	108	-2.47	18.63	-66.7	0.00	33.3
Cycle 9 Day 1	107	8.41	18.93	0.0	0.00	100.0	102	-1.63	21.69	-66.7	0.00	66.7
Cycle 10 Day 1	88	7.20	18.53	0.0	0.00	100.0	85	-2.35	23.45	-66.7	0.00	100.0
Cycle 11 Day 1	82	6.10	15.82	0.0	0.00	100.0	79	-2.95	20.11	-66.7	0.00	66.7
Cycle 12 Day 1	76	6.14	15.11	0.0	0.00	66.7	74	-3.15	20.77	-66.7	0.00	66.7
Cycle 13 Day 1	62	4.84	11.84	0.0	0.00	33.3	60	-5.56	21.41	-66.7	0.00	33.3
Cycle 14 Day 1	56	4.76	13.38	0.0	0.00	66.7	54	-4.94	20.89	-66.7	0.00	66.7
Cycle 15 Day 1	51	1.96	7.92	0.0	0.00	33.3	49	-7.48	20.71	-66.7	0.00	33.3
Cycle 16 Day 1	46	4.35	11.35	0.0	0.00	33.3	44	-6.06	16.51	-66.7	0.00	33.3
Cycle 17 Day 1	41	5.69	12.70	0.0	0.00	33.3	39	-5.13	18.00	-66.7	0.00	33.3
Cycle 18 Day 1	37	3.60	10.49	0.0	0.00	33.3	35	-8.57	20.36	-66.7	0.00	33.3
Cycle 19 Day 1	37	2.70	9.22	0.0	0.00	33.3	35	-10.48	21.04	-66.7	0.00	33.3
Cycle 20 Day 1	35	4.76	11.83	0.0	0.00	33.3	33	-8.08	18.69	-66.7	0.00	33.3
Cycle 21 Day 1	32	4.17	11.20	0.0	0.00	33.3	30	-7.78	18.94	-66.7	0.00	33.3
Cycle 22 Day 1	30	6.67	13.56	0.0	0.00	33.3	28	-4.76	14.95	-33.3	0.00	33.3
Cycle 23 Day 1	28	3.57	10.50	0.0	0.00	33.3	26	-6.41	16.38	-66.7	0.00	0.0
Cycle 24 Day 1	25	6.67	16.67	0.0	0.00	66.7	23	-2.90	19.88	-66.7	0.00	33.3
Cycle 25 Day 1	23	4.35	11.48	0.0	0.00	33.3	21	-4.76	19.11	-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: 07OCT22

Table 302.1.3002.26: 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 26 Day 1	22	4.55	11.71	0.0	0.00	33.3	20	-5.00	19.57	-66.7	0.00	33.3
Cycle 27 Day 1	20	5.00	12.21	0.0	0.00	33.3	18	-5.56	17.15	-66.7	0.00	0.0
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	9	-7.41	22.22	-66.7	0.00	0.0
Cycle 29 Day 1	12	0.00	0.00	0.0	0.00	0.0	10	-6.67	21.08	-66.7	0.00	0.0
Study Disc 1	124	12.63	26.41	0.0	0.00	100.0	122	3.28	22.44	-66.7	0.00	100.0
30 D SFU Z/P	52	10.90	25.33	0.0	0.00	100.0	51	2.61	24.80	-66.7	0.00	100.0
90 D SFU Z/P	48	7.64	17.18	0.0	0.00	66.7	47	4.26	16.47	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	10.51	22.36	0.0	0.00	100.0						
Cycle 2 Day 1	222	6.91	16.24	0.0	0.00	100.0	216	-3.09	19.04	-100.0	0.00	33.3
Cycle 3 Day 1	200	7.33	18.05	0.0	0.00	100.0	196	-3.06	19.15	-100.0	0.00	66.7
Cycle 4 Day 1	171	4.09	13.14	0.0	0.00	100.0	169	-7.10	21.57	-100.0	0.00	33.3
Cycle 5 Day 1	166	5.42	13.39	0.0	0.00	66.7	165	-5.45	23.37	-100.0	0.00	66.7
Cycle 6 Day 1	146	5.48	15.18	0.0	0.00	100.0	145	-4.83	21.51	-100.0	0.00	33.3
Cycle 7 Day 1	126	5.56	16.19	0.0	0.00	100.0	125	-4.53	20.45	-100.0	0.00	66.7
Cycle 8 Day 1	110	5.15	13.69	0.0	0.00	66.7	109	-5.81	21.20	-100.0	0.00	33.3
Cycle 9 Day 1	104	4.81	13.48	0.0	0.00	66.7	103	-5.50	21.44	-100.0	0.00	66.7
Cycle 10 Day 1	81	3.70	10.54	0.0	0.00	33.3	79	-6.33	20.03	-100.0	0.00	33.3
Cycle 11 Day 1	72	3.70	10.55	0.0	0.00	33.3	71	-4.69	19.76	-100.0	0.00	33.3
Cycle 12 Day 1	59	2.26	8.45	0.0	0.00	33.3	57	-4.09	14.18	-33.3	0.00	33.3
Cycle 13 Day 1	47	7.09	15.44	0.0	0.00	66.7	45	0.00	17.41	-33.3	0.00	66.7
Cycle 14 Day 1	44	2.27	8.50	0.0	0.00	33.3	42	-4.76	13.91	-66.7	0.00	0.0
Cycle 15 Day 1	36	4.63	11.69	0.0	0.00	33.3	34	-0.98	10.00	-33.3	0.00	33.3
Cycle 16 Day 1	32	6.25	15.70	0.0	0.00	66.7	30	-1.11	16.34	-66.7	0.00	33.3
Cycle 17 Day 1	26	5.13	15.47	0.0	0.00	66.7	24	-1.39	15.48	-66.7	0.00	33.3
Cycle 18 Day 1	21	3.17	10.03	0.0	0.00	33.3	20	-3.33	14.91	-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: 07OCT22

Table 302.1.3002.26: 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 19 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	-1.75	7.65	-33.3	0.00	0.0
Cycle 20 Day 1	17	5.88	13.10	0.0	0.00	33.3	16	0.00	21.08	-66.7	0.00	33.3
Cycle 21 Day 1	18	1.85	7.86	0.0	0.00	33.3	17	-3.92	16.17	-66.7	0.00	0.0
Cycle 22 Day 1	15	2.22	8.61	0.0	0.00	33.3	14	-4.76	17.82	-66.7	0.00	0.0
Cycle 23 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-6.06	20.10	-66.7	0.00	0.0
Study Disc 1	149	14.32	26.35	0.0	0.00	100.0	144	3.24	25.34	-100.0	0.00	100.0
30 D SFU Z/P	74	13.51	29.15	0.0	0.00	100.0	72	1.85	24.95	-100.0	0.00	100.0
90 D SFU Z/P	70	11.43	23.32	0.0	0.00	100.0	68	2.94	17.02	-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: 07OCT22

Table 302.1.3002.27: 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 + CAPOX (N=254)												
Baseline	242	19.28	24.76	0.0	0.00	100.0						
Cycle 2 Day 1	209	20.73	23.47	0.0	33.33	100.0	208	-0.32	23.40	-66.7	0.00	100.0
Cycle 3 Day 1	186	19.71	24.38	0.0	0.00	100.0	182	-0.55	23.89	-66.7	0.00	100.0
Cycle 4 Day 1	169	18.34	24.10	0.0	0.00	100.0	166	-2.01	25.08	-66.7	0.00	100.0
Cycle 5 Day 1	162	19.55	25.91	0.0	0.00	100.0	159	-1.05	26.89	-66.7	0.00	100.0
Cycle 6 Day 1	151	21.41	26.48	0.0	0.00	100.0	149	0.89	27.93	-100.0	0.00	100.0
Cycle 7 Day 1	121	20.66	27.30	0.0	0.00	100.0	119	-0.28	27.62	-66.7	0.00	100.0
Cycle 8 Day 1	114	18.42	24.33	0.0	0.00	100.0	108	-1.85	25.71	-100.0	0.00	66.7
Cycle 9 Day 1	107	20.56	26.16	0.0	0.00	100.0	102	0.00	28.92	-66.7	0.00	100.0
Cycle 10 Day 1	88	14.02	25.13	0.0	0.00	100.0	85	-5.88	28.72	-66.7	0.00	100.0
Cycle 11 Day 1	82	13.41	22.75	0.0	0.00	100.0	79	-4.64	26.55	-66.7	0.00	66.7
Cycle 12 Day 1	76	10.09	18.87	0.0	0.00	100.0	74	-5.86	26.67	-66.7	0.00	66.7
Cycle 13 Day 1	62	12.37	17.32	0.0	0.00	66.7	60	-5.00	26.63	-66.7	0.00	66.7
Cycle 14 Day 1	56	9.52	16.47	0.0	0.00	66.7	54	-7.41	26.44	-66.7	0.00	66.7
Cycle 15 Day 1	51	12.42	18.81	0.0	0.00	66.7	49	-6.80	24.51	-66.7	0.00	66.7
Cycle 16 Day 1	46	11.59	20.14	0.0	0.00	100.0	44	-7.58	24.76	-66.7	0.00	33.3
Cycle 17 Day 1	41	12.20	20.76	0.0	0.00	100.0	39	-6.84	20.49	-66.7	0.00	33.3
Cycle 18 Day 1	37	13.51	21.46	0.0	0.00	100.0	35	-5.71	18.94	-33.3	0.00	33.3
Cycle 19 Day 1	37	9.91	22.03	0.0	0.00	100.0	35	-9.52	26.29	-66.7	0.00	33.3
Cycle 20 Day 1	35	10.48	21.04	0.0	0.00	100.0	33	-9.09	22.47	-66.7	0.00	33.3
Cycle 21 Day 1	32	13.54	22.17	0.0	0.00	100.0	30	-5.56	24.89	-66.7	0.00	33.3
Cycle 22 Day 1	30	6.67	13.56	0.0	0.00	33.3	28	-10.71	24.09	-66.7	0.00	33.3
Cycle 23 Day 1	28	9.52	15.33	0.0	0.00	33.3	26	-7.69	23.68	-66.7	0.00	33.3
Cycle 24 Day 1	25	10.67	15.87	0.0	0.00	33.3	23	-5.80	25.92	-66.7	0.00	33.3
Cycle 25 Day 1	23	5.80	12.92	0.0	0.00	33.3	21	-9.52	21.46	-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: 07OCT22

Table 302.1.3002.27: 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 26 Day 1	22	7.58	14.30	0.0	0.00	33.3	20	-6.67	27.78	-66.7	0.00	33.3
Cycle 27 Day 1	20	10.00	15.67	0.0	0.00	33.3	18	-7.41	21.56	-33.3	0.00	33.3
Cycle 28 Day 1	11	9.09	15.57	0.0	0.00	33.3	9	-3.70	26.06	-33.3	0.00	33.3
Cycle 29 Day 1	12	11.11	16.41	0.0	0.00	33.3	10	-3.33	29.19	-33.3	0.00	33.3
Study Disc 1	124	20.43	29.05	0.0	0.00	100.0	122	0.55	30.30	-100.0	0.00	100.0
30 D SFU Z/P	52	12.82	26.53	0.0	0.00	100.0	51	-3.27	26.88	-66.7	0.00	100.0
90 D SFU Z/P	48	19.44	29.04	0.0	0.00	100.0	47	5.67	23.38	-33.3	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	241	16.87	23.79	0.0	0.00	100.0						
Cycle 2 Day 1	222	18.17	22.09	0.0	0.00	100.0	216	2.16	23.30	-100.0	0.00	66.7
Cycle 3 Day 1	200	19.83	23.65	0.0	0.00	100.0	196	4.93	26.44	-100.0	0.00	100.0
Cycle 4 Day 1	171	19.69	22.48	0.0	0.00	100.0	169	4.34	28.30	-100.0	0.00	66.7
Cycle 5 Day 1	166	17.07	21.32	0.0	0.00	66.7	165	1.41	27.88	-100.0	0.00	66.7
Cycle 6 Day 1	146	18.26	24.78	0.0	0.00	100.0	145	3.91	27.64	-100.0	0.00	100.0
Cycle 7 Day 1	126	15.87	21.38	0.0	0.00	100.0	125	0.53	28.08	-100.0	0.00	100.0
Cycle 8 Day 1	110	19.09	24.92	0.0	0.00	100.0	109	3.98	29.65	-66.7	0.00	100.0
Cycle 9 Day 1	104	16.67	25.01	0.0	0.00	100.0	103	2.27	28.49	-100.0	0.00	100.0
Cycle 10 Day 1	81	12.35	18.59	0.0	0.00	66.7	79	-2.11	27.39	-66.7	0.00	66.7
Cycle 11 Day 1	72	11.57	16.93	0.0	0.00	66.7	71	-2.35	26.02	-66.7	0.00	66.7
Cycle 12 Day 1	59	14.12	19.77	0.0	0.00	66.7	57	1.17	25.17	-66.7	0.00	66.7
Cycle 13 Day 1	47	12.77	17.79	0.0	0.00	66.7	45	-0.74	27.05	-100.0	0.00	66.7
Cycle 14 Day 1	44	10.61	21.29	0.0	0.00	100.0	42	-2.38	22.56	-66.7	0.00	33.3
Cycle 15 Day 1	36	14.81	23.16	0.0	0.00	100.0	34	1.96	18.24	-33.3	0.00	33.3
Cycle 16 Day 1	32	12.50	18.45	0.0	0.00	66.7	30	0.00	15.16	-33.3	0.00	33.3
Cycle 17 Day 1	26	11.54	16.17	0.0	0.00	33.3	24	2.78	16.79	-33.3	0.00	33.3
Cycle 18 Day 1	21	12.70	16.59	0.0	0.00	33.3	20	5.00	16.31	-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: 07OCT22

Table 302.1.3002.27: 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 19 Day 1	20	11.67	16.31	0.0	0.00	33.3	19	3.51	15.29	-33.3	0.00	33.3
Cycle 20 Day 1	17	11.76	16.42	0.0	0.00	33.3	16	6.25	18.13	-33.3	0.00	33.3
Cycle 21 Day 1	18	11.11	16.17	0.0	0.00	33.3	17	5.88	17.62	-33.3	0.00	33.3
Cycle 22 Day 1	15	13.33	16.90	0.0	0.00	33.3	14	9.52	15.63	0.0	0.00	33.3
Cycle 23 Day 1	12	8.33	15.08	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
Study Disc 1	149	21.92	27.61	0.0	0.00	100.0	144	4.63	29.40	-100.0	0.00	100.0
30 D SFU Z/P	74	21.62	25.54	0.0	16.67	100.0	72	5.09	27.21	-66.7	0.00	100.0
90 D SFU Z/P	70	20.48	26.19	0.0	0.00	100.0	68	6.86	27.95	-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: 07OCT22

Table 302.1.3002.28: 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 + CAPOX (N=254)												
Baseline	242	9.50	21.61	0.0	0.00	100.0						
Cycle 2 Day 1	209	12.92	23.07	0.0	0.00	100.0	208	3.85	22.85	-100.0	0.00	100.0
Cycle 3 Day 1	186	16.49	25.05	0.0	0.00	100.0	182	7.33	25.41	-100.0	0.00	100.0
Cycle 4 Day 1	169	15.19	24.66	0.0	0.00	100.0	166	5.62	24.24	-66.7	0.00	100.0
Cycle 5 Day 1	162	17.08	25.53	0.0	0.00	100.0	159	8.18	26.71	-100.0	0.00	100.0
Cycle 6 Day 1	151	21.85	26.96	0.0	0.00	100.0	149	12.30	27.77	-66.7	0.00	100.0
Cycle 7 Day 1	121	19.01	27.16	0.0	0.00	100.0	119	10.92	28.82	-66.7	0.00	100.0
Cycle 8 Day 1	114	20.47	29.25	0.0	0.00	100.0	108	10.49	25.23	-66.7	0.00	100.0
Cycle 9 Day 1	107	19.63	27.83	0.0	0.00	100.0	102	8.17	29.83	-100.0	0.00	100.0
Cycle 10 Day 1	88	17.80	26.24	0.0	0.00	100.0	85	7.06	29.59	-66.7	0.00	100.0
Cycle 11 Day 1	82	11.79	21.19	0.0	0.00	100.0	79	2.95	27.32	-66.7	0.00	100.0
Cycle 12 Day 1	76	11.84	20.87	0.0	0.00	100.0	74	2.25	26.65	-66.7	0.00	100.0
Cycle 13 Day 1	62	11.29	20.86	0.0	0.00	100.0	60	0.56	32.18	-100.0	0.00	100.0
Cycle 14 Day 1	56	10.12	17.89	0.0	0.00	66.7	54	1.85	26.24	-66.7	0.00	66.7
Cycle 15 Day 1	51	11.11	21.77	0.0	0.00	100.0	49	0.00	28.05	-100.0	0.00	100.0
Cycle 16 Day 1	46	13.77	23.91	0.0	0.00	100.0	44	1.52	26.85	-66.7	0.00	66.7
Cycle 17 Day 1	41	14.63	22.42	0.0	0.00	66.7	39	1.71	25.30	-66.7	0.00	66.7
Cycle 18 Day 1	37	15.32	23.03	0.0	0.00	66.7	35	0.95	26.18	-66.7	0.00	66.7
Cycle 19 Day 1	37	13.51	22.85	0.0	0.00	100.0	35	0.95	23.55	-66.7	0.00	33.3
Cycle 20 Day 1	35	14.29	25.93	0.0	0.00	100.0	33	2.02	23.48	-66.7	0.00	66.7
Cycle 21 Day 1	32	11.46	21.77	0.0	0.00	100.0	30	-1.11	26.96	-66.7	0.00	33.3
Cycle 22 Day 1	30	7.78	20.87	0.0	0.00	100.0	28	-2.38	27.11	-66.7	0.00	33.3
Cycle 23 Day 1	28	9.52	21.96	0.0	0.00	100.0	26	1.28	25.79	-66.7	0.00	33.3
Cycle 24 Day 1	25	9.33	22.61	0.0	0.00	100.0	23	0.00	22.47	-66.7	0.00	33.3
Cycle 25 Day 1	23	10.14	18.63	0.0	0.00	66.7	21	1.59	22.30	-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: 07OCT22

Table 302.1.3002.28: 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 26 Day 1	22	9.09	23.42	0.0	0.00	100.0	20	0.00	21.63	-66.7	0.00	33.3
Cycle 27 Day 1	20	6.67	13.68	0.0	0.00	33.3	18	0.00	22.87	-66.7	0.00	33.3
Cycle 28 Day 1	11	3.03	10.05	0.0	0.00	33.3	9	-3.70	26.06	-66.7	0.00	33.3
Cycle 29 Day 1	12	2.78	9.62	0.0	0.00	33.3	10	-3.33	24.60	-66.7	0.00	33.3
Study Disc 1	124	20.43	29.67	0.0	0.00	100.0	122	9.56	31.34	-100.0	0.00	100.0
30 D SFU Z/P	52	13.46	25.79	0.0	0.00	100.0	51	3.92	24.63	-66.7	0.00	100.0
90 D SFU Z/P	48	11.11	22.10	0.0	0.00	100.0	47	5.67	24.40	-66.7	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	241	7.47	18.50	0.0	0.00	100.0						
Cycle 2 Day 1	222	10.06	20.15	0.0	0.00	100.0	216	2.47	20.69	-100.0	0.00	100.0
Cycle 3 Day 1	200	11.00	19.23	0.0	0.00	100.0	196	5.27	20.55	-66.7	0.00	100.0
Cycle 4 Day 1	171	12.28	21.05	0.0	0.00	100.0	169	5.52	24.31	-66.7	0.00	100.0
Cycle 5 Day 1	166	14.46	23.03	0.0	0.00	100.0	165	8.08	25.01	-66.7	0.00	100.0
Cycle 6 Day 1	146	18.04	25.41	0.0	0.00	100.0	145	11.72	27.65	-66.7	0.00	100.0
Cycle 7 Day 1	126	15.61	23.73	0.0	0.00	100.0	125	9.33	25.96	-66.7	0.00	100.0
Cycle 8 Day 1	110	16.67	24.21	0.0	0.00	100.0	109	10.40	28.58	-66.7	0.00	100.0
Cycle 9 Day 1	104	12.18	19.74	0.0	0.00	100.0	103	6.47	25.16	-66.7	0.00	100.0
Cycle 10 Day 1	81	8.64	18.84	0.0	0.00	100.0	79	2.95	26.25	-66.7	0.00	100.0
Cycle 11 Day 1	72	9.26	18.74	0.0	0.00	100.0	71	4.23	26.39	-66.7	0.00	100.0
Cycle 12 Day 1	59	5.08	12.09	0.0	0.00	33.3	57	0.00	21.82	-66.7	0.00	33.3
Cycle 13 Day 1	47	7.80	14.27	0.0	0.00	33.3	45	2.96	19.88	-66.7	0.00	33.3
Cycle 14 Day 1	44	4.55	11.57	0.0	0.00	33.3	42	0.00	20.82	-66.7	0.00	33.3
Cycle 15 Day 1	36	7.41	14.05	0.0	0.00	33.3	34	1.96	24.54	-66.7	0.00	33.3
Cycle 16 Day 1	32	7.29	14.00	0.0	0.00	33.3	30	3.33	16.02	-33.3	0.00	33.3
Cycle 17 Day 1	26	8.97	15.08	0.0	0.00	33.3	24	8.33	14.74	0.0	0.00	33.3
Cycle 18 Day 1	21	4.76	11.95	0.0	0.00	33.3	20	5.00	12.21	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: 07OCT22

Table 302.1.3002.28: 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 19 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	1.75	7.65	0.0	0.00	33.3
Cycle 20 Day 1	17	5.88	13.10	0.0	0.00	33.3	16	6.25	13.44	0.0	0.00	33.3
Cycle 21 Day 1	18	9.26	15.36	0.0	0.00	33.3	17	9.80	15.66	0.0	0.00	33.3
Cycle 22 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	4.76	12.10	0.0	0.00	33.3
Cycle 23 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
Study Disc 1	149	15.21	26.13	0.0	0.00	100.0	144	7.41	30.39	-100.0	0.00	100.0
30 D SFU Z/P	74	15.32	27.14	0.0	0.00	100.0	72	8.80	29.60	-66.7	0.00	100.0
90 D SFU Z/P	70	13.33	20.77	0.0	0.00	66.7	68	7.84	23.12	-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: 07OCT22

Table 302.1.3002.29: 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 + CAPOX (N=254)												
Baseline	242	18.04	25.77	0.0	0.00	100.0						
Cycle 2 Day 1	209	17.38	23.59	0.0	0.00	100.0	208	-0.80	22.80	-100.0	0.00	66.7
Cycle 3 Day 1	186	18.10	25.25	0.0	0.00	100.0	182	1.47	24.48	-100.0	0.00	66.7
Cycle 4 Day 1	169	18.15	25.19	0.0	0.00	100.0	166	1.00	26.32	-100.0	0.00	100.0
Cycle 5 Day 1	162	20.16	28.86	0.0	0.00	100.0	159	2.52	28.45	-100.0	0.00	100.0
Cycle 6 Day 1	151	21.19	28.41	0.0	0.00	100.0	149	3.58	24.55	-100.0	0.00	100.0
Cycle 7 Day 1	121	18.73	25.78	0.0	0.00	100.0	119	0.28	25.85	-66.7	0.00	66.7
Cycle 8 Day 1	114	22.51	28.22	0.0	0.00	100.0	108	2.78	26.62	-100.0	0.00	100.0
Cycle 9 Day 1	107	23.36	27.17	0.0	33.33	100.0	102	1.31	24.34	-100.0	0.00	66.7
Cycle 10 Day 1	88	21.21	26.35	0.0	0.00	100.0	85	-1.57	29.95	-100.0	0.00	100.0
Cycle 11 Day 1	82	15.04	21.05	0.0	0.00	100.0	79	-5.06	26.74	-100.0	0.00	33.3
Cycle 12 Day 1	76	17.11	24.03	0.0	0.00	100.0	74	-3.60	29.49	-100.0	0.00	66.7
Cycle 13 Day 1	62	14.52	23.08	0.0	0.00	100.0	60	-7.22	30.12	-100.0	0.00	33.3
Cycle 14 Day 1	56	14.29	22.79	0.0	0.00	100.0	54	-6.17	27.53	-100.0	0.00	33.3
Cycle 15 Day 1	51	15.03	23.39	0.0	0.00	100.0	49	-6.12	29.40	-100.0	0.00	66.7
Cycle 16 Day 1	46	15.94	23.03	0.0	0.00	100.0	44	-9.09	28.18	-100.0	0.00	33.3
Cycle 17 Day 1	41	17.89	25.92	0.0	0.00	100.0	39	-6.84	28.80	-100.0	0.00	33.3
Cycle 18 Day 1	37	15.32	23.03	0.0	0.00	100.0	35	-9.52	27.50	-100.0	0.00	33.3
Cycle 19 Day 1	37	16.22	24.37	0.0	0.00	100.0	35	-7.62	25.67	-66.7	0.00	33.3
Cycle 20 Day 1	35	20.00	28.24	0.0	0.00	100.0	33	-4.04	26.03	-33.3	0.00	66.7
Cycle 21 Day 1	32	12.50	22.00	0.0	0.00	100.0	30	-11.11	22.03	-66.7	0.00	33.3
Cycle 22 Day 1	30	17.78	29.99	0.0	0.00	100.0	28	-5.95	25.75	-66.7	0.00	33.3
Cycle 23 Day 1	28	11.90	24.37	0.0	0.00	100.0	26	-10.26	20.59	-66.7	0.00	33.3
Cycle 24 Day 1	25	13.33	25.46	0.0	0.00	100.0	23	-8.70	18.03	-33.3	0.00	33.3
Cycle 25 Day 1	23	14.49	26.26	0.0	0.00	100.0	21	-7.94	25.61	-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: 07OCT22

Table 302.1.3002.29: 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 26 Day 1	22	16.67	26.73	0.0	0.00	100.0	20	-5.00	24.84	-33.3	0.00	33.3
Cycle 27 Day 1	20	16.67	31.53	0.0	0.00	100.0	18	-7.41	21.56	-33.3	0.00	33.3
Cycle 28 Day 1	11	12.12	30.81	0.0	0.00	100.0	9	-7.41	27.78	-66.7	0.00	33.3
Cycle 29 Day 1	12	11.11	29.59	0.0	0.00	100.0	10	-6.67	26.29	-66.7	0.00	33.3
Study Disc 1	124	23.92	29.00	0.0	0.00	100.0	122	8.74	30.84	-100.0	0.00	100.0
30 D SFU Z/P	52	19.87	28.97	0.0	0.00	100.0	51	3.27	30.74	-100.0	0.00	100.0
90 D SFU Z/P	48	18.06	26.59	0.0	0.00	100.0	47	7.80	19.92	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	19.64	23.99	0.0	0.00	100.0						
Cycle 2 Day 1	222	16.52	24.10	0.0	0.00	100.0	216	-2.31	22.04	-66.7	0.00	66.7
Cycle 3 Day 1	200	17.33	26.09	0.0	0.00	100.0	196	-1.53	23.94	-100.0	0.00	66.7
Cycle 4 Day 1	171	17.35	22.39	0.0	0.00	100.0	169	-0.99	22.25	-66.7	0.00	66.7
Cycle 5 Day 1	166	16.67	22.25	0.0	0.00	100.0	165	0.61	22.83	-100.0	0.00	66.7
Cycle 6 Day 1	146	15.75	24.51	0.0	0.00	100.0	145	-1.38	26.61	-100.0	0.00	100.0
Cycle 7 Day 1	126	15.08	23.70	0.0	0.00	100.0	125	-0.80	25.56	-100.0	0.00	66.7
Cycle 8 Day 1	110	15.76	23.34	0.0	0.00	100.0	109	0.00	24.43	-100.0	0.00	66.7
Cycle 9 Day 1	104	14.42	22.16	0.0	0.00	100.0	103	-0.97	24.01	-100.0	0.00	66.7
Cycle 10 Day 1	81	14.40	22.94	0.0	0.00	100.0	79	-0.42	26.95	-100.0	0.00	66.7
Cycle 11 Day 1	72	15.74	23.05	0.0	0.00	100.0	71	0.94	26.41	-100.0	0.00	66.7
Cycle 12 Day 1	59	11.30	21.09	0.0	0.00	100.0	57	-2.34	22.59	-66.7	0.00	66.7
Cycle 13 Day 1	47	14.18	22.78	0.0	0.00	100.0	45	0.74	27.05	-100.0	0.00	66.7
Cycle 14 Day 1	44	9.09	20.79	0.0	0.00	66.7	42	-1.59	25.45	-100.0	0.00	66.7
Cycle 15 Day 1	36	11.11	21.08	0.0	0.00	100.0	34	0.00	28.43	-100.0	0.00	100.0
Cycle 16 Day 1	32	11.46	20.05	0.0	0.00	66.7	30	2.22	26.16	-100.0	0.00	33.3
Cycle 17 Day 1	26	7.69	17.15	0.0	0.00	66.7	24	-1.39	23.01	-100.0	0.00	33.3
Cycle 18 Day 1	21	4.76	11.95	0.0	0.00	33.3	20	-3.33	26.27	-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: 07OCT22

Table 302.1.3002.29: 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 19 Day 1	20	3.33	10.26	0.0	0.00	33.3	19	0.00	11.11	-33.3	0.00	33.3
Cycle 20 Day 1	17	5.88	13.10	0.0	0.00	33.3	16	-4.17	29.50	-100.0	0.00	33.3
Cycle 21 Day 1	18	1.85	7.86	0.0	0.00	33.3	17	-7.84	25.08	-100.0	0.00	0.0
Cycle 22 Day 1	15	6.67	13.80	0.0	0.00	33.3	14	-4.76	31.64	-100.0	0.00	33.3
Cycle 23 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-9.09	33.63	-100.0	0.00	33.3
Study Disc 1	149	27.07	31.33	0.0	33.33	100.0	144	4.63	30.69	-66.7	0.00	100.0
30 D SFU Z/P	74	27.03	33.41	0.0	0.00	100.0	72	5.09	27.21	-33.3	0.00	100.0
90 D SFU Z/P	70	29.05	29.99	0.0	33.33	100.0	68	8.33	29.58	-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: 07OCT22

Table 302.1.3002.30: 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 + CAPOX (N=254)												
Baseline	242	3.86	12.66	0.0	0.00	66.7						
Cycle 2 Day 1	209	4.31	11.67	0.0	0.00	66.7	208	0.48	13.70	-66.7	0.00	33.3
Cycle 3 Day 1	186	4.30	13.62	0.0	0.00	100.0	182	0.00	13.57	-66.7	0.00	33.3
Cycle 4 Day 1	169	4.34	14.35	0.0	0.00	100.0	166	0.20	16.20	-66.7	0.00	100.0
Cycle 5 Day 1	162	3.91	12.54	0.0	0.00	66.7	159	0.21	15.23	-66.7	0.00	66.7
Cycle 6 Day 1	151	6.62	18.06	0.0	0.00	100.0	149	2.91	18.96	-66.7	0.00	100.0
Cycle 7 Day 1	121	5.23	14.91	0.0	0.00	100.0	119	1.40	18.61	-66.7	0.00	100.0
Cycle 8 Day 1	114	4.97	14.86	0.0	0.00	100.0	108	-0.62	15.77	-66.7	0.00	33.3
Cycle 9 Day 1	107	5.61	15.52	0.0	0.00	100.0	102	0.65	15.54	-66.7	0.00	66.7
Cycle 10 Day 1	88	5.68	15.35	0.0	0.00	66.7	85	0.78	17.04	-66.7	0.00	66.7
Cycle 11 Day 1	82	3.66	13.86	0.0	0.00	100.0	79	-0.42	13.60	-66.7	0.00	33.3
Cycle 12 Day 1	76	3.07	11.13	0.0	0.00	66.7	74	0.00	11.03	-33.3	0.00	33.3
Cycle 13 Day 1	62	2.69	9.15	0.0	0.00	33.3	60	0.00	12.27	-33.3	0.00	33.3
Cycle 14 Day 1	56	1.79	7.57	0.0	0.00	33.3	54	-1.23	11.15	-33.3	0.00	33.3
Cycle 15 Day 1	51	1.96	7.92	0.0	0.00	33.3	49	-2.04	14.29	-66.7	0.00	33.3
Cycle 16 Day 1	46	4.35	11.35	0.0	0.00	33.3	44	0.00	17.61	-66.7	0.00	33.3
Cycle 17 Day 1	41	2.44	8.79	0.0	0.00	33.3	39	-2.56	14.07	-66.7	0.00	33.3
Cycle 18 Day 1	37	2.70	9.22	0.0	0.00	33.3	35	-2.86	14.84	-66.7	0.00	33.3
Cycle 19 Day 1	37	3.60	10.49	0.0	0.00	33.3	35	-1.90	16.05	-66.7	0.00	33.3
Cycle 20 Day 1	35	1.90	7.85	0.0	0.00	33.3	33	-4.04	18.18	-66.7	0.00	33.3
Cycle 21 Day 1	32	2.08	8.20	0.0	0.00	33.3	30	-2.22	17.36	-66.7	0.00	33.3
Cycle 22 Day 1	30	1.11	6.09	0.0	0.00	33.3	28	-1.19	11.04	-33.3	0.00	33.3
Cycle 23 Day 1	28	1.19	6.30	0.0	0.00	33.3	26	-1.28	11.47	-33.3	0.00	33.3
Cycle 24 Day 1	25	1.33	6.67	0.0	0.00	33.3	23	-1.45	12.22	-33.3	0.00	33.3
Cycle 25 Day 1	23	2.90	9.60	0.0	0.00	33.3	21	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: 07OCT22

Table 302.1.3002.30: 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 26 Day 1	22	1.52	7.11	0.0	0.00	33.3	20	-1.67	13.13	-33.3	0.00	33.3
Cycle 27 Day 1	20	0.00	0.00	0.0	0.00	0.0	18	-3.70	10.78	-33.3	0.00	0.0
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	9	-3.70	11.11	-33.3	0.00	0.0
Cycle 29 Day 1	12	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
Study Disc 1	124	8.06	20.10	0.0	0.00	100.0	122	4.10	21.25	-66.7	0.00	100.0
30 D SFU Z/P	52	5.77	18.34	0.0	0.00	100.0	51	1.96	21.51	-66.7	0.00	100.0
90 D SFU Z/P	48	2.08	10.67	0.0	0.00	66.7	47	0.00	15.54	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	5.26	15.52	0.0	0.00	100.0						
Cycle 2 Day 1	222	3.15	11.65	0.0	0.00	100.0	216	-1.85	14.62	-66.7	0.00	66.7
Cycle 3 Day 1	200	3.50	12.23	0.0	0.00	100.0	196	-1.19	15.97	-100.0	0.00	100.0
Cycle 4 Day 1	171	4.48	13.98	0.0	0.00	100.0	169	-0.59	16.05	-66.7	0.00	100.0
Cycle 5 Day 1	166	2.61	9.70	0.0	0.00	66.7	165	-2.63	16.04	-66.7	0.00	66.7
Cycle 6 Day 1	146	5.02	13.18	0.0	0.00	66.7	145	0.00	18.84	-66.7	0.00	66.7
Cycle 7 Day 1	126	4.50	12.19	0.0	0.00	66.7	125	-1.33	18.16	-66.7	0.00	66.7
Cycle 8 Day 1	110	2.73	9.18	0.0	0.00	33.3	109	-3.06	16.06	-66.7	0.00	33.3
Cycle 9 Day 1	104	2.88	11.48	0.0	0.00	66.7	103	-3.56	19.75	-66.7	0.00	66.7
Cycle 10 Day 1	81	2.47	12.67	0.0	0.00	100.0	79	-4.22	20.23	-66.7	0.00	100.0
Cycle 11 Day 1	72	2.78	9.28	0.0	0.00	33.3	71	-4.69	18.94	-66.7	0.00	33.3
Cycle 12 Day 1	59	1.69	9.64	0.0	0.00	66.7	57	-4.68	19.35	-66.7	0.00	66.7
Cycle 13 Day 1	47	2.84	11.69	0.0	0.00	66.7	45	-1.48	17.34	-66.7	0.00	66.7
Cycle 14 Day 1	44	3.03	15.78	0.0	0.00	100.0	42	-2.38	23.73	-66.7	0.00	100.0
Cycle 15 Day 1	36	2.78	12.28	0.0	0.00	66.7	34	-4.90	21.92	-66.7	0.00	66.7
Cycle 16 Day 1	32	2.08	8.20	0.0	0.00	33.3	30	-4.44	20.96	-66.7	0.00	33.3
Cycle 17 Day 1	26	0.00	0.00	0.0	0.00	0.0	24	-6.94	19.61	-66.7	0.00	0.0
Cycle 18 Day 1	21	1.59	7.27	0.0	0.00	33.3	20	-6.67	23.20	-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.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3002.30: 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 19 Day 1	20	0.00	0.00	0.0	0.00	0.0	19	-5.26	16.72	-66.7	0.00	0.0
Cycle 20 Day 1	17	0.00	0.00	0.0	0.00	0.0	16	-10.42	23.47	-66.7	0.00	0.0
Cycle 21 Day 1	18	3.70	15.71	0.0	0.00	66.7	17	-5.88	29.43	-66.7	0.00	66.7
Cycle 22 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	-7.14	26.73	-66.7	0.00	33.3
Cycle 23 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-12.12	26.97	-66.7	0.00	0.0
Study Disc 1	149	9.84	20.32	0.0	0.00	100.0	144	4.63	24.81	-100.0	0.00	100.0
30 D SFU Z/P	74	4.50	12.73	0.0	0.00	66.7	72	-1.85	17.59	-66.7	0.00	66.7
90 D SFU Z/P	70	4.29	12.59	0.0	0.00	66.7	68	-1.96	20.67	-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: 07OCT22

Table 302.1.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
0-2	Zolbetuximab + CAPOX (N=189)												
	Baseline	183	3.28	12.16	0.0	0.00	66.7						
	Cycle 2 Day 1	158	4.22	11.74	0.0	0.00	66.7	158	0.63	13.81	-66.7	0.00	33.3
	Cycle 3 Day 1	142	3.76	11.97	0.0	0.00	66.7	140	0.00	13.26	-66.7	0.00	33.3
	Cycle 4 Day 1	127	3.94	14.92	0.0	0.00	100.0	126	0.00	17.38	-66.7	0.00	100.0
	Cycle 5 Day 1	123	3.52	11.93	0.0	0.00	66.7	122	0.55	15.44	-66.7	0.00	66.7
	Cycle 6 Day 1	110	7.27	19.88	0.0	0.00	100.0	110	3.94	21.05	-66.7	0.00	100.0
	Cycle 7 Day 1	93	5.38	15.77	0.0	0.00	100.0	93	2.51	20.40	-66.7	0.00	100.0
	Cycle 8 Day 1	90	3.70	13.63	0.0	0.00	100.0	87	-0.77	16.06	-66.7	0.00	33.3
	Cycle 9 Day 1	80	6.25	16.85	0.0	0.00	100.0	78	1.28	16.51	-66.7	0.00	66.7
	Cycle 10 Day 1	67	5.47	14.90	0.0	0.00	66.7	66	1.01	16.51	-66.7	0.00	66.7
	Cycle 11 Day 1	63	4.23	15.25	0.0	0.00	100.0	62	0.00	14.78	-66.7	0.00	33.3
	Cycle 12 Day 1	59	3.39	11.90	0.0	0.00	66.7	58	0.57	11.67	-33.3	0.00	33.3
	Cycle 13 Day 1	48	2.78	9.31	0.0	0.00	33.3	47	0.71	12.98	-33.3	0.00	33.3
	Cycle 14 Day 1	45	1.48	6.95	0.0	0.00	33.3	44	-0.76	11.34	-33.3	0.00	33.3
	Cycle 15 Day 1	40	1.67	7.36	0.0	0.00	33.3	39	-1.71	15.20	-66.7	0.00	33.3
	Cycle 16 Day 1	38	3.51	10.37	0.0	0.00	33.3	37	0.00	17.57	-66.7	0.00	33.3
	Cycle 17 Day 1	32	2.08	8.20	0.0	0.00	33.3	31	-2.15	14.75	-66.7	0.00	33.3
	Cycle 18 Day 1	28	2.38	8.74	0.0	0.00	33.3	27	-2.47	15.81	-66.7	0.00	33.3
	Cycle 19 Day 1	29	2.30	8.60	0.0	0.00	33.3	28	-2.38	15.53	-66.7	0.00	33.3
	Cycle 20 Day 1	28	2.38	8.74	0.0	0.00	33.3	27	-2.47	18.32	-66.7	0.00	33.3
	Cycle 21 Day 1	27	2.47	8.90	0.0	0.00	33.3	26	-1.28	17.59	-66.7	0.00	33.3
	Cycle 22 Day 1	27	1.23	6.42	0.0	0.00	33.3	26	0.00	9.43	-33.3	0.00	33.3
	Cycle 23 Day 1	25	1.33	6.67	0.0	0.00	33.3	24	0.00	9.83	-33.3	0.00	33.3
	Cycle 24 Day 1	23	1.45	6.95	0.0	0.00	33.3	22	0.00	10.29	-33.3	0.00	33.3
	Cycle 25 Day 1	21	3.17	10.03	0.0	0.00	33.3	20	1.67	13.13	-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: 07OCT22

Table 302.1.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - 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 26 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	0.00	11.11	-33.3	0.00	33.3
	Cycle 27 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 28 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	-3.70	11.11	-33.3	0.00	0.0
	Cycle 29 Day 1	11	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	8.93	21.79	0.0	0.00	100.0	96	4.86	22.67	-66.7	0.00	100.0
	30 D SFU Z/P	41	7.32	20.43	0.0	0.00	100.0	40	3.33	23.63	-66.7	0.00	100.0
	90 D SFU Z/P	35	2.86	12.45	0.0	0.00	66.7	34	0.00	18.35	-66.7	0.00	66.7
	Placebo + CAPOX (N=188)												
	Baseline	181	4.79	14.54	0.0	0.00	100.0						
	Cycle 2 Day 1	169	3.35	12.41	0.0	0.00	100.0	165	-1.41	14.42	-66.7	0.00	66.7
	Cycle 3 Day 1	152	3.29	12.58	0.0	0.00	100.0	149	-1.12	15.21	-100.0	0.00	100.0
	Cycle 4 Day 1	130	4.36	14.01	0.0	0.00	100.0	128	-0.26	14.18	-66.7	0.00	100.0
	Cycle 5 Day 1	125	2.93	10.38	0.0	0.00	66.7	124	-2.15	15.76	-66.7	0.00	66.7
	Cycle 6 Day 1	114	4.39	12.16	0.0	0.00	66.7	113	-0.88	18.61	-66.7	0.00	66.7
	Cycle 7 Day 1	95	4.21	12.15	0.0	0.00	66.7	94	-1.42	17.57	-66.7	0.00	66.7
	Cycle 8 Day 1	86	2.33	8.54	0.0	0.00	33.3	85	-3.14	16.76	-66.7	0.00	33.3
	Cycle 9 Day 1	80	3.33	12.55	0.0	0.00	66.7	79	-2.53	19.81	-66.7	0.00	66.7
	Cycle 10 Day 1	65	3.08	14.10	0.0	0.00	100.0	64	-3.65	21.51	-66.7	0.00	100.0
	Cycle 11 Day 1	58	2.87	9.44	0.0	0.00	33.3	57	-4.09	17.90	-66.7	0.00	33.3
	Cycle 12 Day 1	48	2.08	10.67	0.0	0.00	66.7	47	-2.84	18.16	-66.7	0.00	66.7
	Cycle 13 Day 1	38	2.63	11.96	0.0	0.00	66.7	37	-0.90	16.64	-66.7	0.00	66.7
	Cycle 14 Day 1	36	2.78	16.67	0.0	0.00	100.0	35	-0.95	22.12	-66.7	0.00	100.0
	Cycle 15 Day 1	29	1.15	6.19	0.0	0.00	33.3	28	-4.76	14.95	-66.7	0.00	0.0
	Cycle 16 Day 1	26	0.00	0.00	0.0	0.00	0.0	25	-5.33	15.75	-66.7	0.00	0.0
	Cycle 17 Day 1	24	0.00	0.00	0.0	0.00	0.0	22	-4.55	15.59	-66.7	0.00	0.0
	Cycle 18 Day 1	19	1.75	7.65	0.0	0.00	33.3	18	-3.70	19.43	-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: 07OCT22

Table 302.1.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - 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 19 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 20 Day 1	16	0.00	0.00	0.0	0.00	0.0	15	-6.67	18.69	-66.7	0.00	0.0
	Cycle 21 Day 1	16	4.17	16.67	0.0	0.00	66.7	15	-2.22	26.63	-66.7	0.00	66.7
	Cycle 22 Day 1	13	2.56	9.25	0.0	0.00	33.3	12	-5.56	19.25	-66.7	0.00	0.0
	Cycle 23 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	-7.41	22.22	-66.7	0.00	0.0
	Study Disc 1	113	7.08	16.93	0.0	0.00	100.0	109	1.53	22.40	-100.0	0.00	100.0
	30 D SFU Z/P	60	3.33	10.08	0.0	0.00	33.3	58	-1.72	14.54	-66.7	0.00	33.3
	90 D SFU Z/P	57	2.92	11.41	0.0	0.00	66.7	55	-2.42	21.14	-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: 07OCT22

Table 302.1.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>=3	Zolbetuximab + CAPOX (N= 65)												
	Baseline	59	5.65	14.05	0.0	0.00	66.7						
	Cycle 2 Day 1	51	4.58	11.58	0.0	0.00	33.3	50	0.00	13.47	-33.3	0.00	33.3
	Cycle 3 Day 1	44	6.06	18.00	0.0	0.00	100.0	42	0.00	14.72	-33.3	0.00	33.3
	Cycle 4 Day 1	42	5.56	12.57	0.0	0.00	33.3	40	0.83	11.91	-33.3	0.00	33.3
	Cycle 5 Day 1	39	5.13	14.38	0.0	0.00	66.7	37	-0.90	14.67	-33.3	0.00	33.3
	Cycle 6 Day 1	41	4.88	11.93	0.0	0.00	33.3	39	0.00	10.81	-33.3	0.00	33.3
	Cycle 7 Day 1	28	4.76	11.88	0.0	0.00	33.3	26	-2.56	9.06	-33.3	0.00	0.0
	Cycle 8 Day 1	24	9.72	18.33	0.0	0.00	66.7	21	0.00	14.91	-33.3	0.00	33.3
	Cycle 9 Day 1	27	3.70	10.68	0.0	0.00	33.3	24	-1.39	11.95	-33.3	0.00	33.3
	Cycle 10 Day 1	21	6.35	17.06	0.0	0.00	66.7	19	0.00	19.25	-33.3	0.00	66.7
	Cycle 11 Day 1	19	1.75	7.65	0.0	0.00	33.3	17	-1.96	8.08	-33.3	0.00	0.0
	Cycle 12 Day 1	17	1.96	8.08	0.0	0.00	33.3	16	-2.08	8.33	-33.3	0.00	0.0
	Cycle 13 Day 1	14	2.38	8.91	0.0	0.00	33.3	13	-2.56	9.25	-33.3	0.00	0.0
	Cycle 14 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Cycle 15 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Study Disc 1	27	4.94	12.07	0.0	0.00	33.3	26	1.28	14.85	-33.3	0.00	33.3
	30 D SFU Z/P	11	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
	90 D SFU Z/P	13	0.00	0.00	0.0	0.00	0.0	13	0.00	0.00	0.0	0.00	0.0
	Placebo + CAPOX (N= 65)												
	Baseline	60	6.67	18.21	0.0	0.00	100.0						
	Cycle 2 Day 1	53	2.52	8.89	0.0	0.00	33.3	51	-3.27	15.28	-66.7	0.00	33.3
	Cycle 3 Day 1	48	4.17	11.14	0.0	0.00	33.3	47	-1.42	18.33	-66.7	0.00	33.3
	Cycle 4 Day 1	41	4.88	14.07	0.0	0.00	66.7	41	-1.63	21.02	-66.7	0.00	66.7
	Cycle 5 Day 1	41	1.63	7.27	0.0	0.00	33.3	41	-4.07	16.99	-66.7	0.00	33.3
	Cycle 6 Day 1	32	7.29	16.36	0.0	0.00	66.7	32	3.13	19.60	-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: 07OCT22

Table 302.1.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - 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	31	5.38	12.46	0.0	0.00	33.3	31	-1.08	20.15	-66.7	0.00	33.3
	Cycle 8 Day 1	24	4.17	11.26	0.0	0.00	33.3	24	-2.78	13.61	-33.3	0.00	33.3
	Cycle 9 Day 1	24	1.39	6.80	0.0	0.00	33.3	24	-6.94	19.61	-66.7	0.00	33.3
	Cycle 10 Day 1	16	0.00	0.00	0.0	0.00	0.0	15	-6.67	13.80	-33.3	0.00	0.0
	Cycle 11 Day 1	14	2.38	8.91	0.0	0.00	33.3	14	-7.14	23.31	-66.7	0.00	33.3
	Cycle 12 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	-13.33	23.31	-66.7	0.00	0.0
	Study Disc 1	36	18.52	26.96	0.0	0.00	100.0	35	14.29	29.47	-33.3	0.00	100.0
	30 D SFU Z/P	14	9.52	20.37	0.0	0.00	66.7	14	-2.38	27.62	-33.3	0.00	66.7
	90 D SFU Z/P	13	10.26	16.01	0.0	0.00	33.3	13	0.00	19.25	-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: 07OCT22

Table 302.1.3002.31: 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 + CAPOX (N=254)												
Baseline	242	5.37	14.03	0.0	0.00	100.0						
Cycle 2 Day 1	209	3.99	11.33	0.0	0.00	66.7	208	-1.60	13.81	-66.7	0.00	33.3
Cycle 3 Day 1	186	4.48	13.79	0.0	0.00	100.0	182	-1.10	12.09	-66.7	0.00	33.3
Cycle 4 Day 1	169	3.55	12.09	0.0	0.00	100.0	166	-2.01	14.07	-66.7	0.00	66.7
Cycle 5 Day 1	162	3.91	11.97	0.0	0.00	66.7	159	-1.68	15.82	-66.7	0.00	66.7
Cycle 6 Day 1	151	3.75	13.63	0.0	0.00	100.0	149	-1.12	15.70	-33.3	0.00	66.7
Cycle 7 Day 1	121	5.79	17.57	0.0	0.00	100.0	119	0.56	19.40	-33.3	0.00	100.0
Cycle 8 Day 1	114	5.26	13.73	0.0	0.00	66.7	108	-0.31	14.76	-33.3	0.00	66.7
Cycle 9 Day 1	107	4.67	12.50	0.0	0.00	66.7	102	-0.65	14.82	-33.3	0.00	33.3
Cycle 10 Day 1	88	4.17	13.19	0.0	0.00	66.7	85	-1.96	14.87	-33.3	0.00	66.7
Cycle 11 Day 1	82	4.88	14.93	0.0	0.00	100.0	79	-0.84	15.07	-33.3	0.00	66.7
Cycle 12 Day 1	76	3.51	11.65	0.0	0.00	66.7	74	-2.25	14.94	-33.3	0.00	33.3
Cycle 13 Day 1	62	2.69	9.15	0.0	0.00	33.3	60	-3.33	14.65	-33.3	0.00	33.3
Cycle 14 Day 1	56	3.57	10.40	0.0	0.00	33.3	54	-3.09	11.71	-33.3	0.00	33.3
Cycle 15 Day 1	51	2.61	9.05	0.0	0.00	33.3	49	-4.08	12.97	-33.3	0.00	33.3
Cycle 16 Day 1	46	5.07	12.11	0.0	0.00	33.3	44	-2.27	13.25	-33.3	0.00	33.3
Cycle 17 Day 1	41	5.69	12.70	0.0	0.00	33.3	39	-1.71	7.45	-33.3	0.00	0.0
Cycle 18 Day 1	37	7.21	13.91	0.0	0.00	33.3	35	-0.95	12.75	-33.3	0.00	33.3
Cycle 19 Day 1	37	6.31	13.24	0.0	0.00	33.3	35	-1.90	11.27	-33.3	0.00	33.3
Cycle 20 Day 1	35	4.76	11.83	0.0	0.00	33.3	33	-3.03	12.81	-33.3	0.00	33.3
Cycle 21 Day 1	32	4.17	11.20	0.0	0.00	33.3	30	-2.22	17.36	-33.3	0.00	33.3
Cycle 22 Day 1	30	4.44	11.52	0.0	0.00	33.3	28	-2.38	12.60	-33.3	0.00	33.3
Cycle 23 Day 1	28	3.57	10.50	0.0	0.00	33.3	26	-2.56	16.12	-33.3	0.00	33.3
Cycle 24 Day 1	25	5.33	12.47	0.0	0.00	33.3	23	-1.45	15.82	-33.3	0.00	33.3
Cycle 25 Day 1	23	2.90	9.60	0.0	0.00	33.3	21	-4.76	15.94	-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: 07OCT22

Table 302.1.3002.31: 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 26 Day 1	22	3.03	9.81	0.0	0.00	33.3	20	-5.00	12.21	-33.3	0.00	0.0
Cycle 27 Day 1	20	1.67	7.45	0.0	0.00	33.3	18	-5.56	12.78	-33.3	0.00	0.0
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	9	-7.41	14.70	-33.3	0.00	0.0
Cycle 29 Day 1	12	5.56	12.97	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Study Disc 1	124	7.80	18.09	0.0	0.00	100.0	122	2.73	17.46	-66.7	0.00	66.7
30 D SFU Z/P	52	9.62	24.99	0.0	0.00	100.0	51	3.92	22.75	-33.3	0.00	100.0
90 D SFU Z/P	48	4.17	13.09	0.0	0.00	66.7	47	0.71	16.28	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	6.64	17.00	0.0	0.00	100.0						
Cycle 2 Day 1	222	4.65	13.20	0.0	0.00	100.0	216	-1.54	15.00	-66.7	0.00	66.7
Cycle 3 Day 1	200	4.17	13.75	0.0	0.00	100.0	196	-1.87	17.92	-100.0	0.00	100.0
Cycle 4 Day 1	171	4.87	12.87	0.0	0.00	66.7	169	-1.38	16.41	-66.7	0.00	33.3
Cycle 5 Day 1	166	3.61	11.62	0.0	0.00	66.7	165	-2.42	17.09	-66.7	0.00	66.7
Cycle 6 Day 1	146	4.57	12.76	0.0	0.00	66.7	145	-1.84	18.33	-66.7	0.00	66.7
Cycle 7 Day 1	126	3.70	12.09	0.0	0.00	66.7	125	-2.93	19.41	-66.7	0.00	66.7
Cycle 8 Day 1	110	3.94	10.81	0.0	0.00	33.3	109	-3.67	18.89	-66.7	0.00	33.3
Cycle 9 Day 1	104	5.13	15.24	0.0	0.00	100.0	103	-2.27	19.95	-66.7	0.00	66.7
Cycle 10 Day 1	81	4.12	11.03	0.0	0.00	33.3	79	-2.95	19.39	-66.7	0.00	33.3
Cycle 11 Day 1	72	3.70	10.55	0.0	0.00	33.3	71	-2.82	18.47	-66.7	0.00	33.3
Cycle 12 Day 1	59	3.95	10.87	0.0	0.00	33.3	57	-1.75	15.96	-66.7	0.00	33.3
Cycle 13 Day 1	47	3.55	10.39	0.0	0.00	33.3	45	-4.44	19.59	-66.7	0.00	33.3
Cycle 14 Day 1	44	3.79	16.42	0.0	0.00	100.0	42	-1.59	22.03	-66.7	0.00	100.0
Cycle 15 Day 1	36	6.48	19.22	0.0	0.00	100.0	34	0.98	25.27	-66.7	0.00	100.0
Cycle 16 Day 1	32	6.25	15.70	0.0	0.00	66.7	30	1.11	22.29	-66.7	0.00	66.7
Cycle 17 Day 1	26	2.56	9.06	0.0	0.00	33.3	24	-4.17	22.66	-66.7	0.00	33.3
Cycle 18 Day 1	21	1.59	7.27	0.0	0.00	33.3	20	-3.33	18.42	-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: 07OCT22

Table 302.1.3002.31: 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 19 Day 1	20	0.00	0.00	0.0	0.00	0.0	19	-1.75	7.65	-33.3	0.00	0.0
Cycle 20 Day 1	17	1.96	8.08	0.0	0.00	33.3	16	-6.25	18.13	-66.7	0.00	0.0
Cycle 21 Day 1	18	0.00	0.00	0.0	0.00	0.0	17	-5.88	17.62	-66.7	0.00	0.0
Cycle 22 Day 1	15	2.22	8.61	0.0	0.00	33.3	14	-4.76	22.10	-66.7	0.00	33.3
Cycle 23 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-6.06	20.10	-66.7	0.00	0.0
Study Disc 1	149	6.94	17.01	0.0	0.00	66.7	144	0.00	21.95	-100.0	0.00	66.7
30 D SFU Z/P	74	4.05	15.56	0.0	0.00	100.0	72	-3.24	19.51	-66.7	0.00	66.7
90 D SFU Z/P	70	6.67	15.65	0.0	0.00	66.7	68	-0.49	21.92	-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: 07OCT22

Table 302.1.3002.32: 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 + CAPOX (N=254)												
Baseline	242	10.61	17.51	0.0	0.00	100.0						
Cycle 2 Day 1	209	9.41	16.40	0.0	0.00	66.7	208	-0.48	16.86	-100.0	0.00	66.7
Cycle 3 Day 1	186	7.53	15.21	0.0	0.00	66.7	182	-2.01	17.92	-100.0	0.00	66.7
Cycle 4 Day 1	169	8.28	16.58	0.0	0.00	100.0	166	-1.61	19.00	-100.0	0.00	100.0
Cycle 5 Day 1	162	9.47	15.97	0.0	0.00	66.7	159	0.21	19.30	-100.0	0.00	66.7
Cycle 6 Day 1	151	9.49	18.21	0.0	0.00	100.0	149	0.22	23.41	-100.0	0.00	100.0
Cycle 7 Day 1	121	6.89	16.05	0.0	0.00	100.0	119	-2.24	19.76	-100.0	0.00	66.7
Cycle 8 Day 1	114	7.60	14.73	0.0	0.00	66.7	108	-0.31	17.94	-33.3	0.00	66.7
Cycle 9 Day 1	107	7.17	15.21	0.0	0.00	66.7	102	-3.92	20.06	-66.7	0.00	66.7
Cycle 10 Day 1	88	6.82	15.30	0.0	0.00	66.7	85	-3.53	22.43	-100.0	0.00	66.7
Cycle 11 Day 1	82	6.50	16.09	0.0	0.00	100.0	79	-4.22	22.88	-100.0	0.00	100.0
Cycle 12 Day 1	76	7.46	15.00	0.0	0.00	66.7	74	-2.70	23.25	-100.0	0.00	66.7
Cycle 13 Day 1	62	5.91	16.56	0.0	0.00	100.0	60	-5.00	25.91	-100.0	0.00	100.0
Cycle 14 Day 1	56	1.79	7.57	0.0	0.00	33.3	54	-6.17	15.96	-33.3	0.00	33.3
Cycle 15 Day 1	51	1.96	7.92	0.0	0.00	33.3	49	-8.16	19.87	-100.0	0.00	33.3
Cycle 16 Day 1	46	5.80	12.77	0.0	0.00	33.3	44	-3.79	24.08	-100.0	0.00	33.3
Cycle 17 Day 1	41	2.44	8.79	0.0	0.00	33.3	39	-9.40	22.88	-100.0	0.00	33.3
Cycle 18 Day 1	37	5.41	12.46	0.0	0.00	33.3	35	-7.62	22.99	-66.7	0.00	33.3
Cycle 19 Day 1	37	4.50	11.55	0.0	0.00	33.3	35	-5.71	18.94	-33.3	0.00	33.3
Cycle 20 Day 1	35	3.81	10.76	0.0	0.00	33.3	33	-6.06	19.46	-33.3	0.00	33.3
Cycle 21 Day 1	32	4.17	11.20	0.0	0.00	33.3	30	-5.56	19.74	-33.3	0.00	33.3
Cycle 22 Day 1	30	1.11	6.09	0.0	0.00	33.3	28	-5.95	15.85	-33.3	0.00	33.3
Cycle 23 Day 1	28	3.57	10.50	0.0	0.00	33.3	26	-3.85	19.61	-33.3	0.00	33.3
Cycle 24 Day 1	25	2.67	9.23	0.0	0.00	33.3	23	-2.90	17.15	-33.3	0.00	33.3
Cycle 25 Day 1	23	4.35	11.48	0.0	0.00	33.3	21	-1.59	19.65	-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: 07OCT22

Table 302.1.3002.32: 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 26 Day 1	22	6.06	13.16	0.0	0.00	33.3	20	0.00	18.73	-33.3	0.00	33.3
Cycle 27 Day 1	20	1.67	7.45	0.0	0.00	33.3	18	-3.70	15.71	-33.3	0.00	33.3
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	9	-7.41	14.70	-33.3	0.00	0.0
Cycle 29 Day 1	12	2.78	9.62	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Study Disc 1	124	10.22	19.56	0.0	0.00	100.0	122	0.82	22.05	-33.3	0.00	100.0
30 D SFU Z/P	52	8.33	18.52	0.0	0.00	100.0	51	0.00	22.11	-33.3	0.00	100.0
90 D SFU Z/P	48	9.72	15.31	0.0	0.00	33.3	47	1.42	15.48	-33.3	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	241	9.82	19.49	0.0	0.00	100.0						
Cycle 2 Day 1	222	9.01	17.34	0.0	0.00	100.0	216	-0.77	18.59	-66.7	0.00	66.7
Cycle 3 Day 1	200	9.50	16.50	0.0	0.00	100.0	196	-0.68	19.08	-100.0	0.00	33.3
Cycle 4 Day 1	171	8.38	17.75	0.0	0.00	100.0	169	-0.99	20.39	-100.0	0.00	100.0
Cycle 5 Day 1	166	7.03	15.49	0.0	0.00	100.0	165	-2.63	18.03	-100.0	0.00	33.3
Cycle 6 Day 1	146	7.31	14.90	0.0	0.00	66.7	145	-1.38	16.61	-66.7	0.00	33.3
Cycle 7 Day 1	126	7.67	14.70	0.0	0.00	66.7	125	-1.87	19.54	-66.7	0.00	33.3
Cycle 8 Day 1	110	8.18	15.10	0.0	0.00	66.7	109	-1.22	20.75	-66.7	0.00	66.7
Cycle 9 Day 1	104	7.37	15.38	0.0	0.00	66.7	103	-2.91	21.44	-100.0	0.00	66.7
Cycle 10 Day 1	81	9.05	19.01	0.0	0.00	100.0	79	-2.11	25.79	-100.0	0.00	100.0
Cycle 11 Day 1	72	7.87	17.24	0.0	0.00	100.0	71	-4.23	25.15	-100.0	0.00	100.0
Cycle 12 Day 1	59	5.08	13.58	0.0	0.00	66.7	57	-8.19	22.96	-100.0	0.00	66.7
Cycle 13 Day 1	47	6.38	16.50	0.0	0.00	66.7	45	-6.67	23.14	-66.7	0.00	66.7
Cycle 14 Day 1	44	6.82	15.38	0.0	0.00	66.7	42	-7.14	23.90	-100.0	0.00	66.7
Cycle 15 Day 1	36	6.48	13.38	0.0	0.00	33.3	34	-7.84	21.80	-66.7	0.00	33.3
Cycle 16 Day 1	32	4.17	11.20	0.0	0.00	33.3	30	-8.89	19.44	-66.7	0.00	0.0
Cycle 17 Day 1	26	10.26	15.69	0.0	0.00	33.3	24	2.78	16.79	-33.3	0.00	33.3
Cycle 18 Day 1	21	4.76	11.95	0.0	0.00	33.3	20	-3.33	18.42	-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: 07OCT22

Table 302.1.3002.32: 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 19 Day 1	20	8.33	18.34	0.0	0.00	66.7	19	0.00	0.00	0.0	0.00	0.0
Cycle 20 Day 1	17	3.92	11.07	0.0	0.00	33.3	16	-6.25	21.84	-66.7	0.00	33.3
Cycle 21 Day 1	18	7.41	14.26	0.0	0.00	33.3	17	-1.96	21.96	-66.7	0.00	33.3
Cycle 22 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	-7.14	19.30	-66.7	0.00	0.0
Cycle 23 Day 1	12	5.56	12.97	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
Study Disc 1	149	10.07	20.02	0.0	0.00	100.0	144	0.46	25.54	-100.0	0.00	100.0
30 D SFU Z/P	74	11.71	22.37	0.0	0.00	100.0	72	1.39	29.30	-66.7	0.00	100.0
90 D SFU Z/P	70	10.95	18.58	0.0	0.00	66.7	68	1.47	25.39	-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: 07OCT22

Table 302.1.3002.33: 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 + CAPOX (N=254)												
Baseline	242	3.86	14.37	0.0	0.00	100.0						
Cycle 2 Day 1	209	3.99	12.23	0.0	0.00	66.7	208	0.96	13.07	-66.7	0.00	66.7
Cycle 3 Day 1	186	2.87	10.58	0.0	0.00	66.7	182	-0.18	11.35	-66.7	0.00	66.7
Cycle 4 Day 1	169	2.76	11.74	0.0	0.00	100.0	166	-0.40	12.71	-66.7	0.00	66.7
Cycle 5 Day 1	162	4.12	12.19	0.0	0.00	66.7	159	1.68	11.74	-33.3	0.00	33.3
Cycle 6 Day 1	151	3.97	13.29	0.0	0.00	66.7	149	0.67	13.68	-33.3	0.00	66.7
Cycle 7 Day 1	121	4.13	13.99	0.0	0.00	100.0	119	0.84	15.32	-66.7	0.00	100.0
Cycle 8 Day 1	114	5.26	13.73	0.0	0.00	66.7	108	0.93	12.45	-66.7	0.00	33.3
Cycle 9 Day 1	107	4.98	14.34	0.0	0.00	66.7	102	0.65	15.54	-66.7	0.00	66.7
Cycle 10 Day 1	88	4.17	12.18	0.0	0.00	66.7	85	0.39	14.08	-66.7	0.00	33.3
Cycle 11 Day 1	82	3.66	11.72	0.0	0.00	66.7	79	0.42	12.51	-66.7	0.00	33.3
Cycle 12 Day 1	76	2.19	9.94	0.0	0.00	66.7	74	-1.35	11.62	-66.7	0.00	33.3
Cycle 13 Day 1	62	0.54	4.23	0.0	0.00	33.3	60	-2.78	12.71	-66.7	0.00	33.3
Cycle 14 Day 1	56	0.00	0.00	0.0	0.00	0.0	54	-3.09	11.71	-66.7	0.00	0.0
Cycle 15 Day 1	51	0.65	4.67	0.0	0.00	33.3	49	-3.40	14.02	-66.7	0.00	33.3
Cycle 16 Day 1	46	4.35	11.35	0.0	0.00	33.3	44	0.00	17.61	-66.7	0.00	33.3
Cycle 17 Day 1	41	0.00	0.00	0.0	0.00	0.0	39	-5.13	14.38	-66.7	0.00	0.0
Cycle 18 Day 1	37	0.90	5.48	0.0	0.00	33.3	35	-4.76	11.83	-33.3	0.00	0.0
Cycle 19 Day 1	37	3.60	10.49	0.0	0.00	33.3	35	-0.95	15.09	-33.3	0.00	33.3
Cycle 20 Day 1	35	0.95	5.63	0.0	0.00	33.3	33	-4.04	13.84	-66.7	0.00	0.0
Cycle 21 Day 1	32	1.04	5.89	0.0	0.00	33.3	30	-4.44	16.91	-66.7	0.00	33.3
Cycle 22 Day 1	30	1.11	6.09	0.0	0.00	33.3	28	-3.57	13.88	-66.7	0.00	0.0
Cycle 23 Day 1	28	2.38	8.74	0.0	0.00	33.3	26	-1.28	14.85	-66.7	0.00	33.3
Cycle 24 Day 1	25	1.33	6.67	0.0	0.00	33.3	23	-2.90	13.90	-66.7	0.00	0.0
Cycle 25 Day 1	23	2.90	9.60	0.0	0.00	33.3	21	-1.59	16.59	-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: 07OCT22

Table 302.1.3002.33: 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 26 Day 1	22	3.03	9.81	0.0	0.00	33.3	20	-1.67	17.01	-66.7	0.00	33.3
Cycle 27 Day 1	20	0.00	0.00	0.0	0.00	0.0	18	-3.70	15.71	-66.7	0.00	0.0
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	9	-7.41	22.22	-66.7	0.00	0.0
Cycle 29 Day 1	12	0.00	0.00	0.0	0.00	0.0	10	-6.67	21.08	-66.7	0.00	0.0
Study Disc 1	124	7.53	17.95	0.0	0.00	100.0	122	4.64	18.34	-66.7	0.00	66.7
30 D SFU Z/P	52	8.33	22.75	0.0	0.00	100.0	51	4.58	18.88	-33.3	0.00	100.0
90 D SFU Z/P	48	4.86	11.89	0.0	0.00	33.3	47	4.26	11.24	0.0	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	241	3.60	12.40	0.0	0.00	100.0						
Cycle 2 Day 1	222	3.15	11.65	0.0	0.00	100.0	216	-0.31	9.64	-33.3	0.00	66.7
Cycle 3 Day 1	200	1.83	7.62	0.0	0.00	33.3	196	-1.02	11.65	-100.0	0.00	33.3
Cycle 4 Day 1	171	3.70	11.68	0.0	0.00	66.7	169	0.99	14.28	-33.3	0.00	66.7
Cycle 5 Day 1	166	2.21	9.80	0.0	0.00	66.7	165	-0.81	11.01	-33.3	0.00	66.7
Cycle 6 Day 1	146	3.20	9.85	0.0	0.00	33.3	145	0.46	11.78	-33.3	0.00	33.3
Cycle 7 Day 1	126	2.65	9.05	0.0	0.00	33.3	125	-0.53	11.19	-33.3	0.00	33.3
Cycle 8 Day 1	110	2.42	8.70	0.0	0.00	33.3	109	-1.22	13.55	-66.7	0.00	33.3
Cycle 9 Day 1	104	3.53	11.30	0.0	0.00	66.7	103	0.32	13.60	-33.3	0.00	33.3
Cycle 10 Day 1	81	2.88	10.80	0.0	0.00	66.7	79	-1.27	15.51	-66.7	0.00	66.7
Cycle 11 Day 1	72	1.85	7.69	0.0	0.00	33.3	71	-1.41	13.14	-66.7	0.00	33.3
Cycle 12 Day 1	59	2.26	8.45	0.0	0.00	33.3	57	0.58	7.69	-33.3	0.00	33.3
Cycle 13 Day 1	47	2.13	8.24	0.0	0.00	33.3	45	-1.48	15.82	-66.7	0.00	33.3
Cycle 14 Day 1	44	3.03	12.07	0.0	0.00	66.7	42	0.00	16.46	-66.7	0.00	66.7
Cycle 15 Day 1	36	1.85	7.74	0.0	0.00	33.3	34	-1.96	14.07	-66.7	0.00	33.3
Cycle 16 Day 1	32	3.12	9.87	0.0	0.00	33.3	30	-1.11	16.34	-66.7	0.00	33.3
Cycle 17 Day 1	26	5.13	12.26	0.0	0.00	33.3	24	2.78	13.61	-33.3	0.00	33.3
Cycle 18 Day 1	21	6.35	13.41	0.0	0.00	33.3	20	3.33	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: 07OCT22

Table 302.1.3002.33: 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 19 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	1.75	7.65	0.0	0.00	33.3
Cycle 20 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 21 Day 1	18	7.41	18.28	0.0	0.00	66.7	17	3.92	20.01	-33.3	0.00	66.7
Cycle 22 Day 1	15	2.22	8.61	0.0	0.00	33.3	14	-2.38	20.52	-66.7	0.00	33.3
Cycle 23 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-6.06	20.10	-66.7	0.00	0.0
Study Disc 1	149	7.61	18.22	0.0	0.00	100.0	144	4.86	20.47	-66.7	0.00	100.0
30 D SFU Z/P	74	4.95	15.29	0.0	0.00	66.7	72	2.31	16.14	-33.3	0.00	66.7
90 D SFU Z/P	70	6.19	16.34	0.0	0.00	66.7	68	3.92	21.18	-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: 07OCT22

Table 302.1.3002.34: 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 + CAPOX (N=254)												
Baseline	242	23.00	27.48	0.0	16.67	100.0						
Cycle 2 Day 1	209	23.13	26.59	0.0	33.33	100.0	208	0.16	23.28	-66.7	0.00	100.0
Cycle 3 Day 1	186	23.66	28.40	0.0	16.67	100.0	182	0.92	26.78	-66.7	0.00	66.7
Cycle 4 Day 1	169	23.47	25.62	0.0	33.33	100.0	166	0.00	28.19	-66.7	0.00	100.0
Cycle 5 Day 1	162	25.10	29.50	0.0	33.33	100.0	159	2.52	32.38	-66.7	0.00	100.0
Cycle 6 Day 1	151	22.08	27.73	0.0	0.00	100.0	149	-0.45	25.99	-66.7	0.00	66.7
Cycle 7 Day 1	121	19.28	27.47	0.0	0.00	100.0	119	-2.52	27.84	-66.7	0.00	100.0
Cycle 8 Day 1	114	19.59	25.01	0.0	0.00	100.0	108	-2.47	26.46	-100.0	0.00	66.7
Cycle 9 Day 1	107	18.69	24.73	0.0	0.00	100.0	102	-5.88	29.45	-100.0	0.00	100.0
Cycle 10 Day 1	88	17.42	27.21	0.0	0.00	100.0	85	-7.06	32.57	-100.0	0.00	100.0
Cycle 11 Day 1	82	13.41	25.04	0.0	0.00	100.0	79	-9.70	30.73	-100.0	0.00	66.7
Cycle 12 Day 1	76	13.16	24.99	0.0	0.00	100.0	74	-10.36	30.68	-100.0	0.00	100.0
Cycle 13 Day 1	62	14.52	24.61	0.0	0.00	100.0	60	-11.67	28.67	-100.0	0.00	66.7
Cycle 14 Day 1	56	10.71	23.01	0.0	0.00	100.0	54	-14.20	26.38	-100.0	0.00	66.7
Cycle 15 Day 1	51	11.76	22.92	0.0	0.00	100.0	49	-12.24	26.95	-66.7	0.00	66.7
Cycle 16 Day 1	46	11.59	21.33	0.0	0.00	100.0	44	-15.91	23.28	-66.7	0.00	33.3
Cycle 17 Day 1	41	10.57	22.90	0.0	0.00	100.0	39	-14.53	19.93	-66.7	0.00	0.0
Cycle 18 Day 1	37	15.32	25.57	0.0	0.00	100.0	35	-11.43	26.74	-66.7	0.00	33.3
Cycle 19 Day 1	37	9.91	20.59	0.0	0.00	100.0	35	-17.14	23.39	-66.7	0.00	33.3
Cycle 20 Day 1	35	15.24	24.71	0.0	0.00	100.0	33	-10.10	22.80	-66.7	0.00	33.3
Cycle 21 Day 1	32	10.42	21.48	0.0	0.00	100.0	30	-12.22	23.95	-66.7	0.00	33.3
Cycle 22 Day 1	30	8.89	26.16	0.0	0.00	100.0	28	-14.29	24.73	-66.7	0.00	33.3
Cycle 23 Day 1	28	11.90	26.00	0.0	0.00	100.0	26	-10.26	20.59	-66.7	0.00	33.3
Cycle 24 Day 1	25	13.33	30.43	0.0	0.00	100.0	23	-10.14	29.19	-66.7	0.00	33.3
Cycle 25 Day 1	23	11.59	25.84	0.0	0.00	100.0	21	-11.11	21.94	-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: 07OCT22

Table 302.1.3002.34: 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 26 Day 1	22	9.09	23.42	0.0	0.00	100.0	20	-15.00	25.31	-66.7	0.00	33.3
Cycle 27 Day 1	20	13.33	31.34	0.0	0.00	100.0	18	-12.96	23.26	-66.7	0.00	33.3
Cycle 28 Day 1	11	12.12	30.81	0.0	0.00	100.0	9	-14.81	24.22	-66.7	0.00	0.0
Cycle 29 Day 1	12	8.33	28.87	0.0	0.00	100.0	10	-16.67	23.57	-66.7	0.00	0.0
Study Disc 1	124	26.34	28.91	0.0	33.33	100.0	122	5.74	28.97	-100.0	0.00	66.7
30 D SFU Z/P	52	25.00	29.43	0.0	33.33	100.0	51	-0.65	31.62	-100.0	0.00	66.7
90 D SFU Z/P	48	16.67	26.63	0.0	0.00	100.0	47	0.71	22.51	-33.3	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	241	24.07	28.25	0.0	33.33	100.0						
Cycle 2 Day 1	222	23.42	26.57	0.0	33.33	100.0	216	0.46	26.99	-100.0	0.00	100.0
Cycle 3 Day 1	200	24.00	28.39	0.0	33.33	100.0	196	1.02	27.20	-66.7	0.00	100.0
Cycle 4 Day 1	171	21.64	26.19	0.0	0.00	100.0	169	-1.18	25.69	-66.7	0.00	100.0
Cycle 5 Day 1	166	19.08	26.03	0.0	0.00	100.0	165	-2.42	26.43	-100.0	0.00	100.0
Cycle 6 Day 1	146	17.58	26.03	0.0	0.00	100.0	145	-5.29	29.05	-100.0	0.00	100.0
Cycle 7 Day 1	126	16.67	24.49	0.0	0.00	100.0	125	-3.47	28.02	-100.0	0.00	100.0
Cycle 8 Day 1	110	17.58	25.82	0.0	0.00	100.0	109	-3.67	29.17	-66.7	0.00	100.0
Cycle 9 Day 1	104	15.06	25.39	0.0	0.00	100.0	103	-7.12	29.76	-66.7	0.00	100.0
Cycle 10 Day 1	81	14.81	22.97	0.0	0.00	100.0	79	-5.91	28.12	-100.0	0.00	66.7
Cycle 11 Day 1	72	13.43	24.81	0.0	0.00	100.0	71	-8.45	25.65	-100.0	0.00	66.7
Cycle 12 Day 1	59	10.17	18.83	0.0	0.00	66.7	57	-10.53	24.53	-66.7	0.00	33.3
Cycle 13 Day 1	47	11.35	21.17	0.0	0.00	66.7	45	-11.11	26.59	-66.7	0.00	66.7
Cycle 14 Day 1	44	13.64	21.94	0.0	0.00	66.7	42	-7.14	23.90	-66.7	0.00	66.7
Cycle 15 Day 1	36	14.81	28.11	0.0	0.00	100.0	34	-9.80	30.18	-66.7	0.00	66.7
Cycle 16 Day 1	32	15.62	20.71	0.0	0.00	66.7	30	-8.89	23.05	-66.7	0.00	33.3
Cycle 17 Day 1	26	12.82	21.24	0.0	0.00	66.7	24	-13.89	21.80	-66.7	0.00	33.3
Cycle 18 Day 1	21	11.11	19.25	0.0	0.00	66.7	20	-15.00	27.52	-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: 07OCT22

Table 302.1.3002.34: 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 19 Day 1	20	8.33	14.81	0.0	0.00	33.3	19	-12.28	16.52	-33.3	0.00	0.0
Cycle 20 Day 1	17	9.80	15.66	0.0	0.00	33.3	16	-14.58	24.25	-66.7	0.00	33.3
Cycle 21 Day 1	18	7.41	14.26	0.0	0.00	33.3	17	-15.69	20.81	-66.7	0.00	0.0
Cycle 22 Day 1	15	6.67	13.80	0.0	0.00	33.3	14	-19.05	21.54	-66.7	-16.67	0.0
Cycle 23 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-21.21	30.81	-100.0	0.00	0.0
Study Disc 1	149	26.17	29.91	0.0	33.33	100.0	144	1.85	29.70	-66.7	0.00	100.0
30 D SFU Z/P	74	28.83	30.88	0.0	33.33	100.0	72	5.09	27.78	-66.7	0.00	66.7
90 D SFU Z/P	70	28.57	31.74	0.0	33.33	100.0	68	5.88	30.44	-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: 07OCT22

Table 302.1.3002.35: 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 + CAPOX (N=254)												
Baseline	91	12.09	20.80	0.0	0.00	100.0						
Cycle 2 Day 1	100	10.33	17.53	0.0	0.00	66.7	59	-2.26	18.43	-66.7	0.00	33.3
Cycle 3 Day 1	103	10.36	17.48	0.0	0.00	66.7	54	-3.09	19.71	-66.7	0.00	33.3
Cycle 4 Day 1	90	11.85	18.90	0.0	0.00	66.7	53	-0.63	24.01	-66.7	0.00	66.7
Cycle 5 Day 1	74	12.16	17.94	0.0	0.00	66.7	44	-3.03	20.10	-66.7	0.00	33.3
Cycle 6 Day 1	72	12.96	19.82	0.0	0.00	66.7	45	2.96	23.38	-66.7	0.00	66.7
Cycle 7 Day 1	53	12.58	18.75	0.0	0.00	66.7	30	-3.33	22.06	-66.7	0.00	33.3
Cycle 8 Day 1	53	12.58	19.86	0.0	0.00	66.7	35	-5.71	27.40	-100.0	0.00	66.7
Cycle 9 Day 1	52	12.82	18.85	0.0	0.00	66.7	30	-2.22	26.16	-100.0	0.00	33.3
Cycle 10 Day 1	37	14.41	20.09	0.0	0.00	66.7	20	-1.67	25.31	-100.0	0.00	33.3
Cycle 11 Day 1	37	9.91	15.45	0.0	0.00	33.3	20	-1.67	27.52	-100.0	0.00	33.3
Cycle 12 Day 1	38	7.89	16.32	0.0	0.00	66.7	22	-4.55	25.81	-100.0	0.00	33.3
Cycle 13 Day 1	31	7.53	16.58	0.0	0.00	66.7	19	-5.26	29.94	-100.0	0.00	33.3
Cycle 14 Day 1	22	6.06	13.16	0.0	0.00	33.3	12	-11.11	29.59	-100.0	0.00	0.0
Cycle 15 Day 1	20	13.33	19.94	0.0	0.00	66.7	11	6.06	25.03	-33.3	0.00	66.7
Cycle 16 Day 1	21	7.94	14.55	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 17 Day 1	21	11.11	19.25	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 18 Day 1	18	7.41	14.26	0.0	0.00	33.3	8	-4.17	21.36	-33.3	0.00	33.3
Cycle 19 Day 1	15	8.89	15.26	0.0	0.00	33.3	8	0.00	17.82	-33.3	0.00	33.3
Cycle 20 Day 1	15	8.89	15.26	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 21 Day 1	12	5.56	12.97	0.0	0.00	33.3	8	-4.17	21.36	-33.3	0.00	33.3
Cycle 22 Day 1	10	10.00	16.10	0.0	0.00	33.3	7	0.00	19.25	-33.3	0.00	33.3
Study Disc 1	53	21.38	27.03	0.0	0.00	100.0	28	10.71	30.16	-33.3	0.00	100.0
30 D SFU Z/P	20	18.33	27.52	0.0	0.00	100.0	6	11.11	27.22	-33.3	16.67	33.3
90 D SFU Z/P	28	32.14	32.05	0.0	33.33	100.0	13	25.64	36.40	-33.3	33.33	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: 07OCT22

Table 302.1.3002.35: 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
Placebo + CAPOX (N=253)												
Baseline	85	12.55	23.56	0.0	0.00	100.0						
Cycle 2 Day 1	91	10.26	22.05	0.0	0.00	100.0	60	-1.67	15.56	-33.3	0.00	33.3
Cycle 3 Day 1	78	7.69	16.05	0.0	0.00	66.7	49	-4.76	23.57	-66.7	0.00	33.3
Cycle 4 Day 1	70	11.90	22.01	0.0	0.00	100.0	46	0.00	15.71	-33.3	0.00	66.7
Cycle 5 Day 1	69	12.08	24.23	0.0	0.00	100.0	41	-0.81	18.99	-33.3	0.00	33.3
Cycle 6 Day 1	61	9.84	20.50	0.0	0.00	100.0	36	-4.63	21.31	-66.7	0.00	66.7
Cycle 7 Day 1	57	9.94	20.86	0.0	0.00	100.0	29	-4.60	17.19	-66.7	0.00	33.3
Cycle 8 Day 1	53	6.92	15.13	0.0	0.00	66.7	26	-8.97	20.13	-66.7	0.00	33.3
Cycle 9 Day 1	44	12.88	24.08	0.0	0.00	100.0	21	-9.52	26.13	-100.0	0.00	33.3
Cycle 10 Day 1	40	11.67	24.52	0.0	0.00	100.0	16	-8.33	28.54	-100.0	0.00	33.3
Cycle 11 Day 1	32	11.46	20.05	0.0	0.00	66.7	11	3.03	17.98	-33.3	0.00	33.3
Cycle 12 Day 1	28	11.90	22.62	0.0	0.00	100.0	12	0.00	20.10	-33.3	0.00	33.3
Cycle 13 Day 1	18	14.81	26.13	0.0	0.00	100.0	9	-7.41	22.22	-33.3	0.00	33.3
Cycle 14 Day 1	17	11.76	26.20	0.0	0.00	100.0	6	5.56	13.61	0.0	0.00	33.3
Cycle 15 Day 1	12	11.11	21.71	0.0	0.00	66.7	6	-5.56	13.61	-33.3	0.00	0.0
Cycle 16 Day 1	12	5.56	12.97	0.0	0.00	33.3	4	-8.33	16.67	-33.3	0.00	0.0
Study Disc 1	57	12.87	25.00	0.0	0.00	100.0	30	-2.22	27.59	-100.0	0.00	66.7
30 D SFU Z/P	33	14.14	23.61	0.0	0.00	66.7	14	2.38	30.56	-33.3	0.00	66.7
90 D SFU Z/P	52	30.77	30.85	0.0	33.33	100.0	18	12.96	25.92	-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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

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

Table 302.1.3004.20.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dysphagia (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	116 (45.7%)	112 (44.3%)	
Number of patients censored	138 (54.3%)	141 (55.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.7 [3.5, 10.0]	6.9 [5.0, 10.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.129 [0.868, 1.469]
Log-rank test			
Two-sided stratified log-rank p-value			0.3751

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: 07OCT22

Table 302.1.3004.20.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dysphagia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	81 (46.0)	7.4 [3.2, 10.9]	180	85 (47.2)	6.5 [4.4, 9.0]	1.010 [0.744, 1.370]	0.9617	0.1442
>65 years	78	35 (44.9)	5.4 [1.7, NC]	73	27 (37.0)	14.1 [4.6, NC]	1.560 [0.939, 2.591]	0.0839	
Sex									
Male	159	77 (48.4)	4.4 [2.1, 10.0]	156	72 (46.2)	6.0 [4.6, 8.8]	1.160 [0.841, 1.601]	0.3689	0.9311
Female	95	39 (41.1)	8.8 [5.5, 15.9]	97	40 (41.2)	9.0 [4.2, NC]	1.078 [0.690, 1.683]	0.7464	
Region									
Asia	157	76 (48.4)	6.7 [2.8, 10.5]	158	66 (41.8)	7.4 [5.1, NC]	1.235 [0.886, 1.722]	0.2144	0.4631
Non-Asia	97	40 (41.2)	6.0 [2.6, NC]	95	46 (48.4)	6.4 [3.6, 10.8]	1.023 [0.668, 1.565]	0.9245	
Number of Organs with Metastatic Sites									
0-2	189	83 (43.9)	7.6 [3.8, 23.3]	188	79 (42.0)	8.3 [6.2, 11.7]	1.172 [0.860, 1.597]	0.3203	0.7305
>=3	65	33 (50.8)	3.6 [1.9, 8.8]	65	33 (50.8)	4.2 [1.7, 17.7]	1.077 [0.662, 1.753]	0.7680	

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: 07OCT22

Table 302.1.3004.21.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating Restrictions (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	89 (35.0%)	110 (43.5%)	
Number of patients censored	165 (65.0%)	143 (56.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	23.3 [7.6, NC]	7.4 [5.5, 10.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.897 [0.674, 1.192]
Log-rank test			
Two-sided stratified log-rank p-value			0.4462

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: 07OCT22

Table 302.1.3004.21.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating Restrictions by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	60 (34.1)	NC [7.9, NC]	180	80 (44.4)	7.5 [5.6, 10.4]	0.811 [0.580, 1.135]	0.2176	0.5216
>65 years	78	29 (37.2)	7.6 [3.4, NC]	73	30 (41.1)	6.4 [3.5, NC]	0.976 [0.583, 1.634]	0.9267	
Sex									
Male	159	60 (37.7)	9.7 [5.5, NC]	156	75 (48.1)	6.8 [4.2, 9.2]	0.813 [0.578, 1.143]	0.2308	0.6140
Female	95	29 (30.5)	23.3 [8.4, NC]	97	35 (36.1)	10.2 [6.5, NC]	0.924 [0.562, 1.520]	0.7491	
Region									
Asia	157	55 (35.0)	23.3 [8.4, NC]	158	60 (38.0)	9.9 [6.7, NC]	0.955 [0.661, 1.379]	0.7961	0.3700
Non-Asia	97	34 (35.1)	7.6 [3.8, NC]	95	50 (52.6)	5.3 [3.3, 7.9]	0.748 [0.483, 1.159]	0.1925	
Number of Organs with Metastatic Sites									
0-2	189	69 (36.5)	23.3 [6.7, NC]	188	79 (42.0)	8.3 [6.4, 11.7]	0.953 [0.689, 1.318]	0.7655	0.2189
>=3	65	20 (30.8)	NC [6.0, NC]	65	31 (47.7)	5.1 [2.9, 9.9]	0.627 [0.357, 1.102]	0.0982	

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: 07OCT22

Table 302.1.3004.22.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Reflux (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	120 (47.2%)	110 (43.5%)	
Number of patients censored	134 (52.8%)	143 (56.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.4 [3.3, 6.5]	6.3 [4.5, 11.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.335 [1.025, 1.740]
Log-rank test			
Two-sided stratified log-rank p-value			0.0323

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: 07OCT22

Table 302.1.3004.22.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Reflux by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	84 (47.7)	5.2 [3.0, 9.3]	180	76 (42.2)	8.3 [4.8, 12.8]	1.251 [0.917, 1.707]	0.1558	0.8260
>65 years	78	36 (46.2)	3.8 [2.7, 6.5]	73	34 (46.6)	4.4 [3.2, 14.1]	1.167 [0.730, 1.866]	0.5229	
Sex									
Male	159	81 (50.9)	4.3 [2.7, 6.3]	156	71 (45.5)	4.8 [4.0, 11.8]	1.195 [0.868, 1.645]	0.2710	0.8322
Female	95	39 (41.1)	5.3 [3.2, NC]	97	39 (40.2)	10.6 [4.8, NC]	1.279 [0.819, 1.995]	0.2784	
Region									
Asia	157	74 (47.1)	5.5 [3.3, NC]	158	69 (43.7)	5.9 [4.4, 14.1]	1.178 [0.848, 1.635]	0.3355	0.5729
Non-Asia	97	46 (47.4)	4.0 [2.2, 9.1]	95	41 (43.2)	8.3 [3.8, 12.8]	1.372 [0.898, 2.096]	0.1382	
Number of Organs with Metastatic Sites									
0-2	189	92 (48.7)	5.2 [3.3, 7.9]	188	79 (42.0)	9.2 [4.6, 12.8]	1.369 [1.013, 1.851]	0.0398	0.1775
>=3	65	28 (43.1)	3.7 [2.1, NC]	65	31 (47.7)	4.6 [2.5, 11.9]	0.935 [0.560, 1.560]	0.7904	

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: 07OCT22

Table 302.1.3004.23.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Odynophagia (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	104 (40.9%)	109 (43.1%)	
Number of patients censored	150 (59.1%)	144 (56.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.1 [4.6, NC]	7.4 [5.0, 10.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.029 [0.784, 1.352]
Log-rank test			
Two-sided stratified log-rank p-value			0.8409

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: 07OCT22

Table 302.1.3004.23.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Odynophagia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	76 (43.2)	6.6 [3.9, NC]	180	80 (44.4)	7.4 [5.0, 10.4]	1.060 [0.773, 1.452]	0.7252	0.6958
>65 years	78	28 (35.9)	7.6 [3.2, NC]	73	29 (39.7)	9.3 [3.3, NC]	0.945 [0.562, 1.589]	0.8331	
Sex									
Male	159	70 (44.0)	6.4 [3.6, 8.6]	156	74 (47.4)	6.5 [4.2, 9.3]	1.013 [0.729, 1.406]	0.9477	0.9628
Female	95	34 (35.8)	NC [3.8, NC]	97	35 (36.1)	9.6 [5.1, NC]	1.025 [0.639, 1.644]	0.9153	
Region									
Asia	157	69 (43.9)	7.2 [3.5, NC]	158	60 (38.0)	9.3 [6.2, 14.1]	1.231 [0.870, 1.740]	0.2436	0.0797
Non-Asia	97	35 (36.1)	7.1 [4.2, NC]	95	49 (51.6)	4.4 [2.9, 8.3]	0.746 [0.482, 1.154]	0.1870	
Number of Organs with Metastatic Sites									
0-2	189	77 (40.7)	7.4 [4.7, NC]	188	79 (42.0)	9.2 [5.3, 11.7]	1.048 [0.765, 1.437]	0.7700	0.7116
>=3	65	27 (41.5)	4.6 [2.6, NC]	65	30 (46.2)	5.0 [2.9, 11.9]	0.958 [0.569, 1.615]	0.8629	

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: 07OCT22

Table 302.1.3004.24.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Pain and Discomfort (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	103 (40.6%)	112 (44.3%)	
Number of patients censored	151 (59.4%)	141 (55.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.8 [5.1, 11.2]	6.7 [5.0, 9.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.898 [0.685, 1.178]
Log-rank test			
Two-sided stratified log-rank p-value			0.4347

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: 07OCT22

Table 302.1.3004.24.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Pain and Discomfort by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	77 (43.8)	7.2 [4.4, 11.1]	180	84 (46.7)	6.6 [4.6, 9.2]	0.882 [0.647, 1.203]	0.4347	0.8721
>65 years	78	26 (33.3)	9.8 [4.2, NC]	73	28 (38.4)	9.3 [4.4, NC]	0.976 [0.572, 1.665]	0.9231	
Sex									
Male	159	67 (42.1)	7.2 [4.4, 18.7]	156	71 (45.5)	6.5 [4.4, 9.3]	0.873 [0.625, 1.220]	0.4352	0.7512
Female	95	36 (37.9)	9.7 [4.5, NC]	97	41 (42.3)	7.0 [5.1, 12.2]	0.965 [0.616, 1.513]	0.8723	
Region									
Asia	157	67 (42.7)	9.2 [5.1, 18.7]	158	66 (41.8)	7.0 [5.2, 9.5]	0.951 [0.675, 1.340]	0.7745	0.5860
Non-Asia	97	36 (37.1)	7.3 [4.2, NC]	95	46 (48.4)	5.1 [3.5, 10.4]	0.834 [0.539, 1.291]	0.4184	
Number of Organs with Metastatic Sites									
0-2	189	78 (41.3)	9.2 [5.7, 17.1]	188	84 (44.7)	6.9 [5.2, 9.5]	0.916 [0.672, 1.248]	0.5862	0.8741
>=3	65	25 (38.5)	6.9 [3.9, 19.8]	65	28 (43.1)	5.0 [2.5, 11.9]	0.887 [0.517, 1.522]	0.6443	

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: 07OCT22

Table 302.1.3004.25.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Anxiety (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	118 (46.5%)	104 (41.1%)	
Number of patients censored	136 (53.5%)	149 (58.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.7 [2.8, 5.9]	5.1 [3.7, 9.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.148 [0.879, 1.500]
Log-rank test			
Two-sided stratified log-rank p-value			0.2909

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: 07OCT22

Table 302.1.3004.25.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Anxiety by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	83 (47.2)	4.1 [2.3, 6.7]	180	70 (38.9)	5.1 [3.4, 10.9]	1.159 [0.843, 1.593]	0.3455	0.8864
>65 years	78	35 (44.9)	3.3 [3.0, 6.6]	73	34 (46.6)	4.6 [2.3, 8.3]	1.134 [0.706, 1.821]	0.5985	
Sex									
Male	159	78 (49.1)	3.3 [2.7, 5.1]	156	63 (40.4)	5.1 [3.7, NC]	1.247 [0.895, 1.738]	0.1814	0.4292
Female	95	40 (42.1)	5.9 [2.7, 13.2]	97	41 (42.3)	5.1 [3.0, 9.0]	0.991 [0.640, 1.533]	0.9713	
Region									
Asia	157	76 (48.4)	3.7 [2.7, 6.7]	158	64 (40.5)	6.3 [4.1, 10.9]	1.197 [0.858, 1.670]	0.2829	0.7148
Non-Asia	97	42 (43.3)	3.7 [2.3, 5.9]	95	40 (42.1)	3.7 [2.1, 10.4]	1.047 [0.678, 1.615]	0.8132	
Number of Organs with Metastatic Sites									
0-2	189	90 (47.6)	3.5 [2.8, 5.9]	188	78 (41.5)	4.8 [3.3, 10.9]	1.164 [0.859, 1.577]	0.3210	0.7670
>=3	65	28 (43.1)	4.2 [2.1, NC]	65	26 (40.0)	5.7 [3.0, NC]	1.062 [0.622, 1.813]	0.7889	

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: 07OCT22

Table 302.1.3004.26.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating in Front of Others (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	74 (29.1%)	68 (26.9%)	
Number of patients censored	180 (70.9%)	185 (73.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	17.7 [10.4, NC]	NC [10.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.057 [0.756, 1.477]
Log-rank test			
Two-sided stratified log-rank p-value			0.7557

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: 07OCT22

Table 302.1.3004.26.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating in Front of Others by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	54 (30.7)	17.7 [10.4, NC]	180	51 (28.3)	11.9 [10.1, NC]	1.019 [0.694, 1.497]	0.9258	0.5243
>65 years	78	20 (25.6)	12.0 [7.6, NC]	73	17 (23.3)	NC [7.9, NC]	1.310 [0.685, 2.509]	0.4123	
Sex									
Male	159	49 (30.8)	16.1 [10.0, NC]	156	43 (27.6)	NC [10.1, NC]	1.101 [0.730, 1.660]	0.6448	0.8471
Female	95	25 (26.3)	17.7 [9.5, NC]	97	25 (25.8)	NC [8.2, NC]	1.044 [0.598, 1.824]	0.8801	
Region									
Asia	157	55 (35.0)	16.1 [9.5, NC]	158	46 (29.1)	11.9 [8.8, NC]	1.099 [0.740, 1.634]	0.6408	0.7024
Non-Asia	97	19 (19.6)	NC [9.2, NC]	95	22 (23.2)	NC [10.4, NC]	0.985 [0.533, 1.823]	0.9622	
Number of Organs with Metastatic Sites									
0-2	189	54 (28.6)	17.7 [10.4, NC]	188	49 (26.1)	NC [10.4, NC]	1.116 [0.757, 1.645]	0.5787	0.9408
>=3	65	20 (30.8)	15.8 [5.1, 19.8]	65	19 (29.2)	11.9 [6.0, NC]	1.016 [0.538, 1.918]	0.9608	

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: 07OCT22

Table 302.1.3004.27.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dry Mouth Score (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	99 (39.0%)	129 (51.0%)	
Number of patients censored	155 (61.0%)	124 (49.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.1 [4.3, NC]	4.2 [2.9, 5.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.696 [0.534, 0.908]
Log-rank test			
Two-sided stratified log-rank p-value			0.0071

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: 07OCT22

Table 302.1.3004.27.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dry Mouth Score by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	63 (35.8)	14.8 [4.6, NC]	180	89 (49.4)	4.4 [3.1, 6.6]	0.670 [0.484, 0.926]	0.0149	0.4754
>65 years	78	36 (46.2)	4.2 [2.3, 8.3]	73	40 (54.8)	2.7 [1.6, 4.4]	0.806 [0.514, 1.267]	0.3496	
Sex									
Male	159	63 (39.6)	8.1 [3.7, NC]	156	84 (53.8)	3.8 [2.2, 5.2]	0.661 [0.476, 0.918]	0.0131	0.4514
Female	95	36 (37.9)	8.1 [3.5, NC]	97	45 (46.4)	5.1 [2.9, 8.8]	0.822 [0.530, 1.275]	0.3769	
Region									
Asia	157	59 (37.6)	14.8 [6.5, NC]	158	74 (46.8)	4.4 [3.8, 8.8]	0.714 [0.507, 1.006]	0.0529	0.9684
Non-Asia	97	40 (41.2)	4.1 [2.8, NC]	95	55 (57.9)	2.8 [2.1, 3.9]	0.717 [0.476, 1.079]	0.1100	
Number of Organs with Metastatic Sites									
0-2	189	78 (41.3)	7.9 [4.1, NC]	188	103 (54.8)	4.1 [2.7, 5.1]	0.710 [0.529, 0.954]	0.0226	0.9254
>=3	65	21 (32.3)	14.8 [3.3, NC]	65	26 (40.0)	6.1 [2.1, NC]	0.727 [0.408, 1.295]	0.2766	

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: 07OCT22

Table 302.1.3004.28.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Taste (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	126 (49.6%)	133 (52.6%)	
Number of patients censored	128 (50.4%)	120 (47.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.8 [3.2, 5.1]	4.7 [3.6, 5.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.987 [0.770, 1.264]
Log-rank test			
Two-sided stratified log-rank p-value			0.9243

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: 07OCT22

Table 302.1.3004.28.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Taste by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	88 (50.0)	4.0 [3.1, 6.4]	180	98 (54.4)	4.7 [3.5, 5.1]	0.935 [0.700, 1.249]	0.6557	0.3872
>65 years	78	38 (48.7)	3.6 [2.3, 6.0]	73	35 (47.9)	4.9 [2.8, 9.0]	1.191 [0.751, 1.887]	0.4569	
Sex									
Male	159	80 (50.3)	3.6 [3.0, 5.1]	156	88 (56.4)	4.6 [3.1, 5.0]	0.898 [0.663, 1.217]	0.4909	0.2294
Female	95	46 (48.4)	3.9 [2.8, 6.7]	97	45 (46.4)	5.1 [2.8, 14.8]	1.201 [0.793, 1.817]	0.3908	
Region									
Asia	157	81 (51.6)	3.8 [3.0, 6.7]	158	76 (48.1)	4.9 [3.3, 9.2]	1.127 [0.824, 1.542]	0.4515	0.2500
Non-Asia	97	45 (46.4)	3.6 [2.8, 5.6]	95	57 (60.0)	3.8 [2.3, 5.1]	0.844 [0.570, 1.251]	0.4010	
Number of Organs with Metastatic Sites									
0-2	189	94 (49.7)	3.8 [2.9, 6.4]	188	100 (53.2)	4.9 [3.6, 5.5]	1.020 [0.769, 1.353]	0.8873	0.7735
>=3	65	32 (49.2)	3.8 [3.2, 5.6]	65	33 (50.8)	4.5 [1.6, 7.0]	0.962 [0.591, 1.566]	0.8830	

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: 07OCT22

Table 302.1.3004.29.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Body Image (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	112 (44.1%)	101 (39.9%)	
Number of patients censored	142 (55.9%)	152 (60.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.0 [4.0, 8.2]	8.8 [5.8, 12.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.238 [0.941, 1.629]
Log-rank test			
Two-sided stratified log-rank p-value			0.1230

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: 07OCT22

Table 302.1.3004.29.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Body Image by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	80 (45.5)	7.5 [4.2, 10.4]	180	69 (38.3)	10.6 [5.8, NC]	1.208 [0.875, 1.667]	0.2420	0.9904
>65 years	78	32 (41.0)	4.6 [3.1, 7.0]	73	32 (43.8)	7.1 [3.8, 14.5]	1.256 [0.767, 2.055]	0.3675	
Sex									
Male	159	73 (45.9)	6.7 [4.2, 10.9]	156	58 (37.2)	9.2 [6.0, NC]	1.281 [0.907, 1.808]	0.1578	0.7262
Female	95	39 (41.1)	4.6 [3.0, 8.1]	97	43 (44.3)	7.9 [3.2, 14.5]	1.140 [0.737, 1.763]	0.5458	
Region									
Asia	157	70 (44.6)	6.4 [3.7, 10.9]	158	65 (41.1)	8.8 [4.4, 14.1]	1.130 [0.806, 1.584]	0.4792	0.4363
Non-Asia	97	42 (43.3)	5.9 [3.0, 8.7]	95	36 (37.9)	9.2 [5.0, NC]	1.400 [0.894, 2.191]	0.1308	
Number of Organs with Metastatic Sites									
0-2	189	86 (45.5)	5.9 [3.5, 8.2]	188	74 (39.4)	10.6 [6.0, 14.1]	1.318 [0.966, 1.799]	0.0806	0.2944
>=3	65	26 (40.0)	6.0 [3.6, 13.2]	65	27 (41.5)	7.9 [3.9, 14.5]	0.941 [0.548, 1.617]	0.8441	

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: 07OCT22

Table 302.1.3004.30.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Swallowing Saliva (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	70 (27.6%)	64 (25.3%)	
Number of patients censored	184 (72.4%)	189 (74.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [10.9, NC]	28.7 [14.5, 28.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.278 [0.905, 1.806]
Log-rank test			
Two-sided stratified log-rank p-value			0.1626

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: 07OCT22

Table 302.1.3004.30.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Swallowing Saliva by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	48 (27.3)	NC [11.3, NC]	180	46 (25.6)	28.7 [14.8, 28.7]	1.141 [0.760, 1.714]	0.5249	0.5406
>65 years	78	22 (28.2)	12.5 [4.9, NC]	73	18 (24.7)	NC [14.5, NC]	1.429 [0.766, 2.666]	0.2580	
Sex									
Male	159	45 (28.3)	NC [10.4, NC]	156	42 (26.9)	28.7 [NC, NC]	1.124 [0.736, 1.716]	0.5862	0.5320
Female	95	25 (26.3)	NC [8.1, NC]	97	22 (22.7)	14.8 [14.5, NC]	1.376 [0.775, 2.444]	0.2760	
Region									
Asia	157	40 (25.5)	NC [12.5, NC]	158	34 (21.5)	NC [14.8, NC]	1.188 [0.751, 1.879]	0.4595	0.7930
Non-Asia	97	30 (30.9)	10.4 [5.1, NC]	95	30 (31.6)	14.5 [7.7, 28.7]	1.321 [0.792, 2.206]	0.2847	
Number of Organs with Metastatic Sites									
0-2	189	58 (30.7)	NC [10.4, NC]	188	44 (23.4)	28.7 [14.8, 28.7]	1.490 [1.004, 2.211]	0.0460	0.0438
>=3	65	12 (18.5)	NC [10.6, NC]	65	20 (30.8)	14.5 [7.7, NC]	0.635 [0.309, 1.303]	0.2119	

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: 07OCT22

Table 302.1.3004.31.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Choked When Swallowing Score (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	62 (24.4%)	62 (24.5%)	
Number of patients censored	192 (75.6%)	191 (75.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [15.5, NC]	NC [12.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.039 [0.727, 1.483]
Log-rank test			
Two-sided stratified log-rank p-value			0.8325

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: 07OCT22

Table 302.1.3004.31.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Choked When Swallowing Score by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	43 (24.4)	NC [15.5, NC]	180	45 (25.0)	NC [10.9, NC]	0.957 [0.629, 1.455]	0.8388	0.6176
>65 years	78	19 (24.4)	NC [5.5, NC]	73	17 (23.3)	NC [NC, NC]	1.184 [0.613, 2.286]	0.6108	
Sex									
Male	159	40 (25.2)	NC [14.3, NC]	156	44 (28.2)	12.3 [10.5, NC]	0.841 [0.547, 1.291]	0.4290	0.1510
Female	95	22 (23.2)	NC [15.5, NC]	97	18 (18.6)	NC [NC, NC]	1.445 [0.772, 2.703]	0.2475	
Region									
Asia	157	41 (26.1)	NC [17.1, NC]	158	36 (22.8)	NC [11.1, NC]	1.125 [0.718, 1.763]	0.6049	0.5123
Non-Asia	97	21 (21.6)	NC [8.4, NC]	95	26 (27.4)	NC [9.2, NC]	0.876 [0.493, 1.559]	0.6531	
Number of Organs with Metastatic Sites									
0-2	189	49 (25.9)	NC [14.3, NC]	188	41 (21.8)	NC [12.3, NC]	1.216 [0.802, 1.843]	0.3542	0.1058
>=3	65	13 (20.0)	NC [8.5, NC]	65	21 (32.3)	11.1 [5.1, NC]	0.640 [0.320, 1.279]	0.2022	

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: 07OCT22

Table 302.1.3004.32.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Coughing (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	84 (33.1%)	93 (36.8%)	
Number of patients censored	170 (66.9%)	160 (63.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.9 [8.3, 18.9]	11.6 [6.8, 17.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.950 [0.704, 1.283]
Log-rank test			
Two-sided stratified log-rank p-value			0.7422

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: 07OCT22

Table 302.1.3004.32.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Coughing by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	57 (32.4)	11.9 [10.0, NC]	180	70 (38.9)	10.4 [6.1, NC]	0.805 [0.567, 1.142]	0.2237	0.1608
>65 years	78	27 (34.6)	7.8 [5.1, NC]	73	23 (31.5)	14.1 [6.0, NC]	1.306 [0.747, 2.285]	0.3480	
Sex									
Male	159	58 (36.5)	10.6 [8.0, 15.8]	156	58 (37.2)	11.6 [6.0, NC]	0.957 [0.665, 1.377]	0.8166	0.6954
Female	95	26 (27.4)	18.9 [7.5, NC]	97	35 (36.1)	10.3 [6.5, NC]	0.818 [0.490, 1.366]	0.4400	
Region									
Asia	157	46 (29.3)	11.9 [10.5, NC]	158	60 (38.0)	11.6 [6.5, NC]	0.730 [0.497, 1.073]	0.1080	0.0550
Non-Asia	97	38 (39.2)	6.8 [4.2, 18.9]	95	33 (34.7)	10.4 [5.8, NC]	1.321 [0.828, 2.108]	0.2426	
Number of Organs with Metastatic Sites									
0-2	189	66 (34.9)	10.9 [8.0, 18.9]	188	71 (37.8)	11.6 [6.7, NC]	0.970 [0.693, 1.356]	0.8590	0.5659
>=3	65	18 (27.7)	15.8 [6.9, NC]	65	22 (33.8)	10.5 [5.1, 17.1]	0.786 [0.418, 1.478]	0.4544	

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: 07OCT22

Table 302.1.3004.33.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Talking (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	62 (24.4%)	63 (24.9%)	
Number of patients censored	192 (75.6%)	190 (75.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [12.9, NC]	NC [14.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.055 [0.741, 1.502]
Log-rank test			
Two-sided stratified log-rank p-value			0.7687

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: 07OCT22

Table 302.1.3004.33.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Talking by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	46 (26.1)	NC [10.9, NC]	180	48 (26.7)	NC [11.1, NC]	1.005 [0.670, 1.507]	0.9832	0.6266
>65 years	78	16 (20.5)	NC [9.1, NC]	73	15 (20.5)	NC [NC, NC]	1.227 [0.606, 2.485]	0.5694	
Sex									
Male	159	40 (25.2)	NC [10.4, NC]	156	44 (28.2)	NC [10.5, NC]	0.924 [0.602, 1.418]	0.7144	0.2669
Female	95	22 (23.2)	NC [NC, NC]	97	19 (19.6)	NC [14.8, NC]	1.439 [0.778, 2.663]	0.2451	
Region									
Asia	157	37 (23.6)	NC [12.9, NC]	158	38 (24.1)	NC [14.8, NC]	0.980 [0.623, 1.543]	0.9292	0.5618
Non-Asia	97	25 (25.8)	NC [6.6, NC]	95	25 (26.3)	NC [9.2, NC]	1.216 [0.698, 2.117]	0.4908	
Number of Organs with Metastatic Sites									
0-2	189	45 (23.8)	NC [NC, NC]	188	43 (22.9)	NC [14.8, NC]	1.130 [0.744, 1.717]	0.5678	0.6330
>=3	65	17 (26.2)	12.9 [10.3, NC]	65	20 (30.8)	11.1 [6.0, NC]	0.914 [0.477, 1.752]	0.7839	

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: 07OCT22

Table 302.1.3004.34.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Weight Loss (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	112 (44.1%)	104 (41.1%)	
Number of patients censored	142 (55.9%)	149 (58.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.4 [3.4, 9.1]	8.3 [5.1, 11.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.080 [0.825, 1.415]
Log-rank test			
Two-sided stratified log-rank p-value			0.5626

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: 07OCT22

Table 302.1.3004.34.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Weight Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	80 (45.5)	6.9 [4.0, 13.2]	180	72 (40.0)	8.7 [5.0, NC]	1.070 [0.778, 1.472]	0.6686	0.6855
>65 years	78	32 (41.0)	3.1 [2.0, NC]	73	32 (43.8)	5.8 [2.7, NC]	1.218 [0.745, 1.991]	0.4285	
Sex									
Male	159	71 (44.7)	7.2 [2.8, 13.2]	156	66 (42.3)	8.3 [4.8, 10.9]	1.022 [0.731, 1.430]	0.8870	0.4839
Female	95	41 (43.2)	5.2 [3.1, 7.4]	97	38 (39.2)	11.6 [3.8, NC]	1.264 [0.812, 1.968]	0.2936	
Region									
Asia	157	67 (42.7)	9.1 [4.6, 17.0]	158	69 (43.7)	6.3 [4.8, 11.6]	0.902 [0.644, 1.263]	0.5543	0.0625
Non-Asia	97	45 (46.4)	3.5 [2.3, 7.4]	95	35 (36.8)	9.2 [3.9, NC]	1.583 [1.015, 2.467]	0.0393	
Number of Organs with Metastatic Sites									
0-2	189	86 (45.5)	6.4 [3.3, 8.0]	188	75 (39.9)	9.2 [5.0, NC]	1.171 [0.859, 1.596]	0.3096	0.4258
>=3	65	26 (40.0)	5.6 [2.1, NC]	65	29 (44.6)	6.3 [3.6, 9.2]	0.905 [0.531, 1.540]	0.7149	

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: 07OCT22

Table 302.1.3004.35.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Hair Loss (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	27 (10.6%)	21 (8.3%)	
Number of patients censored	227 (89.4%)	232 (91.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	23.0 [5.6, NC]	9.0 [7.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.020 [0.559, 1.863]
Log-rank test			
Two-sided stratified log-rank p-value			0.9502

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: 07OCT22

Table 302.1.3004.35.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Hair Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	20 (11.4)	NC [5.1, NC]	180	15 (8.3)	9.0 [6.7, NC]	1.045 [0.535, 2.044]	0.8945	0.6116
>65 years	78	7 (9.0)	23.0 [1.9, 23.0]	73	6 (8.2)	8.5 [4.9, NC]	1.352 [0.435, 4.201]	0.6006	
Sex									
Male	159	13 (8.2)	23.0 [8.0, NC]	156	13 (8.3)	NC [7.5, NC]	0.864 [0.394, 1.899]	0.7152	0.3443
Female	95	14 (14.7)	5.6 [3.5, NC]	97	8 (8.2)	9.0 [6.7, NC]	1.504 [0.628, 3.599]	0.3563	
Region									
Asia	157	19 (12.1)	23.0 [9.4, NC]	158	16 (10.1)	8.8 [6.7, NC]	0.922 [0.469, 1.810]	0.8122	0.1845
Non-Asia	97	8 (8.2)	5.1 [2.1, NC]	95	5 (5.3)	9.0 [1.4, NC]	2.370 [0.707, 7.948]	0.1471	
Number of Organs with Metastatic Sites									
0-2	189	18 (9.5)	23.0 [8.0, NC]	188	15 (8.0)	9.0 [7.5, NC]	1.047 [0.523, 2.098]	0.8981	0.8585
>=3	65	9 (13.8)	9.4 [2.3, NC]	65	6 (9.2)	NC [1.4, NC]	1.132 [0.402, 3.193]	0.8127	

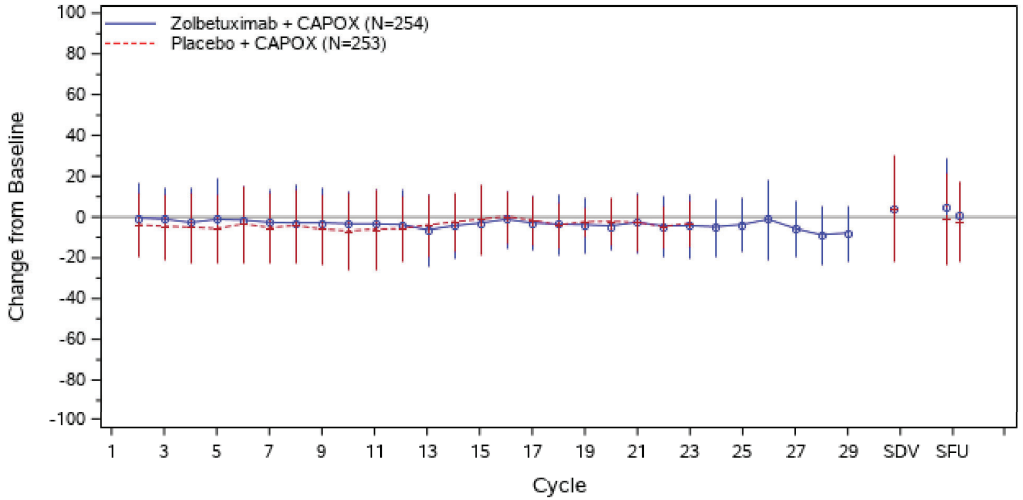
Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

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

The SAS System

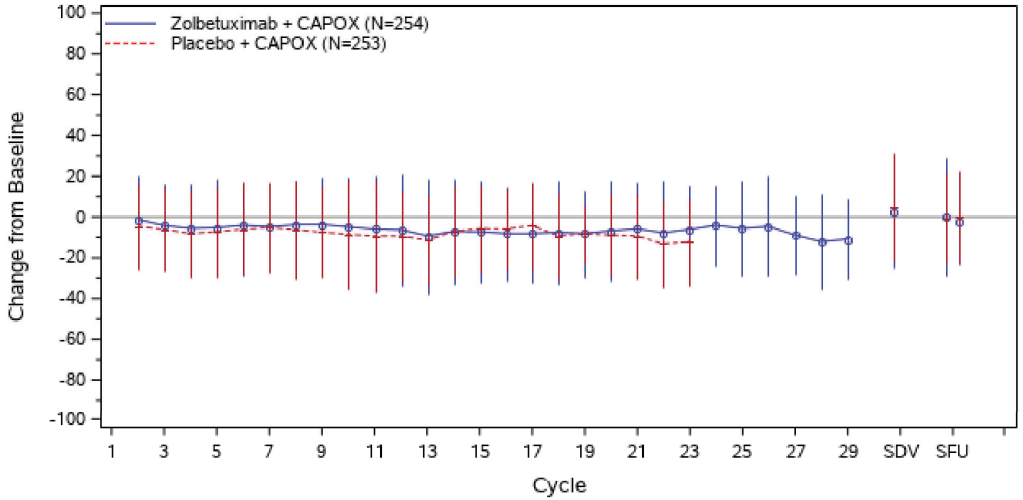
Figure 302.1.3002.20: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dysphagia - Full Analysis Set



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: 07OCT22

The SAS System

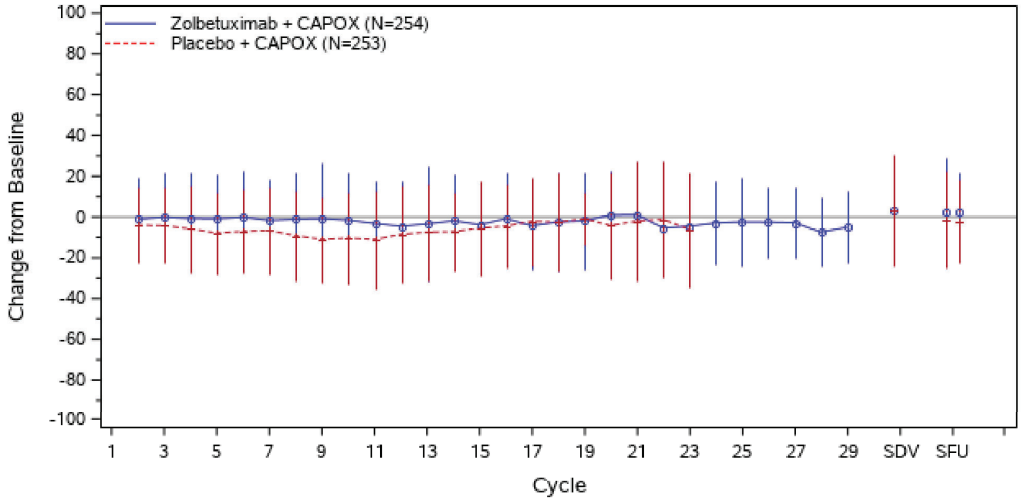
Figure 302.1.3002.21: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Eating Restrictions - Full Analysis Set



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: 07OCT22

The SAS System

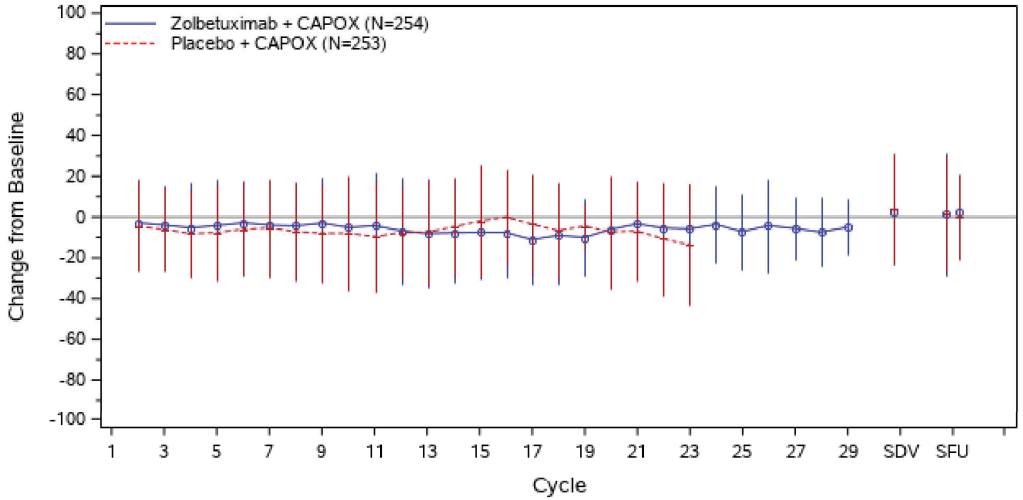
Figure 302.1.3002.22: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Reflux - Full Analysis Set



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: 07OCT22

The SAS System

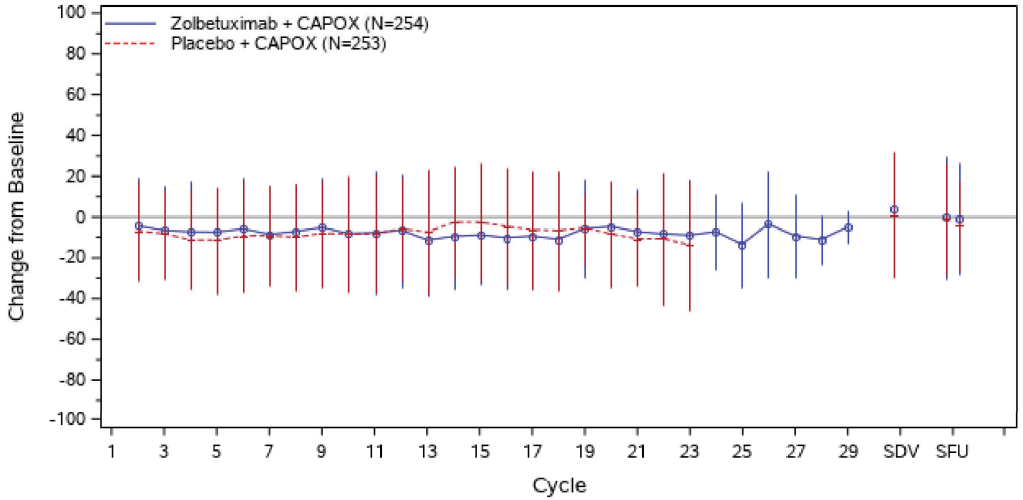
Figure 302.1.3002.23: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Odynophagia - Full Analysis Set



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: 07OCT22

The SAS System

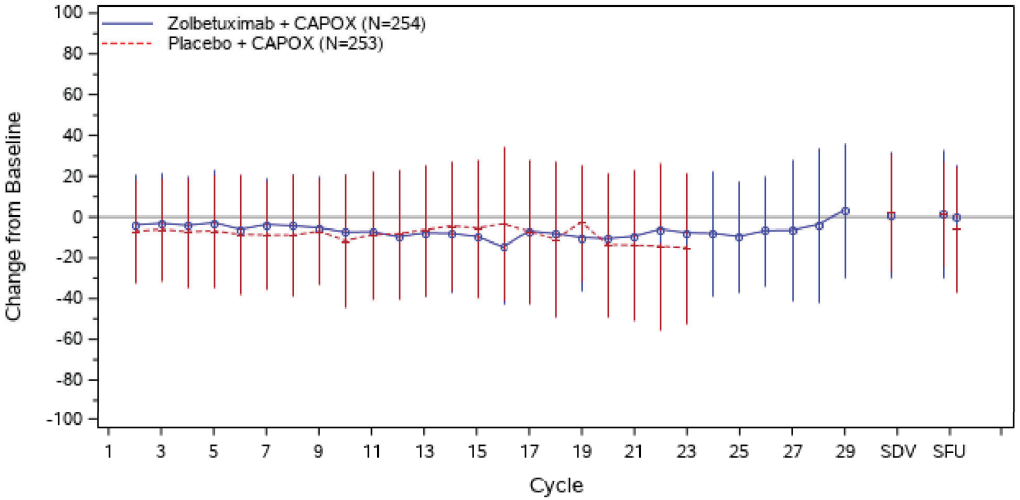
Figure 302.1.3002.24: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Pain and Discomfort - Full Analysis Set



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: 07OCT22

The SAS System

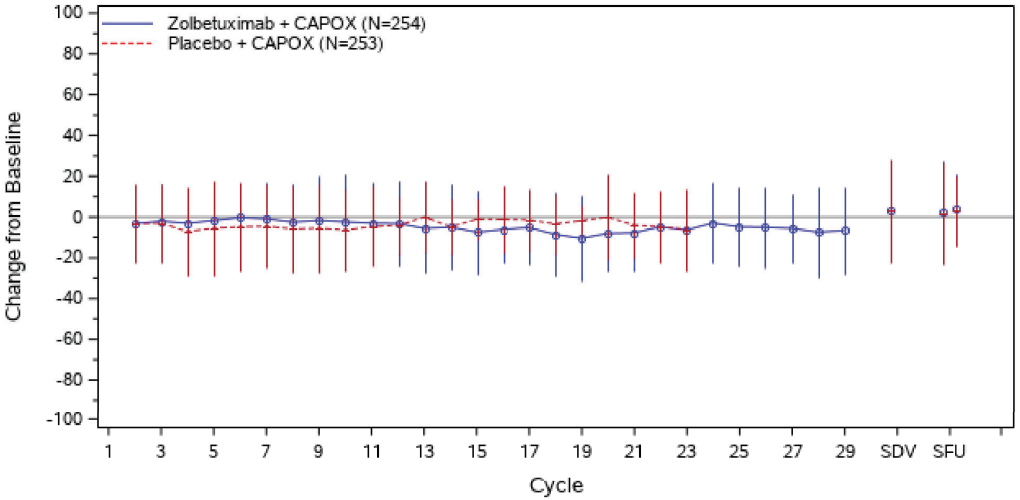
Figure 302.1.3002.25: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Anxiety - Full Analysis Set



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: 07OCT22

The SAS System

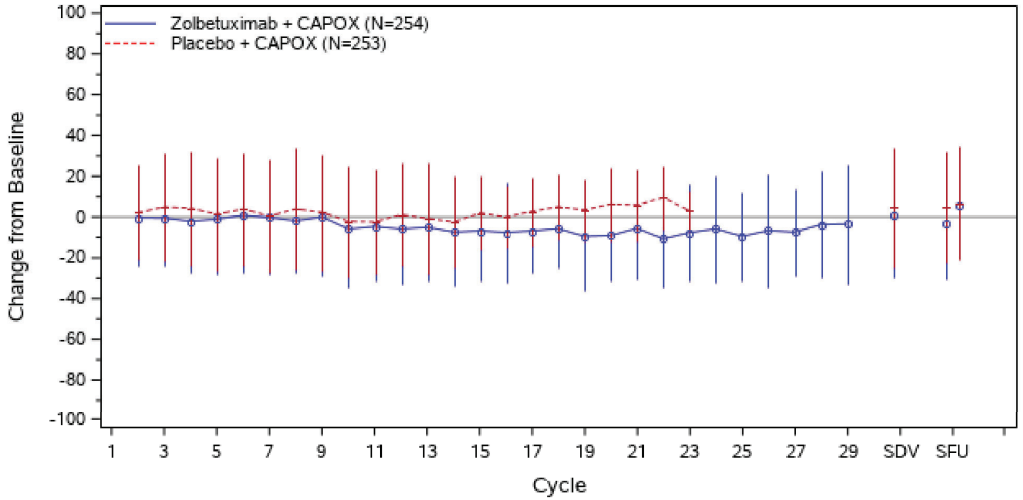
Figure 302.1.3002.26: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Eating in Front of Others - Full Analysis Set



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: 07OCT22

The SAS System

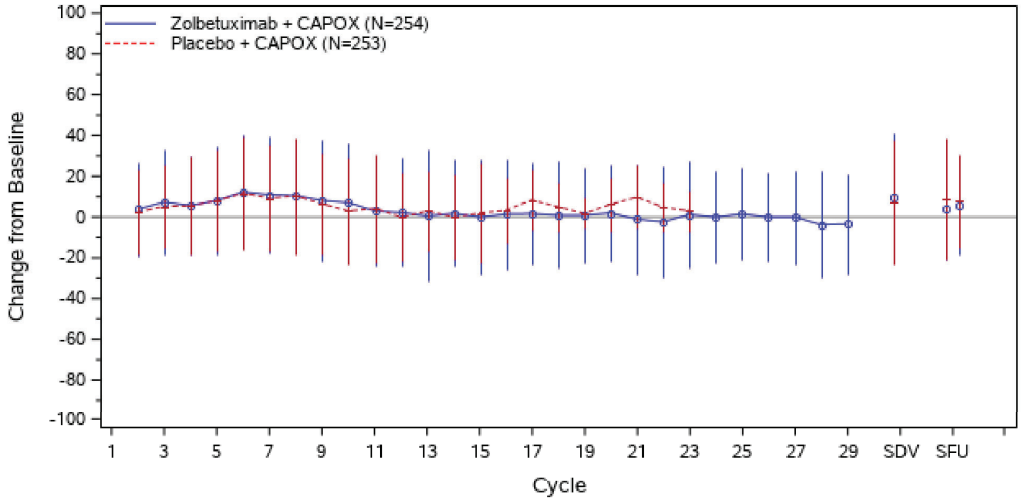
Figure 302.1.3002.27: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dry Mouth - Full Analysis Set



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: 07OCT22

The SAS System

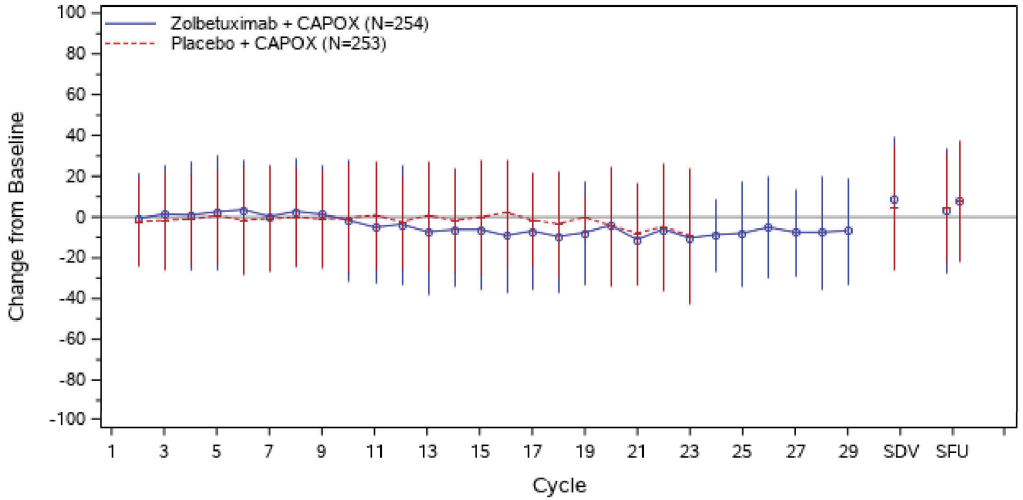
Figure 302.1.3002.28: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Taste - Full Analysis Set



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: 07OCT22

The SAS System

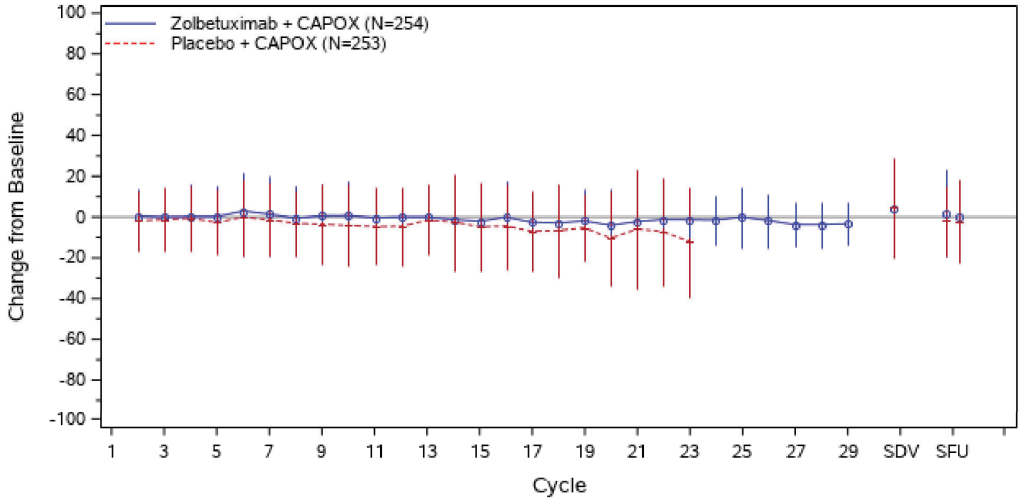
Figure 302.1.3002.29: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Body Image - Full Analysis Set



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: 07OCT22

The SAS System

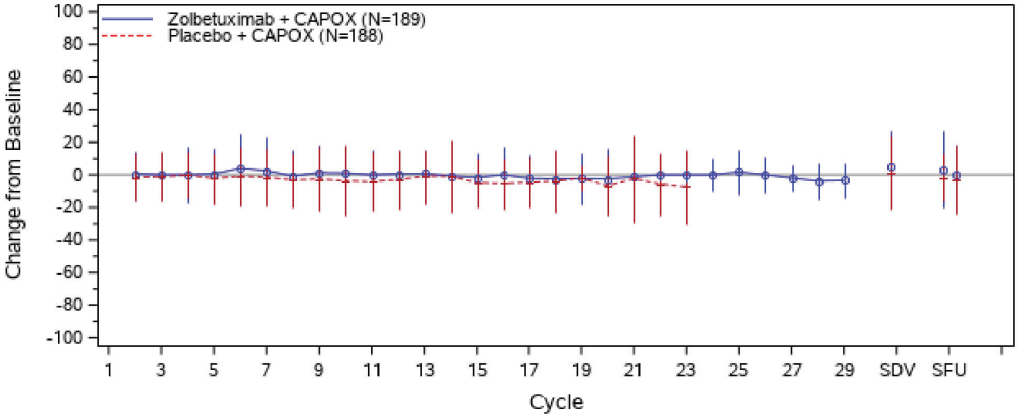
Figure 302.1.3002.30: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set



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: 07OCT22

The SAS System

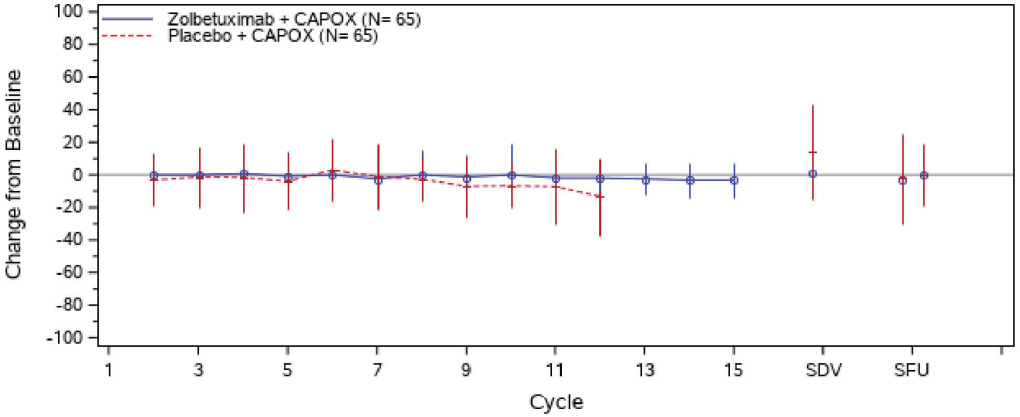
Figure 302.1.3002.30.4: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - Full Analysis Set
Number of Organs with Metastatic Sites: 0-2



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: 07OCT22

The SAS System

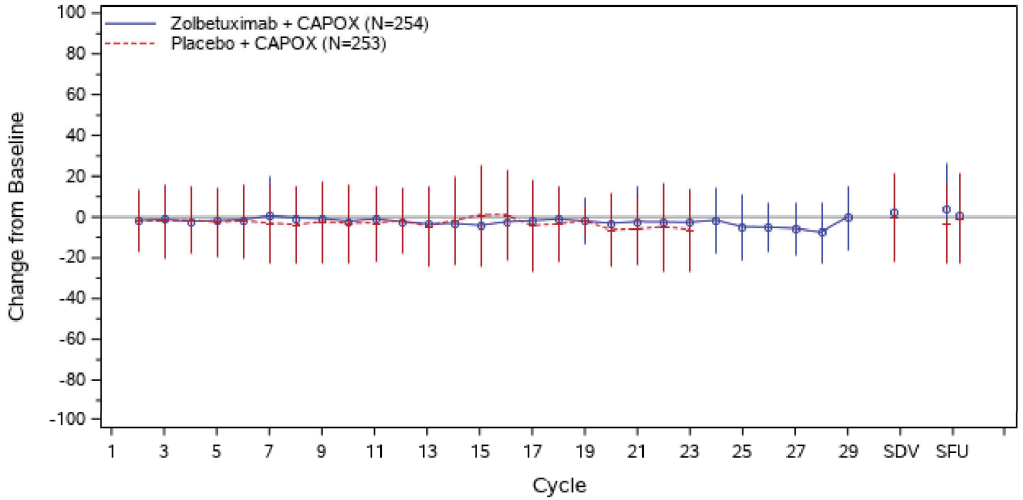
Figure 302.1.3002.30.4: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - Full Analysis Set Number of Organs with Metastatic Sites: >=3



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: 07OCT22

The SAS System

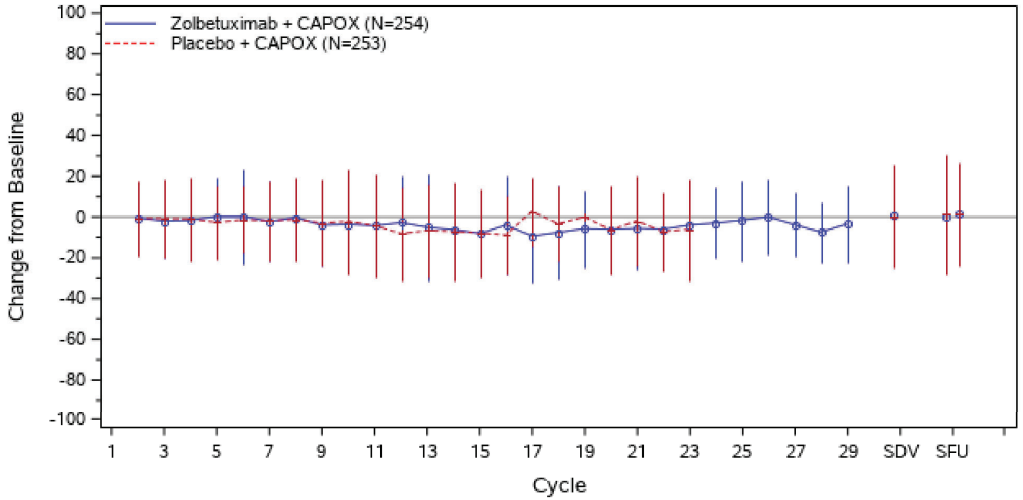
Figure 302.1.3002.31: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Choked when Swallowing Score - Full Analysis Set



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: 07OCT22

The SAS System

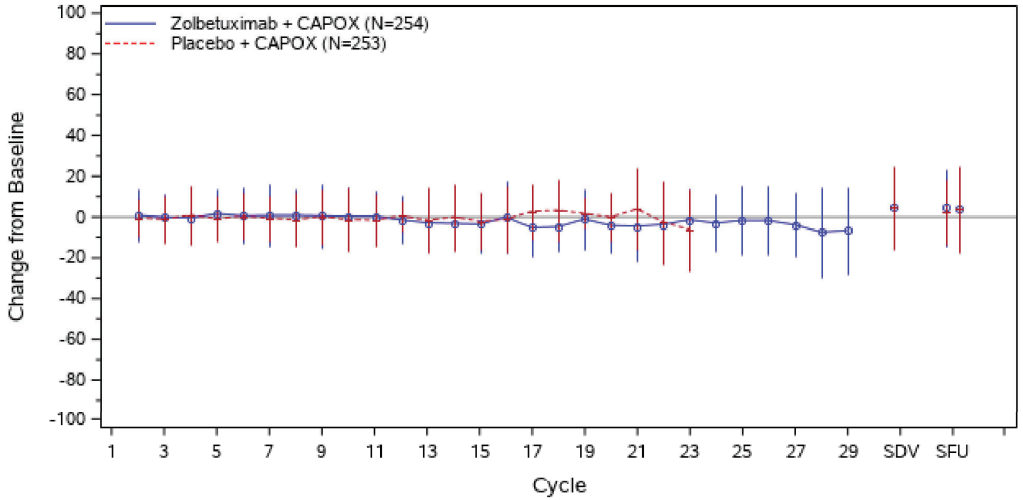
Figure 302.1.3002.32: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Coughing - Full Analysis Set



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: 07OCT22

The SAS System

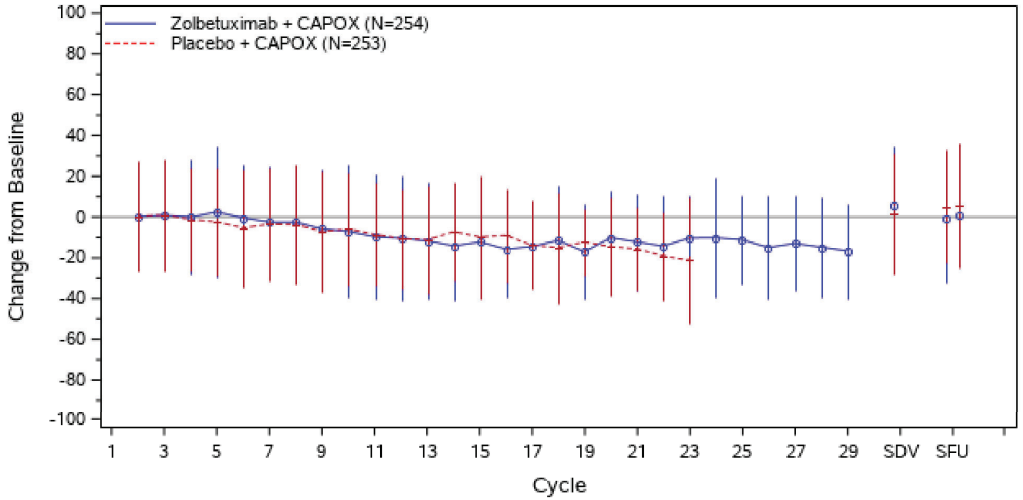
Figure 302.1.3002.33: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Talking - Full Analysis Set



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: 07OCT22

The SAS System

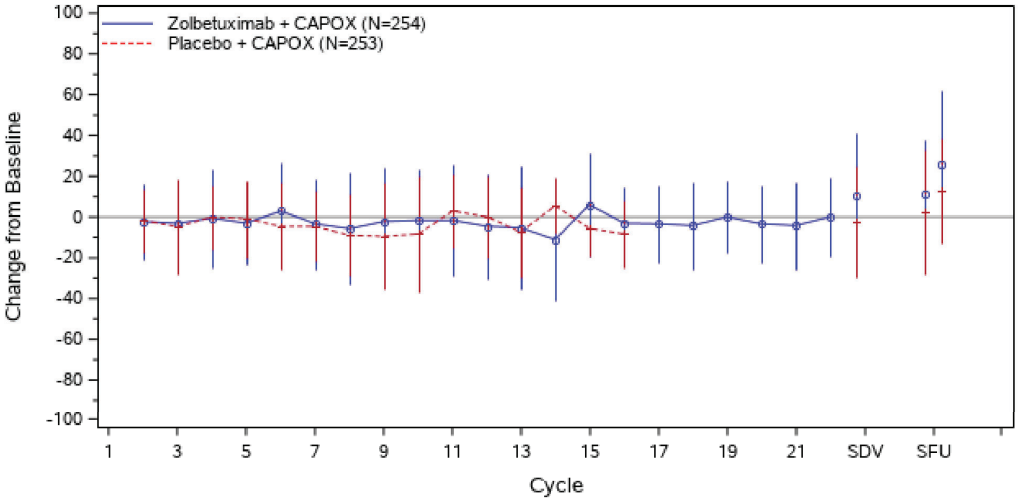
Figure 302.1.3002.34: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Weight Loss - Full Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.3002.35: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Hair Loss - Full Analysis Set



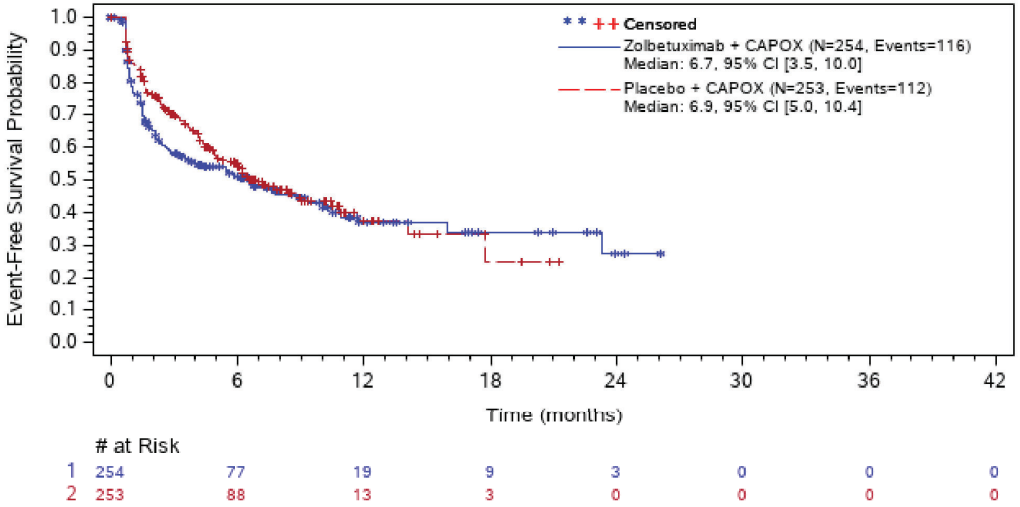
Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

5. Kaplan-Meier-Plots

The SAS System

Figure 302.1.3004.20: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia (MID=10) - Full Analysis Set



# at Risk								
1	254	77	19	9	3	0	0	0
2	253	88	13	3	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.

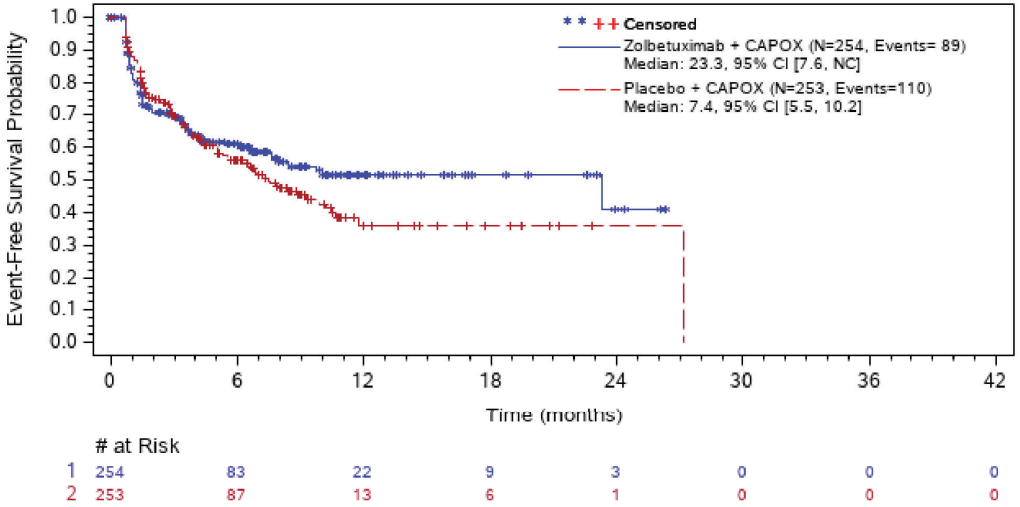
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.21: 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.

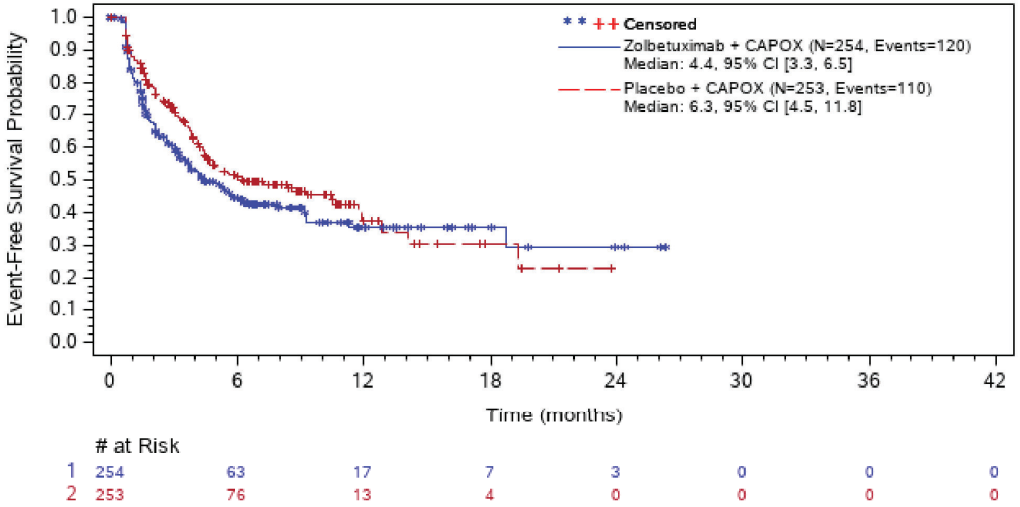
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.22: 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.

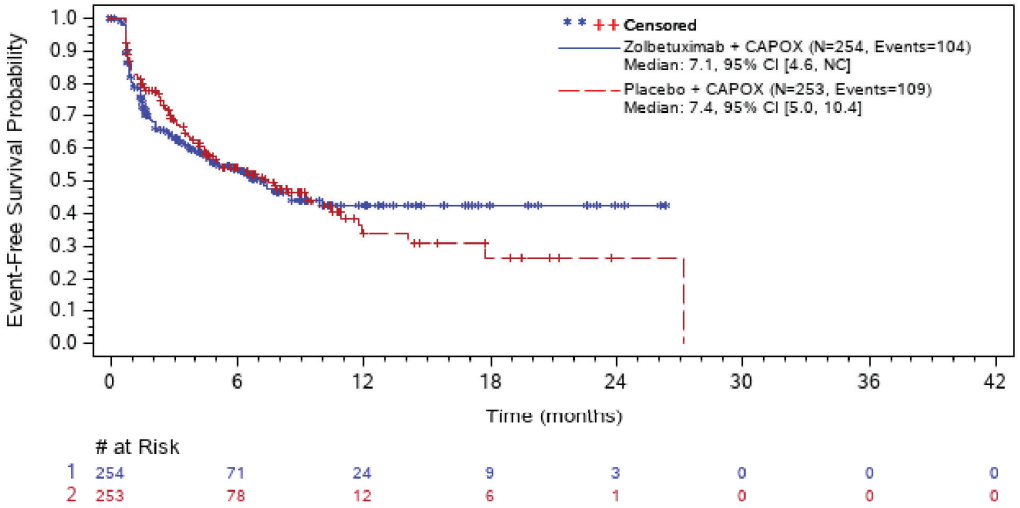
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.23: 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.

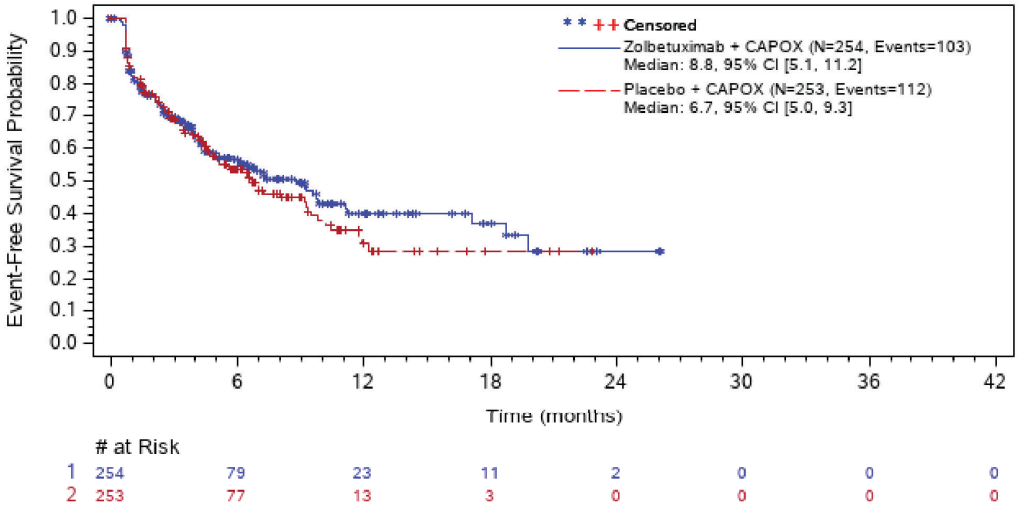
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.24: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Pain and Discomfort (MID=10) - Full Analysis Set



at Risk

1	254	79	23	11	2	0	0	0
2	253	77	13	3	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.

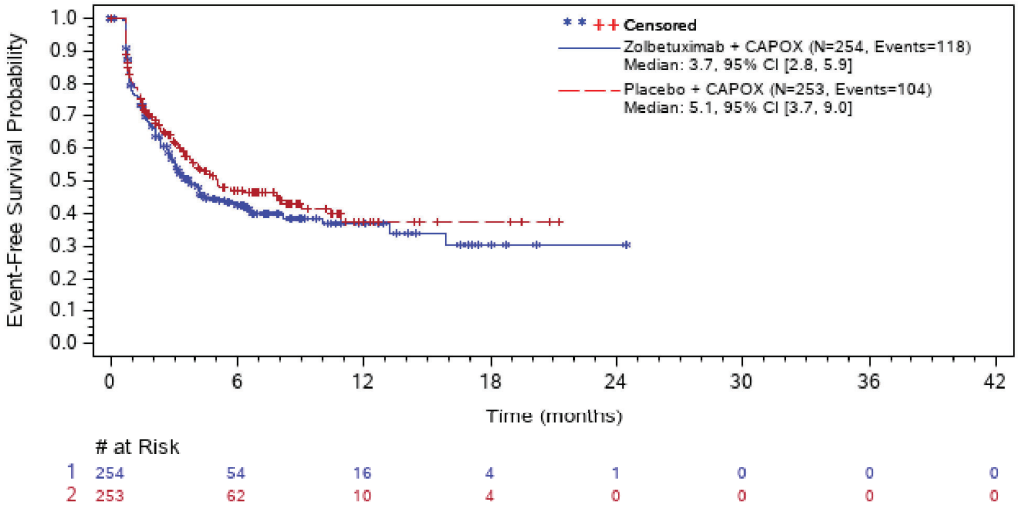
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.25: 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.

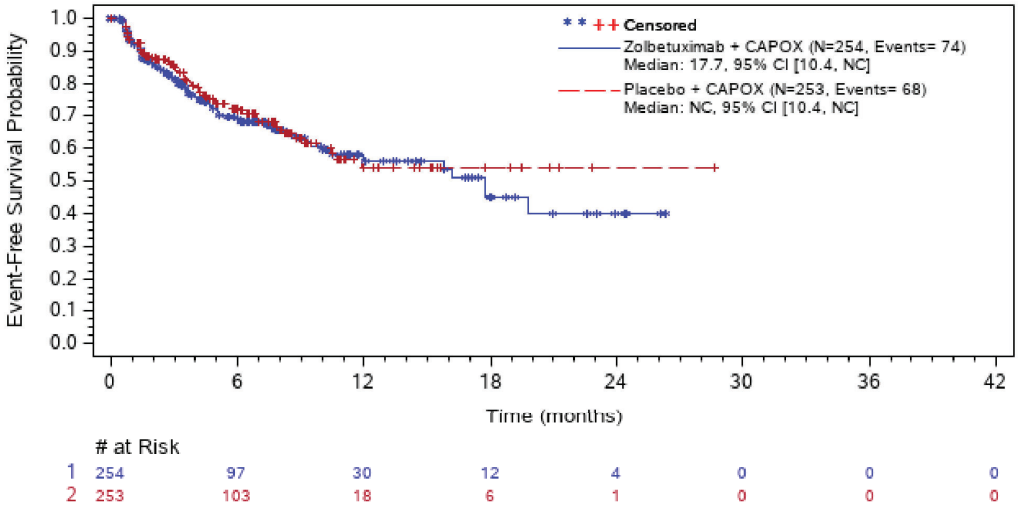
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.26: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Eating in Front of Others (MID=10) - Full Analysis Set



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.

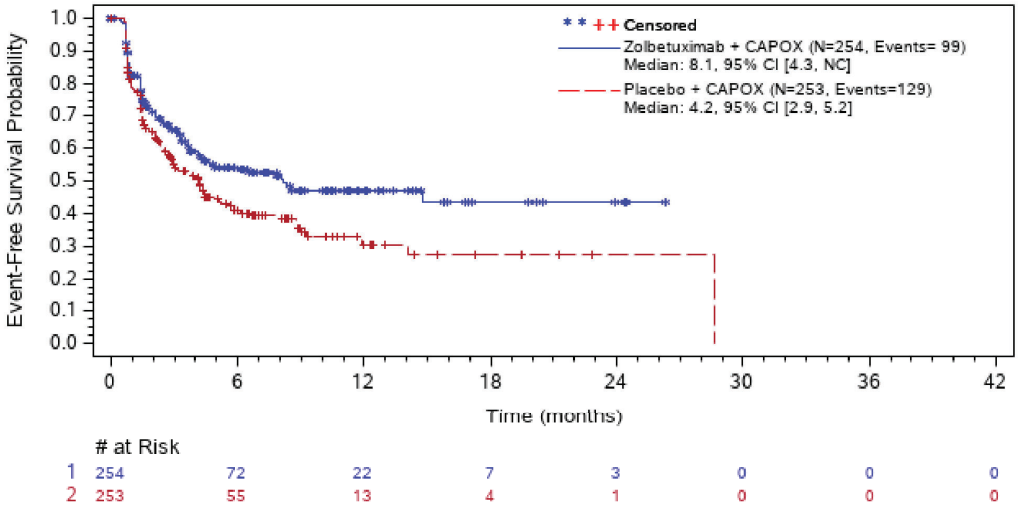
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.27: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dry Mouth Score (MID=10) - Full Analysis Set



# at Risk								
1	254	72	22	7	3	0	0	0
2	253	55	13	4	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.

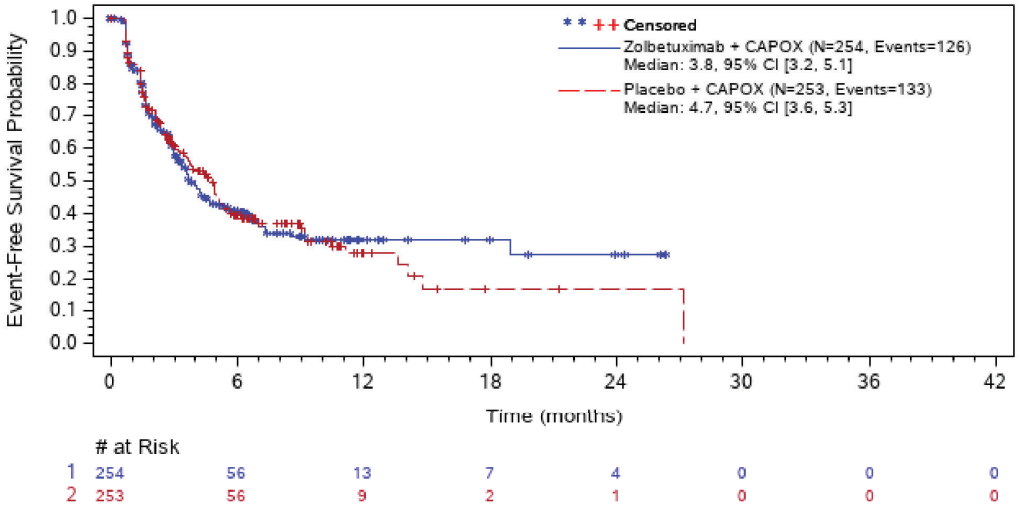
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.28: 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.

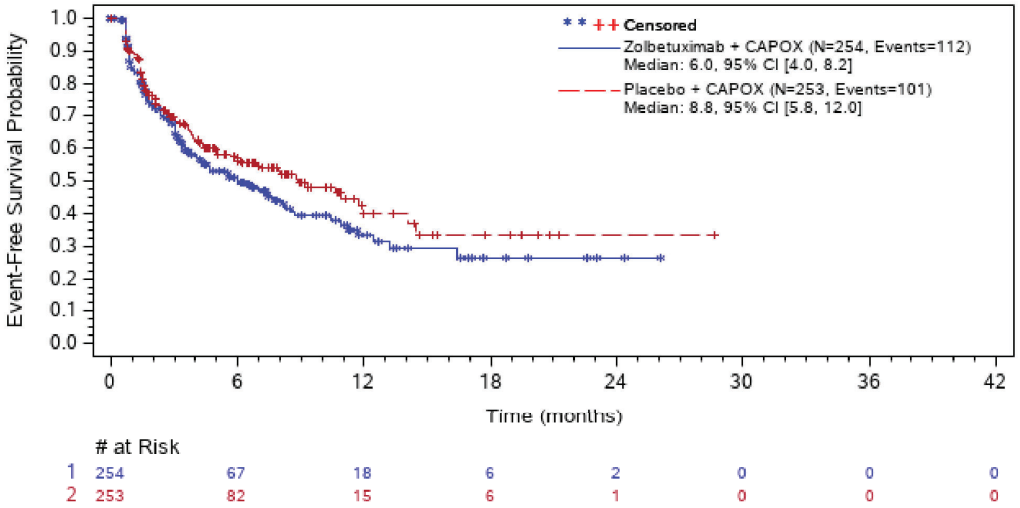
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.29: 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.

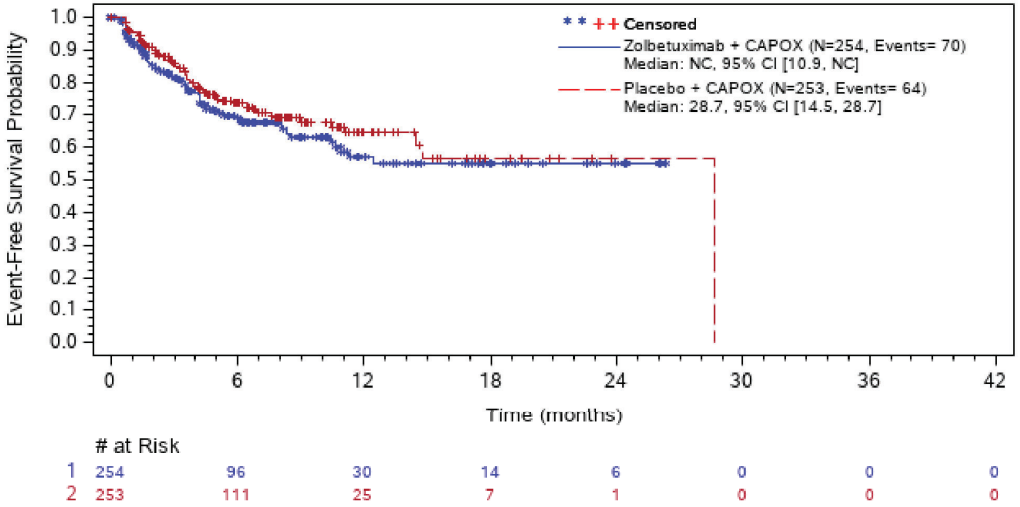
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.30: 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.

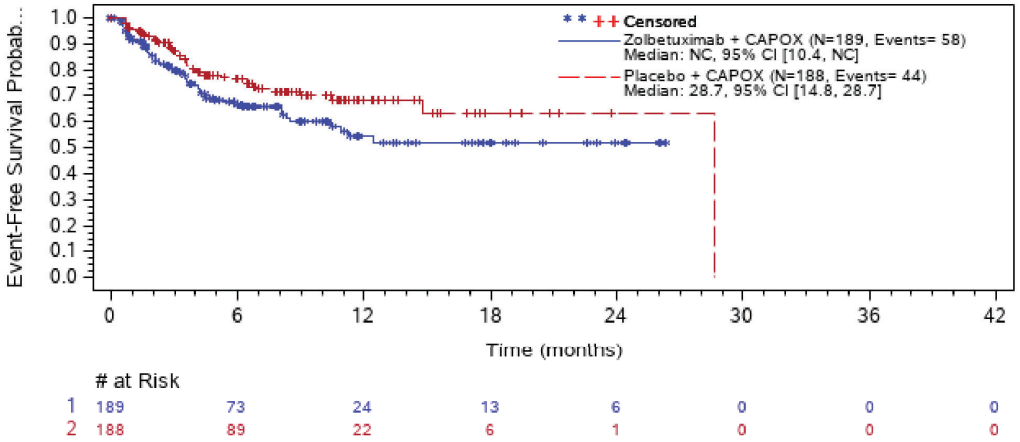
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 07OCT22

The SAS System

Figure 302.1.3004.30.4: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites (MID=10) - Full Analysis Set

Number of Organs with Metastatic Sites: 0-2



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.

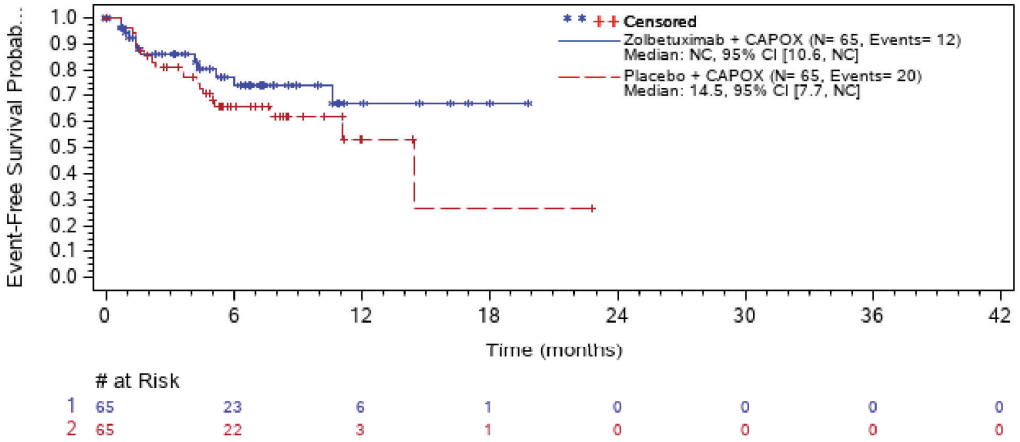
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 07OCT22

The SAS System

Figure 302.1.3004.30.4: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites (MID=10) - Full Analysis Set

Number of Organs with Metastatic Sites: >=3



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.

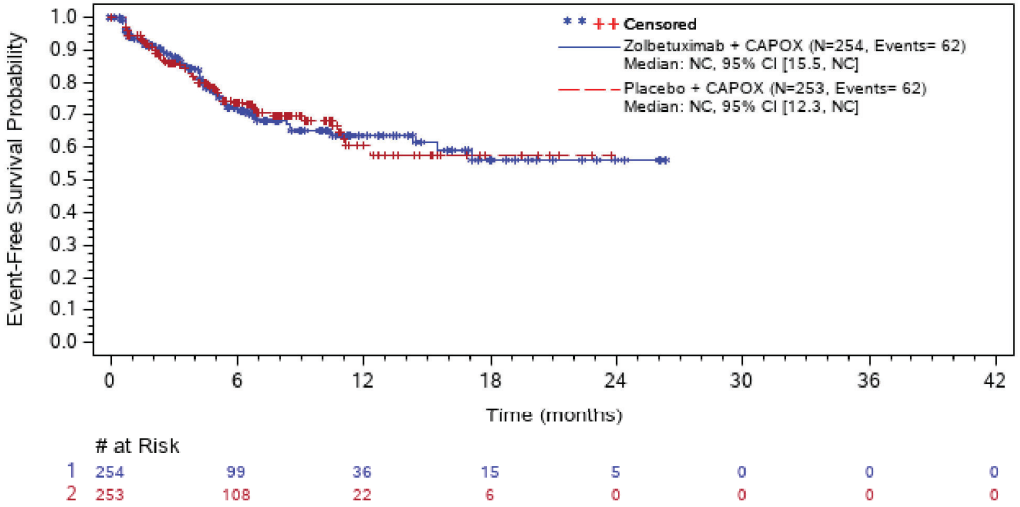
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.31: 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.

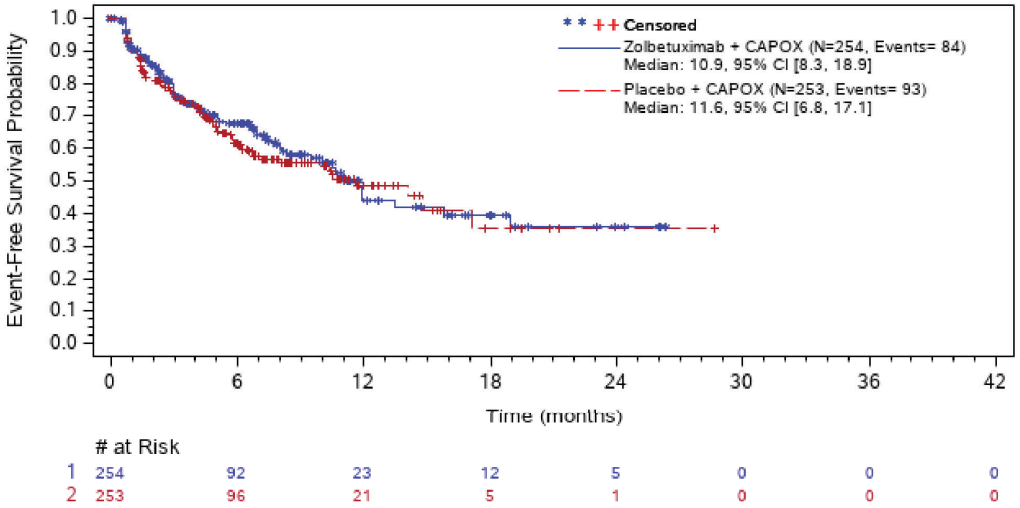
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.32: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble with Coughing (MID=10) - Full Analysis Set



# at Risk								
1	254	92	23	12	5	0	0	0
2	253	96	21	5	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.

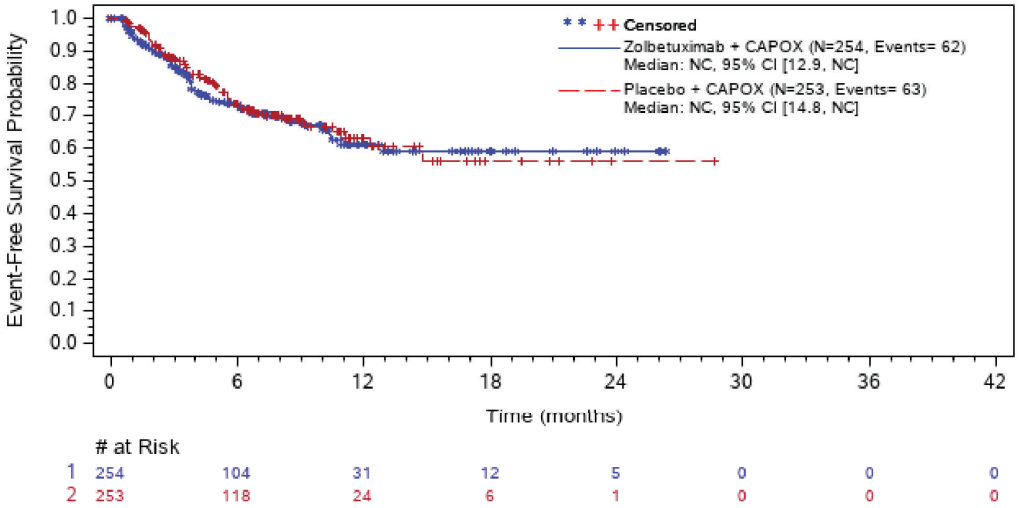
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.33: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Talking (MID=10) - Full Analysis Set



# at Risk								
1	254	104	31	12	5	0	0	0
2	253	118	24	6	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.

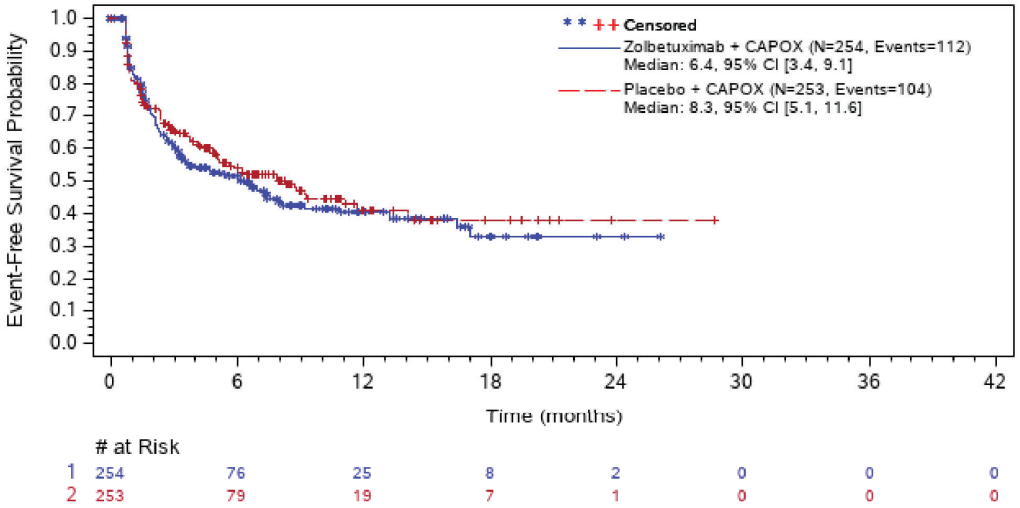
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.34: 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.

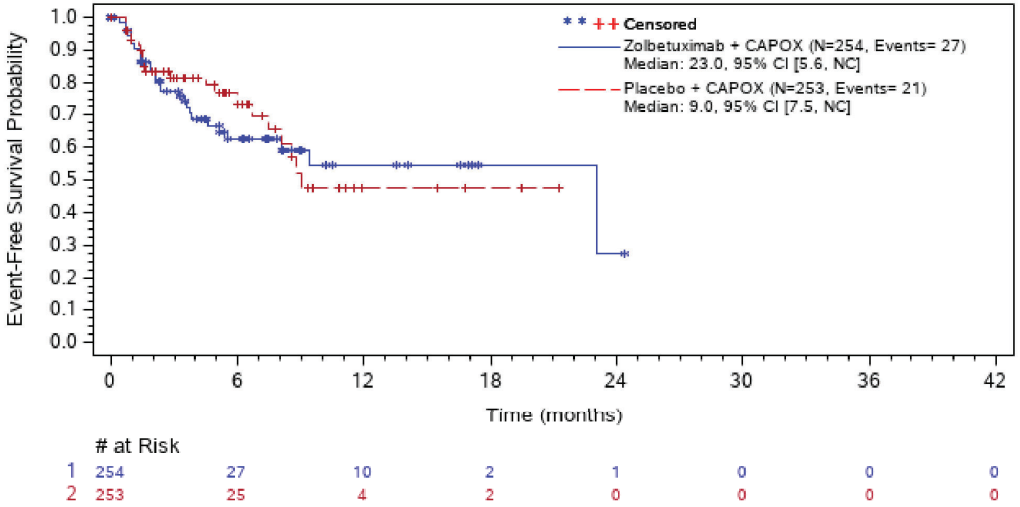
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 07OCT22

The SAS System

Figure 302.1.3004.35: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022

Anhang 4-G1 Patientenberichtete Endpunkte

Anhang 4-G1 Symptomatik anhand des EORTC QLQ-STO22 (Belching subscale)

1. Rücklaufquoten

Table 302.1.3001.36: EORTC QLQ-STO22 - Completion Status of Belching - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/223 (83.0%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/202 (59.9%)	121/254 (47.6%)	125/141 (88.7%)	126/220 (57.3%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/199 (56.8%)	114/254 (44.9%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; 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: 07OCT22

Table 302.1.3001.36: EORTC QLQ-STO22 - Completion Status of Belching - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	128/198 (64.6%)	128/228 (56.1%)	128/254 (50.4%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-STO22 (Belching subscale)

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

Table 302.1.3002.36: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Belching - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + CAPOX (N=254)												
Baseline	242	12.12	18.66	0.0	0.00	83.3						
Cycle 2 Day 1	209	10.37	15.12	0.0	0.00	83.3	208	-1.52	15.68	-66.7	0.00	50.0
Cycle 3 Day 1	186	12.19	17.95	0.0	0.00	100.0	182	0.92	17.84	-66.7	0.00	100.0
Cycle 4 Day 1	169	11.54	15.21	0.0	0.00	66.7	166	0.20	16.51	-66.7	0.00	50.0
Cycle 5 Day 1	162	12.45	17.85	0.0	0.00	100.0	159	1.68	17.81	-66.7	0.00	66.7
Cycle 6 Day 1	151	11.70	16.75	0.0	0.00	83.3	149	0.00	16.67	-66.7	0.00	33.3
Cycle 7 Day 1	121	10.47	14.45	0.0	0.00	50.0	119	0.28	17.36	-66.7	0.00	33.3
Cycle 8 Day 1	114	13.30	19.98	0.0	0.00	83.3	108	1.54	20.95	-66.7	0.00	66.7
Cycle 9 Day 1	107	12.93	19.60	0.0	0.00	83.3	102	1.31	18.27	-66.7	0.00	50.0
Cycle 10 Day 1	88	10.98	18.55	0.0	0.00	83.3	85	0.39	18.54	-50.0	0.00	66.7
Cycle 11 Day 1	82	8.54	15.55	0.0	0.00	66.7	79	-2.11	17.37	-66.7	0.00	33.3
Cycle 12 Day 1	76	7.68	13.46	0.0	0.00	50.0	74	-1.80	16.22	-66.7	0.00	33.3
Cycle 13 Day 1	62	9.41	16.15	0.0	0.00	66.7	60	-0.28	20.00	-66.7	0.00	50.0
Cycle 14 Day 1	56	8.04	13.48	0.0	0.00	50.0	54	0.00	17.44	-66.7	0.00	33.3
Cycle 15 Day 1	51	7.84	14.28	0.0	0.00	50.0	49	-1.02	16.81	-66.7	0.00	33.3
Cycle 16 Day 1	46	7.97	13.02	0.0	0.00	50.0	44	-1.14	18.11	-66.7	0.00	33.3
Cycle 17 Day 1	41	7.72	12.96	0.0	0.00	50.0	39	-1.71	19.04	-66.7	0.00	33.3
Cycle 18 Day 1	37	9.46	16.92	0.0	0.00	66.7	35	-0.95	17.59	-66.7	0.00	33.3
Cycle 19 Day 1	37	10.36	17.72	0.0	0.00	83.3	35	0.95	16.14	-50.0	0.00	33.3
Cycle 20 Day 1	35	11.90	18.33	0.0	0.00	83.3	33	2.53	18.22	-66.7	0.00	33.3
Cycle 21 Day 1	32	8.85	17.95	0.0	0.00	83.3	30	0.00	13.84	-50.0	0.00	16.7
Cycle 22 Day 1	30	7.78	12.93	0.0	0.00	50.0	28	0.60	17.85	-66.7	0.00	33.3
Cycle 23 Day 1	28	4.76	10.98	0.0	0.00	50.0	26	-2.56	16.12	-66.7	0.00	16.7
Cycle 24 Day 1	25	8.67	14.53	0.0	0.00	50.0	23	1.45	16.60	-50.0	0.00	33.3
Cycle 25 Day 1	23	7.97	14.97	0.0	0.00	50.0	21	0.00	19.72	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3002.36: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Belching - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 26 Day 1	22	10.61	15.89	0.0	0.00	50.0	20	3.33	17.61	-33.3	0.00	33.3
Cycle 27 Day 1	20	8.33	14.81	0.0	0.00	50.0	18	0.00	15.12	-33.3	0.00	33.3
Cycle 28 Day 1	11	7.58	15.57	0.0	0.00	50.0	9	0.00	14.43	-33.3	0.00	16.7
Cycle 29 Day 1	12	6.94	13.22	0.0	0.00	33.3	10	0.00	17.57	-33.3	0.00	33.3
Study Disc 1	124	12.50	21.42	0.0	0.00	100.0	122	2.05	20.73	-66.7	0.00	66.7
30 D SFU Z/P	52	15.06	23.16	0.0	0.00	100.0	51	4.58	21.62	-50.0	0.00	100.0
90 D SFU Z/P	48	6.60	10.73	0.0	0.00	33.3	47	-1.42	15.08	-50.0	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	241	14.11	21.01	0.0	0.00	100.0						
Cycle 2 Day 1	222	10.44	15.04	0.0	0.00	100.0	216	-3.09	14.93	-66.7	0.00	33.3
Cycle 3 Day 1	200	10.75	15.93	0.0	0.00	83.3	196	-1.87	16.94	-83.3	0.00	83.3
Cycle 4 Day 1	171	9.75	13.97	0.0	0.00	66.7	169	-3.16	18.81	-83.3	0.00	33.3
Cycle 5 Day 1	166	8.33	13.70	0.0	0.00	66.7	165	-5.35	18.59	-83.3	0.00	33.3
Cycle 6 Day 1	146	10.05	15.72	0.0	0.00	66.7	145	-4.02	20.53	-66.7	0.00	50.0
Cycle 7 Day 1	126	9.79	14.65	0.0	0.00	66.7	125	-5.07	20.66	-83.3	0.00	50.0
Cycle 8 Day 1	110	9.24	16.06	0.0	0.00	66.7	109	-5.05	21.46	-83.3	0.00	66.7
Cycle 9 Day 1	104	5.77	11.79	0.0	0.00	50.0	103	-9.39	20.44	-83.3	0.00	33.3
Cycle 10 Day 1	81	6.79	13.12	0.0	0.00	50.0	79	-7.38	19.93	-83.3	0.00	33.3
Cycle 11 Day 1	72	5.32	10.77	0.0	0.00	50.0	71	-9.62	21.21	-83.3	0.00	33.3
Cycle 12 Day 1	59	6.78	13.53	0.0	0.00	66.7	57	-7.60	18.65	-83.3	0.00	33.3
Cycle 13 Day 1	47	7.09	16.57	0.0	0.00	100.0	45	-6.67	22.02	-100.0	0.00	16.7
Cycle 14 Day 1	44	7.58	14.58	0.0	0.00	66.7	42	-4.76	20.26	-100.0	0.00	33.3
Cycle 15 Day 1	36	7.87	15.16	0.0	0.00	66.7	34	-3.92	18.83	-83.3	0.00	33.3
Cycle 16 Day 1	32	7.29	14.00	0.0	0.00	50.0	30	-5.00	21.95	-83.3	0.00	33.3
Cycle 17 Day 1	26	3.85	8.57	0.0	0.00	33.3	24	-4.17	22.12	-100.0	0.00	16.7
Cycle 18 Day 1	21	8.73	13.56	0.0	0.00	33.3	20	-1.67	26.98	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3002.36: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Belching - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 19 Day 1	20	4.17	9.17	0.0	0.00	33.3	19	-0.88	8.74	-16.7	0.00	16.7
Cycle 20 Day 1	17	3.92	7.29	0.0	0.00	16.7	16	-6.25	21.84	-83.3	0.00	16.7
Cycle 21 Day 1	18	5.56	9.90	0.0	0.00	33.3	17	-3.92	23.96	-83.3	0.00	33.3
Cycle 22 Day 1	15	7.78	17.67	0.0	0.00	66.7	14	-3.57	30.08	-83.3	0.00	66.7
Cycle 23 Day 1	12	2.78	6.49	0.0	0.00	16.7	11	-9.09	26.21	-83.3	0.00	16.7
Study Disc 1	149	13.42	20.93	0.0	0.00	100.0	144	0.93	24.12	-66.7	0.00	100.0
30 D SFU Z/P	74	12.16	19.56	0.0	0.00	100.0	72	-0.93	16.04	-50.0	0.00	33.3
90 D SFU Z/P	70	9.29	17.64	0.0	0.00	100.0	68	-1.23	16.11	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-STO22 (Belching subscale)

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

Table 302.1.3004.36.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Belching (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	119 (46.9%)	112 (44.3%)	
Number of patients censored	135 (53.1%)	141 (55.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.3 [3.4, 6.5]	7.7 [4.4, 9.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.239 [0.952, 1.612]
Log-rank test			
Two-sided stratified log-rank p-value			0.1048

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; HR=hazard ratio; MID=minimally important difference; N=number of patients.
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: 07OCT22

Table 302.1.3004.36.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Belching by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	86 (48.9)	4.8 [3.5, 7.3]	180	82 (45.6)	7.0 [4.4, 10.4]	1.155 [0.853, 1.564]	0.3402	0.6146
>65 years	78	33 (42.3)	3.8 [2.3, NC]	73	30 (41.1)	9.2 [2.8, NC]	1.306 [0.791, 2.156]	0.2975	
Sex									
Male	159	81 (50.9)	4.3 [3.2, 5.6]	156	74 (47.4)	4.7 [3.0, 9.2]	1.123 [0.819, 1.540]	0.4613	0.6350
Female	95	38 (40.0)	7.4 [3.3, 22.9]	97	38 (39.2)	9.2 [5.7, NC]	1.245 [0.790, 1.963]	0.3403	
Region									
Asia	157	81 (51.6)	4.2 [3.0, 5.6]	158	67 (42.4)	8.8 [4.4, NC]	1.376 [0.994, 1.903]	0.0509	0.1601
Non-Asia	97	38 (39.2)	6.1 [3.6, 10.4]	95	45 (47.4)	7.0 [3.0, 9.2]	0.945 [0.613, 1.458]	0.8066	
Number of Organs with Metastatic Sites									
0-2	189	92 (48.7)	4.8 [3.3, 7.3]	188	85 (45.2)	7.5 [4.2, 10.4]	1.230 [0.915, 1.653]	0.1645	0.6603
>=3	65	27 (41.5)	4.2 [3.2, NC]	65	27 (41.5)	7.7 [2.2, NC]	1.070 [0.627, 1.827]	0.8078	

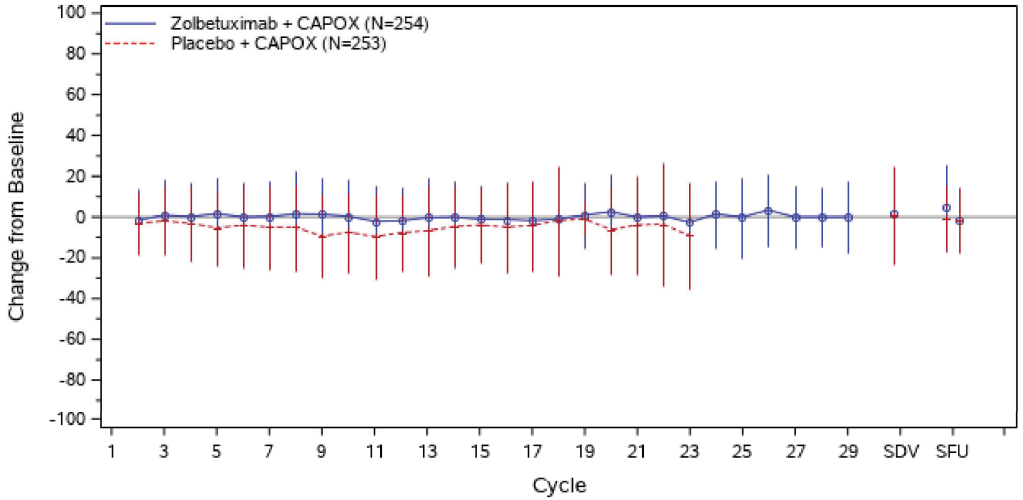
Abbreviations: CI=confidence interval; EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event.
Note: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-STO22 (Belching subscale)

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

The SAS System

Figure 302.1.3002.36: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Belching - Full Analysis Set



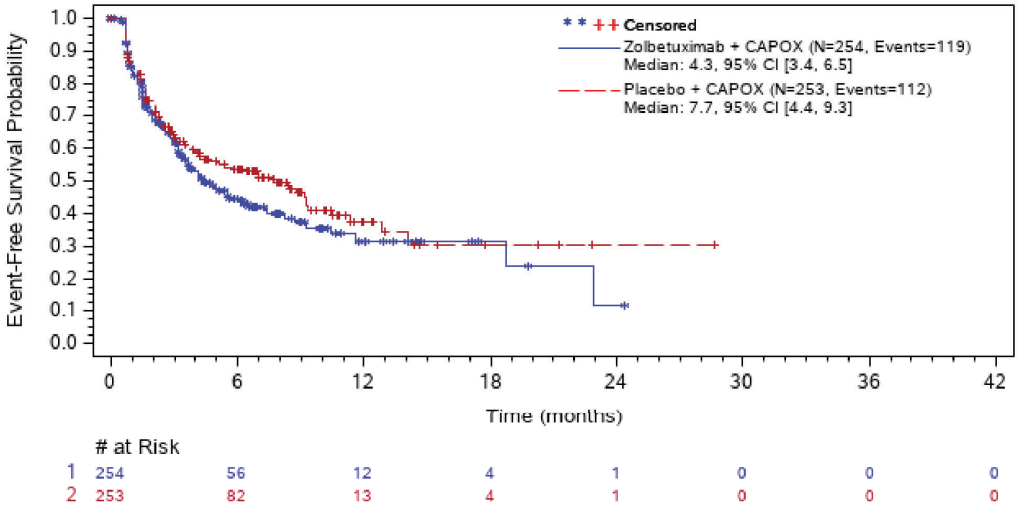
Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-STO22 (Belching subscale)

5. Kaplan-Meier-Plots

The SAS System

Figure 302.1.3004.36: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Belching (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; MID=minimally important difference; 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022

Anhang 4-G1 Patientenberichtete Endpunkte

Anhang 4-G1 Schmerzintensität anhand der NRS

1. Rücklaufquoten

Table 302.1.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	236/250 (94.4%)	236/252 (93.7%)	236/253 (93.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/236 (88.6%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	179/197 (90.9%)	183/223 (82.1%)	184/254 (72.4%)	198/215 (92.1%)	198/232 (85.3%)	198/253 (78.3%)
Cycle 4 Day 1	165/182 (90.7%)	169/220 (76.8%)	169/254 (66.5%)	169/192 (88.0%)	171/229 (74.7%)	171/253 (67.6%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	166/181 (91.7%)	166/228 (72.8%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	146/165 (88.5%)	146/222 (65.8%)	146/253 (57.7%)
Cycle 7 Day 1	109/128 (85.2%)	118/202 (58.4%)	118/254 (46.5%)	124/141 (87.9%)	125/220 (56.8%)	125/253 (49.4%)
Cycle 8 Day 1	107/119 (89.9%)	111/199 (55.8%)	112/254 (44.1%)	109/125 (87.2%)	110/220 (50.0%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 89 (93.3%)	88/192 (45.8%)	88/254 (34.6%)	78/ 91 (85.7%)	80/216 (37.0%)	80/253 (31.6%)
Cycle 11 Day 1	78/ 83 (94.0%)	82/191 (42.9%)	82/254 (32.3%)	70/ 78 (89.7%)	71/215 (33.0%)	71/253 (28.1%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	56/191 (29.3%)	56/254 (22.0%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

Abbreviations: 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: 07OCT22

Table 302.1.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	127/198 (64.1%)	127/228 (55.7%)	127/254 (50.0%)	154/213 (72.3%)	154/231 (66.7%)	154/253 (60.9%)
30 D SFU Z/P	52/187 (27.8%)	52/220 (23.6%)	52/254 (20.5%)	74/201 (36.8%)	74/219 (33.8%)	74/253 (29.2%)
90 D SFU Z/P	48/166 (28.9%)	48/205 (23.4%)	48/254 (18.9%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

Abbreviations: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Schmerzintensität anhand der NRS

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

Table 302.1.3002.4: 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 + CAPOX (N=254)												
Baseline	242	2.44	2.49	0.0	2.00	10.0						
Cycle 2 Day 1	209	1.81	2.18	0.0	1.00	10.0	208	-0.60	2.61	-8.0	0.00	7.0
Cycle 3 Day 1	184	1.61	2.30	0.0	1.00	9.0	180	-0.74	2.30	-8.0	0.00	8.0
Cycle 4 Day 1	169	1.78	2.42	0.0	1.00	9.0	166	-0.63	2.58	-8.0	0.00	6.0
Cycle 5 Day 1	162	1.85	2.59	0.0	0.50	10.0	159	-0.37	2.89	-8.0	0.00	9.0
Cycle 6 Day 1	151	1.83	2.45	0.0	1.00	10.0	149	-0.51	2.61	-7.0	0.00	9.0
Cycle 7 Day 1	118	1.67	2.36	0.0	1.00	9.0	117	-0.61	2.65	-7.0	0.00	9.0
Cycle 8 Day 1	112	1.75	2.36	0.0	1.00	10.0	106	-0.59	2.45	-9.0	0.00	8.0
Cycle 9 Day 1	107	1.76	2.33	0.0	1.00	9.0	102	-0.65	2.62	-9.0	0.00	8.0
Cycle 10 Day 1	88	1.56	2.43	0.0	0.00	10.0	85	-0.71	2.67	-9.0	0.00	10.0
Cycle 11 Day 1	82	1.74	2.52	0.0	1.00	10.0	79	-0.41	2.98	-9.0	0.00	10.0
Cycle 12 Day 1	76	2.17	2.88	0.0	1.00	10.0	74	0.08	2.93	-9.0	0.00	10.0
Cycle 13 Day 1	62	2.10	2.86	0.0	0.00	9.0	60	0.05	3.40	-9.0	0.00	8.0
Cycle 14 Day 1	56	1.05	1.90	0.0	0.00	7.0	54	-0.96	2.66	-9.0	0.00	5.0
Cycle 15 Day 1	51	1.24	1.95	0.0	0.00	9.0	49	-0.82	2.67	-8.0	0.00	6.0
Cycle 16 Day 1	46	2.09	2.70	0.0	0.50	9.0	44	-0.02	3.09	-8.0	0.00	6.0
Cycle 17 Day 1	41	1.34	1.88	0.0	0.00	6.0	39	-0.62	2.34	-6.0	0.00	4.0
Cycle 18 Day 1	37	2.38	2.77	0.0	1.00	8.0	35	0.46	3.32	-6.0	0.00	8.0
Cycle 19 Day 1	37	1.68	2.17	0.0	0.00	8.0	35	0.00	2.34	-6.0	0.00	5.0
Cycle 20 Day 1	35	1.86	2.34	0.0	1.00	8.0	33	0.24	2.53	-5.0	0.00	7.0
Cycle 21 Day 1	32	1.81	2.71	0.0	0.00	9.0	30	0.20	2.72	-6.0	0.00	7.0
Cycle 22 Day 1	30	1.77	2.62	0.0	0.00	8.0	28	0.29	2.61	-5.0	0.00	7.0
Cycle 23 Day 1	28	1.14	1.98	0.0	0.00	6.0	26	-0.15	2.33	-5.0	0.00	5.0
Cycle 24 Day 1	25	1.40	2.53	0.0	0.00	9.0	23	0.17	3.20	-5.0	0.00	8.0
Cycle 25 Day 1	23	0.61	1.27	0.0	0.00	5.0	21	-0.57	1.60	-5.0	0.00	2.0

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: 07OCT22

Table 302.1.3002.4: 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 26 Day 1	22	0.82	1.30	0.0	0.00	5.0	20	-0.60	1.64	-4.0	0.00	2.0
Cycle 27 Day 1	20	0.50	1.10	0.0	0.00	4.0	18	-0.78	1.59	-5.0	0.00	1.0
Cycle 28 Day 1	11	0.36	0.50	0.0	0.00	1.0	9	-0.33	1.22	-3.0	0.00	1.0
Cycle 29 Day 1	12	0.42	0.79	0.0	0.00	2.0	10	-0.20	1.32	-3.0	0.00	2.0
Study Disc 1	123	2.92	2.81	0.0	2.00	10.0	122	0.58	3.17	-8.0	0.00	10.0
30 D SFU Z/P	52	2.81	3.21	0.0	2.00	10.0	51	0.55	3.24	-8.0	0.00	8.0
90 D SFU Z/P	48	2.40	3.30	0.0	1.00	10.0	47	0.38	3.46	-8.0	0.00	9.0
Placebo + CAPOX (N=253)												
Baseline	236	2.64	2.55	0.0	2.00	10.0						
Cycle 2 Day 1	222	1.92	2.23	0.0	1.00	10.0	211	-0.63	2.59	-10.0	0.00	9.0
Cycle 3 Day 1	198	1.73	2.34	0.0	1.00	10.0	190	-0.82	2.33	-10.0	0.00	10.0
Cycle 4 Day 1	171	1.67	2.27	0.0	0.00	9.0	167	-0.91	2.68	-10.0	-1.00	9.0
Cycle 5 Day 1	166	1.71	2.41	0.0	1.00	9.0	164	-0.79	2.84	-10.0	0.00	9.0
Cycle 6 Day 1	146	1.88	2.62	0.0	1.00	10.0	143	-0.57	3.00	-10.0	0.00	9.0
Cycle 7 Day 1	125	1.78	2.28	0.0	1.00	10.0	122	-0.38	2.74	-8.0	0.00	10.0
Cycle 8 Day 1	110	1.94	2.59	0.0	1.00	10.0	109	-0.36	2.48	-6.0	0.00	9.0
Cycle 9 Day 1	104	1.86	2.57	0.0	1.00	10.0	103	-0.36	2.63	-7.0	0.00	10.0
Cycle 10 Day 1	80	1.45	2.01	0.0	0.00	7.0	78	-0.71	2.65	-7.0	-0.50	7.0
Cycle 11 Day 1	71	1.39	1.96	0.0	0.00	8.0	70	-0.61	2.55	-7.0	0.00	8.0
Cycle 12 Day 1	59	1.19	1.85	0.0	0.00	8.0	57	-0.53	2.41	-7.0	0.00	8.0
Cycle 13 Day 1	47	1.34	2.01	0.0	0.00	8.0	45	-0.60	2.48	-7.0	0.00	8.0
Cycle 14 Day 1	44	1.43	2.39	0.0	0.00	8.0	42	-0.36	2.13	-7.0	0.00	6.0
Cycle 15 Day 1	36	1.25	2.18	0.0	0.00	7.0	34	-0.47	1.80	-7.0	0.00	3.0
Cycle 16 Day 1	32	1.53	2.53	0.0	0.00	10.0	30	0.13	2.26	-3.0	0.00	10.0
Cycle 17 Day 1	26	0.65	1.60	0.0	0.00	7.0	24	-0.17	1.34	-4.0	0.00	3.0
Cycle 18 Day 1	21	0.48	1.17	0.0	0.00	5.0	20	-0.35	1.18	-4.0	0.00	2.0

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: 07OCT22

Table 302.1.3002.4: 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 19 Day 1	20	0.40	0.75	0.0	0.00	3.0	19	-0.11	0.74	-2.0	0.00	1.0
Cycle 20 Day 1	17	1.24	2.70	0.0	0.00	10.0	16	0.25	3.02	-5.0	0.00	10.0
Cycle 21 Day 1	18	1.33	2.87	0.0	0.00	9.0	17	0.41	3.22	-4.0	0.00	9.0
Cycle 22 Day 1	15	0.80	2.31	0.0	0.00	9.0	14	-0.29	3.15	-5.0	0.00	9.0
Cycle 23 Day 1	12	1.58	3.06	0.0	0.00	9.0	11	0.64	3.75	-5.0	0.00	9.0
Study Disc 1	149	3.46	2.95	0.0	3.00	10.0	141	0.75	3.07	-10.0	0.00	10.0
30 D SFU Z/P	74	2.93	2.97	0.0	2.00	9.0	70	0.50	2.63	-7.0	0.00	9.0
90 D SFU Z/P	70	2.87	3.08	0.0	1.50	10.0	66	0.58	2.79	-7.0	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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Schmerzintensität anhand der NRS

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

Table 302.1.3004.4.1: Global Pain - Summary of Time to First Deterioration of PI01 - Pain Intensity (MID=2) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	120 (47.2%)	115 (45.5%)	
Number of patients censored	134 (52.8%)	138 (54.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.6 [4.6, 8.8]	7.2 [5.2, 10.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.039 [0.800, 1.349]
Log-rank test			
Two-sided stratified log-rank p-value			0.7632

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: 07OCT22

Table 302.1.3004.4.2: Global Pain - Summary of Time to First Deterioration of PI01 - Pain Intensity by Subgroups (MID=2) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	86 (48.9)	6.0 [3.8, 8.1]	180	86 (47.8)	6.5 [4.4, 9.2]	1.044 [0.773, 1.408]	0.7690	0.9029
>65 years	78	34 (43.6)	9.2 [5.1, 13.2]	73	29 (39.7)	10.9 [4.4, 15.2]	1.078 [0.651, 1.785]	0.7761	
Sex									
Male	159	76 (47.8)	6.6 [4.1, 8.4]	156	69 (44.2)	6.4 [4.4, 10.9]	1.067 [0.769, 1.479]	0.6964	0.8896
Female	95	44 (46.3)	8.3 [4.6, 10.8]	97	46 (47.4)	7.9 [4.4, 10.2]	0.972 [0.637, 1.483]	0.8971	
Region									
Asia	157	82 (52.2)	6.6 [4.2, 8.8]	158	73 (46.2)	6.5 [4.4, 10.2]	1.105 [0.804, 1.520]	0.5380	0.6099
Non-Asia	97	38 (39.2)	6.7 [4.1, 22.2]	95	42 (44.2)	7.9 [4.4, 11.5]	0.940 [0.605, 1.462]	0.7966	
Number of Organs with Metastatic Sites									
0-2	189	87 (46.0)	7.4 [5.0, 10.2]	188	88 (46.8)	7.2 [4.8, 10.9]	0.988 [0.733, 1.332]	0.9440	0.3770
>=3	65	33 (50.8)	4.8 [3.4, 8.8]	65	27 (41.5)	7.8 [3.7, 15.7]	1.233 [0.738, 2.060]	0.4246	

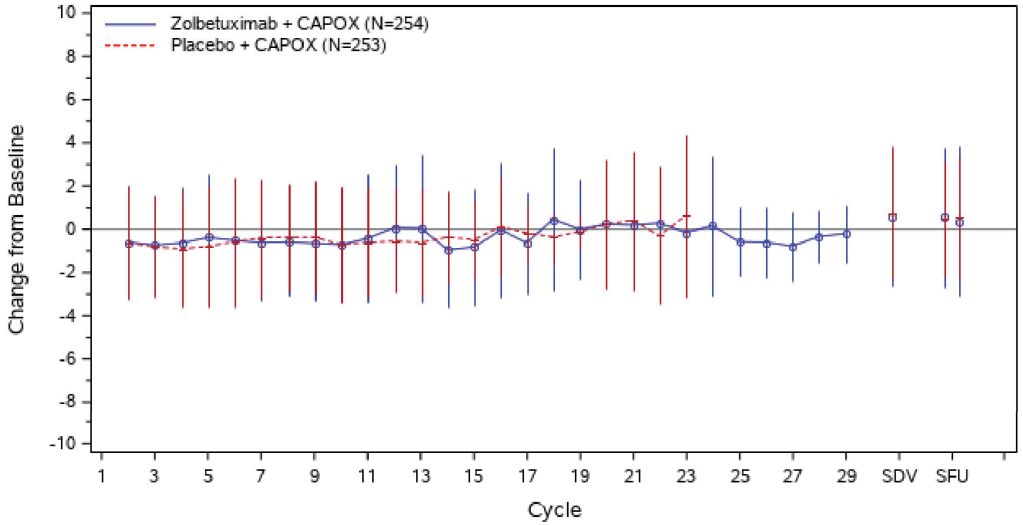
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Schmerzintensität anhand der NRS

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

The SAS System

Figure 302.1.3002.4: Global Pain(GP) - Plot of Mean Change from Baseline of PI01 - Pain Intensity - Full Analysis Set



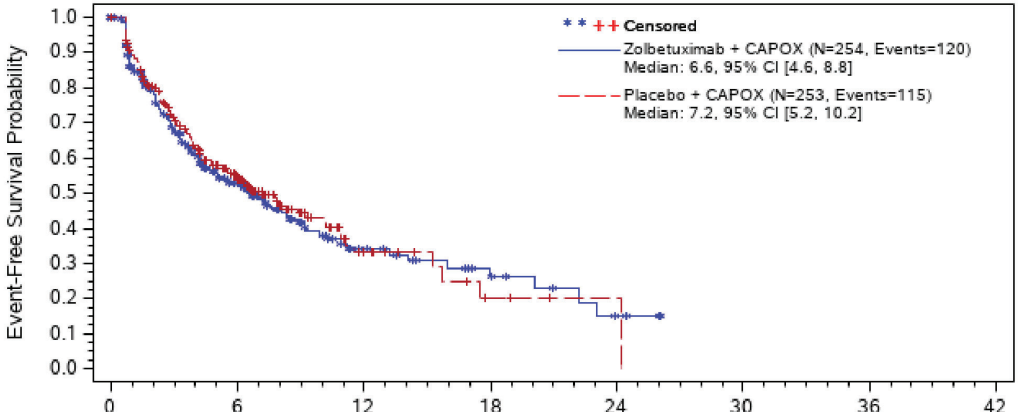
Abbreviations: N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Schmerzintensität anhand der NRS

5. Kaplan-Meier-Plots

The SAS System

Figure 302.1.3004.4: Global Pain - Kaplan-Meier Plot of Time to First Deterioration of PI01 - Pain Intensity (MID=2) - Full Analysis Set



at Risk

1	254	77	22	10	3	0	0	0
2	253	85	14	3	1	0	0	0

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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022

Anhang 4-G1 Patientenberichtete Endpunkte

Anhang 4-G1 EQ-5D VAS

1. Rücklaufquoten

Table 302.1.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	242/253 (95.7%)	242/253 (95.7%)	242/254 (95.3%)	243/250 (97.2%)	243/252 (96.4%)	243/253 (96.0%)
Cycle 2 Day 1	209/224 (93.3%)	210/236 (89.0%)	210/254 (82.7%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	183/197 (92.9%)	187/223 (83.9%)	188/254 (74.0%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/220 (78.2%)	172/254 (67.7%)	170/192 (88.5%)	172/229 (75.1%)	172/253 (68.0%)
Cycle 5 Day 1	157/172 (91.3%)	160/215 (74.4%)	162/254 (63.8%)	167/181 (92.3%)	167/228 (73.2%)	167/253 (66.0%)
Cycle 6 Day 1	144/155 (92.9%)	150/208 (72.1%)	151/254 (59.4%)	147/165 (89.1%)	147/222 (66.2%)	147/253 (58.1%)
Cycle 7 Day 1	114/128 (89.1%)	123/202 (60.9%)	123/254 (48.4%)	126/141 (89.4%)	127/220 (57.7%)	127/253 (50.2%)
Cycle 8 Day 1	110/119 (92.4%)	114/199 (57.3%)	115/254 (45.3%)	110/125 (88.0%)	111/220 (50.5%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/196 (54.6%)	107/254 (42.1%)	100/110 (90.9%)	103/217 (47.5%)	104/253 (41.1%)
Cycle 10 Day 1	84/ 89 (94.4%)	89/192 (46.4%)	89/254 (35.0%)	79/ 91 (86.8%)	81/216 (37.5%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 83 (95.2%)	83/191 (43.5%)	83/254 (32.7%)	71/ 78 (91.0%)	72/215 (33.5%)	72/253 (28.5%)
Cycle 12 Day 1	73/ 76 (96.1%)	76/191 (39.8%)	76/254 (29.9%)	58/ 68 (85.3%)	59/214 (27.6%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 66 (92.4%)	62/191 (32.5%)	62/254 (24.4%)	47/ 54 (87.0%)	47/213 (22.1%)	47/253 (18.6%)
Cycle 14 Day 1	56/ 58 (96.6%)	57/191 (29.8%)	57/254 (22.4%)	43/ 47 (91.5%)	44/213 (20.7%)	44/253 (17.4%)
Cycle 15 Day 1	48/ 52 (92.3%)	49/189 (25.9%)	51/254 (20.1%)	35/ 41 (85.4%)	36/211 (17.1%)	36/253 (14.2%)
Cycle 16 Day 1	44/ 45 (97.8%)	45/189 (23.8%)	46/254 (18.1%)	31/ 33 (93.9%)	32/211 (15.2%)	32/253 (12.6%)
Cycle 17 Day 1	40/ 42 (95.2%)	41/189 (21.7%)	41/254 (16.1%)	26/ 27 (96.3%)	26/210 (12.4%)	26/253 (10.3%)
Cycle 18 Day 1	36/ 38 (94.7%)	37/189 (19.6%)	37/254 (14.6%)	21/ 22 (95.5%)	21/210 (10.0%)	21/253 (8.3%)
Cycle 19 Day 1	37/ 38 (97.4%)	37/189 (19.6%)	37/254 (14.6%)	19/ 21 (90.5%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 20 Day 1	35/ 36 (97.2%)	35/188 (18.6%)	35/254 (13.8%)	17/ 19 (89.5%)	17/210 (8.1%)	17/253 (6.7%)
Cycle 21 Day 1	32/ 33 (97.0%)	32/188 (17.0%)	32/254 (12.6%)	18/ 18 (100.0%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 22 Day 1	30/ 30 (100.0%)	30/187 (16.0%)	30/254 (11.8%)	15/ 16 (93.8%)	15/210 (7.1%)	15/253 (5.9%)
Cycle 23 Day 1	28/ 29 (96.6%)	28/187 (15.0%)	28/254 (11.0%)	12/ 13 (92.3%)	12/210 (5.7%)	12/253 (4.7%)
Cycle 24 Day 1	25/ 25 (100.0%)	25/187 (13.4%)	25/254 (9.8%)	9/ 10 (90.0%)	9/210 (4.3%)	9/253 (3.6%)
Cycle 25 Day 1	23/ 24 (95.8%)	23/187 (12.3%)	23/254 (9.1%)	8/ 8 (100.0%)	8/210 (3.8%)	8/253 (3.2%)
Cycle 26 Day 1	22/ 22 (100.0%)	22/187 (11.8%)	22/254 (8.7%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)

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: 07OCT22

Table 302.1.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	18/ 18 (100.0%)	20/187 (10.7%)	20/254 (7.9%)	7/ 7 (100.0%)	7/210 (3.3%)	7/253 (2.8%)
Cycle 28 Day 1	11/ 12 (91.7%)	11/187 (5.9%)	11/254 (4.3%)	6/ 7 (85.7%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 29 Day 1	12/ 12 (100.0%)	12/187 (6.4%)	12/254 (4.7%)	6/ 6 (100.0%)	6/210 (2.9%)	6/253 (2.4%)
Cycle 30 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	3/ 3 (100.0%)	3/210 (1.4%)	3/253 (1.2%)
Cycle 31 Day 1	9/ 9 (100.0%)	9/187 (4.8%)	9/254 (3.5%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 32 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	8/ 8 (100.0%)	8/187 (4.3%)	8/254 (3.1%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 34 Day 1	6/ 6 (100.0%)	6/187 (3.2%)	6/254 (2.4%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 35 Day 1	5/ 5 (100.0%)	5/187 (2.7%)	5/254 (2.0%)	2/ 2 (100.0%)	2/210 (1.0%)	2/253 (0.8%)
Cycle 36 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 37 Day 1	3/ 3 (100.0%)	3/187 (1.6%)	3/254 (1.2%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	1/ 1 (100.0%)	1/210 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	1/ 1 (100.0%)	1/187 (0.5%)	1/254 (0.4%)	0	0/210 (0.0%)	0/253 (0.0%)
Study Disc	129/198 (65.2%)	129/228 (56.6%)	129/254 (50.8%)	157/213 (73.7%)	157/231 (68.0%)	157/253 (62.1%)
30 D SFU Z/P	53/187 (28.3%)	53/220 (24.1%)	53/254 (20.9%)	76/201 (37.8%)	76/219 (34.7%)	76/253 (30.0%)
90 D SFU Z/P	50/166 (30.1%)	50/205 (24.4%)	50/254 (19.7%)	70/160 (43.8%)	70/182 (38.5%)	70/253 (27.7%)

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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EQ-5D VAS

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

Table 302.1.3002.3: 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 + CAPOX (N=254)												
Baseline	242	71.47	19.63	0.0	77.00	100.0						
Cycle 2 Day 1	210	75.45	17.14	0.0	80.00	100.0	208	3.01	15.83	-63.0	1.00	80.0
Cycle 3 Day 1	188	74.61	17.89	1.0	79.00	100.0	183	2.17	15.19	-49.0	1.00	49.0
Cycle 4 Day 1	172	76.51	17.74	9.0	80.00	100.0	169	3.89	16.60	-52.0	2.00	97.0
Cycle 5 Day 1	162	74.07	19.01	2.0	79.00	100.0	159	1.50	17.20	-63.0	0.00	50.0
Cycle 6 Day 1	151	74.04	18.81	13.0	80.00	100.0	149	1.18	17.61	-50.0	0.00	100.0
Cycle 7 Day 1	123	77.08	16.51	4.0	80.00	100.0	121	3.21	15.60	-62.0	2.00	40.0
Cycle 8 Day 1	115	76.25	16.87	0.0	80.00	100.0	109	3.22	19.72	-50.0	0.00	100.0
Cycle 9 Day 1	107	74.31	19.46	0.0	80.00	100.0	102	0.96	17.32	-61.0	0.00	48.0
Cycle 10 Day 1	89	76.09	17.99	2.0	80.00	100.0	85	2.88	20.07	-64.0	1.00	77.0
Cycle 11 Day 1	83	73.22	18.69	5.0	75.00	100.0	80	-1.14	18.24	-61.0	0.50	42.0
Cycle 12 Day 1	76	76.14	18.63	4.0	79.50	100.0	74	1.58	18.61	-62.0	2.00	40.0
Cycle 13 Day 1	62	77.87	14.64	14.0	80.00	100.0	60	4.30	17.81	-30.0	2.00	58.0
Cycle 14 Day 1	57	77.88	16.73	1.0	80.00	100.0	55	3.96	21.95	-65.0	2.00	76.0
Cycle 15 Day 1	51	76.78	19.20	2.0	81.00	100.0	49	2.86	19.67	-64.0	1.00	58.0
Cycle 16 Day 1	46	75.83	19.02	1.0	78.50	100.0	44	2.77	18.87	-65.0	0.00	51.0
Cycle 17 Day 1	41	78.00	20.08	2.0	81.00	100.0	39	4.21	19.57	-64.0	2.00	59.0
Cycle 18 Day 1	37	81.32	11.91	59.0	80.00	100.0	35	8.09	20.99	-27.0	4.00	77.0
Cycle 19 Day 1	37	76.51	22.00	0.0	80.00	100.0	35	2.97	17.15	-47.0	0.00	33.0
Cycle 20 Day 1	35	75.91	21.69	7.0	78.00	100.0	33	2.36	21.75	-81.0	0.00	42.0
Cycle 21 Day 1	32	73.84	23.38	3.0	77.00	100.0	30	1.00	20.48	-72.0	1.00	38.0
Cycle 22 Day 1	30	78.00	20.78	8.0	82.00	100.0	28	4.82	15.33	-20.0	3.50	33.0
Cycle 23 Day 1	28	79.75	20.49	7.0	84.00	100.0	26	5.58	15.28	-20.0	4.00	34.0
Cycle 24 Day 1	25	79.96	18.55	11.0	81.00	100.0	23	6.57	16.39	-19.0	5.00	39.0
Cycle 25 Day 1	23	75.04	24.50	4.0	79.00	100.0	21	1.24	22.71	-62.0	-2.00	45.0

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;
30 D SFU 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.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3002.3: 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 26 Day 1	22	79.27	21.87	6.0	87.00	100.0	20	5.75	17.84	-33.0	7.50	36.0
Cycle 27 Day 1	20	73.75	27.33	1.0	80.00	100.0	18	1.50	23.52	-65.0	5.00	46.0
Cycle 28 Day 1	11	86.91	13.83	58.0	92.00	100.0	9	7.11	22.52	-30.0	8.00	44.0
Cycle 29 Day 1	12	89.00	10.19	69.0	93.50	100.0	10	9.40	18.02	-19.0	8.50	41.0
Study Disc 1	124	66.17	22.05	7.0	70.50	100.0	122	-7.52	22.12	-90.0	-5.00	41.0
30 D SFU Z/P	53	67.68	22.80	2.0	74.00	100.0	52	-6.44	24.05	-73.0	-3.50	40.0
90 D SFU Z/P	50	74.14	20.71	3.0	77.00	100.0	49	-5.06	20.97	-88.0	0.00	34.0
Placebo + CAPOX (N=253)												
Baseline	243	72.65	18.73	0.0	75.00	100.0						
Cycle 2 Day 1	222	75.04	17.03	0.0	80.00	100.0	218	1.67	13.60	-41.0	0.00	50.0
Cycle 3 Day 1	200	74.91	17.43	0.0	79.00	100.0	198	2.07	14.70	-40.0	0.00	53.0
Cycle 4 Day 1	172	76.45	17.33	10.0	80.00	100.0	171	3.27	18.37	-80.0	2.00	95.0
Cycle 5 Day 1	167	76.82	16.63	8.0	80.00	100.0	167	3.74	17.32	-46.0	2.00	95.0
Cycle 6 Day 1	147	75.81	17.53	12.0	80.00	100.0	147	1.95	15.93	-58.0	0.00	58.0
Cycle 7 Day 1	127	76.02	18.57	2.0	80.00	100.0	127	2.73	19.74	-79.0	2.00	87.0
Cycle 8 Day 1	111	75.05	18.46	1.0	80.00	100.0	111	1.73	17.82	-73.0	2.00	60.0
Cycle 9 Day 1	104	76.21	16.79	1.0	80.00	100.0	104	2.49	18.01	-41.0	2.00	85.0
Cycle 10 Day 1	81	77.84	14.75	4.0	79.00	100.0	80	1.48	17.73	-50.0	1.50	55.0
Cycle 11 Day 1	72	77.32	16.74	10.0	80.00	100.0	72	1.50	18.57	-51.0	1.00	55.0
Cycle 12 Day 1	59	78.61	16.91	20.0	81.00	100.0	58	1.36	24.31	-69.0	0.00	96.0
Cycle 13 Day 1	47	77.43	16.58	10.0	80.00	100.0	46	0.39	20.47	-79.0	0.00	42.0
Cycle 14 Day 1	44	78.55	18.18	10.0	80.50	100.0	43	1.70	23.59	-79.0	1.00	76.0
Cycle 15 Day 1	36	78.22	20.47	11.0	86.50	100.0	35	-2.26	20.04	-78.0	2.00	34.0
Cycle 16 Day 1	32	80.78	18.73	10.0	87.00	100.0	31	2.58	25.32	-79.0	3.00	85.0
Cycle 17 Day 1	26	84.46	13.58	47.0	88.50	100.0	25	2.04	13.84	-36.0	4.00	35.0
Cycle 18 Day 1	21	86.52	10.12	68.0	90.00	100.0	21	4.71	12.98	-20.0	4.00	42.0

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; 30 D SFU 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.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.3002.3: 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 19 Day 1	20	88.80	10.15	70.0	90.00	100.0	20	4.75	8.90	-10.0	4.50	19.0
Cycle 20 Day 1	17	86.53	11.30	64.0	90.00	100.0	17	4.71	14.78	-24.0	6.00	41.0
Cycle 21 Day 1	18	88.39	11.04	60.0	90.50	100.0	18	6.39	11.77	-6.0	5.00	41.0
Cycle 22 Day 1	15	84.27	12.57	60.0	89.00	100.0	15	3.80	14.39	-20.0	2.00	36.0
Cycle 23 Day 1	12	85.83	13.72	60.0	90.00	100.0	12	6.75	15.65	-16.0	6.50	42.0
Study Disc 1	152	60.87	22.51	1.0	62.50	100.0	147	-11.12	21.23	-69.0	-10.00	50.0
30 D SFU Z/P	76	64.50	20.98	0.0	68.50	100.0	74	-8.09	20.56	-68.0	-6.00	30.0
90 D SFU Z/P	70	69.07	19.57	20.0	72.00	100.0	69	-4.04	20.76	-80.0	-3.00	50.0

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;
30 D SFU 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.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EQ-5D VAS

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

Table 302.1.3004.3.1: EQ-5D-5L - Summary of Time to First Deterioration of Visual Analog Scale (MID=15) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	95 (37.4%)	112 (44.3%)	
Number of patients censored	159 (62.6%)	141 (55.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.0 [6.9, 13.9]	6.7 [5.1, 9.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.865 [0.655, 1.142]
Log-rank test			
Two-sided stratified log-rank p-value			0.3033

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: 07OCT22

Table 302.1.3004.3.2: EQ-5D-5L - Summary of Time to First Deterioration of Visual Analog Scale by Subgroups (MID=15) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	66 (37.5)	12.4 [7.2, 14.1]	180	77 (42.8)	7.8 [5.7, 28.7]	0.851 [0.611, 1.185]	0.3397	0.8954
>65 years	78	29 (37.2)	6.6 [4.2, NC]	73	35 (47.9)	5.1 [3.4, 6.8]	0.911 [0.557, 1.490]	0.7079	
Sex									
Male	159	62 (39.0)	9.0 [6.9, 13.9]	156	68 (43.6)	6.7 [4.9, 10.4]	0.888 [0.628, 1.256]	0.5027	0.7813
Female	95	33 (34.7)	12.1 [6.0, NC]	97	44 (45.4)	6.7 [4.2, NC]	0.832 [0.529, 1.308]	0.4274	
Region									
Asia	157	62 (39.5)	12.1 [6.7, 14.1]	158	70 (44.3)	6.7 [5.0, 8.8]	0.806 [0.572, 1.137]	0.2191	0.5765
Non-Asia	97	33 (34.0)	7.3 [5.6, NC]	95	42 (44.2)	6.4 [4.2, 28.7]	0.954 [0.602, 1.509]	0.8371	
Number of Organs with Metastatic Sites									
0-2	189	68 (36.0)	10.0 [7.1, 21.0]	188	85 (45.2)	6.7 [5.1, 10.2]	0.821 [0.596, 1.131]	0.2267	0.4781
>=3	65	27 (41.5)	7.2 [5.5, 13.9]	65	27 (41.5)	6.1 [4.1, NC]	0.981 [0.572, 1.685]	0.9446	

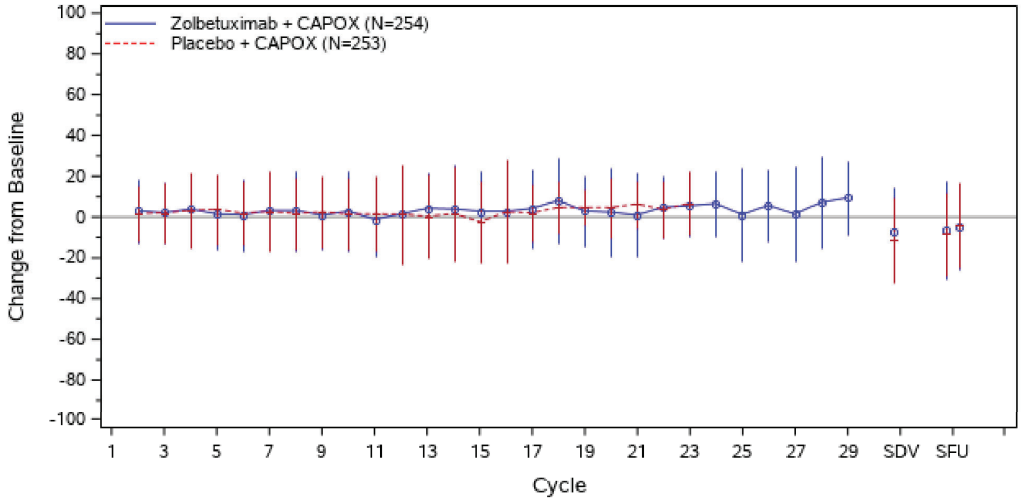
Abbreviations: CI=confidence interval; EQ-5D-5L=european quality of life 5 dimensions 5 level; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EQ-5D VAS

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

The SAS System

Figure 302.1.3002.3: EQ-5D-5L - Plot of Mean Change from Baseline of Visual Analog Scale - Full Analysis Set



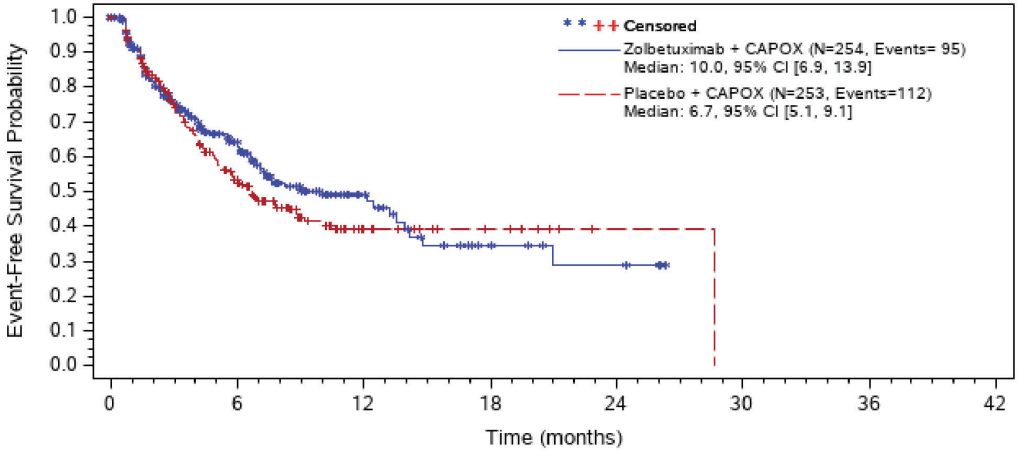
Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EQ-5D VAS

5. Kaplan-Meier-Plots

The SAS System

Figure 302.1.3004.3: EQ-5D-5L - Kaplan-Meier Plot of Time to First Deterioration of Visual Analog Scale (MID=15) - Full Analysis Set



# at Risk								
1	254	90	28	10	5	0	0	0
2	253	89	16	7	1	0	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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022

Anhang 4-G1 Sicherheit

Anhang 4-G1 Unerwünschte Ereignisse

1. Time-to Event-Analysen

Table 302.1.2001.1.1: Summary and Results of TEAEs - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	251 (98.8%)	244 (98.0%)	
Number of patients censored	3 (1.2%)	5 (2.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.1 [0.1, 0.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.256 [1.867, 2.726]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.1.2: Summary and Results of TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	174 (98.9)	0.0 [NC, NC]	177	173 (97.7)	0.1 [0.1, 0.2]	2.144 [1.724, 2.667]	<.0001	0.8732
>65 years	78	77 (98.7)	0.0 [NC, NC]	72	71 (98.6)	0.2 [0.1, 0.5]	2.197 [1.573, 3.069]	<.0001	
Sex									
Male	160	158 (98.8)	0.0 [NC, NC]	152	149 (98.0)	0.1 [0.1, 0.2]	2.060 [1.634, 2.598]	<.0001	0.6923
Female	94	93 (98.9)	0.0 [NC, NC]	97	95 (97.9)	0.1 [0.1, 0.3]	2.449 [1.815, 3.303]	<.0001	
Region									
Asia	157	157 (100.0)	0.0 [NC, NC]	156	151 (96.8)	0.1 [0.1, 0.2]	2.381 [1.886, 3.005]	<.0001	0.4126
Non-Asia	97	94 (96.9)	0.0 [NC, NC]	93	93 (100.0)	0.2 [0.1, 0.5]	1.898 [1.411, 2.553]	0.0002	
Number of Organs with Metastatic Sites									
0-2	190	189 (99.5)	0.0 [NC, NC]	186	182 (97.8)	0.1 [0.1, 0.2]	2.016 [1.633, 2.487]	<.0001	0.3421
>=3	64	62 (96.9)	0.0 [NC, NC]	63	62 (98.4)	0.4 [0.1, 0.7]	2.646 [1.830, 3.824]	<.0001	

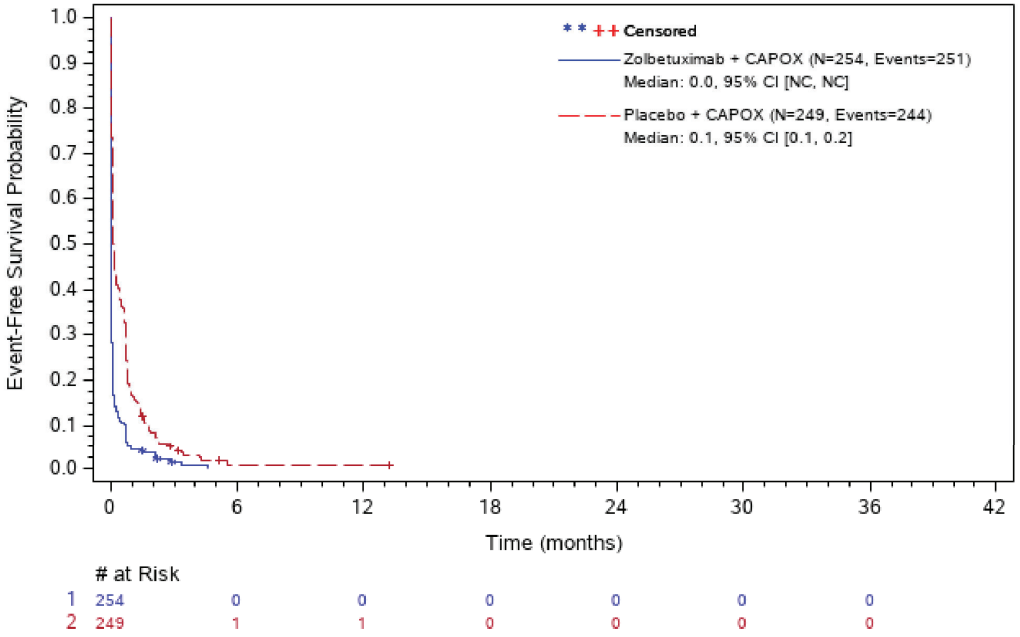
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated;
TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study
treatment + 30 days, death date). [a] Based on the Brookmeyer-Crowley Method, [b] Calculated from 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 302.1.2001.1: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwere unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table 302.1.2001.3.1: Summary and Results of Severe TEAEs - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	185 (72.8%)	174 (69.9%)	
Number of patients censored	69 (27.2%)	75 (30.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.6 [1.9, 3.3]	3.6 [3.0, 4.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.241 [1.006, 1.531]
Log-rank test			
Two-sided stratified log-rank p-value			0.0477

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.3.2: Summary and Results of Severe TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	123 (69.9)	2.3 [1.8, 3.5]	177	117 (66.1)	4.2 [3.0, 5.3]	1.259 [0.977, 1.623]	0.0830	0.7298
>65 years	78	62 (79.5)	2.9 [1.5, 3.5]	72	57 (79.2)	3.3 [2.4, 4.1]	1.169 [0.814, 1.679]	0.4008	
Sex									
Male	160	114 (71.3)	2.9 [2.1, 3.8]	152	110 (72.4)	3.6 [2.9, 4.6]	1.089 [0.837, 1.417]	0.5440	0.1017
Female	94	71 (75.5)	1.7 [1.1, 3.2]	97	64 (66.0)	3.6 [2.8, 6.0]	1.542 [1.098, 2.166]	0.0129	
Region									
Asia	157	110 (70.1)	2.8 [1.6, 3.5]	156	109 (69.9)	3.4 [2.8, 4.3]	1.111 [0.852, 1.449]	0.4574	0.1756
Non-Asia	97	75 (77.3)	2.1 [1.5, 3.7]	93	65 (69.9)	4.1 [3.0, 5.8]	1.500 [1.072, 2.097]	0.0189	
Number of Organs with Metastatic Sites									
0-2	190	133 (70.0)	2.9 [1.6, 3.5]	186	127 (68.3)	3.7 [3.0, 4.8]	1.226 [0.961, 1.564]	0.1089	0.8294
>=3	64	52 (81.3)	2.3 [1.1, 3.0]	63	47 (74.6)	3.6 [2.1, 4.9]	1.254 [0.844, 1.864]	0.2737	

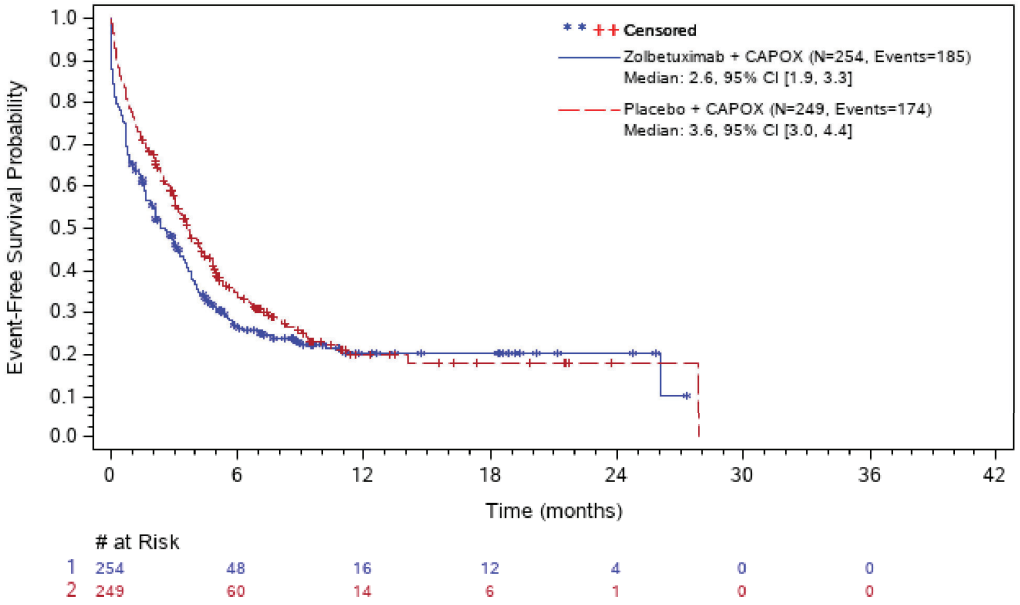
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date). [a] Based on the Brookmeyer-Crowley Method, [b] Calculated from 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwere unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 302.1.2001.3: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwerwiegende unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table 302.1.2001.4.1: Summary and Results of TESAEs - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	120 (47.2%)	124 (49.8%)	
Number of patients censored	134 (52.8%)	125 (50.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.9 [5.8, 20.0]	8.0 [5.6, 12.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.986 [0.765, 1.272]
Log-rank test			
Two-sided stratified log-rank p-value			0.9065

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.4.2: Summary and Results of TESAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	78 (44.3)	10.7 [6.5, 21.2]	177	88 (49.7)	8.0 [5.1, 14.1]	0.876 [0.645, 1.191]	0.3908	0.1959
>65 years	78	42 (53.8)	3.9 [3.2, 10.2]	72	36 (50.0)	8.8 [4.9, 19.9]	1.304 [0.833, 2.041]	0.2445	
Sex									
Male	160	81 (50.6)	6.5 [4.0, 10.4]	152	77 (50.7)	7.8 [5.3, 14.1]	1.063 [0.777, 1.454]	0.7073	0.3862
Female	94	39 (41.5)	15.9 [6.1, NC]	97	47 (48.5)	9.0 [3.7, NC]	0.844 [0.551, 1.293]	0.4347	
Region									
Asia	157	71 (45.2)	10.2 [5.6, NC]	156	77 (49.4)	8.0 [5.1, 14.1]	0.899 [0.650, 1.244]	0.5146	0.4290
Non-Asia	97	49 (50.5)	6.5 [4.0, NC]	93	47 (50.5)	8.8 [4.3, 28.4]	1.121 [0.749, 1.677]	0.5827	
Number of Organs with Metastatic Sites									
0-2	190	82 (43.2)	15.9 [6.5, NC]	186	89 (47.8)	9.0 [6.2, 28.4]	0.933 [0.690, 1.262]	0.6499	0.5054
>=3	64	38 (59.4)	4.2 [3.6, 10.2]	63	35 (55.6)	5.6 [3.7, 10.8]	1.115 [0.704, 1.765]	0.6531	

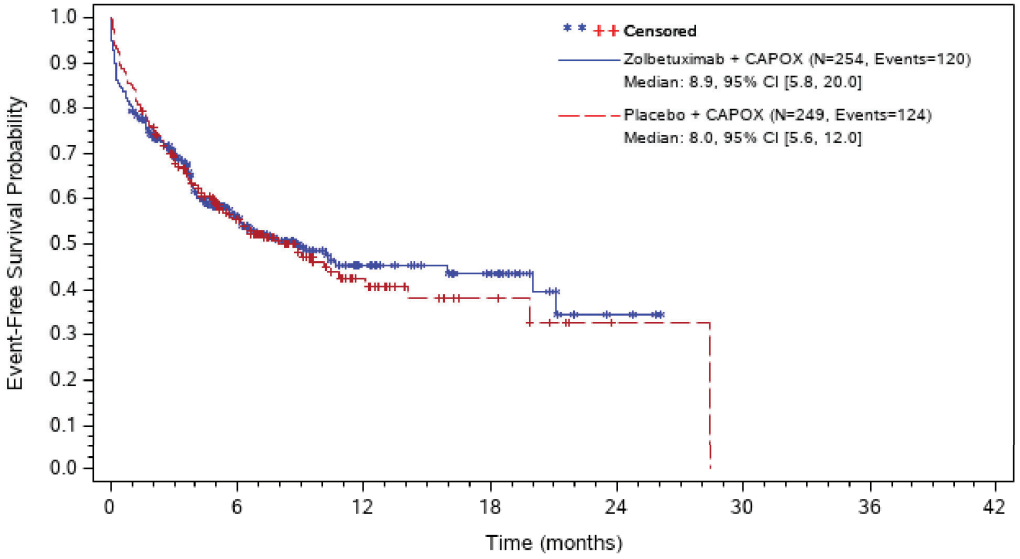
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated;
TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study
treatment + 30 days, death date). [a] Based on the Brookmeyer-Crowley Method, [b] Calculated from 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwerwiegende unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 302.1.2001.4: Kaplan-Meier Plot of Time to first TESAE - Safety Analysis Set



# at Risk							
1	254	96	34	19	4	0	0
2	249	96	25	8	1	0	0

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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Abbruch der Studienmedikation aufgrund unerwünschter Ereignisse

1. Time-to-Event-Analysen

Table 302.1.2001.5.1: Summary and Results of Permanent Treatment Discontinuation due to TEAEs - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	79 (31.1%)	63 (25.3%)	
Number of patients censored	175 (68.9%)	186 (74.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [11.4, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.283 [0.920, 1.791]
Log-rank test			
Two-sided stratified log-rank p-value			0.1420

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.5.2: Summary and Results of Permanent Treatment Discontinuation due to TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	53 (30.1)	NC [11.4, NC]	177	40 (22.6)	NC [NC, NC]	1.330 [0.881, 2.006]	0.1728	0.6209
>65 years	78	26 (33.3)	NC [6.2, NC]	72	23 (31.9)	NC [7.8, NC]	1.107 [0.632, 1.941]	0.7248	
Sex									
Male	160	53 (33.1)	NC [7.4, NC]	152	41 (27.0)	NC [NC, NC]	1.253 [0.833, 1.884]	0.2780	0.9641
Female	94	26 (27.7)	NC [16.4, NC]	97	22 (22.7)	NC [NC, NC]	1.243 [0.703, 2.198]	0.4513	
Region									
Asia	157	47 (29.9)	NC [11.4, NC]	156	38 (24.4)	NC [NC, NC]	1.187 [0.773, 1.823]	0.4309	0.6750
Non-Asia	97	32 (33.0)	NC [7.4, NC]	93	25 (26.9)	NC [8.6, NC]	1.383 [0.819, 2.334]	0.2228	
Number of Organs with Metastatic Sites									
0-2	190	63 (33.2)	NC [9.2, NC]	186	43 (23.1)	NC [NC, NC]	1.497 [1.016, 2.207]	0.0404	0.0833
>=3	64	16 (25.0)	NC [10.2, NC]	63	20 (31.7)	NC [7.4, NC]	0.765 [0.396, 1.478]	0.4231	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated;
TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study
treatment + 30 days, death date). [a] Based on the Brookmeyer-Crowley Method, [b] Calculated from 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
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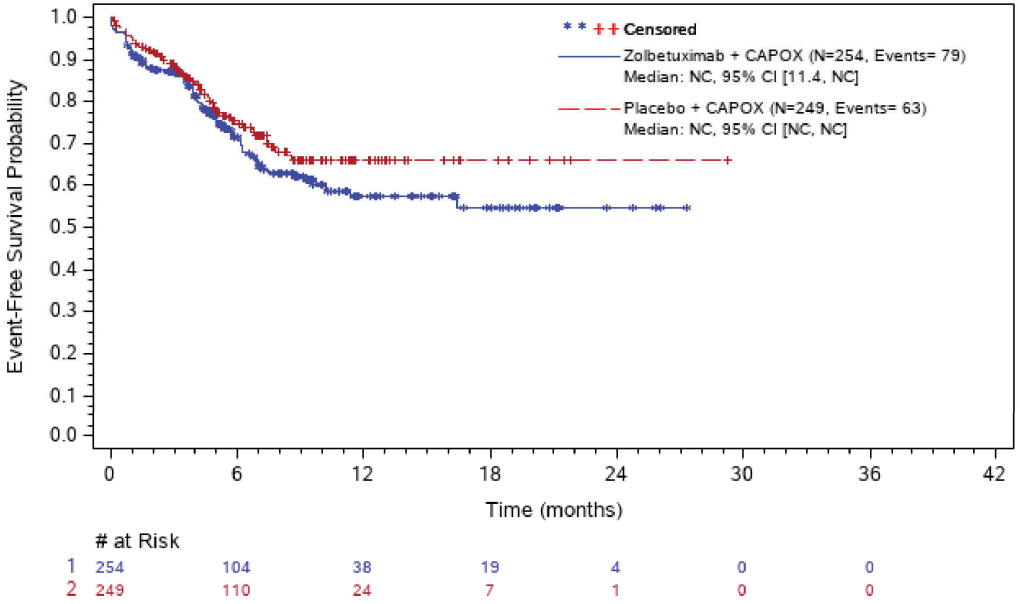
2. Kaplan-Meier-Plots

The SAS System

Figure 302.1.2001.5: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 302.1.2001.6.1: Summary and Results of TEAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	131 (51.6%)	126 (50.6%)	
Number of patients censored	123 (48.4%)	123 (49.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.4 [3.6, 5.6]	4.8 [3.6, 6.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.102 [0.861, 1.409]
Log-rank test			
Two-sided stratified log-rank p-value			0.4486

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.7.1: Summary and Results of TEAEs - Anaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	90 (35.4%)	91 (36.5%)	
Number of patients censored	164 (64.6%)	158 (63.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [8.2, NC]	18.1 [8.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.955 [0.713, 1.280]
Log-rank test			
Two-sided stratified log-rank p-value			0.7544

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.8.1: Summary and Results of TEAEs - Leukopenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	17 (6.7%)	8 (3.2%)	
Number of patients censored	237 (93.3%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.050 [0.881, 4.769]
Log-rank test			
Two-sided stratified log-rank p-value			0.0887

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.9.1: Summary and Results of TEAEs - Neutropenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	50 (19.7%)	35 (14.1%)	
Number of patients censored	204 (80.3%)	214 (85.9%)	
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			1.491 [0.967, 2.300]
Log-rank test			
Two-sided stratified log-rank p-value			0.0693

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.10.1: Summary and Results of TEAEs - Thrombocytopenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	28 (11.0%)	31 (12.4%)	
Number of patients censored	226 (89.0%)	218 (87.6%)	
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			0.896 [0.537, 1.497]
Log-rank test			
Two-sided stratified log-rank p-value			0.6776

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.11.1: Summary and Results of TEAEs - Cardiac Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	24 (9.4%)	31 (12.4%)	
Number of patients censored	230 (90.6%)	218 (87.6%)	
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			0.697 [0.406, 1.197]
Log-rank test			
Two-sided stratified log-rank p-value			0.1923

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.12.1: Summary and Results of TEAEs - Sinus Bradycardia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	9 (3.6%)	
Number of patients censored	250 (98.4%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.423 [0.130, 1.376]
Log-rank test			
Two-sided stratified log-rank p-value			0.1422

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.13.1: Summary and Results of TEAEs - Sinus Tachycardia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	6 (2.4%)	
Number of patients censored	249 (98.0%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.853 [0.259, 2.803]
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: 07OCT22

Table 302.1.2001.14.1: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	234 (92.1%)	199 (79.9%)	
Number of patients censored	20 (7.9%)	50 (20.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.5 [0.2, 0.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.291 [1.881, 2.791]
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: 07OCT22

Table 302.1.2001.14.2: Summary and Results of TEAEs by Subgroups - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	160 (90.9)	0.0 [NC, NC]	177	145 (81.9)	0.4 [0.2, 0.7]	2.230 [1.773, 2.806]	<.0001	0.7038
>65 years	78	74 (94.9)	0.0 [0.0, 0.1]	72	54 (75.0)	0.7 [0.1, 3.3]	2.264 [1.584, 3.235]	<.0001	
Sex									
Male	160	146 (91.3)	0.0 [NC, NC]	152	119 (78.3)	0.7 [0.2, 0.9]	2.106 [1.648, 2.693]	<.0001	0.7317
Female	94	88 (93.6)	0.0 [NC, NC]	97	80 (82.5)	0.4 [0.1, 0.7]	2.459 [1.803, 3.356]	<.0001	
Region									
Asia	157	148 (94.3)	0.0 [NC, NC]	156	126 (80.8)	0.2 [0.1, 0.7]	2.429 [1.906, 3.095]	<.0001	0.4431
Non-Asia	97	86 (88.7)	0.0 [0.0, 0.1]	93	73 (78.5)	0.7 [0.4, 1.7]	1.912 [1.393, 2.623]	0.0004	
Number of Organs with Metastatic Sites									
0-2	190	177 (93.2)	0.0 [NC, NC]	186	154 (82.8)	0.4 [0.2, 0.8]	2.104 [1.689, 2.621]	<.0001	0.4102
>=3	64	57 (89.1)	0.0 [NC, NC]	63	45 (71.4)	0.7 [0.2, 1.5]	2.462 [1.652, 3.670]	<.0001	

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: 07OCT22

Table 302.1.2001.15.1: Summary and Results of TEAEs - Abdominal Discomfort (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	8 (3.2%)	
Number of patients censored	248 (97.6%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.592 [0.191, 1.836]
Log-rank test			
Two-sided stratified log-rank p-value			0.3592

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.16.1: Summary and Results of TEAEs - Abdominal Distension (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	15 (6.0%)	
Number of patients censored	240 (94.5%)	234 (94.0%)	
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			0.903 [0.435, 1.877]
Log-rank test			
Two-sided stratified log-rank p-value			0.7852

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.17.1: Summary and Results of TEAEs - Abdominal Pain (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	40 (15.7%)	54 (21.7%)	
Number of patients censored	214 (84.3%)	195 (78.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [14.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.686 [0.453, 1.038]
Log-rank test			
Two-sided stratified log-rank p-value			0.0712

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.18.1: Summary and Results of TEAEs - Abdominal Pain Upper (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	23 (9.1%)	13 (5.2%)	
Number of patients censored	231 (90.9%)	236 (94.8%)	
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			1.851 [0.919, 3.729]
Log-rank test			
Two-sided stratified log-rank p-value			0.0797

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.19.1: Summary and Results of TEAEs - Ascites (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	16 (6.4%)	
Number of patients censored	245 (96.5%)	233 (93.6%)	
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			0.453 [0.193, 1.064]
Log-rank test			
Two-sided stratified log-rank p-value			0.0622

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.20.1: Summary and Results of TEAEs - Constipation (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	39 (15.4%)	52 (20.9%)	
Number of patients censored	215 (84.6%)	197 (79.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.734 [0.482, 1.116]
Log-rank test			
Two-sided stratified log-rank p-value			0.1463

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.21.1: Summary and Results of TEAEs - Diarrhoea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	80 (31.5%)	86 (34.5%)	
Number of patients censored	174 (68.5%)	163 (65.5%)	
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			0.892 [0.657, 1.210]
Log-rank test			
Two-sided stratified log-rank p-value			0.4641

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.22.1: Summary and Results of TEAEs - Dyspepsia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	8 (3.2%)	
Number of patients censored	242 (95.3%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.510 [0.616, 3.699]
Log-rank test			
Two-sided stratified log-rank p-value			0.3645

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.23.1: Summary and Results of TEAEs - Dysphagia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	9 (3.6%)	
Number of patients censored	245 (96.5%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.073 [0.425, 2.707]
Log-rank test			
Two-sided stratified log-rank p-value			0.8811

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.24.1: Summary and Results of TEAEs - Gastrooesophageal Reflux Disease (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	4 (1.6%)	
Number of patients censored	245 (96.5%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.343 [0.721, 7.617]
Log-rank test			
Two-sided stratified log-rank p-value			0.1453

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.25.1: Summary and Results of TEAEs - Nausea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	174 (68.5%)	125 (50.2%)	
Number of patients censored	80 (31.5%)	124 (49.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.1, 0.4]	5.5 [2.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.954 [1.547, 2.467]
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: 07OCT22

Table 302.1.2001.25.2: Summary and Results of TEAEs by Subgroups - Nausea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	124 (70.5)	0.1 [0.0, 0.1]	177	95 (53.7)	2.9 [0.9, NC]	1.899 [1.452, 2.484]	<.0001	0.6827
>65 years	78	50 (64.1)	0.5 [0.1, 3.8]	72	30 (41.7)	12.8 [2.9, NC]	2.029 [1.286, 3.202]	0.0022	
Sex									
Male	160	108 (67.5)	0.1 [0.0, 0.7]	152	72 (47.4)	7.6 [2.3, NC]	1.958 [1.451, 2.642]	<.0001	0.7241
Female	94	66 (70.2)	0.1 [0.0, 0.7]	97	53 (54.6)	2.9 [0.8, NC]	1.848 [1.285, 2.658]	0.0019	
Region									
Asia	157	113 (72.0)	0.1 [0.0, 0.4]	156	77 (49.4)	6.3 [0.8, NC]	2.031 [1.518, 2.717]	<.0001	0.5131
Non-Asia	97	61 (62.9)	0.1 [0.1, 0.9]	93	48 (51.6)	5.5 [2.0, NC]	1.724 [1.179, 2.522]	0.0091	
Number of Organs with Metastatic Sites									
0-2	190	133 (70.0)	0.1 [0.0, 0.1]	186	101 (54.3)	2.9 [1.0, 8.3]	1.816 [1.400, 2.355]	<.0001	0.3822
>=3	64	41 (64.1)	0.7 [0.0, 2.9]	63	24 (38.1)	12.8 [2.9, 12.8]	2.244 [1.353, 3.722]	0.0019	

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: 07OCT22

Table 302.1.2001.26.1: Summary and Results of TEAEs - Stomatitis (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	7 (2.8%)	
Number of patients censored	246 (96.9%)	242 (97.2%)	
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			1.065 [0.383, 2.959]
Log-rank test			
Two-sided stratified log-rank p-value			0.9034

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.27.1: Summary and Results of TEAEs - Upper Gastrointestinal Haemorrhage (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	5 (2.0%)	
Number of patients censored	246 (96.9%)	244 (98.0%)	
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			1.695 [0.554, 5.189]
Log-rank test			
Two-sided stratified log-rank p-value			0.3514

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.28.1: Summary and Results of TEAEs - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	168 (66.1%)	77 (30.9%)	
Number of patients censored	86 (33.9%)	172 (69.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.0, 0.7]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.394 [2.583, 4.458]
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: 07OCT22

Table 302.1.2001.28.2: Summary and Results of TEAEs by Subgroups - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	121 (68.8)	0.0 [0.0, 0.2]	177	58 (32.8)	NC [NC, NC]	3.483 [2.541, 4.774]	<.0001	0.9309
>65 years	78	47 (60.3)	0.9 [0.2, 6.8]	72	19 (26.4)	NC [NC, NC]	3.174 [1.858, 5.423]	<.0001	
Sex									
Male	160	101 (63.1)	0.3 [0.1, 1.4]	152	41 (27.0)	NC [NC, NC]	3.512 [2.439, 5.058]	<.0001	0.6620
Female	94	67 (71.3)	0.0 [0.0, 0.2]	97	36 (37.1)	NC [7.2, NC]	3.280 [2.179, 4.938]	<.0001	
Region									
Asia	157	109 (69.4)	0.0 [0.0, 0.2]	156	45 (28.8)	NC [NC, NC]	3.911 [2.757, 5.549]	<.0001	0.1748
Non-Asia	97	59 (60.8)	0.7 [0.1, 2.4]	93	32 (34.4)	NC [NC, NC]	2.633 [1.708, 4.059]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	124 (65.3)	0.2 [0.0, 0.9]	186	58 (31.2)	NC [NC, NC]	3.195 [2.336, 4.372]	<.0001	0.5962
>=3	64	44 (68.8)	0.1 [0.0, 0.7]	63	19 (30.2)	NC [NC, NC]	3.870 [2.246, 6.668]	<.0001	

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: 07OCT22

Table 302.1.2001.29.1: Summary and Results of TEAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	139 (54.7%)	125 (50.2%)	
Number of patients censored	115 (45.3%)	124 (49.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.2 [2.8, 7.2]	6.5 [3.1, 9.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.156 [0.906, 1.474]
Log-rank test			
Two-sided stratified log-rank p-value			0.2600

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.30.1: Summary and Results of TEAEs - Asthenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	33 (13.0%)	32 (12.9%)	
Number of patients censored	221 (87.0%)	217 (87.1%)	
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			1.068 [0.656, 1.739]
Log-rank test			
Two-sided stratified log-rank p-value			0.7958

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.31.1: Summary and Results of TEAEs - Chest Discomfort (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	7 (2.8%)	
Number of patients censored	244 (96.1%)	242 (97.2%)	
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			1.312 [0.486, 3.539]
Log-rank test			
Two-sided stratified log-rank p-value			0.5905

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.32.1: Summary and Results of TEAEs - Chills (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	5 (2.0%)	
Number of patients censored	243 (95.7%)	244 (98.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.229 [0.774, 6.421]
Log-rank test			
Two-sided stratified log-rank p-value			0.1277

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.33.1: Summary and Results of TEAEs - Fatigue (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	34 (13.4%)	42 (16.9%)	
Number of patients censored	220 (86.6%)	207 (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			0.754 [0.479, 1.186]
Log-rank test			
Two-sided stratified log-rank p-value			0.2207

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.34.1: Summary and Results of TEAEs - Malaise (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	31 (12.2%)	22 (8.8%)	
Number of patients censored	223 (87.8%)	227 (91.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.416 [0.816, 2.457]
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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.35.1: Summary and Results of TEAEs - Mucosal Inflammation (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	6 (2.4%)	
Number of patients censored	247 (97.2%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.140 [0.383, 3.393]
Log-rank test			
Two-sided stratified log-rank p-value			0.8113

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.36.1: Summary and Results of TEAEs - Oedema Peripheral (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	26 (10.2%)	6 (2.4%)	
Number of patients censored	228 (89.8%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			4.477 [1.838, 10.909]
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: 07OCT22

Table 302.1.2001.36.2: Summary and Results of TEAEs by Subgroups - Oedema Peripheral (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	16 (9.1)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	3.174 [1.160, 8.689]	0.0177	0.3334
>65 years	78	10 (12.8)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	9.978 [1.275, 78.087]	0.0068	
Sex									
Male	160	20 (12.5)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	9.701 [2.264, 41.565]	0.0002	0.0638
Female	94	6 (6.4)	NC [NC, NC]	97	4 (4.1)	NC [NC, NC]	1.636 [0.461, 5.803]	0.4423	
Region									
Asia	157	18 (11.5)	NC [NC, NC]	156	5 (3.2)	NC [NC, NC]	3.708 [1.376, 9.988]	0.0054	0.4924
Non-Asia	97	8 (8.2)	NC [16.8, NC]	93	1 (1.1)	NC [NC, NC]	7.927 [0.990, 63.487]	0.0206	
Number of Organs with Metastatic Sites									
0-2	190	13 (6.8)	NC [NC, NC]	186	5 (2.7)	NC [NC, NC]	2.535 [0.901, 7.135]	0.0681	0.1529
>=3	64	13 (20.3)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	13.893 [1.817, 106.22]	0.0009	

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: 07OCT22

Table 302.1.2001.37.1: Summary and Results of TEAEs - Pyrexia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	34 (13.4%)	23 (9.2%)	
Number of patients censored	220 (86.6%)	226 (90.8%)	
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			1.474 [0.867, 2.507]
Log-rank test			
Two-sided stratified log-rank p-value			0.1498

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.38.1: Summary and Results of TEAEs - Hepatobiliary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	17 (6.7%)	15 (6.0%)	
Number of patients censored	237 (93.3%)	234 (94.0%)	
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			1.150 [0.572, 2.310]
Log-rank test			
Two-sided stratified log-rank p-value			0.6943

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.39.1: Summary and Results of TEAEs - Immune System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	7 (2.8%)	
Number of patients censored	247 (97.2%)	242 (97.2%)	
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 [0.344, 2.848]
Log-rank test			
Two-sided stratified log-rank p-value			0.9846

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.40.1: Summary and Results of TEAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	70 (27.6%)	67 (26.9%)	
Number of patients censored	184 (72.4%)	182 (73.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	17.0 [13.1, NC]	14.4 [11.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.980 [0.698, 1.376]
Log-rank test			
Two-sided stratified log-rank p-value			0.9087

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.41.1: Summary and Results of TEAEs - Covid-19 (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	11 (4.4%)	
Number of patients censored	243 (95.7%)	238 (95.6%)	
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			0.882 [0.367, 2.124]
Log-rank test			
Two-sided stratified log-rank p-value			0.7801

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.42.1: Summary and Results of TEAEs - Pneumonia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	10 (4.0%)	
Number of patients censored	242 (95.3%)	239 (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			1.283 [0.553, 2.977]
Log-rank test			
Two-sided stratified log-rank p-value			0.5595

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.43.1: Summary and Results of TEAEs - Urinary Tract Infection (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	6 (2.4%)	
Number of patients censored	247 (97.2%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.085 [0.362, 3.255]
Log-rank test			
Two-sided stratified log-rank p-value			0.8836

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.44.1: Summary and Results of TEAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	27 (10.6%)	15 (6.0%)	
Number of patients censored	227 (89.4%)	234 (94.0%)	
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			1.720 [0.910, 3.248]
Log-rank test			
Two-sided stratified log-rank p-value			0.0934

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.45.1: Summary and Results of TEAEs - Infusion Related Reaction (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	2 (0.8%)	
Number of patients censored	243 (95.7%)	247 (99.2%)	
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			5.357 [1.186, 24.200]
Log-rank test			
Two-sided stratified log-rank p-value			0.0146

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.45.2: Summary and Results of TEAEs by Subgroups - Infusion Related Reaction (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	7 (4.0)		177	2 (1.1)				
>65 years	78	4 (5.1)		72	0 (0.0)				
Sex									
Male	160	4 (2.5)		152	2 (1.3)				
Female	94	7 (7.4)		97	0 (0.0)				
Region									
Asia	157	5 (3.2)		156	0 (0.0)				
Non-Asia	97	6 (6.2)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	7 (3.7)		186	2 (1.1)				
>=3	64	4 (6.3)		63	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: 07OCT22

Table 302.1.2001.46.1: Summary and Results of TEAEs - Investigations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	153 (60.2%)	150 (60.2%)	
Number of patients censored	101 (39.8%)	99 (39.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.5 [1.6, 3.0]	2.8 [2.2, 3.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.061 [0.844, 1.333]
Log-rank test			
Two-sided stratified log-rank p-value			0.6083

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.47.1: Summary and Results of TEAEs - Alanine Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	48 (18.9%)	52 (20.9%)	
Number of patients censored	206 (81.1%)	197 (79.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [25.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.907 [0.610, 1.347]
Log-rank test			
Two-sided stratified log-rank p-value			0.6221

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.48.1: Summary and Results of TEAEs - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	63 (24.8%)	72 (28.9%)	
Number of patients censored	191 (75.2%)	177 (71.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	25.8 [25.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.852 [0.606, 1.197]
Log-rank test			
Two-sided stratified log-rank p-value			0.3520

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.49.1: Summary and Results of TEAEs - Blood Alkaline Phosphatase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	20 (8.0%)	
Number of patients censored	240 (94.5%)	229 (92.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [19.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.661 [0.332, 1.314]
Log-rank test			
Two-sided stratified log-rank p-value			0.2352

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.50.1: Summary and Results of TEAEs - Blood Bilirubin Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	24 (9.4%)	23 (9.2%)	
Number of patients censored	230 (90.6%)	226 (90.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [26.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.941 [0.525, 1.685]
Log-rank test			
Two-sided stratified log-rank p-value			0.8370

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.51.1: Summary and Results of TEAEs - Blood Creatinine Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	4 (1.6%)	
Number of patients censored	246 (96.9%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.779 [0.519, 6.098]
Log-rank test			
Two-sided stratified log-rank p-value			0.3525

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.52.1: Summary and Results of TEAEs - Electrocardiogram Qt Prolonged (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	6 (2.4%)	
Number of patients censored	248 (97.6%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.038 [0.332, 3.243]
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: 07OCT22

Table 302.1.2001.53.1: Summary and Results of TEAEs - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	10 (4.0%)	
Number of patients censored	245 (96.5%)	239 (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			0.893 [0.360, 2.215]
Log-rank test			
Two-sided stratified log-rank p-value			0.8063

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.54.1: Summary and Results of TEAEs - Lymphocyte Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	5 (2.0%)	
Number of patients censored	246 (96.9%)	244 (98.0%)	
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			1.613 [0.526, 4.950]
Log-rank test			
Two-sided stratified log-rank p-value			0.3987

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.55.1: Summary and Results of TEAEs - Neutrophil Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	70 (27.6%)	59 (23.7%)	
Number of patients censored	184 (72.4%)	190 (76.3%)	
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			1.150 [0.811, 1.630]
Log-rank test			
Two-sided stratified log-rank p-value			0.4315

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.56.1: Summary and Results of TEAEs - Platelet Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	61 (24.0%)	60 (24.1%)	
Number of patients censored	193 (76.0%)	189 (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			1.003 [0.701, 1.434]
Log-rank test			
Two-sided stratified log-rank p-value			0.9869

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.57.1: Summary and Results of TEAEs - Weight Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	50 (19.7%)	25 (10.0%)	
Number of patients censored	204 (80.3%)	224 (90.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [22.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.052 [1.264, 3.329]
Log-rank test			
Two-sided stratified log-rank p-value			0.0030

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.57.2: Summary and Results of TEAEs by Subgroups - Weight Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	34 (19.3)	NC [NC, NC]	177	20 (11.3)	NC [NC, NC]	1.824 [1.049, 3.170]	0.0307	0.3192
>65 years	78	16 (20.5)	NC [22.6, NC]	72	5 (6.9)	NC [NC, NC]	3.093 [1.123, 8.521]	0.0214	
Sex									
Male	160	35 (21.9)	NC [NC, NC]	152	13 (8.6)	NC [NC, NC]	2.798 [1.480, 5.291]	0.0009	0.1458
Female	94	15 (16.0)	NC [22.6, NC]	97	12 (12.4)	NC [NC, NC]	1.293 [0.602, 2.777]	0.5092	
Region									
Asia	157	33 (21.0)	NC [22.6, NC]	156	17 (10.9)	NC [NC, NC]	1.987 [1.102, 3.582]	0.0199	0.7842
Non-Asia	97	17 (17.5)	NC [NC, NC]	93	8 (8.6)	NC [NC, NC]	2.243 [0.967, 5.203]	0.0532	
Number of Organs with Metastatic Sites									
0-2	190	36 (18.9)	NC [22.6, NC]	186	21 (11.3)	NC [NC, NC]	1.776 [1.035, 3.049]	0.0347	0.2230
>=3	64	14 (21.9)	NC [12.5, NC]	63	4 (6.3)	NC [NC, NC]	3.720 [1.222, 11.325]	0.0132	

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: 07OCT22

Table 302.1.2001.58.1: Summary and Results of TEAEs - White Blood Cell Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	51 (20.1%)	39 (15.7%)	
Number of patients censored	203 (79.9%)	210 (84.3%)	
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			1.272 [0.837, 1.932]
Log-rank test			
Two-sided stratified log-rank p-value			0.2563

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.59.1: Summary and Results of TEAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	154 (60.6%)	138 (55.4%)	
Number of patients censored	100 (39.4%)	111 (44.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.1 [1.4, 3.4]	3.8 [2.9, 7.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.296 [1.027, 1.635]
Log-rank test			
Two-sided stratified log-rank p-value			0.0305

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.59.2: Summary and Results of TEAEs by Subgroups - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	108 (61.4)	2.1 [1.4, 3.9]	177	97 (54.8)	4.5 [3.3, 8.1]	1.361 [1.034, 1.791]	0.0299	0.5673
>65 years	78	46 (59.0)	2.0 [0.9, 4.4]	72	41 (56.9)	3.1 [1.1, NC]	1.174 [0.770, 1.791]	0.4548	
Sex									
Male	160	100 (62.5)	1.6 [1.1, 3.1]	152	85 (55.9)	3.5 [2.1, 7.8]	1.339 [1.002, 1.788]	0.0503	0.8610
Female	94	54 (57.4)	3.2 [1.4, 7.2]	97	53 (54.6)	4.2 [2.8, 11.8]	1.262 [0.863, 1.845]	0.2389	
Region									
Asia	157	105 (66.9)	1.5 [0.7, 2.2]	156	96 (61.5)	2.9 [2.0, 4.0]	1.267 [0.960, 1.672]	0.1017	0.6523
Non-Asia	97	49 (50.5)	3.8 [2.0, 8.6]	93	42 (45.2)	10.3 [4.1, NC]	1.422 [0.939, 2.153]	0.0960	
Number of Organs with Metastatic Sites									
0-2	190	111 (58.4)	2.2 [1.4, 4.6]	186	105 (56.5)	3.8 [2.6, 7.8]	1.214 [0.929, 1.586]	0.1628	0.3230
>=3	64	43 (67.2)	1.6 [1.0, 3.5]	63	33 (52.4)	4.1 [2.5, 11.8]	1.602 [1.015, 2.527]	0.0415	

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: 07OCT22

Table 302.1.2001.60.1: Summary and Results of TEAEs - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	105 (41.3%)	84 (33.7%)	
Number of patients censored	149 (58.7%)	165 (66.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [5.9, NC]	19.9 [13.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.387 [1.038, 1.852]
Log-rank test			
Two-sided stratified log-rank p-value			0.0268

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.60.2: Summary and Results of TEAEs by Subgroups - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	71 (40.3)	NC [7.2, NC]	177	62 (35.0)	16.2 [10.3, NC]	1.281 [0.910, 1.802]	0.1674	0.5263
>65 years	78	34 (43.6)	6.8 [2.2, NC]	72	22 (30.6)	19.9 [NC, NC]	1.541 [0.898, 2.644]	0.1105	
Sex									
Male	160	74 (46.3)	7.7 [2.6, NC]	152	52 (34.2)	19.9 [10.3, NC]	1.536 [1.077, 2.192]	0.0179	0.2878
Female	94	31 (33.0)	NC [NC, NC]	97	32 (33.0)	16.2 [11.8, NC]	1.097 [0.669, 1.799]	0.7374	
Region									
Asia	157	66 (42.0)	NC [5.2, NC]	156	57 (36.5)	16.2 [11.8, NC]	1.242 [0.871, 1.771]	0.2455	0.3417
Non-Asia	97	39 (40.2)	18.2 [4.9, NC]	93	27 (29.0)	NC [10.3, NC]	1.720 [1.050, 2.817]	0.0292	
Number of Organs with Metastatic Sites									
0-2	190	76 (40.0)	NC [7.2, NC]	186	69 (37.1)	16.2 [10.3, NC]	1.175 [0.847, 1.628]	0.3475	0.0712
>=3	64	29 (45.3)	6.8 [1.6, NC]	63	15 (23.8)	NC [11.8, NC]	2.323 [1.243, 4.341]	0.0066	

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: 07OCT22

Table 302.1.2001.61.1: Summary and Results of TEAEs - Dehydration (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	4 (1.6%)	
Number of patients censored	248 (97.6%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.509 [0.425, 5.352]
Log-rank test			
Two-sided stratified log-rank p-value			0.5215

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.62.1: Summary and Results of TEAEs - Hyperuricaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	7 (2.8%)	
Number of patients censored	250 (98.4%)	242 (97.2%)	
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			0.500 [0.142, 1.770]
Log-rank test			
Two-sided stratified log-rank p-value			0.2744

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.63.1: Summary and Results of TEAEs - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	57 (22.4%)	35 (14.1%)	
Number of patients censored	197 (77.6%)	214 (85.9%)	
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			1.762 [1.155, 2.689]
Log-rank test			
Two-sided stratified log-rank p-value			0.0079

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.63.2: Summary and Results of TEAEs by Subgroups - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	40 (22.7)	NC [NC, NC]	177	24 (13.6)	NC [NC, NC]	1.825 [1.099, 3.030]	0.0184	0.8165
>65 years	78	17 (21.8)	NC [NC, NC]	72	11 (15.3)	NC [NC, NC]	1.671 [0.781, 3.575]	0.1797	
Sex									
Male	160	37 (23.1)	NC [NC, NC]	152	26 (17.1)	NC [NC, NC]	1.459 [0.883, 2.410]	0.1388	0.2035
Female	94	20 (21.3)	NC [NC, NC]	97	9 (9.3)	NC [NC, NC]	2.687 [1.222, 5.908]	0.0105	
Region									
Asia	157	44 (28.0)	NC [NC, NC]	156	30 (19.2)	NC [NC, NC]	1.648 [1.036, 2.623]	0.0337	0.3745
Non-Asia	97	13 (13.4)	NC [16.8, NC]	93	5 (5.4)	NC [NC, NC]	2.792 [0.995, 7.839]	0.0415	
Number of Organs with Metastatic Sites									
0-2	190	41 (21.6)	NC [NC, NC]	186	24 (12.9)	NC [NC, NC]	1.867 [1.127, 3.092]	0.0138	0.6788
>=3	64	16 (25.0)	NC [NC, NC]	63	11 (17.5)	NC [NC, NC]	1.577 [0.731, 3.399]	0.2400	

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: 07OCT22

Table 302.1.2001.64.1: Summary and Results of TEAEs - Hypocalcaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	13 (5.1%)	12 (4.8%)	
Number of patients censored	241 (94.9%)	237 (95.2%)	
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			1.072 [0.488, 2.355]
Log-rank test			
Two-sided stratified log-rank p-value			0.8606

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.65.1: Summary and Results of TEAEs - Hypokalaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	36 (14.2%)	36 (14.5%)	
Number of patients censored	218 (85.8%)	213 (85.5%)	
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			0.965 [0.606, 1.536]
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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.66.1: Summary and Results of TEAEs - Hyponatraemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	18 (7.2%)	
Number of patients censored	239 (94.1%)	231 (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			0.799 [0.399, 1.598]
Log-rank test			
Two-sided stratified log-rank p-value			0.5249

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.67.1: Summary and Results of TEAEs - Hypophosphataemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	7 (2.8%)	
Number of patients censored	246 (96.9%)	242 (97.2%)	
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			1.222 [0.442, 3.382]
Log-rank test			
Two-sided stratified log-rank p-value			0.6985

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.68.1: Summary and Results of TEAEs - Hypoproteinaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	4 (1.6%)	
Number of patients censored	248 (97.6%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.559 [0.437, 5.561]
Log-rank test			
Two-sided stratified log-rank p-value			0.4900

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.69.1: Summary and Results of TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	31 (12.2%)	52 (20.9%)	
Number of patients censored	223 (87.8%)	197 (79.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.533 [0.341, 0.833]
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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.69.2: Summary and Results of TEAEs by Subgroups - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	28 (15.9)	NC [NC, NC]	177	37 (20.9)	NC [NC, NC]	0.705 [0.431, 1.153]	0.1626	0.0475
>65 years	78	3 (3.8)	NC [NC, NC]	72	15 (20.8)	NC [11.9, NC]	0.186 [0.054, 0.641]	0.0028	
Sex									
Male	160	18 (11.3)	NC [NC, NC]	152	34 (22.4)	NC [11.9, NC]	0.461 [0.260, 0.818]	0.0067	0.2791
Female	94	13 (13.8)	NC [NC, NC]	97	18 (18.6)	NC [NC, NC]	0.762 [0.373, 1.555]	0.4545	
Region									
Asia	157	17 (10.8)	NC [NC, NC]	156	24 (15.4)	NC [NC, NC]	0.664 [0.357, 1.237]	0.1951	0.4277
Non-Asia	97	14 (14.4)	NC [NC, NC]	93	28 (30.1)	NC [10.2, NC]	0.450 [0.237, 0.855]	0.0123	
Number of Organs with Metastatic Sites									
0-2	190	22 (11.6)	NC [NC, NC]	186	40 (21.5)	NC [NC, NC]	0.505 [0.300, 0.849]	0.0087	0.5153
>=3	64	9 (14.1)	NC [NC, NC]	63	12 (19.0)	NC [9.8, NC]	0.718 [0.302, 1.704]	0.4496	

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: 07OCT22

Table 302.1.2001.70.1: Summary and Results of TEAEs - Arthralgia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	7 (2.8%)	
Number of patients censored	250 (98.4%)	242 (97.2%)	
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			0.553 [0.161, 1.898]
Log-rank test			
Two-sided stratified log-rank p-value			0.3397

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.71.1: Summary and Results of TEAEs - Back Pain (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	20 (8.0%)	
Number of patients censored	246 (96.9%)	229 (92.0%)	
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			0.380 [0.167, 0.865]
Log-rank test			
Two-sided stratified log-rank p-value			0.0166

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.71.2: Summary and Results of TEAEs by Subgroups - Back Pain (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	8 (4.5)	NC [NC, NC]	177	14 (7.9)	NC [NC, NC]	0.556 [0.233, 1.330]	0.1809	0.9877
>65 years	78	0 (0.0)	NC [NC, NC]	72	6 (8.3)	NC [NC, NC]	0.000 [0.000, NC]	0.0137	
Sex									
Male	160	4 (2.5)	NC [NC, NC]	152	11 (7.2)	NC [NC, NC]	0.343 [0.109, 1.076]	0.0545	0.6687
Female	94	4 (4.3)	NC [NC, NC]	97	9 (9.3)	NC [NC, NC]	0.467 [0.143, 1.519]	0.1948	
Region									
Asia	157	4 (2.5)	NC [NC, NC]	156	12 (7.7)	NC [NC, NC]	0.314 [0.101, 0.973]	0.0339	0.5190
Non-Asia	97	4 (4.1)	NC [NC, NC]	93	8 (8.6)	NC [NC, NC]	0.511 [0.154, 1.700]	0.2651	
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)	NC [NC, NC]	186	14 (7.5)	NC [NC, NC]	0.348 [0.125, 0.969]	0.0345	0.7386
>=3	64	3 (4.7)	NC [NC, NC]	63	6 (9.5)	NC [NC, NC]	0.487 [0.122, 1.945]	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 10% of subjects in at least 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: 07OCT22

Table 302.1.2001.72.1: Summary and Results of TEAEs - Pain In Extremity (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	6 (2.4%)	
Number of patients censored	248 (97.6%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.964 [0.311, 2.991]
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: 07OCT22

Table 302.1.2001.73.1: Summary and Results of TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	20 (8.0%)	
Number of patients censored	242 (95.3%)	229 (92.0%)	
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			0.554 [0.261, 1.176]
Log-rank test			
Two-sided stratified log-rank p-value			0.1192

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.74.1: Summary and Results of TEAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	13 (5.2%)	
Number of patients censored	245 (96.5%)	236 (94.8%)	
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			0.648 [0.264, 1.593]
Log-rank test			
Two-sided stratified log-rank p-value			0.3408

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.75.1: Summary and Results of TEAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	138 (54.3%)	143 (57.4%)	
Number of patients censored	116 (45.7%)	106 (42.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.6 [3.6, 5.6]	3.5 [2.3, 4.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.907 [0.717, 1.147]
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: 07OCT22

Table 302.1.2001.76.1: Summary and Results of TEAEs - Dizziness (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	11 (4.4%)	
Number of patients censored	240 (94.5%)	238 (95.6%)	
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 [0.576, 2.796]
Log-rank test			
Two-sided stratified log-rank p-value			0.5519

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.77.1: Summary and Results of TEAEs - Dysaesthesia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	5 (2.0%)	
Number of patients censored	247 (97.2%)	244 (98.0%)	
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			1.344 [0.426, 4.241]
Log-rank test			
Two-sided stratified log-rank p-value			0.6134

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.78.1: Summary and Results of TEAEs - Dysgeusia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	18 (7.1%)	12 (4.8%)	
Number of patients censored	236 (92.9%)	237 (95.2%)	
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			1.547 [0.743, 3.223]
Log-rank test			
Two-sided stratified log-rank p-value			0.2406

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.79.1: Summary and Results of TEAEs - Headache (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	8 (3.2%)	
Number of patients censored	246 (96.9%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.942 [0.350, 2.534]
Log-rank test			
Two-sided stratified log-rank p-value			0.9061

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.80.1: Summary and Results of TEAEs - Hypoaesthesia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	30 (11.8%)	30 (12.0%)	
Number of patients censored	224 (88.2%)	219 (88.0%)	
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			0.977 [0.588, 1.622]
Log-rank test			
Two-sided stratified log-rank p-value			0.9027

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.81.1: Summary and Results of TEAEs - Neuropathy Peripheral (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	13 (5.1%)	13 (5.2%)	
Number of patients censored	241 (94.9%)	236 (94.8%)	
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			1.000 [0.463, 2.161]
Log-rank test			
Two-sided stratified log-rank p-value			0.9954

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.82.1: Summary and Results of TEAEs - Neurotoxicity (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	19 (7.6%)	
Number of patients censored	240 (94.5%)	230 (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			0.715 [0.358, 1.426]
Log-rank test			
Two-sided stratified log-rank p-value			0.3360

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.83.1: Summary and Results of TEAEs - Paraesthesia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	13 (5.1%)	11 (4.4%)	
Number of patients censored	241 (94.9%)	238 (95.6%)	
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			1.187 [0.531, 2.652]
Log-rank test			
Two-sided stratified log-rank p-value			0.6730

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.84.1: Summary and Results of TEAEs - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	56 (22.0%)	56 (22.5%)	
Number of patients censored	198 (78.0%)	193 (77.5%)	
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			0.970 [0.669, 1.406]
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: 07OCT22

Table 302.1.2001.85.1: Summary and Results of TEAEs - Psychiatric Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	33 (13.0%)	25 (10.0%)	
Number of patients censored	221 (87.0%)	224 (90.0%)	
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			1.291 [0.765, 2.177]
Log-rank test			
Two-sided stratified log-rank p-value			0.3385

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.86.1: Summary and Results of TEAEs - Insomnia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	27 (10.6%)	16 (6.4%)	
Number of patients censored	227 (89.4%)	233 (93.6%)	
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			1.643 [0.882, 3.059]
Log-rank test			
Two-sided stratified log-rank p-value			0.1144

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.87.1: Summary and Results of TEAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	23 (9.1%)	19 (7.6%)	
Number of patients censored	231 (90.9%)	230 (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			1.181 [0.641, 2.174]
Log-rank test			
Two-sided stratified log-rank p-value			0.5941

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.88.1: Summary and Results of TEAEs - Reproductive System And Breast Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	8 (3.2%)	
Number of patients censored	249 (98.0%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.576 [0.187, 1.773]
Log-rank test			
Two-sided stratified log-rank p-value			0.3307

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.89.1: Summary and Results of TEAEs - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	52 (20.5%)	61 (24.5%)	
Number of patients censored	202 (79.5%)	188 (75.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	28.4 [16.8, 28.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.840 [0.578, 1.220]
Log-rank test			
Two-sided stratified log-rank p-value			0.3575

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.90.1: Summary and Results of TEAEs - Cough (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	14 (5.6%)	
Number of patients censored	243 (95.7%)	235 (94.4%)	
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			0.802 [0.362, 1.775]
Log-rank test			
Two-sided stratified log-rank p-value			0.5852

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.91.1: Summary and Results of TEAEs - Dyspnoea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	13 (5.2%)	
Number of patients censored	239 (94.1%)	236 (94.8%)	
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			1.136 [0.534, 2.418]
Log-rank test			
Two-sided stratified log-rank p-value			0.7396

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.92.1: Summary and Results of TEAEs - Hiccups (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	7 (2.8%)	
Number of patients censored	243 (95.7%)	242 (97.2%)	
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			1.489 [0.577, 3.845]
Log-rank test			
Two-sided stratified log-rank p-value			0.4086

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.93.1: Summary and Results of TEAEs - Pleural Effusion (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	7 (2.8%)	
Number of patients censored	249 (98.0%)	242 (97.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	28.4 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.893 [0.264, 3.013]
Log-rank test			
Two-sided stratified log-rank p-value			0.8545

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.94.1: Summary and Results of TEAEs - Productive Cough (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	6 (2.4%)	
Number of patients censored	250 (98.4%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.555 [0.151, 2.037]
Log-rank test			
Two-sided stratified log-rank p-value			0.3684

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.95.1: Summary and Results of TEAEs - Pulmonary Embolism (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	11 (4.4%)	
Number of patients censored	248 (97.6%)	238 (95.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	28.4 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.576 [0.208, 1.593]
Log-rank test			
Two-sided stratified log-rank p-value			0.2815

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.96.1: Summary and Results of TEAEs - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	78 (30.7%)	74 (29.7%)	
Number of patients censored	176 (69.3%)	175 (70.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [11.9, NC]	19.9 [13.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.005 [0.728, 1.387]
Log-rank test			
Two-sided stratified log-rank p-value			0.9839

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.97.1: Summary and Results of TEAEs - Alopecia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	4 (1.6%)	
Number of patients censored	247 (97.2%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.554 [0.437, 5.519]
Log-rank test			
Two-sided stratified log-rank p-value			0.4923

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.98.1: Summary and Results of TEAEs - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	41 (16.1%)	49 (19.7%)	
Number of patients censored	213 (83.9%)	200 (80.3%)	
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			0.809 [0.532, 1.230]
Log-rank test			
Two-sided stratified log-rank p-value			0.3212

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.99.1: Summary and Results of TEAEs - Pruritus (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	8 (3.2%)	
Number of patients censored	245 (96.5%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.892 [0.323, 2.461]
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: 07OCT22

Table 302.1.2001.100.1: Summary and Results of TEAEs - Rash (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	6 (2.4%)	
Number of patients censored	249 (98.0%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.785 [0.239, 2.575]
Log-rank test			
Two-sided stratified log-rank p-value			0.6883

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.101.1: Summary and Results of TEAEs - Rash Maculo-Papular (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	7 (2.8%)	
Number of patients censored	249 (98.0%)	242 (97.2%)	
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			0.664 [0.209, 2.102]
Log-rank test			
Two-sided stratified log-rank p-value			0.4828

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.102.1: Summary and Results of TEAEs - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	53 (20.9%)	29 (11.6%)	
Number of patients censored	201 (79.1%)	220 (88.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	27.9 [20.8, 27.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.998 [1.263, 3.161]
Log-rank test			
Two-sided stratified log-rank p-value			0.0027

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.102.2: Summary and Results of TEAEs by Subgroups - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	40 (22.7)	NC [NC, NC]	177	22 (12.4)	27.9 [NC, NC]	1.905 [1.132, 3.206]	0.0139	0.9564
>65 years	78	13 (16.7)	NC [NC, NC]	72	7 (9.7)	20.8 [NC, NC]	1.846 [0.732, 4.658]	0.1864	
Sex									
Male	160	33 (20.6)	NC [NC, NC]	152	19 (12.5)	27.9 [20.8, 27.9]	1.783 [1.003, 3.168]	0.0457	0.6094
Female	94	20 (21.3)	NC [NC, NC]	97	10 (10.3)	NC [NC, NC]	2.344 [1.095, 5.015]	0.0244	
Region									
Asia	157	32 (20.4)	NC [NC, NC]	156	19 (12.2)	NC [20.8, NC]	1.736 [0.983, 3.066]	0.0554	0.5157
Non-Asia	97	21 (21.6)	NC [12.6, NC]	93	10 (10.8)	27.9 [NC, NC]	2.513 [1.150, 5.493]	0.0168	
Number of Organs with Metastatic Sites									
0-2	190	39 (20.5)	NC [NC, NC]	186	22 (11.8)	27.9 [20.8, 27.9]	1.944 [1.143, 3.306]	0.0127	0.9190
>=3	64	14 (21.9)	NC [NC, NC]	63	7 (11.1)	NC [NC, NC]	2.062 [0.832, 5.110]	0.1109	

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: 07OCT22

Table 302.1.2001.103.1: Summary and Results of TEAEs - Hypertension (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	7 (2.8%)	
Number of patients censored	239 (94.1%)	242 (97.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	27.9 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.512 [0.973, 6.482]
Log-rank test			
Two-sided stratified log-rank p-value			0.0514

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2001.104.1: Summary and Results of TEAEs - Hypotension (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	7 (2.8%)	
Number of patients censored	239 (94.1%)	242 (97.2%)	
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			2.126 [0.866, 5.218]
Log-rank test			
Two-sided stratified log-rank p-value			0.0917

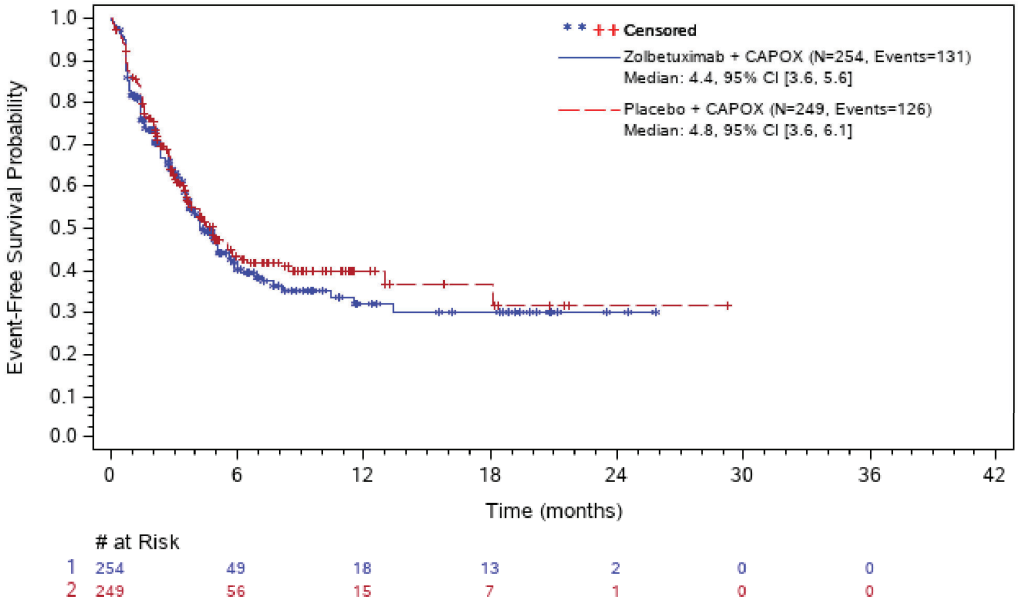
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

Figure 302.1.2001.6: Kaplan-Meier Plot of Time to first TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

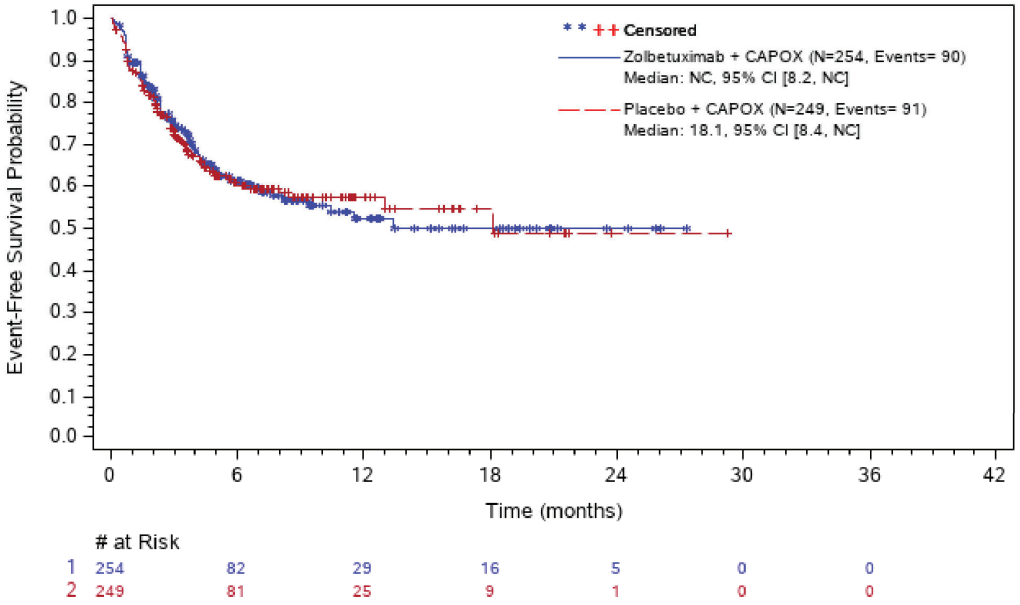


# at Risk							
1	254	49	18	13	2	0	0
2	249	56	15	7	1	0	0

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: 07OCT22

The SAS System

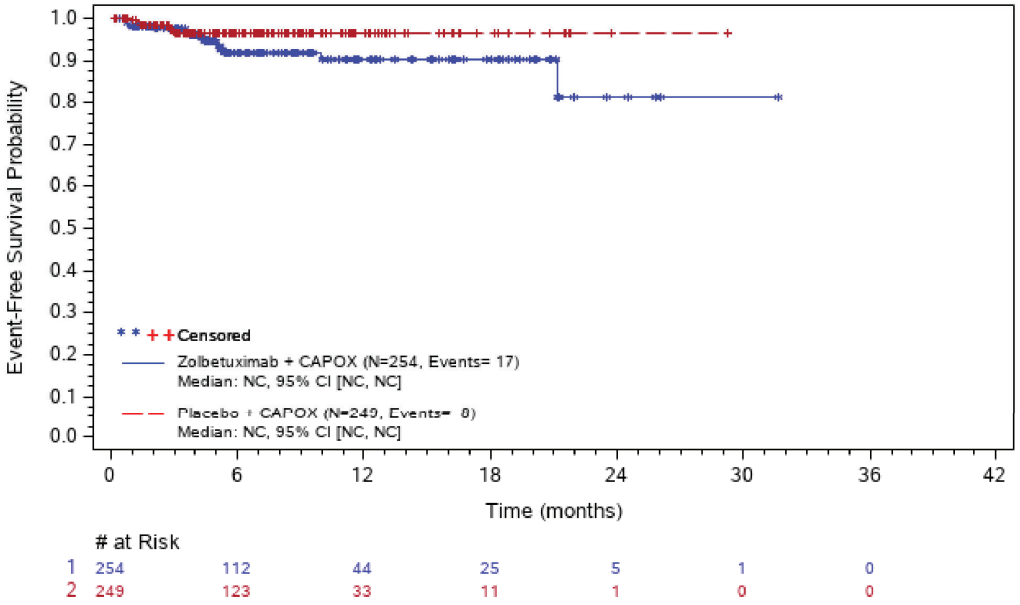
Figure 302.1.2001.7: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

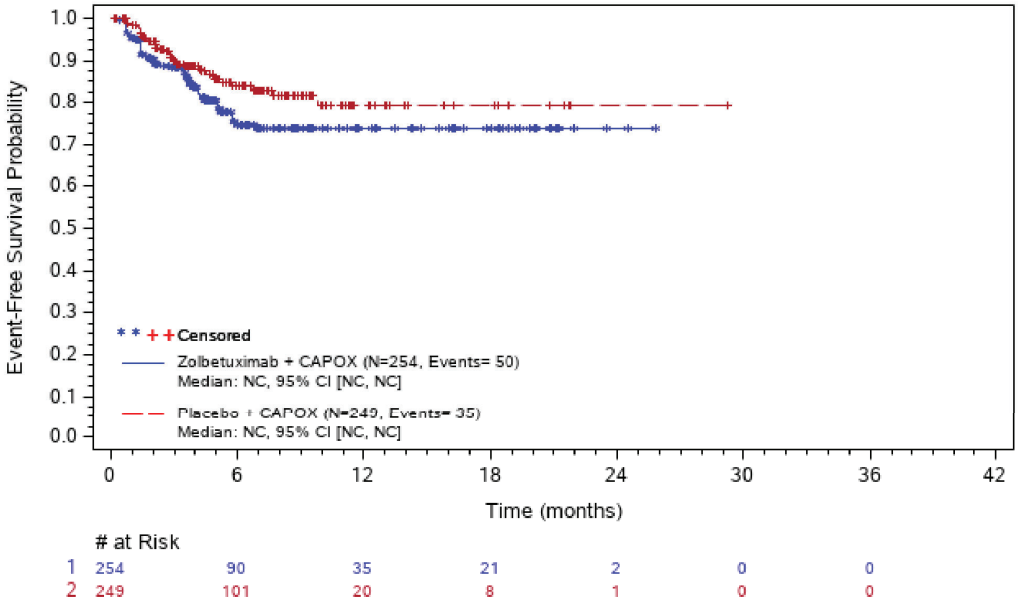
Figure 302.1.2001.8: Kaplan-Meier Plot of Time to first TEAE - Leukopenia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

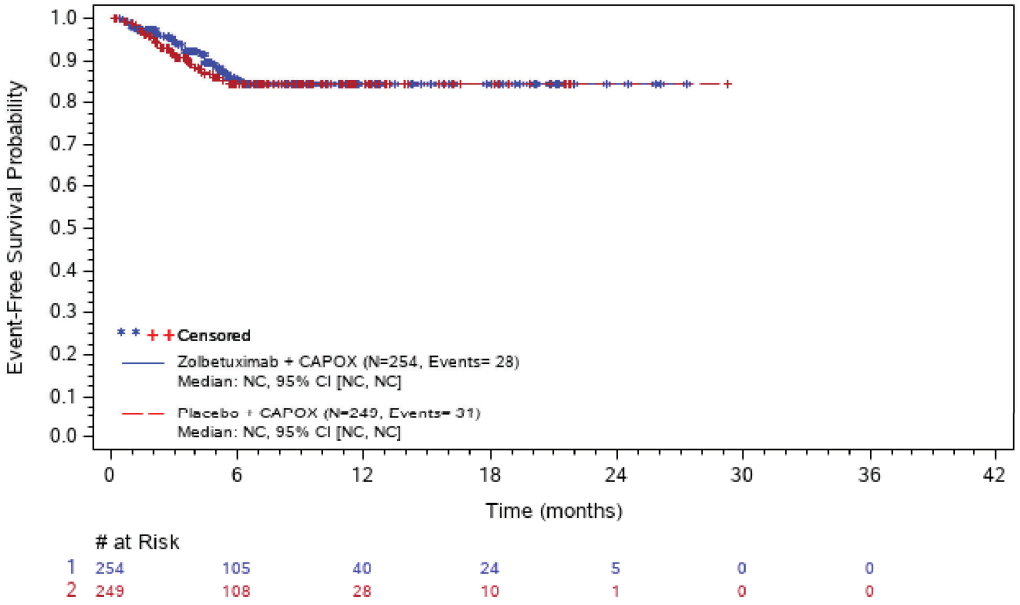
Figure 302.1.2001.9: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.10: Kaplan-Meier Plot of Time to first TEAE - Thrombocytopenia (PT) - Safety Analysis Set

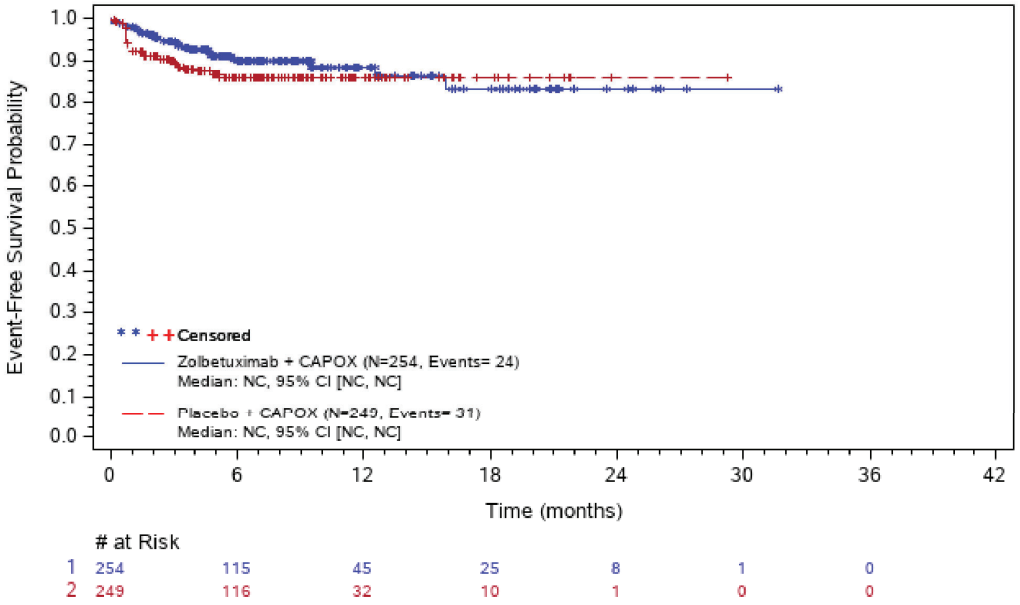


# at Risk							
1	254	105	40	24	5	0	0
2	249	108	28	10	1	0	0

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: 07OCT22

The SAS System

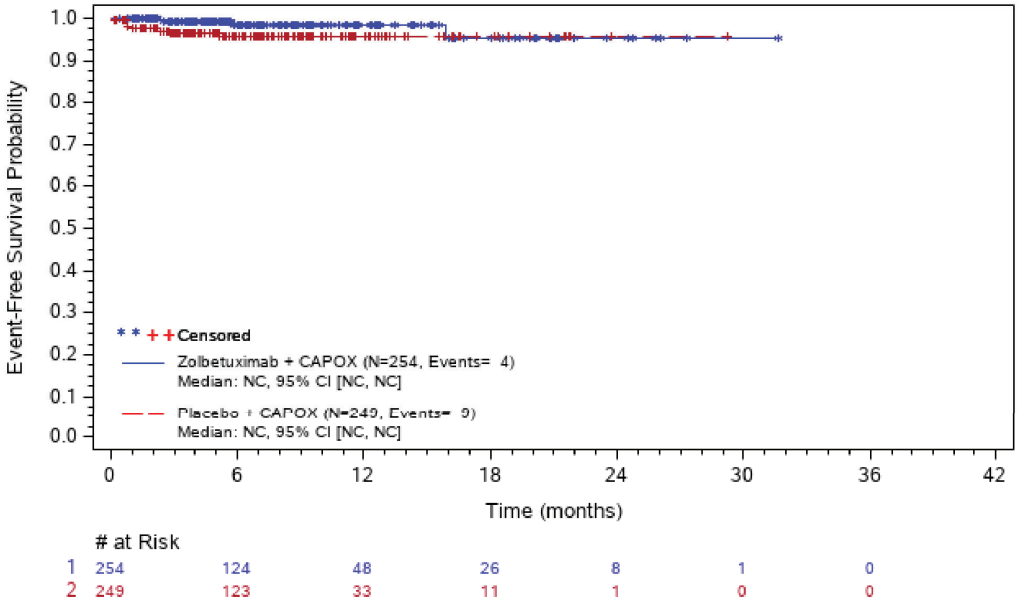
Figure 302.1.2001.11: Kaplan-Meier Plot of Time to first TEAE - Cardiac Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

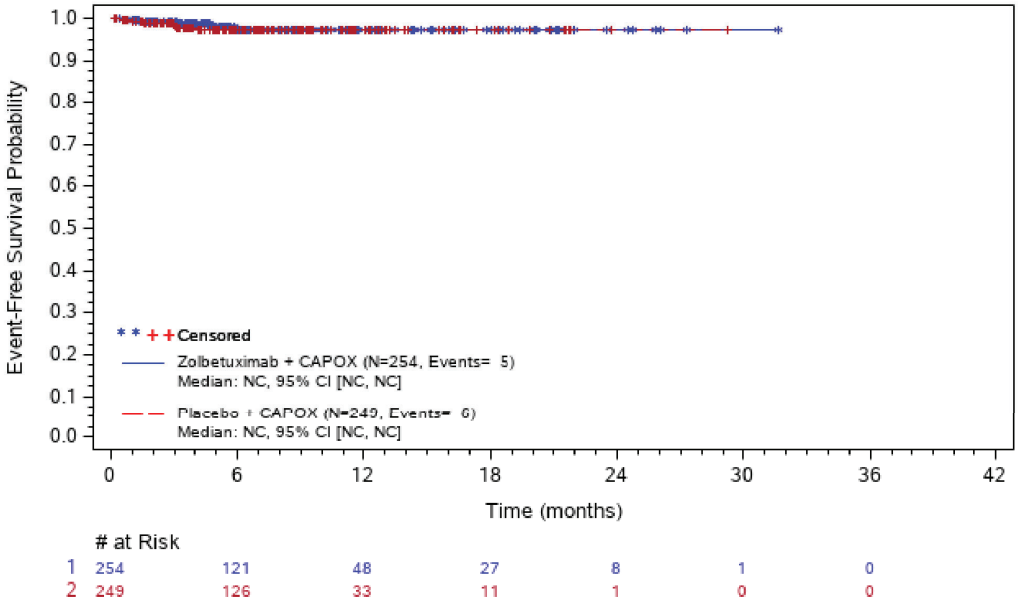
Figure 302.1.2001.12: Kaplan-Meier Plot of Time to first TEAE - Sinus Bradycardia (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 07OCT22

The SAS System

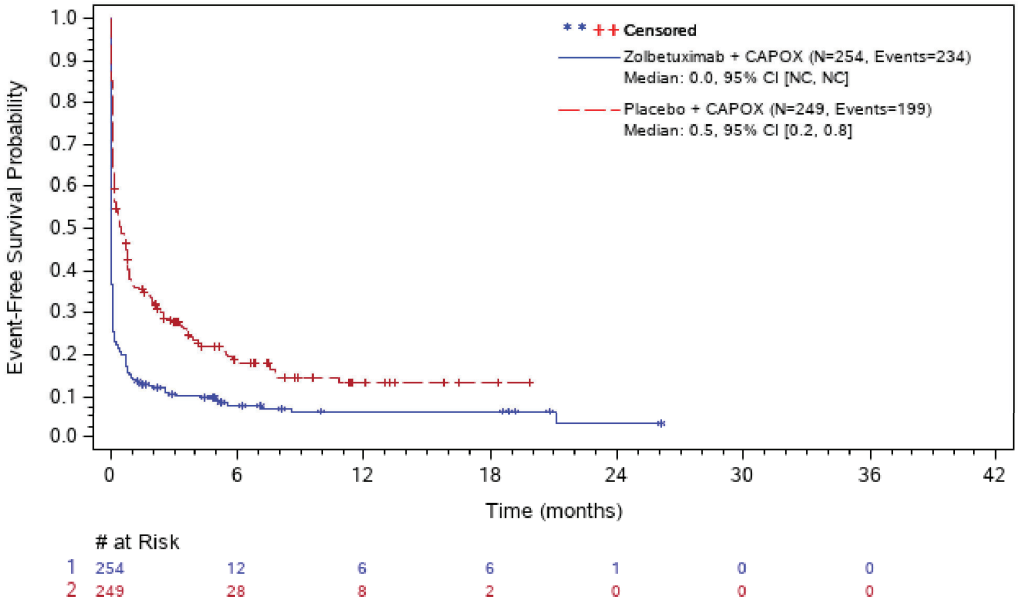
Figure 302.1.2001.13: Kaplan-Meier Plot of Time to first TEAE - Sinus Tachycardia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

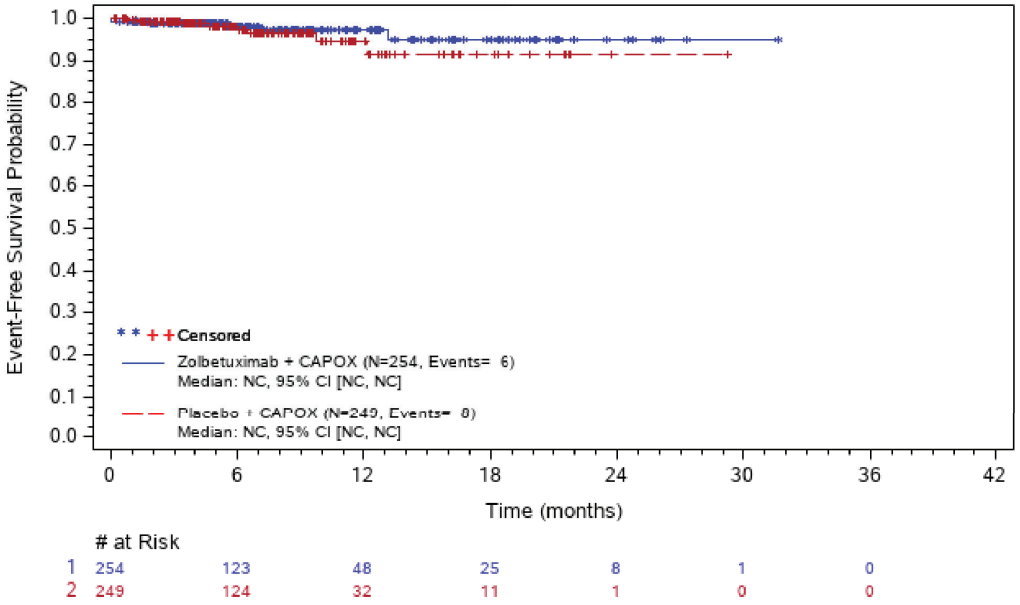
Figure 302.1.2001.14: Kaplan-Meier Plot of Time to first TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

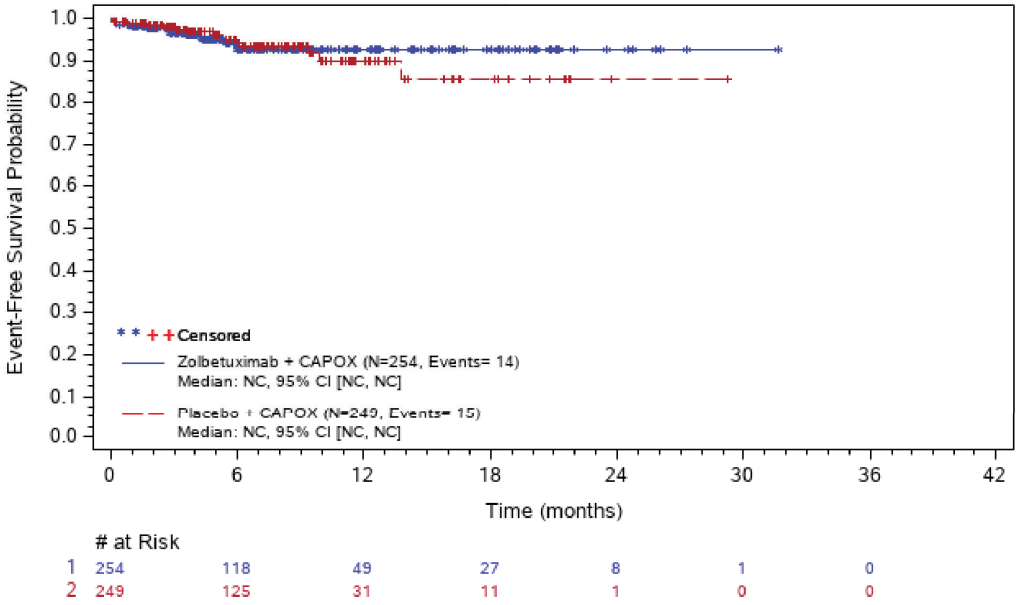
Figure 302.1.2001.15: Kaplan-Meier Plot of Time to first TEAE - Abdominal Discomfort (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.16: Kaplan-Meier Plot of Time to first TEAE - Abdominal Distension (PT) - Safety Analysis Set

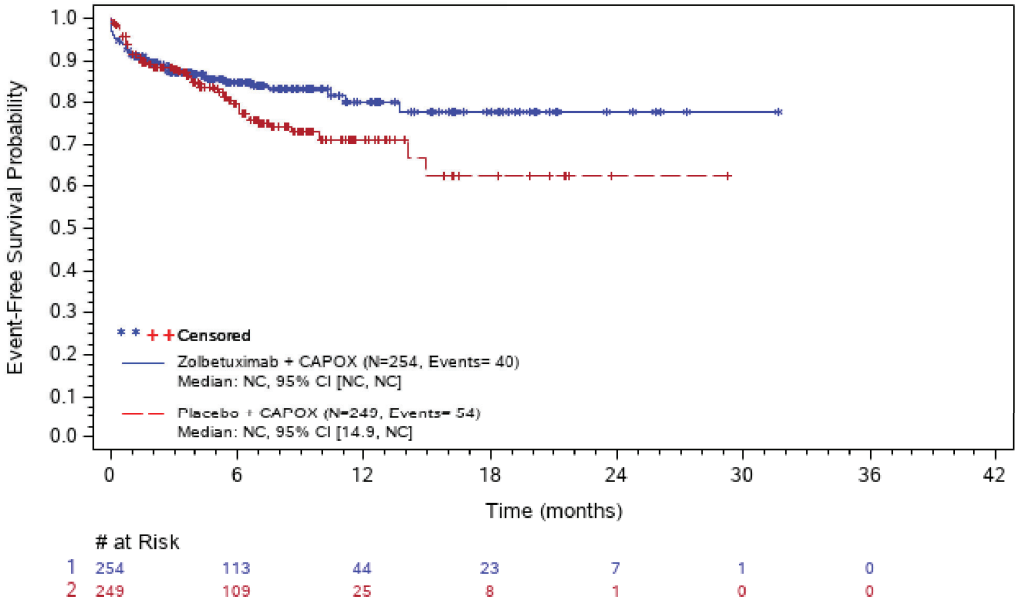


# at Risk							
1	254	118	49	27	8	1	0
2	249	125	31	11	1	0	0

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: 07OCT22

The SAS System

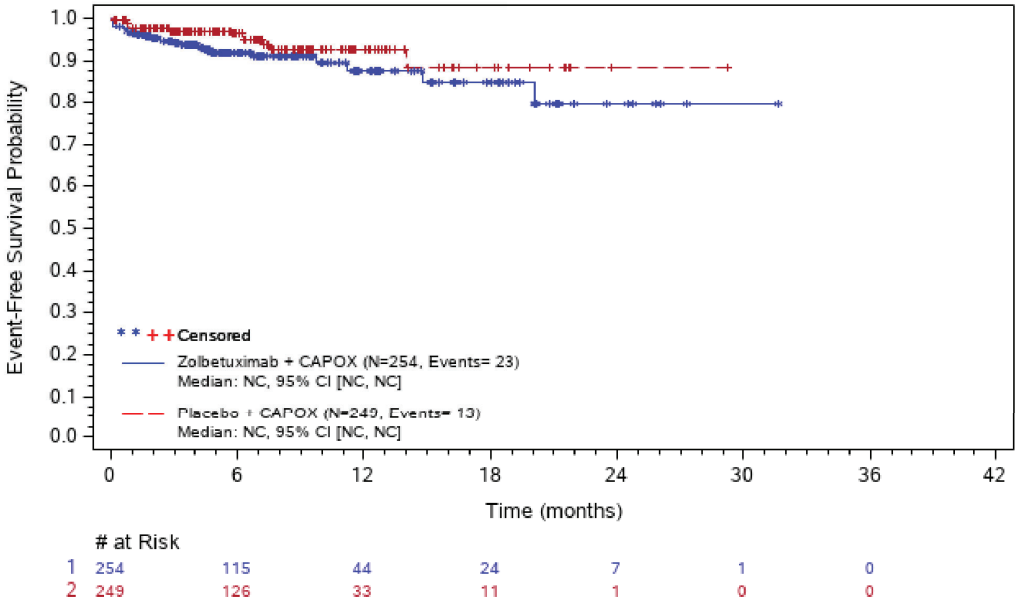
Figure 302.1.2001.17: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

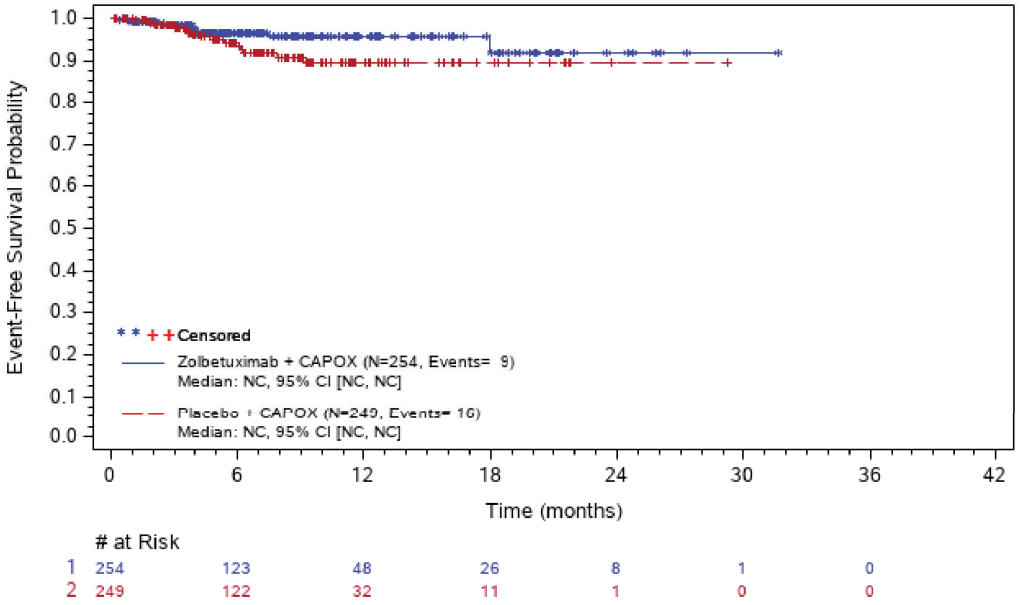
Figure 302.1.2001.18: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain Upper (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

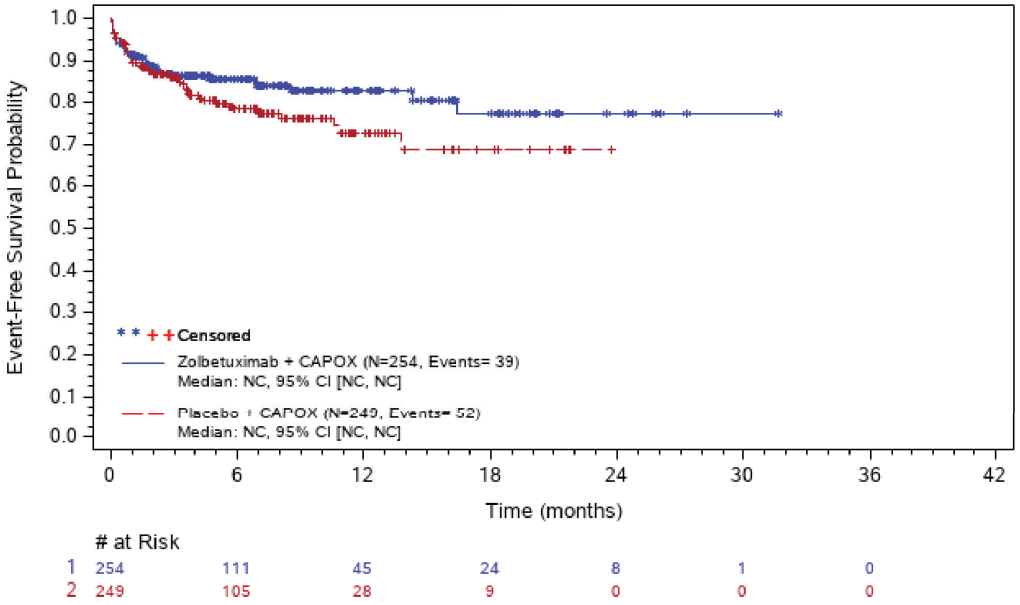
Figure 302.1.2001.19: Kaplan-Meier Plot of Time to first TEAE - Ascites (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

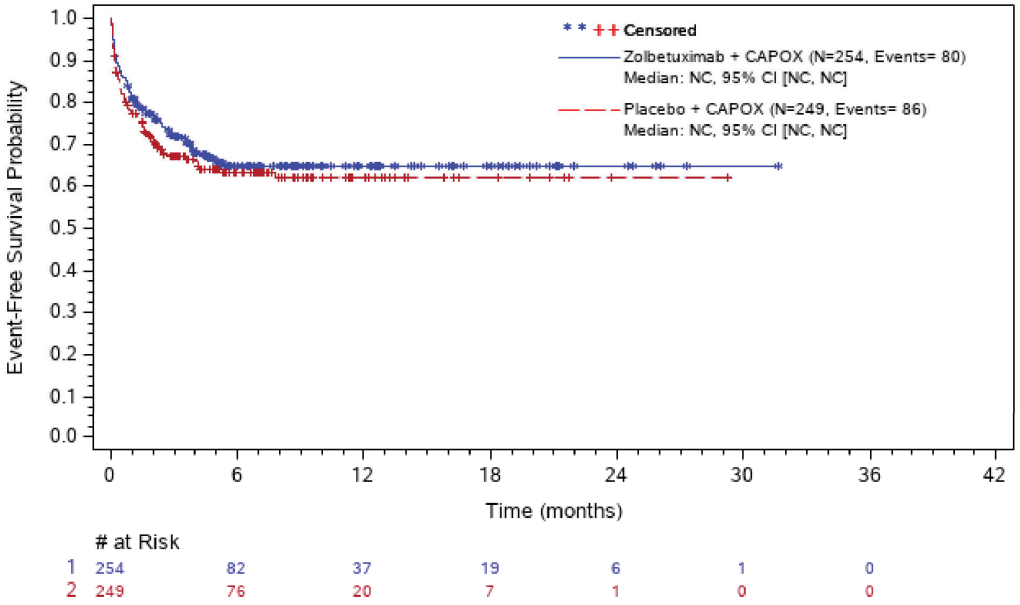
Figure 302.1.2001.20: Kaplan-Meier Plot of Time to first TEAE - Constipation (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

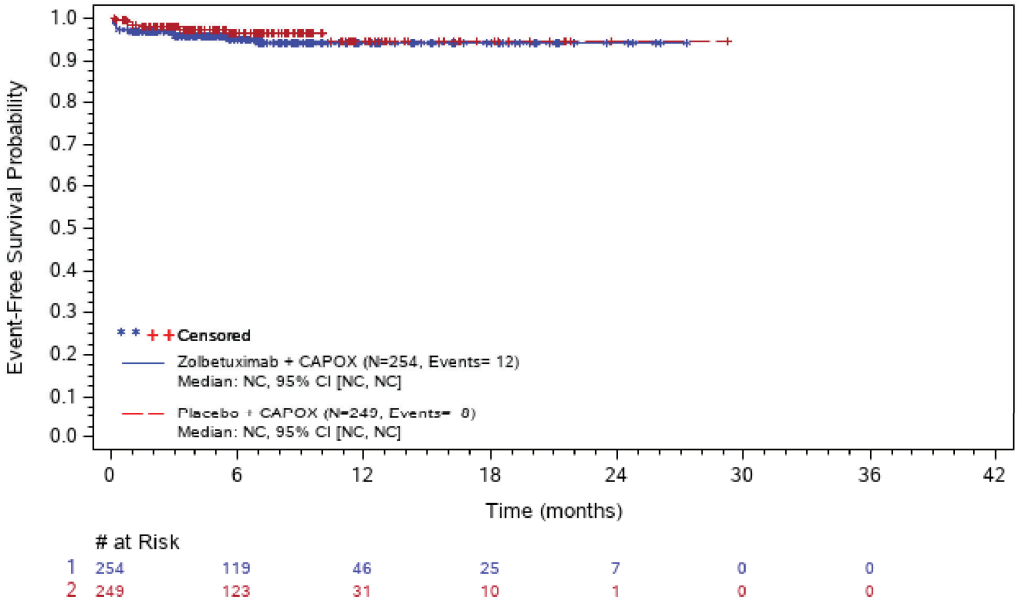
Figure 302.1.2001.21: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

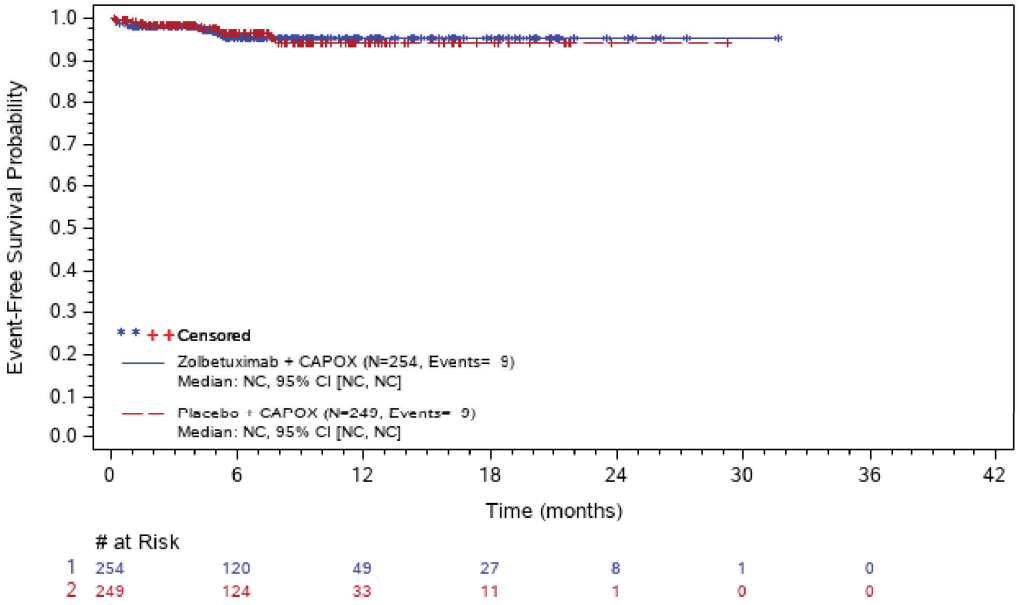
Figure 302.1.2001.22: Kaplan-Meier Plot of Time to first TEAE - Dyspepsia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.23: 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: 07OCT22

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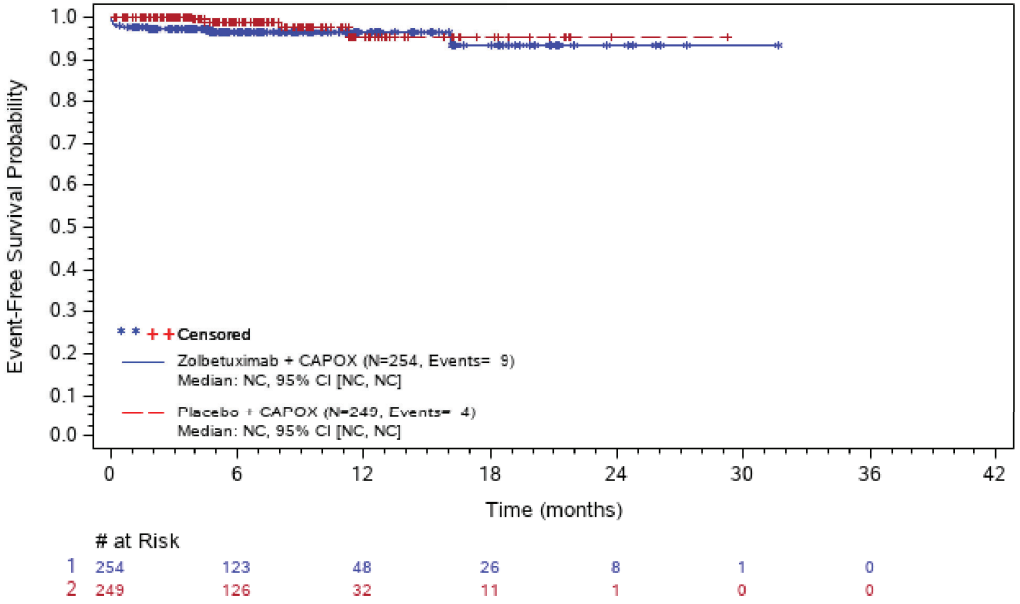
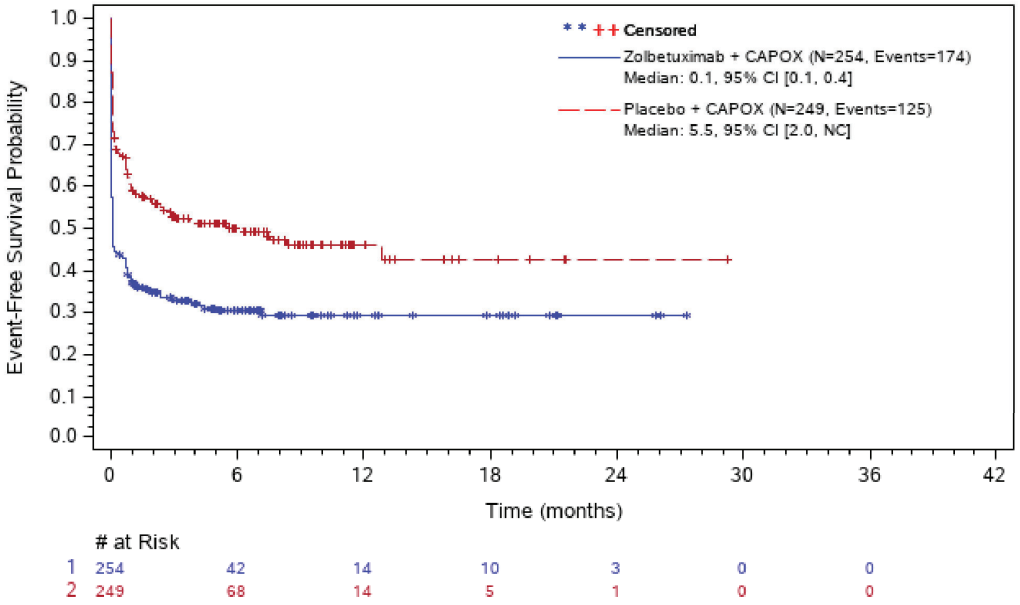
Figure 302.1.2001.24: Kaplan-Meier Plot of Time to first TEAE - Gastrooesophageal Reflux Disease (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

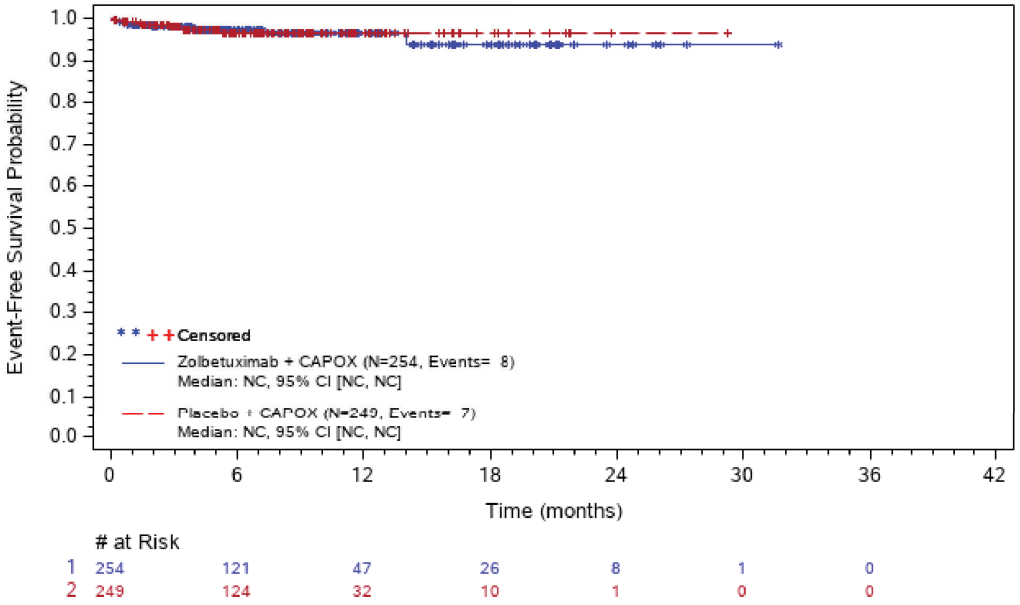
Figure 302.1.2001.25: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

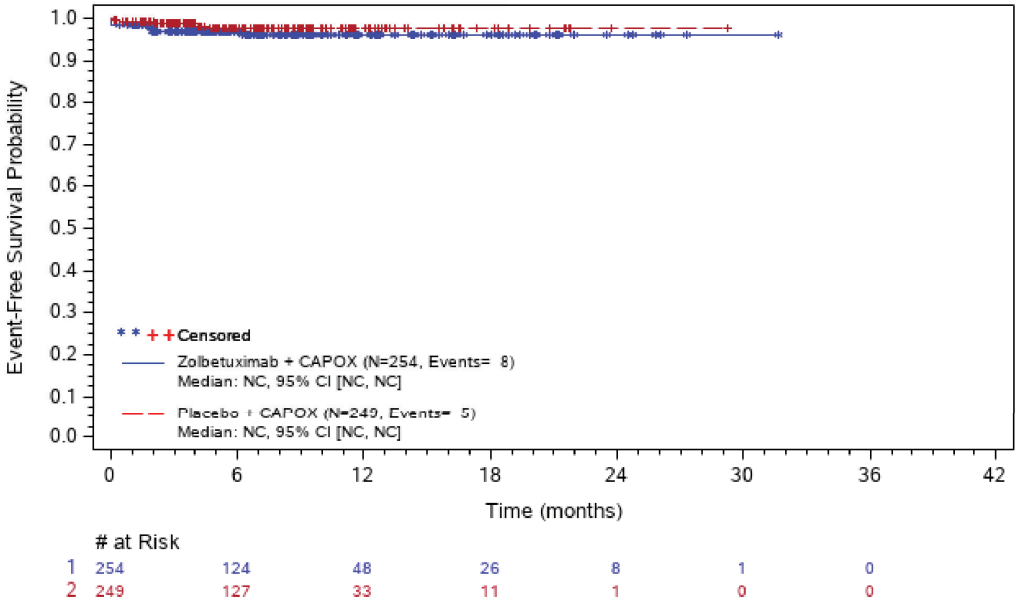
Figure 302.1.2001.26: Kaplan-Meier Plot of Time to first TEAE - Stomatitis (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

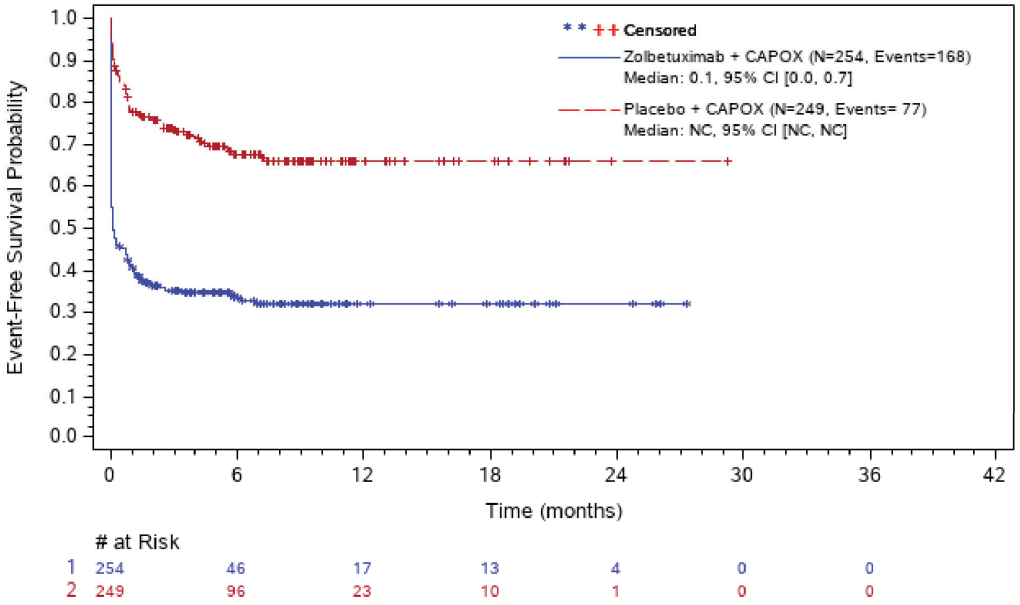
Figure 302.1.2001.27: Kaplan-Meier Plot of Time to first TEAE - Upper Gastrointestinal Haemorrhage (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 07OCT22

The SAS System

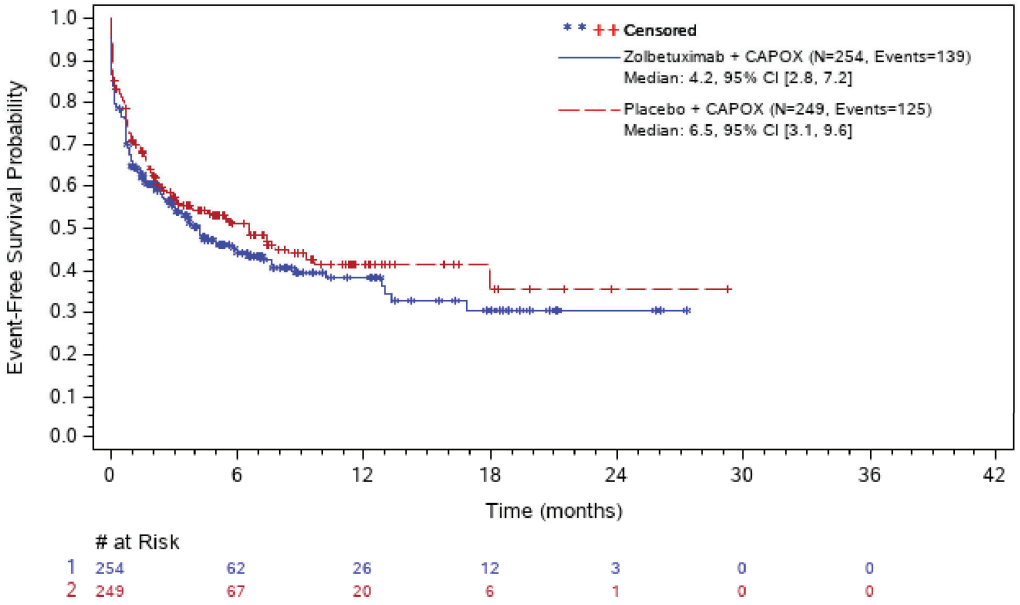
Figure 302.1.2001.28: Kaplan-Meier Plot of Time to first TEAE - Vomiting (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

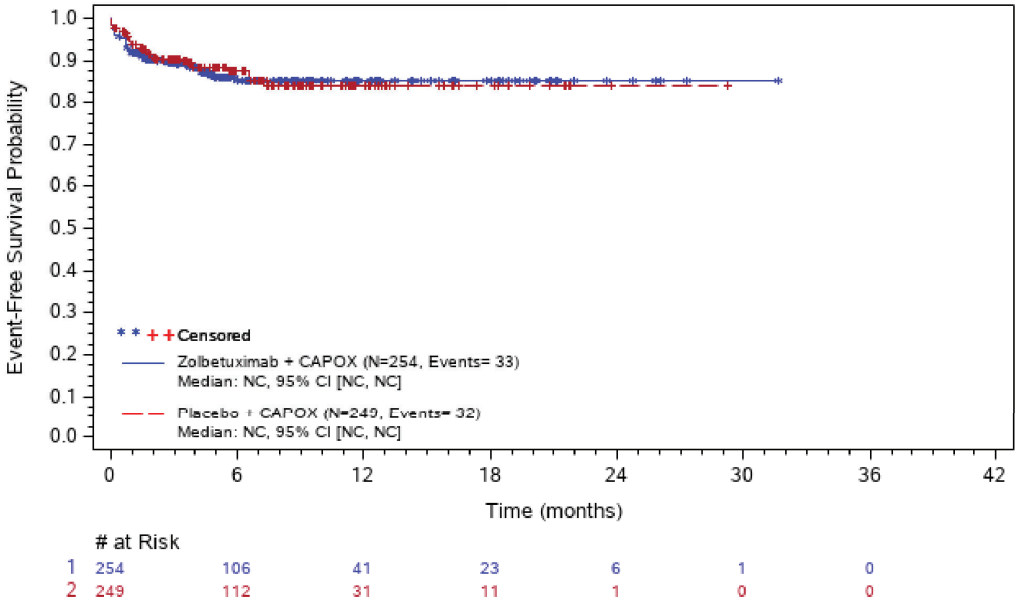
Figure 302.1.2001.29: Kaplan-Meier Plot of Time to first TEAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

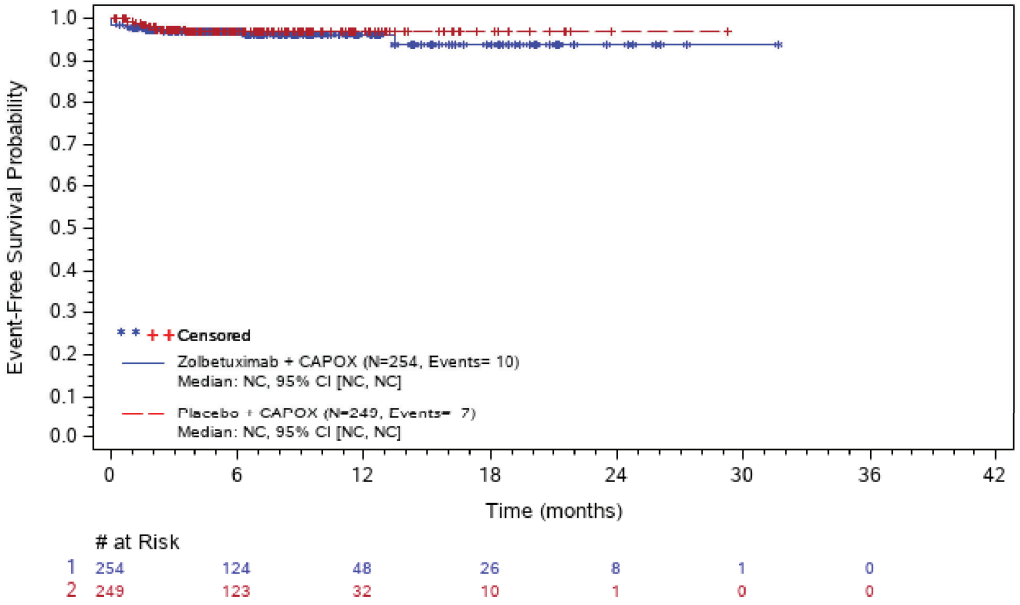
Figure 302.1.2001.30: Kaplan-Meier Plot of Time to first TEAE - Asthenia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

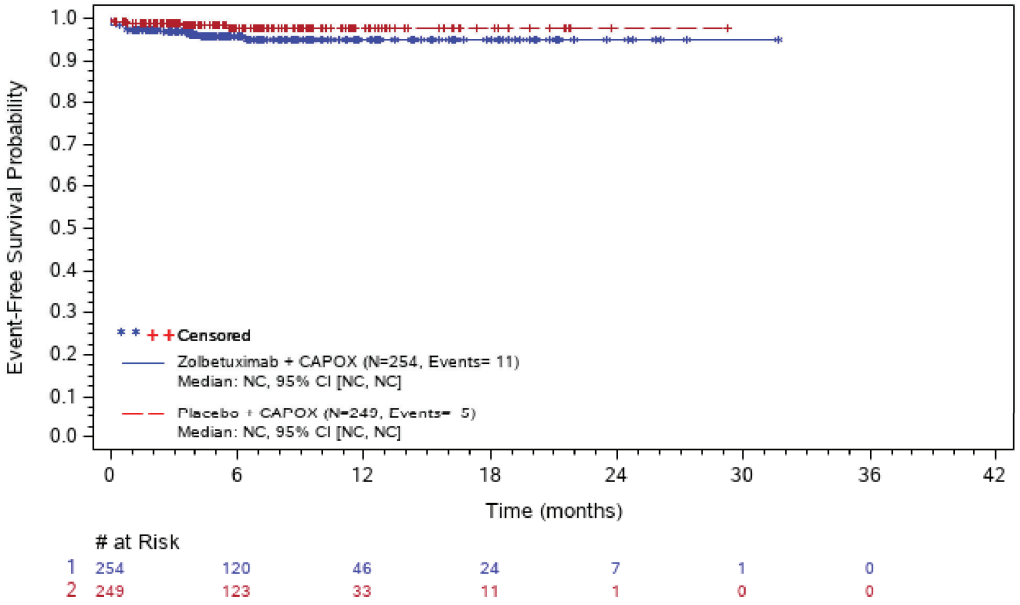
Figure 302.1.2001.31: Kaplan-Meier Plot of Time to first TEAE - Chest Discomfort (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

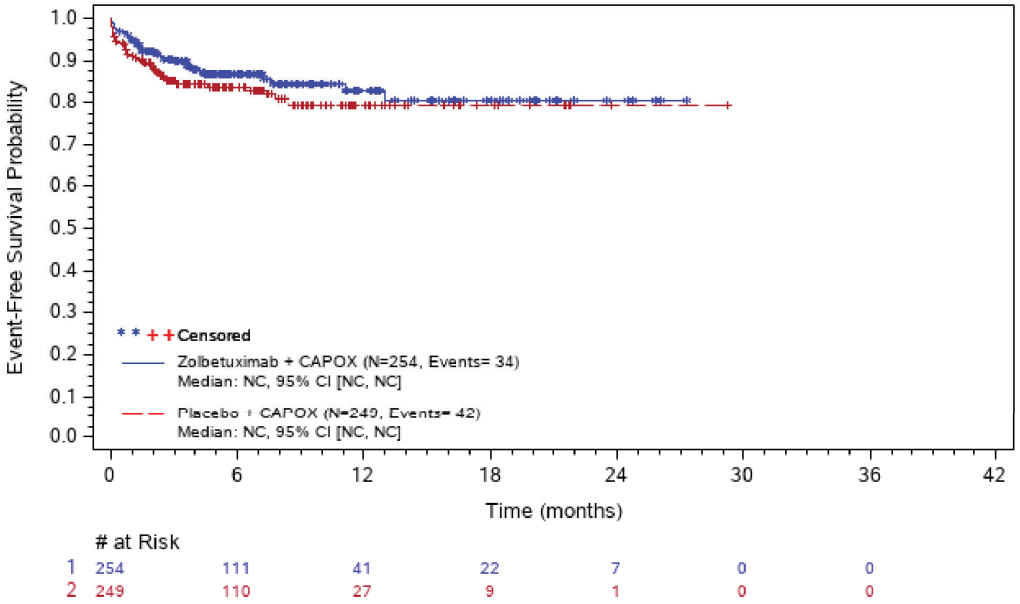
Figure 302.1.2001.32: Kaplan-Meier Plot of Time to first TEAE - Chills (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

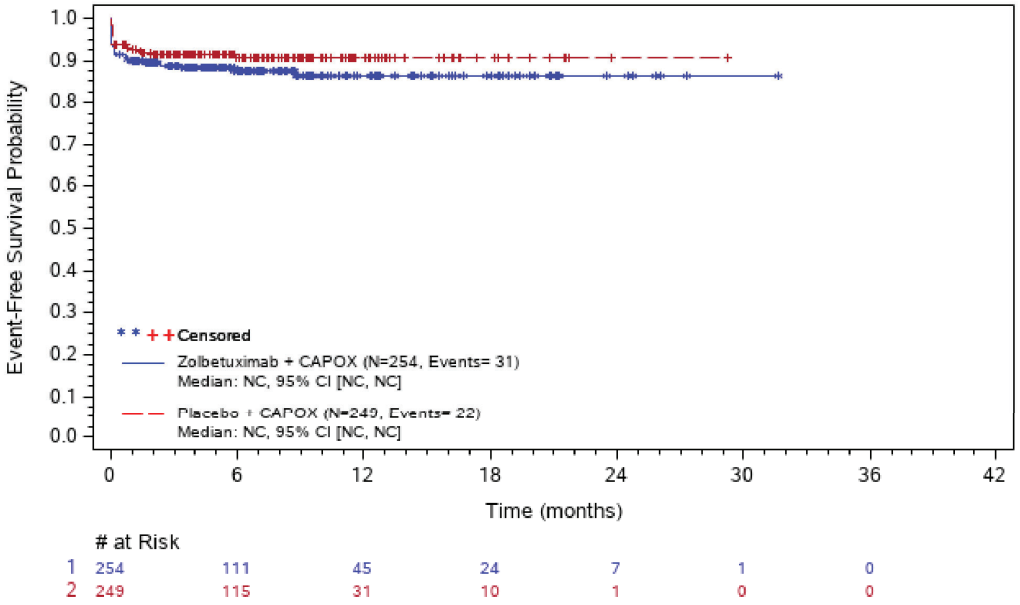
Figure 302.1.2001.33: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

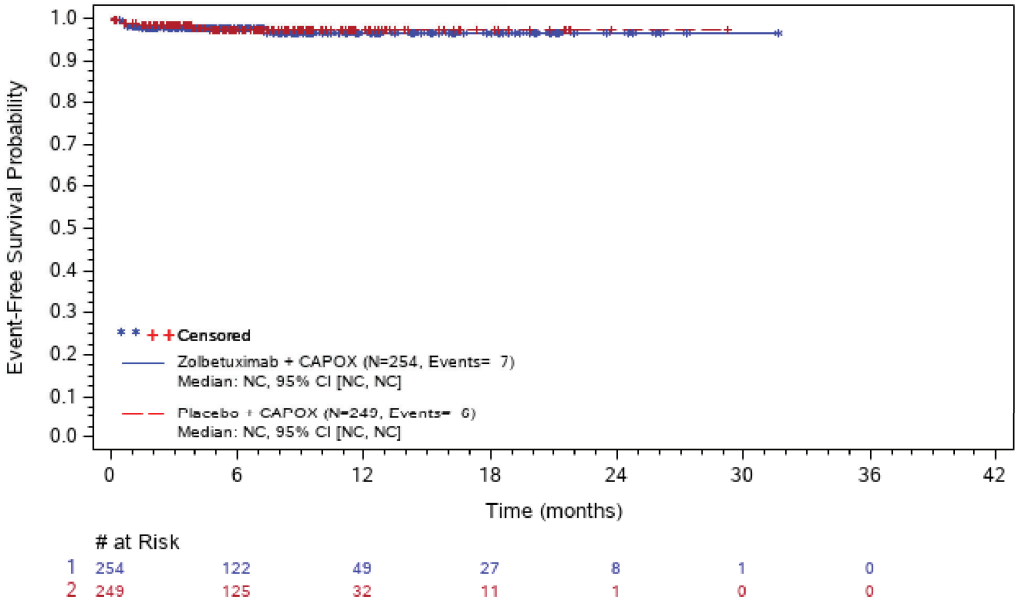
Figure 302.1.2001.34: Kaplan-Meier Plot of Time to first TEAE - Malaise (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

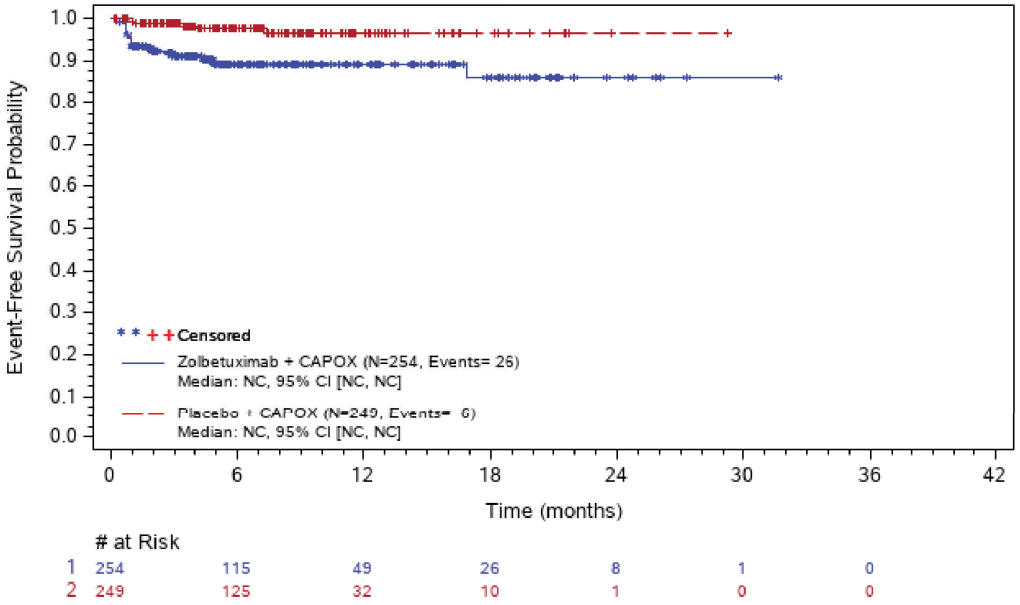
Figure 302.1.2001.35: Kaplan-Meier Plot of Time to first TEAE - Mucosal Inflammation (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

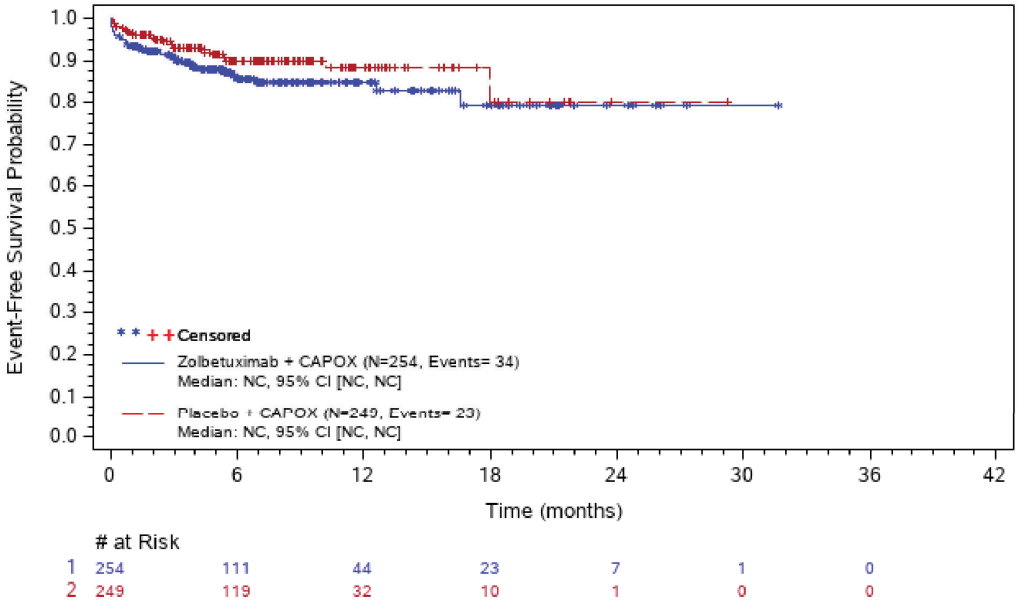
Figure 302.1.2001.36: Kaplan-Meier Plot of Time to first TEAE - Oedema Peripheral (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

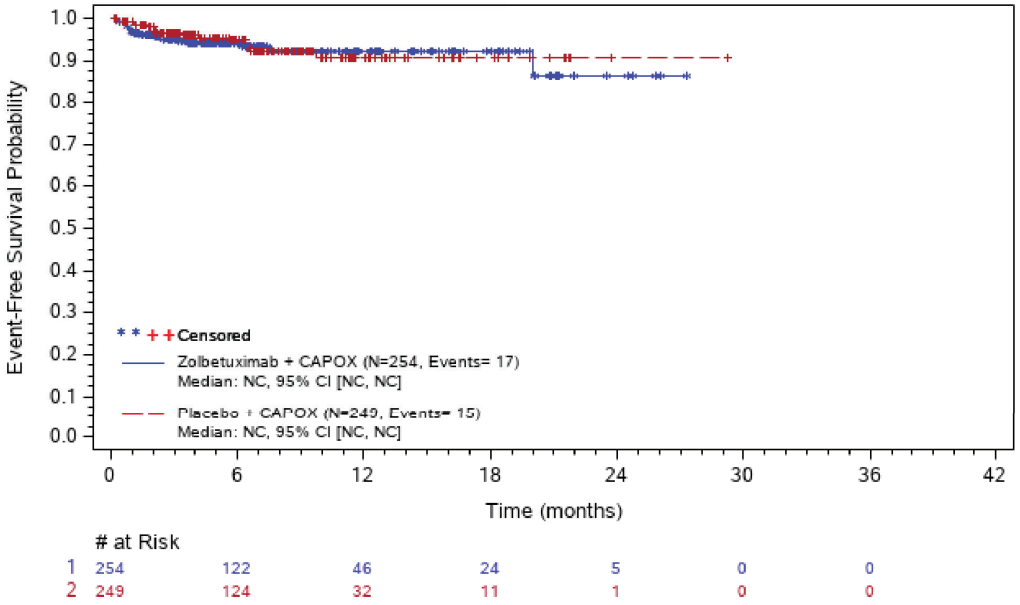
Figure 302.1.2001.37: Kaplan-Meier Plot of Time to first TEAE - Pyrexia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

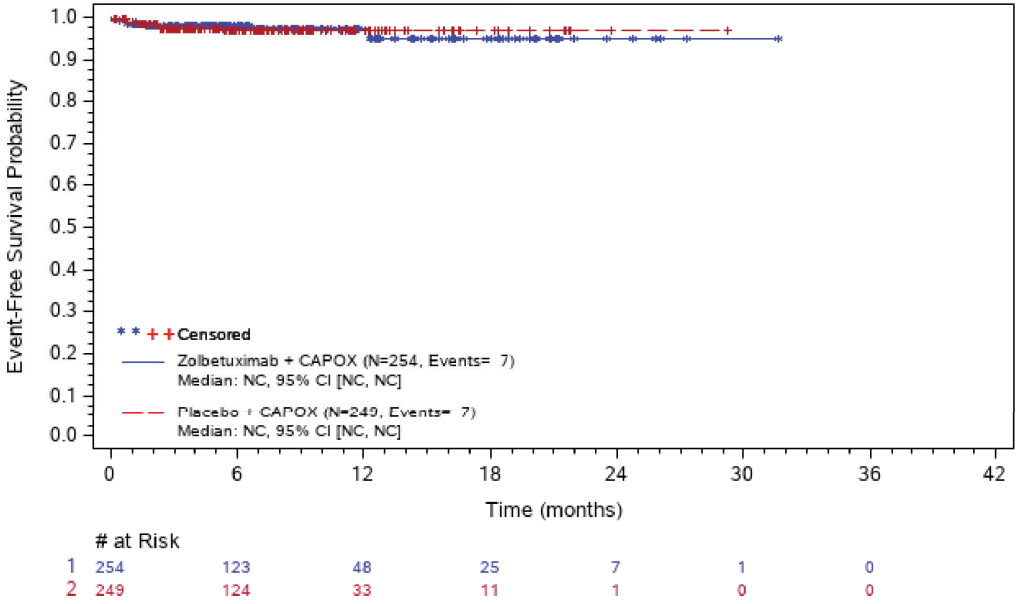
Figure 302.1.2001.38: Kaplan-Meier Plot of Time to first TEAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

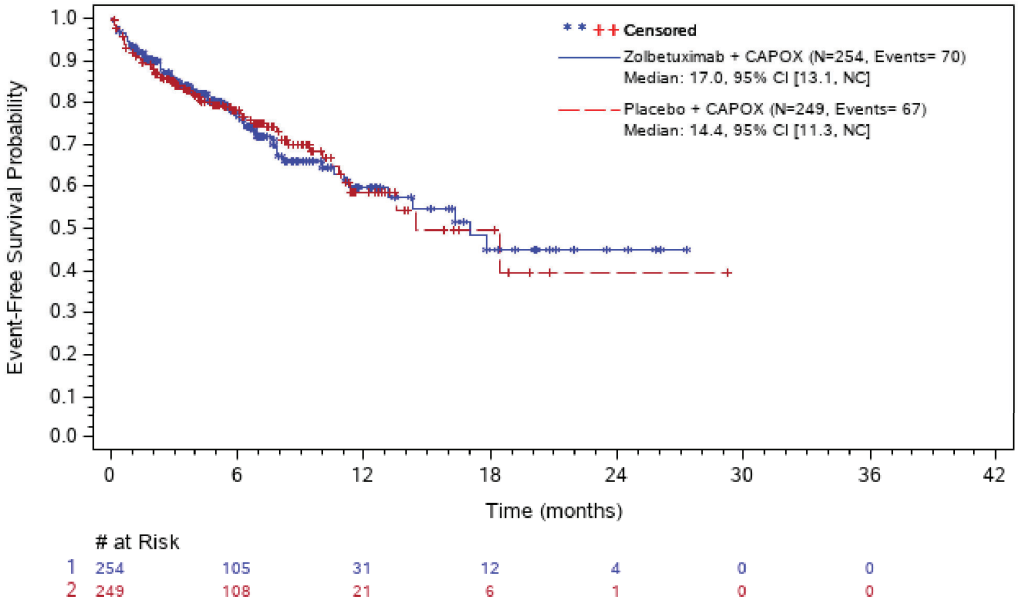
Figure 302.1.2001.39: Kaplan-Meier Plot of Time to first TEAE - Immune System Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

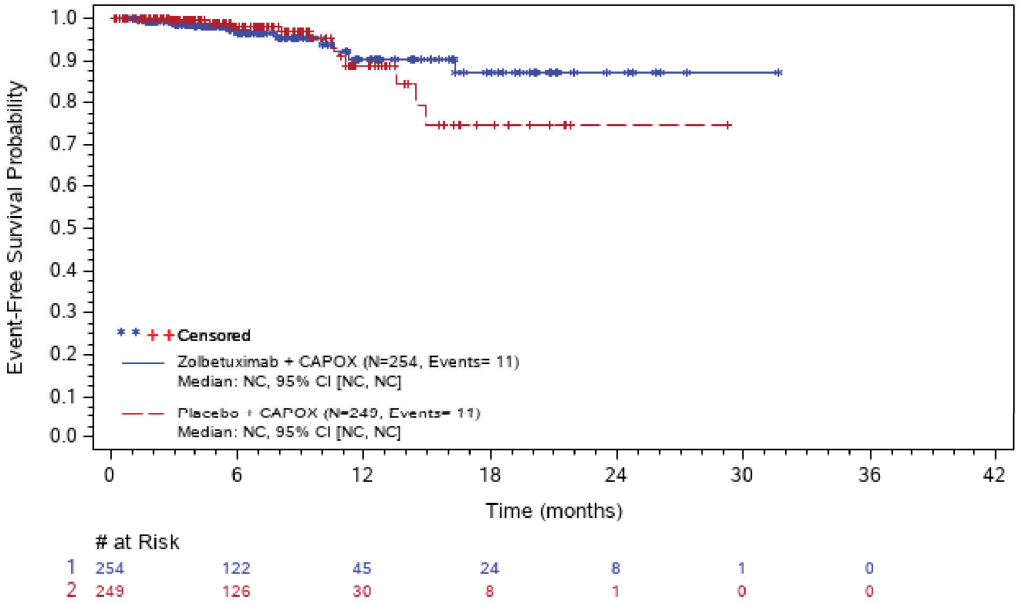
Figure 302.1.2001.40: Kaplan-Meier Plot of Time to first TEAE - Infections And Infestations (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

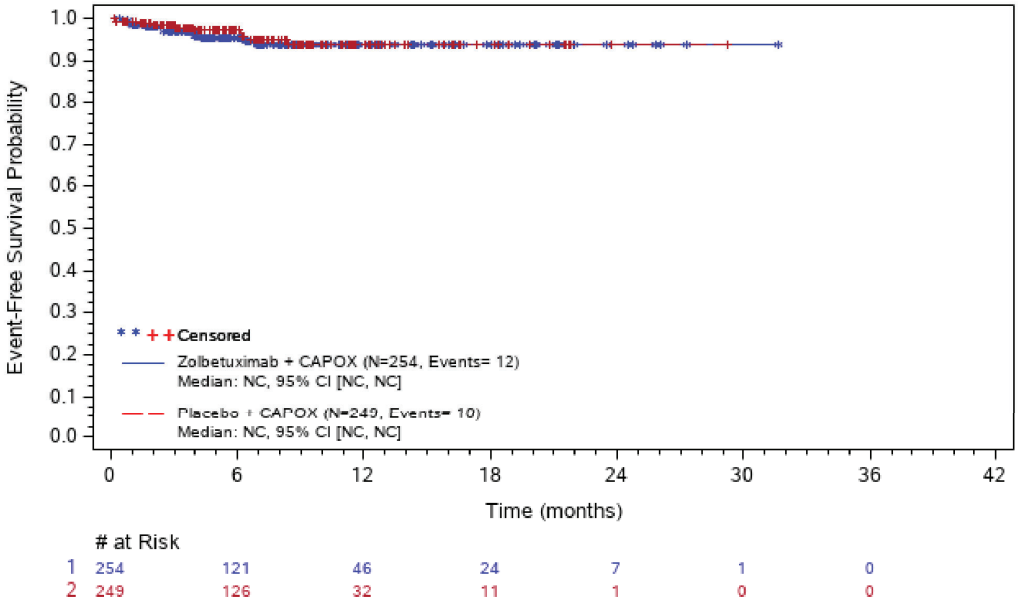
Figure 302.1.2001.41: Kaplan-Meier Plot of Time to first TEAE - Covid-19 (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

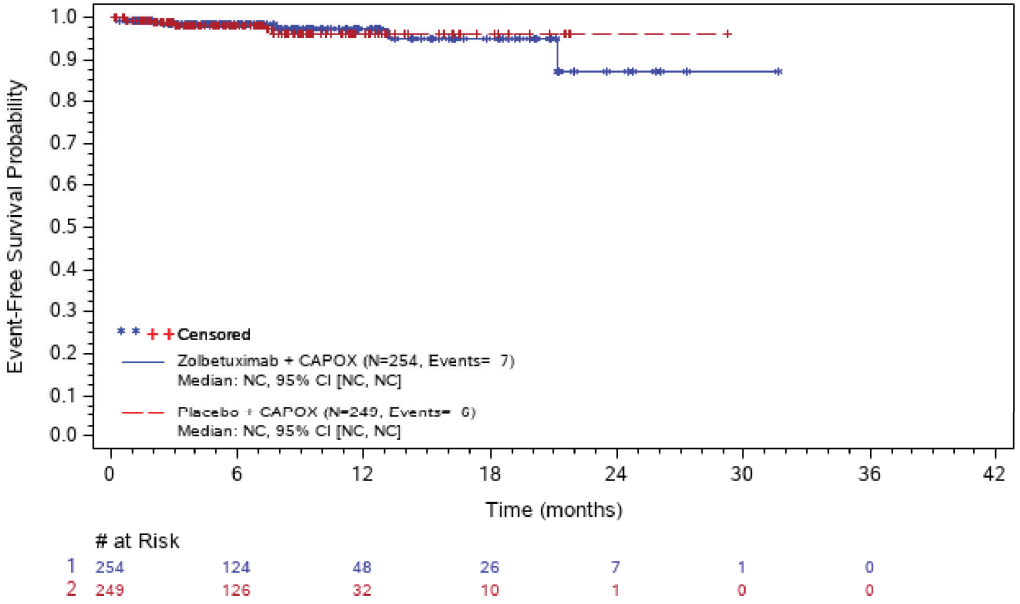
Figure 302.1.2001.42: Kaplan-Meier Plot of Time to first TEAE - Pneumonia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

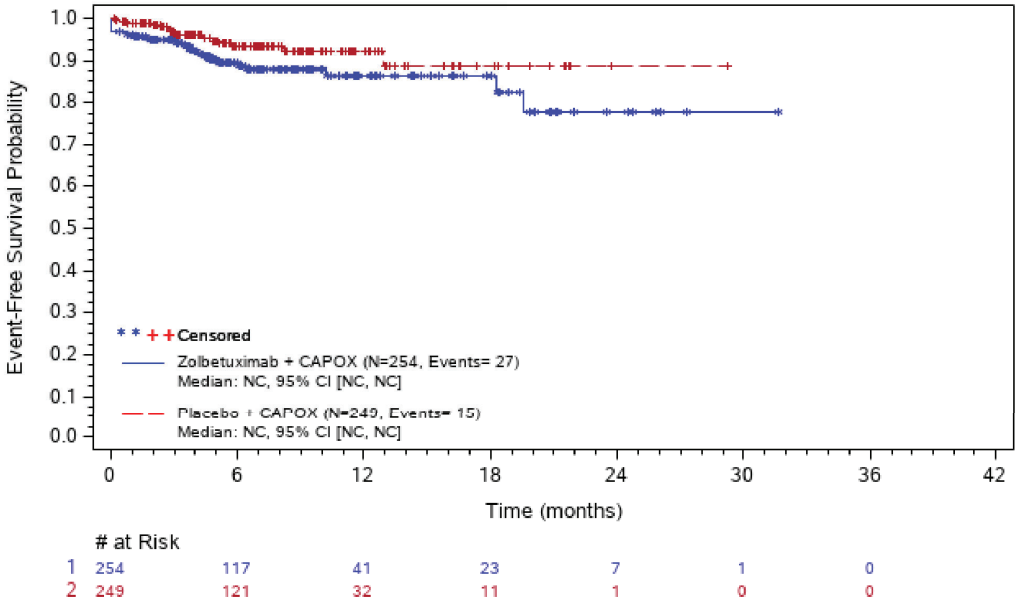
Figure 302.1.2001.43: Kaplan-Meier Plot of Time to first TEAE - Urinary Tract Infection (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

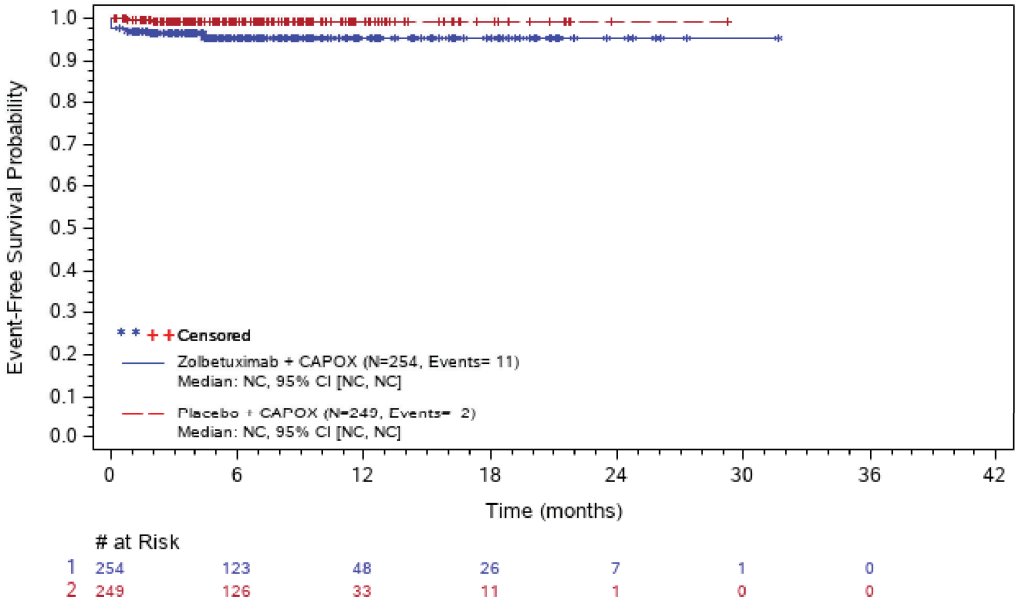
Figure 302.1.2001.44: Kaplan-Meier Plot of Time to first TEAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

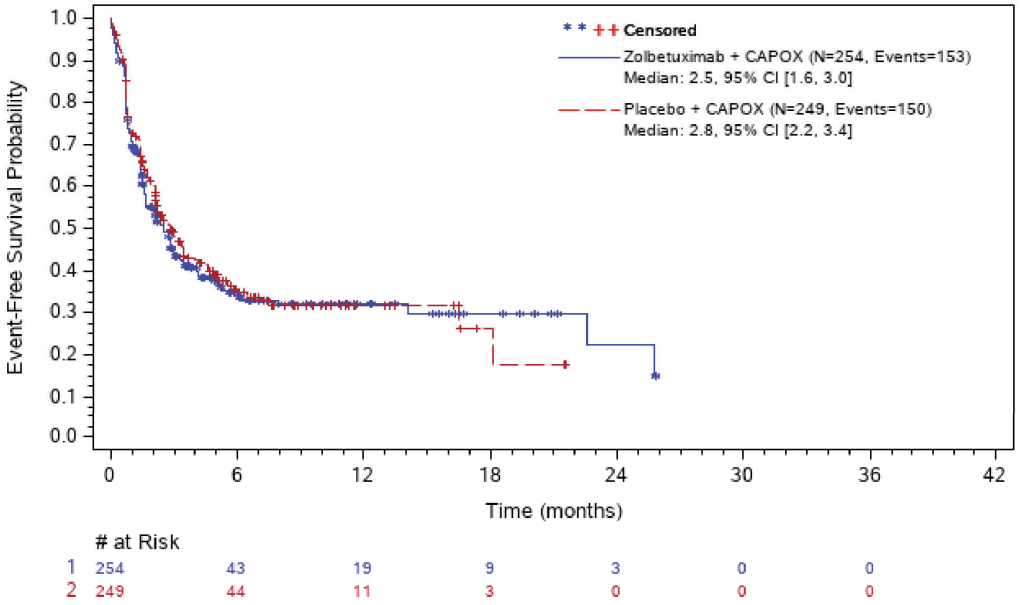
Figure 302.1.2001.45: Kaplan-Meier Plot of Time to first TEAE - Infusion Related Reaction (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

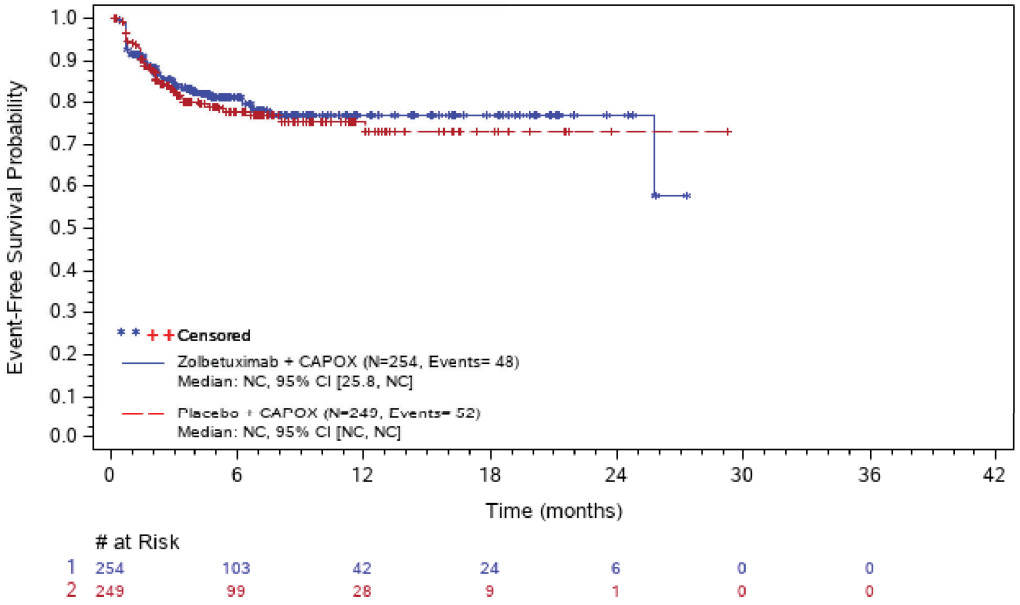
Figure 302.1.2001.46: Kaplan-Meier Plot of Time to first TEAE - Investigations (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

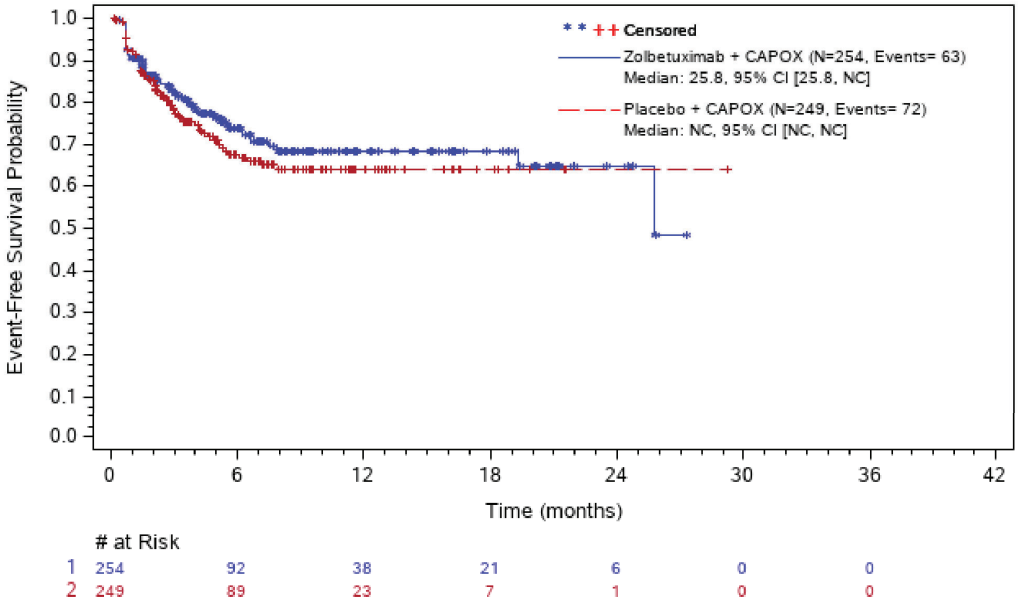
Figure 302.1.2001.47: Kaplan-Meier Plot of Time to first TEAE - Alanine Aminotransferase Increased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

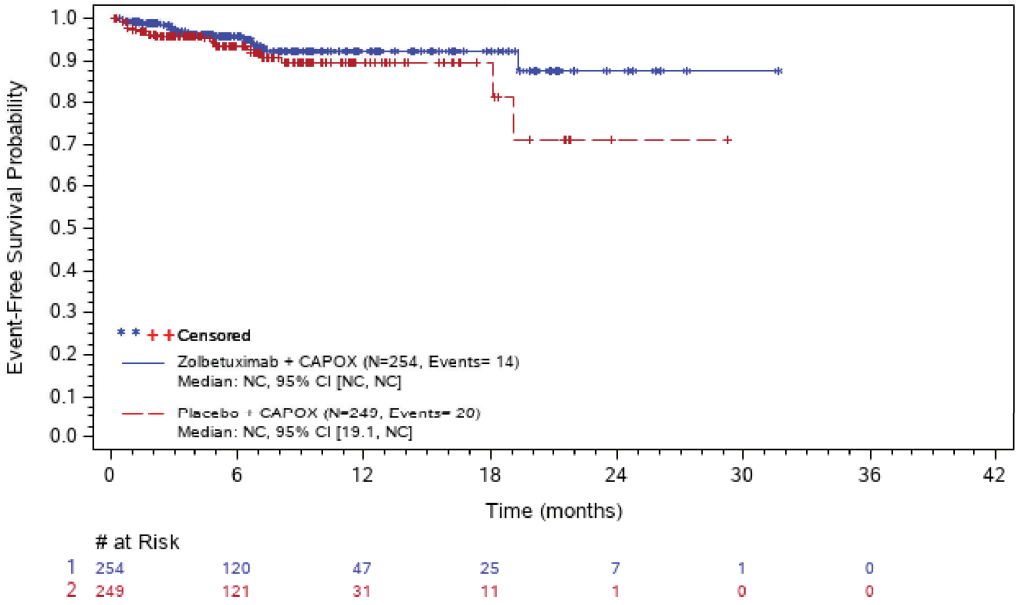
Figure 302.1.2001.48: Kaplan-Meier Plot of Time to first TEAE - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

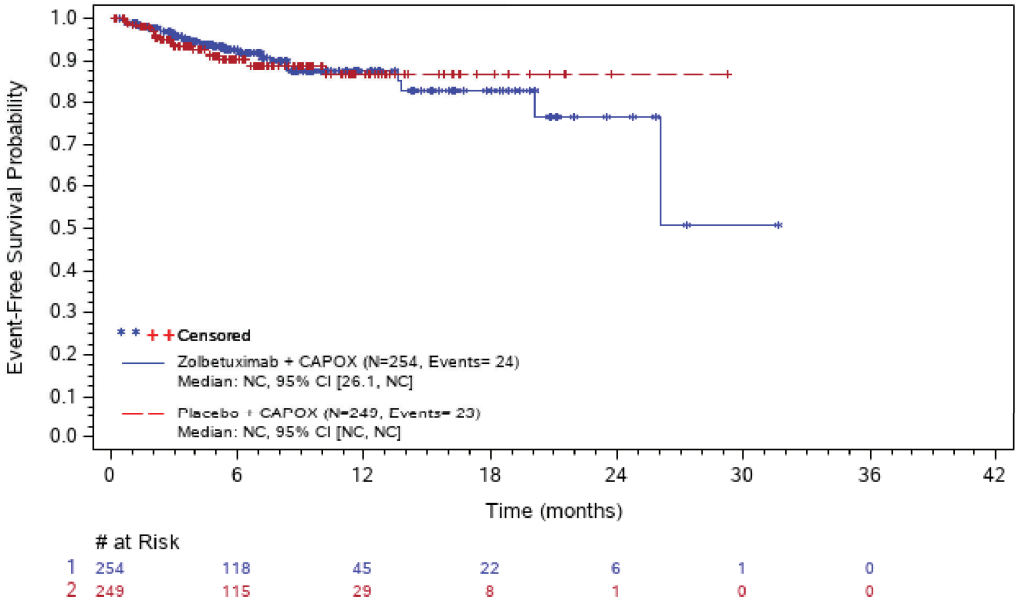
Figure 302.1.2001.49: Kaplan-Meier Plot of Time to first TEAE - Blood Alkaline Phosphatase Increased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.50: Kaplan-Meier Plot of Time to first TEAE - Blood Bilirubin Increased (PT) - Safety Analysis Set



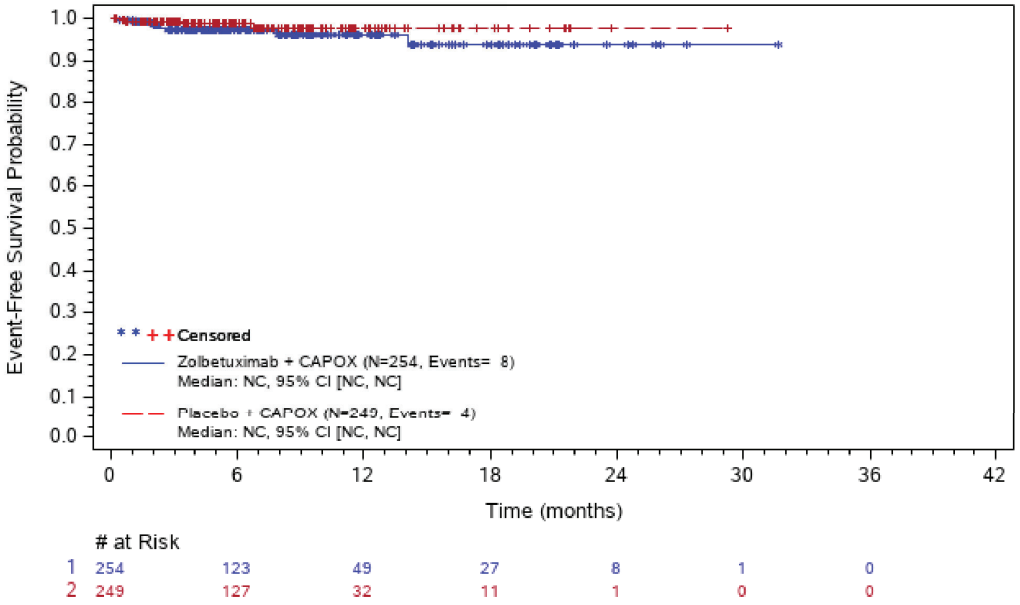
at Risk

1	254	118	45	22	6	1	0
2	249	115	29	8	1	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: 07OCT22

The SAS System

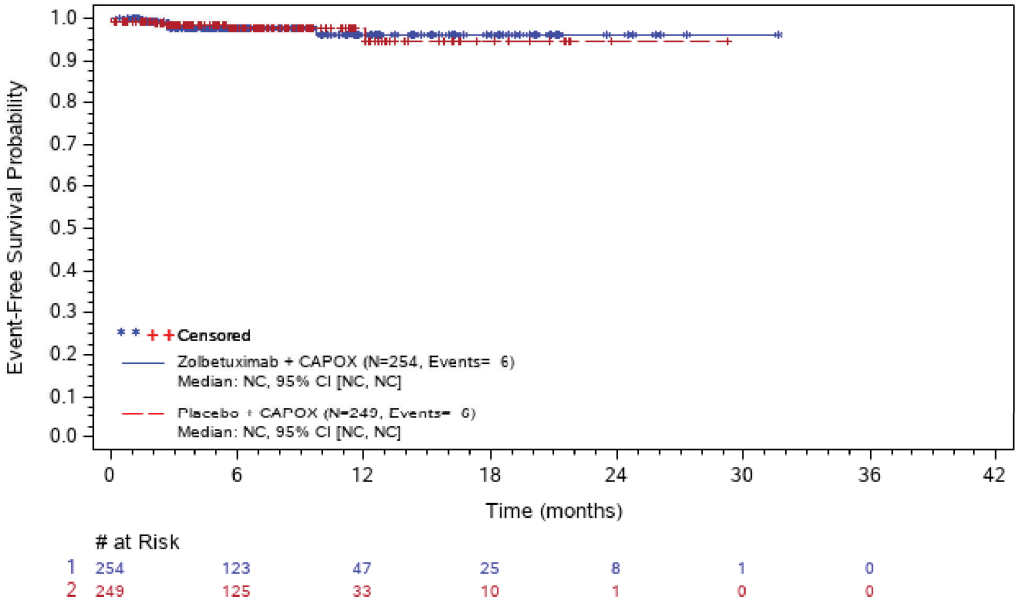
Figure 302.1.2001.51: Kaplan-Meier Plot of Time to first TEAE - Blood Creatinine Increased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

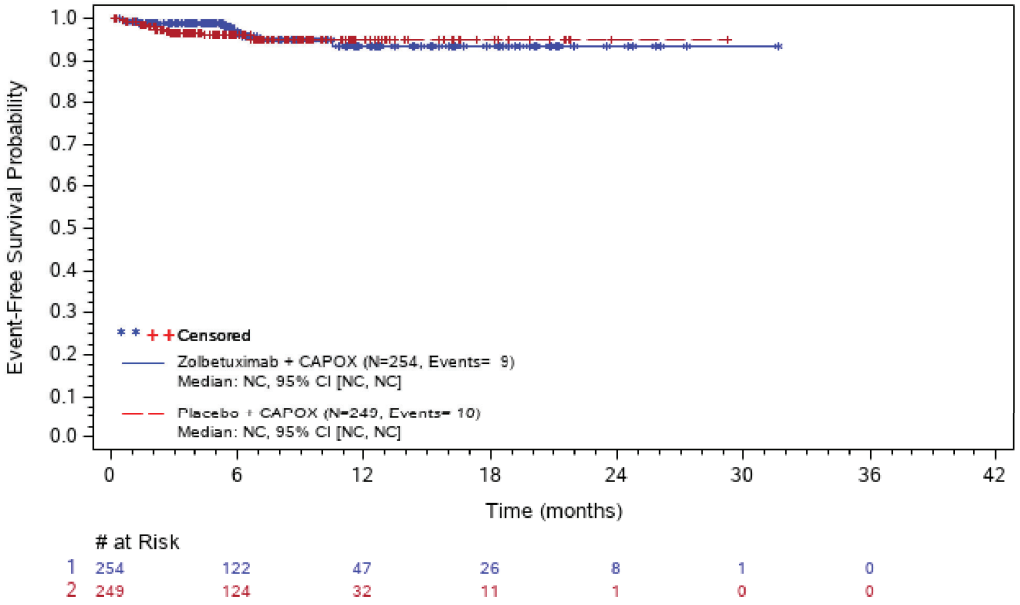
Figure 302.1.2001.52: Kaplan-Meier Plot of Time to first TEAE - Electrocardiogram Qt Prolonged (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

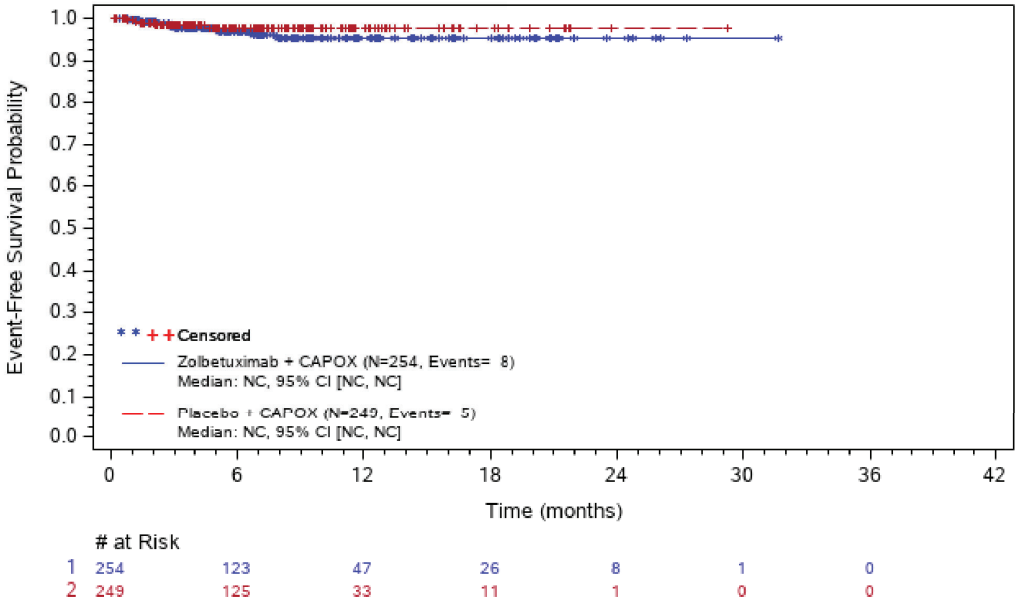
Figure 302.1.2001.53: Kaplan-Meier Plot of Time to first TEAE - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.54: 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.
ASTELLAS Data Cutoff Date: 07OCT22

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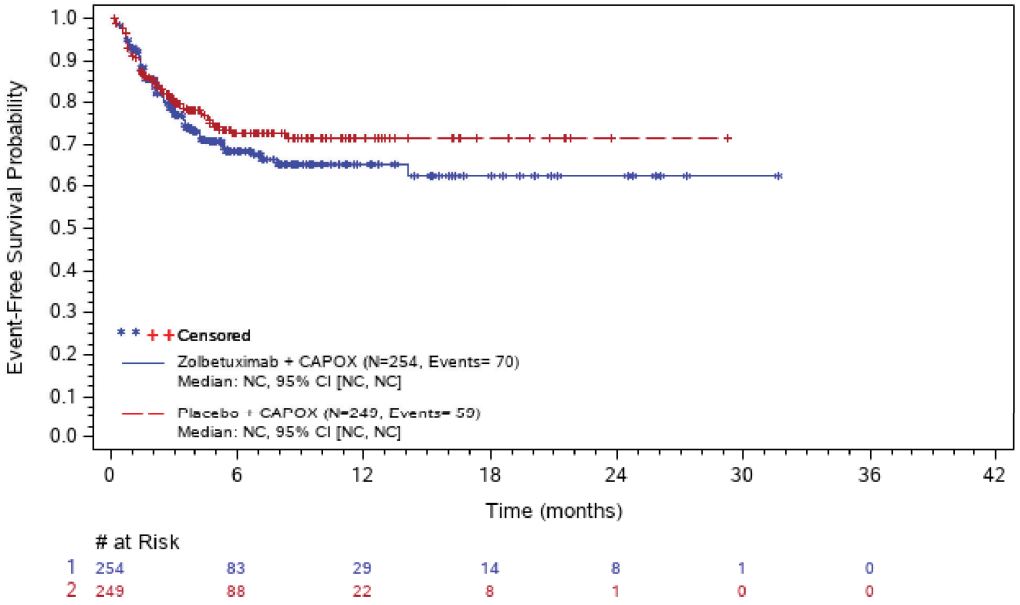
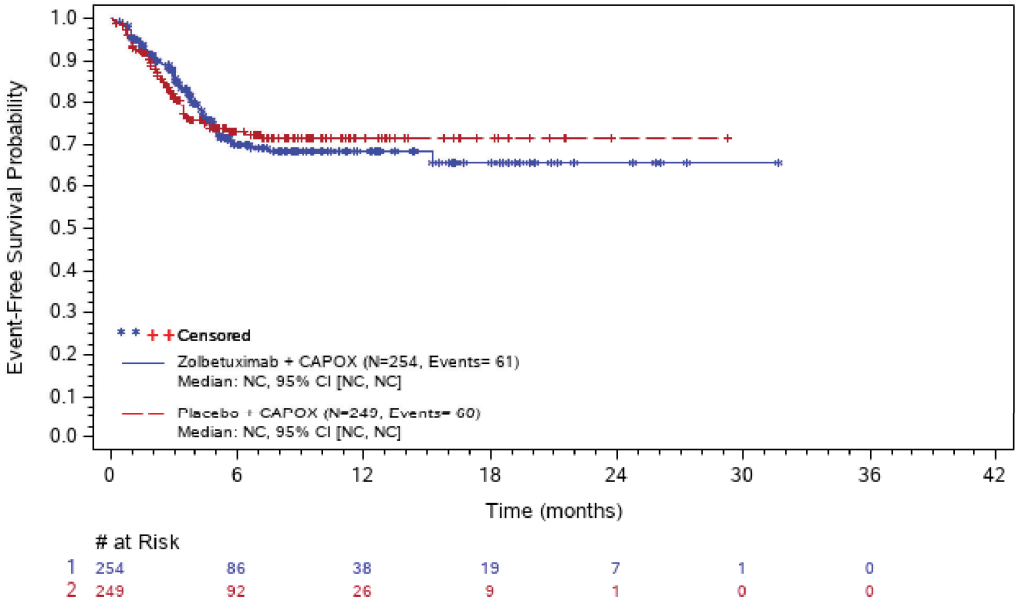
Figure 302.1.2001.55: Kaplan-Meier Plot of Time to first TEAE - Neutrophil Count Decreased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.56: 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: 07OCT22

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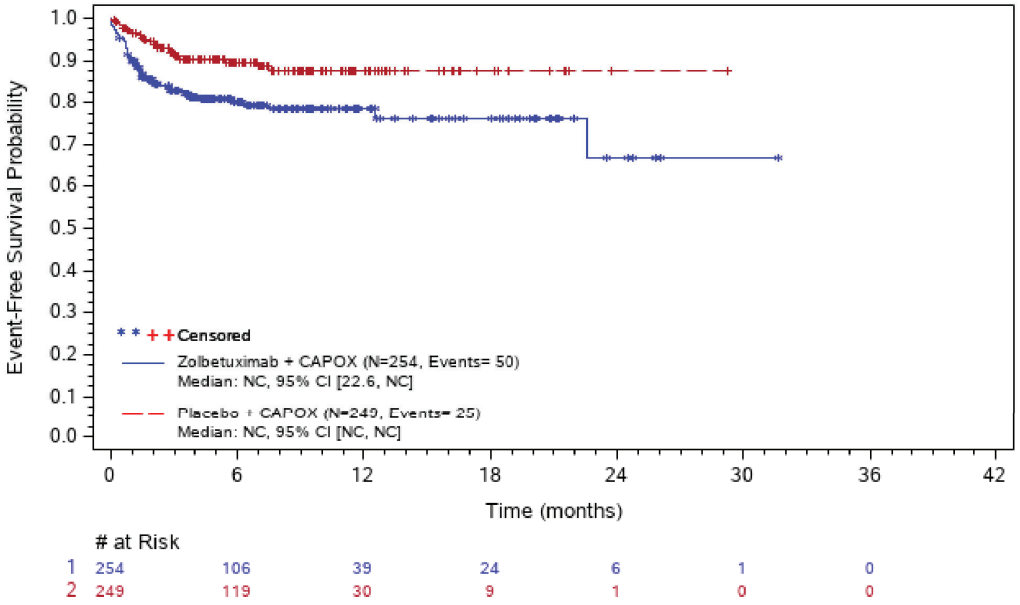
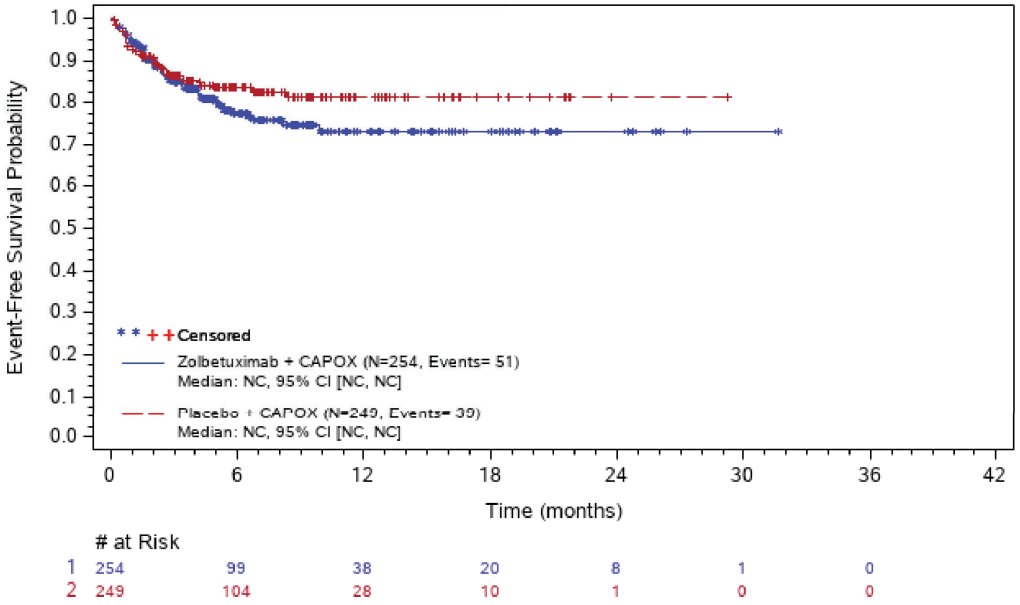
Figure 302.1.2001.57: Kaplan-Meier Plot of Time to first TEAE - Weight Decreased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

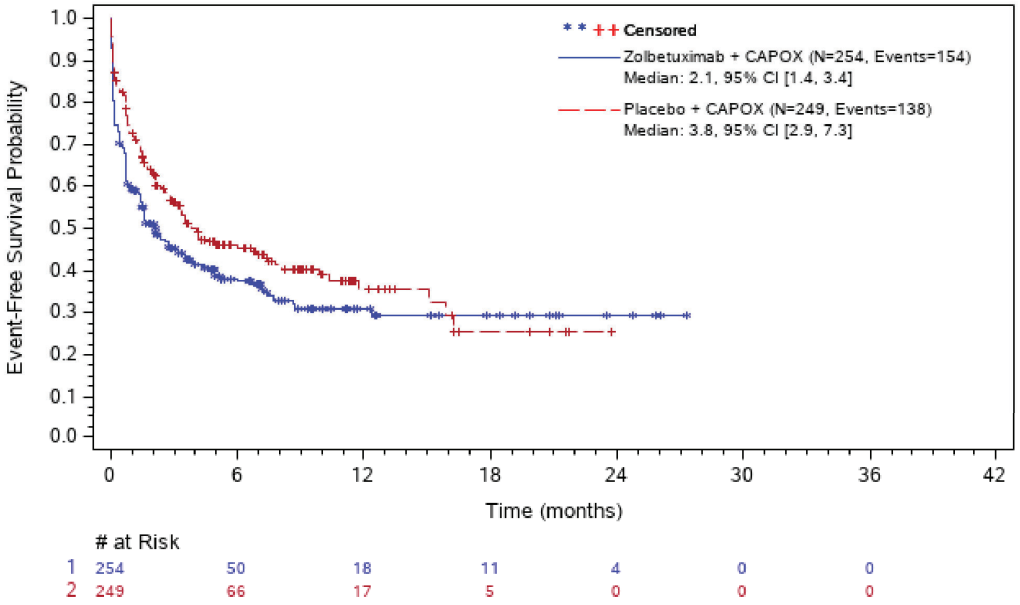
Figure 302.1.2001.58: Kaplan-Meier Plot of Time to first TEAE - White Blood Cell Count Decreased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

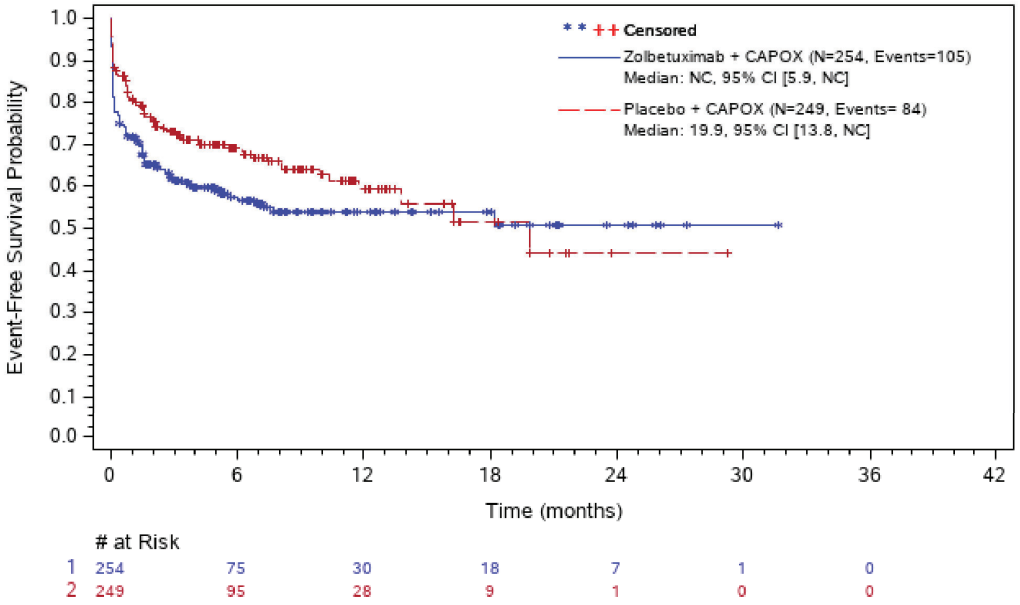
Figure 302.1.2001.59: Kaplan-Meier Plot of Time to first TEAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

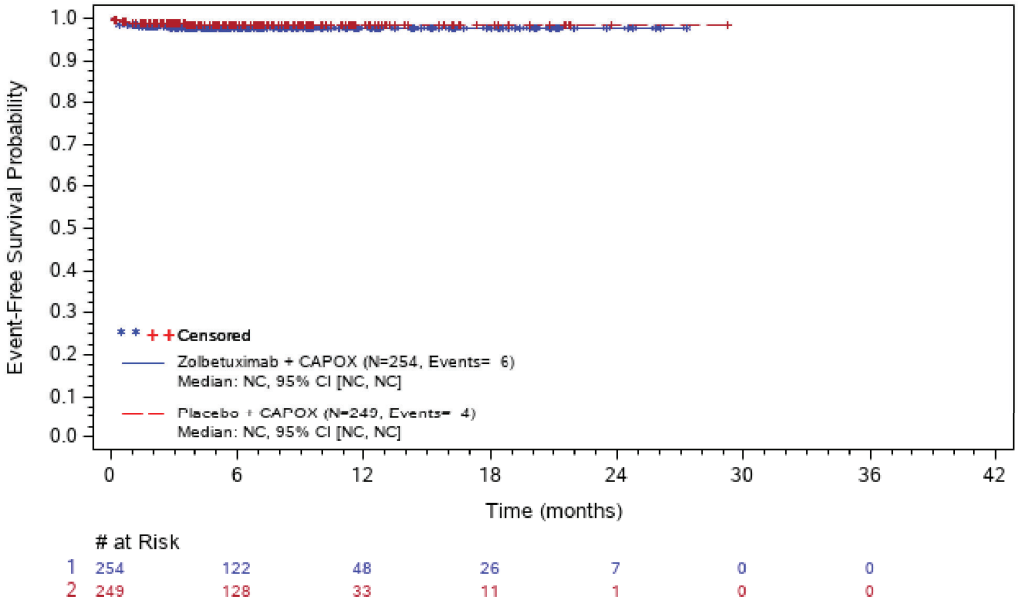
Figure 302.1.2001.60: Kaplan-Meier Plot of Time to first TEAE - Decreased Appetite (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

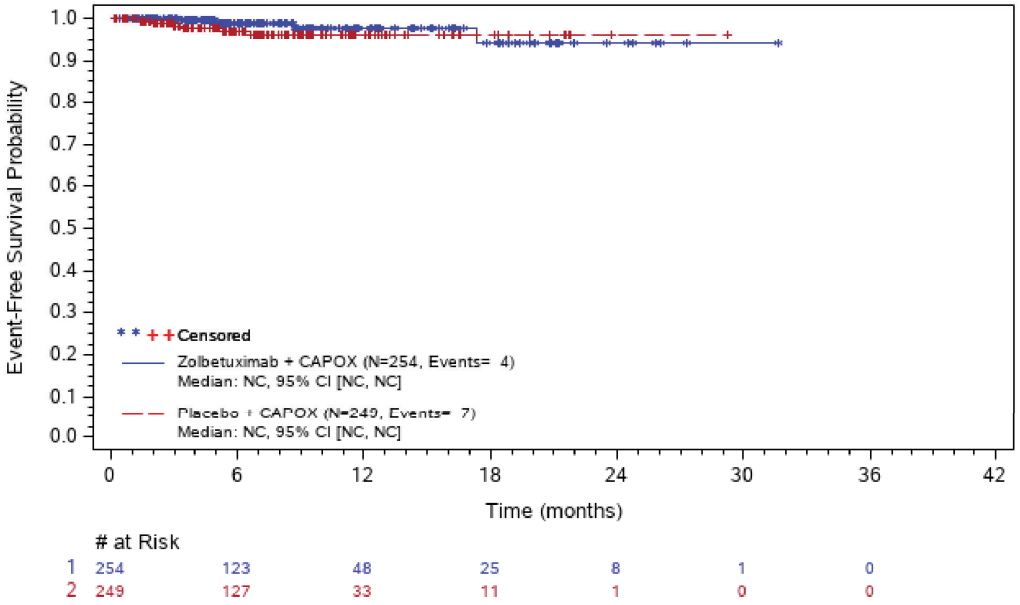
Figure 302.1.2001.61: Kaplan-Meier Plot of Time to first TEAE - Dehydration (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

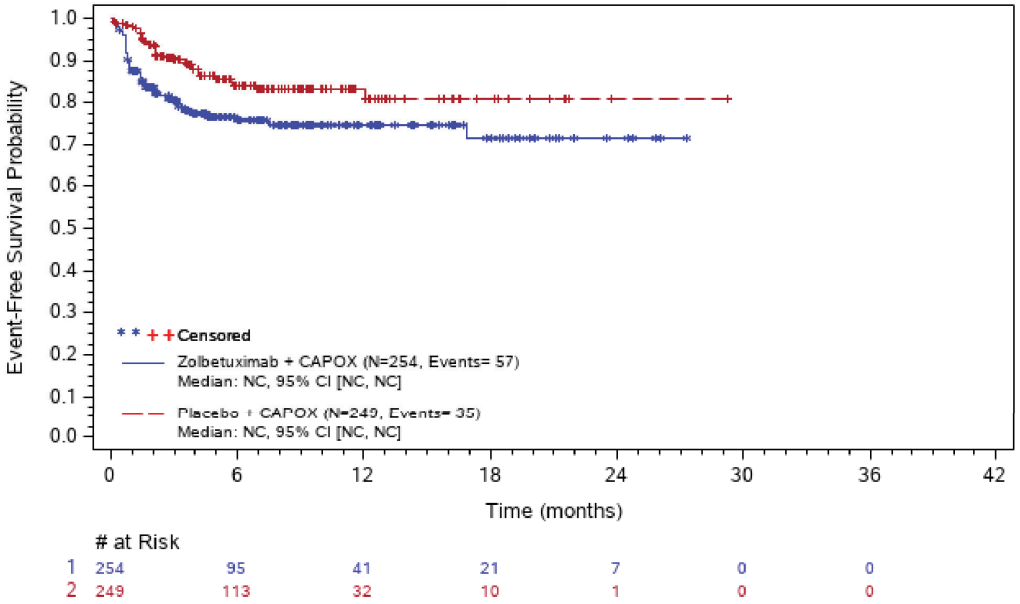
Figure 302.1.2001.62: Kaplan-Meier Plot of Time to first TEAE - Hyperuricaemia (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 07OCT22

The SAS System

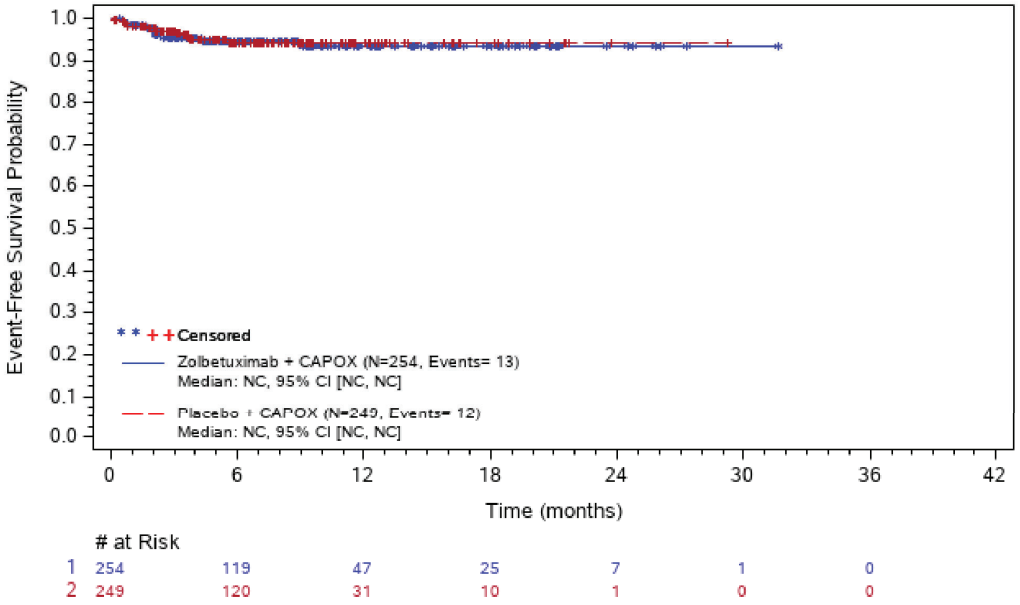
Figure 302.1.2001.63: Kaplan-Meier Plot of Time to first TEAE - Hypoalbuminaemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

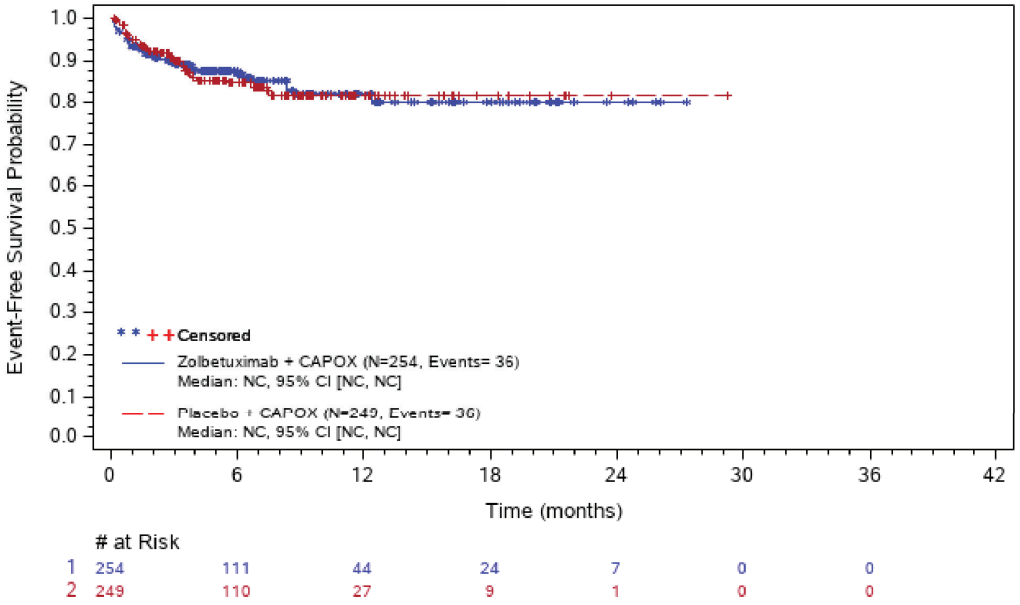
Figure 302.1.2001.64: Kaplan-Meier Plot of Time to first TEAE - Hypocalcaemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

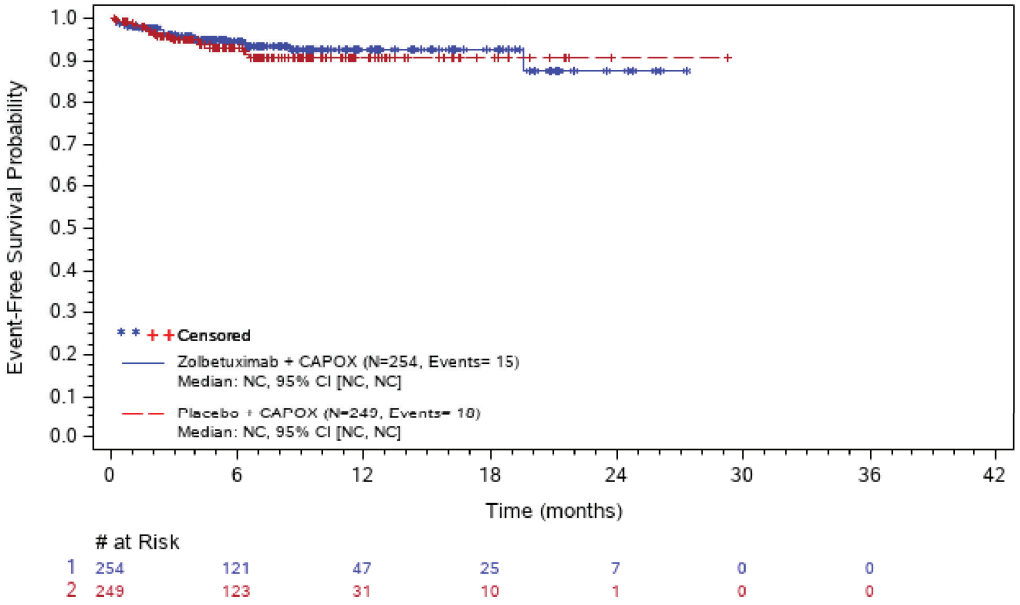
Figure 302.1.2001.65: Kaplan-Meier Plot of Time to first TEAE - Hypokalaemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

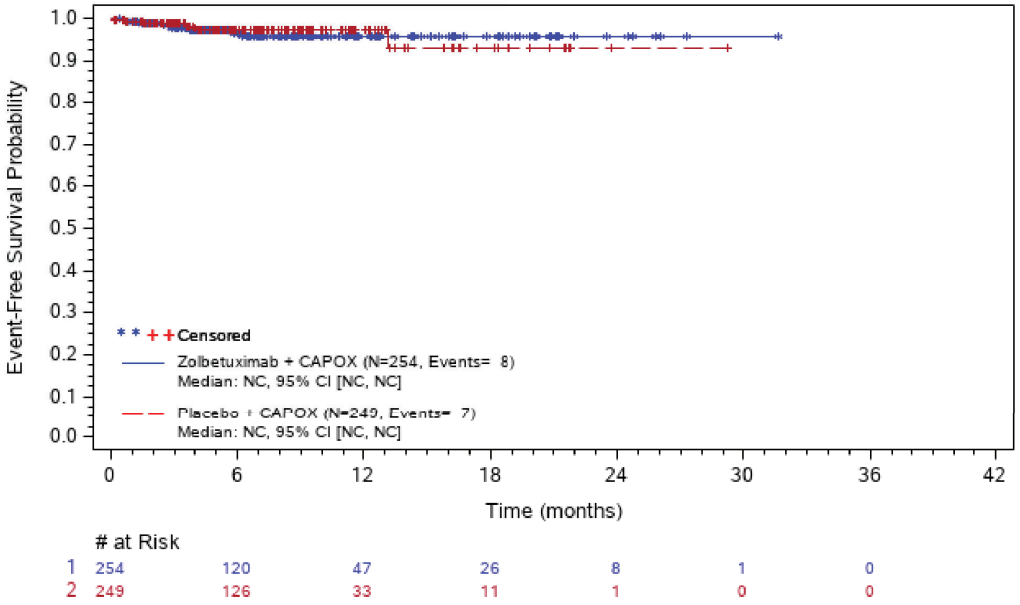
Figure 302.1.2001.66: Kaplan-Meier Plot of Time to first TEAE - Hyponatraemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

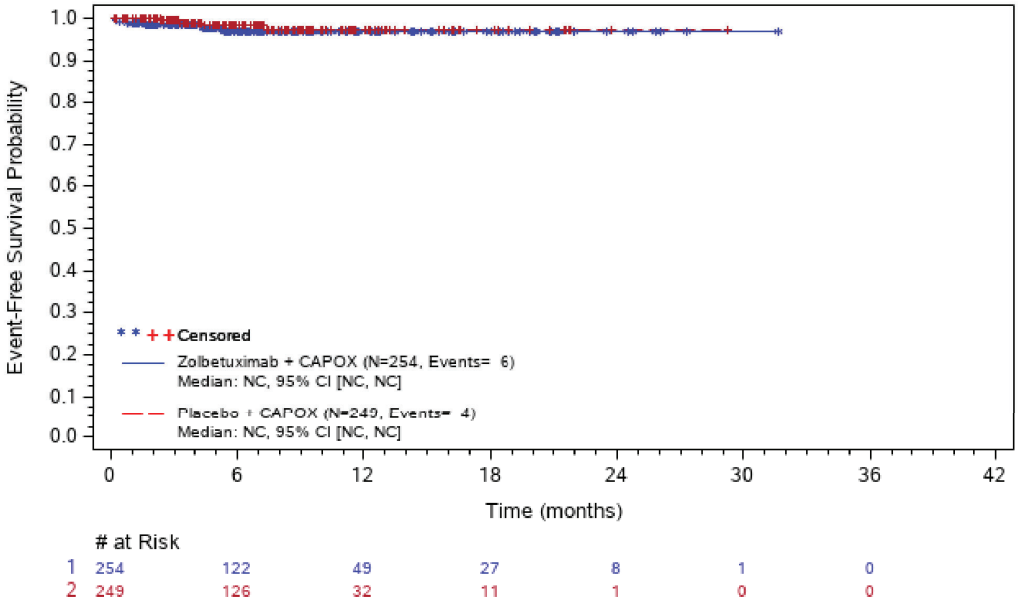
Figure 302.1.2001.67: Kaplan-Meier Plot of Time to first TEAE - Hypophosphataemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

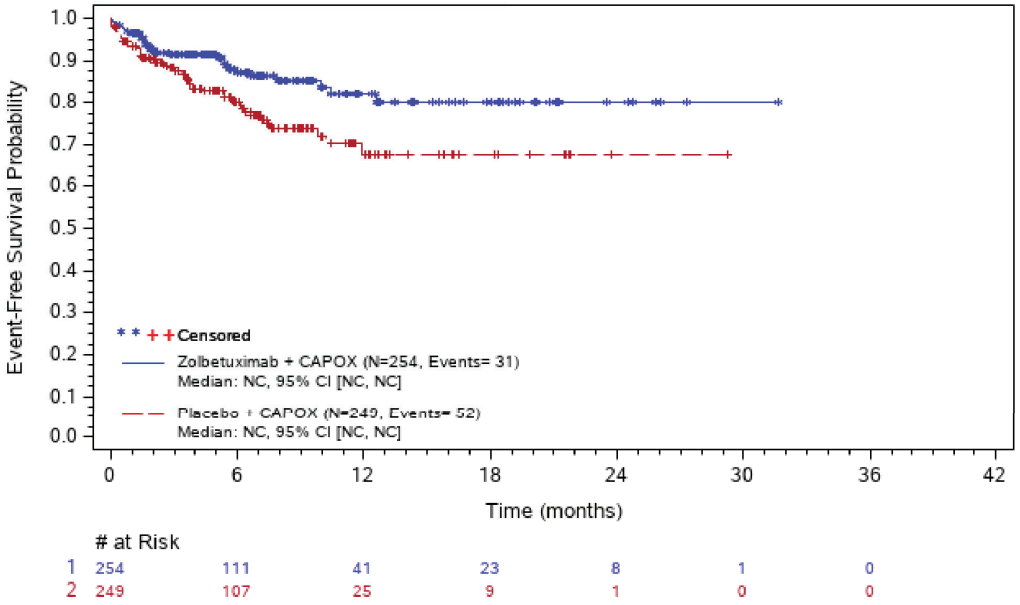
Figure 302.1.2001.68: Kaplan-Meier Plot of Time to first TEAE - Hypoproteinaemia (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 07OCT22

The SAS System

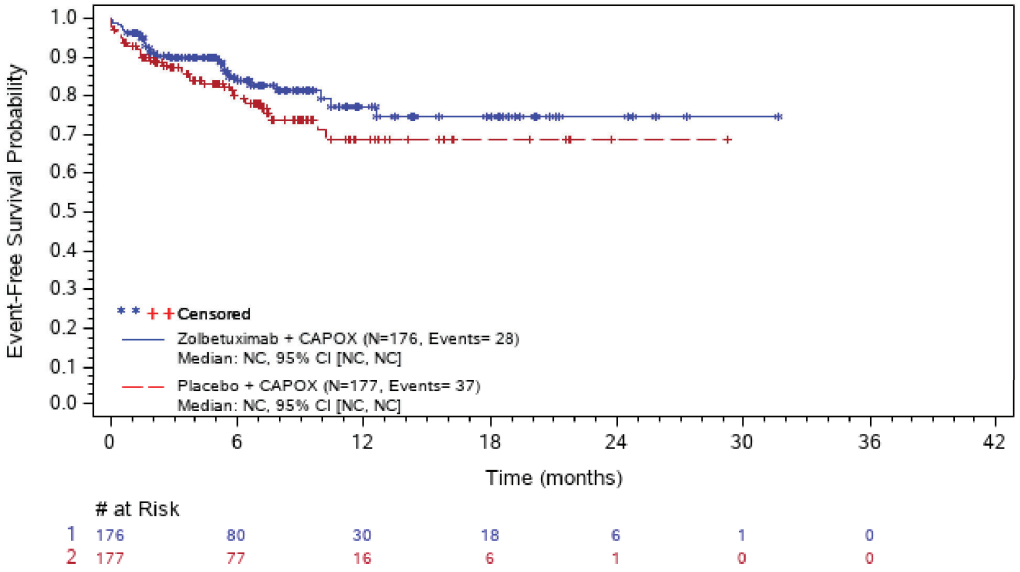
Figure 302.1.2001.69: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

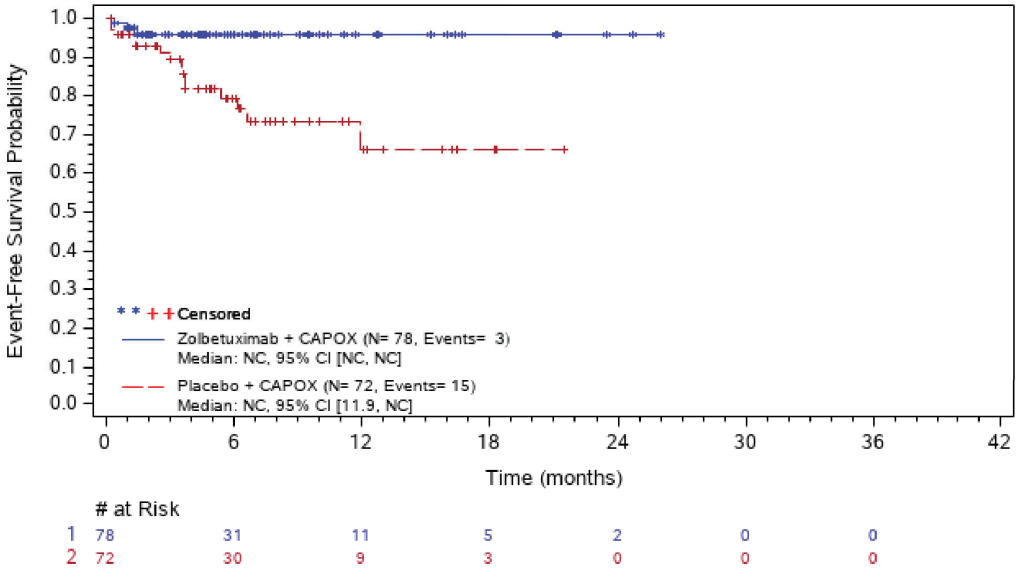
Figure 302.1.2001.69.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set Pooled Age Group 1: <=65 years



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: 07OCT22

The SAS System

Figure 302.1.2001.69.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set Pooled Age Group 1: >65 years

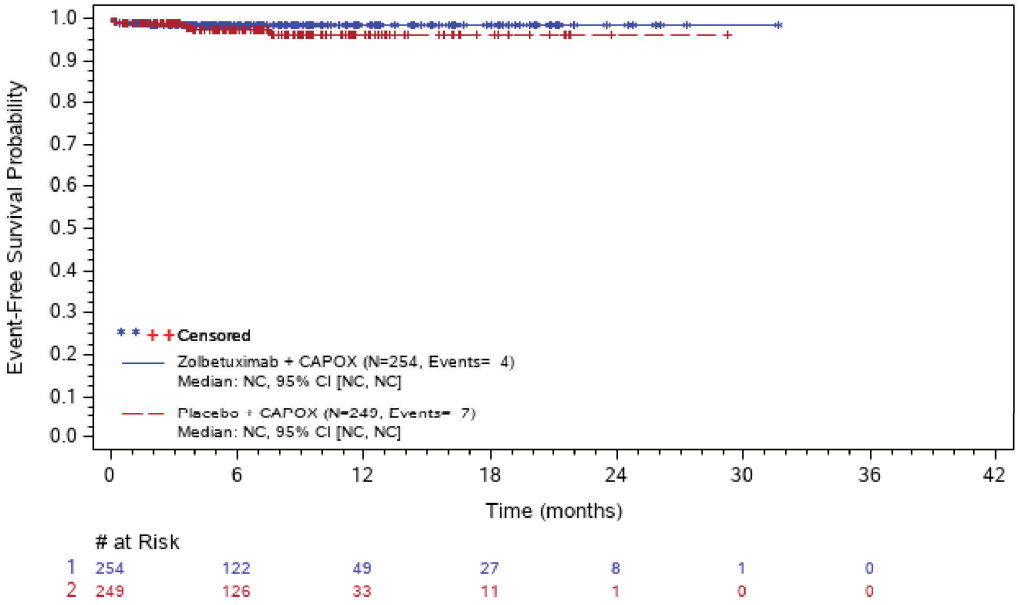


# at Risk							
1	78	31	11	5	2	0	0
2	72	30	9	3	0	0	0

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: 07OCT22

The SAS System

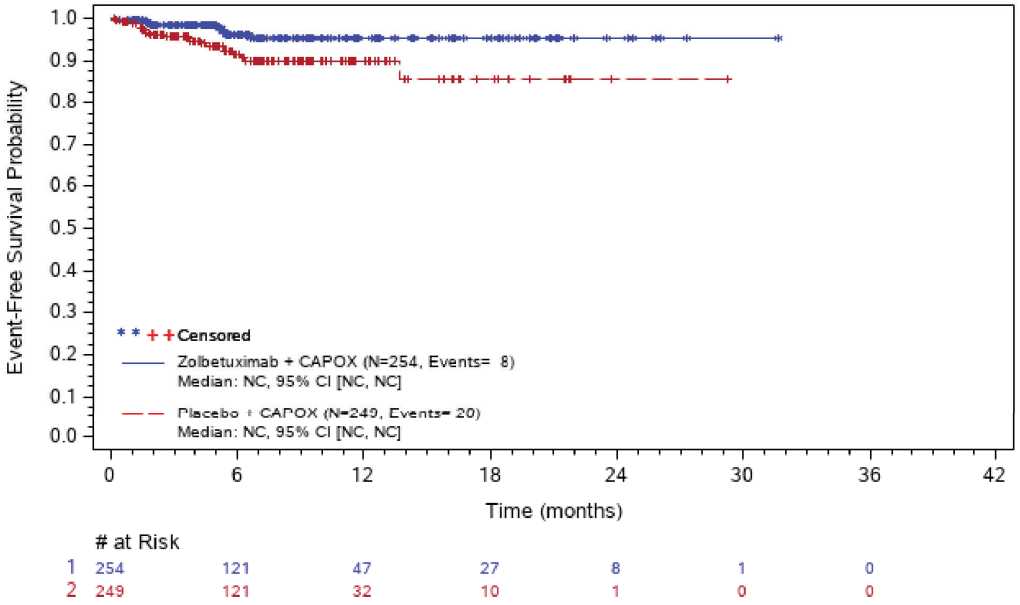
Figure 302.1.2001.70: Kaplan-Meier Plot of Time to first TEAE - Arthralgia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

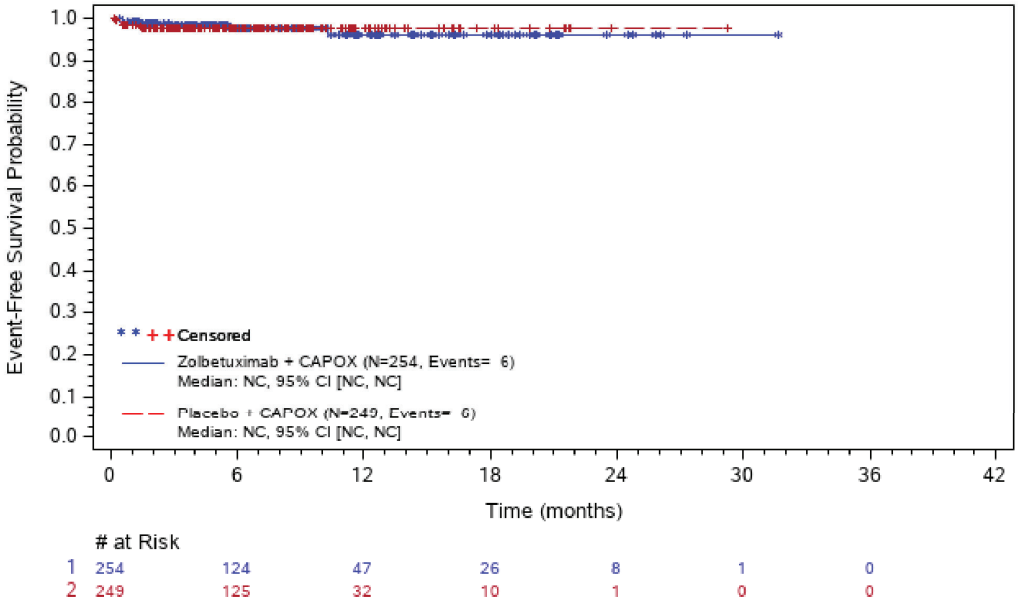
Figure 302.1.2001.71: Kaplan-Meier Plot of Time to first TEAE - Back Pain (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

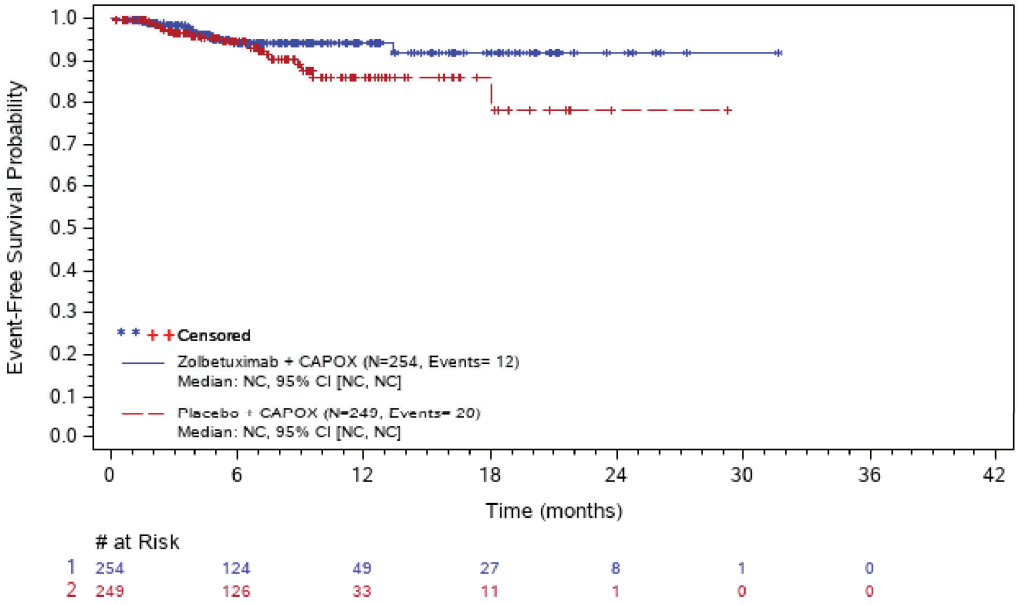
Figure 302.1.2001.72: Kaplan-Meier Plot of Time to first TEAE - Pain In Extremity (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

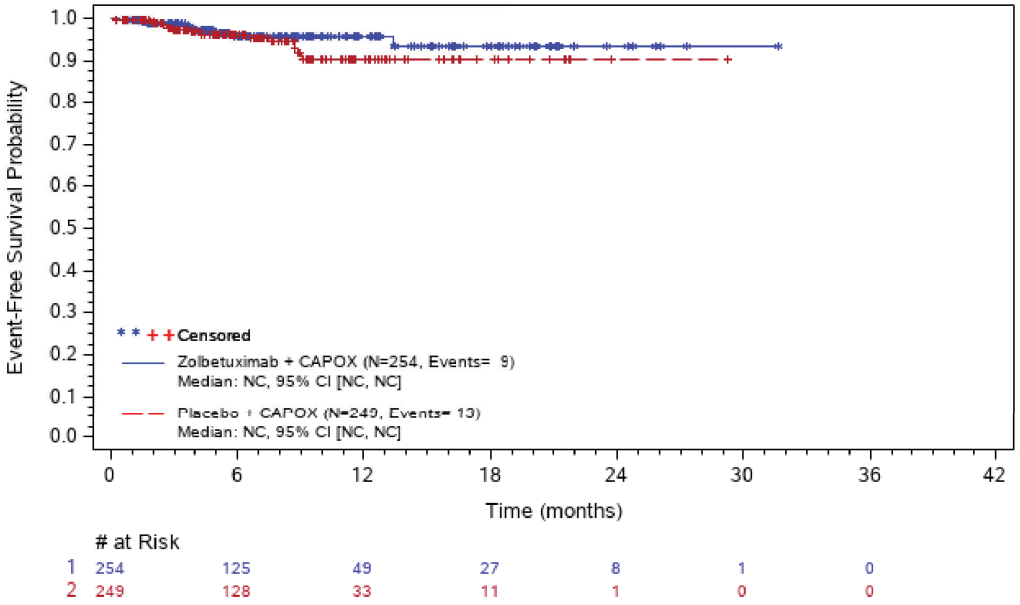
Figure 302.1.2001.73: Kaplan-Meier Plot of Time to first TEAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

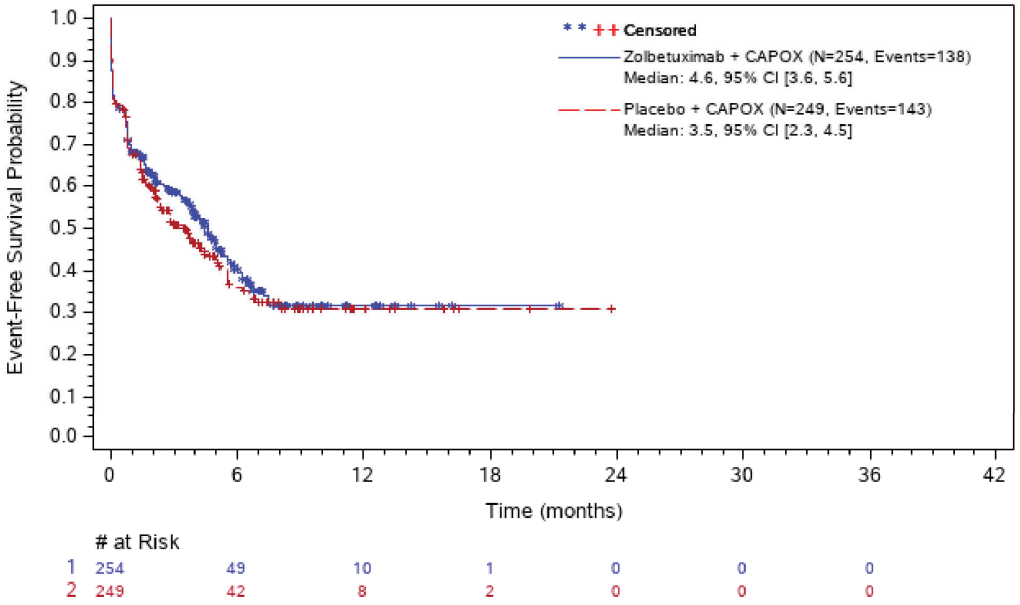
Figure 302.1.2001.74: Kaplan-Meier Plot of Time to first TEAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.75: Kaplan-Meier Plot of Time to first TEAE - Nervous System Disorders (SOC) - Safety Analysis Set



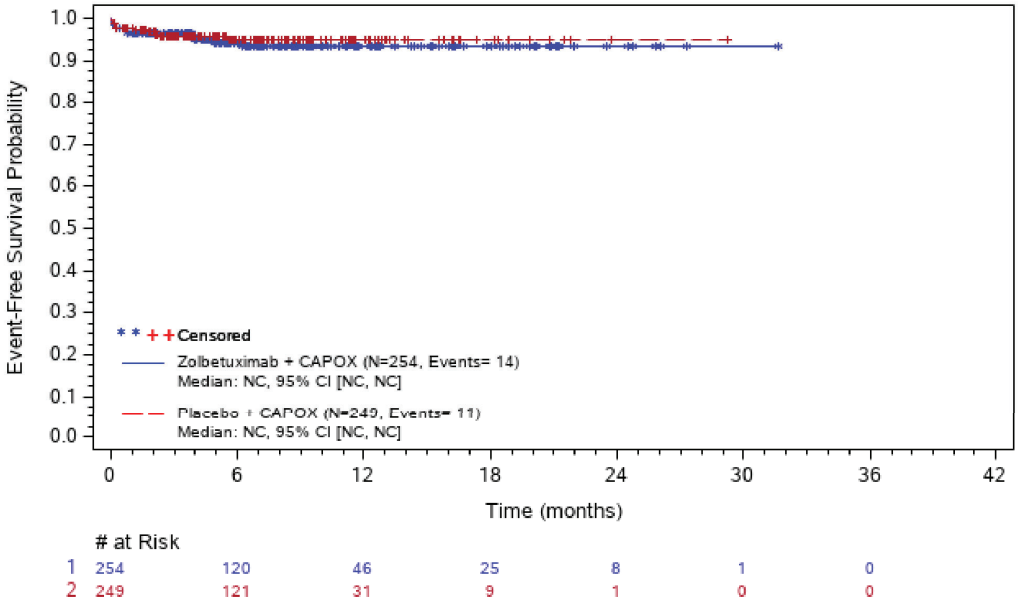
at Risk

1	254	49	10	1	0	0	0
2	249	42	8	2	0	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: 07OCT22

The SAS System

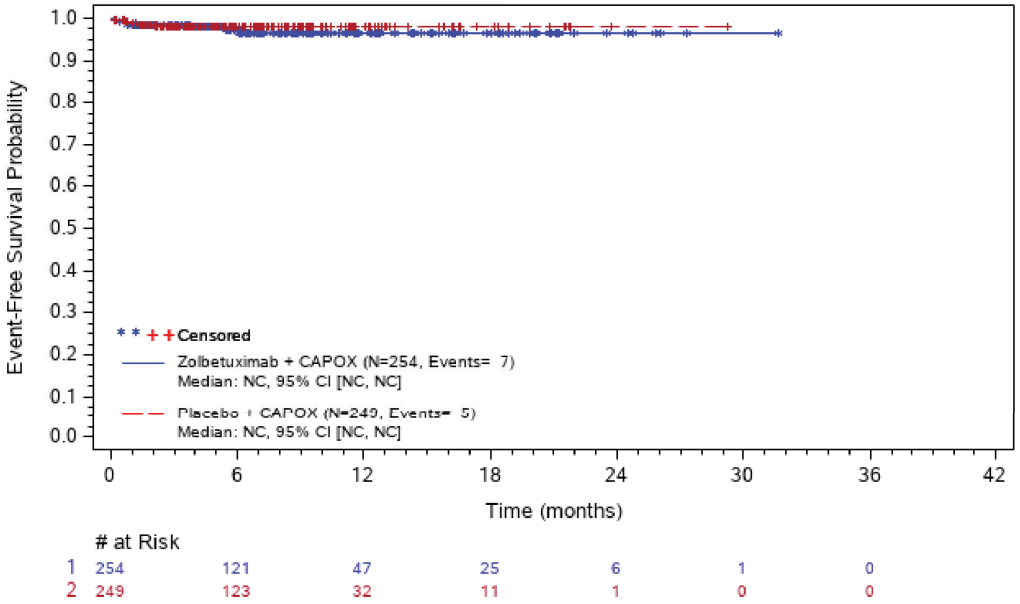
Figure 302.1.2001.76: Kaplan-Meier Plot of Time to first TEAE - Dizziness (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

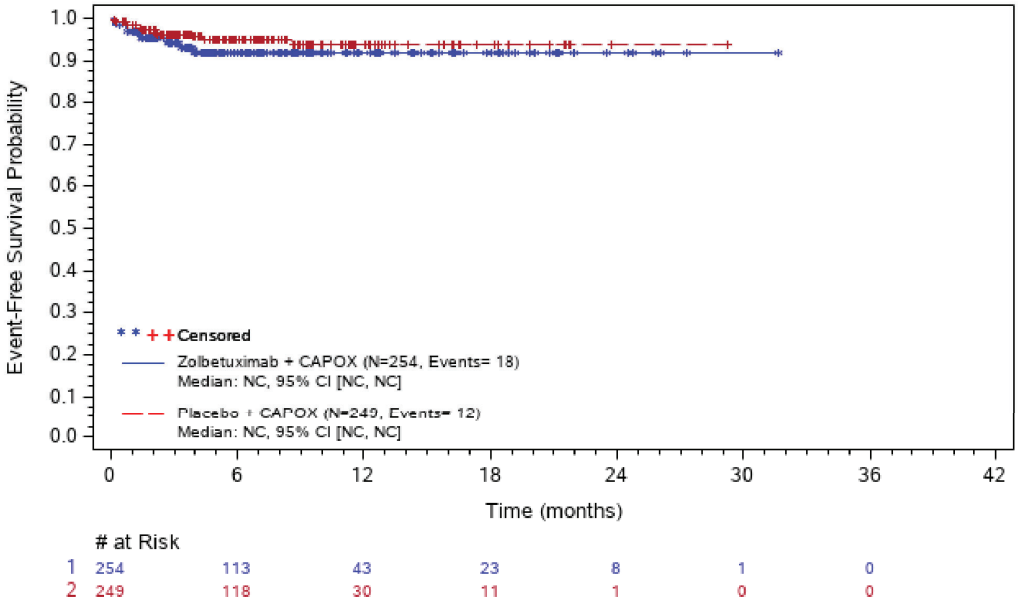
Figure 302.1.2001.77: Kaplan-Meier Plot of Time to first TEAE - Dysaesthesia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

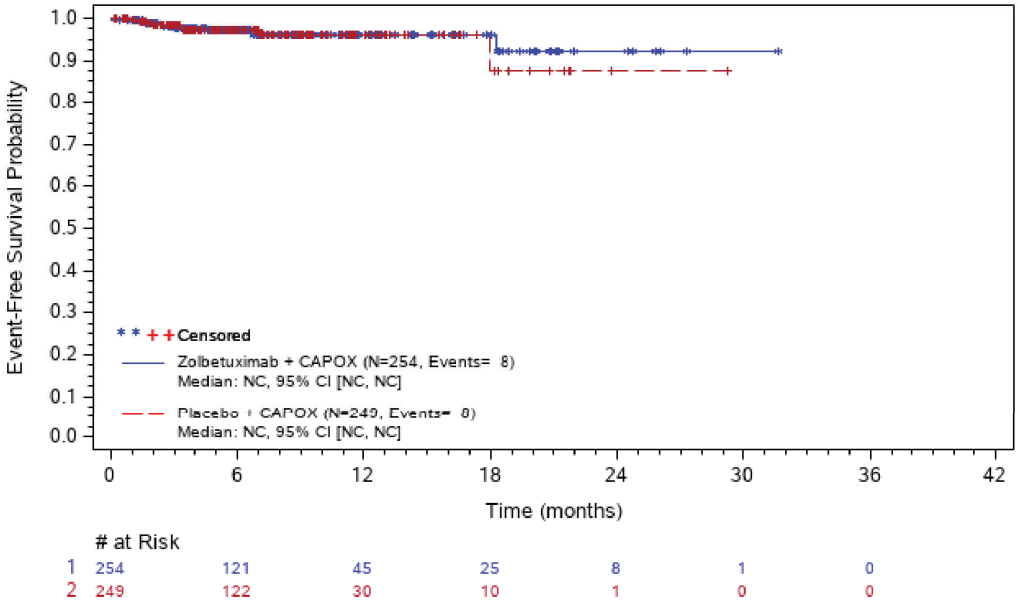
Figure 302.1.2001.78: Kaplan-Meier Plot of Time to first TEAE - Dysgeusia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.79: Kaplan-Meier Plot of Time to first TEAE - Headache (PT) - Safety Analysis Set

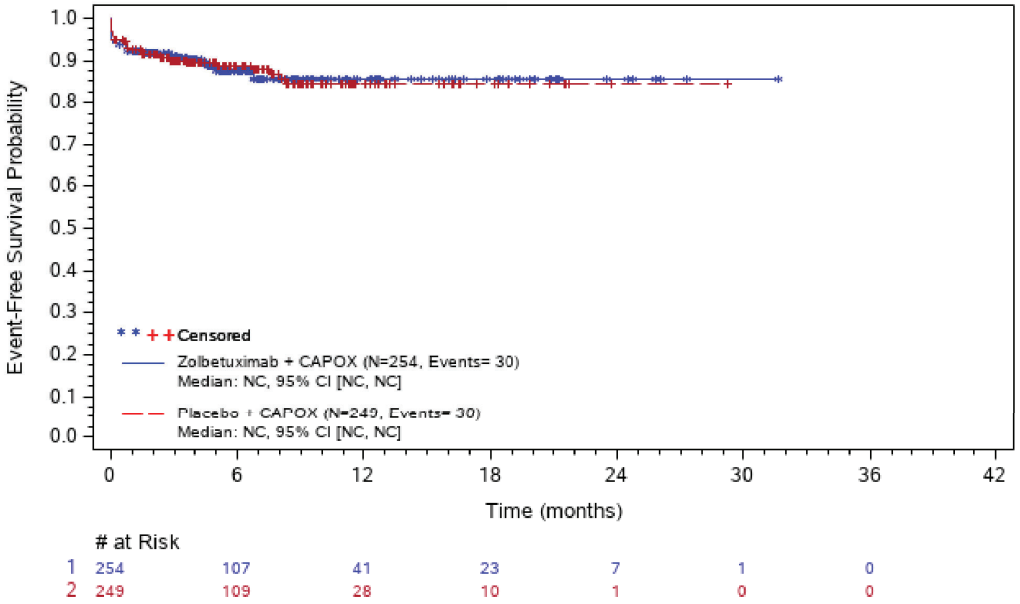


	# at Risk						
1	254	121	45	25	8	1	0
2	249	122	30	10	1	0	0

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: 07OCT22

The SAS System

Figure 302.1.2001.80: Kaplan-Meier Plot of Time to first TEAE - Hypoaesthesia (PT) - Safety Analysis Set

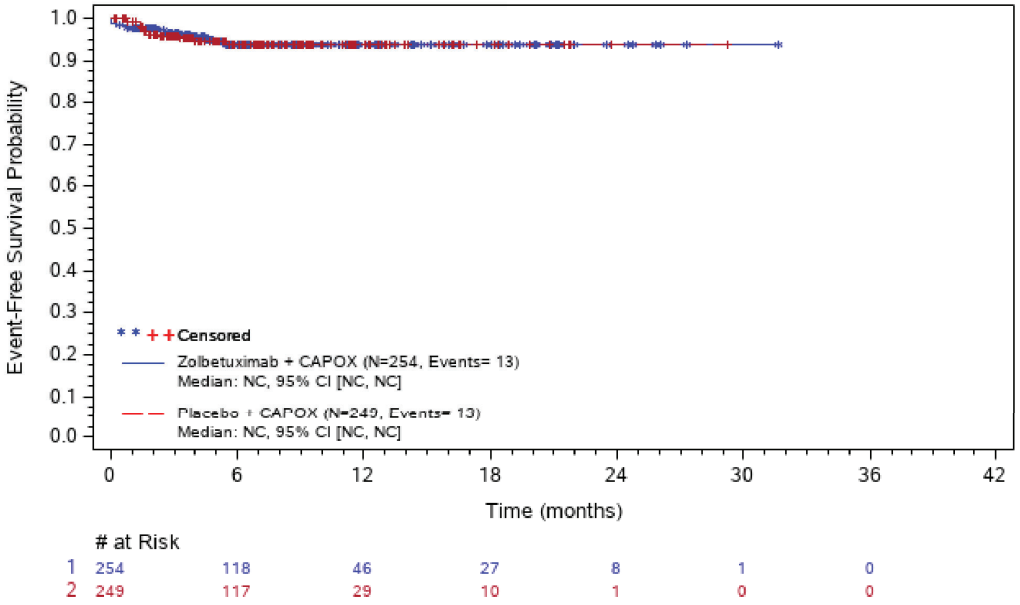


# at Risk							
1	254	107	41	23	7	1	0
2	249	109	28	10	1	0	0

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: 07OCT22

The SAS System

Figure 302.1.2001.81: Kaplan-Meier Plot of Time to first TEAE - Neuropathy Peripheral (PT) - Safety Analysis Set

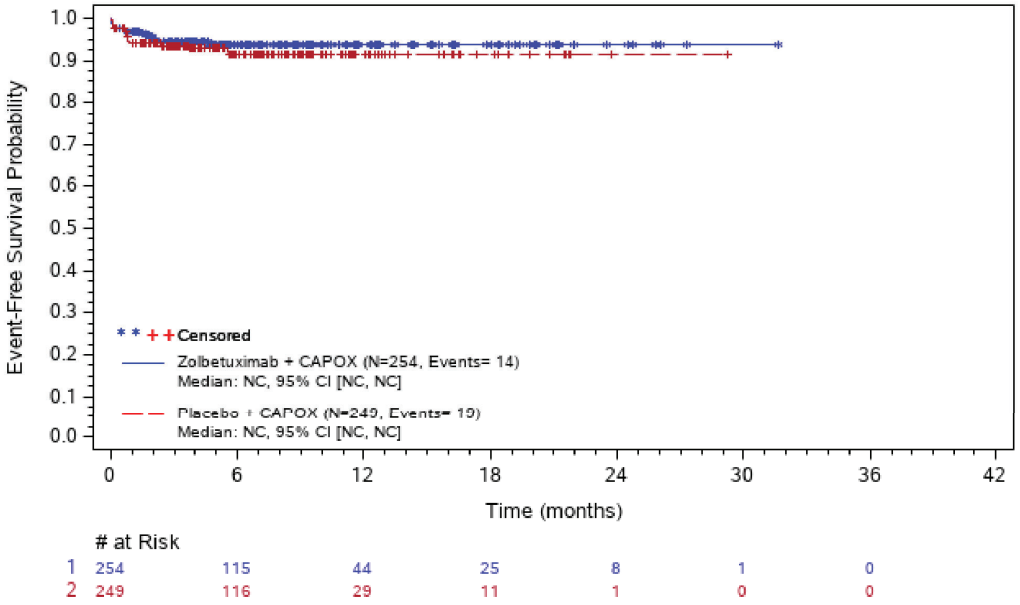


	# at Risk						
1	254	118	46	27	8	1	0
2	249	117	29	10	1	0	0

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: 07OCT22

The SAS System

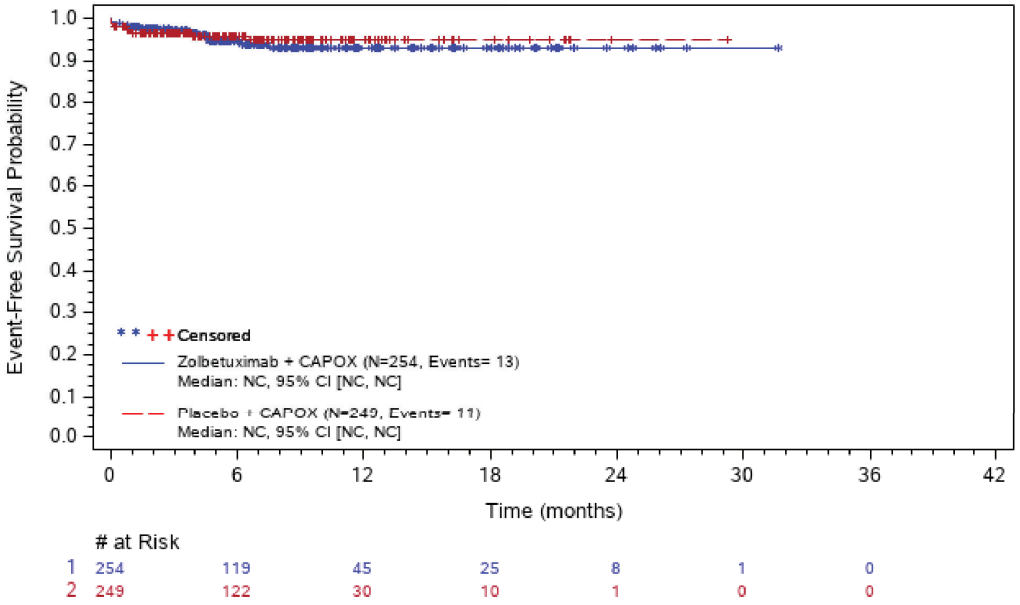
Figure 302.1.2001.82: Kaplan-Meier Plot of Time to first TEAE - Neurotoxicity (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

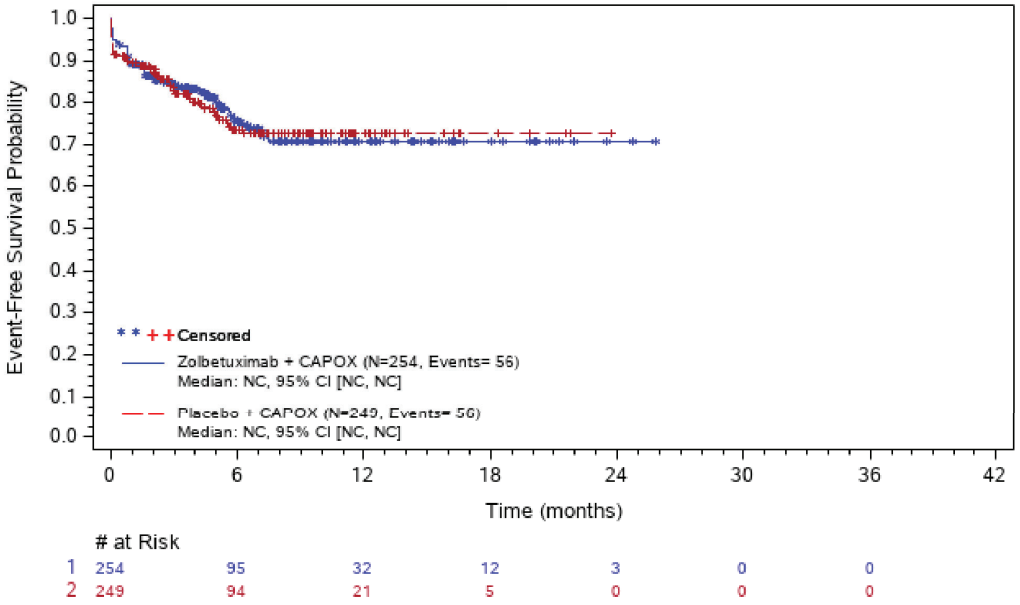
Figure 302.1.2001.83: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.84: Kaplan-Meier Plot of Time to first TEAE - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

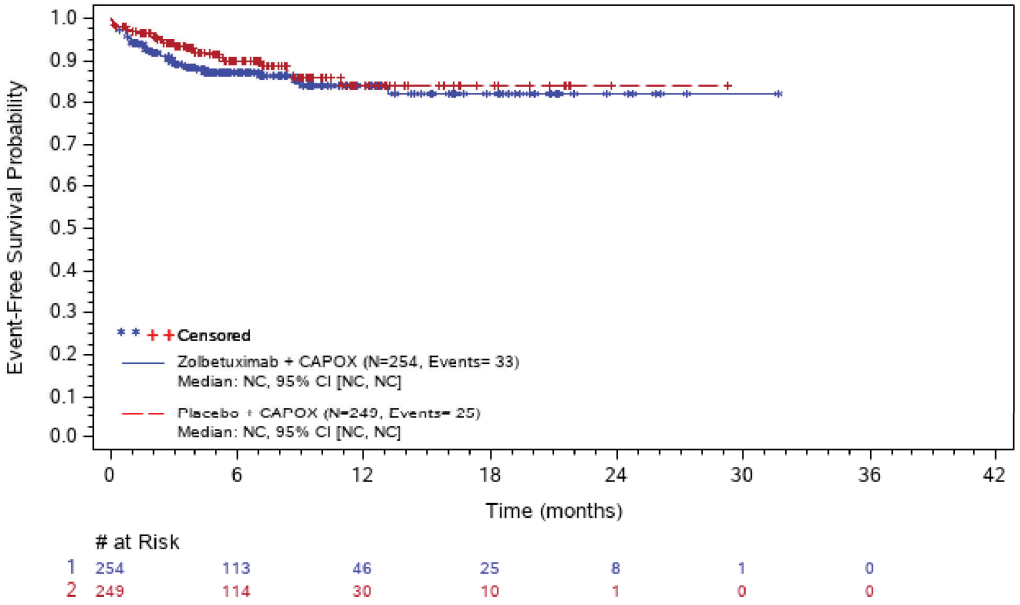


# at Risk							
1	254	95	32	12	3	0	0
2	249	94	21	5	0	0	0

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: 07OCT22

The SAS System

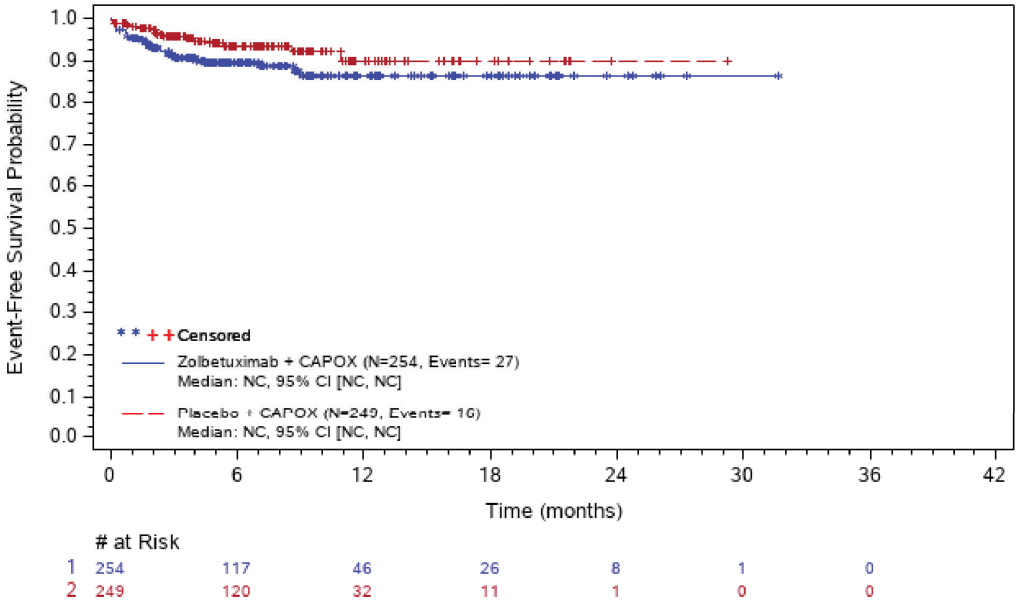
Figure 302.1.2001.85: Kaplan-Meier Plot of Time to first TEAE - Psychiatric Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

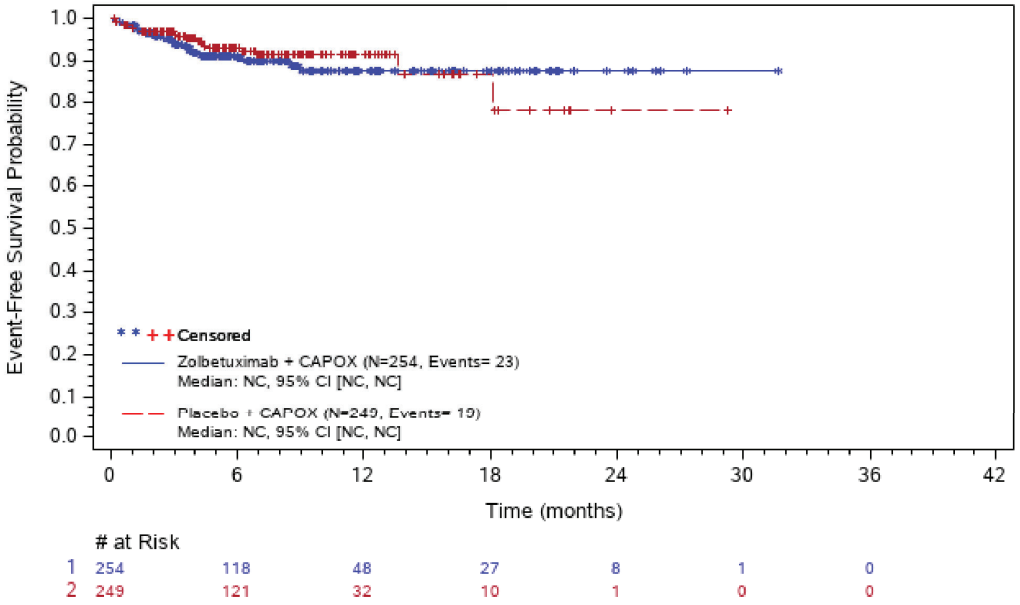
Figure 302.1.2001.86: Kaplan-Meier Plot of Time to first TEAE - Insomnia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.87: Kaplan-Meier Plot of Time to first TEAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set

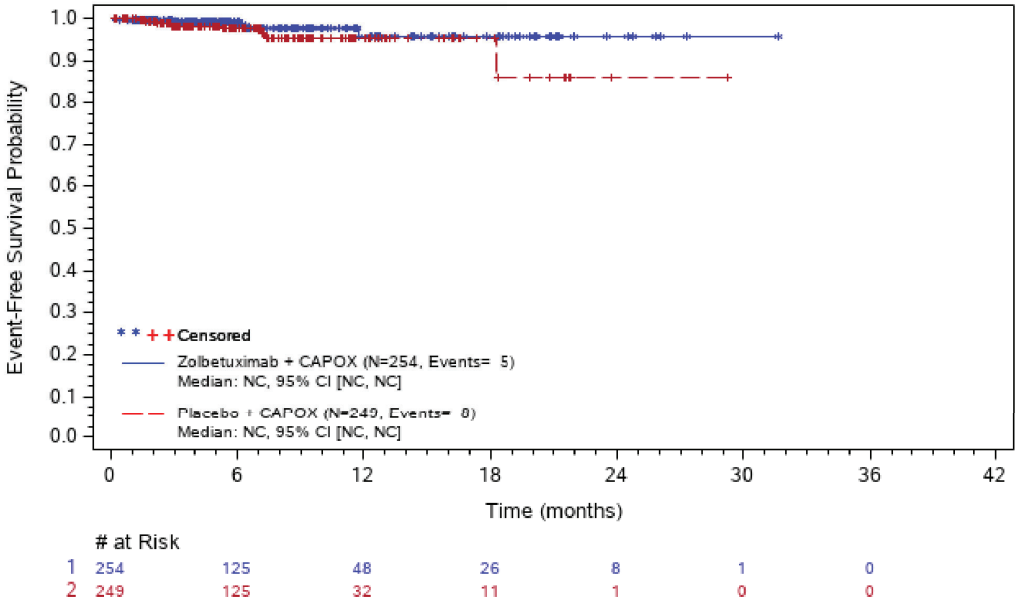


# at Risk							
1	254	118	48	27	8	1	0
2	249	121	32	10	1	0	0

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: 07OCT22

The SAS System

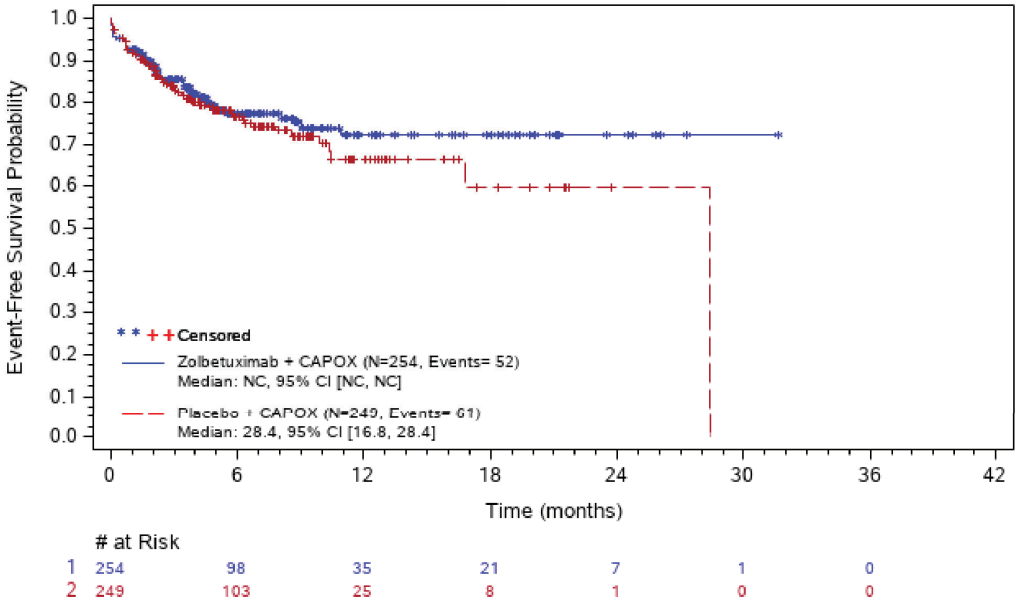
Figure 302.1.2001.88: Kaplan-Meier Plot of Time to first TEAE - Reproductive System And Breast Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

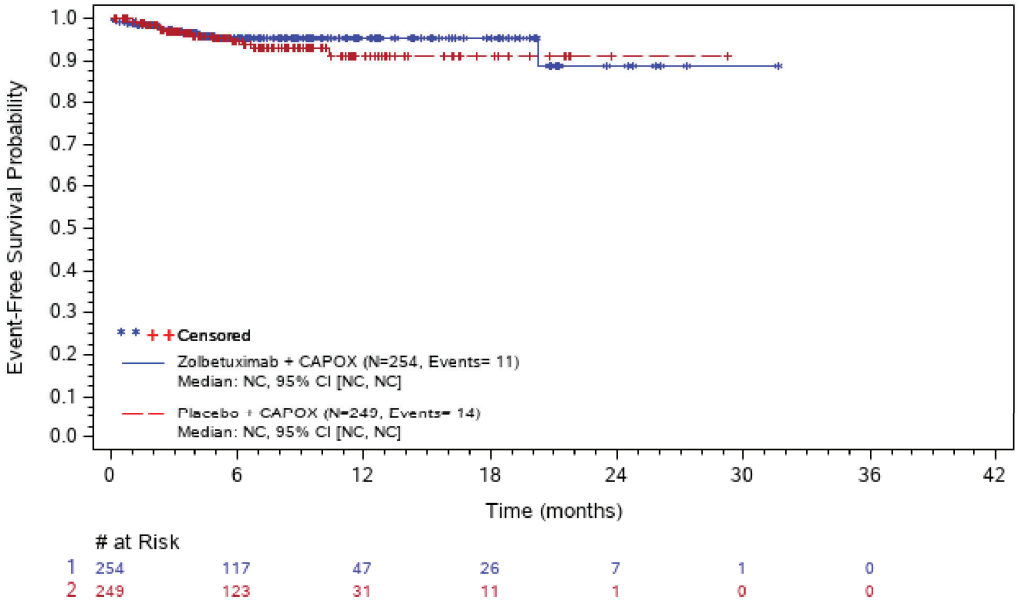
Figure 302.1.2001.89: Kaplan-Meier Plot of Time to first TEAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

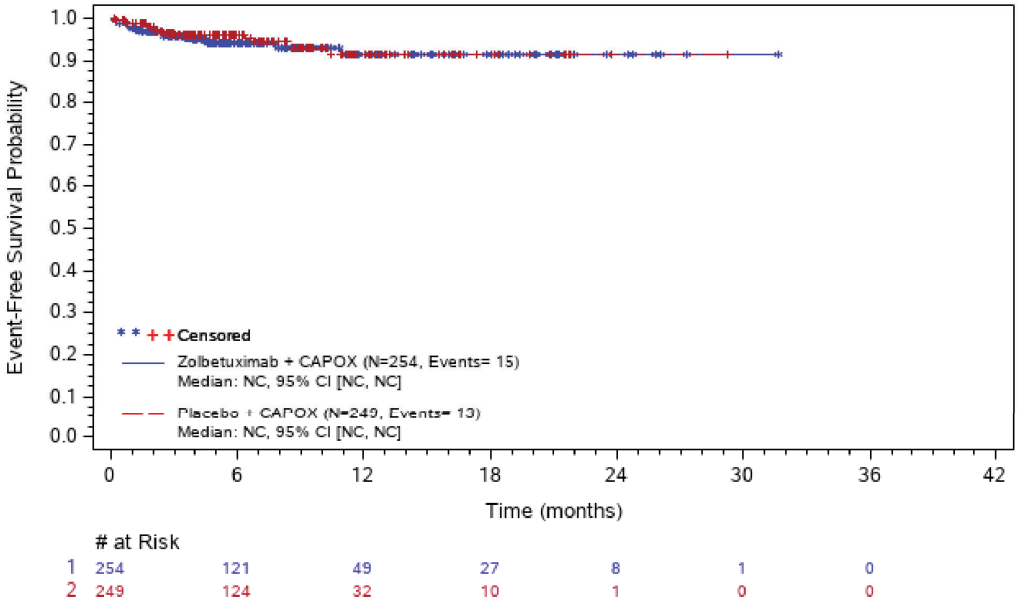
Figure 302.1.2001.90: Kaplan-Meier Plot of Time to first TEAE - Cough (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

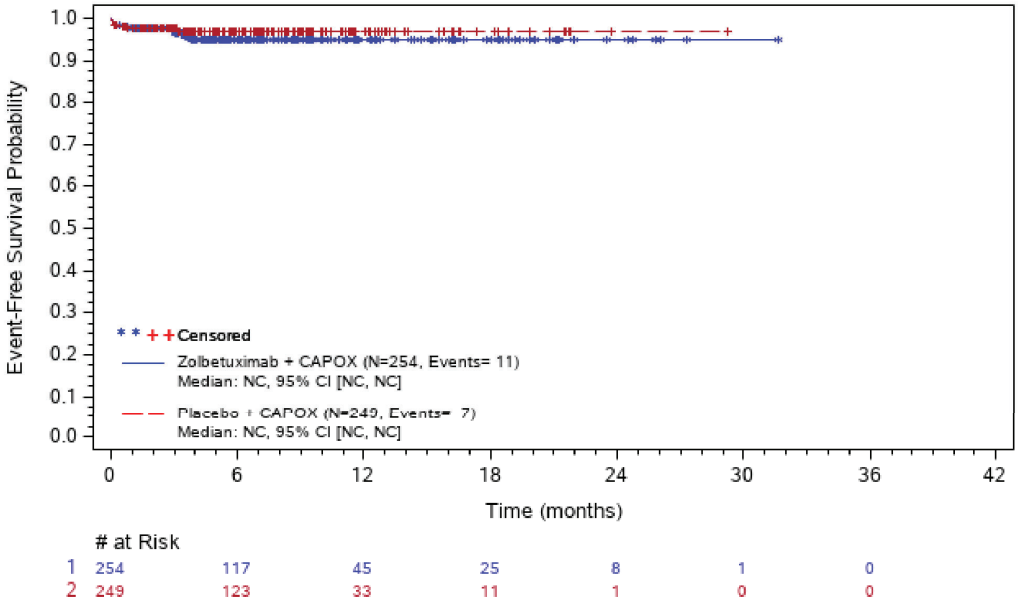
Figure 302.1.2001.91: Kaplan-Meier Plot of Time to first TEAE - Dyspnoea (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

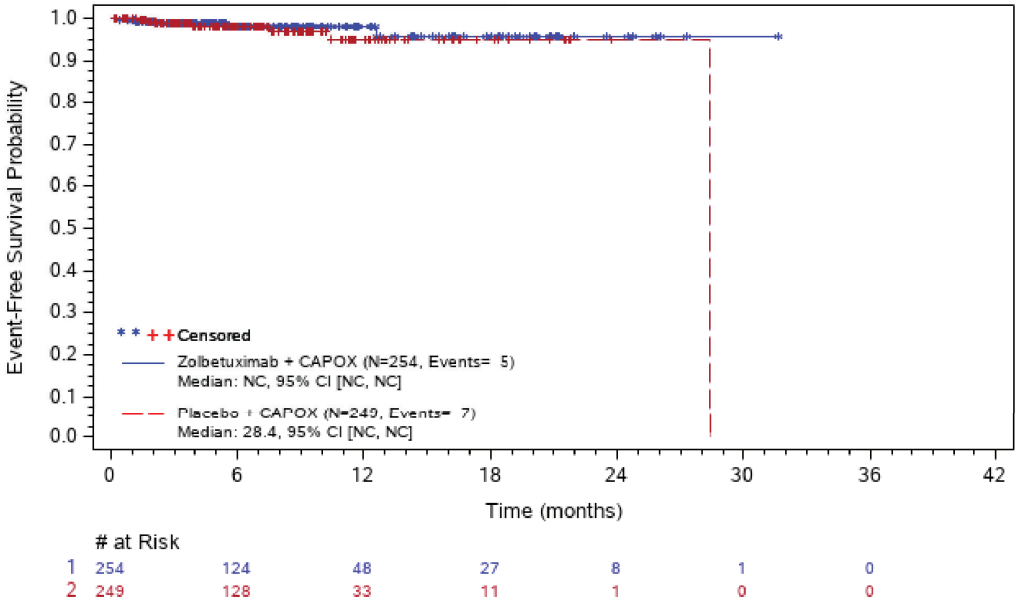
Figure 302.1.2001.92: Kaplan-Meier Plot of Time to first TEAE - Hiccups (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.93: Kaplan-Meier Plot of Time to first TEAE - Pleural Effusion (PT) - Safety Analysis Set

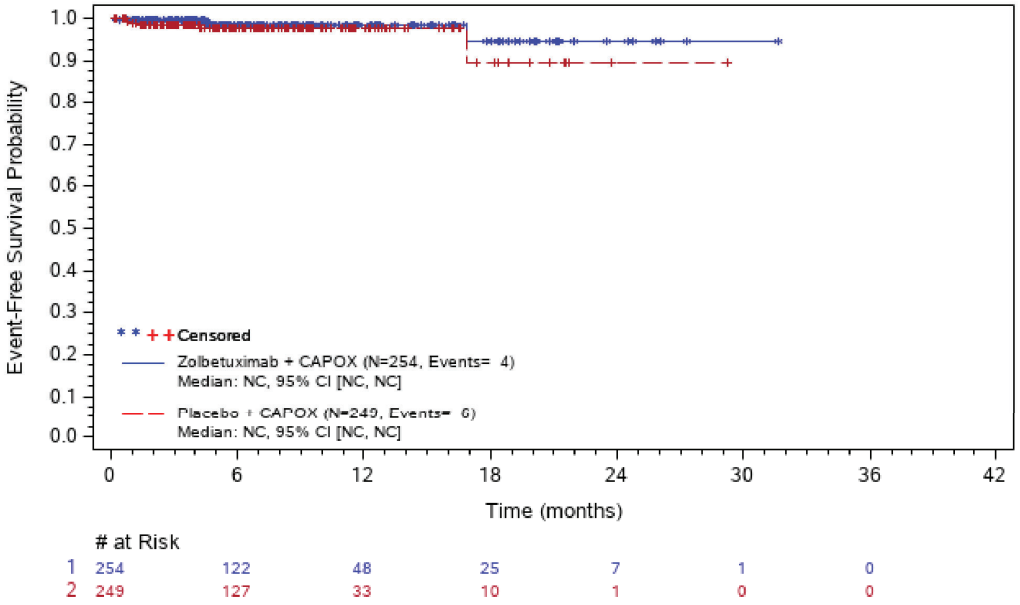


# at Risk							
1	254	124	48	27	8	1	0
2	249	128	33	11	1	0	0

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: 07OCT22

The SAS System

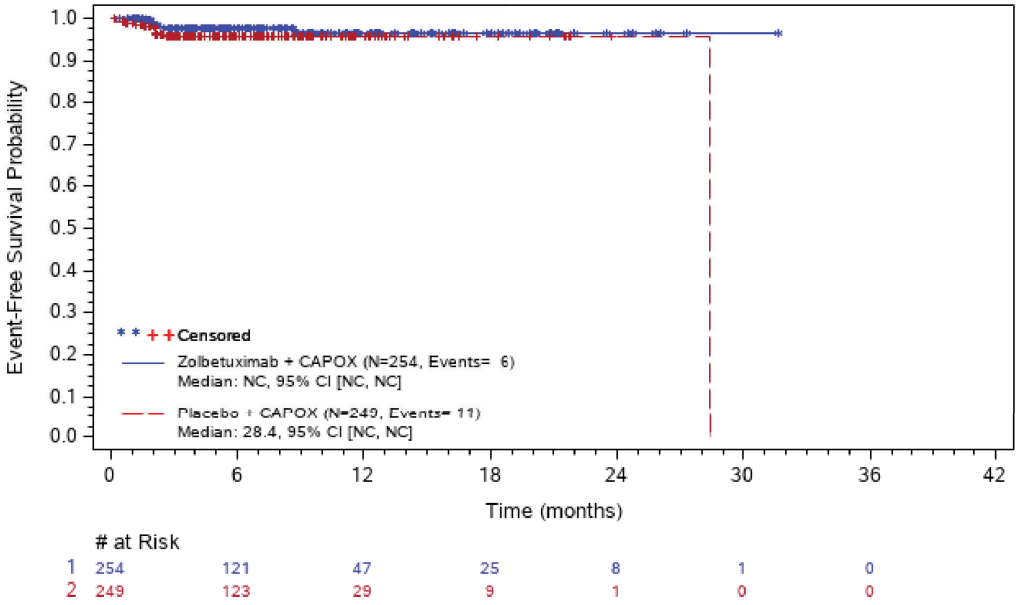
Figure 302.1.2001.94: Kaplan-Meier Plot of Time to first TEAE - Productive Cough (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

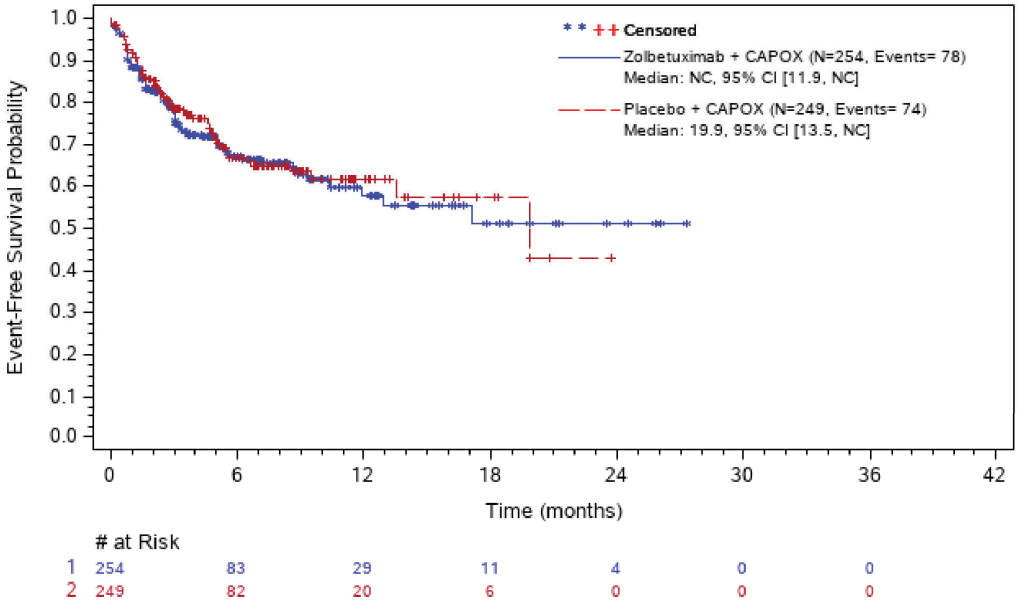
Figure 302.1.2001.95: Kaplan-Meier Plot of Time to first TEAE - Pulmonary Embolism (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

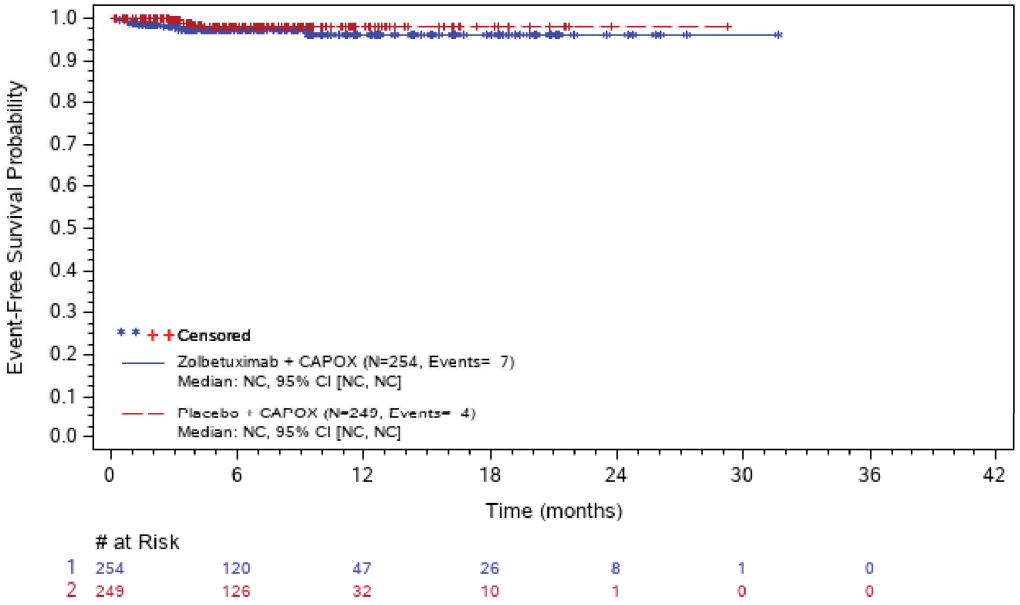
Figure 302.1.2001.96: Kaplan-Meier Plot of Time to first TEAE - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

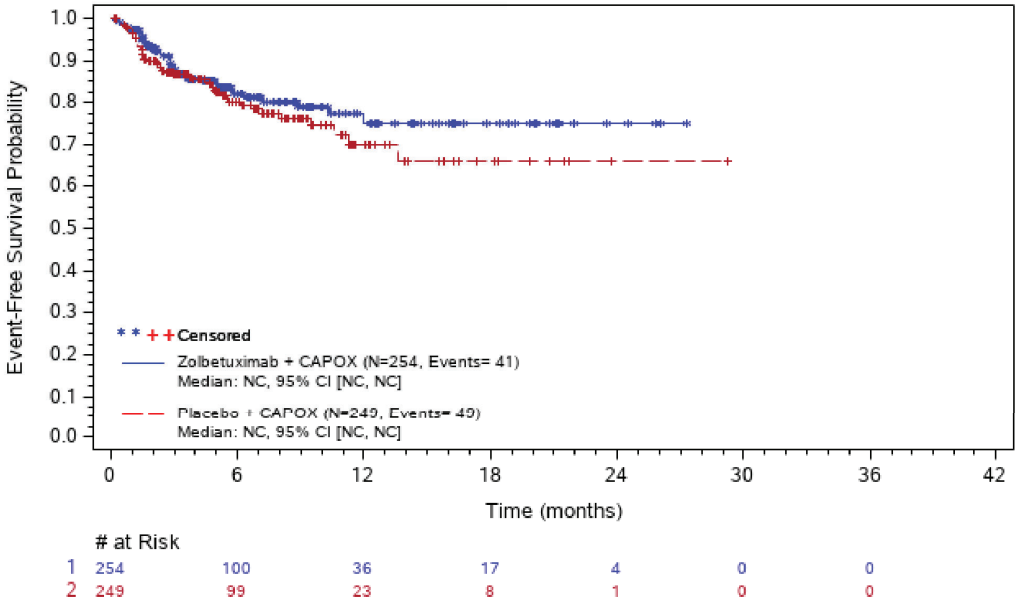
Figure 302.1.2001.97: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.98: Kaplan-Meier Plot of Time to first TEAE - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

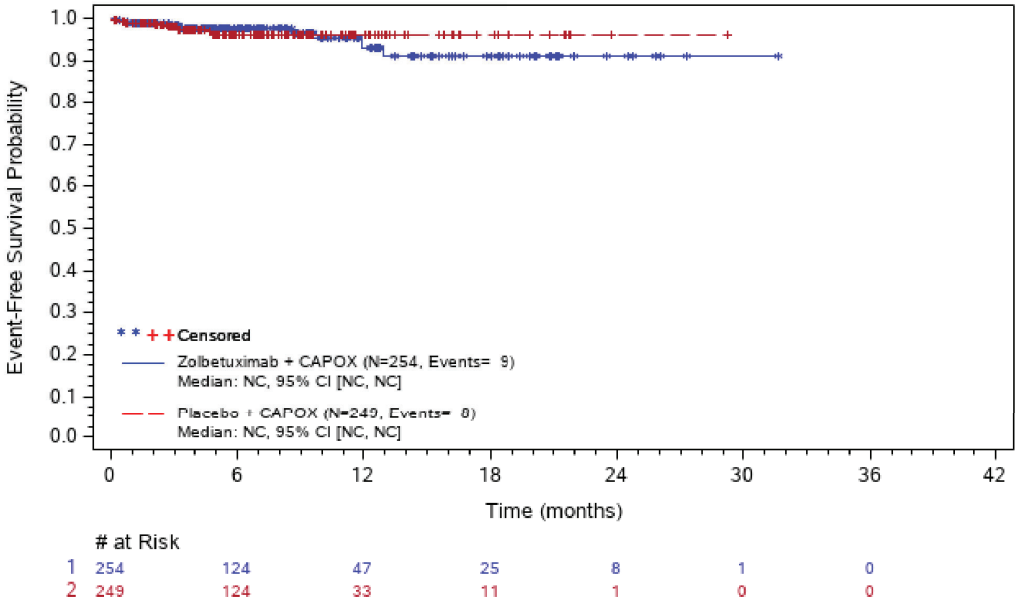


# at Risk						
1	254	100	36	17	4	0	0
2	249	99	23	8	1	0	0

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: 07OCT22

The SAS System

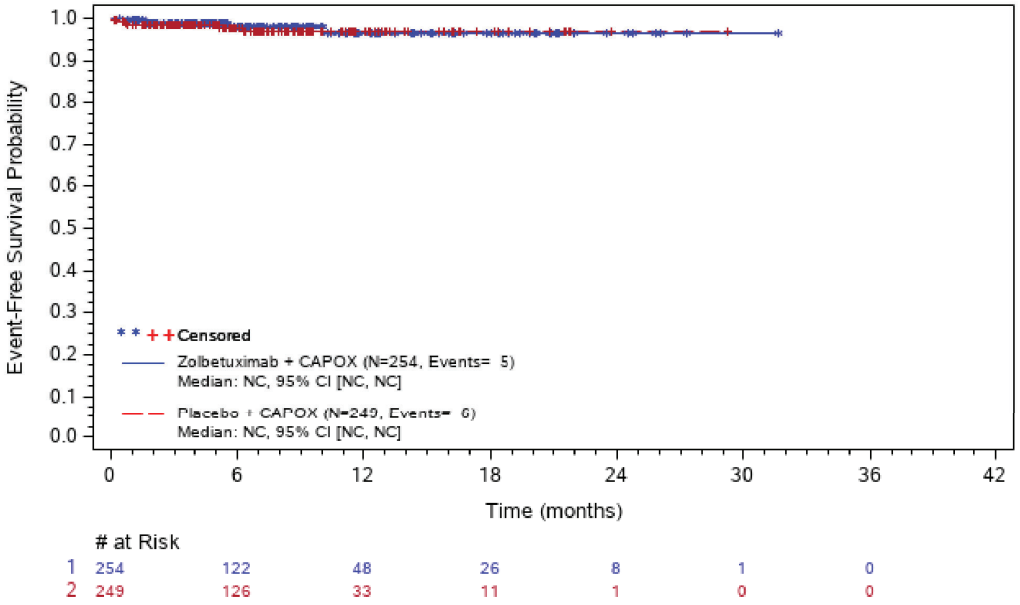
Figure 302.1.2001.99: Kaplan-Meier Plot of Time to first TEAE - Pruritus (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

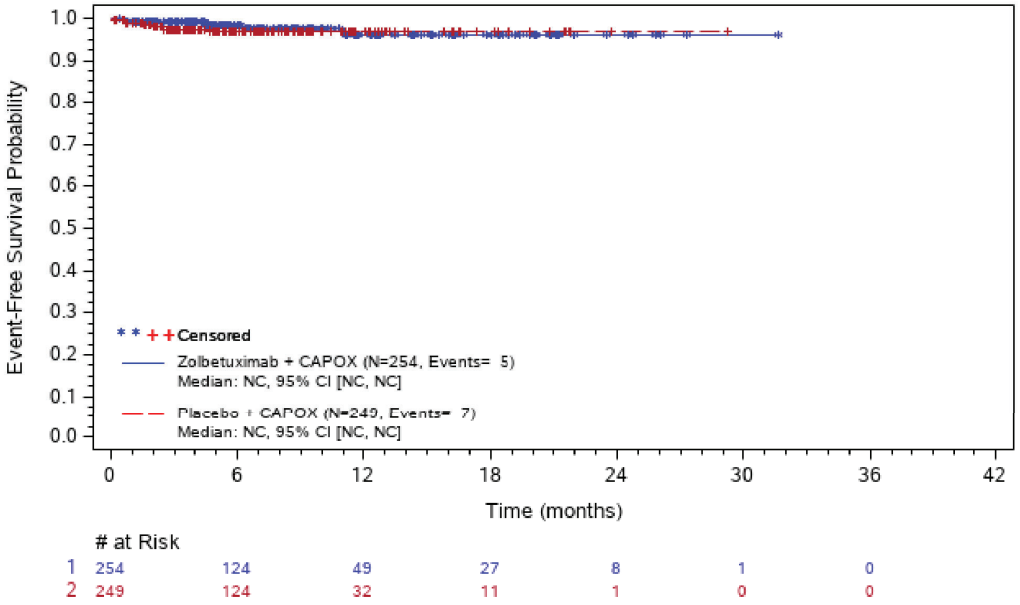
Figure 302.1.2001.100: Kaplan-Meier Plot of Time to first TEAE - Rash (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

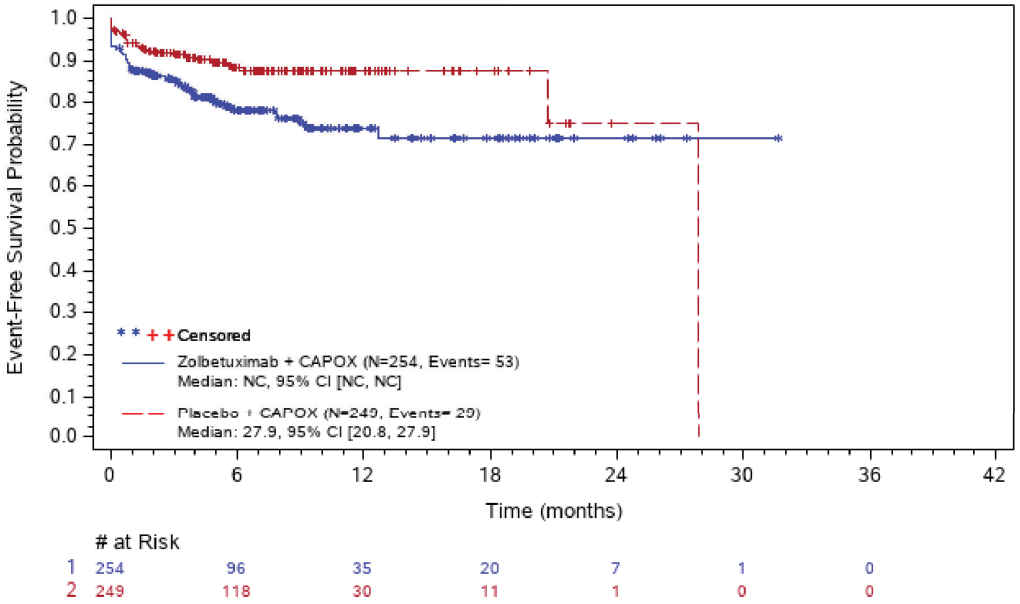
Figure 302.1.2001.101: Kaplan-Meier Plot of Time to first TEAE - Rash Maculo-Papular (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.102: Kaplan-Meier Plot of Time to first TEAE - Vascular Disorders (SOC) - Safety Analysis Set

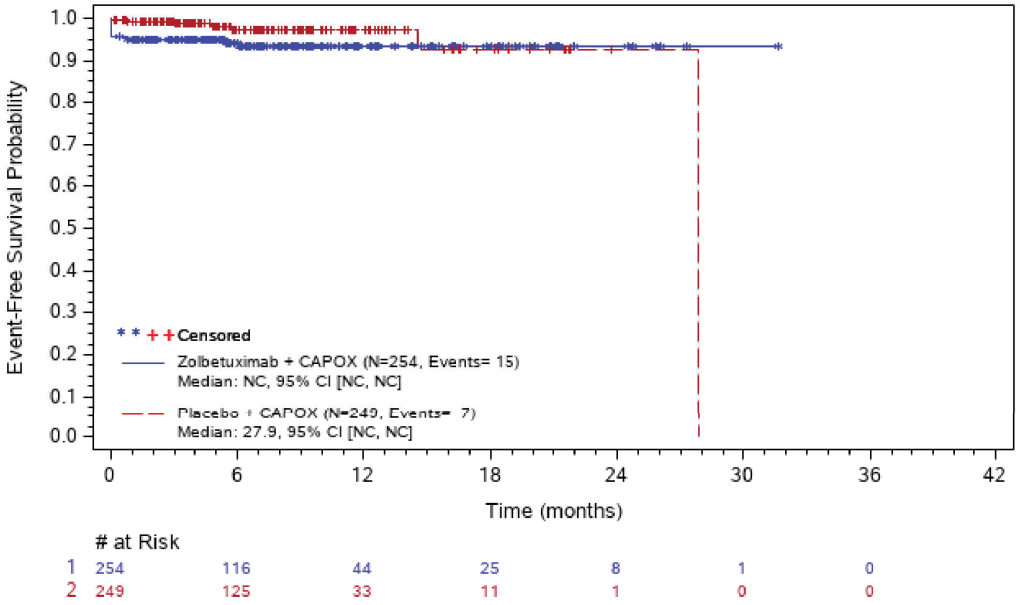


# at Risk							
1	254	96	35	20	7	1	0
2	249	118	30	11	1	0	0

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: 07OCT22

The SAS System

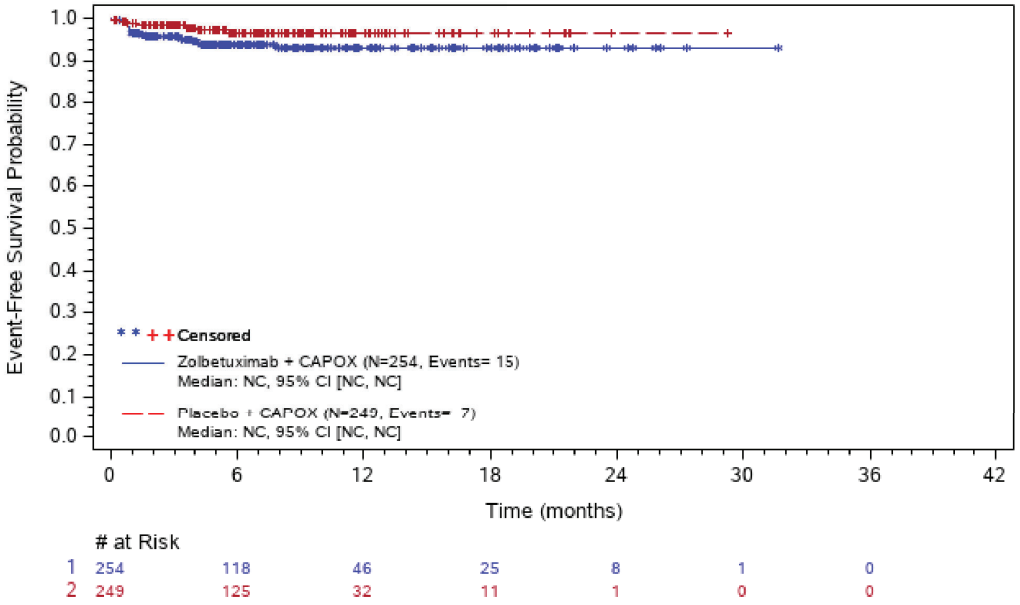
Figure 302.1.2001.103: Kaplan-Meier Plot of Time to first TEAE - Hypertension (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.104: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwere unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 302.1.2001.128.1: Summary and Results of Severe TEAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	49 (19.3%)	44 (17.7%)	
Number of patients censored	205 (80.7%)	205 (82.3%)	
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			1.032 [0.684, 1.557]
Log-rank test			
Two-sided stratified log-rank p-value			0.8789

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.129.1: Summary and Results of Severe TEAEs - Anaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	27 (10.6%)	28 (11.2%)	
Number of patients censored	227 (89.4%)	221 (88.8%)	
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			0.856 [0.500, 1.463]
Log-rank test			
Two-sided stratified log-rank p-value			0.5701

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.130.1: Summary and Results of Severe TEAEs - Neutropenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	18 (7.1%)	7 (2.8%)	
Number of patients censored	236 (92.9%)	242 (97.2%)	
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			2.538 [1.058, 6.091]
Log-rank test			
Two-sided stratified log-rank p-value			0.0308

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.130.2: Summary and Results of Severe TEAEs by Subgroups - Neutropenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	11 (6.3)	NC [NC, NC]	177	4 (2.3)	NC [NC, NC]	2.768 [0.881, 8.694]	0.0688	0.9208
>65 years	78	7 (9.0)	NC [NC, NC]	72	3 (4.2)	NC [NC, NC]	2.503 [0.646, 9.695]	0.1694	
Sex									
Male	160	8 (5.0)	NC [NC, NC]	152	4 (2.6)	NC [NC, NC]	1.785 [0.537, 5.938]	0.3381	0.4223
Female	94	10 (10.6)	NC [NC, NC]	97	3 (3.1)	NC [NC, NC]	3.864 [1.063, 14.052]	0.0270	
Region									
Asia	157	8 (5.1)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	2.489 [0.658, 9.416]	0.1648	0.9658
Non-Asia	97	10 (10.3)	NC [NC, NC]	93	4 (4.3)	NC [NC, NC]	2.679 [0.840, 8.547]	0.0832	
Number of Organs with Metastatic Sites									
0-2	190	13 (6.8)	NC [NC, NC]	186	6 (3.2)	NC [NC, NC]	2.206 [0.838, 5.808]	0.1003	0.5294
>=3	64	5 (7.8)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	4.707 [0.549, 40.335]	0.1192	

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: 07OCT22

Table 302.1.2001.131.1: Summary and Results of Severe TEAEs - Thrombocytopenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	7 (2.8%)	
Number of patients censored	247 (97.2%)	242 (97.2%)	
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			1.028 [0.359, 2.938]
Log-rank test			
Two-sided stratified log-rank p-value			0.9596

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.132.1: Summary and Results of Severe TEAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	75 (29.5%)	60 (24.1%)	
Number of patients censored	179 (70.5%)	189 (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			1.323 [0.941, 1.860]
Log-rank test			
Two-sided stratified log-rank p-value			0.1129

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.133.1: Summary and Results of Severe TEAEs - Ascites (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	8 (3.2%)	
Number of patients censored	249 (98.0%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.465 [0.140, 1.549]
Log-rank test			
Two-sided stratified log-rank p-value			0.2012

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.134.1: Summary and Results of Severe TEAEs - Diarrhoea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	18 (7.2%)	
Number of patients censored	239 (94.1%)	231 (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			0.814 [0.409, 1.617]
Log-rank test			
Two-sided stratified log-rank p-value			0.5554

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.135.1: Summary and Results of Severe TEAEs - Nausea (PT) - Safety Analysis Set

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

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.135.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	15 (8.5)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	3.117 [1.133, 8.577]	0.0204	0.5092
>65 years	78	7 (9.0)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	6.790 [0.835, 55.195]	0.0378	
Sex									
Male	160	14 (8.8)	NC [NC, NC]	152	3 (2.0)	NC [NC, NC]	4.600 [1.322, 16.007]	0.0084	0.6162
Female	94	8 (8.5)	NC [NC, NC]	97	3 (3.1)	NC [NC, NC]	2.870 [0.761, 10.821]	0.1037	
Region									
Asia	157	15 (9.6)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	5.221 [1.512, 18.035]	0.0035	0.3816
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	3 (3.2)	NC [NC, NC]	2.298 [0.594, 8.888]	0.2142	
Number of Organs with Metastatic Sites									
0-2	190	14 (7.4)	NC [NC, NC]	186	6 (3.2)	NC [NC, NC]	2.365 [0.909, 6.154]	0.0691	0.9890
>=3	64	8 (12.5)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	3.07E7 [0.000, NC]	0.0040	

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: 07OCT22

Table 302.1.2001.136.1: Summary and Results of Severe TEAEs - Vomiting (PT) - Safety Analysis Set

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

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.136.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	21 (11.9)	NC [NC, NC]	177	7 (4.0)	NC [NC, NC]	3.200 [1.360, 7.527]	0.0052	0.6169
>65 years	78	10 (12.8)	NC [NC, NC]	72	2 (2.8)	NC [NC, NC]	5.021 [1.100, 22.927]	0.0208	
Sex									
Male	160	17 (10.6)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	2.440 [1.012, 5.885]	0.0415	0.1815
Female	94	14 (14.9)	NC [NC, NC]	97	2 (2.1)	NC [NC, NC]	7.882 [1.791, 34.695]	0.0012	
Region									
Asia	157	18 (11.5)	NC [NC, NC]	156	4 (2.6)	NC [NC, NC]	4.782 [1.618, 14.131]	0.0019	0.4411
Non-Asia	97	13 (13.4)	NC [NC, NC]	93	5 (5.4)	NC [NC, NC]	2.661 [0.948, 7.465]	0.0543	
Number of Organs with Metastatic Sites									
0-2	190	22 (11.6)	NC [NC, NC]	186	8 (4.3)	NC [NC, NC]	2.871 [1.278, 6.449]	0.0080	0.2899
>=3	64	9 (14.1)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	9.621 [1.218, 75.962]	0.0085	

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: 07OCT22

Table 302.1.2001.137.1: Summary and Results of Severe TEAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	25 (9.8%)	18 (7.2%)	
Number of patients censored	229 (90.2%)	231 (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			1.374 [0.749, 2.521]
Log-rank test			
Two-sided stratified log-rank p-value			0.3033

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.138.1: Summary and Results of Severe TEAEs - Asthenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	3 (1.2%)	
Number of patients censored	247 (97.2%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.330 [0.602, 9.015]
Log-rank test			
Two-sided stratified log-rank p-value			0.2084

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.139.1: Summary and Results of Severe TEAEs - Fatigue (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	9 (3.6%)	
Number of patients censored	247 (97.2%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.755 [0.281, 2.029]
Log-rank test			
Two-sided stratified log-rank p-value			0.5755

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.140.1: Summary and Results of Severe TEAEs - Hepatobiliary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	9 (3.6%)	
Number of patients censored	245 (96.5%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.994 [0.391, 2.529]
Log-rank test			
Two-sided stratified log-rank p-value			0.9902

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.141.1: Summary and Results of Severe TEAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	23 (9.1%)	30 (12.0%)	
Number of patients censored	231 (90.9%)	219 (88.0%)	
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			0.749 [0.433, 1.294]
Log-rank test			
Two-sided stratified log-rank p-value			0.2985

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.142.1: Summary and Results of Severe TEAEs - Pneumonia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	6 (2.4%)	
Number of patients censored	247 (97.2%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.250 [0.419, 3.730]
Log-rank test			
Two-sided stratified log-rank p-value			0.6884

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.143.1: Summary and Results of Severe TEAEs - Investigations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	56 (22.0%)	53 (21.3%)	
Number of patients censored	198 (78.0%)	196 (78.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	26.1 [26.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.023 [0.699, 1.498]
Log-rank test			
Two-sided stratified log-rank p-value			0.9080

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.144.1: Summary and Results of Severe TEAEs - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	7 (2.8%)	
Number of patients censored	248 (97.6%)	242 (97.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [26.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.783 [0.248, 2.475]
Log-rank test			
Two-sided stratified log-rank p-value			0.6764

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.145.1: Summary and Results of Severe TEAEs - Neutrophil Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	26 (10.2%)	24 (9.6%)	
Number of patients censored	228 (89.8%)	225 (90.4%)	
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			1.064 [0.607, 1.865]
Log-rank test			
Two-sided stratified log-rank p-value			0.8309

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.146.1: Summary and Results of Severe TEAEs - Platelet Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	19 (7.5%)	20 (8.0%)	
Number of patients censored	235 (92.5%)	229 (92.0%)	
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			0.950 [0.506, 1.784]
Log-rank test			
Two-sided stratified log-rank p-value			0.8719

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.147.1: Summary and Results of Severe TEAEs - White Blood Cell Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	9 (3.6%)	
Number of patients censored	249 (98.0%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.580 [0.194, 1.738]
Log-rank test			
Two-sided stratified log-rank p-value			0.3250

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.148.1: Summary and Results of Severe TEAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	41 (16.1%)	31 (12.4%)	
Number of patients censored	213 (83.9%)	218 (87.6%)	
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			1.379 [0.863, 2.203]
Log-rank test			
Two-sided stratified log-rank p-value			0.1776

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.149.1: Summary and Results of Severe TEAEs - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	17 (6.7%)	4 (1.6%)	
Number of patients censored	237 (93.3%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			4.606 [1.548, 13.709]
Log-rank test			
Two-sided stratified log-rank p-value			0.0026

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.149.2: Summary and Results of Severe TEAEs by Subgroups - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	11 (6.3)	NC [NC, NC]	177	4 (2.3)	NC [NC, NC]	2.856 [0.910, 8.971]	0.0601	0.9898
>65 years	78	6 (7.7)	NC [NC, NC]	72	0 (0.0)	NC [NC, NC]	3.09E7 [0.000, NC]	0.0126	
Sex									
Male	160	15 (9.4)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	7.487 [1.712, 32.742]	0.0016	0.1191
Female	94	2 (2.1)	NC [NC, NC]	97	2 (2.1)	NC [NC, NC]	1.061 [0.149, 7.535]	0.9527	
Region									
Asia	157	10 (6.4)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	3.438 [0.946, 12.493]	0.0460	0.5636
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	1 (1.1)	NC [NC, NC]	7.310 [0.899, 59.441]	0.0291	
Number of Organs with Metastatic Sites									
0-2	190	11 (5.8)	NC [NC, NC]	186	3 (1.6)	NC [NC, NC]	3.755 [1.047, 13.459]	0.0291	0.6910
>=3	64	6 (9.4)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	6.093 [0.734, 50.592]	0.0560	

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: 07OCT22

Table 302.1.2001.150.1: Summary and Results of Severe TEAEs - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	4 (1.6%)	
Number of patients censored	246 (96.9%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.039 [0.613, 6.784]
Log-rank test			
Two-sided stratified log-rank p-value			0.2355

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.151.1: Summary and Results of Severe TEAEs - Hypokalaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	16 (6.4%)	
Number of patients censored	240 (94.5%)	233 (93.6%)	
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			0.831 [0.403, 1.717]
Log-rank test			
Two-sided stratified log-rank p-value			0.6173

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.152.1: Summary and Results of Severe TEAEs - Hyponatraemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	9 (3.6%)	
Number of patients censored	250 (98.4%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.469 [0.144, 1.524]
Log-rank test			
Two-sided stratified log-rank p-value			0.1971

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.153.1: Summary and Results of Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	16 (6.4%)	
Number of patients censored	244 (96.1%)	233 (93.6%)	
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			0.600 [0.262, 1.376]
Log-rank test			
Two-sided stratified log-rank p-value			0.2228

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.154.1: Summary and Results of Severe TEAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	13 (5.2%)	
Number of patients censored	245 (96.5%)	236 (94.8%)	
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			0.648 [0.264, 1.593]
Log-rank test			
Two-sided stratified log-rank p-value			0.3408

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.155.1: Summary and Results of Severe TEAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	14 (5.6%)	
Number of patients censored	243 (95.7%)	235 (94.4%)	
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			0.785 [0.356, 1.731]
Log-rank test			
Two-sided stratified log-rank p-value			0.5475

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.156.1: Summary and Results of Severe TEAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	6 (2.4%)	
Number of patients censored	246 (96.9%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.372 [0.475, 3.965]
Log-rank test			
Two-sided stratified log-rank p-value			0.5575

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.157.1: Summary and Results of Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	22 (8.8%)	
Number of patients censored	244 (96.1%)	227 (91.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	28.4 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.493 [0.231, 1.055]
Log-rank test			
Two-sided stratified log-rank p-value			0.0626

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.158.1: Summary and Results of Severe TEAEs - Pulmonary Embolism (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	9 (3.6%)	
Number of patients censored	250 (98.4%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	28.4 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.502 [0.151, 1.667]
Log-rank test			
Two-sided stratified log-rank p-value			0.2505

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.159.1: Summary and Results of Severe TEAEs - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	10 (4.0%)	
Number of patients censored	246 (96.9%)	239 (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			0.793 [0.312, 2.017]
Log-rank test			
Two-sided stratified log-rank p-value			0.6255

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.160.1: Summary and Results of Severe TEAEs - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	9 (3.6%)	
Number of patients censored	250 (98.4%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.429 [0.131, 1.400]
Log-rank test			
Two-sided stratified log-rank p-value			0.1487

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.161.1: Summary and Results of Severe TEAEs - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	5 (2.0%)	
Number of patients censored	242 (95.3%)	244 (98.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	27.9 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.973 [0.957, 9.234]
Log-rank test			
Two-sided stratified log-rank p-value			0.0483

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.161.2: Summary and Results of Severe TEAEs by Subgroups - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	9 (5.1)	NC [NC, NC]	177	3 (1.7)	27.9 [NC, NC]	2.963 [0.802, 10.948]	0.0876	0.5267
>65 years	78	3 (3.8)	NC [NC, NC]	72	2 (2.8)	NC [NC, NC]	1.472 [0.246, 8.821]	0.6722	
Sex									
Male	160	8 (5.0)	NC [NC, NC]	152	5 (3.3)	27.9 [NC, NC]	1.852 [0.557, 6.154]	0.3072	0.9893
Female	94	4 (4.3)	NC [NC, NC]	97	0 (0.0)	NC [NC, NC]	3.1E7 [0.000, NC]	0.0408	
Region									
Asia	157	6 (3.8)		156	2 (1.3)				
Non-Asia	97	6 (6.2)		93	3 (3.2)				
Number of Organs with Metastatic Sites									
0-2	190	7 (3.7)	NC [NC, NC]	186	4 (2.2)	27.9 [NC, NC]	2.350 [0.608, 9.090]	0.2022	0.5336
>=3	64	5 (7.8)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	4.804 [0.560, 41.188]	0.1139	

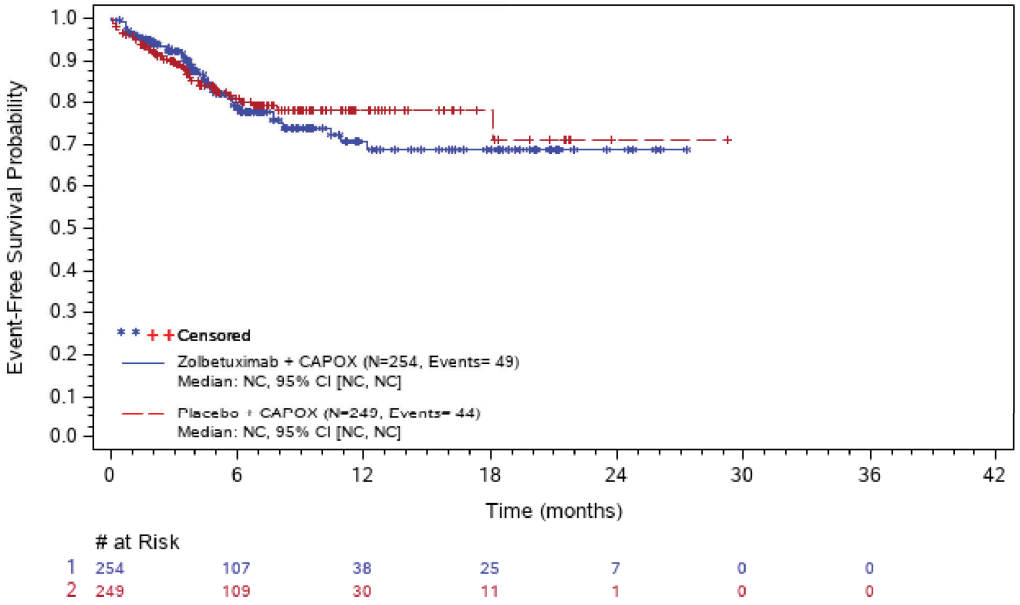
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwere unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

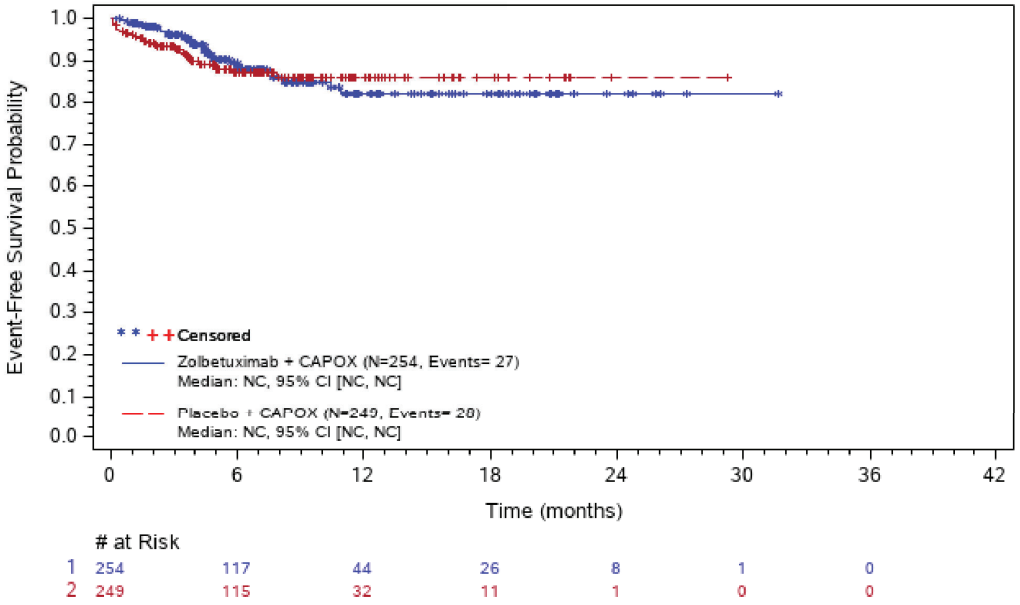
Figure 302.1.2001.128: Kaplan-Meier Plot of Time to first Severe TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.129: Kaplan-Meier Plot of Time to first Severe TEAE - Anaemia (PT) - Safety Analysis Set

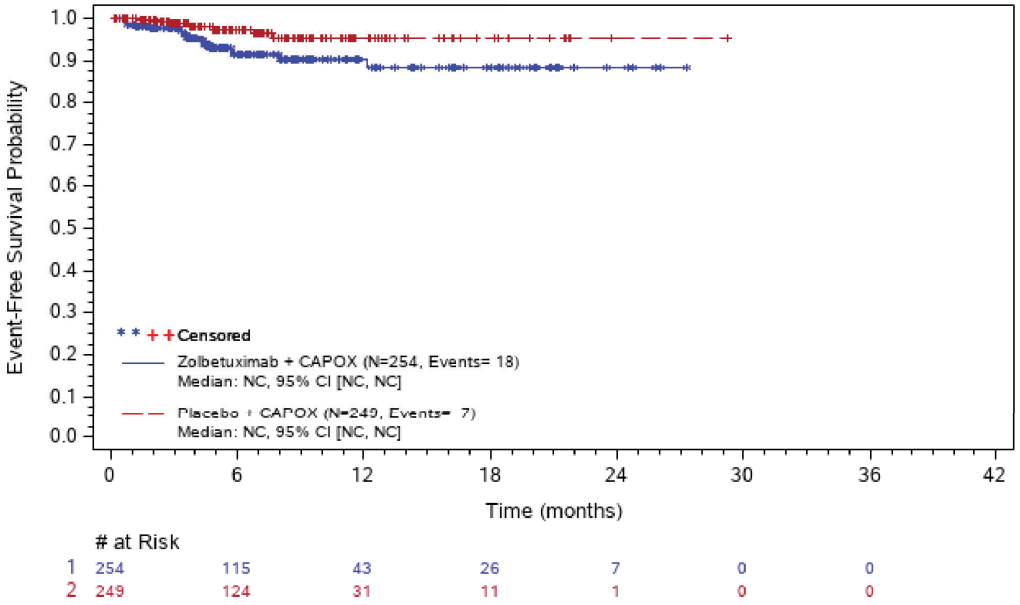


# at Risk							
1	254	117	44	26	8	1	0
2	249	115	32	11	1	0	0

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: 07OCT22

The SAS System

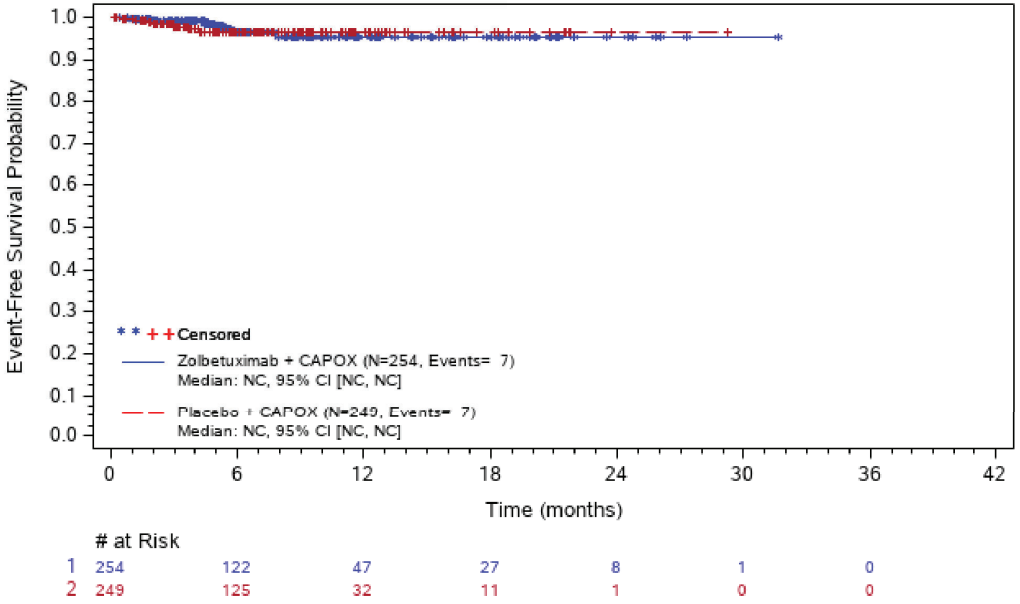
Figure 302.1.2001.130: Kaplan-Meier Plot of Time to first Severe TEAE - Neutropenia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

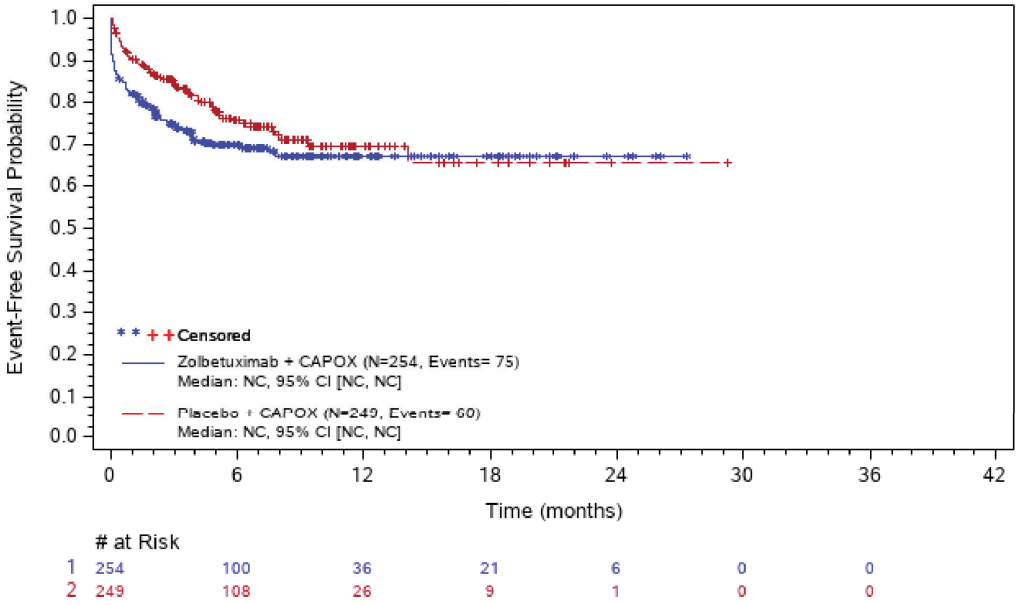
Figure 302.1.2001.131: Kaplan-Meier Plot of Time to first Severe TEAE - Thrombocytopenia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

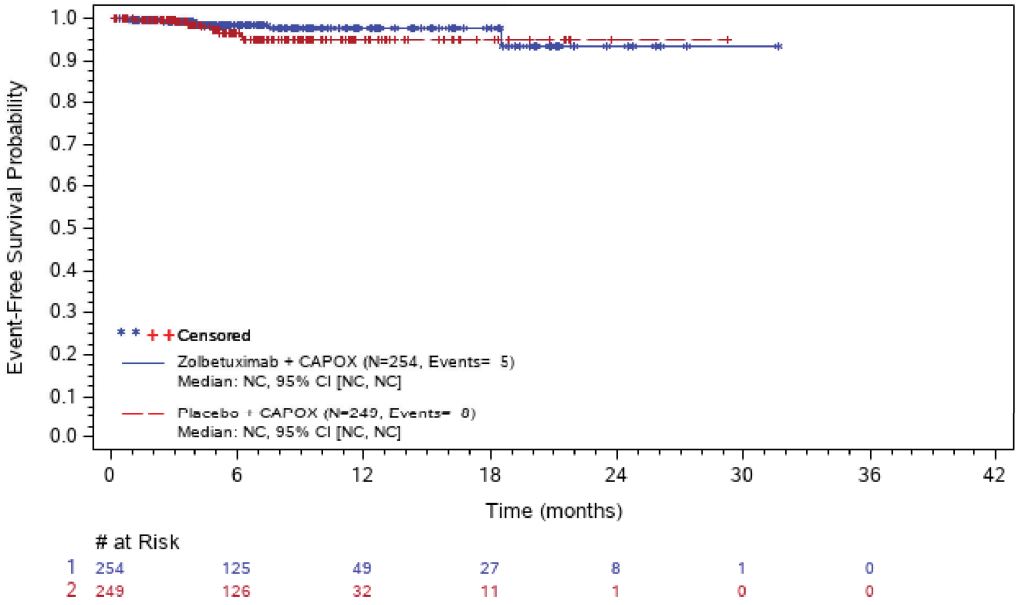
Figure 302.1.2001.132: Kaplan-Meier Plot of Time to first Severe TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

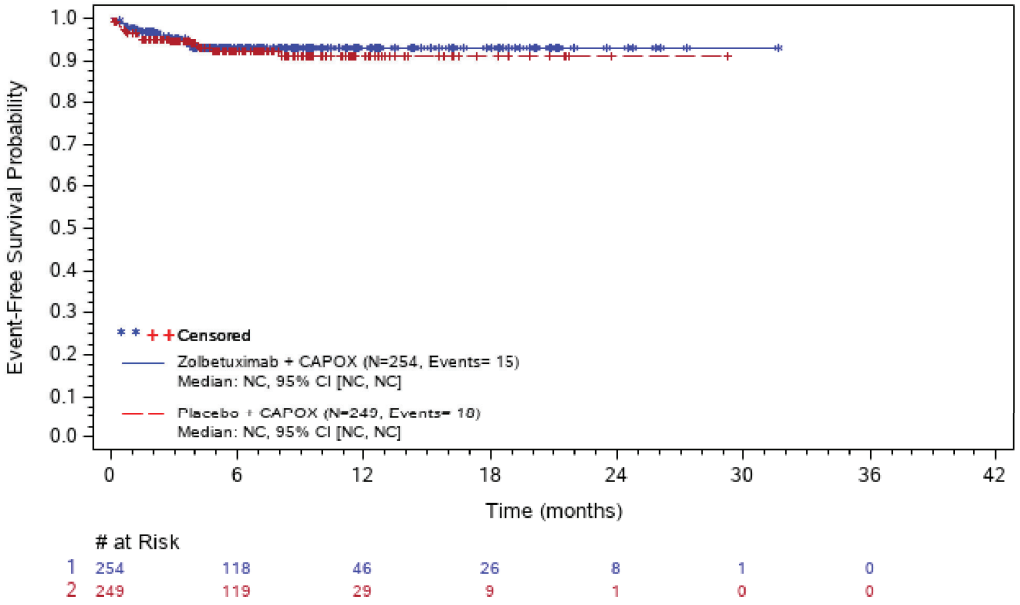
Figure 302.1.2001.133: Kaplan-Meier Plot of Time to first Severe TEAE - Ascites (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 07OCT22

The SAS System

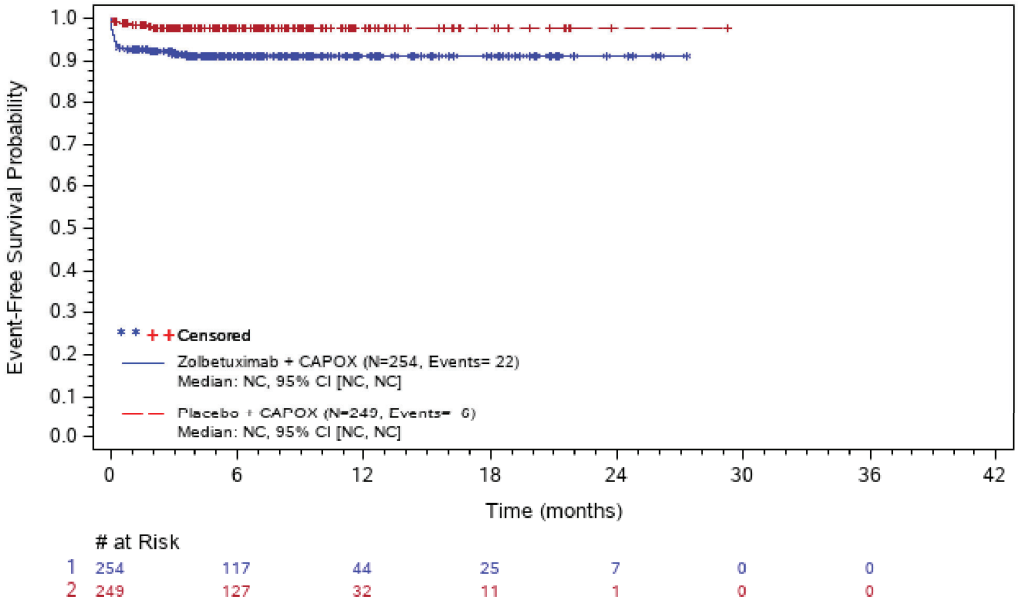
Figure 302.1.2001.134: Kaplan-Meier Plot of Time to first Severe TEAE - Diarrhoea (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

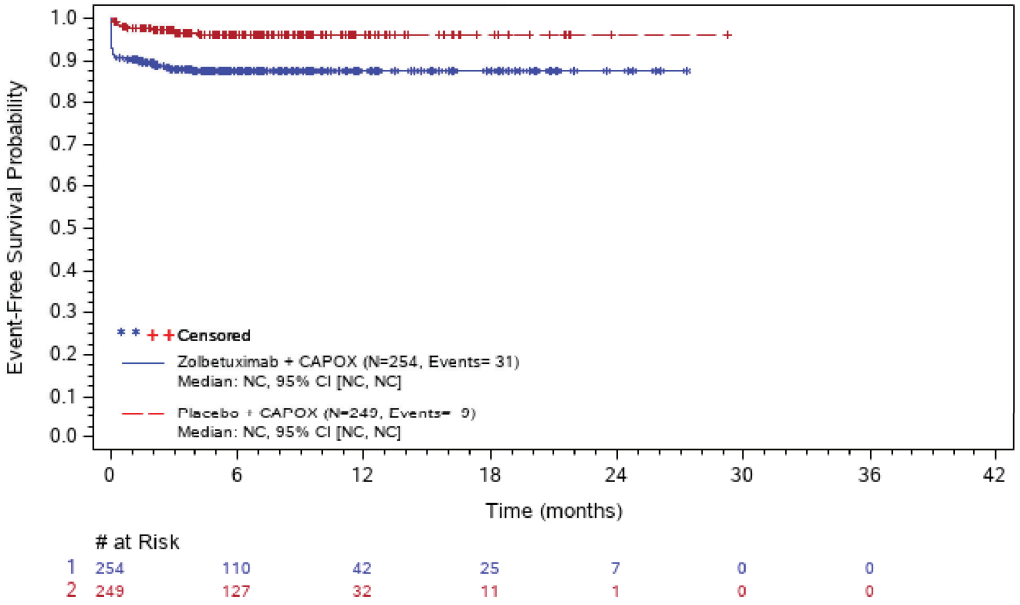
Figure 302.1.2001.135: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

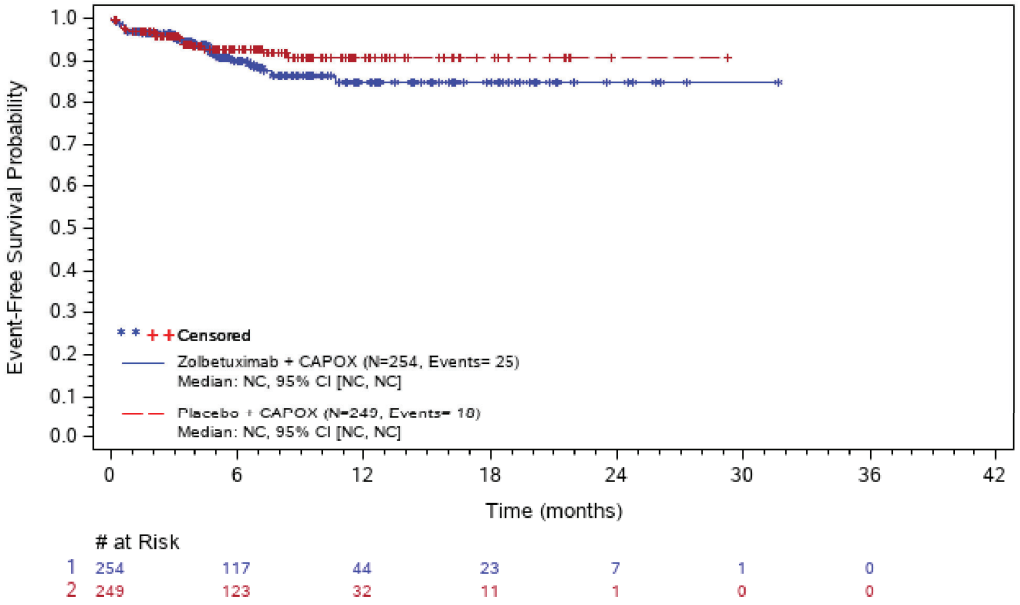
Figure 302.1.2001.136: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

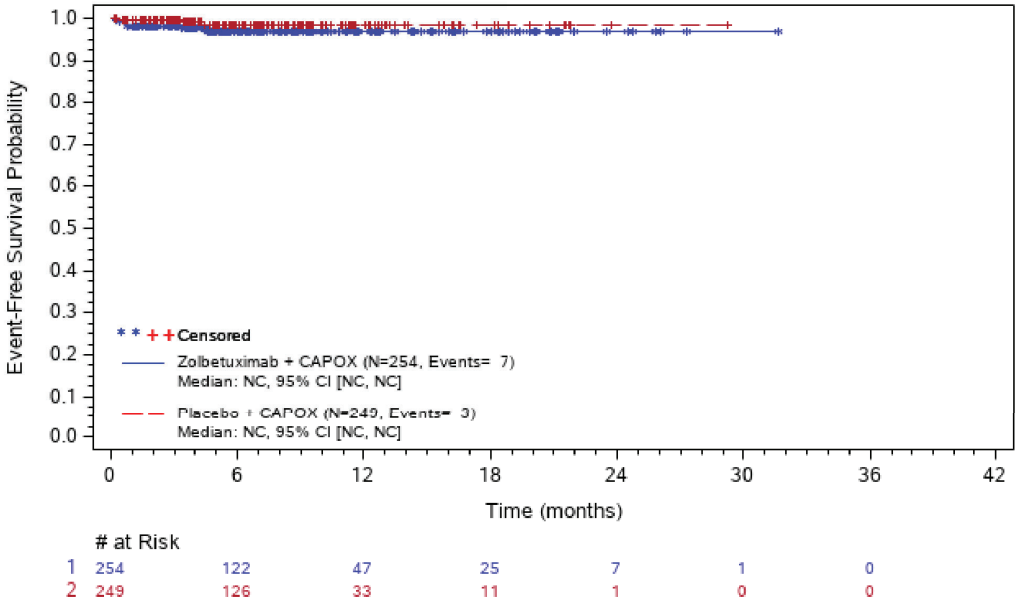
Figure 302.1.2001.137: Kaplan-Meier Plot of Time to first Severe TEAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

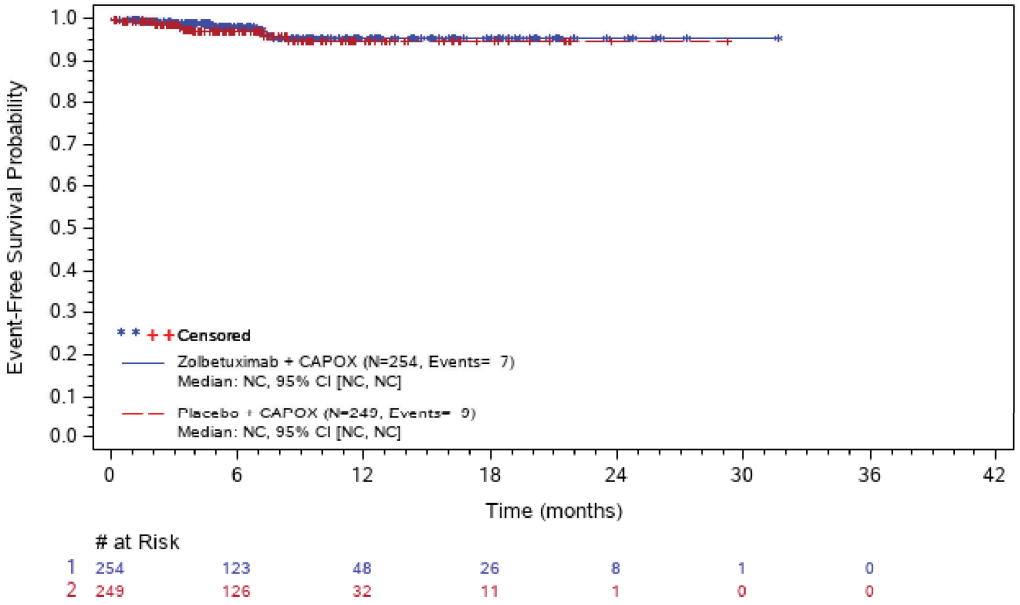
Figure 302.1.2001.138: Kaplan-Meier Plot of Time to first Severe TEAE - Asthenia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

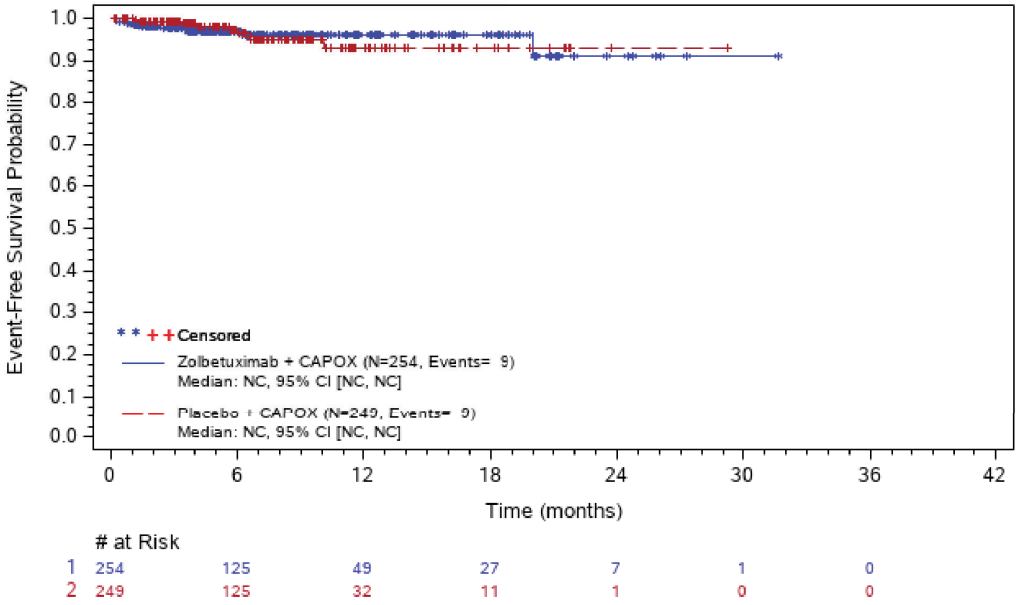
Figure 302.1.2001.139: Kaplan-Meier Plot of Time to first Severe TEAE - Fatigue (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

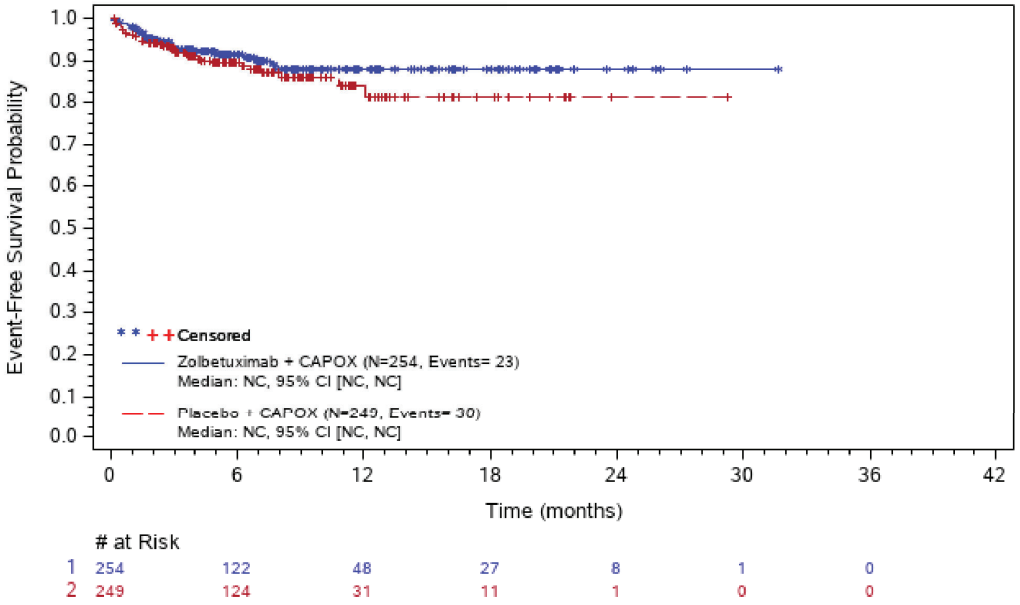
Figure 302.1.2001.140: Kaplan-Meier Plot of Time to first Severe TEAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

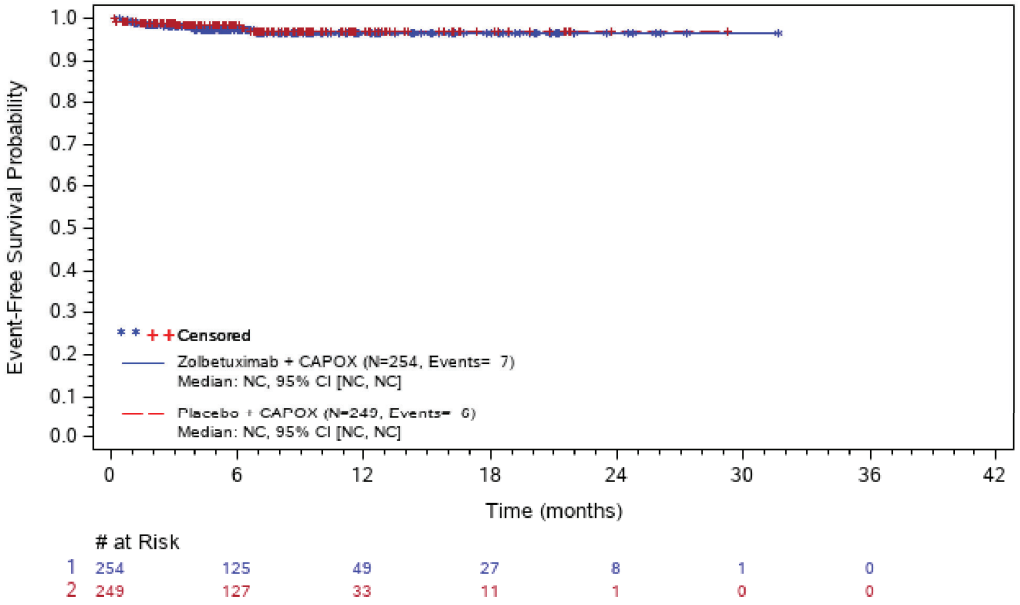
Figure 302.1.2001.141: Kaplan-Meier Plot of Time to first Severe TEAE - Infections And Infestations (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

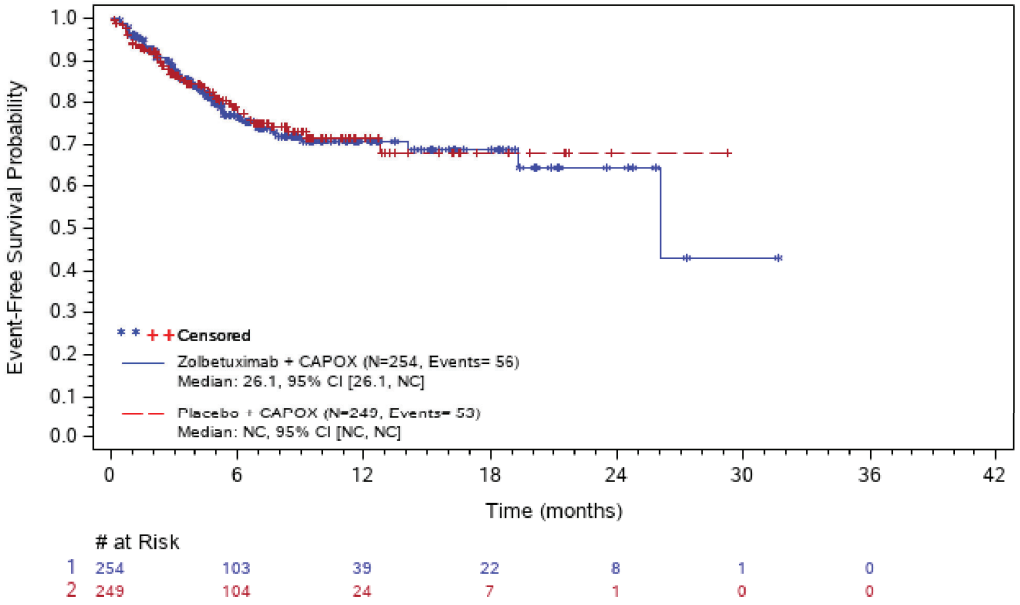
Figure 302.1.2001.142: Kaplan-Meier Plot of Time to first Severe TEAE - Pneumonia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

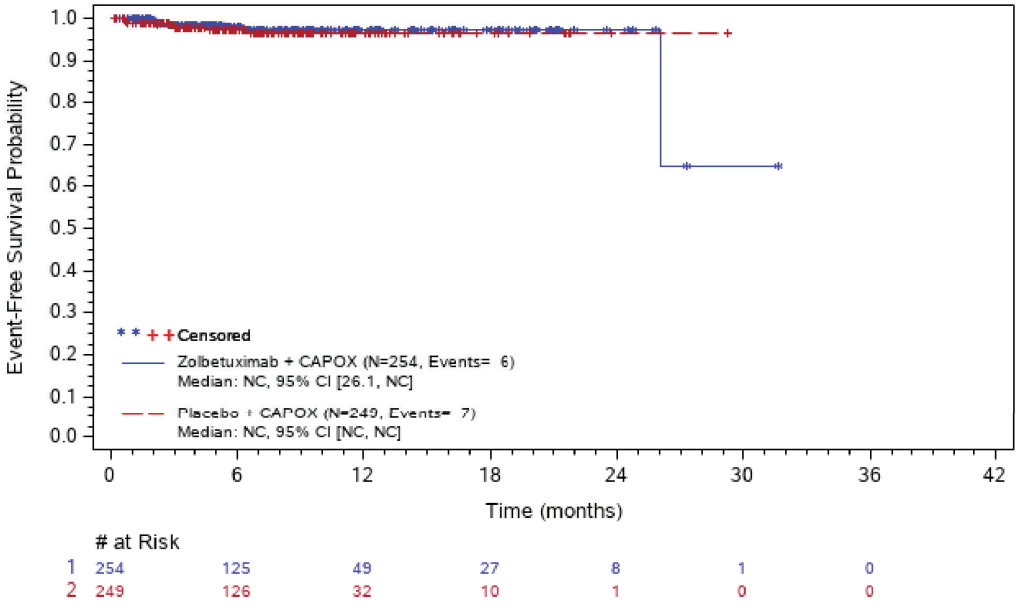
Figure 302.1.2001.143: Kaplan-Meier Plot of Time to first Severe TEAE - Investigations (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

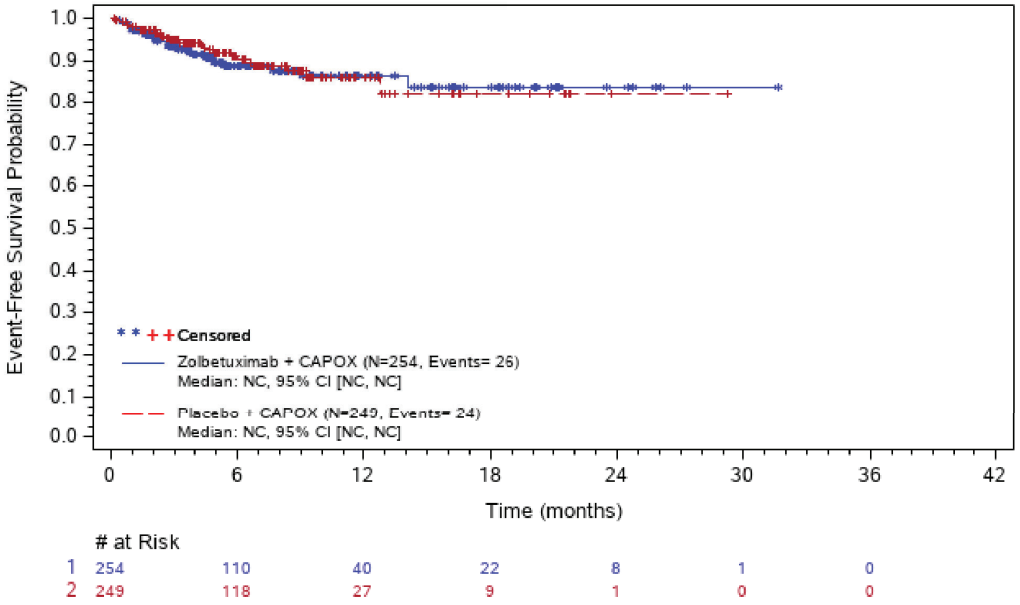
Figure 302.1.2001.144: Kaplan-Meier Plot of Time to first Severe TEAE - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

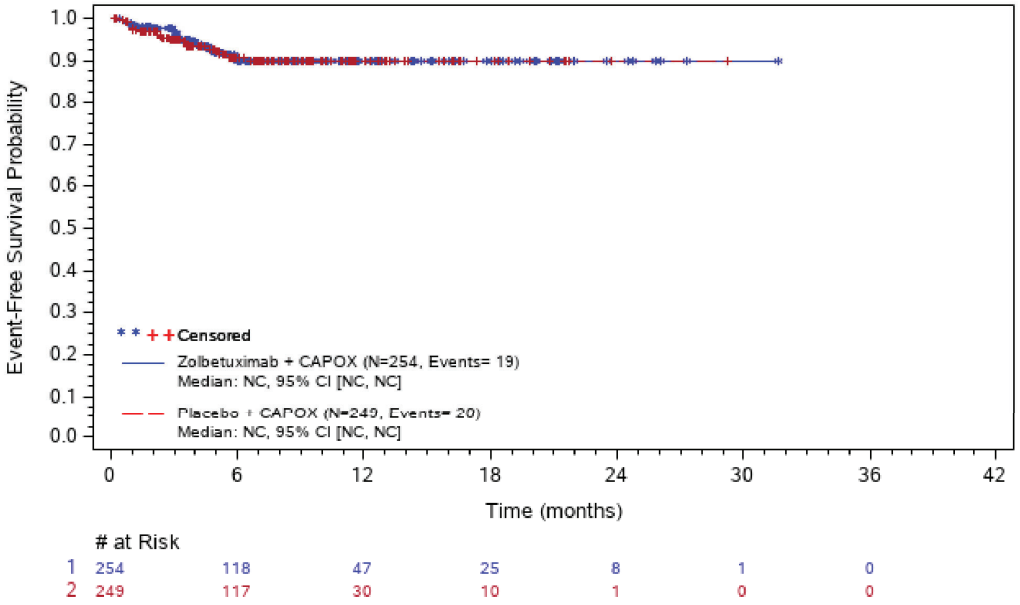
Figure 302.1.2001.145: Kaplan-Meier Plot of Time to first Severe TEAE - Neutrophil Count Decreased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

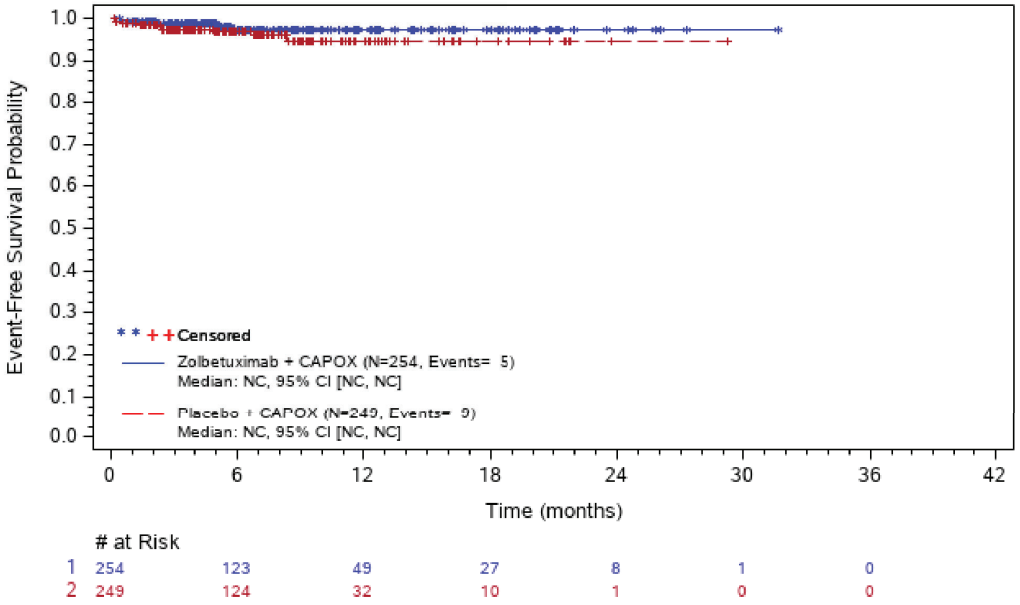
Figure 302.1.2001.146: Kaplan-Meier Plot of Time to first Severe TEAE - Platelet Count Decreased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

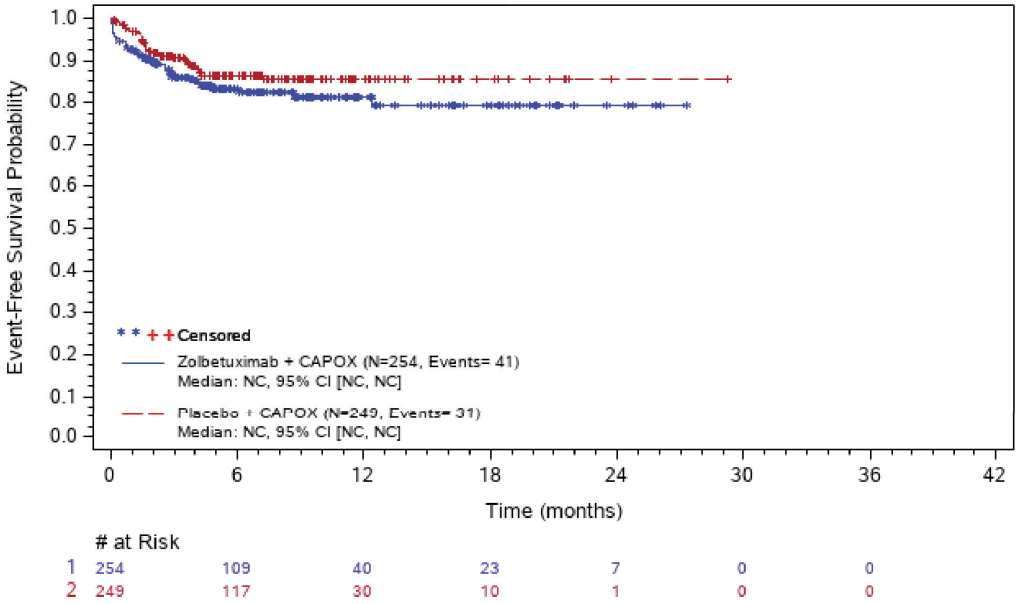
Figure 302.1.2001.147: Kaplan-Meier Plot of Time to first Severe TEAE - White Blood Cell Count Decreased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

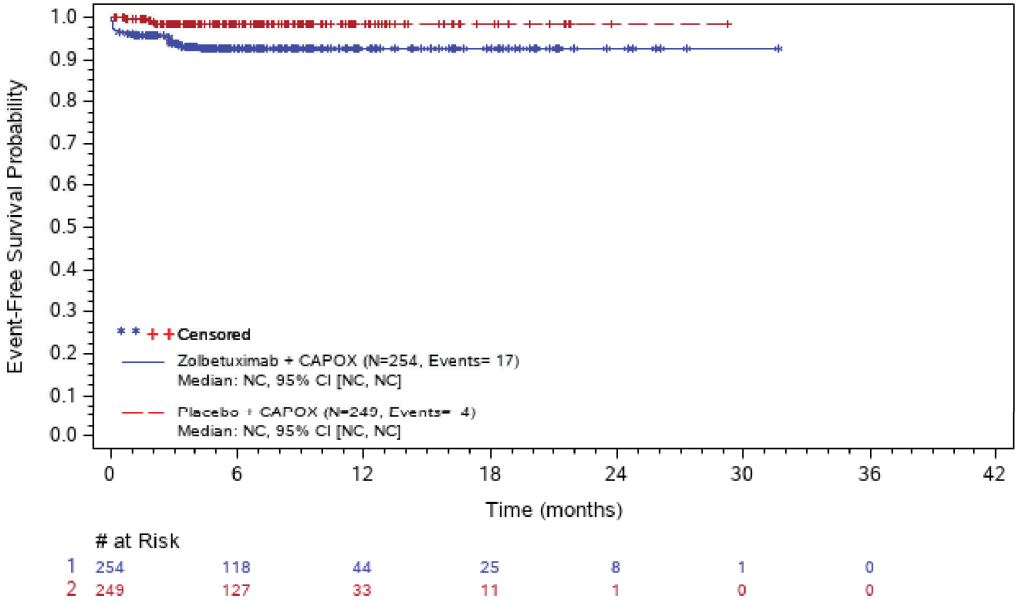
Figure 302.1.2001.148: Kaplan-Meier Plot of Time to first Severe TEAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

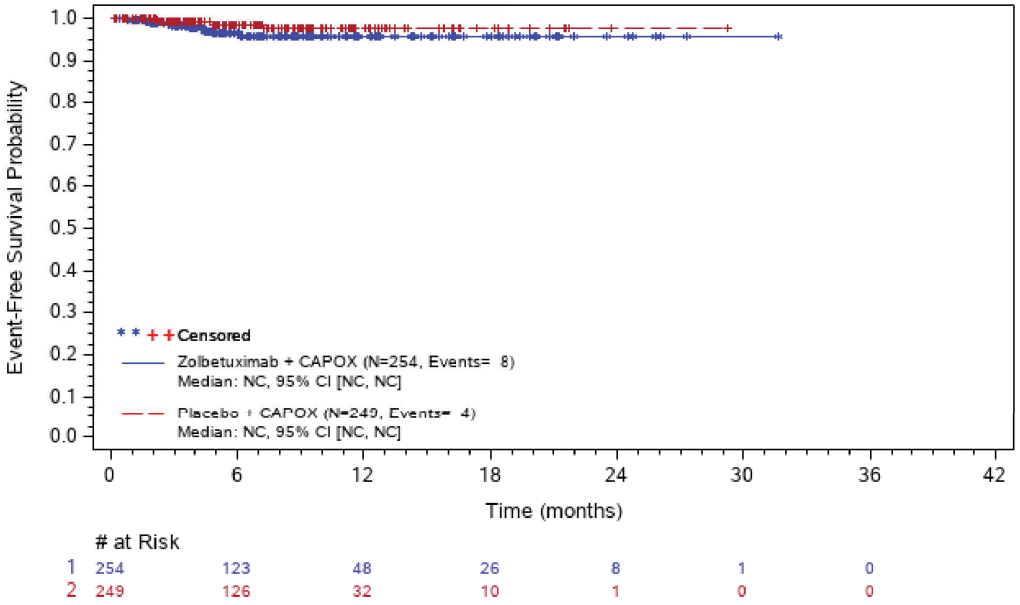
Figure 302.1.2001.149: Kaplan-Meier Plot of Time to first Severe TEAE - Decreased Appetite (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

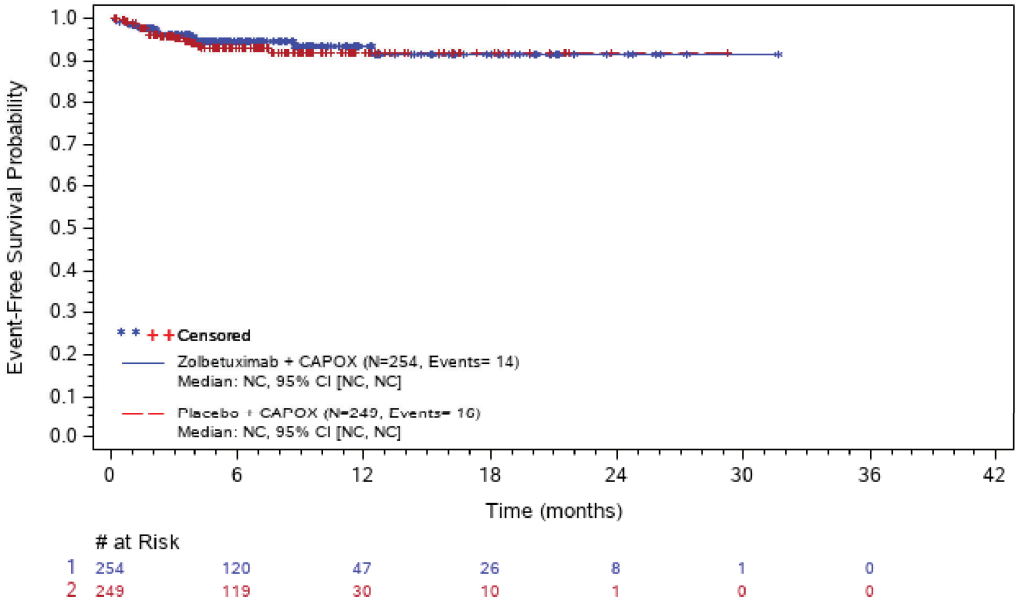
Figure 302.1.2001.150: Kaplan-Meier Plot of Time to first Severe TEAE - Hypoalbuminaemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

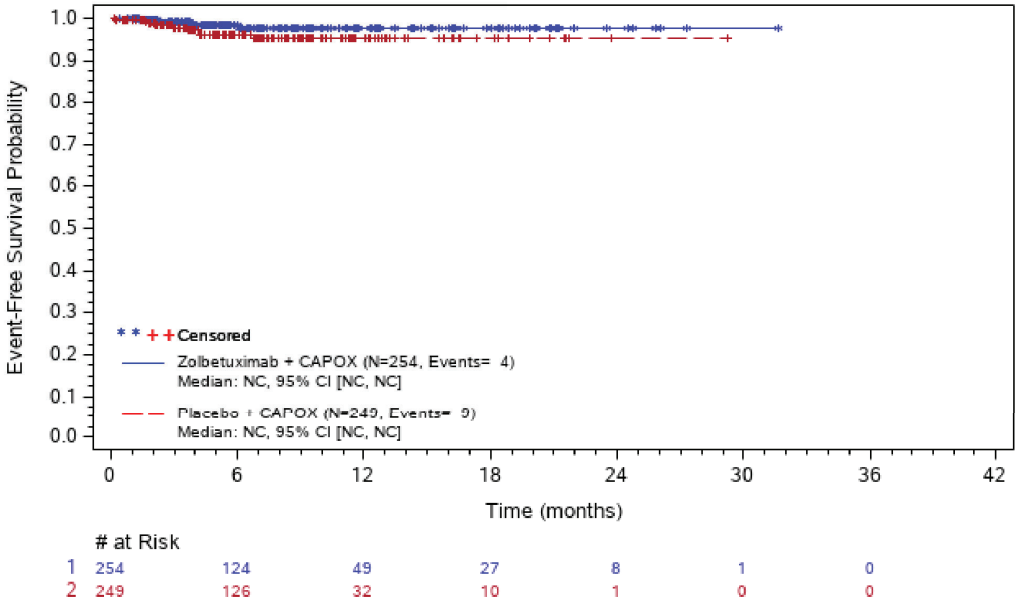
Figure 302.1.2001.151: Kaplan-Meier Plot of Time to first Severe TEAE - Hypokalaemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

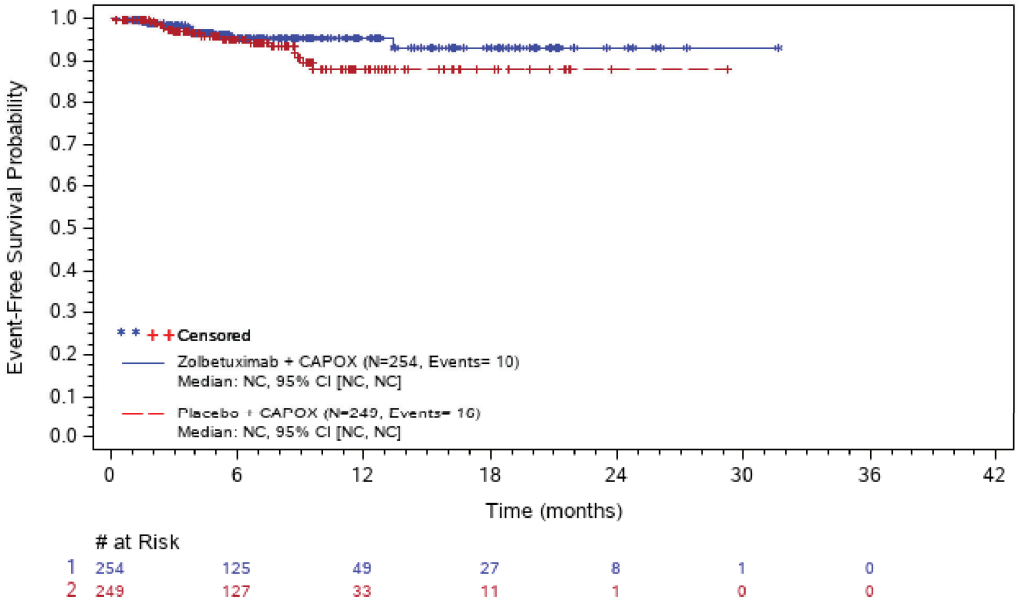
Figure 302.1.2001.152: Kaplan-Meier Plot of Time to first Severe TEAE - Hyponatraemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

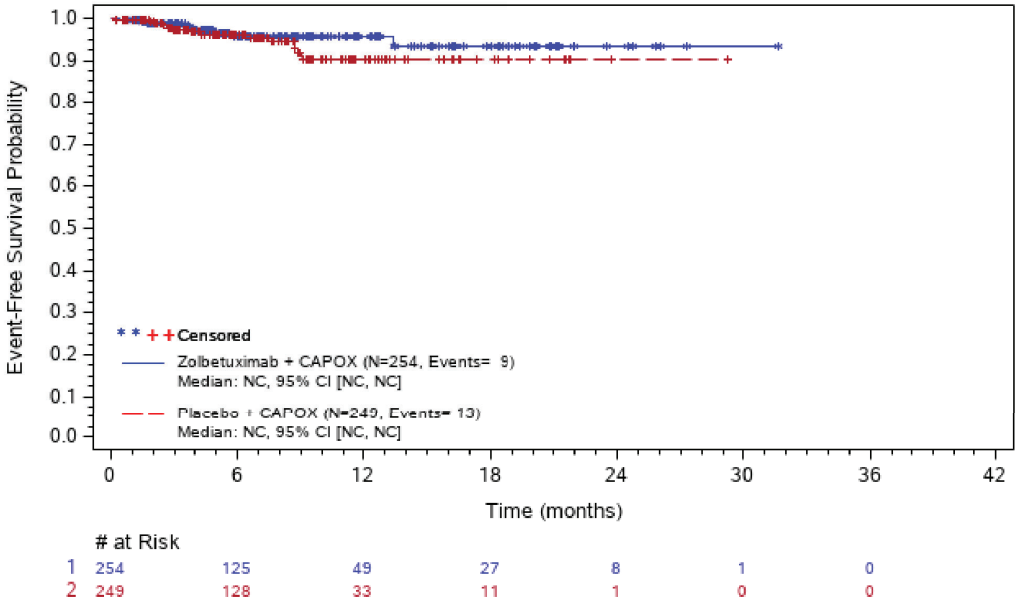
Figure 302.1.2001.153: Kaplan-Meier Plot of Time to first Severe TEAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

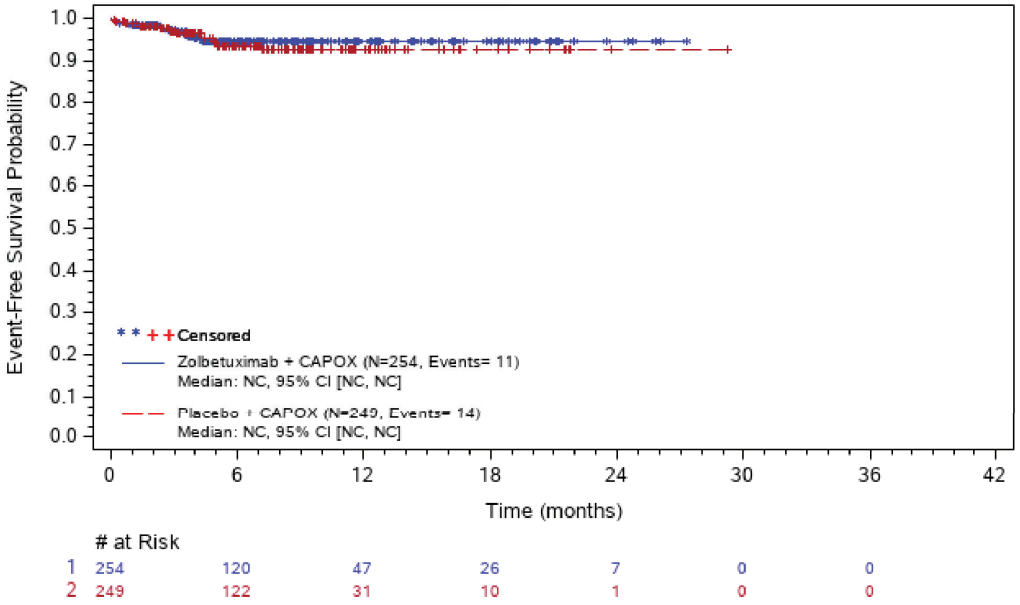
Figure 302.1.2001.154: Kaplan-Meier Plot of Time to first Severe TEAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

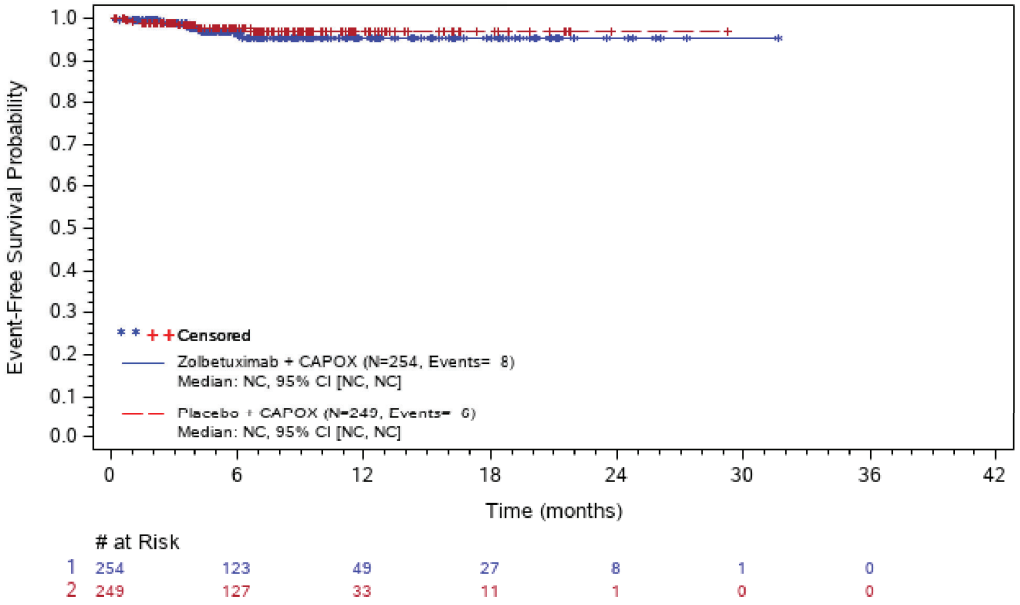
Figure 302.1.2001.155: Kaplan-Meier Plot of Time to first Severe TEAE - Nervous System Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

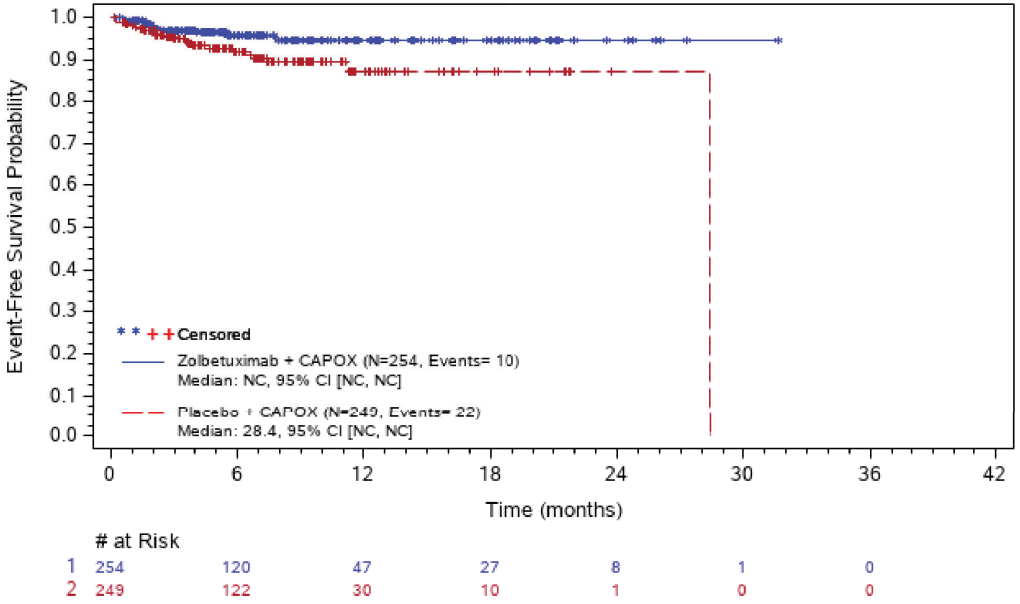
Figure 302.1.2001.156: Kaplan-Meier Plot of Time to first Severe TEAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

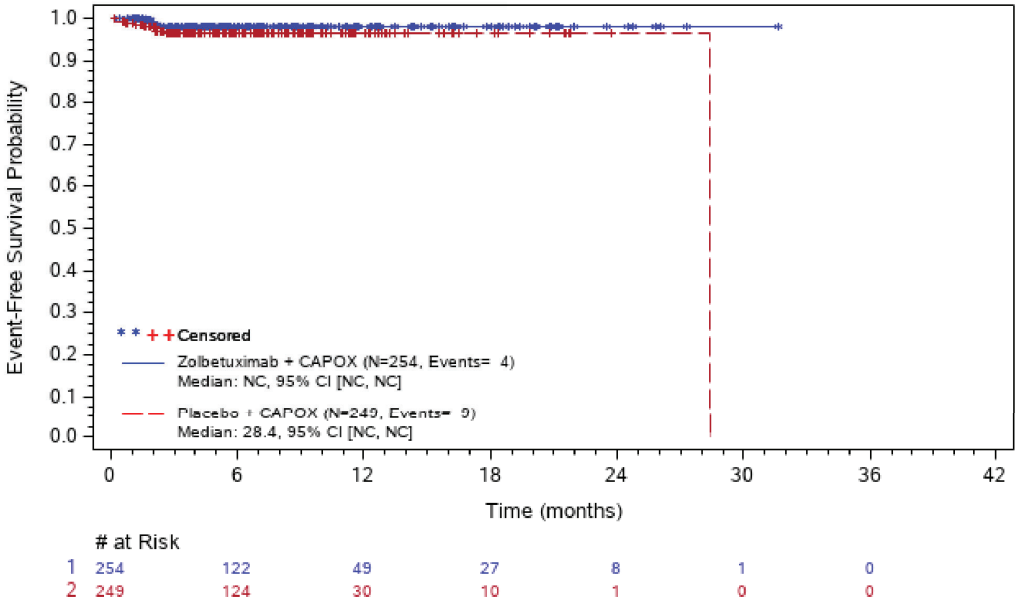
Figure 302.1.2001.157: Kaplan-Meier Plot of Time to first Severe TEAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

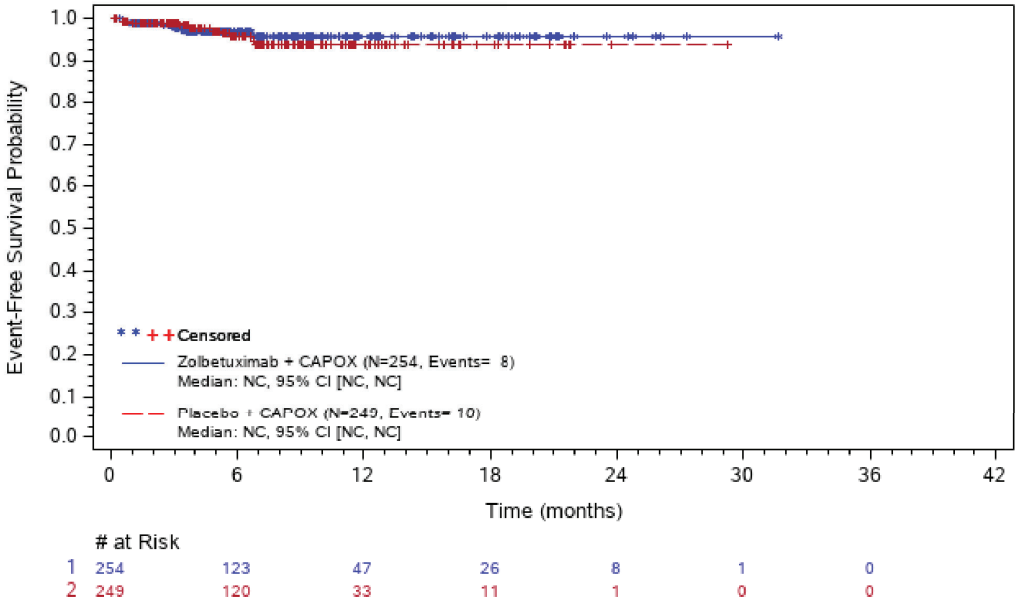
Figure 302.1.2001.158: Kaplan-Meier Plot of Time to first Severe TEAE - Pulmonary Embolism (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

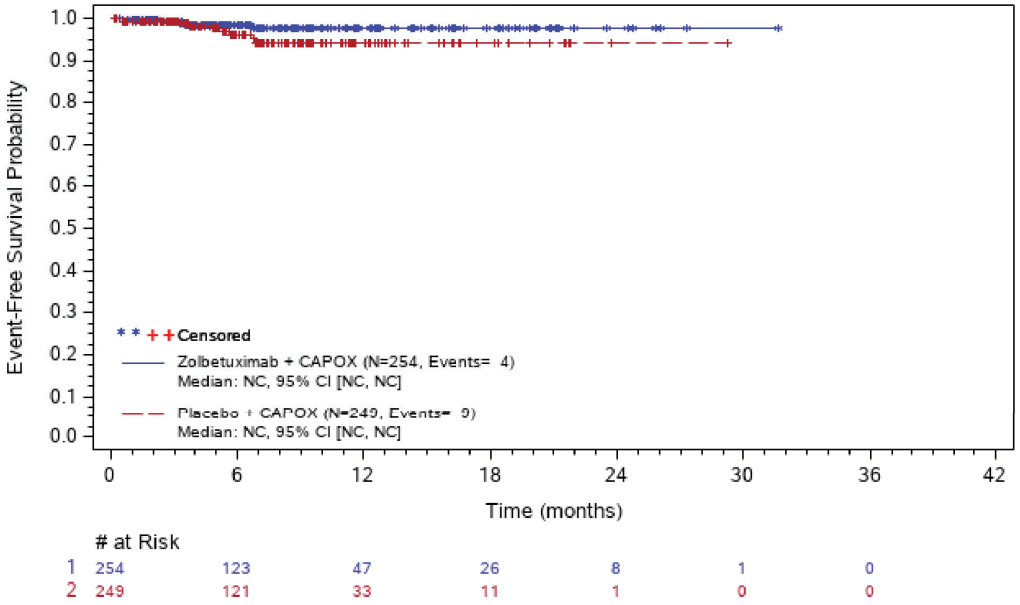
Figure 302.1.2001.159: Kaplan-Meier Plot of Time to first Severe TEAE - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

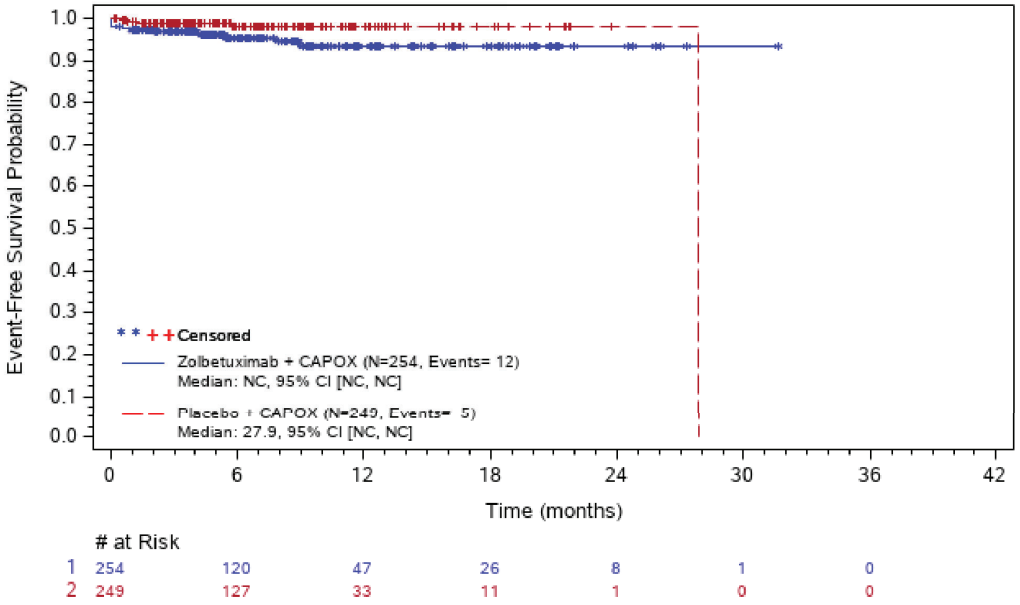
Figure 302.1.2001.160: Kaplan-Meier Plot of Time to first Severe TEAE - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.161: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwerwiegende unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 302.1.2001.105.1: Summary and Results of TESAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	15 (6.0%)	
Number of patients censored	242 (95.3%)	234 (94.0%)	
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			0.789 [0.368, 1.693]
Log-rank test			
Two-sided stratified log-rank p-value			0.5424

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.106.1: Summary and Results of TESAEs - Anaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	6 (2.4%)	
Number of patients censored	249 (98.0%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.821 [0.250, 2.696]
Log-rank test			
Two-sided stratified log-rank p-value			0.7453

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.107.1: Summary and Results of TESAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	57 (22.4%)	50 (20.1%)	
Number of patients censored	197 (77.6%)	199 (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			1.161 [0.793, 1.701]
Log-rank test			
Two-sided stratified log-rank p-value			0.4447

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.108.1: Summary and Results of TESAEs - Diarrhoea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	10 (4.0%)	
Number of patients censored	247 (97.2%)	239 (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			0.683 [0.260, 1.798]
Log-rank test			
Two-sided stratified log-rank p-value			0.4377

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.109.1: Summary and Results of TESAEs - Nausea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	6 (2.4%)	
Number of patients censored	243 (95.7%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.833 [0.677, 4.963]
Log-rank test			
Two-sided stratified log-rank p-value			0.2263

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.110.1: Summary and Results of TESAEs - Upper Gastrointestinal Haemorrhage (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	4 (1.6%)	
Number of patients censored	247 (97.2%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.885 [0.551, 6.449]
Log-rank test			
Two-sided stratified log-rank p-value			0.3048

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.111.1: Summary and Results of TESAEs - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	11 (4.4%)	
Number of patients censored	239 (94.1%)	238 (95.6%)	
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			1.359 [0.624, 2.961]
Log-rank test			
Two-sided stratified log-rank p-value			0.4382

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.112.1: Summary and Results of TESAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	18 (7.1%)	13 (5.2%)	
Number of patients censored	236 (92.9%)	236 (94.8%)	
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			1.326 [0.649, 2.711]
Log-rank test			
Two-sided stratified log-rank p-value			0.4361

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.113.1: Summary and Results of TESAEs - Hepatobiliary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	7 (2.8%)	
Number of patients censored	245 (96.5%)	242 (97.2%)	
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			1.311 [0.484, 3.552]
Log-rank test			
Two-sided stratified log-rank p-value			0.5933

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.114.1: Summary and Results of TESAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	25 (9.8%)	21 (8.4%)	
Number of patients censored	229 (90.2%)	228 (91.6%)	
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			1.182 [0.659, 2.119]
Log-rank test			
Two-sided stratified log-rank p-value			0.5731

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.115.1: Summary and Results of TESAEs - Pneumonia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	5 (2.0%)	
Number of patients censored	248 (97.6%)	244 (98.0%)	
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			1.311 [0.399, 4.308]
Log-rank test			
Two-sided stratified log-rank p-value			0.6549

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.116.1: Summary and Results of TESAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	1 (0.4%)	
Number of patients censored	245 (96.5%)	248 (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			8.914 [1.124, 70.701]
Log-rank test			
Two-sided stratified log-rank p-value			0.0124

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.116.2: Summary and Results of TESAEs by Subgroups - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	0 (0.0)				
>65 years	78	5 (6.4)		72	1 (1.4)				
Sex									
Male	160	8 (5.0)		152	1 (0.7)				
Female	94	1 (1.1)		97	0 (0.0)				
Region									
Asia	157	4 (2.5)		156	1 (0.6)				
Non-Asia	97	5 (5.2)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)		186	1 (0.5)				
>=3	64	3 (4.7)		63	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 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: 07OCT22

Table 302.1.2001.117.1: Summary and Results of TESAEs - Investigations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	13 (5.1%)	10 (4.0%)	
Number of patients censored	241 (94.9%)	239 (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			1.261 [0.550, 2.889]
Log-rank test			
Two-sided stratified log-rank p-value			0.5830

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.118.1: Summary and Results of TESAEs - Platelet Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	6 (2.4%)	
Number of patients censored	246 (96.9%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.335 [0.463, 3.853]
Log-rank test			
Two-sided stratified log-rank p-value			0.5918

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.119.1: Summary and Results of TESAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	18 (7.1%)	15 (6.0%)	
Number of patients censored	236 (92.9%)	234 (94.0%)	
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			1.262 [0.633, 2.516]
Log-rank test			
Two-sided stratified log-rank p-value			0.5068

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.120.1: Summary and Results of TESAEs - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	3 (1.2%)	
Number of patients censored	244 (96.1%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.510 [0.963, 12.792]
Log-rank test			
Two-sided stratified log-rank p-value			0.0425

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.120.2: Summary and Results of TESAEs by Subgroups - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	6 (3.4)		177	1 (0.6)				
>65 years	78	4 (5.1)		72	2 (2.8)				
Sex									
Male	160	9 (5.6)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	4.381 [0.947, 20.277]	0.0387	0.3811
Female	94	1 (1.1)	NC [NC, NC]	97	1 (1.0)	NC [NC, NC]	1.021 [0.064, 16.330]	0.9881	
Region									
Asia	157	7 (4.5)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	2.367 [0.612, 9.151]	0.1977	0.9910
Non-Asia	97	3 (3.1)	NC [NC, NC]	93	0 (0.0)	NC [NC, NC]	3.04E7 [0.000, NC]	0.0793	
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)		186	2 (1.1)				
>=3	64	4 (6.3)		63	1 (1.6)				

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: 07OCT22

Table 302.1.2001.121.1: Summary and Results of TESAEs - Hypokalaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	6 (2.4%)	
Number of patients censored	248 (97.6%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.036 [0.331, 3.244]
Log-rank test			
Two-sided stratified log-rank p-value			0.9510

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.122.1: Summary and Results of TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	17 (6.8%)	
Number of patients censored	244 (96.1%)	232 (93.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [19.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.532 [0.233, 1.214]
Log-rank test			
Two-sided stratified log-rank p-value			0.1276

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.123.1: Summary and Results of TESAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	13 (5.2%)	
Number of patients censored	245 (96.5%)	236 (94.8%)	
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			0.648 [0.264, 1.593]
Log-rank test			
Two-sided stratified log-rank p-value			0.3408

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.124.1: Summary and Results of TESAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	3 (1.2%)	
Number of patients censored	247 (97.2%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.390 [0.618, 9.243]
Log-rank test			
Two-sided stratified log-rank p-value			0.1926

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.125.1: Summary and Results of TESAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	8 (3.2%)	
Number of patients censored	247 (97.2%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.885 [0.320, 2.449]
Log-rank test			
Two-sided stratified log-rank p-value			0.8138

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.126.1: Summary and Results of TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	22 (8.8%)	
Number of patients censored	245 (96.5%)	227 (91.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	28.4 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.418 [0.190, 0.918]
Log-rank test			
Two-sided stratified log-rank p-value			0.0251

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 07OCT22

Table 302.1.2001.126.2: Summary and Results of TESAEs by Subgroups - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	7 (4.0)	NC [NC, NC]	177	17 (9.6)	28.4 [NC, NC]	0.390 [0.162, 0.941]	0.0298	0.9860
>65 years	78	2 (2.6)	NC [NC, NC]	72	5 (6.9)	NC [NC, NC]	0.390 [0.076, 2.010]	0.2430	
Sex									
Male	160	8 (5.0)	NC [NC, NC]	152	17 (11.2)	28.4 [NC, NC]	0.454 [0.194, 1.062]	0.0618	0.4908
Female	94	1 (1.1)	NC [NC, NC]	97	5 (5.2)	NC [NC, NC]	0.211 [0.025, 1.804]	0.1166	
Region									
Asia	157	4 (2.5)	NC [NC, NC]	156	5 (3.2)	NC [NC, NC]	0.747 [0.200, 2.796]	0.6642	0.2985
Non-Asia	97	5 (5.2)	NC [NC, NC]	93	17 (18.3)	28.4 [NC, NC]	0.310 [0.114, 0.846]	0.0156	
Number of Organs with Metastatic Sites									
0-2	190	2 (1.1)	NC [NC, NC]	186	14 (7.5)	28.4 [NC, NC]	0.154 [0.035, 0.683]	0.0046	0.0723
>=3	64	7 (10.9)	NC [NC, NC]	63	8 (12.7)	NC [NC, NC]	0.797 [0.289, 2.201]	0.6612	

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: 07OCT22

Table 302.1.2001.127.1: Summary and Results of TESAEs - Pulmonary Embolism (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	2 (0.8%)	8 (3.2%)	
Number of patients censored	252 (99.2%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	28.4 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.290 [0.060, 1.395]
Log-rank test			
Two-sided stratified log-rank p-value			0.0995

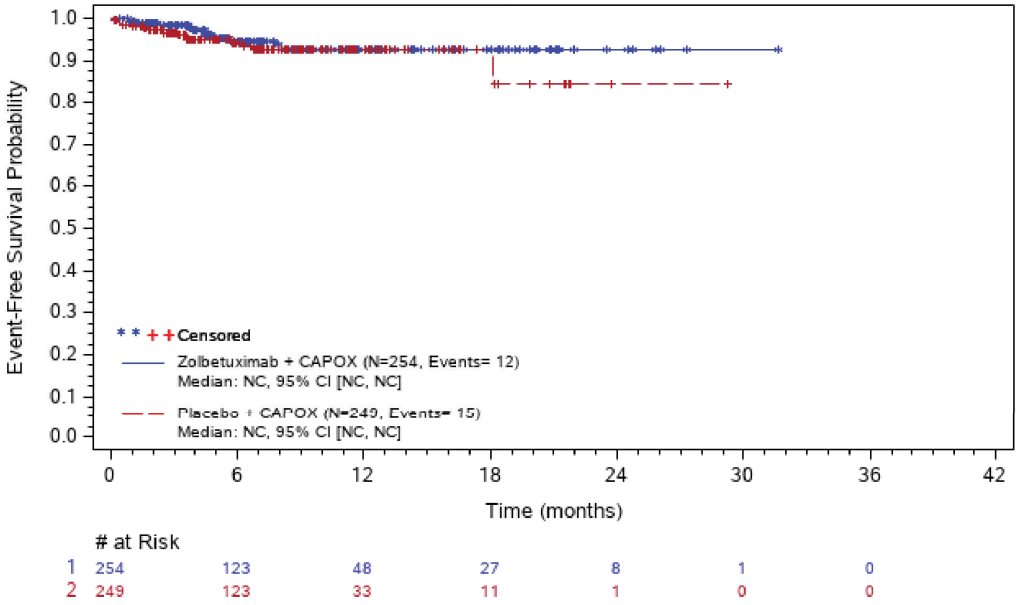
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 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 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwerwiegende unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

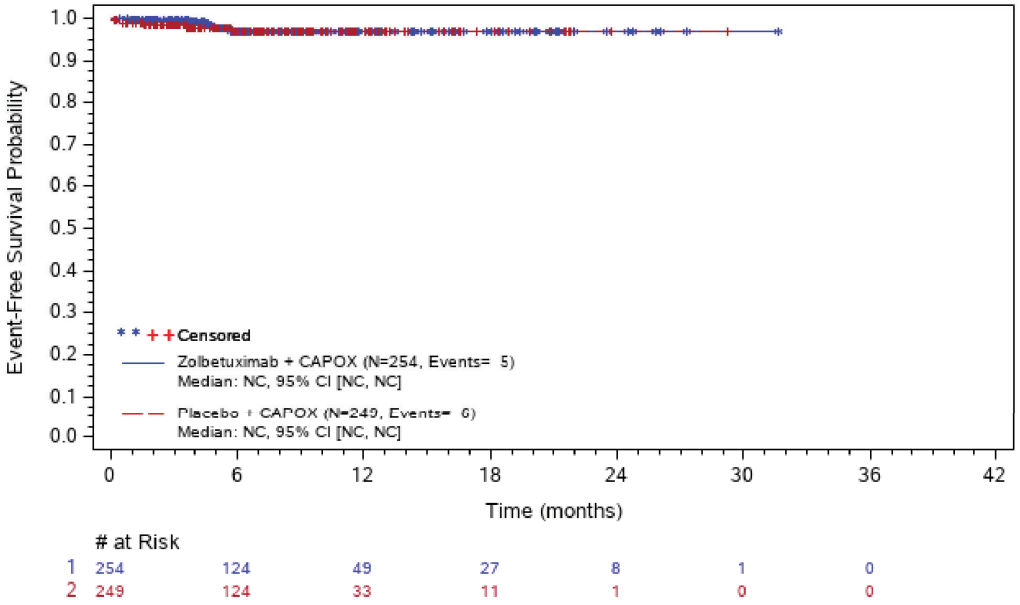
Figure 302.1.2001.105: Kaplan-Meier Plot of Time to first TESAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

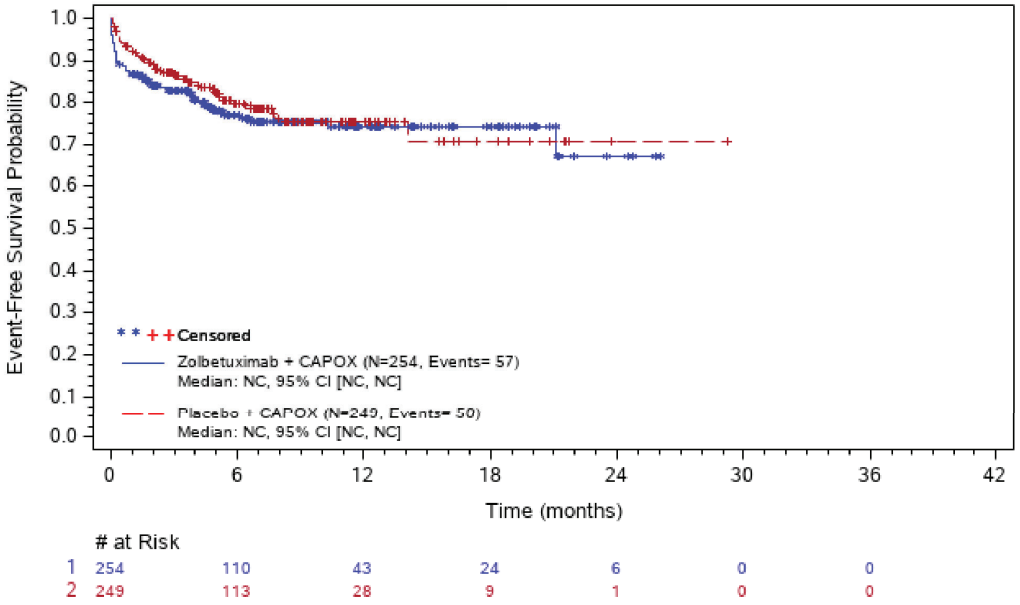
Figure 302.1.2001.106: Kaplan-Meier Plot of Time to first TESAE - Anaemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.107: Kaplan-Meier Plot of Time to first TESAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set

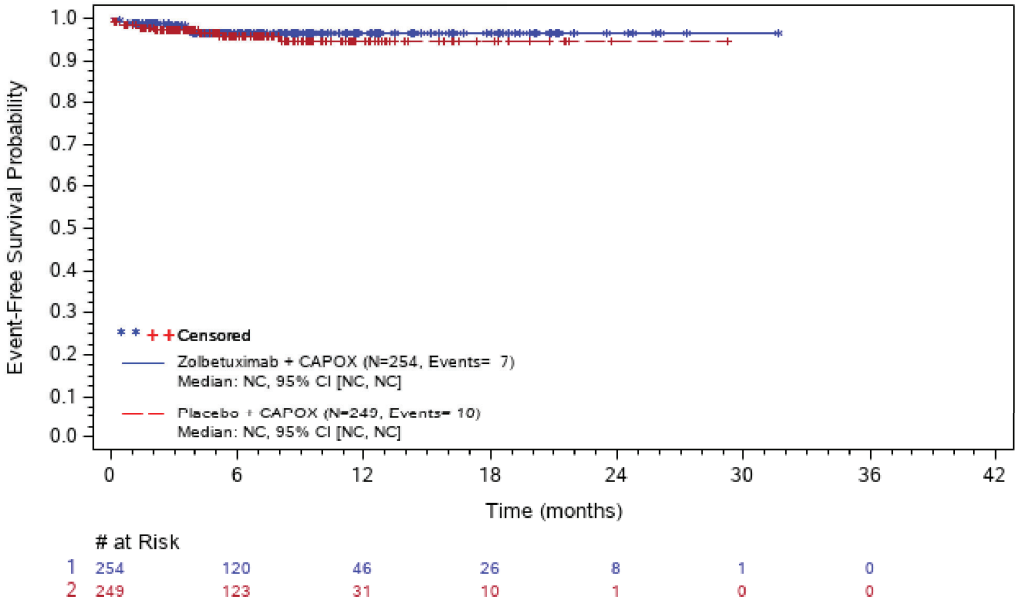


# at Risk							
1	254	110	43	24	6	0	0
2	249	113	28	9	1	0	0

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: 07OCT22

The SAS System

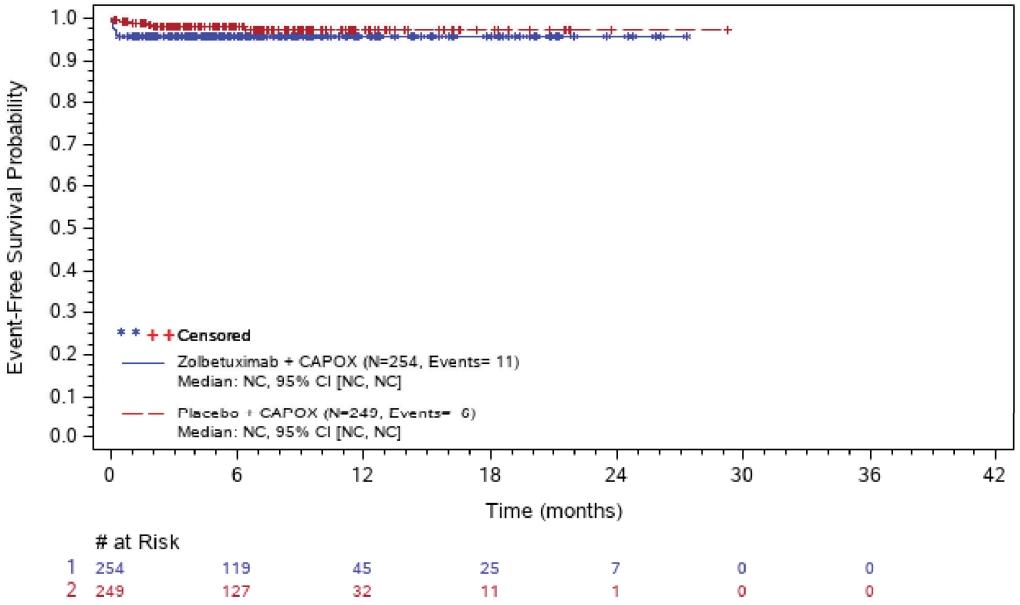
Figure 302.1.2001.108: Kaplan-Meier Plot of Time to first TESAE - Diarrhoea (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

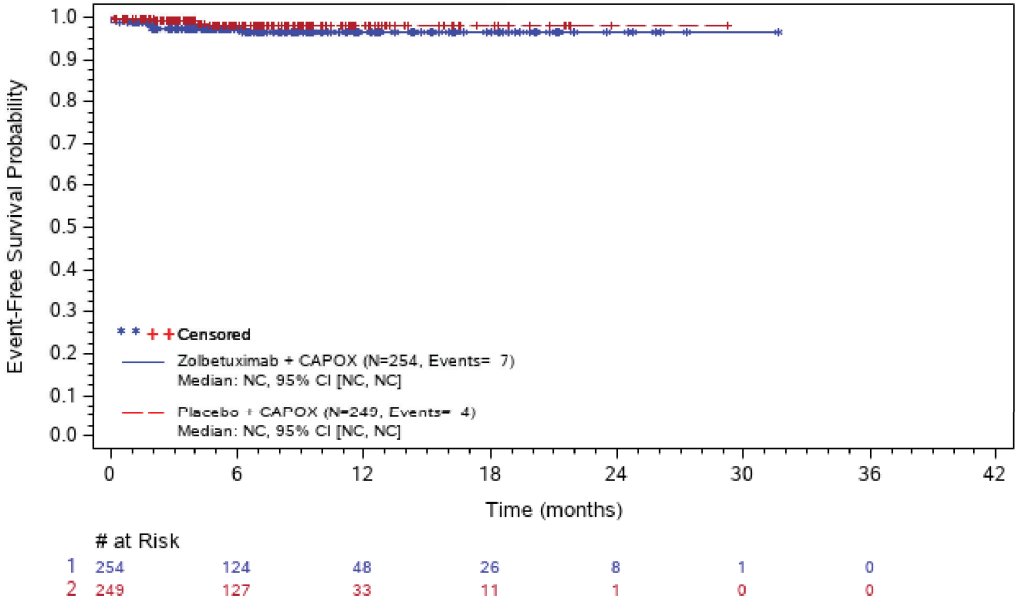
Figure 302.1.2001.109: Kaplan-Meier Plot of Time to first TESAE - Nausea (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

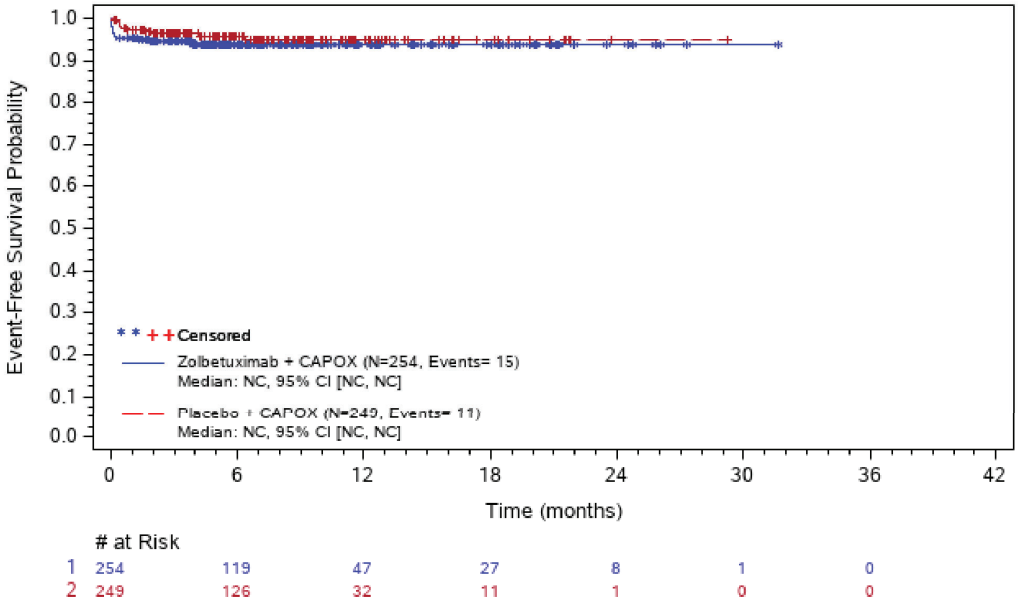
Figure 302.1.2001.110: Kaplan-Meier Plot of Time to first TESAE - Upper Gastrointestinal Haemorrhage (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 07OCT22

The SAS System

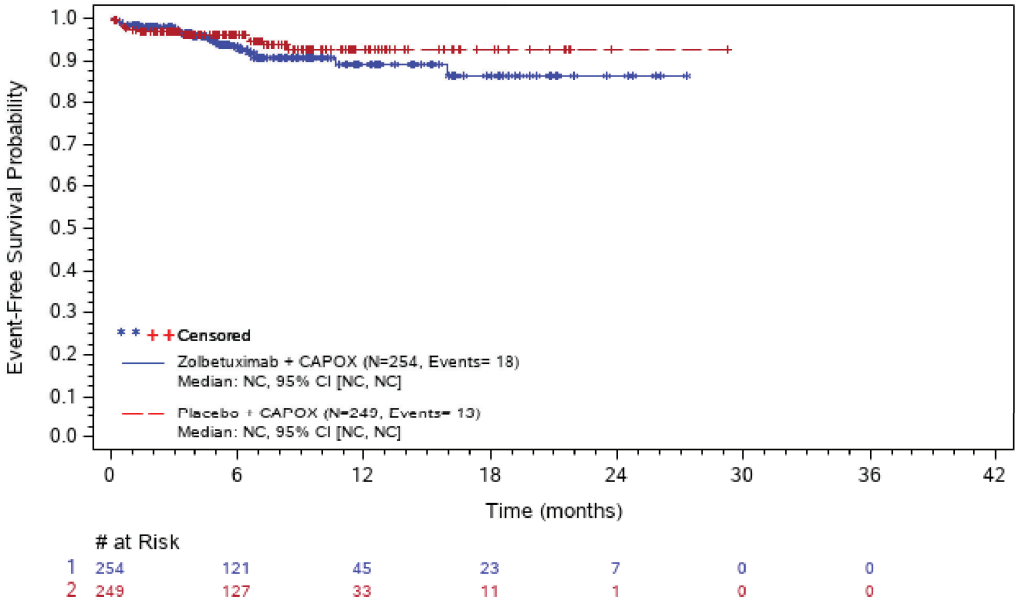
Figure 302.1.2001.111: Kaplan-Meier Plot of Time to first TESAE - Vomiting (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

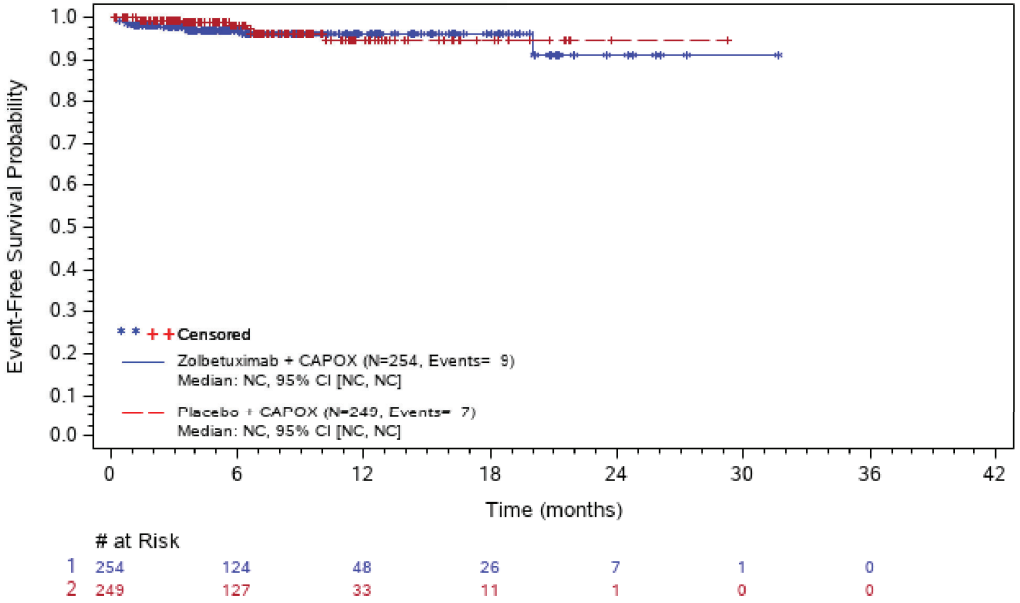
Figure 302.1.2001.112: Kaplan-Meier Plot of Time to first TESAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.113: Kaplan-Meier Plot of Time to first TESAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set

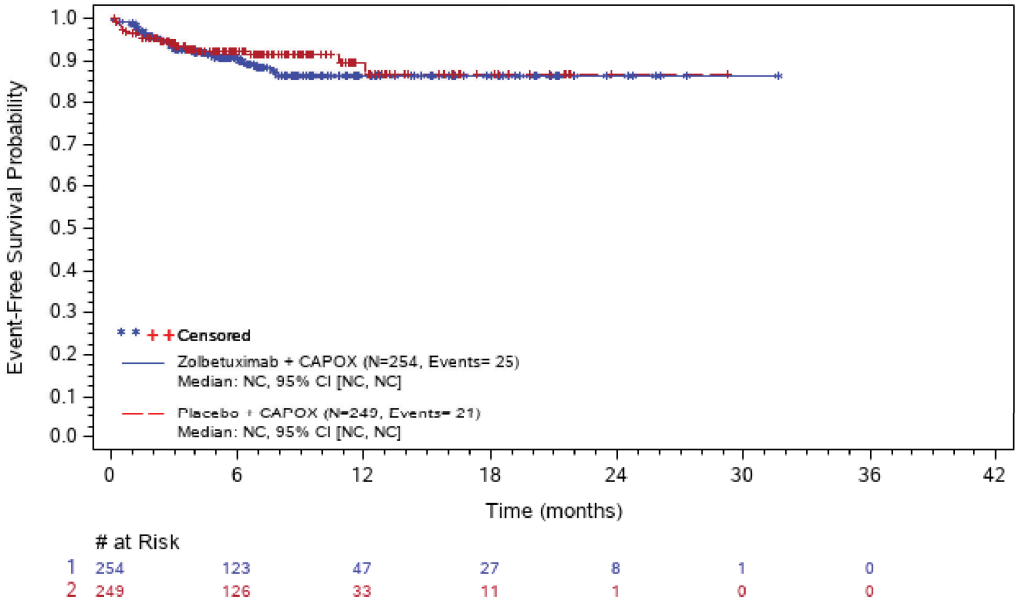


	# at Risk						
1	254	124	48	26	7	1	0
2	249	127	33	11	1	0	0

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: 07OCT22

The SAS System

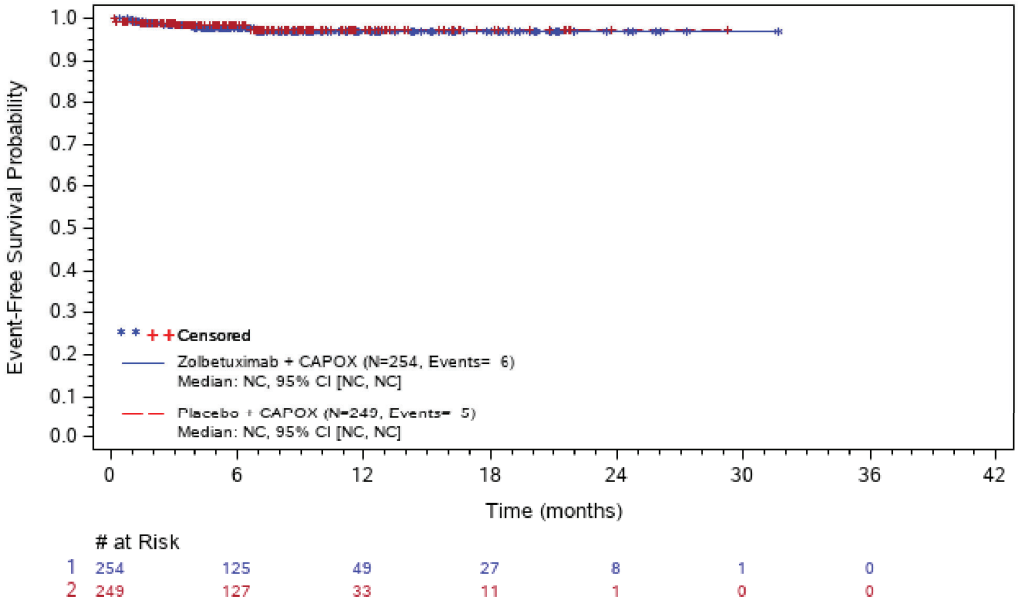
Figure 302.1.2001.114: Kaplan-Meier Plot of Time to first TESAE - Infections And Infestations (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

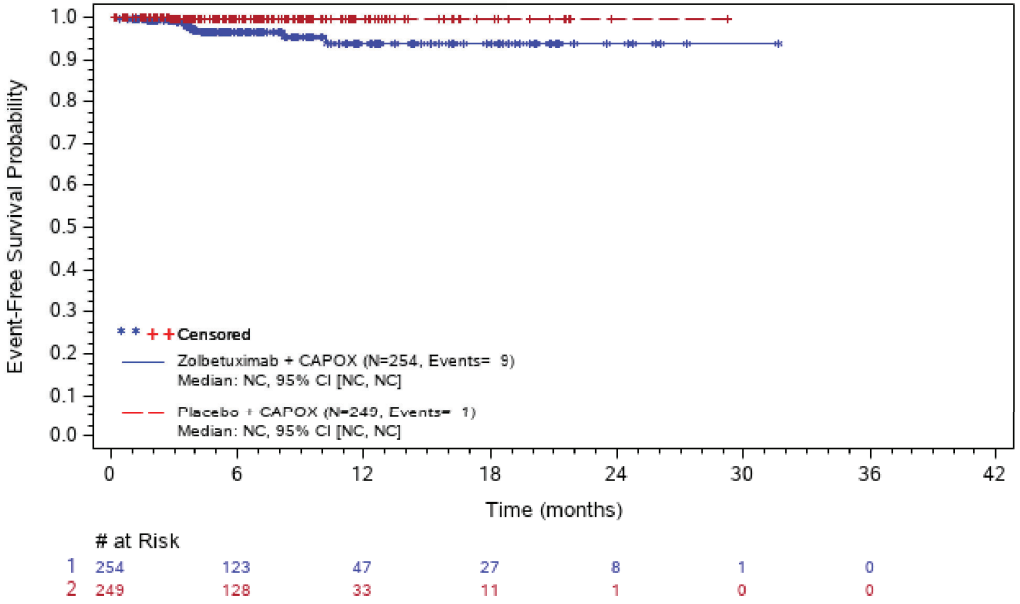
Figure 302.1.2001.115: Kaplan-Meier Plot of Time to first TESAE - Pneumonia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

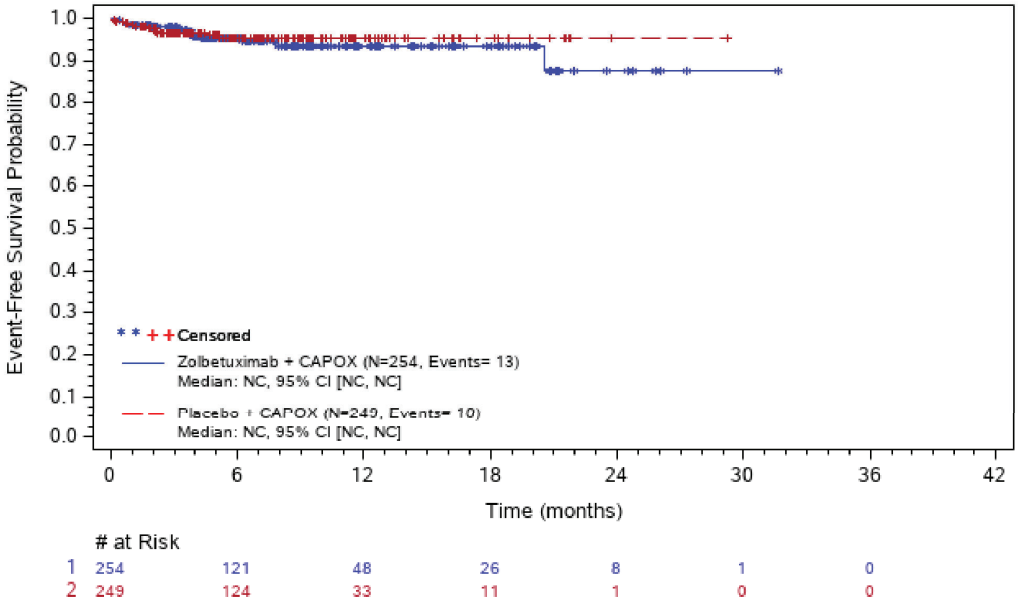
Figure 302.1.2001.116: Kaplan-Meier Plot of Time to first TESAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

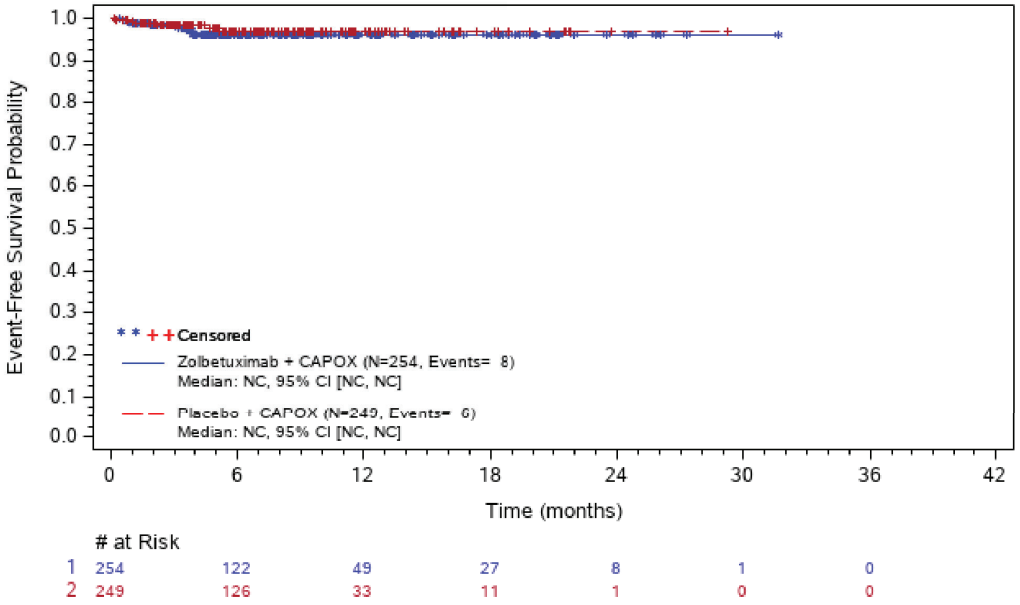
Figure 302.1.2001.117: Kaplan-Meier Plot of Time to first TESAE - Investigations (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

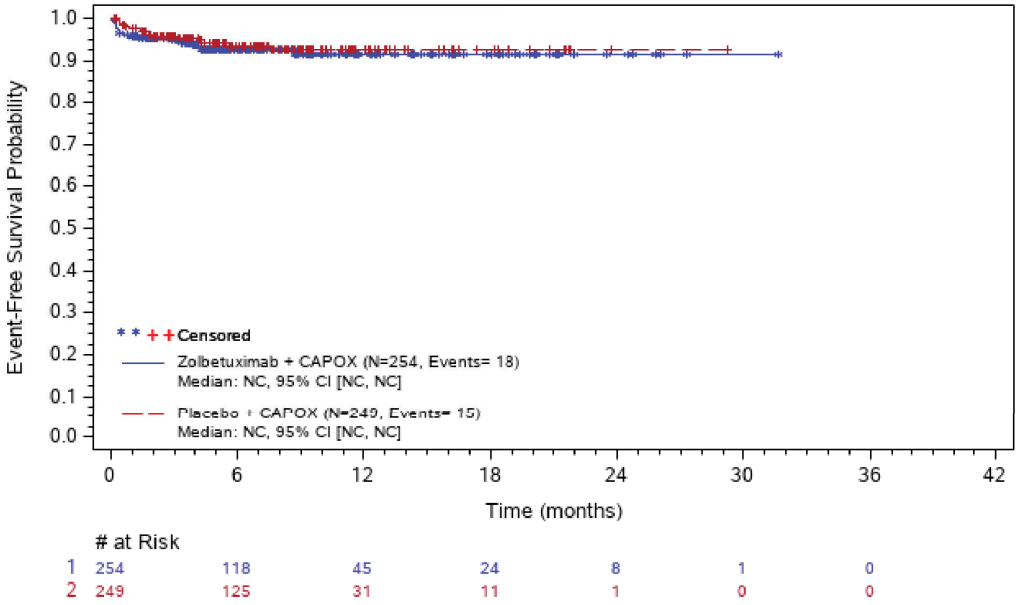
Figure 302.1.2001.118: Kaplan-Meier Plot of Time to first TESAE - Platelet Count Decreased (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

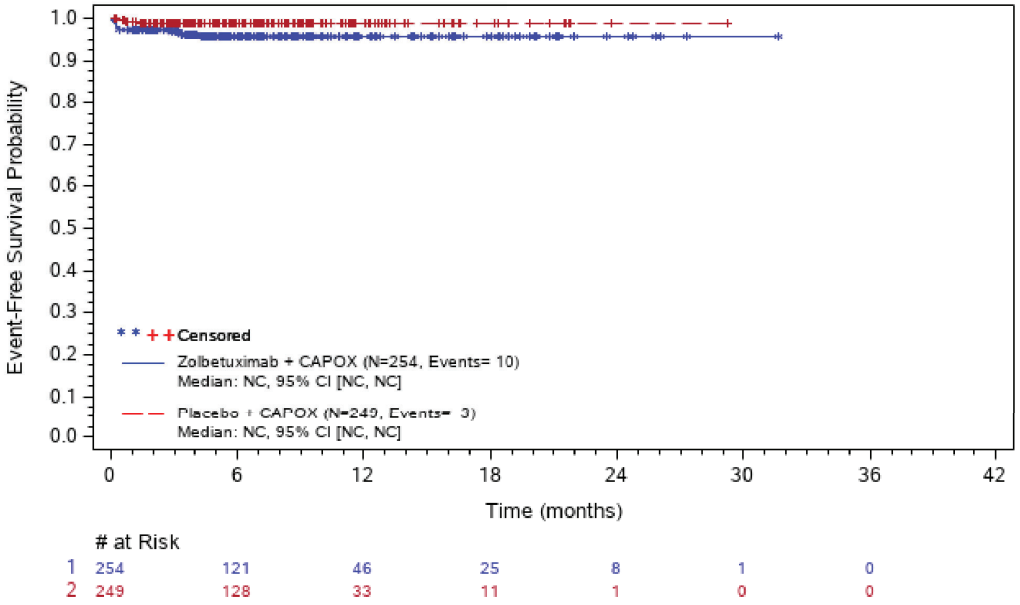
Figure 302.1.2001.119: Kaplan-Meier Plot of Time to first TESAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

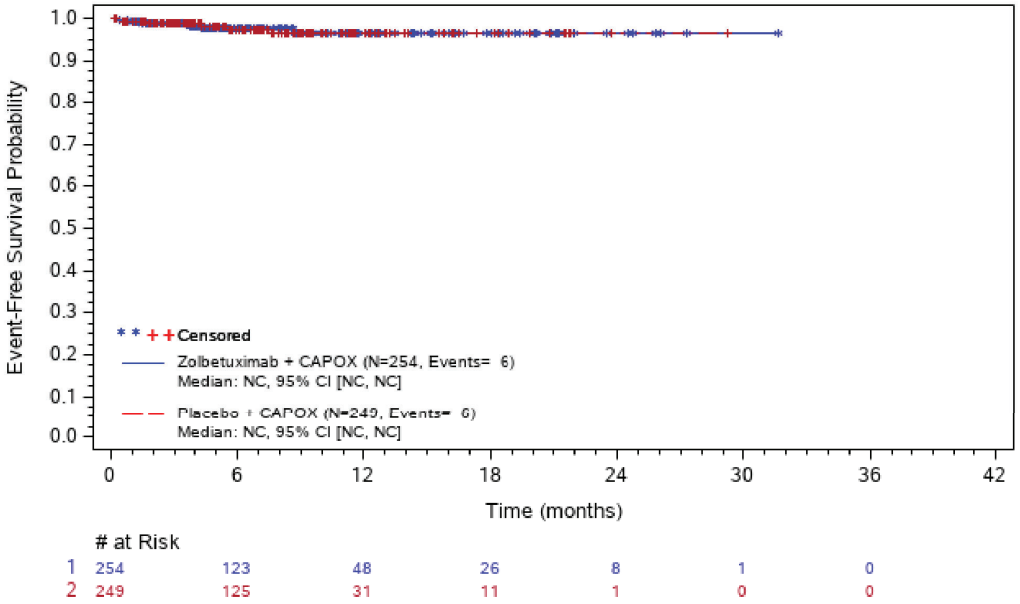
Figure 302.1.2001.120: Kaplan-Meier Plot of Time to first TESAE - Decreased Appetite (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

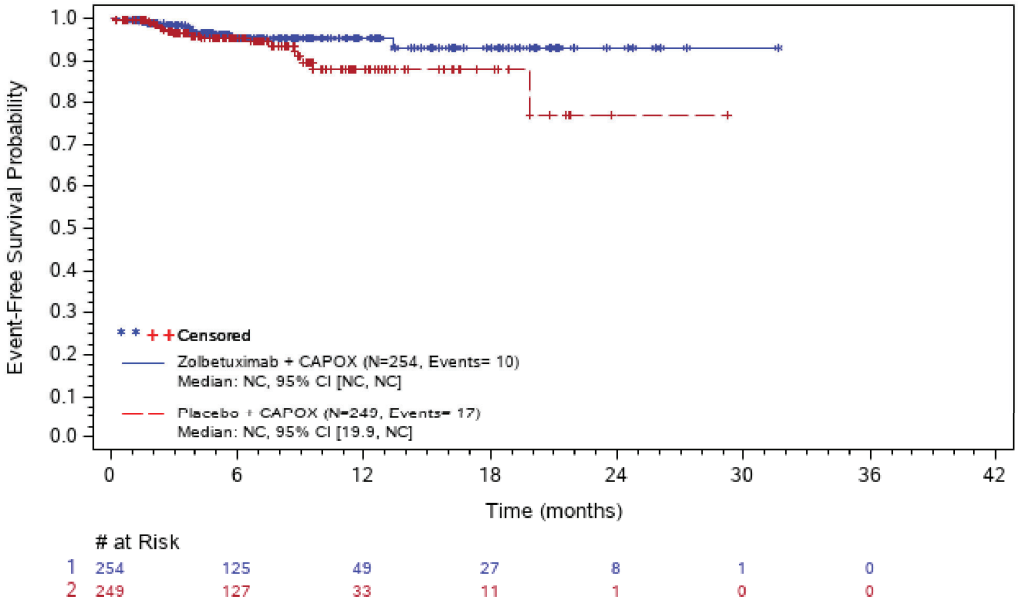
Figure 302.1.2001.121: Kaplan-Meier Plot of Time to first TESAE - Hypokalaemia (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

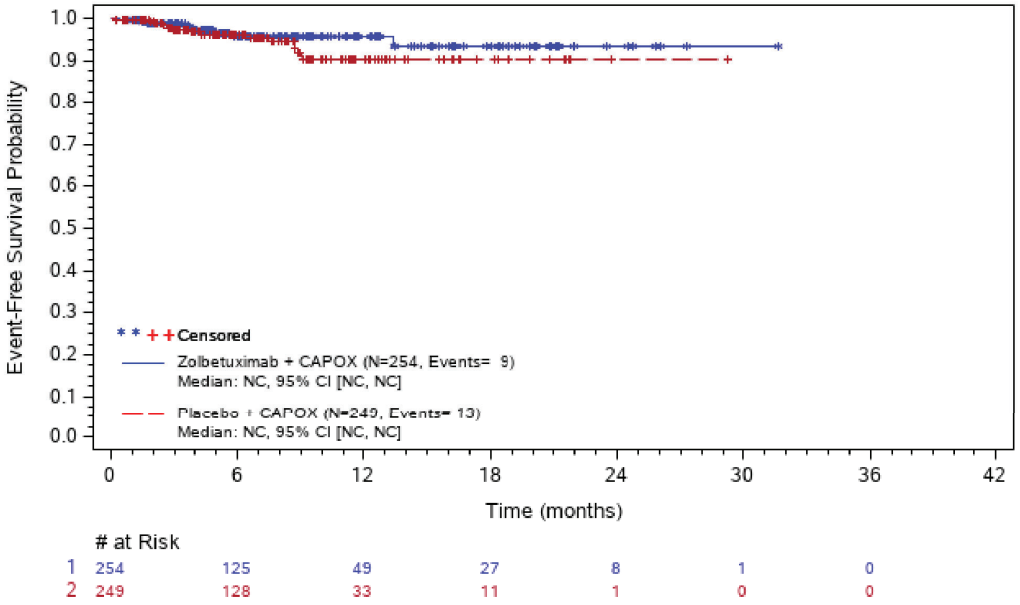
Figure 302.1.2001.122: Kaplan-Meier Plot of Time to first TESAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

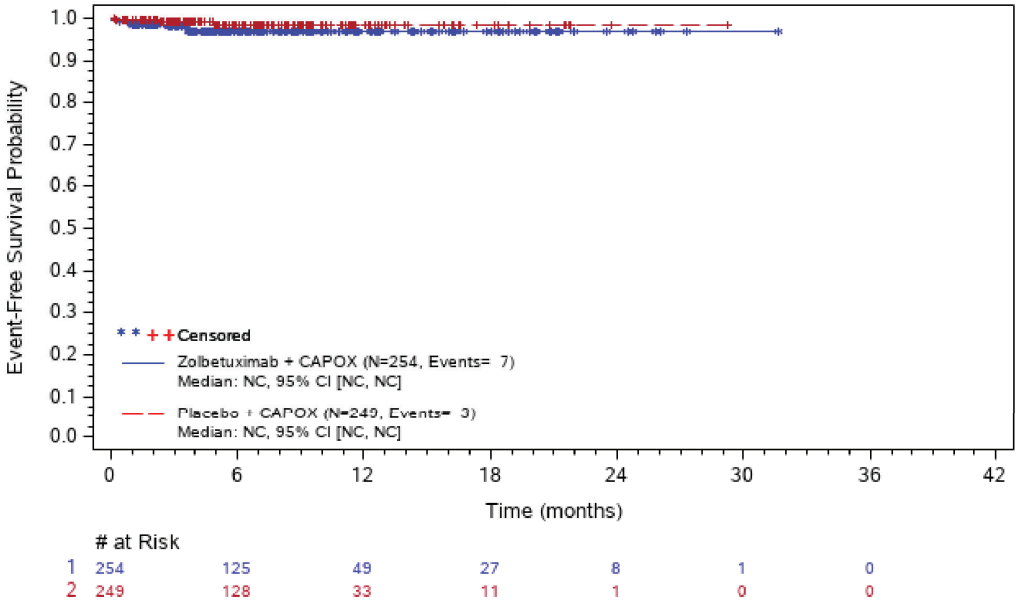
Figure 302.1.2001.123: Kaplan-Meier Plot of Time to first TESAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



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: 07OCT22

The SAS System

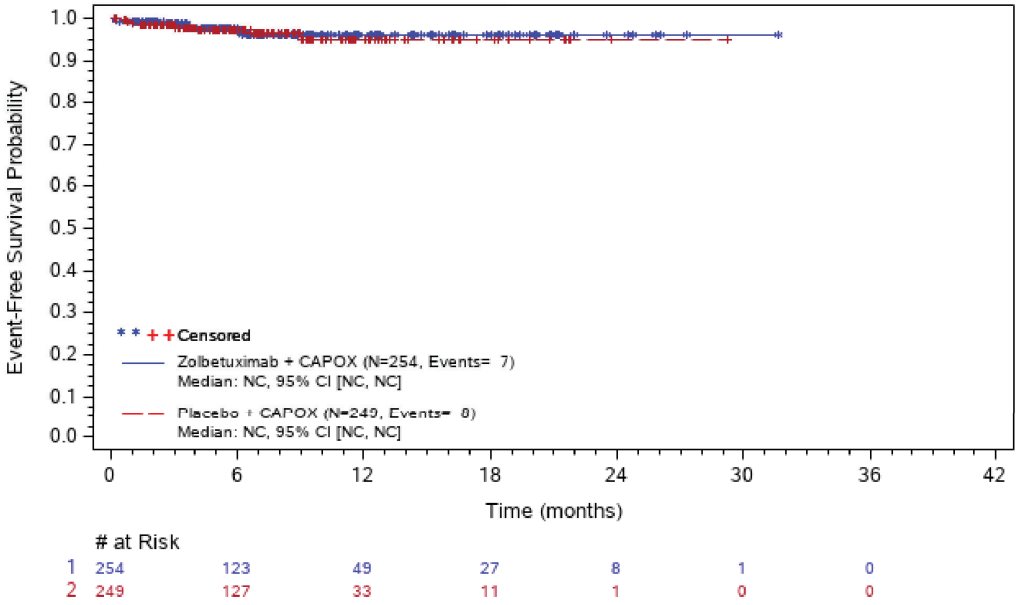
Figure 302.1.2001.124: Kaplan-Meier Plot of Time to first TESAE - Nervous System Disorders (SOC) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.125: Kaplan-Meier Plot of Time to first TESAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set

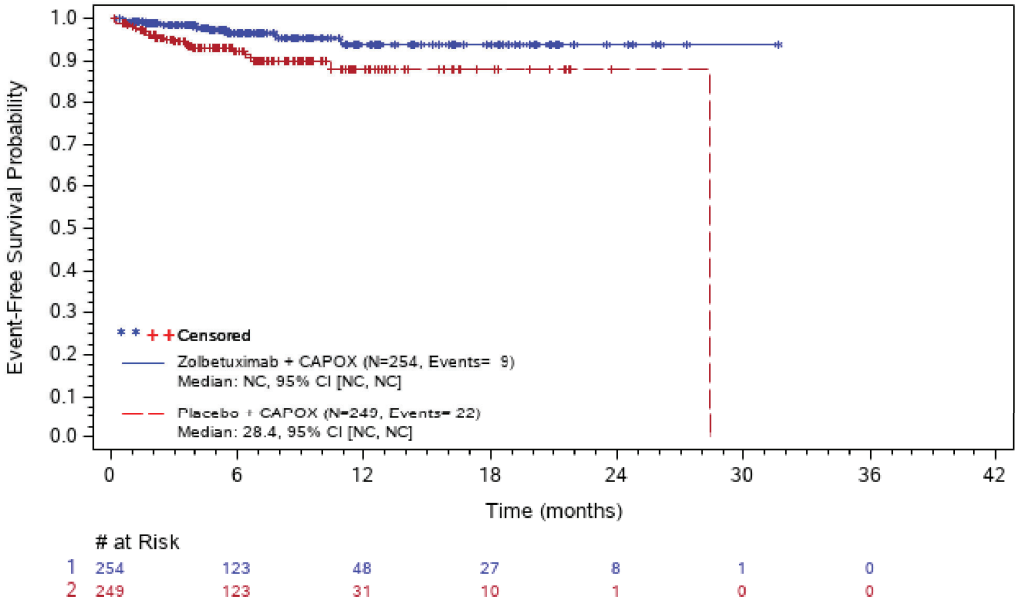


# at Risk							
1	254	123	49	27	8	1	0
2	249	127	33	11	1	0	0

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: 07OCT22

The SAS System

Figure 302.1.2001.126: Kaplan-Meier Plot of Time to first TESAE - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

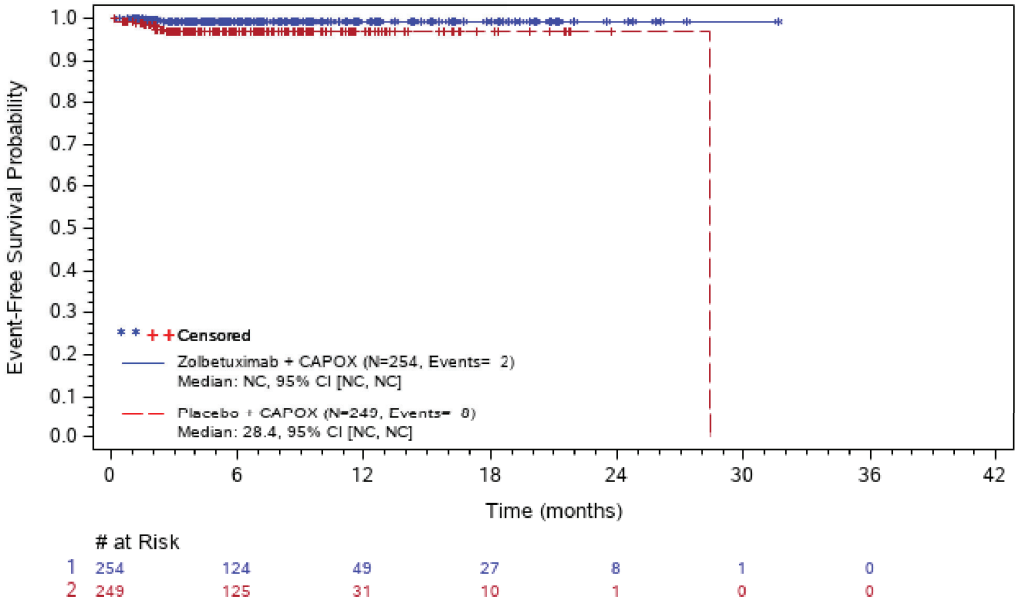


# at Risk							
1	254	123	48	27	8	1	0
2	249	123	31	10	1	0	0

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: 07OCT22

The SAS System

Figure 302.1.2001.127: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Abbruchgründe – SOC und PT

Table 302.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Overall	79 (31.1%)	63 (25.3%)	142 (28.2%)
Gastrointestinal Disorders	27 (10.6%)	12 (4.8%)	39 (7.8%)
Vomiting	9 (3.5%)	4 (1.6%)	13 (2.6%)
Nausea	6 (2.4%)	3 (1.2%)	9 (1.8%)
Diarrhoea	5 (2.0%)	2 (0.8%)	7 (1.4%)
Upper Gastrointestinal Haemorrhage	3 (1.2%)	1 (0.4%)	4 (0.8%)
Abdominal Pain	3 (1.2%)	0	3 (0.6%)
Abdominal Pain Upper	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dysphagia	2 (0.8%)	0	2 (0.4%)
Obstruction Gastric	2 (0.8%)	0	2 (0.4%)
Enterocolitis	0	1 (0.4%)	1 (0.2%)
Gastric Haemorrhage	0	1 (0.4%)	1 (0.2%)
Gastric Stenosis	1 (0.4%)	0	1 (0.2%)
Haematemesis	0	1 (0.4%)	1 (0.2%)
Haemorrhagic Ascites	1 (0.4%)	0	1 (0.2%)
Ileus	1 (0.4%)	0	1 (0.2%)
Intestinal Obstruction	1 (0.4%)	0	1 (0.2%)
Intra-Abdominal Haemorrhage	0	1 (0.4%)	1 (0.2%)
Swollen Tongue	1 (0.4%)	0	1 (0.2%)
Nervous System Disorders	14 (5.5%)	10 (4.0%)	24 (4.8%)
Peripheral Sensory Neuropathy	5 (2.0%)	5 (2.0%)	10 (2.0%)
Neuropathy Peripheral	1 (0.4%)	2 (0.8%)	3 (0.6%)
Dizziness	1 (0.4%)	1 (0.4%)	2 (0.4%)
Paraesthesia	2 (0.8%)	0	2 (0.4%)
Cerebral Haemorrhage	1 (0.4%)	0	1 (0.2%)
Cerebrovascular Accident	1 (0.4%)	0	1 (0.2%)
Dysaesthesia	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: 07OCT22

Table 302.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Dysarthria	0	1 (0.4%)	1 (0.2%)
Epilepsy	0	1 (0.4%)	1 (0.2%)
Hypoaesthesia	1 (0.4%)	0	1 (0.2%)
Intracranial Pressure Increased	1 (0.4%)	0	1 (0.2%)
Neurotoxicity	0	1 (0.4%)	1 (0.2%)
Investigations	14 (5.5%)	8 (3.2%)	22 (4.4%)
Platelet Count Decreased	5 (2.0%)	3 (1.2%)	8 (1.6%)
Neutrophil Count Decreased	3 (1.2%)	2 (0.8%)	5 (1.0%)
Alanine Aminotransferase Increased	3 (1.2%)	1 (0.4%)	4 (0.8%)
Aspartate Aminotransferase Increased	2 (0.8%)	2 (0.8%)	4 (0.8%)
Blood Bilirubin Increased	4 (1.6%)	0	4 (0.8%)
Blood Pressure Decreased	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%)
Weight Decreased	1 (0.4%)	0	1 (0.2%)
White Blood Cell Count Decreased	0	1 (0.4%)	1 (0.2%)
Blood And Lymphatic System Disorders	7 (2.8%)	9 (3.6%)	16 (3.2%)
Neutropenia	4 (1.6%)	5 (2.0%)	9 (1.8%)
Anaemia	0	3 (1.2%)	3 (0.6%)
Thrombocytopenia	2 (0.8%)	0	2 (0.4%)
Coagulopathy	0	1 (0.4%)	1 (0.2%)
Disseminated Intravascular Coagulation	1 (0.4%)	0	1 (0.2%)
Leukopenia	0	1 (0.4%)	1 (0.2%)
General Disorders And Administration Site Conditions	9 (3.5%)	6 (2.4%)	15 (3.0%)
Asthenia	1 (0.4%)	2 (0.8%)	3 (0.6%)
Chest Discomfort	2 (0.8%)	1 (0.4%)	3 (0.6%)
Death	2 (0.8%)	1 (0.4%)	3 (0.6%)

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: 07OCT22

Table 302.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Malaise	2 (0.8%)	0	2 (0.4%)
Fatigue	1 (0.4%)	0	1 (0.2%)
Mucosal Inflammation	0	1 (0.4%)	1 (0.2%)
Performance Status Decreased	0	1 (0.4%)	1 (0.2%)
Sudden Death	1 (0.4%)	0	1 (0.2%)
Infections And Infestations	6 (2.4%)	7 (2.8%)	13 (2.6%)
Pneumonia	3 (1.2%)	2 (0.8%)	5 (1.0%)
Septic Shock	1 (0.4%)	2 (0.8%)	3 (0.6%)
Abdominal Infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Escherichia Infection	0	1 (0.4%)	1 (0.2%)
Infection	0	1 (0.4%)	1 (0.2%)
Lower Respiratory Tract Infection	1 (0.4%)	0	1 (0.2%)
Mucosal Infection	0	1 (0.4%)	1 (0.2%)
Metabolism And Nutrition Disorders	5 (2.0%)	6 (2.4%)	11 (2.2%)
Decreased Appetite	2 (0.8%)	3 (1.2%)	5 (1.0%)
Acidosis	0	1 (0.4%)	1 (0.2%)
Dehydration	1 (0.4%)	0	1 (0.2%)
Electrolyte Imbalance	0	1 (0.4%)	1 (0.2%)
Hypoalbuminaemia	0	1 (0.4%)	1 (0.2%)
Hypokalaemia	1 (0.4%)	0	1 (0.2%)
Hypophosphataemia	1 (0.4%)	0	1 (0.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	3 (1.2%)	7 (2.8%)	10 (2.0%)
Malignant Neoplasm Progression	3 (1.2%)	4 (1.6%)	7 (1.4%)
Metastases To Meninges	0	1 (0.4%)	1 (0.2%)
Metastases To Peritoneum	0	1 (0.4%)	1 (0.2%)
Tumour Haemorrhage	0	1 (0.4%)	1 (0.2%)
Respiratory, Thoracic And Mediastinal Disorders	1 (0.4%)	9 (3.6%)	10 (2.0%)

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: 07OCT22

Table 302.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Dyspnoea	1 (0.4%)	3 (1.2%)	4 (0.8%)
Pleural Effusion	0	4 (1.6%)	4 (0.8%)
Acute Respiratory Distress Syndrome	0	1 (0.4%)	1 (0.2%)
Epistaxis	0	1 (0.4%)	1 (0.2%)
Pulmonary Oedema	0	1 (0.4%)	1 (0.2%)
Respiratory Failure	0	1 (0.4%)	1 (0.2%)
Skin And Subcutaneous Tissue Disorders	5 (2.0%)	2 (0.8%)	7 (1.4%)
Palmar-Plantar Erythrodysaesthesia Syndrome	2 (0.8%)	1 (0.4%)	3 (0.6%)
Cold Sweat	0	1 (0.4%)	1 (0.2%)
Pruritus	1 (0.4%)	0	1 (0.2%)
Rash Erythematous	1 (0.4%)	0	1 (0.2%)
Skin Necrosis	1 (0.4%)	0	1 (0.2%)
Hepatobiliary Disorders	3 (1.2%)	3 (1.2%)	6 (1.2%)
Deficiency Of Bile Secretion	1 (0.4%)	0	1 (0.2%)
Hepatic Failure	1 (0.4%)	0	1 (0.2%)
Hepatic Function Abnormal	1 (0.4%)	0	1 (0.2%)
Hepatitis Acute	0	1 (0.4%)	1 (0.2%)
Hepatotoxicity	0	1 (0.4%)	1 (0.2%)
Hyperbilirubinaemia	0	1 (0.4%)	1 (0.2%)
Jaundice	1 (0.4%)	0	1 (0.2%)
Renal And Urinary Disorders	2 (0.8%)	3 (1.2%)	5 (1.0%)
Acute Kidney Injury	1 (0.4%)	2 (0.8%)	3 (0.6%)
Choluria	1 (0.4%)	0	1 (0.2%)
Chronic Kidney Disease	0	1 (0.4%)	1 (0.2%)
Cardiac Disorders	2 (0.8%)	2 (0.8%)	4 (0.8%)
Cardio-Respiratory Arrest	1 (0.4%)	1 (0.4%)	2 (0.4%)
Atrial Fibrillation	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: 07OCT22

Table 302.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Cardiac Arrest	0	1 (0.4%)	1 (0.2%)
Immune System Disorders	3 (1.2%)	1 (0.4%)	4 (0.8%)
Anaphylactic Reaction	3 (1.2%)	1 (0.4%)	4 (0.8%)
Injury, Poisoning And Procedural Complications	3 (1.2%)	0	3 (0.6%)
Fall	1 (0.4%)	0	1 (0.2%)
Head Injury	1 (0.4%)	0	1 (0.2%)
Infusion Related Reaction	1 (0.4%)	0	1 (0.2%)
Procedural Complication	1 (0.4%)	0	1 (0.2%)
Vascular Disorders	2 (0.8%)	0	2 (0.4%)
Embolism Venous	1 (0.4%)	0	1 (0.2%)
Flushing	1 (0.4%)	0	1 (0.2%)
Hypotension	1 (0.4%)	0	1 (0.2%)
Congenital, Familial And Genetic Disorders	1 (0.4%)	0	1 (0.2%)
Gene Mutation	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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022

Anhang 4-G1 Sicherheit

Anhang 4-G1 Unerwünschte Ereignisse von besonderem Interesse

1. Time-to-Event-Analysen

Table 302.1.2001.162.1: Summary and Results of TEAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	59 (23.2%)	63 (25.3%)	
Number of patients censored	195 (76.8%)	186 (74.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [14.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.931 [0.652, 1.329]
Log-rank test			
Two-sided stratified log-rank p-value			0.6883

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.162.2: Summary and Results of TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	39 (22.2)	NC [NC, NC]	177	48 (27.1)	NC [14.1, NC]	0.790 [0.517, 1.207]	0.2730	0.1782
>65 years	78	20 (25.6)	NC [NC, NC]	72	15 (20.8)	NC [NC, NC]	1.382 [0.707, 2.701]	0.3438	
Sex									
Male	160	37 (23.1)	NC [NC, NC]	152	36 (23.7)	NC [14.1, NC]	0.995 [0.628, 1.576]	0.9807	0.7262
Female	94	22 (23.4)	NC [14.7, NC]	97	27 (27.8)	NC [14.9, NC]	0.859 [0.489, 1.509]	0.5922	
Region									
Asia	157	37 (23.6)	NC [NC, NC]	156	37 (23.7)	NC [14.1, NC]	1.008 [0.638, 1.592]	0.9761	0.6152
Non-Asia	97	22 (22.7)	NC [14.7, NC]	93	26 (28.0)	NC [NC, NC]	0.831 [0.471, 1.466]	0.5181	
Number of Organs with Metastatic Sites									
0-2	190	43 (22.6)	NC [NC, NC]	186	49 (26.3)	NC [14.1, NC]	0.883 [0.586, 1.330]	0.5464	0.6064
>=3	64	16 (25.0)	NC [7.5, NC]	63	14 (22.2)	NC [8.5, NC]	1.120 [0.546, 2.294]	0.7591	

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; 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: 07OCT22

Table 302.1.2001.163.1: Summary and Results of TEAEs - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	90 (35.4%)	92 (36.9%)	
Number of patients censored	164 (64.6%)	157 (63.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [8.2, NC]	18.1 [8.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.945 [0.706, 1.265]
Log-rank test			
Two-sided stratified log-rank p-value			0.6988

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.163.2: Summary and Results of TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	65 (36.9)	13.4 [6.7, NC]	177	63 (35.6)	18.1 [8.4, NC]	1.026 [0.725, 1.451]	0.8873	0.5300
>65 years	78	25 (32.1)	NC [4.9, NC]	72	29 (40.3)	NC [3.7, NC]	0.834 [0.488, 1.424]	0.5004	
Sex									
Male	160	48 (30.0)	NC [NC, NC]	152	56 (36.8)	18.1 [6.4, NC]	0.775 [0.527, 1.141]	0.1939	0.0613
Female	94	42 (44.7)	5.1 [3.9, 13.4]	97	36 (37.1)	NC [5.5, NC]	1.378 [0.882, 2.153]	0.1571	
Region									
Asia	157	60 (38.2)	13.4 [5.6, NC]	156	67 (42.9)	8.4 [4.2, NC]	0.841 [0.594, 1.193]	0.3301	0.1714
Non-Asia	97	30 (30.9)	NC [9.4, NC]	93	25 (26.9)	NC [18.1, NC]	1.322 [0.777, 2.250]	0.3034	
Number of Organs with Metastatic Sites									
0-2	190	64 (33.7)	NC [9.4, NC]	186	63 (33.9)	NC [12.9, NC]	1.009 [0.713, 1.430]	0.9580	0.6557
>=3	64	26 (40.6)	7.7 [3.6, NC]	63	29 (46.0)	6.0 [3.2, NC]	0.867 [0.511, 1.473]	0.5947	

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; 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: 07OCT22

Table 302.1.2001.164.1: Summary and Results of TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	36 (14.2%)	27 (10.8%)	
Number of patients censored	218 (85.8%)	222 (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			1.349 [0.818, 2.225]
Log-rank test			
Two-sided stratified log-rank p-value			0.2422

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.164.2: Summary and Results of TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	26 (14.8)	NC [NC, NC]	177	18 (10.2)	NC [NC, NC]	1.434 [0.785, 2.620]	0.2395	0.5876
>65 years	78	10 (12.8)	NC [NC, NC]	72	9 (12.5)	NC [NC, NC]	1.053 [0.428, 2.592]	0.9136	
Sex									
Male	160	21 (13.1)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	1.629 [0.800, 3.317]	0.1733	0.3886
Female	94	15 (16.0)	NC [NC, NC]	97	15 (15.5)	NC [NC, NC]	1.070 [0.523, 2.189]	0.8688	
Region									
Asia	157	21 (13.4)	NC [NC, NC]	156	14 (9.0)	NC [NC, NC]	1.429 [0.725, 2.817]	0.3009	0.6580
Non-Asia	97	15 (15.5)	NC [NC, NC]	93	13 (14.0)	NC [NC, NC]	1.168 [0.555, 2.455]	0.6870	
Number of Organs with Metastatic Sites									
0-2	190	26 (13.7)	NC [NC, NC]	186	20 (10.8)	NC [NC, NC]	1.268 [0.707, 2.273]	0.4257	0.8156
>=3	64	10 (15.6)	NC [NC, NC]	63	7 (11.1)	NC [NC, NC]	1.446 [0.550, 3.801]	0.4552	

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; 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: 07OCT22

Table 302.1.2001.165.1: Summary and Results of TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	91 (35.8%)	25 (10.0%)	
Number of patients censored	163 (64.2%)	224 (90.0%)	
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			4.543 [2.909, 7.094]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.165.2: Summary and Results of TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	65 (36.9)	NC [NC, NC]	177	21 (11.9)	NC [NC, NC]	3.783 [2.312, 6.190]	<.0001	0.2583
>65 years	78	26 (33.3)	NC [NC, NC]	72	4 (5.6)	NC [NC, NC]	7.217 [2.515, 20.709]	<.0001	
Sex									
Male	160	55 (34.4)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	5.242 [2.806, 9.793]	<.0001	0.3717
Female	94	36 (38.3)	NC [10.7, NC]	97	13 (13.4)	NC [NC, NC]	3.543 [1.877, 6.687]	<.0001	
Region									
Asia	157	44 (28.0)	NC [NC, NC]	156	12 (7.7)	NC [NC, NC]	4.082 [2.155, 7.731]	<.0001	0.8243
Non-Asia	97	47 (48.5)	6.3 [0.7, NC]	93	13 (14.0)	NC [NC, NC]	4.879 [2.633, 9.039]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	71 (37.4)	NC [NC, NC]	186	20 (10.8)	NC [NC, NC]	4.280 [2.604, 7.034]	<.0001	0.8701
>=3	64	20 (31.3)	NC [NC, NC]	63	5 (7.9)	NC [NC, NC]	4.649 [1.743, 12.397]	0.0008	

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; 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: 07OCT22

Table 302.1.2001.166.1: Summary and Results of TEAEs - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	174 (68.5%)	125 (50.2%)	
Number of patients censored	80 (31.5%)	124 (49.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.1, 0.4]	5.5 [2.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.954 [1.547, 2.467]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.166.2: Summary and Results of TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	124 (70.5)	0.1 [0.0, 0.1]	177	95 (53.7)	2.9 [0.9, NC]	1.899 [1.452, 2.484]	<.0001	0.6827
>65 years	78	50 (64.1)	0.5 [0.1, 3.8]	72	30 (41.7)	12.8 [2.9, NC]	2.029 [1.286, 3.202]	0.0022	
Sex									
Male	160	108 (67.5)	0.1 [0.0, 0.7]	152	72 (47.4)	7.6 [2.3, NC]	1.958 [1.451, 2.642]	<.0001	0.7241
Female	94	66 (70.2)	0.1 [0.0, 0.7]	97	53 (54.6)	2.9 [0.8, NC]	1.848 [1.285, 2.658]	0.0019	
Region									
Asia	157	113 (72.0)	0.1 [0.0, 0.4]	156	77 (49.4)	6.3 [0.8, NC]	2.031 [1.518, 2.717]	<.0001	0.5131
Non-Asia	97	61 (62.9)	0.1 [0.1, 0.9]	93	48 (51.6)	5.5 [2.0, NC]	1.724 [1.179, 2.522]	0.0091	
Number of Organs with Metastatic Sites									
0-2	190	133 (70.0)	0.1 [0.0, 0.1]	186	101 (54.3)	2.9 [1.0, 8.3]	1.816 [1.400, 2.355]	<.0001	0.3822
>=3	64	41 (64.1)	0.7 [0.0, 2.9]	63	24 (38.1)	12.8 [2.9, 12.8]	2.244 [1.353, 3.722]	0.0019	

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; 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: 07OCT22

Table 302.1.2001.167.1: Summary and Results of TEAEs - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	118 (46.5%)	95 (38.2%)	
Number of patients censored	136 (53.5%)	154 (61.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.1 [3.8, 5.9]	9.8 [5.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.307 [0.995, 1.717]
Log-rank test			
Two-sided stratified log-rank p-value			0.0546

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.167.2: Summary and Results of TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	82 (46.6)	5.3 [3.8, 7.9]	177	62 (35.0)	NC [6.7, NC]	1.413 [1.016, 1.966]	0.0387	0.5445
>65 years	78	36 (46.2)	4.1 [2.3, NC]	72	33 (45.8)	5.7 [3.1, 8.3]	1.206 [0.750, 1.937]	0.4490	
Sex									
Male	160	69 (43.1)	5.3 [3.8, NC]	152	52 (34.2)	NC [6.1, NC]	1.344 [0.937, 1.927]	0.1063	0.9798
Female	94	49 (52.1)	4.1 [3.1, 5.4]	97	43 (44.3)	8.3 [4.4, NC]	1.370 [0.908, 2.067]	0.1325	
Region									
Asia	157	79 (50.3)	4.2 [3.4, 5.9]	156	63 (40.4)	9.8 [4.4, NC]	1.300 [0.933, 1.811]	0.1185	0.8619
Non-Asia	97	39 (40.2)	5.7 [4.1, NC]	93	32 (34.4)	NC [5.8, NC]	1.398 [0.875, 2.233]	0.1610	
Number of Organs with Metastatic Sites									
0-2	190	91 (47.9)	5.1 [3.6, 5.8]	186	75 (40.3)	NC [4.7, NC]	1.298 [0.956, 1.763]	0.0940	0.6695
>=3	64	27 (42.2)	4.2 [3.5, NC]	63	20 (31.7)	9.8 [5.7, NC]	1.458 [0.812, 2.615]	0.2031	

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; 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: 07OCT22

Table 302.1.2001.168.1: Summary and Results of TEAEs - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	169 (66.5%)	77 (30.9%)	
Number of patients censored	85 (33.5%)	172 (69.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.0, 0.7]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.435 [2.615, 4.512]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.168.2: Summary and Results of TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	122 (69.3)	0.0 [0.0, 0.2]	177	58 (32.8)	NC [NC, NC]	3.545 [2.587, 4.858]	<.0001	0.8934
>65 years	78	47 (60.3)	0.9 [0.2, 6.8]	72	19 (26.4)	NC [NC, NC]	3.174 [1.858, 5.423]	<.0001	
Sex									
Male	160	101 (63.1)	0.3 [0.1, 1.4]	152	41 (27.0)	NC [NC, NC]	3.512 [2.439, 5.058]	<.0001	0.7368
Female	94	68 (72.3)	0.0 [0.0, 0.2]	97	36 (37.1)	NC [7.2, NC]	3.395 [2.257, 5.107]	<.0001	
Region									
Asia	157	109 (69.4)	0.0 [0.0, 0.2]	156	45 (28.8)	NC [NC, NC]	3.911 [2.757, 5.549]	<.0001	0.2079
Non-Asia	97	60 (61.9)	0.7 [0.1, 1.9]	93	32 (34.4)	NC [NC, NC]	2.720 [1.766, 4.189]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	125 (65.8)	0.1 [0.0, 0.9]	186	58 (31.2)	NC [NC, NC]	3.247 [2.374, 4.441]	<.0001	0.6268
>=3	64	44 (68.8)	0.1 [0.0, 0.7]	63	19 (30.2)	NC [NC, NC]	3.870 [2.246, 6.668]	<.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; 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: 07OCT22

Table 302.1.2001.169.1: Summary and Results of Non-Severe TEAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	59 (23.2%)	61 (24.5%)	
Number of patients censored	195 (76.8%)	188 (75.5%)	
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 [0.676, 1.386]
Log-rank test			
Two-sided stratified log-rank p-value			0.8554

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.169.2: Summary and Results of Non-Severe TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	39 (22.2)	NC [NC, NC]	177	46 (26.0)	NC [14.9, NC]	0.836 [0.545, 1.283]	0.4092	0.2258
>65 years	78	20 (25.6)	NC [NC, NC]	72	15 (20.8)	NC [NC, NC]	1.382 [0.707, 2.701]	0.3438	
Sex									
Male	160	37 (23.1)	NC [NC, NC]	152	34 (22.4)	NC [NC, NC]	1.065 [0.668, 1.698]	0.7923	0.6336
Female	94	22 (23.4)	NC [14.7, NC]	97	27 (27.8)	NC [14.9, NC]	0.869 [0.494, 1.526]	0.6200	
Region									
Asia	157	37 (23.6)	NC [NC, NC]	156	35 (22.4)	NC [14.9, NC]	1.083 [0.682, 1.722]	0.7360	0.4993
Non-Asia	97	22 (22.7)	NC [14.7, NC]	93	26 (28.0)	NC [NC, NC]	0.831 [0.471, 1.466]	0.5181	
Number of Organs with Metastatic Sites									
0-2	190	43 (22.6)	NC [NC, NC]	186	48 (25.8)	NC [14.9, NC]	0.910 [0.603, 1.374]	0.6503	0.5281
>=3	64	16 (25.0)	NC [7.5, NC]	63	13 (20.6)	NC [NC, NC]	1.207 [0.580, 2.510]	0.6159	

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; 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: 07OCT22

Table 302.1.2001.170.1: Summary and Results of Non-Severe TEAEs - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	81 (31.9%)	87 (34.9%)	
Number of patients censored	173 (68.1%)	162 (65.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [11.5, NC]	18.1 [12.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.900 [0.664, 1.219]
Log-rank test			
Two-sided stratified log-rank p-value			0.4923

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.170.2: Summary and Results of Non-Severe TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	58 (33.0)	NC [11.5, NC]	177	59 (33.3)	18.1 [12.9, NC]	0.968 [0.673, 1.391]	0.8584	0.5525
>65 years	78	23 (29.5)	NC [9.4, NC]	72	28 (38.9)	NC [3.9, NC]	0.792 [0.456, 1.376]	0.4040	
Sex									
Male	160	44 (27.5)	NC [NC, NC]	152	54 (35.5)	18.1 [6.4, NC]	0.731 [0.491, 1.090]	0.1217	0.0735
Female	94	37 (39.4)	10.4 [4.4, NC]	97	33 (34.0)	NC [8.4, NC]	1.290 [0.806, 2.064]	0.2857	
Region									
Asia	157	54 (34.4)	NC [7.7, NC]	156	64 (41.0)	12.9 [4.5, NC]	0.786 [0.546, 1.129]	0.1905	0.1483
Non-Asia	97	27 (27.8)	NC [9.4, NC]	93	23 (24.7)	NC [18.1, NC]	1.286 [0.737, 2.245]	0.3769	
Number of Organs with Metastatic Sites									
0-2	190	59 (31.1)	NC [11.5, NC]	186	60 (32.3)	NC [12.9, NC]	0.974 [0.679, 1.395]	0.8844	0.5092
>=3	64	22 (34.4)	NC [4.2, NC]	63	27 (42.9)	6.0 [3.6, NC]	0.780 [0.444, 1.371]	0.3851	

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; 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: 07OCT22

Table 302.1.2001.171.1: Summary and Results of Non-Severe TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	32 (12.6%)	25 (10.0%)	
Number of patients censored	222 (87.4%)	224 (90.0%)	
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			1.292 [0.764, 2.184]
Log-rank test			
Two-sided stratified log-rank p-value			0.3400

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.171.2: Summary and Results of Non-Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	23 (13.1)	NC [NC, NC]	177	17 (9.6)	NC [NC, NC]	1.328 [0.708, 2.491]	0.3767	0.7279
>65 years	78	9 (11.5)	NC [NC, NC]	72	8 (11.1)	NC [NC, NC]	1.075 [0.415, 2.790]	0.8829	
Sex									
Male	160	18 (11.3)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	1.378 [0.662, 2.866]	0.3879	0.7106
Female	94	14 (14.9)	NC [NC, NC]	97	13 (13.4)	NC [NC, NC]	1.162 [0.546, 2.473]	0.7083	
Region									
Asia	157	20 (12.7)	NC [NC, NC]	156	12 (7.7)	NC [NC, NC]	1.577 [0.769, 3.237]	0.2107	0.3017
Non-Asia	97	12 (12.4)	NC [NC, NC]	93	13 (14.0)	NC [NC, NC]	0.929 [0.424, 2.037]	0.8503	
Number of Organs with Metastatic Sites									
0-2	190	22 (11.6)	NC [NC, NC]	186	18 (9.7)	NC [NC, NC]	1.184 [0.634, 2.210]	0.5967	0.7377
>=3	64	10 (15.6)	NC [NC, NC]	63	7 (11.1)	NC [NC, NC]	1.448 [0.551, 3.806]	0.4524	

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; 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: 07OCT22

Table 302.1.2001.172.1: Summary and Results of Non-Severe TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	84 (33.1%)	24 (9.6%)	
Number of patients censored	170 (66.9%)	225 (90.4%)	
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			4.271 [2.706, 6.741]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.172.2: Summary and Results of Non-Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	62 (35.2)	NC [NC, NC]	177	21 (11.9)	NC [NC, NC]	3.564 [2.172, 5.850]	<.0001	0.2089
>65 years	78	22 (28.2)	NC [NC, NC]	72	3 (4.2)	NC [NC, NC]	7.972 [2.383, 26.675]	<.0001	
Sex									
Male	160	53 (33.1)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	4.996 [2.669, 9.354]	<.0001	0.3437
Female	94	31 (33.0)	NC [10.7, NC]	97	12 (12.4)	NC [NC, NC]	3.222 [1.653, 6.279]	0.0004	
Region									
Asia	157	41 (26.1)	NC [NC, NC]	156	11 (7.1)	NC [NC, NC]	4.113 [2.113, 8.005]	<.0001	0.9686
Non-Asia	97	43 (44.3)	NC [0.7, NC]	93	13 (14.0)	NC [NC, NC]	4.323 [2.320, 8.058]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	64 (33.7)	NC [NC, NC]	186	19 (10.2)	NC [NC, NC]	3.976 [2.381, 6.639]	<.0001	0.7864
>=3	64	20 (31.3)	NC [NC, NC]	63	5 (7.9)	NC [NC, NC]	4.637 [1.739, 12.364]	0.0008	

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; 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: 07OCT22

Table 302.1.2001.173.1: Summary and Results of Non-Severe TEAEs - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	167 (65.7%)	123 (49.4%)	
Number of patients censored	87 (34.3%)	126 (50.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.1, 0.7]	6.3 [2.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.853 [1.463, 2.348]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.173.2: Summary and Results of Non-Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	118 (67.0)	0.1 [0.0, 0.7]	177	93 (52.5)	3.1 [1.1, NC]	1.791 [1.363, 2.354]	0.0001	0.6674
>65 years	78	49 (62.8)	0.7 [0.1, 3.8]	72	30 (41.7)	12.8 [2.9, NC]	1.939 [1.227, 3.065]	0.0042	
Sex									
Male	160	103 (64.4)	0.1 [0.1, 0.9]	152	71 (46.7)	8.3 [2.3, NC]	1.845 [1.362, 2.499]	0.0002	0.7899
Female	94	64 (68.1)	0.1 [0.0, 0.8]	97	52 (53.6)	2.9 [0.8, NC]	1.770 [1.226, 2.557]	0.0042	
Region									
Asia	157	108 (68.8)	0.1 [0.0, 0.7]	156	77 (49.4)	6.3 [0.9, NC]	1.871 [1.395, 2.509]	<.0001	0.7232
Non-Asia	97	59 (60.8)	0.2 [0.1, 1.4]	93	46 (49.5)	7.4 [2.3, NC]	1.717 [1.165, 2.530]	0.0108	
Number of Organs with Metastatic Sites									
0-2	190	127 (66.8)	0.1 [0.1, 0.7]	186	99 (53.2)	3.7 [1.2, NC]	1.720 [1.321, 2.239]	0.0002	0.3892
>=3	64	40 (62.5)	0.7 [0.0, 4.4]	63	24 (38.1)	12.8 [2.9, 12.8]	2.131 [1.282, 3.543]	0.0040	

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; 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: 07OCT22

Table 302.1.2001.174.1: Summary and Results of Non-Severe TEAEs - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	110 (43.3%)	82 (32.9%)	
Number of patients censored	144 (56.7%)	167 (67.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.3 [4.2, NC]	14.7 [9.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.398 [1.049, 1.864]
Log-rank test			
Two-sided stratified log-rank p-value			0.0221

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.174.2: Summary and Results of Non-Severe TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	75 (42.6)	5.8 [4.6, NC]	177	55 (31.1)	NC [NC, NC]	1.425 [1.006, 2.018]	0.0443	0.9023
>65 years	78	35 (44.9)	4.1 [2.8, NC]	72	27 (37.5)	7.9 [5.3, NC]	1.475 [0.891, 2.444]	0.1298	
Sex									
Male	160	65 (40.6)	5.9 [4.2, NC]	152	46 (30.3)	NC [NC, NC]	1.423 [0.975, 2.076]	0.0652	0.8715
Female	94	45 (47.9)	5.1 [3.5, 7.9]	97	36 (37.1)	14.7 [5.3, NC]	1.471 [0.948, 2.284]	0.0837	
Region									
Asia	157	74 (47.1)	4.8 [3.7, 7.9]	156	55 (35.3)	14.7 [7.9, NC]	1.387 [0.978, 1.967]	0.0643	0.8536
Non-Asia	97	36 (37.1)	6.0 [4.1, NC]	93	27 (29.0)	NC [NC, NC]	1.502 [0.911, 2.475]	0.1082	
Number of Organs with Metastatic Sites									
0-2	190	87 (45.8)	5.2 [4.1, 7.9]	186	63 (33.9)	NC [7.9, NC]	1.474 [1.066, 2.040]	0.0183	0.6954
>=3	64	23 (35.9)	NC [3.8, NC]	63	19 (30.2)	NC [5.7, NC]	1.286 [0.700, 2.363]	0.4141	

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; 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: 07OCT22

Table 302.1.2001.175.1: Summary and Results of Non-Severe TEAEs - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	161 (63.4%)	73 (29.3%)	
Number of patients censored	93 (36.6%)	176 (70.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.5 [0.1, 1.1]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.294 [2.491, 4.355]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. 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: 07OCT22

Table 302.1.2001.175.2: Summary and Results of Non-Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	117 (66.5)	0.1 [0.0, 0.8]	177	56 (31.6)	NC [NC, NC]	3.344 [2.427, 4.607]	<.0001	0.9756
>65 years	78	44 (56.4)	1.1 [0.3, NC]	72	17 (23.6)	NC [NC, NC]	3.157 [1.800, 5.540]	<.0001	
Sex									
Male	160	97 (60.6)	0.9 [0.2, 2.4]	152	38 (25.0)	NC [NC, NC]	3.506 [2.405, 5.110]	<.0001	0.5459
Female	94	64 (68.1)	0.1 [0.0, 0.8]	97	35 (36.1)	NC [7.2, NC]	3.063 [2.022, 4.641]	<.0001	
Region									
Asia	157	105 (66.9)	0.1 [0.0, 0.9]	156	43 (27.6)	NC [NC, NC]	3.761 [2.632, 5.374]	<.0001	0.1987
Non-Asia	97	56 (57.7)	1.1 [0.2, NC]	93	30 (32.3)	NC [NC, NC]	2.582 [1.653, 4.033]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	118 (62.1)	0.7 [0.1, 1.6]	186	54 (29.0)	NC [NC, NC]	3.131 [2.266, 4.327]	<.0001	0.6985
>=3	64	43 (67.2)	0.2 [0.0, 1.2]	63	19 (30.2)	NC [NC, NC]	3.643 [2.111, 6.286]	<.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; 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: 07OCT22

Table 302.1.2001.176.1: Summary and Results of Severe TEAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	1 (0.4%)	5 (2.0%)	
Number of patients censored	253 (99.6%)	244 (98.0%)	
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			0.166 [0.019, 1.449]
Log-rank test			
Two-sided stratified log-rank p-value			0.0662

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.176.2: Summary and Results of Severe TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	1 (0.6)		177	5 (2.8)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	1 (0.6)		152	4 (2.6)				
Female	94	0 (0.0)		97	1 (1.0)				
Region									
Asia	157	0 (0.0)		156	4 (2.6)				
Non-Asia	97	1 (1.0)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	1 (0.5)		186	3 (1.6)				
>=3	64	0 (0.0)		63	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; 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: 07OCT22

Table 302.1.2001.177.1: Summary and Results of Severe TEAEs - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	27 (10.6%)	28 (11.2%)	
Number of patients censored	227 (89.4%)	221 (88.8%)	
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			0.856 [0.500, 1.463]
Log-rank test			
Two-sided stratified log-rank p-value			0.5701

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.177.2: Summary and Results of Severe TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	21 (11.9)	NC [NC, NC]	177	18 (10.2)	NC [NC, NC]	1.120 [0.597, 2.103]	0.7220	0.2971
>65 years	78	6 (7.7)	NC [NC, NC]	72	10 (13.9)	NC [NC, NC]	0.599 [0.218, 1.650]	0.3162	
Sex									
Male	160	15 (9.4)	NC [NC, NC]	152	19 (12.5)	NC [NC, NC]	0.707 [0.359, 1.391]	0.3117	0.1873
Female	94	12 (12.8)	NC [NC, NC]	97	9 (9.3)	NC [NC, NC]	1.497 [0.630, 3.555]	0.3579	
Region									
Asia	157	20 (12.7)	NC [NC, NC]	156	20 (12.8)	NC [NC, NC]	0.931 [0.501, 1.733]	0.8231	0.9566
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	8 (8.6)	NC [NC, NC]	0.911 [0.330, 2.513]	0.8569	
Number of Organs with Metastatic Sites									
0-2	190	16 (8.4)	NC [NC, NC]	186	16 (8.6)	NC [NC, NC]	1.000 [0.500, 2.000]	0.9987	0.7622
>=3	64	11 (17.2)	NC [10.4, NC]	63	12 (19.0)	NC [NC, NC]	0.833 [0.367, 1.891]	0.6646	

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; 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: 07OCT22

Table 302.1.2001.178.1: Summary and Results of Severe TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	4 (1.6%)	
Number of patients censored	248 (97.6%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.486 [0.419, 5.269]
Log-rank test			
Two-sided stratified log-rank p-value			0.5373

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.178.2: Summary and Results of Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	5 (2.8)		177	2 (1.1)				
>65 years	78	1 (1.3)		72	2 (2.8)				
Sex									
Male	160	4 (2.5)		152	1 (0.7)				
Female	94	2 (2.1)		97	3 (3.1)				
Region									
Asia	157	2 (1.3)		156	3 (1.9)				
Non-Asia	97	4 (4.1)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	4 (2.2)				
>=3	64	1 (1.6)		63	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; 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: 07OCT22

Table 302.1.2001.179.1: Summary and Results of Severe TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	17 (6.7%)	1 (0.4%)	
Number of patients censored	237 (93.3%)	248 (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			16.899 [2.248, 127.02]
Log-rank test			
Two-sided stratified log-rank p-value			0.0002

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.179.2: Summary and Results of Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	10 (5.7)	NC [NC, NC]	177	0 (0.0)	NC [NC, NC]	3.06E7 [0.000, NC]	0.0013	0.9922
>65 years	78	7 (9.0)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	6.680 [0.821, 54.323]	0.0398	
Sex									
Male	160	9 (5.6)		152	0 (0.0)				
Female	94	8 (8.5)		97	1 (1.0)				
Region									
Asia	157	8 (5.1)		156	1 (0.6)				
Non-Asia	97	9 (9.3)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	13 (6.8)	NC [NC, NC]	186	1 (0.5)	NC [NC, NC]	13.164 [1.722, 100.62]	0.0012	0.9927
>=3	64	4 (6.3)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	3.04E7 [0.000, NC]	0.0426	

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; 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: 07OCT22

Table 302.1.2001.180.1: Summary and Results of Severe TEAEs - Nausea (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.180.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	15 (8.5)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	3.117 [1.133, 8.577]	0.0204	0.5092
>65 years	78	7 (9.0)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	6.790 [0.835, 55.195]	0.0378	
Sex									
Male	160	14 (8.8)	NC [NC, NC]	152	3 (2.0)	NC [NC, NC]	4.600 [1.322, 16.007]	0.0084	0.6162
Female	94	8 (8.5)	NC [NC, NC]	97	3 (3.1)	NC [NC, NC]	2.870 [0.761, 10.821]	0.1037	
Region									
Asia	157	15 (9.6)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	5.221 [1.512, 18.035]	0.0035	0.3816
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	3 (3.2)	NC [NC, NC]	2.298 [0.594, 8.888]	0.2142	
Number of Organs with Metastatic Sites									
0-2	190	14 (7.4)	NC [NC, NC]	186	6 (3.2)	NC [NC, NC]	2.365 [0.909, 6.154]	0.0691	0.9890
>=3	64	8 (12.5)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	3.07E7 [0.000, NC]	0.0040	

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; 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: 07OCT22

Table 302.1.2001.181.1: Summary and Results of Severe TEAEs - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	44 (17.3%)	35 (14.1%)	
Number of patients censored	210 (82.7%)	214 (85.9%)	
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			1.278 [0.817, 2.001]
Log-rank test			
Two-sided stratified log-rank p-value			0.2812

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.181.2: Summary and Results of Severe TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	32 (18.2)	NC [NC, NC]	177	16 (9.0)	NC [NC, NC]	2.100 [1.152, 3.829]	0.0133	0.0115
>65 years	78	12 (15.4)	NC [12.1, NC]	72	19 (26.4)	12.7 [7.6, NC]	0.624 [0.302, 1.287]	0.1964	
Sex									
Male	160	23 (14.4)	NC [NC, NC]	152	17 (11.2)	NC [NC, NC]	1.270 [0.677, 2.381]	0.4554	0.9526
Female	94	21 (22.3)	NC [NC, NC]	97	18 (18.6)	NC [NC, NC]	1.352 [0.720, 2.540]	0.3451	
Region									
Asia	157	31 (19.7)	NC [NC, NC]	156	25 (16.0)	NC [12.7, NC]	1.212 [0.714, 2.057]	0.4767	0.7772
Non-Asia	97	13 (13.4)	NC [NC, NC]	93	10 (10.8)	NC [NC, NC]	1.421 [0.623, 3.244]	0.4014	
Number of Organs with Metastatic Sites									
0-2	190	34 (17.9)	NC [NC, NC]	186	31 (16.7)	NC [NC, NC]	1.136 [0.698, 1.850]	0.6072	0.1977
>=3	64	10 (15.6)	NC [14.0, NC]	63	4 (6.3)	NC [NC, NC]	2.462 [0.768, 7.890]	0.1172	

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; 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: 07OCT22

Table 302.1.2001.182.1: Summary and Results of Severe TEAEs - Vomiting (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.182.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	21 (11.9)	NC [NC, NC]	177	7 (4.0)	NC [NC, NC]	3.200 [1.360, 7.527]	0.0052	0.6169
>65 years	78	10 (12.8)	NC [NC, NC]	72	2 (2.8)	NC [NC, NC]	5.021 [1.100, 22.927]	0.0208	
Sex									
Male	160	17 (10.6)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	2.440 [1.012, 5.885]	0.0415	0.1815
Female	94	14 (14.9)	NC [NC, NC]	97	2 (2.1)	NC [NC, NC]	7.882 [1.791, 34.695]	0.0012	
Region									
Asia	157	18 (11.5)	NC [NC, NC]	156	4 (2.6)	NC [NC, NC]	4.782 [1.618, 14.131]	0.0019	0.4411
Non-Asia	97	13 (13.4)	NC [NC, NC]	93	5 (5.4)	NC [NC, NC]	2.661 [0.948, 7.465]	0.0543	
Number of Organs with Metastatic Sites									
0-2	190	22 (11.6)	NC [NC, NC]	186	8 (4.3)	NC [NC, NC]	2.871 [1.278, 6.449]	0.0080	0.2899
>=3	64	9 (14.1)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	9.621 [1.218, 75.962]	0.0085	

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; 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: 07OCT22

Table 302.1.2001.183.1: Summary and Results of TESAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	3 (1.2%)	6 (2.4%)	
Number of patients censored	251 (98.8%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.406 [0.099, 1.667]
Log-rank test			
Two-sided stratified log-rank p-value			0.1975

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.183.2: Summary and Results of TESAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	2 (1.1)		177	6 (3.4)				
>65 years	78	1 (1.3)		72	0 (0.0)				
Sex									
Male	160	3 (1.9)		152	5 (3.3)				
Female	94	0 (0.0)		97	1 (1.0)				
Region									
Asia	157	2 (1.3)		156	4 (2.6)				
Non-Asia	97	1 (1.0)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	1 (0.5)		186	4 (2.2)				
>=3	64	2 (3.1)		63	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; 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: 07OCT22

Table 302.1.2001.184.1: Summary and Results of TESAEs - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	6 (2.4%)	
Number of patients censored	249 (98.0%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.821 [0.250, 2.696]
Log-rank test			
Two-sided stratified log-rank p-value			0.7453

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.184.2: Summary and Results of TESAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	4 (2.3)				
>65 years	78	1 (1.3)		72	2 (2.8)				
Sex									
Male	160	3 (1.9)		152	3 (2.0)				
Female	94	2 (2.1)		97	3 (3.1)				
Region									
Asia	157	2 (1.3)		156	5 (3.2)				
Non-Asia	97	3 (3.1)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	1 (0.5)				
>=3	64	0 (0.0)		63	5 (7.9)				

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; 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: 07OCT22

Table 302.1.2001.185.1: Summary and Results of TESAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	3 (1.2%)	
Number of patients censored	247 (97.2%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.394 [0.618, 9.266]
Log-rank test			
Two-sided stratified log-rank p-value			0.1921

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.185.2: Summary and Results of TESAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	5 (2.8)		177	3 (1.7)				
>65 years	78	2 (2.6)		72	0 (0.0)				
Sex									
Male	160	5 (3.1)		152	1 (0.7)				
Female	94	2 (2.1)		97	2 (2.1)				
Region									
Asia	157	3 (1.9)		156	1 (0.6)				
Non-Asia	97	4 (4.1)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	4 (2.1)		186	3 (1.6)				
>=3	64	3 (4.7)		63	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; 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: 07OCT22

Table 302.1.2001.186.1: Summary and Results of TESAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	0 (0.0%)	
Number of patients censored	245 (96.5%)	249 (100.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.0028

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.186.2: Summary and Results of TESAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	6 (3.4)		177	0 (0.0)				
>65 years	78	3 (3.8)		72	0 (0.0)				
Sex									
Male	160	6 (3.8)		152	0 (0.0)				
Female	94	3 (3.2)		97	0 (0.0)				
Region									
Asia	157	4 (2.5)		156	0 (0.0)				
Non-Asia	97	5 (5.2)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	0 (0.0)				
>=3	64	4 (6.3)		63	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; 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: 07OCT22

Table 302.1.2001.187.1: Summary and Results of TESAEs - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	6 (2.4%)	
Number of patients censored	243 (95.7%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.833 [0.677, 4.963]
Log-rank test			
Two-sided stratified log-rank p-value			0.2263

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.187.2: Summary and Results of TESAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	6 (3.4)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	1.224 [0.374, 4.011]	0.7385	0.2713
>65 years	78	5 (6.4)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	4.822 [0.563, 41.282]	0.1127	
Sex									
Male	160	6 (3.8)		152	3 (2.0)				
Female	94	5 (5.3)		97	3 (3.1)				
Region									
Asia	157	9 (5.7)	NC [NC, NC]	156	2 (1.3)	NC [NC, NC]	4.632 [1.001, 21.439]	0.0310	0.0547
Non-Asia	97	2 (2.1)	NC [NC, NC]	93	4 (4.3)	NC [NC, NC]	0.491 [0.090, 2.682]	0.4012	
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)	NC [NC, NC]	186	6 (3.2)	NC [NC, NC]	0.999 [0.322, 3.099]	0.9974	0.9910
>=3	64	5 (7.8)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	2.99E7 [0.000, NC]	0.0246	

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; 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: 07OCT22

Table 302.1.2001.188.1: Summary and Results of TESAEs - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	7 (2.8%)	
Number of patients censored	249 (98.0%)	242 (97.2%)	
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			0.709 [0.224, 2.241]
Log-rank test			
Two-sided stratified log-rank p-value			0.5558

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.188.2: Summary and Results of TESAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	5 (2.8)		177	4 (2.3)				
>65 years	78	0 (0.0)		72	3 (4.2)				
Sex									
Male	160	3 (1.9)		152	4 (2.6)				
Female	94	2 (2.1)		97	3 (3.1)				
Region									
Asia	157	2 (1.3)		156	2 (1.3)				
Non-Asia	97	3 (3.1)		93	5 (5.4)				
Number of Organs with Metastatic Sites									
0-2	190	2 (1.1)		186	6 (3.2)				
>=3	64	3 (4.7)		63	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; 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: 07OCT22

Table 302.1.2001.189.1: Summary and Results of TESAEs - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	11 (4.4%)	
Number of patients censored	239 (94.1%)	238 (95.6%)	
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			1.359 [0.624, 2.961]
Log-rank test			
Two-sided stratified log-rank p-value			0.4382

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.189.2: Summary and Results of TESAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	8 (4.5)	NC [NC, NC]	177	7 (4.0)	NC [NC, NC]	1.173 [0.425, 3.236]	0.7600	0.6494
>65 years	78	7 (9.0)	NC [NC, NC]	72	4 (5.6)	NC [NC, NC]	1.706 [0.499, 5.832]	0.3892	
Sex									
Male	160	10 (6.3)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	1.407 [0.535, 3.696]	0.4888	0.9495
Female	94	5 (5.3)	NC [NC, NC]	97	4 (4.1)	NC [NC, NC]	1.335 [0.358, 4.972]	0.6652	
Region									
Asia	157	8 (5.1)	NC [NC, NC]	156	4 (2.6)	NC [NC, NC]	2.052 [0.618, 6.815]	0.2313	0.3735
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	7 (7.5)	NC [NC, NC]	0.997 [0.350, 2.843]	0.9942	
Number of Organs with Metastatic Sites									
0-2	190	10 (5.3)	NC [NC, NC]	186	9 (4.8)	NC [NC, NC]	1.125 [0.457, 2.769]	0.7997	0.3925
>=3	64	5 (7.8)	NC [NC, NC]	63	2 (3.2)	NC [NC, NC]	2.530 [0.491, 13.040]	0.2510	

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; 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: 07OCT22

Table 302.1.2001.190.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	1 (0.4%)	
Number of patients censored	250 (98.4%)	248 (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			3.649 [0.408, 32.666]
Log-rank test			
Two-sided stratified log-rank p-value			0.2150

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.190.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	1 (1.4)				
Sex									
Male	160	3 (1.9)		152	0 (0.0)				
Female	94	1 (1.1)		97	1 (1.0)				
Region									
Asia	157	3 (1.9)		156	1 (0.6)				
Non-Asia	97	1 (1.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	3 (1.6)		186	0 (0.0)				
>=3	64	1 (1.6)		63	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; 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: 07OCT22

Table 302.1.2001.191.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	0 (0.0%)	3 (1.2%)	
Number of patients censored	254 (100.0%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.0988

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.191.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	2 (1.1)				
>65 years	78	0 (0.0)		72	1 (1.4)				
Sex									
Male	160	0 (0.0)		152	2 (1.3)				
Female	94	0 (0.0)		97	1 (1.0)				
Region									
Asia	157	0 (0.0)		156	2 (1.3)				
Non-Asia	97	0 (0.0)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	2 (1.1)				
>=3	64	0 (0.0)		63	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; 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: 07OCT22

Table 302.1.2001.192.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	1 (0.4%)	
Number of patients censored	247 (97.2%)	248 (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			6.978 [0.858, 56.754]
Log-rank test			
Two-sided stratified log-rank p-value			0.0344

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.192.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	6 (3.4)		177	1 (0.6)				
>65 years	78	1 (1.3)		72	0 (0.0)				
Sex									
Male	160	4 (2.5)		152	0 (0.0)				
Female	94	3 (3.2)		97	1 (1.0)				
Region									
Asia	157	1 (0.6)		156	1 (0.6)				
Non-Asia	97	6 (6.2)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	1 (0.5)				
>=3	64	2 (3.1)		63	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; 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: 07OCT22

Table 302.1.2001.193.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	1 (0.4%)	
Number of patients censored	244 (96.1%)	248 (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			9.604 [1.229, 75.046]
Log-rank test			
Two-sided stratified log-rank p-value			0.0082

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.193.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	7 (4.0)		177	1 (0.6)				
>65 years	78	3 (3.8)		72	0 (0.0)				
Sex									
Male	160	5 (3.1)		152	0 (0.0)				
Female	94	5 (5.3)		97	1 (1.0)				
Region									
Asia	157	4 (2.5)		156	1 (0.6)				
Non-Asia	97	6 (6.2)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	8 (4.2)		186	1 (0.5)				
>=3	64	2 (3.1)		63	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; 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: 07OCT22

Table 302.1.2001.194.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.194.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	5 (2.8)		177	3 (1.7)				
>65 years	78	1 (1.3)		72	0 (0.0)				
Sex									
Male	160	4 (2.5)		152	1 (0.7)				
Female	94	2 (2.1)		97	2 (2.1)				
Region									
Asia	157	2 (1.3)		156	2 (1.3)				
Non-Asia	97	4 (4.1)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	3 (1.6)				
>=3	64	1 (1.6)		63	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; 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: 07OCT22

Table 302.1.2001.195.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	7 (2.8%)	
Number of patients censored	247 (97.2%)	242 (97.2%)	
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			0.850 [0.292, 2.475]
Log-rank test			
Two-sided stratified log-rank p-value			0.7651

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.195.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	3 (1.7)				
>65 years	78	3 (3.8)		72	4 (5.6)				
Sex									
Male	160	4 (2.5)		152	3 (2.0)				
Female	94	3 (3.2)		97	4 (4.1)				
Region									
Asia	157	6 (3.8)	NC [NC, NC]	156	4 (2.6)	NC [NC, NC]	1.209 [0.335, 4.355]	0.7717	0.3308
Non-Asia	97	1 (1.0)	NC [NC, NC]	93	3 (3.2)	NC [NC, NC]	0.357 [0.037, 3.433]	0.3514	
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)	NC [NC, NC]	186	5 (2.7)	NC [NC, NC]	1.081 [0.326, 3.587]	0.8970	0.4725
>=3	64	1 (1.6)	NC [NC, NC]	63	2 (3.2)	NC [NC, NC]	0.395 [0.036, 4.370]	0.4326	

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; 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: 07OCT22

Table 302.1.2001.196.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.196.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	2 (1.1)				
>65 years	78	5 (6.4)		72	2 (2.8)				
Sex									
Male	160	4 (2.5)		152	2 (1.3)				
Female	94	5 (5.3)		97	2 (2.1)				
Region									
Asia	157	5 (3.2)		156	2 (1.3)				
Non-Asia	97	4 (4.1)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	8 (4.2)	NC [NC, NC]	186	4 (2.2)	NC [NC, NC]	1.969 [0.593, 6.539]	0.2598	0.9929
>=3	64	1 (1.6)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	2.82E7 [0.000, NC]	0.3293	

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; 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: 07OCT22

Table 302.1.2001.218.1: Summary and Results of TEAEs leading to Death - Abdominal Pain (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.218.2: Summary and Results of TEAEs leading to Death by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 07OCT22

Table 302.1.2001.219.1: Summary and Results of TEAEs leading to Death - Anemia (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.219.2: Summary and Results of TEAEs leading to Death by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 07OCT22

Table 302.1.2001.220.1: Summary and Results of TEAEs leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.220.2: Summary and Results of TEAEs leading to Death by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 07OCT22

Table 302.1.2001.221.1: Summary and Results of TEAEs leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.221.2: Summary and Results of TEAEs leading to Death by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 07OCT22

Table 302.1.2001.222.1: Summary and Results of TEAEs leading to Death - Nausea (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.222.2: Summary and Results of TEAEs leading to Death by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 07OCT22

Table 302.1.2001.223.1: Summary and Results of TEAEs leading to Death - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	0 (0.0%)	2 (0.8%)	
Number of patients censored	254 (100.0%)	247 (99.2%)	
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			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.1546

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.223.2: Summary and Results of TEAEs leading to Death by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	1 (0.6)				
>65 years	78	0 (0.0)		72	1 (1.4)				
Sex									
Male	160	0 (0.0)		152	1 (0.7)				
Female	94	0 (0.0)		97	1 (1.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	2 (1.1)				
>=3	64	0 (0.0)		63	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; 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: 07OCT22

Table 302.1.2001.224.1: Summary and Results of TEAEs leading to Death - Vomiting (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 07OCT22

Table 302.1.2001.224.2: Summary and Results of TEAEs leading to Death by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	0 (0.0)				

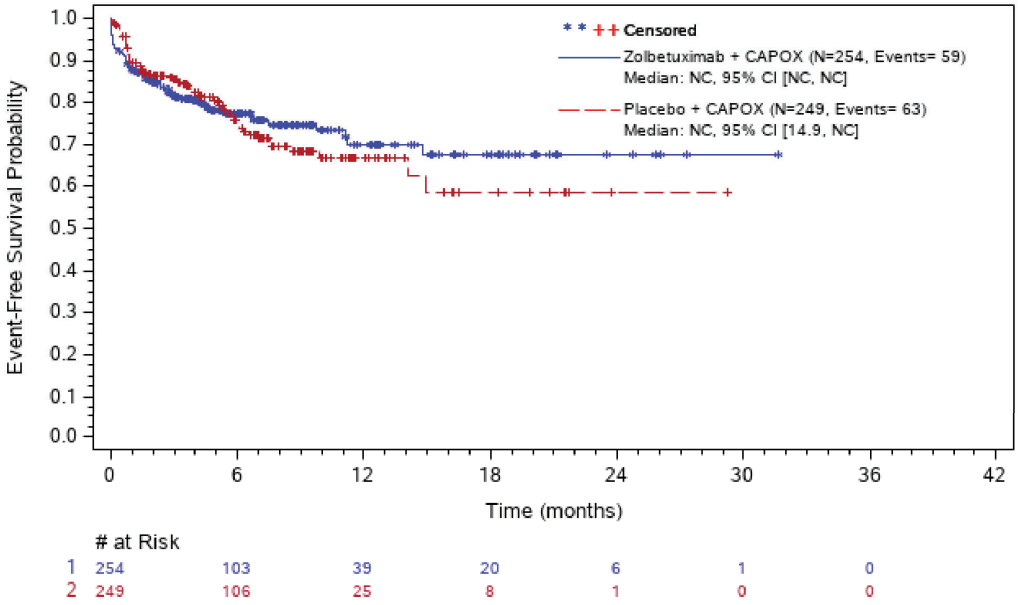
Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse von besonderem Interesse

2. Kaplan-Meier-Plots

The SAS System

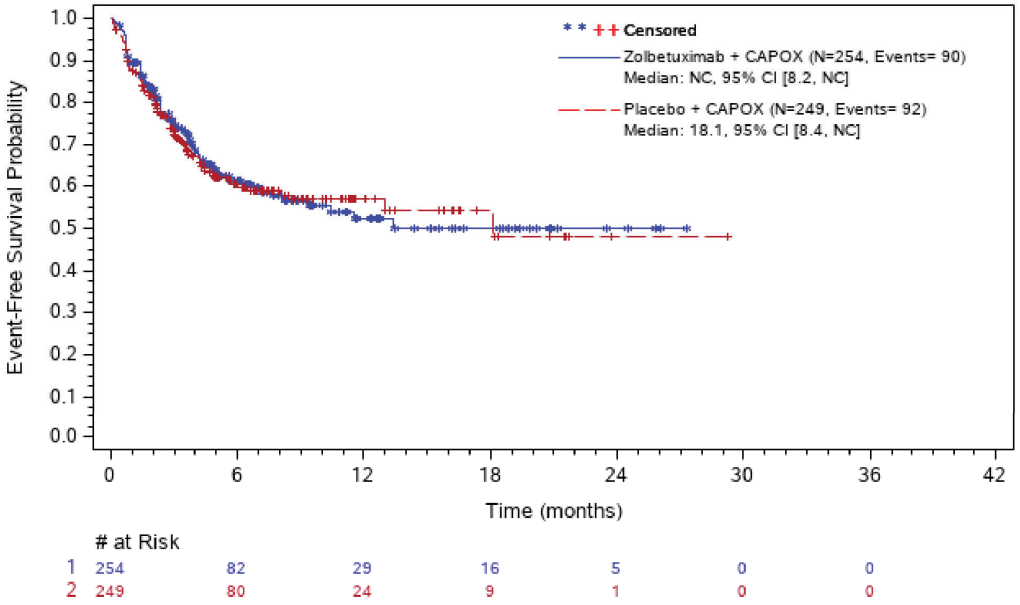
Figure 302.1.2001.162: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.163: Kaplan-Meier Plot of Time to first TEAE - Anemia (AESI) - Safety Analysis Set



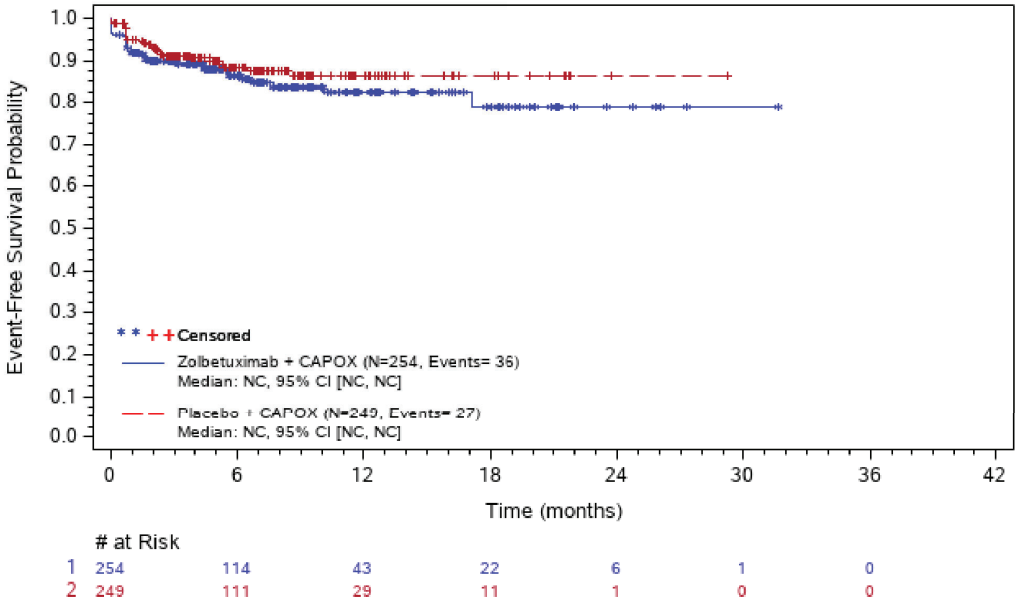
at Risk

1	254	82	29	16	5	0	0
2	249	80	24	9	1	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: 07OCT22

The SAS System

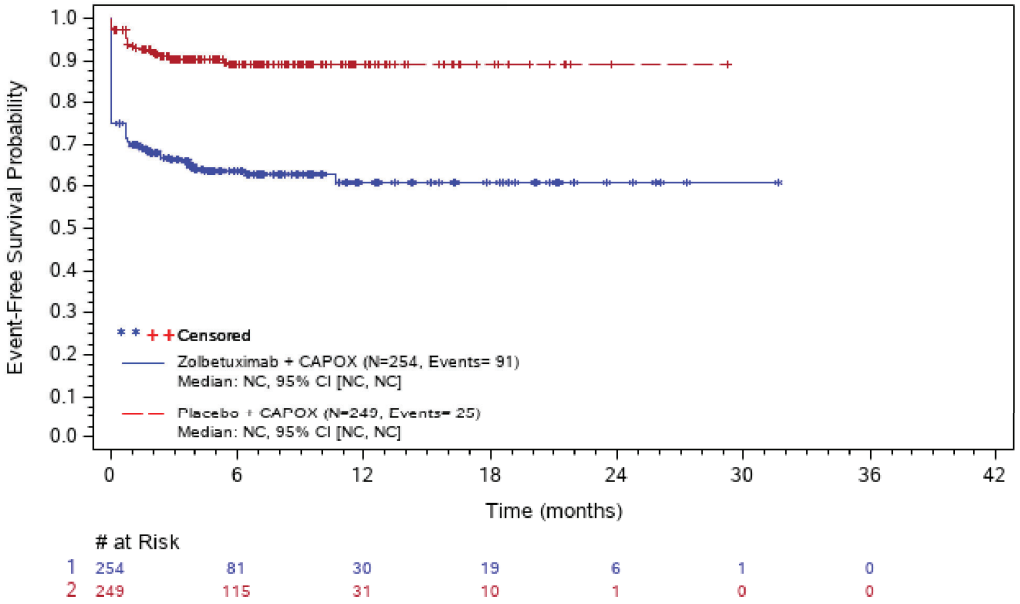
Figure 302.1.2001.164: Kaplan-Meier Plot of Time to first TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.165: Kaplan-Meier Plot of Time to first TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



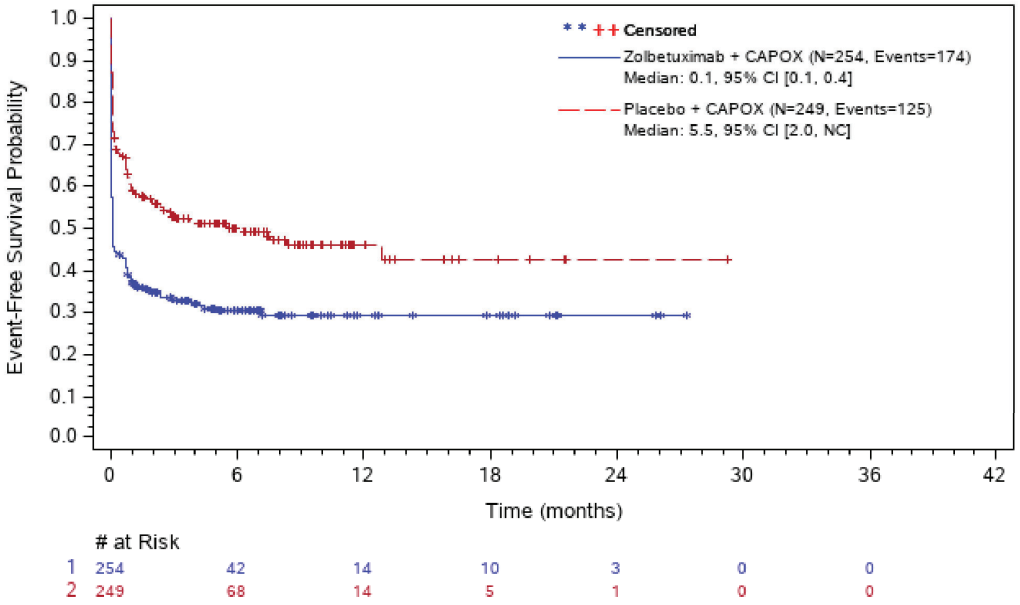
at Risk

1	254	81	30	19	6	1	0
2	249	115	31	10	1	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: 07OCT22

The SAS System

Figure 302.1.2001.166: Kaplan-Meier Plot of Time to first TEAE - Nausea (AESI) - Safety Analysis Set

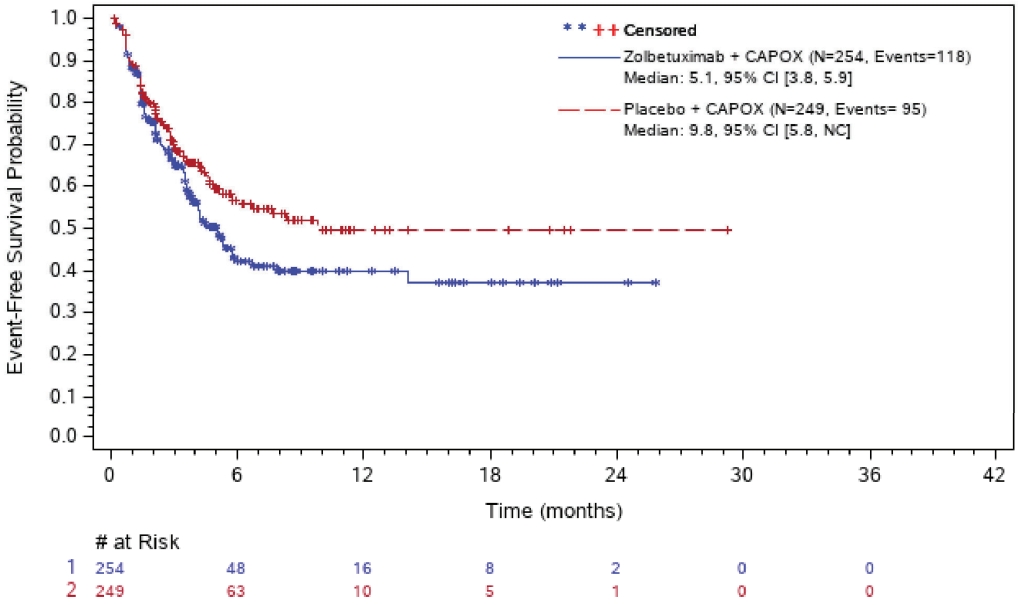


# at Risk							
1	254	42	14	10	3	0	0
2	249	68	14	5	1	0	0

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: 07OCT22

The SAS System

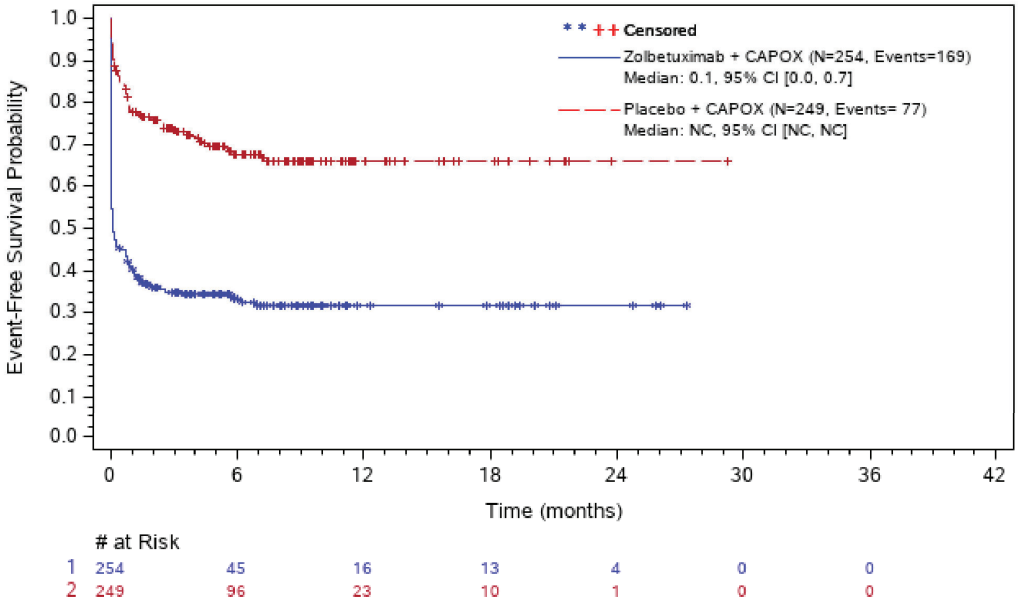
Figure 302.1.2001.167: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.168: Kaplan-Meier Plot of Time to first TEAE - Vomiting (AESI) - Safety Analysis Set

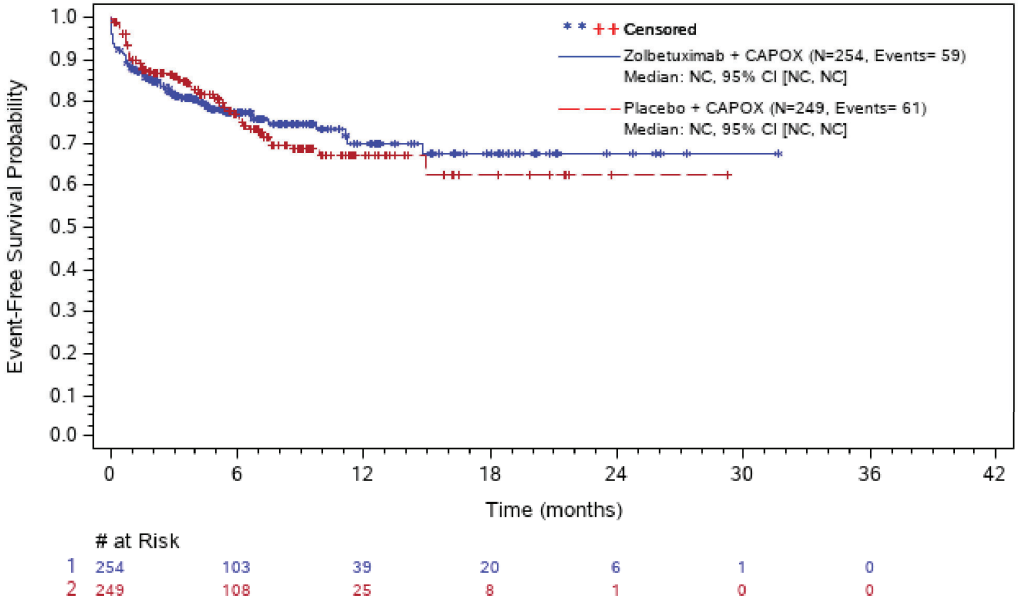


	# at Risk						
1	254	45	16	13	4	0	0
2	249	96	23	10	1	0	0

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: 07OCT22

The SAS System

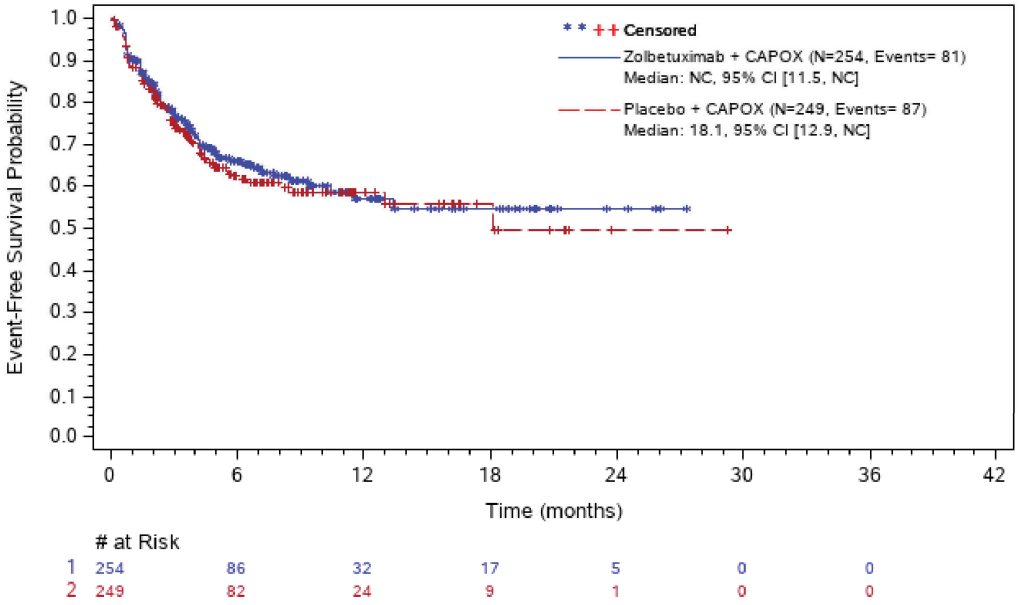
Figure 302.1.2001.169: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Abdominal Pain (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

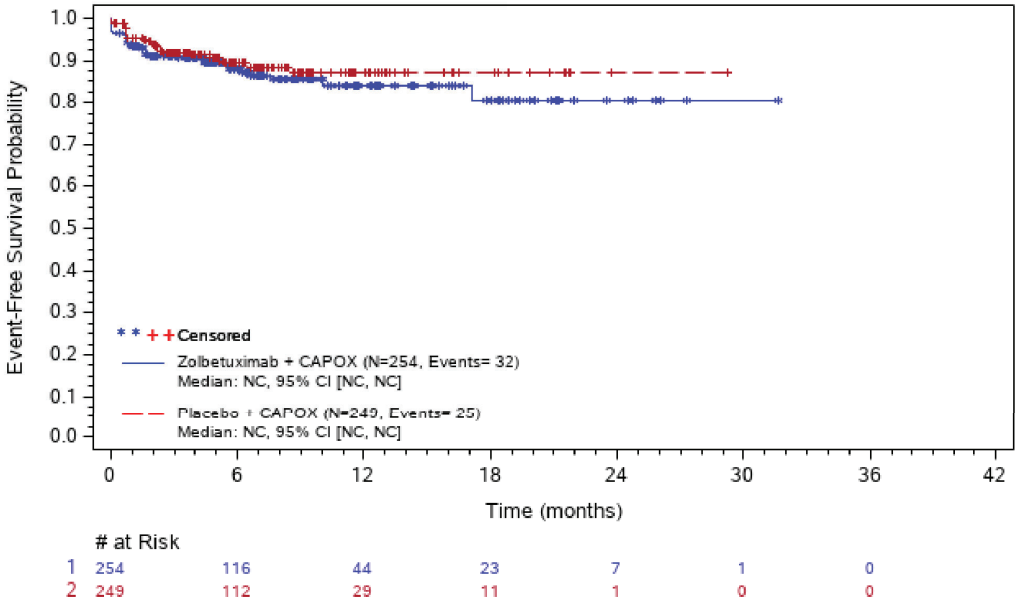
Figure 302.1.2001.170: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Anemia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

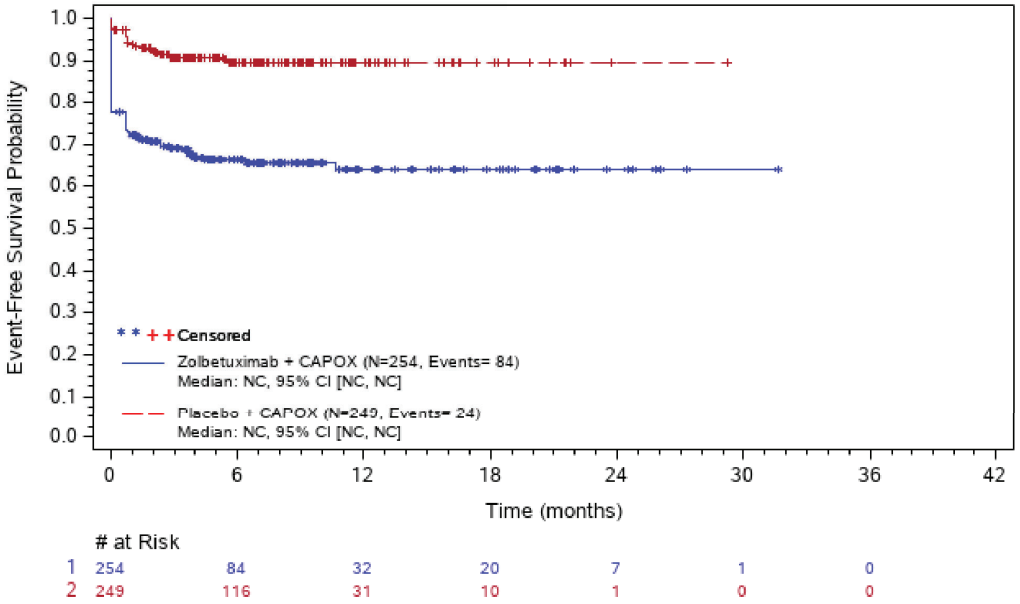
Figure 302.1.2001.171: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

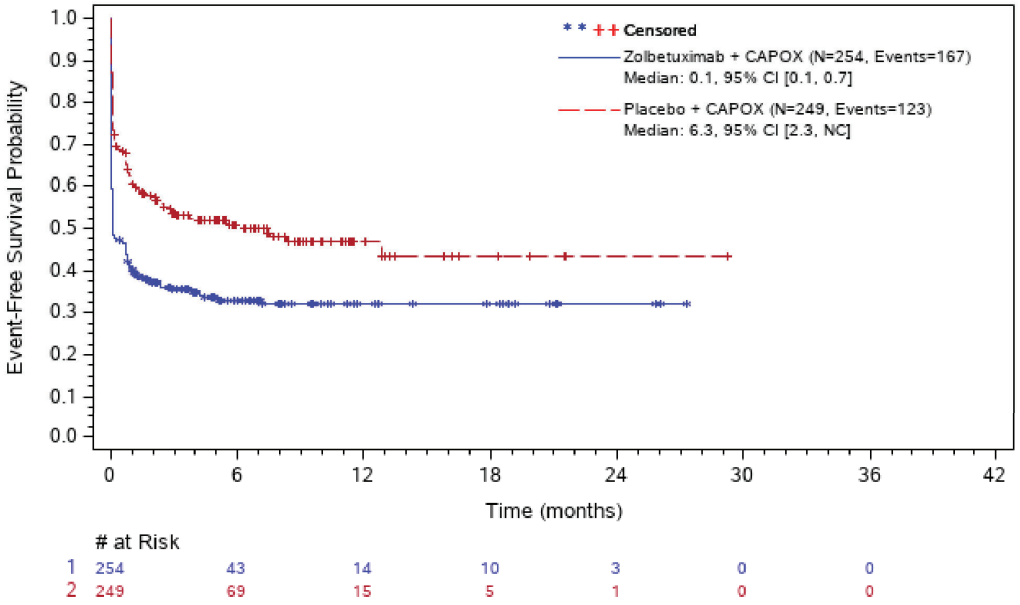
Figure 302.1.2001.172: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

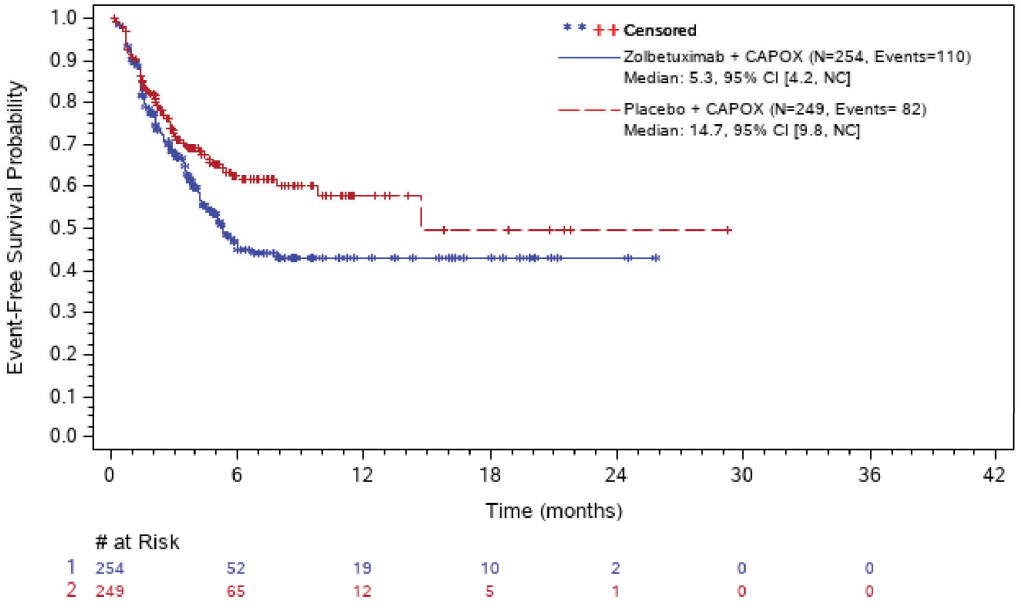
Figure 302.1.2001.173: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Nausea (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

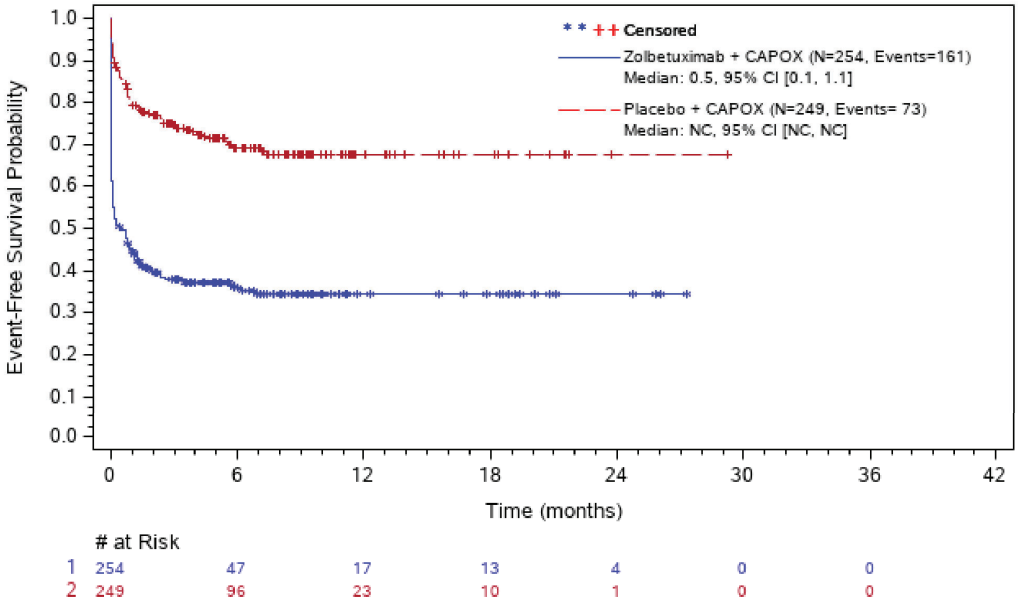
Figure 302.1.2001.174: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Neutropenia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

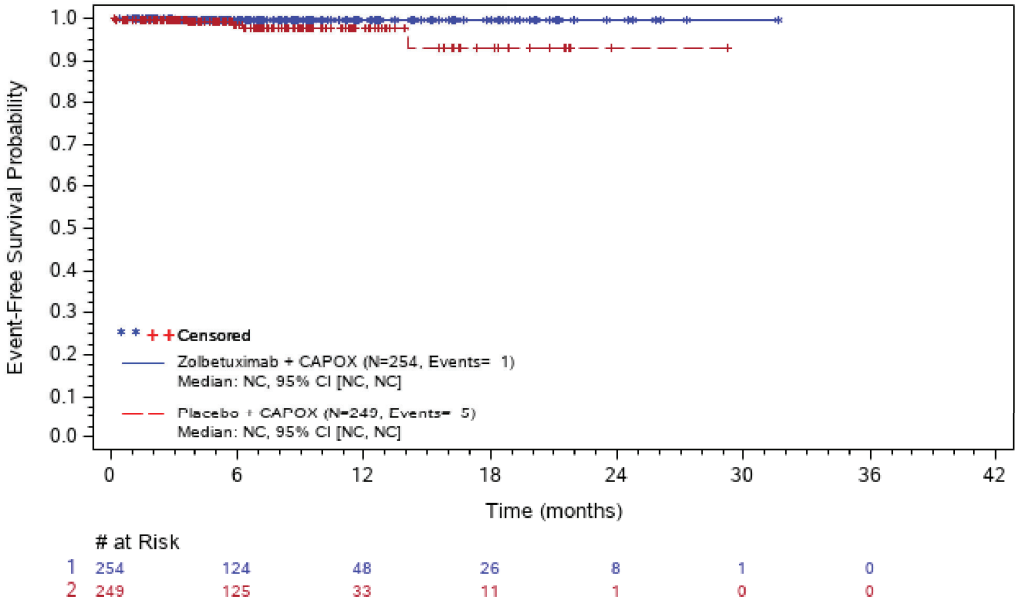
Figure 302.1.2001.175: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Vomiting (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

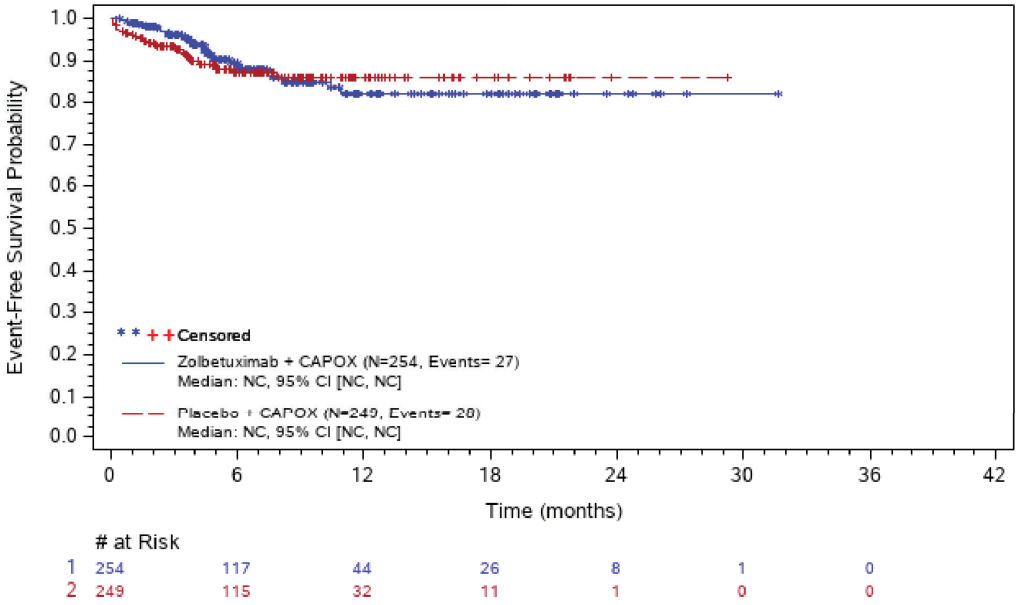
Figure 302.1.2001.176: Kaplan-Meier Plot of Time to first Severe TEAE - Abdominal Pain (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

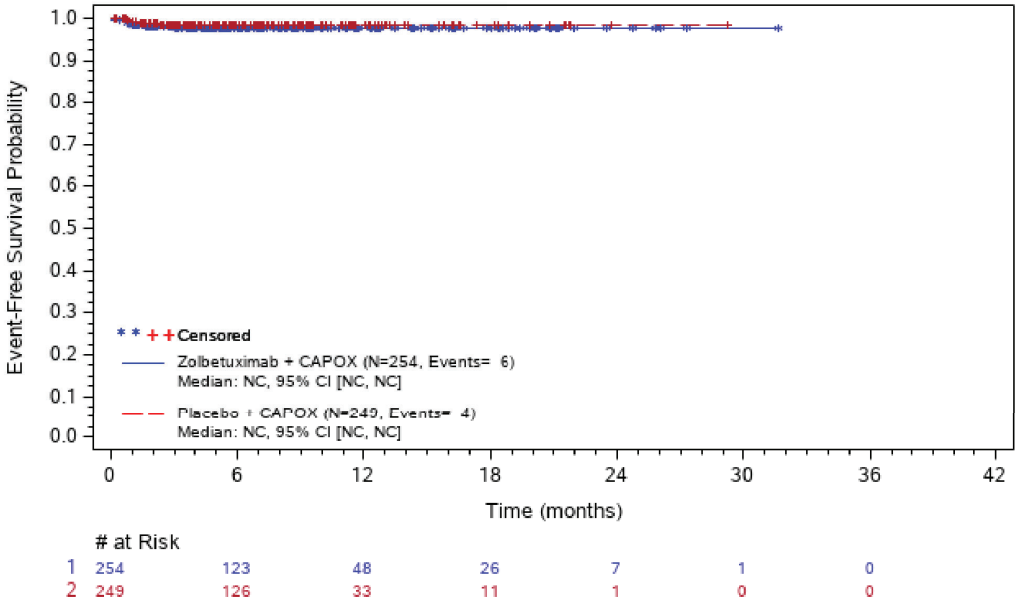
Figure 302.1.2001.177: Kaplan-Meier Plot of Time to first TEAE - Severe Anemia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

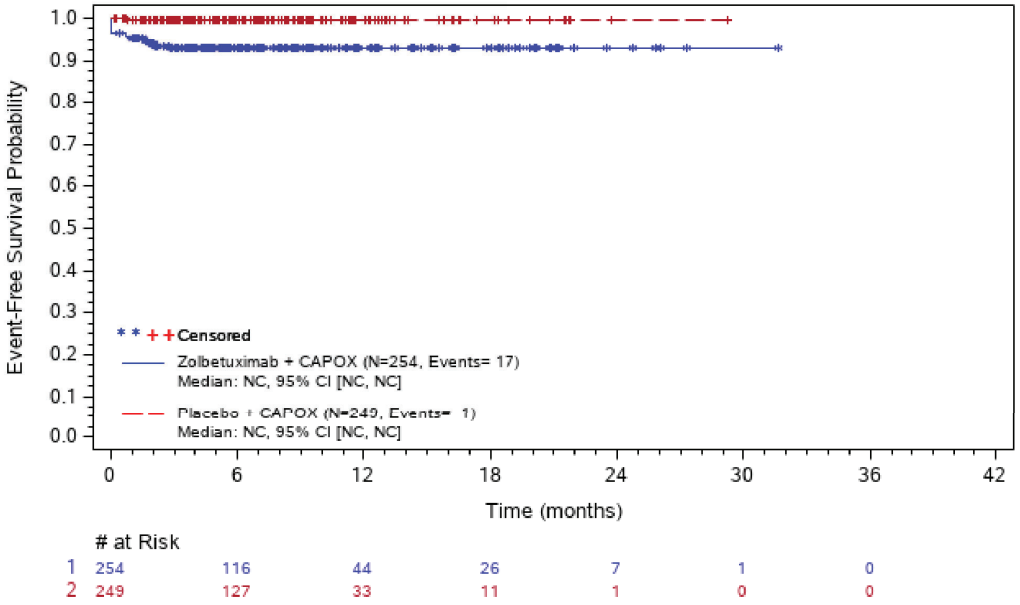
Figure 302.1.2001.178: Kaplan-Meier Plot of Time to first Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

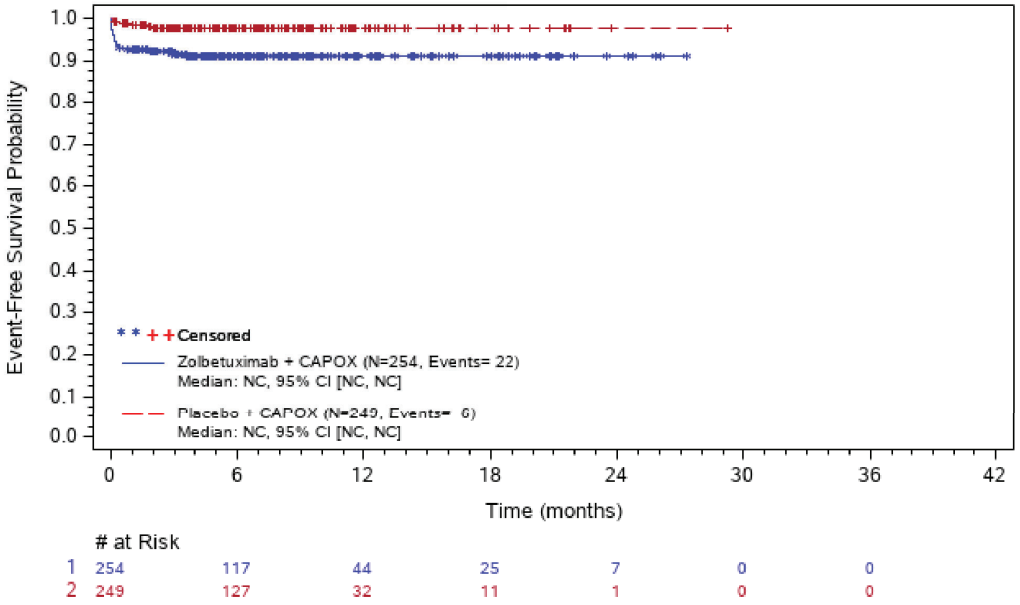
Figure 302.1.2001.179: Kaplan-Meier Plot of Time to first Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

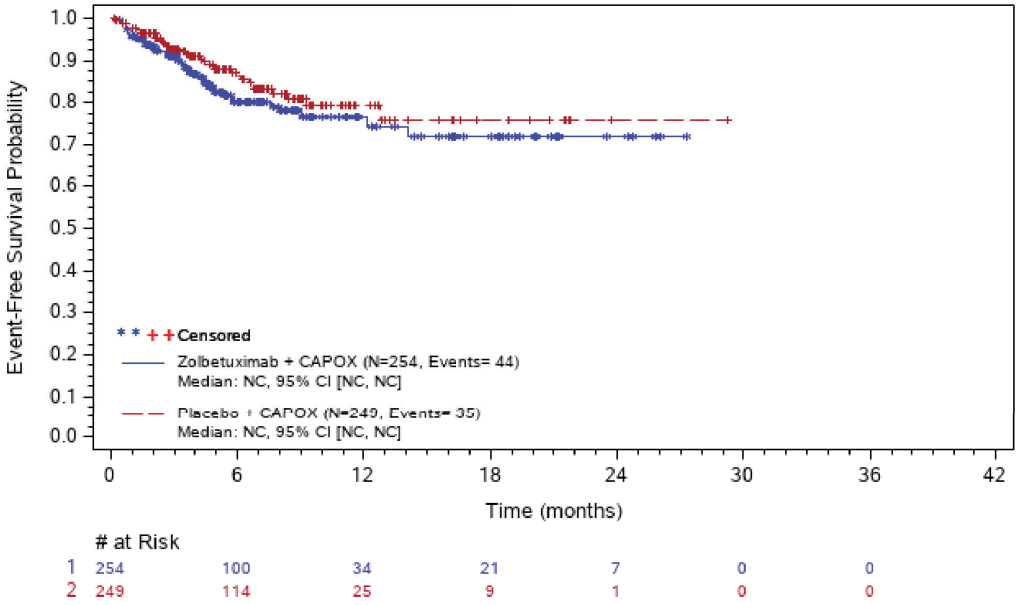
Figure 302.1.2001.180: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

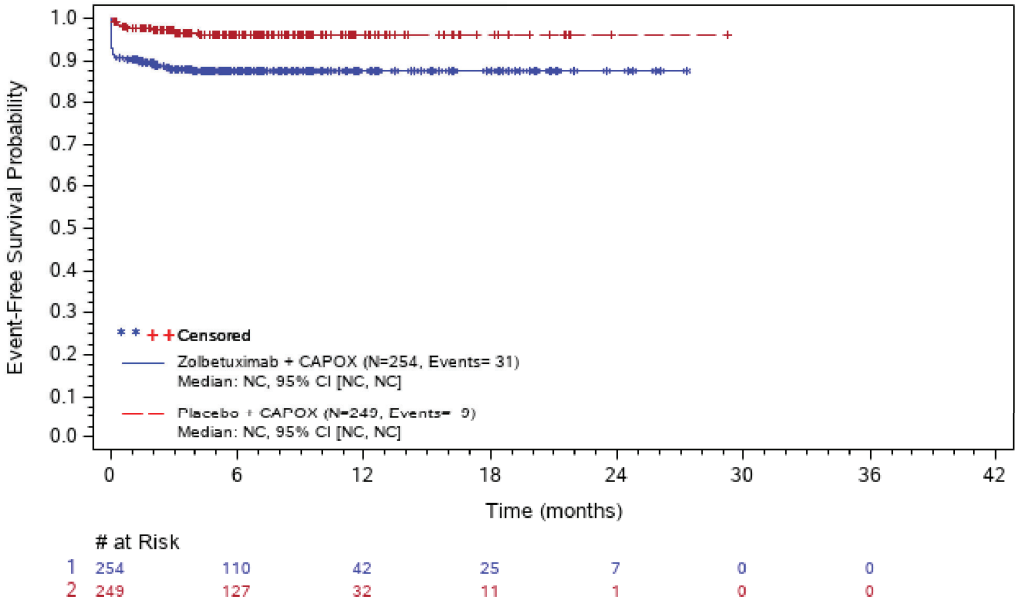
Figure 302.1.2001.181: Kaplan-Meier Plot of Time to first TEAE - Severe Neutropenia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

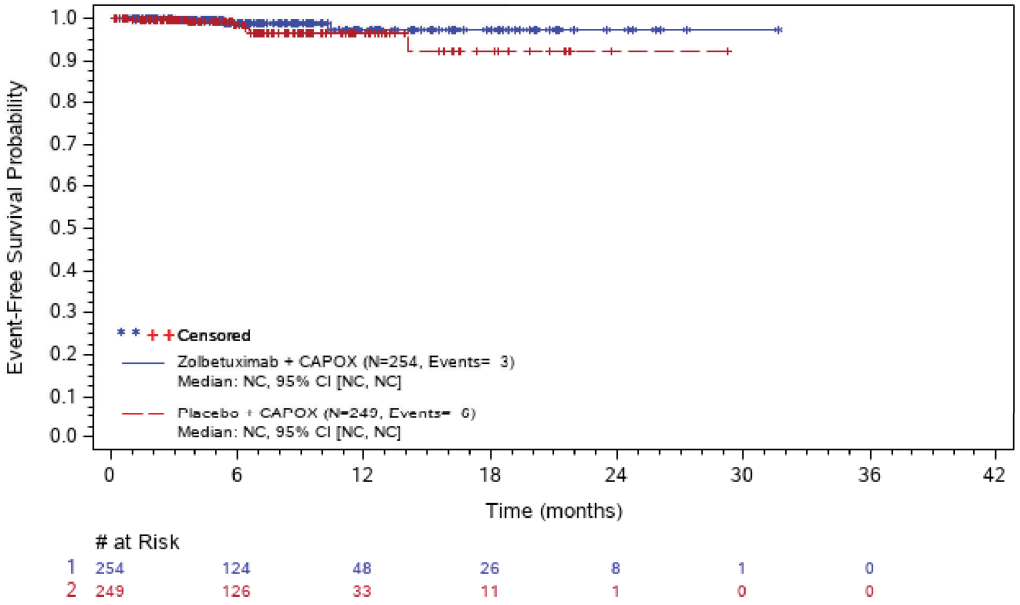
Figure 302.1.2001.182: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

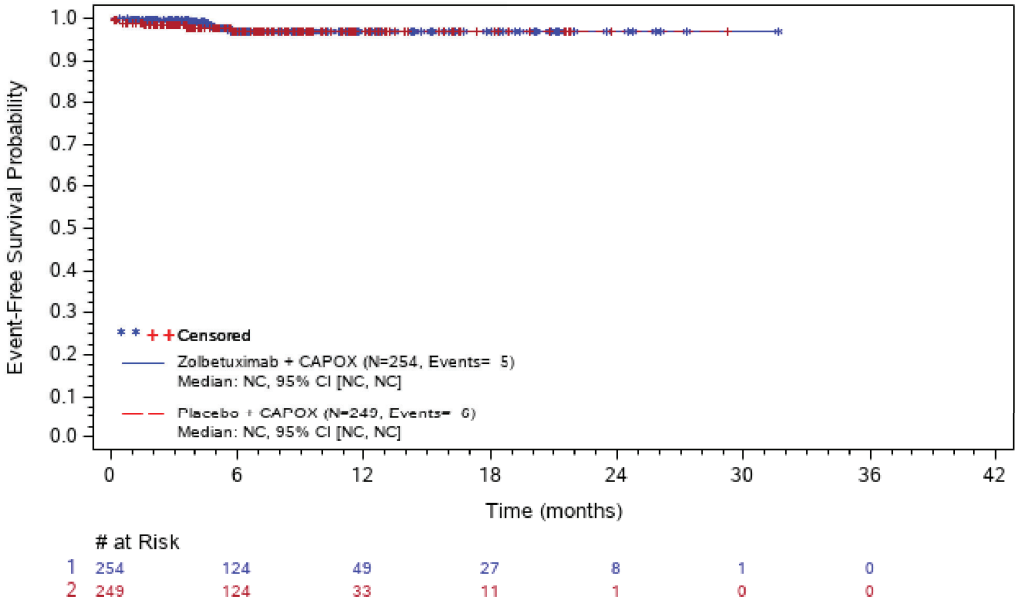
Figure 302.1.2001.183: Kaplan-Meier Plot of Time to first TESAE - Abdominal Pain (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

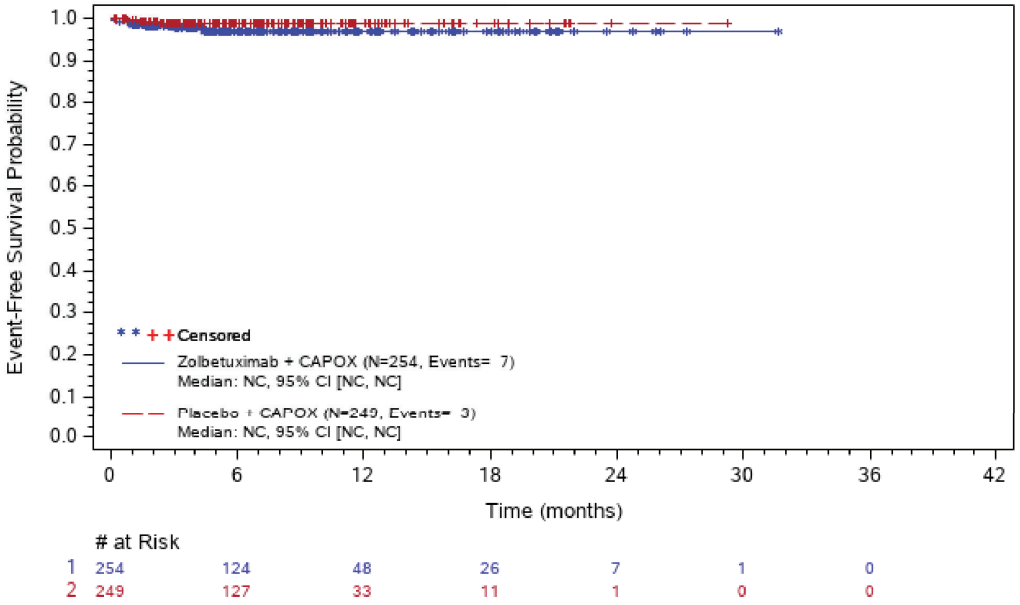
Figure 302.1.2001.184: Kaplan-Meier Plot of Time to first TESAE - Anemia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

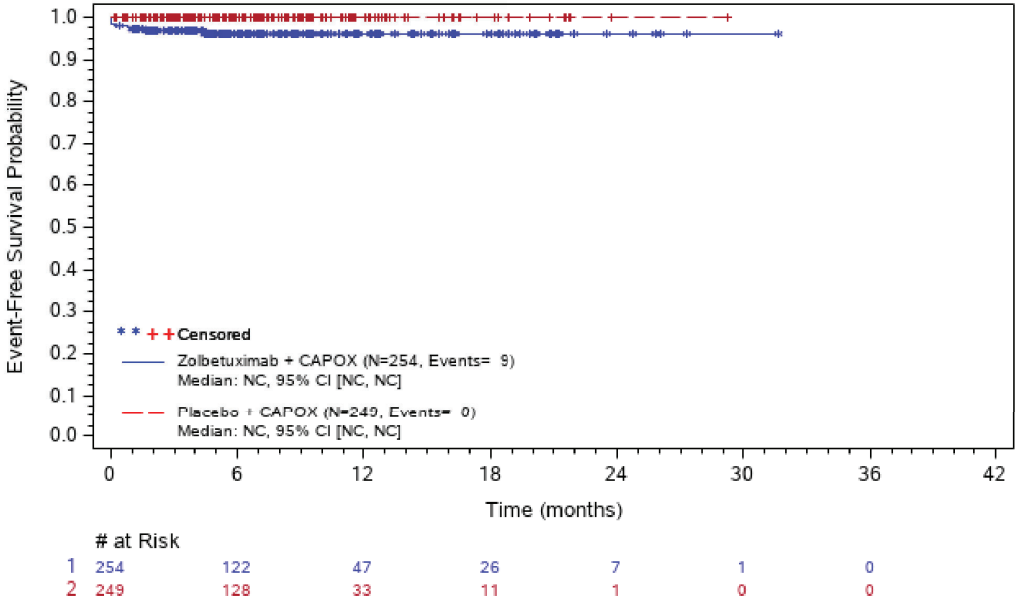
Figure 302.1.2001.185: Kaplan-Meier Plot of Time to first TESAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

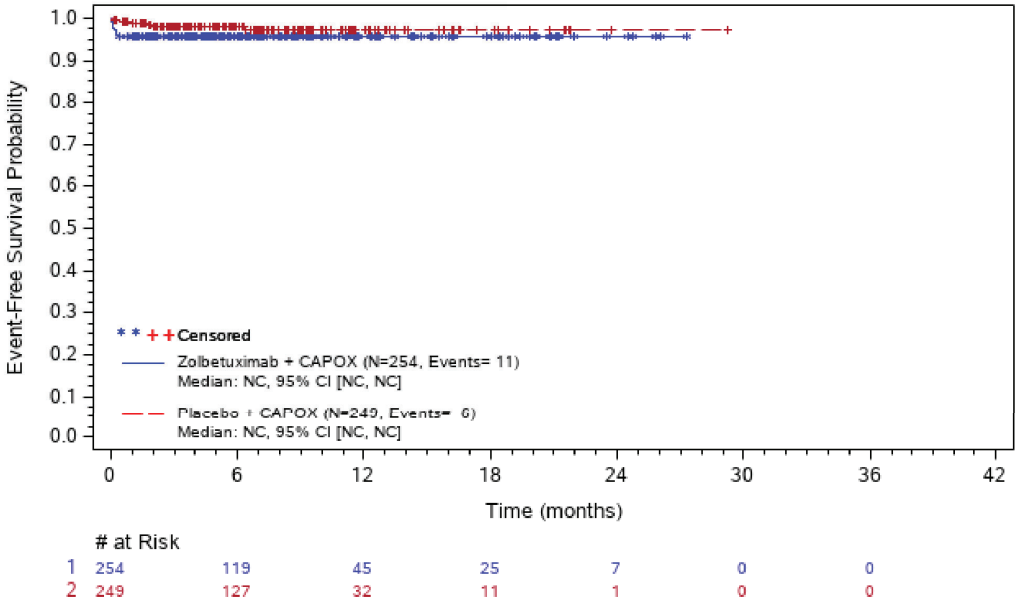
Figure 302.1.2001.186: Kaplan-Meier Plot of Time to first TESAE - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

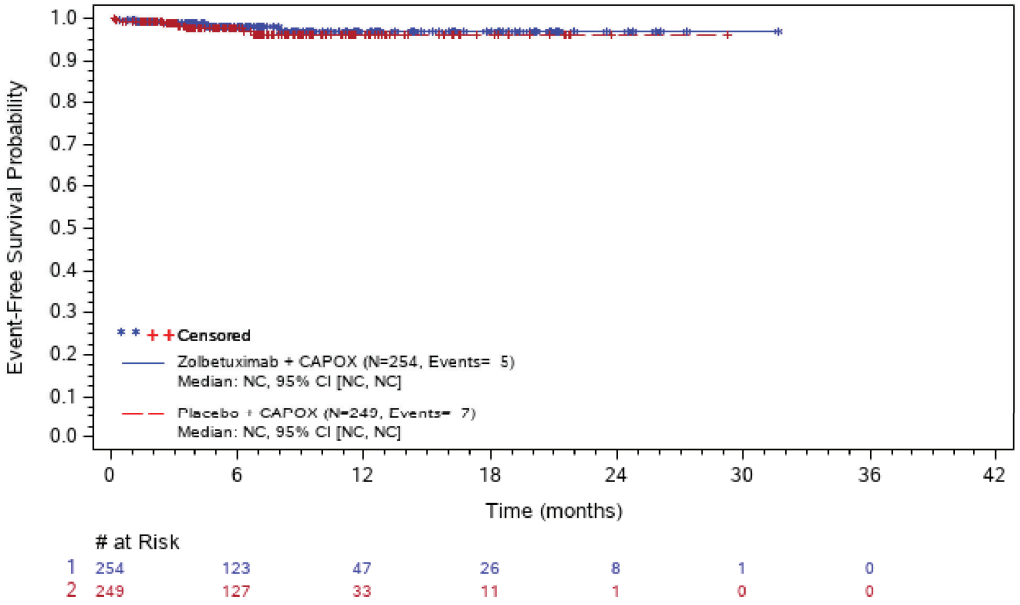
Figure 302.1.2001.187: Kaplan-Meier Plot of Time to first TESAE - Nausea (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

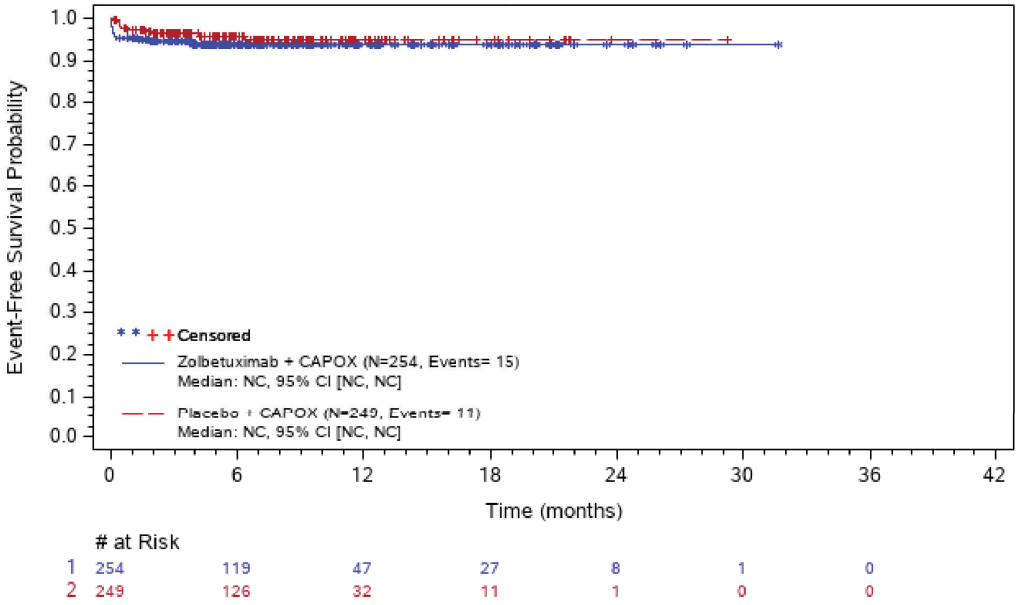
Figure 302.1.2001.188: Kaplan-Meier Plot of Time to first TESAE - Neutropenia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

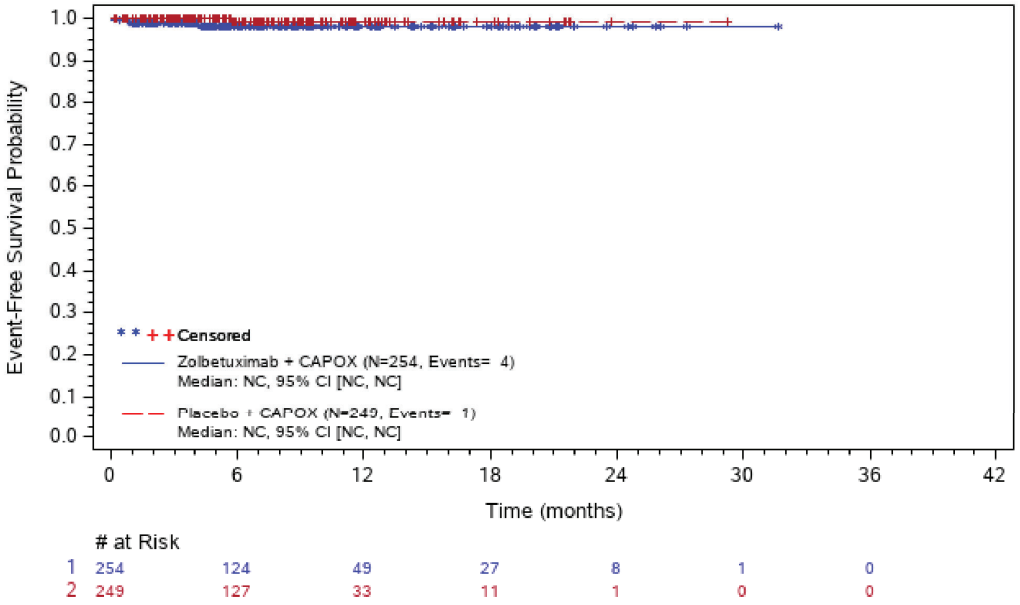
Figure 302.1.2001.189: Kaplan-Meier Plot of Time to first TESAE - Vomiting (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.190: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Abdominal Pain (AESI) - Safety Analysis Set

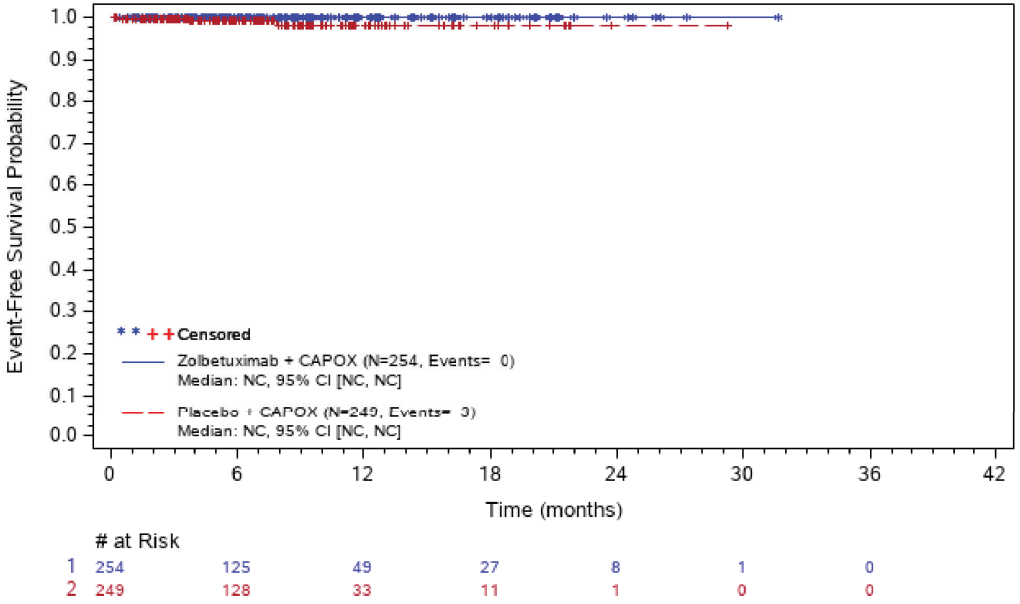


	# at Risk						
1	254	124	49	27	8	1	0
2	249	127	33	11	1	0	0

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: 07OCT22

The SAS System

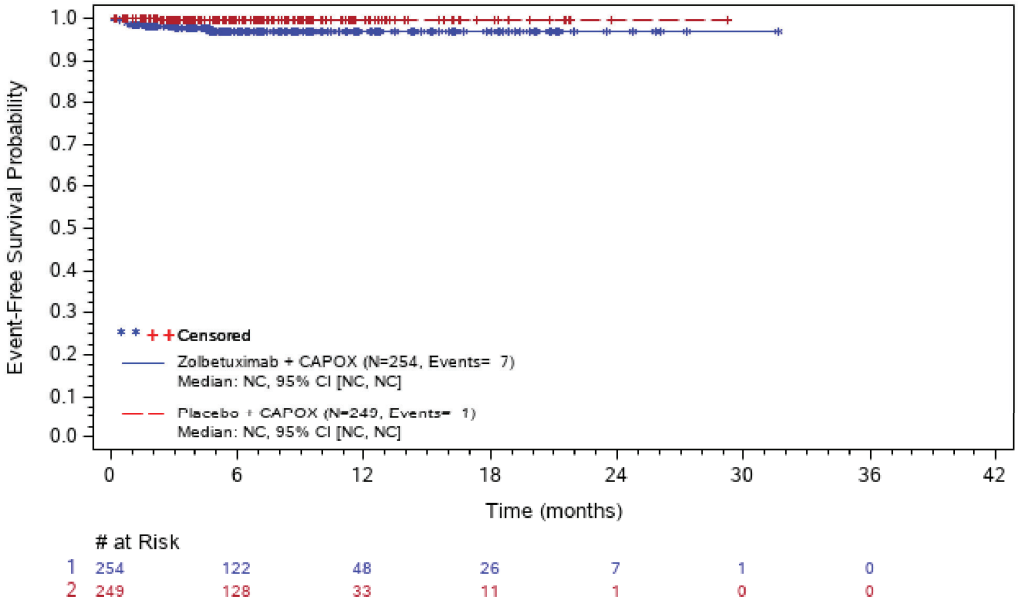
Figure 302.1.2001.191: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Anemia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

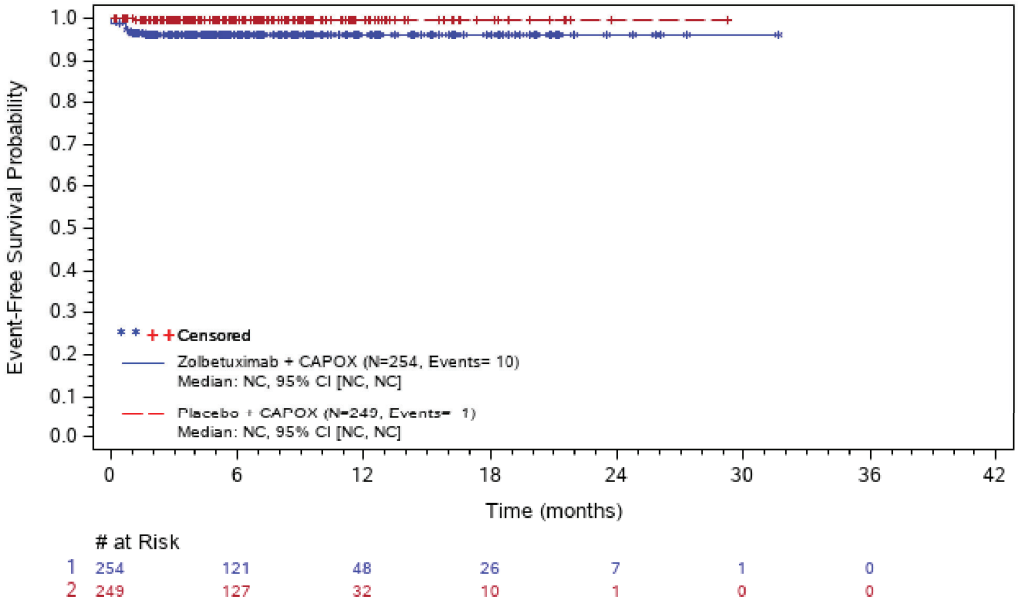
Figure 302.1.2001.192: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

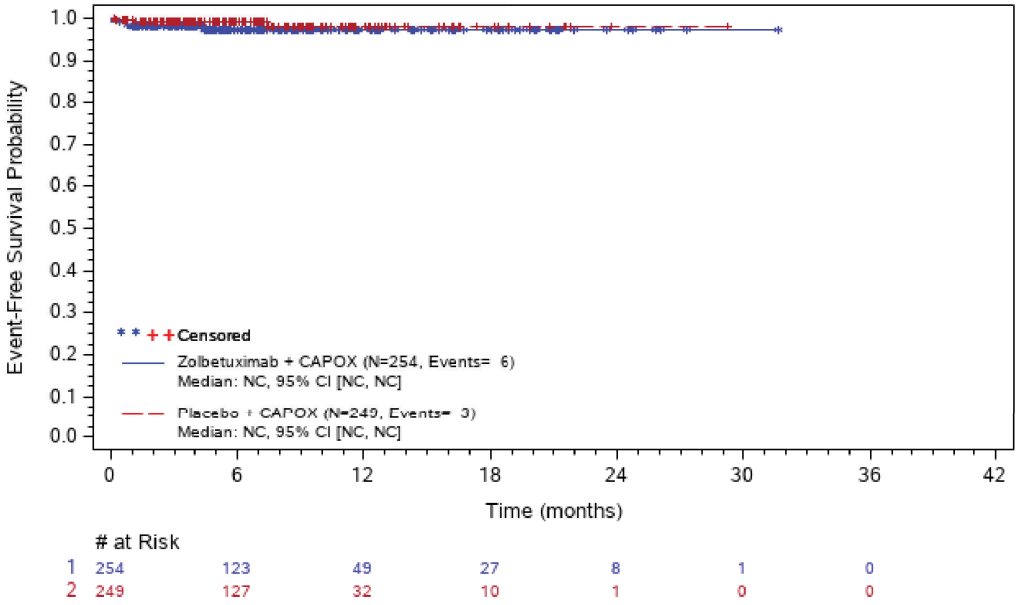
Figure 302.1.2001.193: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

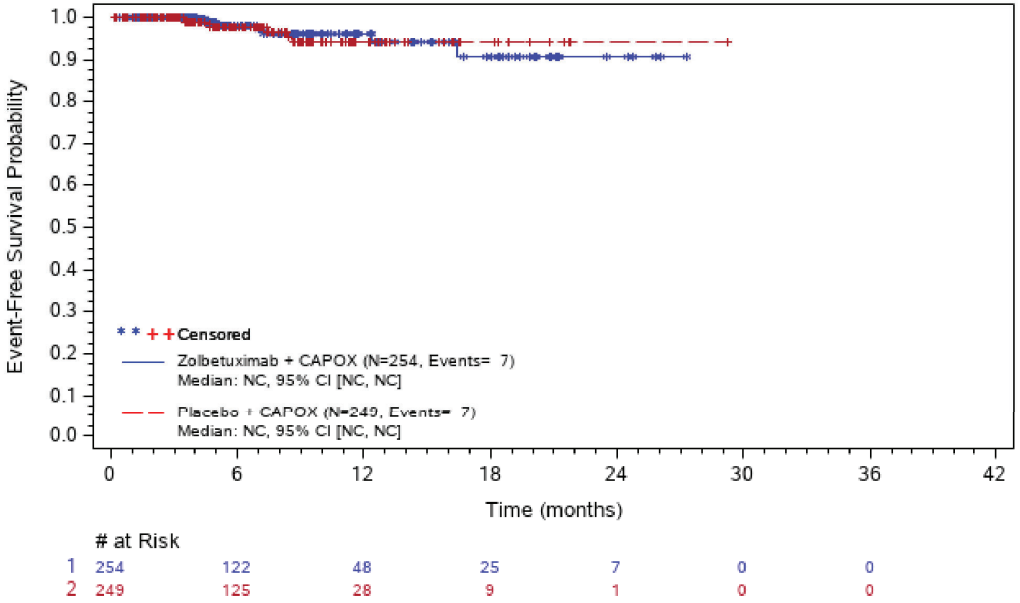
Figure 302.1.2001.194: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.195: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Neutropenia (AESI) - Safety Analysis Set

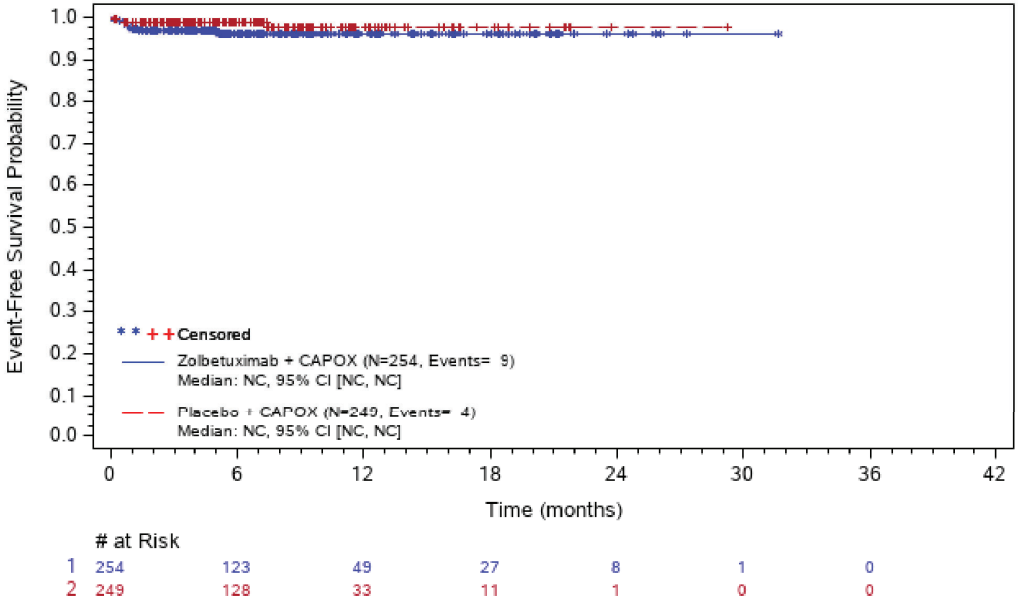


# at Risk							
1	254	122	48	25	7	0	0
2	249	125	28	9	1	0	0

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: 07OCT22

The SAS System

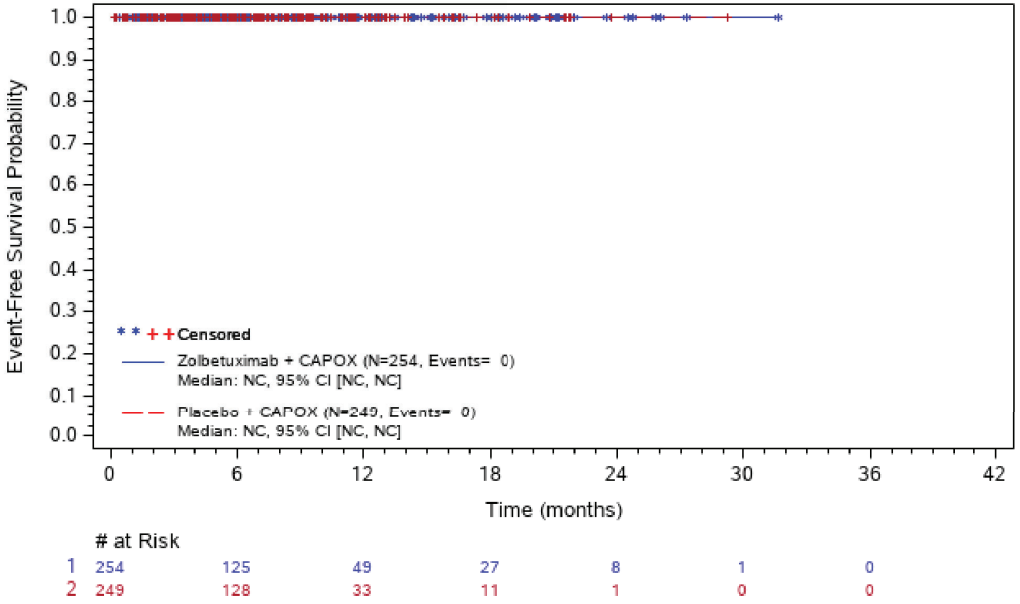
Figure 302.1.2001.196: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.218: Kaplan-Meier Plot of Time to first TEAE leading to Death - Abdominal Pain (AESI) - Safety Analysis Set

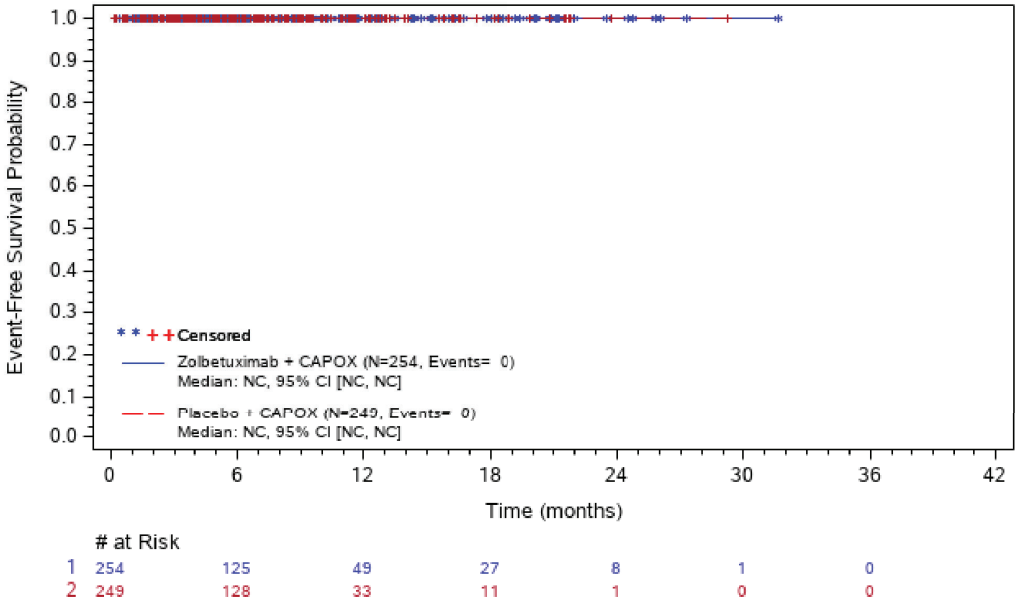


	# at Risk						
1	254	125	49	27	8	1	0
2	249	128	33	11	1	0	0

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: 07OCT22

The SAS System

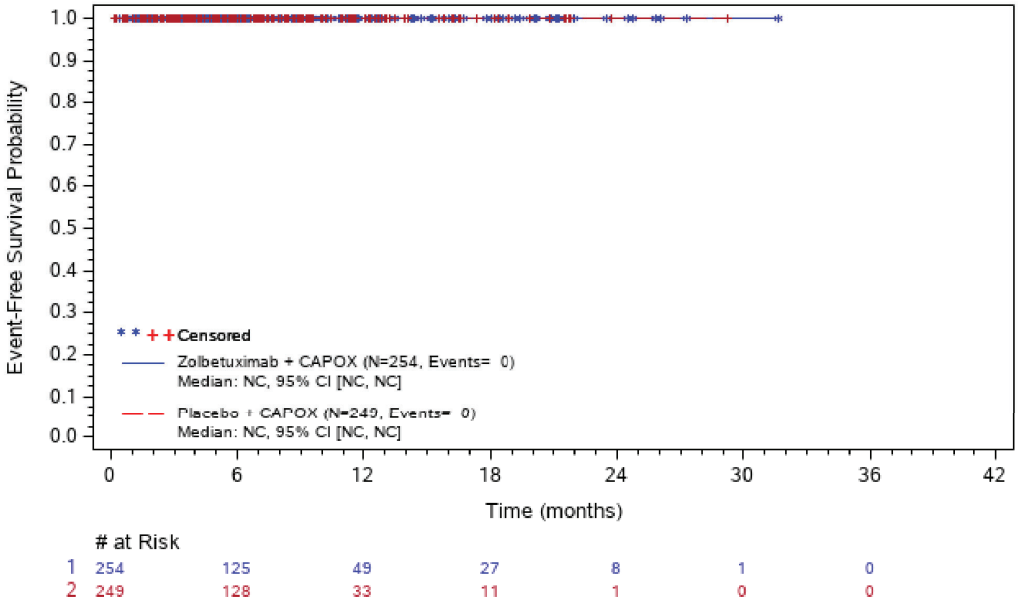
Figure 302.1.2001.219: Kaplan-Meier Plot of Time to first TEAE leading to Death - Anemia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

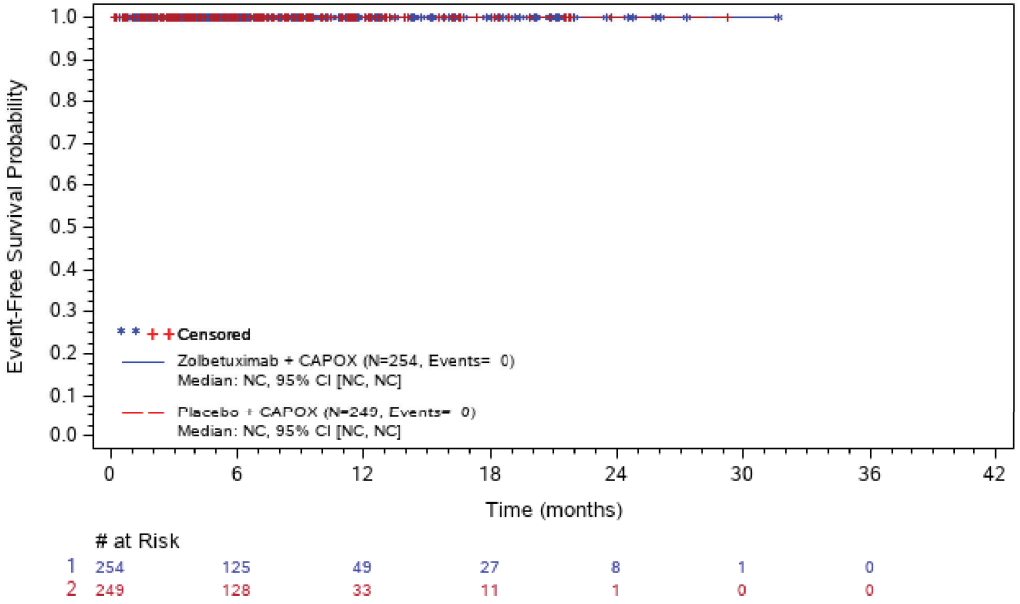
Figure 302.1.2001.220: Kaplan-Meier Plot of Time to first TEAE leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

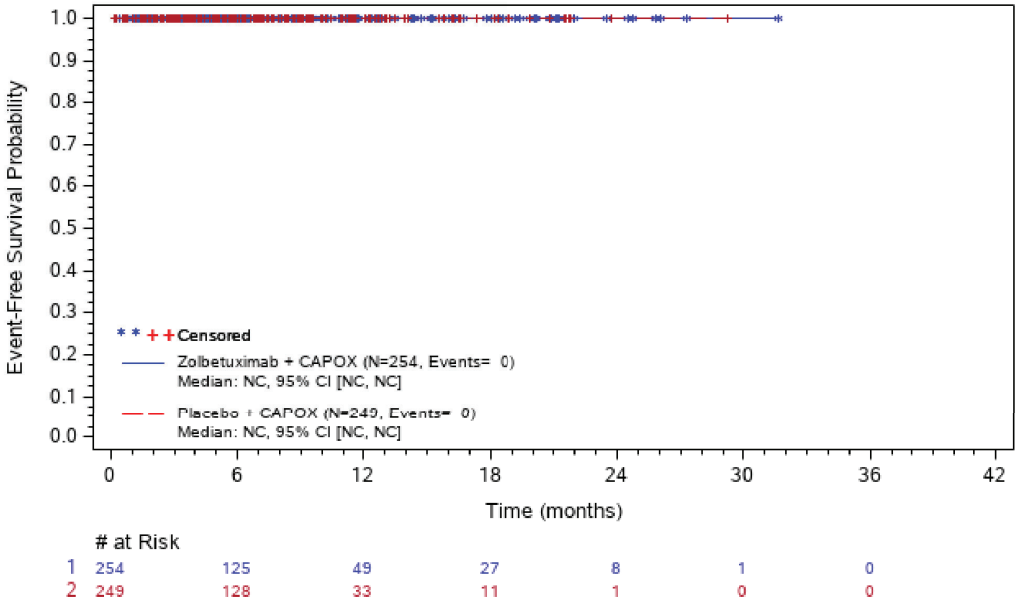
Figure 302.1.2001.221: Kaplan-Meier Plot of Time to first TEAE leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

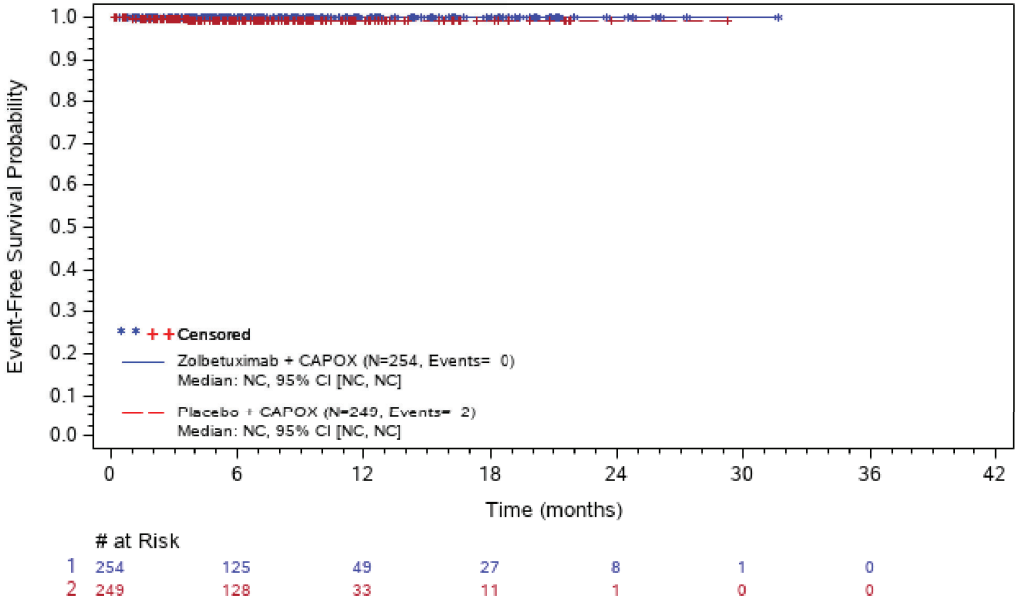
Figure 302.1.2001.222: Kaplan-Meier Plot of Time to first TEAE leading to Death - Nausea (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

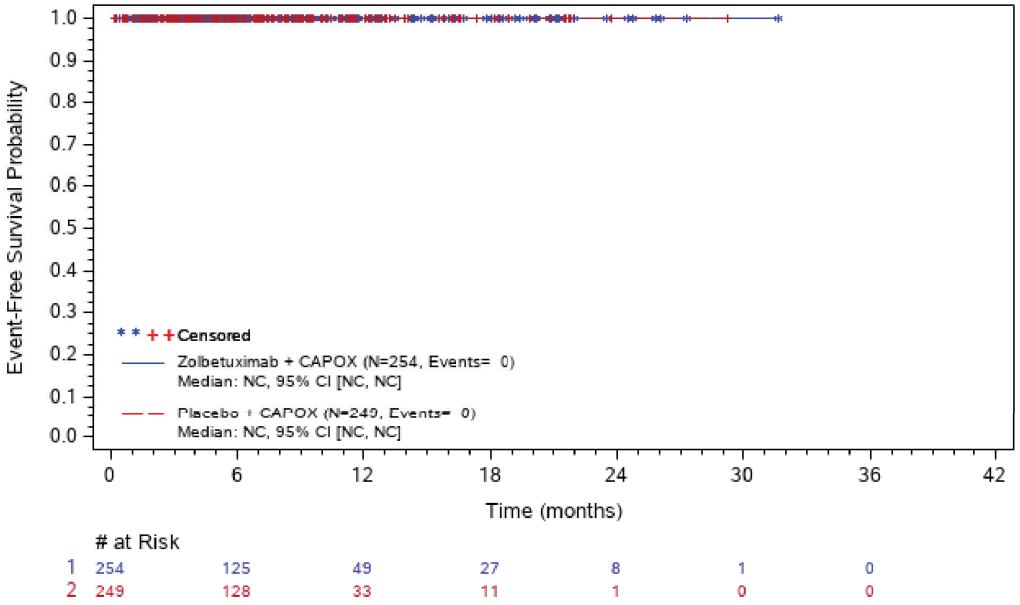
Figure 302.1.2001.223: Kaplan-Meier Plot of Time to first TEAE leading to Death - Neutropenia (AESI) - Safety Analysis Set



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: 07OCT22

The SAS System

Figure 302.1.2001.224: 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022

Anhang 4-G1 Weitere Analysen

Anhang 4-G1 Beobachtungsdauern

Table 302.1.1001.2.1: Summary of Duration of Observation Time of Overall Survival - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	254	253
Mean (SD)	11.7 (7.30)	10.9 (6.95)
Median	10.8	9.9
Q1-Q3	6.4 - 16.5	5.5 - 15.4
Range	0 - 36	0 - 34

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: 07OCT22

Table 302.1.1001.2.2: Summary of Duration of Observation Time of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	254	253
Mean (SD)	7.2 (6.05)	6.3 (4.60)
Median	6.1	6.0
Q1-Q3	2.7 - 9.2	2.9 - 8.3
Range	0 - 29	0 - 30

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: 07OCT22

Table 302.1.1001.2.3: Summary of Duration of Observation Time of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	254	253
Mean (SD)	7.0 (6.00)	6.3 (4.70)
Median	5.9	5.4
Q1-Q3	2.3 - 9.0	3.1 - 8.3
Range	0 - 29	0 - 26

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: 07OCT22

Table 302.1.3000.1: EORTC QLQ-C30 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	251	249
Mean (SD)	7.5 (6.45)	7.1 (4.98)
Median	6.2	6.5
Q1-Q3	2.8 - 10.2	3.4 - 9.3
Range	0 - 31	0 - 29

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: 07OCT22

Table 302.1.3000.2: EORTC QLQ-OG25 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	251	249
Mean (SD)	7.5 (6.45)	7.0 (4.98)
Median	6.2	6.5
Q1-Q3	2.8 - 10.2	3.4 - 9.3
Range	0 - 31	0 - 29

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: 07OCT22

Table 302.1.3000.3: EQ-5D Visual Analog Scale - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	251	249
Mean (SD)	7.5 (6.44)	7.1 (4.98)
Median	6.2	6.5
Q1-Q3	2.8 - 10.2	3.4 - 9.3
Range	0 - 31	0 - 29

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: 07OCT22

Table 302.1.3000.4: Global Pain - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	251	249
Mean (SD)	7.5 (6.45)	7.0 (4.98)
Median	6.2	6.5
Q1-Q3	2.8 - 10.2	3.4 - 9.3
Range	0 - 31	0 - 29

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: 07OCT22

Table 302.1.3000.5: EORTC QLQ-STO22 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	251	249
Mean (SD)	7.5 (6.45)	7.0 (4.98)
Median	6.2	6.5
Q1-Q3	2.8 - 10.2	3.4 - 9.3
Range	0 - 31	0 - 29

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for EORTC QLQ-STO22 questionnaire includes the time from randomisation until the last date data were collected for EORTC QLQ-STO22 questionnaire.
ASTELLAS Data Cutoff Date: 07OCT22

Table 302.1.2000.6.1: Summary of Duration of Observation Time for Safety Endpoints - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Duration of observation period (months)		
n	254	249
Mean (SD)	9.2 (5.97)	8.7 (4.96)
Median	7.9	7.9
Q1-Q3	4.4 - 11.5	5.2 - 11.3
Range	0 - 31	0 - 30

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: 07OCT22

Table 302.1.2000.6.2: Summary of Duration of Observation Time for any TEAE - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Duration of observation period (months)		
n	254	249
Mean (SD)	7.9 (6.10)	7.4 (4.82)
Median	6.2	6.6
Q1-Q3	3.2 - 10.2	3.7 - 9.4
Range	0 - 31	0 - 30

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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Weitere Analysen
Anhang 4-G1 Begleitmedikationen

Table 302.1.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Overall	247 (97.2%)	246 (97.2%)
Agents Acting On The Renin-Angiotensin System	40 (15.7%)	28 (11.1%)
All Other Therapeutic Products	15 (5.9%)	13 (5.1%)
Analgesics	116 (45.7%)	121 (47.8%)
Anesthetics	17 (6.7%)	7 (2.8%)
Anti-Acne Preparations	0	2 (0.8%)
Anti-Parkinson Drugs	0	1 (0.4%)
Antianemic Preparations	54 (21.3%)	66 (26.1%)
Antibacterials For Systemic Use	64 (25.2%)	52 (20.6%)
Antibiotics And Chemotherapeutics For Dermatological Use	12 (4.7%)	11 (4.3%)
Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents	68 (26.8%)	72 (28.5%)
Antiemetics And Antinauseants	207 (81.5%)	187 (73.9%)
Antiepileptics	1 (0.4%)	0
Antifungals For Dermatological Use	4 (1.6%)	5 (2.0%)
Antigout Preparations	4 (1.6%)	12 (4.7%)
Antihemorrhagics	32 (12.6%)	24 (9.5%)
Antihistamines For Systemic Use	87 (34.3%)	59 (23.3%)
Antihypertensives	1 (0.4%)	3 (1.2%)
Antiinflammatory And Antirheumatic Products	40 (15.7%)	46 (18.2%)
Antimycobacterials	1 (0.4%)	1 (0.4%)
Antimycotics For Systemic Use	0	4 (1.6%)
Antineoplastic Agents	2 (0.8%)	0
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	11 (4.3%)	5 (2.0%)
Antiseptics And Disinfectants	2 (0.8%)	1 (0.4%)
Antithrombotic Agents	43 (16.9%)	34 (13.4%)
Antivirals For Systemic Use	7 (2.8%)	4 (1.6%)
Appetite Stimulants	27 (10.6%)	28 (11.1%)
Beta Blocking Agents	11 (4.3%)	14 (5.5%)
Bile And Liver Therapy	51 (20.1%)	40 (15.8%)
Blood Substitutes And Perfusion Solutions	86 (33.9%)	71 (28.1%)
Calcium Channel Blockers	33 (13.0%)	27 (10.7%)
Cardiac Therapy	12 (4.7%)	14 (5.5%)
Contrast Media	2 (0.8%)	3 (1.2%)
Corticosteroids For Systemic Use	100 (39.4%)	72 (28.5%)
Corticosteroids, Dermatological Preparations	22 (8.7%)	14 (5.5%)
Cough And Cold Preparations	9 (3.5%)	17 (6.7%)
Diagnostic Agents	0	1 (0.4%)

Therapeutic Subgroup	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Digestives, Incl. Enzymes	7 (2.8%)	14 (5.5%)
Diuretics	39 (15.4%)	34 (13.4%)
Drugs For Acid Related Disorders	195 (76.8%)	171 (67.6%)
Drugs For Constipation	64 (25.2%)	92 (36.4%)
Drugs For Functional Gastrointestinal Disorders	77 (30.3%)	66 (26.1%)
Drugs For Obstructive Airway Diseases	15 (5.9%)	13 (5.1%)
Drugs For Treatment Of Bone Diseases	11 (4.3%)	7 (2.8%)
Drugs Used In Diabetes	31 (12.2%)	28 (11.1%)
Emollients And Protectives	29 (11.4%)	37 (14.6%)
General Nutrients	37 (14.6%)	36 (14.2%)
Gynecological Antiinfectives And Antiseptics	1 (0.4%)	1 (0.4%)
Immune Sera And Immunoglobulins	0	1 (0.4%)
Immunostimulants	66 (26.0%)	45 (17.8%)
Immunosuppressants	0	1 (0.4%)
Lipid Modifying Agents	28 (11.0%)	23 (9.1%)
Mineral Supplements	48 (18.9%)	31 (12.3%)
Muscle Relaxants	5 (2.0%)	13 (5.1%)
Nasal Preparations	2 (0.8%)	2 (0.8%)
Ophthalmologicals	7 (2.8%)	6 (2.4%)
Other Alimentary Tract And Metabolism Products	11 (4.3%)	13 (5.1%)
Other Dermatological Preparations	7 (2.8%)	6 (2.4%)
Other Drugs For Disorders Of The Musculo-Skeletal System	1 (0.4%)	0
Other Gynecologicals	0	1 (0.4%)
Other Hematological Agents	1 (0.4%)	4 (1.6%)
Other Nervous System Drugs	18 (7.1%)	9 (3.6%)
Pituitary And Hypothalamic Hormones And Analogues	4 (1.6%)	3 (1.2%)
Preparations For Treatment Of Wounds And Ulcers	4 (1.6%)	2 (0.8%)
Psychoanaleptics	16 (6.3%)	16 (6.3%)
Psycholeptics	89 (35.0%)	81 (32.0%)
Sex Hormones And Modulators Of The Genital System	2 (0.8%)	3 (1.2%)
Stomatological Preparations	17 (6.7%)	12 (4.7%)
Throat Preparations	5 (2.0%)	9 (3.6%)
Thyroid Therapy	10 (3.9%)	5 (2.0%)
Tonics	0	2 (0.8%)
Topical Products For Joint And Muscular Pain	7 (2.8%)	3 (1.2%)
Unspecified Herbal And Traditional Medicine	8 (3.1%)	12 (4.7%)
Urologicals	14 (5.5%)	15 (5.9%)
Vaccines	17 (6.7%)	20 (7.9%)
Vasoprotectives	20 (7.9%)	10 (4.0%)
Vitamins	59 (23.2%)	40 (15.8%)

Therapeutic Subgroup	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Weitere Analysen
Anhang 4-G1 Studienmedikation - Exposition

Table 302.1.1001.6: Summary of Study Drug Exposure - Safety Analysis Set

	Zolbetuximab + CAPOX (N=253)	**Placebo + CAPOX (N=250)**
Duration of Zolbetuximab/Placebo (days)		
n	252	250
Mean (SD)	195.0 (192.2)	176.6 (148.1)
Median	134.0	148.5
Range	1 - 933	1 - 848
Duration of Oxaliplatin (days)		
n	249	250
Mean (SD)	110.1 (62.02)	110.5 (58.85)
Median	123.0	119.5
Range	1 - 240	1 - 223
Duration of Capecitabine (days)		
n	247	250
Mean (SD)	189.8 (167.3)	170.6 (134.5)
Median	141.0	141.0
Range	1 - 757	1 - 862

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 + CAPOX components: Zolbetuximab, Oxaliplatin and Capecitabine.
Placebo + CAPOX components: Placebo, Oxaliplatin and Capecitabine.
ASTELLAS Data Cutoff Date: 07OCT22

Anhang 4-*G1 Post hoc* Analysen für die Studie GLOW, primärer Datenschnitt 07.10.2022
Anhang 4-G1 Weitere Analysen
Anhang 4-G1 Patientenfluss

Table 302.1.1001.7: Summary of Disposition of Subjects

	Zolbetuximab + CAPOX	Placebo + CAPOX	Total
Number of Subjects with Informed Consent			2333
Discontinued Before Randomization to Treatment			1826 (78.3%)
Randomized to Treatment			507 (21.7%)
Number of Randomized Patients	254	253	507
Safety Analysis Set [1]	254 (100.0%)	249 (98.4%)	503 (99.2%)
Full Analysis Set	254 (100.0%)	253 (100.0%)	507 (100.0%)
Pharmacokinetics Analysis Set	245 (96.5%)	0	245 (48.3%)
Overall Treatment Discontinuation [2]			
Yes	212 (83.5%)	217 (85.8%)	429 (84.6%)
No	42 (16.5%)	36 (14.2%)	78 (15.4%)
Reason for Overall Treatment Discontinuation [3]			
Adverse Event	29 (11.4%)	16 (6.3%)	45 (8.9%)
Death	23 (9.1%)	20 (7.9%)	43 (8.5%)
Lost to Follow-Up	1 (0.4%)	1 (0.4%)	2 (0.4%)
Other	30 (11.8%)	20 (7.9%)	50 (9.9%)
Pregnancy	0	0	0
Progressive Disease	99 (39.0%)	144 (56.9%)	243 (47.9%)
Protocol Deviation	2 (0.8%)	1 (0.4%)	3 (0.6%)
Withdrawal by Subject	37 (14.6%)	22 (8.7%)	59 (11.6%)
Post-Treatment Follow-Up Discontinuation			
Yes	203 (79.9%)	218 (86.2%)	421 (83.0%)
No	51 (20.1%)	35 (13.8%)	86 (17.0%)
Primary Post-Treatment Follow-Up Status			
Adverse Event	1 (0.4%)	2 (0.8%)	3 (0.6%)
Death	84 (33.1%)	100 (39.5%)	184 (36.3%)
Lost to Follow-Up	4 (1.6%)	1 (0.4%)	5 (1.0%)
Other	30 (11.8%)	32 (12.6%)	62 (12.2%)
Pregnancy	0	0	0
Progressive Disease	47 (18.5%)	61 (24.1%)	108 (21.3%)
Protocol Deviation	2 (0.8%)	0	2 (0.4%)
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	35 (13.8%)	22 (8.7%)	57 (11.2%)
Survival Follow-Up Discontinuation			
Yes	174 (68.5%)	196 (77.5%)	370 (73.0%)
No	80 (31.5%)	57 (22.5%)	137 (27.0%)

	Zolbetuximab + CAPOX	Placebo + CAPOX	Total
Primary Survival Follow-Up Status			
Death	142 (55.9%)	170 (67.2%)	312 (61.5%)
Lost to Follow-Up	3 (1.2%)	1 (0.4%)	4 (0.8%)
Other	2 (0.8%)	1 (0.4%)	3 (0.6%)
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	27 (10.6%)	24 (9.5%)	51 (10.1%)

[1] All subjects who received at least one dose of any study drug (Zolbetuximab/Placebo/CAPOX). If a subject received at least one dose of zolbetuximab, the subject is counted under the zolbetuximab arm.
[2] Of both treatments.
[3] 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: 07OCT22

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024

Anhang 4-G1 Baseline Charakteristika

Table 302.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Sex		
Male	159 (62.6%)	156 (61.7%)
Female	95 (37.4%)	97 (38.3%)
Unknown	0	0
Age (years)		
n	254	253
Mean (SD)	58.56 (12.09)	56.67 (13.04)
Median	61.0	59.0
Range	22.0 - 82.0	21.0 - 83.0
Age (years)		
>=18 to <=64	167 (65.7%)	173 (68.4%)
>=65 to <85	87 (34.3%)	80 (31.6%)
Age Group 1 (years)		
<=65	176 (69.3%)	180 (71.1%)
>65	78 (30.7%)	73 (28.9%)
Age Group 2 (years)		
<=75	242 (95.3%)	239 (94.5%)
>75	12 (4.7%)	14 (5.5%)
Race		
White	94 (37.3%)	90 (36.3%)
Black or African American	0	0
Asian	158 (62.7%)	158 (63.7%)
American Indian or Alaska Native	0	0
Native Hawaiian or Other Pacific Islander	0	0
Other	0	0
Missing	2	5

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: 12JAN24

Table 302.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Ethnicity		
Hispanic or Latino	10 (4.0%)	7 (2.8%)
Not Hispanic or Latino	242 (96.0%)	241 (97.2%)
Missing	2	5
Country 1		
Japan	24 (9.4%)	27 (10.7%)
Non-Japan	230 (90.6%)	226 (89.3%)
Country 2		
China	76 (29.9%)	69 (27.3%)
Non-China	178 (70.1%)	184 (72.7%)
Height (cm)		
n	253	250
Mean (SD)	164.66 (8.68)	165.11 (8.52)
Median	165.0	165.0
Range	145.0 - 189.0	141.5 - 189.0
Weight (kg)		
n	253	250
Mean (SD)	61.60 (13.60)	60.17 (12.73)
Median	60.5	59.6
Range	35.5 - 111.2	29.1 - 100.0
BMI (kg/m^2)		
<18.5	38 (15.0%)	42 (16.8%)
>=18.5 to <25	145 (57.3%)	154 (61.6%)
>=25 to <30	59 (23.3%)	49 (19.6%)
>=30	11 (4.3%)	5 (2.0%)
Missing	1	3

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: 12JAN24

Table 302.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
BSA (m^2)		
n	253	250
Mean (SD)	1.67 (0.20)	1.65 (0.20)
Median	1.7	1.6
Range	1.2 - 2.3	1.1 - 2.3
BSA (m^2)		
<1.7	134 (53.0%)	146 (58.4%)
>=1.7	119 (47.0%)	104 (41.6%)
Missing	1	3
Tobacco History		
Never	128 (51.2%)	132 (53.0%)
Current	32 (12.8%)	33 (13.3%)
Former	90 (36.0%)	84 (33.7%)
Missing	4	4
Baseline ECOG Status		
0	108 (42.7%)	108 (43.2%)
>=1	145 (57.3%)	142 (56.8%)
Missing	1	3
Region (IRT)		
Asia	157 (61.8%)	158 (62.5%)
Non-Asia	97 (38.2%)	95 (37.5%)
Region (eCRF)		
Asia	157 (61.8%)	158 (62.5%)
Non-Asia	97 (38.2%)	95 (37.5%)
Number of Organs with Metastatic Sites (IRT)		
0-2	189 (74.4%)	188 (74.3%)

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: 12JAN24

Table 302.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
>=3	65 (25.6%)	65 (25.7%)
Number of Organs with Metastatic Sites (eCRF)		
0-2	186 (73.2%)	186 (73.5%)
>=3	68 (26.8%)	67 (26.5%)
Prior Gastrectomy (IRT)		
Yes	75 (29.5%)	75 (29.6%)
No	179 (70.5%)	178 (70.4%)
Prior Gastrectomy (eCRF)		
Yes	73 (28.7%)	66 (26.1%)
No	181 (71.3%)	187 (73.9%)
CPS Status		
<5	129 (50.8%)	128 (50.6%)
>=5	35 (13.8%)	40 (15.8%)
Unknown	90 (35.4%)	85 (33.6%)

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: 12JAN24

Table 302.3.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Medical Condition	Gastric Adenocarcinoma	219 (86.2%)	209 (82.6%)
	Gastro-Esophageal Junction Adenocarcinoma	35 (13.8%)	44 (17.4%)
Duration Since Initial Diagnosis (days)	n	242	246
	Mean (SD)	230.17 (461.97)	243.02 (609.48)
	Median	44.0	43.5
	Range	12 - 2396	2 - 6010
Tumor Location			
All	Proximal	88 (34.6%)	94 (37.2%)
	Distal	100 (39.4%)	96 (37.9%)
	Unknown	66 (26.0%)	63 (24.9%)
Gastric	n	219	209
	Proximal	73 (33.3%)	73 (34.9%)
	Distal	90 (41.1%)	83 (39.7%)
	Unknown	56 (25.6%)	53 (25.4%)
GEJ	n	35	44
	Proximal	15 (42.9%)	21 (47.7%)
	Distal	10 (28.6%)	13 (29.5%)
	Unknown	10 (28.6%)	10 (22.7%)
Tumor Type	Diffuse	87 (34.4%)	100 (39.5%)
	Intestinal	36 (14.2%)	41 (16.2%)
	Mixed	20 (7.9%)	21 (8.3%)
	Other	34 (13.4%)	27 (10.7%)
	Unknown	76 (30.0%)	64 (25.3%)
	Missing	1	0
Primary Tumor	TX	65 (25.6%)	47 (18.6%)
	T0	1 (0.4%)	0
	Tis	0	0
	T1	1 (0.4%)	1 (0.4%)
	T1a	0	2 (0.8%)
	T1b	1 (0.4%)	2 (0.8%)
	T2	20 (7.9%)	12 (4.7%)

Parameter	Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
	T3	63 (24.8%)	63 (24.9%)
	T4	36 (14.2%)	44 (17.4%)
	T4a	47 (18.5%)	62 (24.5%)
	T4b	20 (7.9%)	20 (7.9%)
Regional Lymph Nodes	NX	82 (32.3%)	64 (25.3%)
	N0	23 (9.1%)	25 (9.9%)
	N1	48 (18.9%)	39 (15.4%)
	N2	45 (17.7%)	51 (20.2%)
	N3	31 (12.2%)	47 (18.6%)
	N3a	15 (5.9%)	14 (5.5%)
	N3b	10 (3.9%)	13 (5.1%)
Distant Metastasis [1]	M0	59 (23.3%)	56 (22.1%)
	M1	194 (76.7%)	197 (77.9%)
	Missing	1	0
Tumor Metastatic [1]	Yes	222 (87.4%)	222 (87.7%)
	No	32 (12.6%)	31 (12.3%)
Metastasis Location	Abdominal Cavity	16 (6.3%)	9 (3.6%)
	Adrenal Gland	12 (4.7%)	10 (4.0%)
	Bile Duct	0	1 (0.4%)
	Bladder	2 (0.8%)	0
	Bone	18 (7.1%)	26 (10.3%)
	Colon	7 (2.8%)	4 (1.6%)
	Esophagus	0	1 (0.4%)
	Kidney	0	1 (0.4%)
	Liver	73 (28.7%)	57 (22.5%)
	Lung	18 (7.1%)	21 (8.3%)
	Lymph Node	131 (51.6%)	119 (47.0%)
	Mediastinum	3 (1.2%)	3 (1.2%)
	Neck	0	1 (0.4%)
	Omentum	10 (3.9%)	10 (4.0%)
	Other	11 (4.3%)	19 (7.5%)
	Ovary	21 (8.3%)	21 (8.3%)
	Pancreas	0	5 (2.0%)
	Pelvis	7 (2.8%)	2 (0.8%)
	Pericardium	2 (0.8%)	1 (0.4%)
	Peritoneum	83 (32.7%)	91 (36.0%)
	Pleura	8 (3.1%)	4 (1.6%)
	Rectum	0	2 (0.8%)

Parameter	Category/Statistic	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
	Retroperitoneum	3 (1.2%)	3 (1.2%)
	Skin	0	1 (0.4%)
	Small Intestine	3 (1.2%)	1 (0.4%)
	Spleen	1 (0.4%)	3 (1.2%)
	Stomach	5 (2.0%)	4 (1.6%)
	Testis	1 (0.4%)	0
History of Helicobacter pylori Infection	Yes	44 (17.3%)	35 (13.8%)
	No	102 (40.2%)	114 (45.1%)
	Unknown	108 (42.5%)	104 (41.1%)
Barrett's Esophagus Diagnosed	Yes	4 (1.6%)	3 (1.2%)
	No	150 (59.1%)	163 (64.4%)
	Unknown	100 (39.4%)	87 (34.4%)
CLDN18.2 Testing Result	<75%	0	0
	>=75%	254 (100.0%)	253 (100.0%)
	Not Applicable	0	0
HER2 Status	Positive	0	0
	Negative	254 (100.0%)	253 (100.0%)
	Not Applicable	0	0
Measurable Disease based on Central	Yes	195 (76.8%)	204 (80.6%)
	No	59 (23.2%)	49 (19.4%)
Measurable Disease based on Local	Yes	206 (81.1%)	209 (82.6%)
	No	48 (18.9%)	44 (17.4%)

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Overall	214 (84.3%)	214 (84.6%)	428 (84.4%)
Blood And Lymphatic System Disorders	44 (17.3%)	56 (22.1%)	100 (19.7%)
Anaemia	36 (14.2%)	54 (21.3%)	90 (17.8%)
Iron Deficiency Anaemia	3 (1.2%)	2 (0.8%)	5 (1.0%)
Hypocoagulable State	0	3 (1.2%)	3 (0.6%)
Thrombocytopenia	3 (1.2%)	0	3 (0.6%)
Lymphadenopathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Splenomegaly	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal Lymphadenopathy	0	1 (0.4%)	1 (0.2%)
Coagulopathy	0	1 (0.4%)	1 (0.2%)
Hilar Lymphadenopathy	1 (0.4%)	0	1 (0.2%)
Lymphadenopathy Mediastinal	1 (0.4%)	0	1 (0.2%)
Mastocytosis	1 (0.4%)	0	1 (0.2%)
Pernicious Anaemia	1 (0.4%)	0	1 (0.2%)
Thrombocytosis	1 (0.4%)	0	1 (0.2%)
Cardiac Disorders	27 (10.6%)	22 (8.7%)	49 (9.7%)
Coronary Artery Disease	8 (3.1%)	2 (0.8%)	10 (2.0%)
Sinus Bradycardia	6 (2.4%)	3 (1.2%)	9 (1.8%)
Atrial Fibrillation	2 (0.8%)	3 (1.2%)	5 (1.0%)
Myocardial Ischaemia	3 (1.2%)	2 (0.8%)	5 (1.0%)
Angina Pectoris	1 (0.4%)	3 (1.2%)	4 (0.8%)
Arrhythmia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Supraventricular Extrasystoles	1 (0.4%)	3 (1.2%)	4 (0.8%)
Cardiac Failure Chronic	1 (0.4%)	2 (0.8%)	3 (0.6%)
Tachycardia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Arteriosclerosis Coronary Artery	2 (0.8%)	0	2 (0.4%)
Pericardial Effusion	2 (0.8%)	0	2 (0.4%)
Aortic Valve Stenosis	0	1 (0.4%)	1 (0.2%)
Atrioventricular Block First Degree	0	1 (0.4%)	1 (0.2%)
Bradycardia	0	1 (0.4%)	1 (0.2%)
Bundle Branch Block Right	0	1 (0.4%)	1 (0.2%)
Cardiac Failure Congestive	1 (0.4%)	0	1 (0.2%)
Cardiomyopathy	1 (0.4%)	0	1 (0.2%)
Coronary Artery Occlusion	1 (0.4%)	0	1 (0.2%)
Defect Conduction Intraventricular	1 (0.4%)	0	1 (0.2%)
Left Ventricular Hypertrophy	1 (0.4%)	0	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Myocardial Hypoxia	1 (0.4%)	0	1 (0.2%)
Myocardial Injury	0	1 (0.4%)	1 (0.2%)
Prinzmetal Angina	1 (0.4%)	0	1 (0.2%)
Sinus Tachycardia	0	1 (0.4%)	1 (0.2%)
Ventricular Arrhythmia	0	1 (0.4%)	1 (0.2%)
Congenital, Familial And Genetic Disorders	7 (2.8%)	2 (0.8%)	9 (1.8%)
Thalassaemia Minor	2 (0.8%)	0	2 (0.4%)
Adrenogenital Syndrome	1 (0.4%)	0	1 (0.2%)
Albinism	1 (0.4%)	0	1 (0.2%)
Cataract Congenital	0	1 (0.4%)	1 (0.2%)
Hydrocele	1 (0.4%)	0	1 (0.2%)
Oesophageal Atresia	0	1 (0.4%)	1 (0.2%)
Polycystic Liver Disease	1 (0.4%)	0	1 (0.2%)
Retinitis Pigmentosa	1 (0.4%)	0	1 (0.2%)
Ear And Labyrinth Disorders	3 (1.2%)	1 (0.4%)	4 (0.8%)
Vertigo	2 (0.8%)	0	2 (0.4%)
Deafness	0	1 (0.4%)	1 (0.2%)
Deafness Unilateral	1 (0.4%)	0	1 (0.2%)
Endocrine Disorders	14 (5.5%)	9 (3.6%)	23 (4.5%)
Hypothyroidism	8 (3.1%)	4 (1.6%)	12 (2.4%)
Hyperthyroidism	2 (0.8%)	1 (0.4%)	3 (0.6%)
Goitre	1 (0.4%)	1 (0.4%)	2 (0.4%)
Thyroid Mass	1 (0.4%)	1 (0.4%)	2 (0.4%)
Autoimmune Thyroiditis	0	1 (0.4%)	1 (0.2%)
Hyperplasia Adrenal	1 (0.4%)	0	1 (0.2%)
Primary Hypothyroidism	1 (0.4%)	0	1 (0.2%)
Thyroid Disorder	0	1 (0.4%)	1 (0.2%)
Eye Disorders	5 (2.0%)	9 (3.6%)	14 (2.8%)
Cataract	2 (0.8%)	3 (1.2%)	5 (1.0%)
Glaucoma	2 (0.8%)	3 (1.2%)	5 (1.0%)
Age-Related Macular Degeneration	0	1 (0.4%)	1 (0.2%)
Lacrimation Increased	1 (0.4%)	0	1 (0.2%)
Narrow Anterior Chamber Angle	0	1 (0.4%)	1 (0.2%)
Optic Atrophy	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Disorders	111 (43.7%)	107 (42.3%)	218 (43.0%)
Abdominal Pain	29 (11.4%)	28 (11.1%)	57 (11.2%)
Constipation	27 (10.6%)	25 (9.9%)	52 (10.3%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Abdominal Pain Upper	21 (8.3%)	15 (5.9%)	36 (7.1%)
Abdominal Distension	15 (5.9%)	15 (5.9%)	30 (5.9%)
Gastrooesophageal Reflux Disease	12 (4.7%)	11 (4.3%)	23 (4.5%)
Nausea	9 (3.5%)	13 (5.1%)	22 (4.3%)
Dyspepsia	8 (3.1%)	9 (3.6%)	17 (3.4%)
Chronic Gastritis	8 (3.1%)	8 (3.2%)	16 (3.2%)
Dysphagia	7 (2.8%)	7 (2.8%)	14 (2.8%)
Gastric Ulcer	7 (2.8%)	6 (2.4%)	13 (2.6%)
Vomiting	5 (2.0%)	6 (2.4%)	11 (2.2%)
Ascites	5 (2.0%)	5 (2.0%)	10 (2.0%)
Haemorrhoids	4 (1.6%)	5 (2.0%)	9 (1.8%)
Diarrhoea	5 (2.0%)	1 (0.4%)	6 (1.2%)
Eructation	4 (1.6%)	2 (0.8%)	6 (1.2%)
Duodenal Ulcer	1 (0.4%)	4 (1.6%)	5 (1.0%)
Flatulence	3 (1.2%)	2 (0.8%)	5 (1.0%)
Gastritis	2 (0.8%)	3 (1.2%)	5 (1.0%)
Inguinal Hernia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Abdominal Discomfort	3 (1.2%)	0	3 (0.6%)
Abdominal Pain Lower	2 (0.8%)	1 (0.4%)	3 (0.6%)
Barrett's Oesophagus	2 (0.8%)	1 (0.4%)	3 (0.6%)
Large Intestine Polyp	2 (0.8%)	1 (0.4%)	3 (0.6%)
Regurgitation	0	3 (1.2%)	3 (0.6%)
Diverticulum Intestinal	2 (0.8%)	0	2 (0.4%)
Functional Gastrointestinal Disorder	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gastritis Erosive	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hiatus Hernia	2 (0.8%)	0	2 (0.4%)
Intestinal Obstruction	0	2 (0.8%)	2 (0.4%)
Obstruction Gastric	1 (0.4%)	1 (0.4%)	2 (0.4%)
Peptic Ulcer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Upper Gastrointestinal Haemorrhage	2 (0.8%)	0	2 (0.4%)
Abdominal Wall Mass	0	1 (0.4%)	1 (0.2%)
Bezoar	0	1 (0.4%)	1 (0.2%)
Breath Odour	1 (0.4%)	0	1 (0.2%)
Diverticulum	0	1 (0.4%)	1 (0.2%)
Dry Mouth	0	1 (0.4%)	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Dyschezia	1 (0.4%)	0	1 (0.2%)
Epigastric Discomfort	1 (0.4%)	0	1 (0.2%)
Gastric Perforation	1 (0.4%)	0	1 (0.2%)
Gastric Polyps	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Disorder	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Haemorrhage	1 (0.4%)	0	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Gastrointestinal Stenosis	0	1 (0.4%)	1 (0.2%)
Large Intestinal Obstruction	0	1 (0.4%)	1 (0.2%)
Large Intestinal Stenosis	0	1 (0.4%)	1 (0.2%)
Mallory-Weiss Syndrome	0	1 (0.4%)	1 (0.2%)
Pancreatitis Acute	0	1 (0.4%)	1 (0.2%)
Pancreatitis Chronic	0	1 (0.4%)	1 (0.2%)
Periodontal Disease	0	1 (0.4%)	1 (0.2%)
Proctalgia	1 (0.4%)	0	1 (0.2%)
Rectal Prolapse	0	1 (0.4%)	1 (0.2%)
General Disorders And Administration Site Conditions	31 (12.2%)	13 (5.1%)	44 (8.7%)
Asthenia	14 (5.5%)	3 (1.2%)	17 (3.4%)
Pain	5 (2.0%)	3 (1.2%)	8 (1.6%)
Fatigue	3 (1.2%)	3 (1.2%)	6 (1.2%)
Oedema Peripheral	4 (1.6%)	0	4 (0.8%)
Chest Pain	2 (0.8%)	1 (0.4%)	3 (0.6%)
Early Satiety	3 (1.2%)	0	3 (0.6%)
Drug Intolerance	1 (0.4%)	1 (0.4%)	2 (0.4%)
Malaise	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gait Disturbance	0	1 (0.4%)	1 (0.2%)
Mucosal Inflammation	1 (0.4%)	0	1 (0.2%)
Non-Cardiac Chest Pain	1 (0.4%)	0	1 (0.2%)
Peripheral Swelling	0	1 (0.4%)	1 (0.2%)
Hepatobiliary Disorders	20 (7.9%)	19 (7.5%)	39 (7.7%)
Hepatic Cyst	9 (3.5%)	3 (1.2%)	12 (2.4%)
Cholelithiasis	5 (2.0%)	3 (1.2%)	8 (1.6%)
Cholecystitis	1 (0.4%)	3 (1.2%)	4 (0.8%)
Gallbladder Polyp	1 (0.4%)	3 (1.2%)	4 (0.8%)
Hepatic Function Abnormal	3 (1.2%)	1 (0.4%)	4 (0.8%)
Biliary Obstruction	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hepatic Steatosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Biliary Dilatation	0	1 (0.4%)	1 (0.2%)
Hepatic Calcification	1 (0.4%)	0	1 (0.2%)
Hepatic Cirrhosis	0	1 (0.4%)	1 (0.2%)
Hepatic Cytolysis	0	1 (0.4%)	1 (0.2%)
Hepatic Failure	0	1 (0.4%)	1 (0.2%)
Hepatitis	0	1 (0.4%)	1 (0.2%)
Jaundice	0	1 (0.4%)	1 (0.2%)
Jaundice Cholestatic	0	1 (0.4%)	1 (0.2%)
Portal Vein Thrombosis	0	1 (0.4%)	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Immune System Disorders	7 (2.8%)	5 (2.0%)	12 (2.4%)
Seasonal Allergy	1 (0.4%)	4 (1.6%)	5 (1.0%)
Drug Hypersensitivity	3 (1.2%)	1 (0.4%)	4 (0.8%)
Allergy To Plants	1 (0.4%)	0	1 (0.2%)
Hypersensitivity	1 (0.4%)	0	1 (0.2%)
Sarcoidosis	1 (0.4%)	0	1 (0.2%)
Infections And Infestations	29 (11.4%)	23 (9.1%)	52 (10.3%)
Appendicitis	3 (1.2%)	4 (1.6%)	7 (1.4%)
Pneumonia	4 (1.6%)	2 (0.8%)	6 (1.2%)
Helicobacter Infection	3 (1.2%)	2 (0.8%)	5 (1.0%)
Hepatitis B	2 (0.8%)	3 (1.2%)	5 (1.0%)
Bronchitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Biliary Tract Infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Covid-19	2 (0.8%)	0	2 (0.4%)
Fungal Oesophagitis	2 (0.8%)	0	2 (0.4%)
Hepatitis A	0	2 (0.8%)	2 (0.4%)
Oral Herpes	1 (0.4%)	1 (0.4%)	2 (0.4%)
Periodontitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pulmonary Tuberculosis	2 (0.8%)	0	2 (0.4%)
Bronchiolitis	1 (0.4%)	0	1 (0.2%)
Chronic Hepatitis B	1 (0.4%)	0	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Helicobacter Gastritis	0	1 (0.4%)	1 (0.2%)
Hepatitis C	0	1 (0.4%)	1 (0.2%)
Hepatitis Viral	0	1 (0.4%)	1 (0.2%)
Myelitis	0	1 (0.4%)	1 (0.2%)
Papilloma Viral Infection	0	1 (0.4%)	1 (0.2%)
Pneumonia Legionella	0	1 (0.4%)	1 (0.2%)
Poliomyelitis	1 (0.4%)	0	1 (0.2%)
Pyelonephritis Acute	1 (0.4%)	0	1 (0.2%)
Skin Infection	1 (0.4%)	0	1 (0.2%)
Syphilis	0	1 (0.4%)	1 (0.2%)
Viral Hepatitis Carrier	0	1 (0.4%)	1 (0.2%)
Injury, Poisoning And Procedural Complications	3 (1.2%)	5 (2.0%)	8 (1.6%)
Lower Limb Fracture	0	2 (0.8%)	2 (0.4%)
Chest Injury	1 (0.4%)	0	1 (0.2%)
Fall	1 (0.4%)	0	1 (0.2%)
Head Injury	1 (0.4%)	0	1 (0.2%)
Limb Injury	0	1 (0.4%)	1 (0.2%)
Meniscus Injury	1 (0.4%)	0	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Procedural Pain	1 (0.4%)	0	1 (0.2%)
Radiation Injury	0	1 (0.4%)	1 (0.2%)
Stoma Site Pain	0	1 (0.4%)	1 (0.2%)
Upper Limb Fracture	1 (0.4%)	0	1 (0.2%)
Wrist Fracture	1 (0.4%)	0	1 (0.2%)
Investigations	24 (9.4%)	30 (11.9%)	54 (10.7%)
Weight Decreased	10 (3.9%)	8 (3.2%)	18 (3.6%)
Aspartate Aminotransferase Increased	1 (0.4%)	5 (2.0%)	6 (1.2%)
Blood Alkaline Phosphatase Increased	0	6 (2.4%)	6 (1.2%)
Blood Cholesterol Increased	4 (1.6%)	2 (0.8%)	6 (1.2%)
Blood Creatinine Increased	0	4 (1.6%)	4 (0.8%)
Alanine Aminotransferase Increased	1 (0.4%)	2 (0.8%)	3 (0.6%)
Gamma-Glutamyltransferase Increased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lymphocyte Count Decreased	1 (0.4%)	2 (0.8%)	3 (0.6%)
Arthroscopy	1 (0.4%)	0	1 (0.2%)
Blood Bilirubin Increased	1 (0.4%)	0	1 (0.2%)
Blood Fibrinogen Increased	0	1 (0.4%)	1 (0.2%)
Blood Glucose Increased	1 (0.4%)	0	1 (0.2%)
Blood Thyroid Stimulating Hormone Increased	0	1 (0.4%)	1 (0.2%)
Blood Urea Increased	0	1 (0.4%)	1 (0.2%)
Carbohydrate Antigen 19-9 Increased	1 (0.4%)	0	1 (0.2%)
Electrocardiogram Abnormal	1 (0.4%)	0	1 (0.2%)
Electrocardiogram St-T Change	1 (0.4%)	0	1 (0.2%)
Electrocardiogram T Wave Abnormal	0	1 (0.4%)	1 (0.2%)
Fibrin D Dimer Increased	0	1 (0.4%)	1 (0.2%)
Gastric Ph Decreased	0	1 (0.4%)	1 (0.2%)
Lipoprotein Increased	0	1 (0.4%)	1 (0.2%)
Neutrophil Count Decreased	1 (0.4%)	0	1 (0.2%)
Paracentesis	1 (0.4%)	0	1 (0.2%)
Platelet Count Decreased	0	1 (0.4%)	1 (0.2%)
Sars-Cov-2 Test Positive	0	1 (0.4%)	1 (0.2%)
Vitamin B12 Decreased	0	1 (0.4%)	1 (0.2%)
Vitamin D Decreased	1 (0.4%)	0	1 (0.2%)
White Blood Cell Count	0	1 (0.4%)	1 (0.2%)
Metabolism And Nutrition Disorders	78 (30.7%)	78 (30.8%)	156 (30.8%)
Decreased Appetite	24 (9.4%)	22 (8.7%)	46 (9.1%)
Diabetes Mellitus	18 (7.1%)	17 (6.7%)	35 (6.9%)
Dyslipidaemia	17 (6.7%)	16 (6.3%)	33 (6.5%)
Type 2 Diabetes Mellitus	14 (5.5%)	11 (4.3%)	25 (4.9%)
Hyperuricaemia	4 (1.6%)	6 (2.4%)	10 (2.0%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Hypoalbuminaemia	6 (2.4%)	4 (1.6%)	10 (2.0%)
Gout	2 (0.8%)	7 (2.8%)	9 (1.8%)
Hyperlipidaemia	6 (2.4%)	1 (0.4%)	7 (1.4%)
Hypoproteinaemia	3 (1.2%)	4 (1.6%)	7 (1.4%)
Malnutrition	4 (1.6%)	2 (0.8%)	6 (1.2%)
Hypercholesterolaemia	1 (0.4%)	3 (1.2%)	4 (0.8%)
Hyponatraemia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Hyperglycaemia	1 (0.4%)	2 (0.8%)	3 (0.6%)
Vitamin B12 Deficiency	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hypocalcaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Iron Deficiency	0	2 (0.8%)	2 (0.4%)
Type 1 Diabetes Mellitus	1 (0.4%)	1 (0.4%)	2 (0.4%)
Feeding Disorder	1 (0.4%)	0	1 (0.2%)
Hypertriglyceridaemia	1 (0.4%)	0	1 (0.2%)
Hypoglycaemia	1 (0.4%)	0	1 (0.2%)
Hypokalaemia	1 (0.4%)	0	1 (0.2%)
Hypouricaemia	1 (0.4%)	0	1 (0.2%)
Obesity	1 (0.4%)	0	1 (0.2%)
Vitamin D Deficiency	0	1 (0.4%)	1 (0.2%)
Musculoskeletal And Connective Tissue Disorders	31 (12.2%)	29 (11.5%)	60 (11.8%)
Back Pain	13 (5.1%)	14 (5.5%)	27 (5.3%)
Osteoarthritis	6 (2.4%)	1 (0.4%)	7 (1.4%)
Arthralgia	2 (0.8%)	4 (1.6%)	6 (1.2%)
Intervertebral Disc Protrusion	1 (0.4%)	2 (0.8%)	3 (0.6%)
Musculoskeletal Chest Pain	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pain In Extremity	0	3 (1.2%)	3 (0.6%)
Spinal Stenosis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bone Pain	2 (0.8%)	0	2 (0.4%)
Osteopenia	2 (0.8%)	0	2 (0.4%)
Rheumatoid Arthritis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dupuytren's Contracture	0	1 (0.4%)	1 (0.2%)
Fibromyalgia	1 (0.4%)	0	1 (0.2%)
Gouty Arthritis	0	1 (0.4%)	1 (0.2%)
Intervertebral Disc Degeneration	1 (0.4%)	0	1 (0.2%)
Musculoskeletal Disorder	0	1 (0.4%)	1 (0.2%)
Neck Mass	1 (0.4%)	0	1 (0.2%)
Neck Pain	0	1 (0.4%)	1 (0.2%)
Osteoporosis	0	1 (0.4%)	1 (0.2%)
Periarthritis	1 (0.4%)	0	1 (0.2%)
Psoriatic Arthropathy	0	1 (0.4%)	1 (0.2%)
Rotator Cuff Syndrome	1 (0.4%)	0	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Spinal Osteoarthritis	0	1 (0.4%)	1 (0.2%)
Spinal Pain	0	1 (0.4%)	1 (0.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	31 (12.2%)	33 (13.0%)	64 (12.6%)
Cancer Pain	5 (2.0%)	12 (4.7%)	17 (3.4%)
Uterine Leiomyoma	6 (2.4%)	4 (1.6%)	10 (2.0%)
Prostate Cancer	3 (1.2%)	1 (0.4%)	4 (0.8%)
Benign Neoplasm Of Thyroid Gland	1 (0.4%)	2 (0.8%)	3 (0.6%)
Breast Cancer	3 (1.2%)	0	3 (0.6%)
Haemangioma Of Liver	2 (0.8%)	1 (0.4%)	3 (0.6%)
Metastases To Bone	3 (1.2%)	0	3 (0.6%)
Tumour Pain	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bladder Cancer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Colorectal Adenoma	2 (0.8%)	0	2 (0.4%)
Gastric Cancer	0	2 (0.8%)	2 (0.4%)
Haemangioma	1 (0.4%)	1 (0.4%)	2 (0.4%)
Adrenal Adenoma	0	1 (0.4%)	1 (0.2%)
Adrenal Neoplasm	1 (0.4%)	0	1 (0.2%)
Benign Lung Neoplasm	1 (0.4%)	0	1 (0.2%)
Bowen's Disease	0	1 (0.4%)	1 (0.2%)
Breast Cancer In Situ	1 (0.4%)	0	1 (0.2%)
Essential Thrombocythaemia	1 (0.4%)	0	1 (0.2%)
Follicular Lymphoma	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Tract Adenoma	1 (0.4%)	0	1 (0.2%)
Intraductal Papillary Mucinous Neoplasm	1 (0.4%)	0	1 (0.2%)
Leser-Trelat Sign	0	1 (0.4%)	1 (0.2%)
Lipoma	0	1 (0.4%)	1 (0.2%)
Lymphoma	0	1 (0.4%)	1 (0.2%)
Metastases To Peritoneum	1 (0.4%)	0	1 (0.2%)
Oesophageal Carcinoma	0	1 (0.4%)	1 (0.2%)
Oesophageal Neoplasm	1 (0.4%)	0	1 (0.2%)
Oropharyngeal Neoplasm	1 (0.4%)	0	1 (0.2%)
Ovarian Cancer	1 (0.4%)	0	1 (0.2%)
Ovarian Epithelial Cancer	1 (0.4%)	0	1 (0.2%)
Pyogenic Granuloma	0	1 (0.4%)	1 (0.2%)
Renal Cancer	1 (0.4%)	0	1 (0.2%)
Tongue Neoplasm Benign	0	1 (0.4%)	1 (0.2%)
Nervous System Disorders	17 (6.7%)	13 (5.1%)	30 (5.9%)
Migraine	1 (0.4%)	2 (0.8%)	3 (0.6%)
Hypoaesthesia	2 (0.8%)	0	2 (0.4%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Intracranial Aneurysm	2 (0.8%)	0	2 (0.4%)
Lethargy	0	2 (0.8%)	2 (0.4%)
Neuropathy Peripheral	2 (0.8%)	0	2 (0.4%)
Restless Legs Syndrome	1 (0.4%)	1 (0.4%)	2 (0.4%)
Anosmia	1 (0.4%)	0	1 (0.2%)
Carotid Arteriosclerosis	1 (0.4%)	0	1 (0.2%)
Carotid Artery Stenosis	1 (0.4%)	0	1 (0.2%)
Cerebellar Haemorrhage	1 (0.4%)	0	1 (0.2%)
Cerebellar Stroke	0	1 (0.4%)	1 (0.2%)
Cerebral Infarction	1 (0.4%)	0	1 (0.2%)
Cerebrovascular Accident	1 (0.4%)	0	1 (0.2%)
Diabetic Neuropathy	0	1 (0.4%)	1 (0.2%)
Dizziness	1 (0.4%)	0	1 (0.2%)
Dysgeusia	1 (0.4%)	0	1 (0.2%)
Essential Tremor	1 (0.4%)	0	1 (0.2%)
Intention Tremor	0	1 (0.4%)	1 (0.2%)
Occipital Neuralgia	0	1 (0.4%)	1 (0.2%)
Optic Neuritis	0	1 (0.4%)	1 (0.2%)
Parkinson's Disease	0	1 (0.4%)	1 (0.2%)
Peripheral Sensorimotor Neuropathy	0	1 (0.4%)	1 (0.2%)
Sensory Disturbance	1 (0.4%)	0	1 (0.2%)
Subarachnoid Haemorrhage	0	1 (0.4%)	1 (0.2%)
Transient Ischaemic Attack	0	1 (0.4%)	1 (0.2%)
Vascular Headache	1 (0.4%)	0	1 (0.2%)
Pregnancy, Puerperium And Perinatal Conditions	1 (0.4%)	0	1 (0.2%)
Gestational Diabetes	1 (0.4%)	0	1 (0.2%)
Psychiatric Disorders	18 (7.1%)	23 (9.1%)	41 (8.1%)
Insomnia	8 (3.1%)	13 (5.1%)	21 (4.1%)
Anxiety	4 (1.6%)	5 (2.0%)	9 (1.8%)
Depression	4 (1.6%)	3 (1.2%)	7 (1.4%)
Sleep Disorder	1 (0.4%)	2 (0.8%)	3 (0.6%)
Adjustment Disorder	0	1 (0.4%)	1 (0.2%)
Anxiety Disorder	1 (0.4%)	0	1 (0.2%)
Bipolar Disorder	0	1 (0.4%)	1 (0.2%)
Stress	0	1 (0.4%)	1 (0.2%)
Renal And Urinary Disorders	25 (9.8%)	17 (6.7%)	42 (8.3%)
Renal Cyst	10 (3.9%)	4 (1.6%)	14 (2.8%)
Nephrolithiasis	8 (3.1%)	3 (1.2%)	11 (2.2%)
Chronic Kidney Disease	2 (0.8%)	2 (0.8%)	4 (0.8%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Hydronephrosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Renal Colic	2 (0.8%)	1 (0.4%)	3 (0.6%)
Nocturia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ureteric Dilatation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acute Kidney Injury	0	1 (0.4%)	1 (0.2%)
Bladder Hypertrophy	1 (0.4%)	0	1 (0.2%)
Calculus Bladder	1 (0.4%)	0	1 (0.2%)
Glomerulonephritis Chronic	1 (0.4%)	0	1 (0.2%)
Hypercalciuria	1 (0.4%)	0	1 (0.2%)
Hypertonic Bladder	0	1 (0.4%)	1 (0.2%)
Lower Urinary Tract Symptoms	0	1 (0.4%)	1 (0.2%)
Micturition Urgency	0	1 (0.4%)	1 (0.2%)
Pollakiuria	0	1 (0.4%)	1 (0.2%)
Pyelocaliectasis	0	1 (0.4%)	1 (0.2%)
Renal Atrophy	0	1 (0.4%)	1 (0.2%)
Renal Failure	0	1 (0.4%)	1 (0.2%)
Renal Impairment	0	1 (0.4%)	1 (0.2%)
Ureteral Wall Thickening	1 (0.4%)	0	1 (0.2%)
Reproductive System And Breast Disorders	20 (7.9%)	20 (7.9%)	40 (7.9%)
Benign Prostatic Hyperplasia	13 (5.1%)	11 (4.3%)	24 (4.7%)
Ovarian Cyst	0	4 (1.6%)	4 (0.8%)
Prostatic Calcification	2 (0.8%)	1 (0.4%)	3 (0.6%)
Prostatomegaly	1 (0.4%)	2 (0.8%)	3 (0.6%)
Breast Fibrosis	0	1 (0.4%)	1 (0.2%)
Genital Haemorrhage	1 (0.4%)	0	1 (0.2%)
Menstruation Irregular	0	1 (0.4%)	1 (0.2%)
Ovarian Mass	1 (0.4%)	0	1 (0.2%)
Ovarian Vein Thrombosis	1 (0.4%)	0	1 (0.2%)
Premature Menopause	0	1 (0.4%)	1 (0.2%)
Prostatitis	0	1 (0.4%)	1 (0.2%)
Uterine Polyp	1 (0.4%)	0	1 (0.2%)
Uterine Prolapse	1 (0.4%)	0	1 (0.2%)
Respiratory, Thoracic And Mediastinal Disorders	31 (12.2%)	28 (11.1%)	59 (11.6%)
Emphysema	6 (2.4%)	4 (1.6%)	10 (2.0%)
Asthma	5 (2.0%)	2 (0.8%)	7 (1.4%)
Chronic Obstructive Pulmonary Disease	3 (1.2%)	4 (1.6%)	7 (1.4%)
Hiccups	3 (1.2%)	4 (1.6%)	7 (1.4%)
Cough	2 (0.8%)	2 (0.8%)	4 (0.8%)
Pulmonary Mass	3 (1.2%)	1 (0.4%)	4 (0.8%)
Dyspnoea	2 (0.8%)	1 (0.4%)	3 (0.6%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Pleural Effusion	1 (0.4%)	2 (0.8%)	3 (0.6%)
Sleep Apnoea Syndrome	2 (0.8%)	1 (0.4%)	3 (0.6%)
Atelectasis	0	2 (0.8%)	2 (0.4%)
Bronchiectasis	0	2 (0.8%)	2 (0.4%)
Bronchitis Chronic	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dysphonia	2 (0.8%)	0	2 (0.4%)
Pneumothorax Spontaneous	0	2 (0.8%)	2 (0.4%)
Rhinitis Allergic	1 (0.4%)	1 (0.4%)	2 (0.4%)
Apnoea	1 (0.4%)	0	1 (0.2%)
Cystic Lung Disease	1 (0.4%)	0	1 (0.2%)
Diffuse Panbronchiolitis	1 (0.4%)	0	1 (0.2%)
Obstructive Airways Disorder	0	1 (0.4%)	1 (0.2%)
Oropharyngeal Pain	1 (0.4%)	0	1 (0.2%)
Pneumonitis	0	1 (0.4%)	1 (0.2%)
Productive Cough	1 (0.4%)	0	1 (0.2%)
Pulmonary Artery Thrombosis	0	1 (0.4%)	1 (0.2%)
Pulmonary Embolism	0	1 (0.4%)	1 (0.2%)
Skin And Subcutaneous Tissue Disorders	3 (1.2%)	11 (4.3%)	14 (2.8%)
Eczema	0	2 (0.8%)	2 (0.4%)
Eczema Asteatotic	0	2 (0.8%)	2 (0.4%)
Chronic Spontaneous Urticaria	0	1 (0.4%)	1 (0.2%)
Dermal Cyst	0	1 (0.4%)	1 (0.2%)
Dermatitis	0	1 (0.4%)	1 (0.2%)
Dermatosis	1 (0.4%)	0	1 (0.2%)
Dry Skin	1 (0.4%)	0	1 (0.2%)
Hyperhidrosis	0	1 (0.4%)	1 (0.2%)
Leukoderma	0	1 (0.4%)	1 (0.2%)
Pruritus	1 (0.4%)	0	1 (0.2%)
Seborrhoeic Dermatitis	0	1 (0.4%)	1 (0.2%)
Skin Oedema	0	1 (0.4%)	1 (0.2%)
Social Circumstances	1 (0.4%)	0	1 (0.2%)
Ex-Tobacco User	1 (0.4%)	0	1 (0.2%)
Surgical And Medical Procedures	27 (10.6%)	33 (13.0%)	60 (11.8%)
Cholecystectomy	6 (2.4%)	4 (1.6%)	10 (2.0%)
Appendicectomy	3 (1.2%)	3 (1.2%)	6 (1.2%)
Caesarean Section	0	4 (1.6%)	4 (0.8%)
Coronary Arterial Stent Insertion	2 (0.8%)	2 (0.8%)	4 (0.8%)
Gastrectomy	2 (0.8%)	2 (0.8%)	4 (0.8%)
Cataract Operation	3 (1.2%)	0	3 (0.6%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Inguinal Hernia Repair	0	3 (1.2%)	3 (0.6%)
Thyroidectomy	2 (0.8%)	1 (0.4%)	3 (0.6%)
Adenoidectomy	0	2 (0.8%)	2 (0.4%)
Amygdalotomy	0	2 (0.8%)	2 (0.4%)
Endometriosis Ablation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Knee Arthroplasty	2 (0.8%)	0	2 (0.4%)
Papilloma Excision	1 (0.4%)	1 (0.4%)	2 (0.4%)
Radical Prostatectomy	0	2 (0.8%)	2 (0.4%)
Salpingo-Oophorectomy Bilateral	2 (0.8%)	0	2 (0.4%)
Spinal Operation	0	2 (0.8%)	2 (0.4%)
Splenectomy	0	2 (0.8%)	2 (0.4%)
Tonsillectomy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Varicose Vein Operation	0	2 (0.8%)	2 (0.4%)
Abdominoplasty	1 (0.4%)	0	1 (0.2%)
Anal Fistula Repair	0	1 (0.4%)	1 (0.2%)
Ankle Operation	1 (0.4%)	0	1 (0.2%)
Bladder Neoplasm Surgery	0	1 (0.4%)	1 (0.2%)
Bone Operation	0	1 (0.4%)	1 (0.2%)
Breast Conserving Surgery	0	1 (0.4%)	1 (0.2%)
Breast Operation	1 (0.4%)	0	1 (0.2%)
Bunion Operation	1 (0.4%)	0	1 (0.2%)
Cardiac Ablation	1 (0.4%)	0	1 (0.2%)
Central Venous Catheterisation	1 (0.4%)	0	1 (0.2%)
Cyst Removal	1 (0.4%)	0	1 (0.2%)
Dermatofibroma Removal	1 (0.4%)	0	1 (0.2%)
Enterostomy	1 (0.4%)	0	1 (0.2%)
Female Sterilisation	0	1 (0.4%)	1 (0.2%)
Gastric Stent Insertion	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Tube Insertion	0	1 (0.4%)	1 (0.2%)
Hepatectomy	1 (0.4%)	0	1 (0.2%)
Hernia Repair	0	1 (0.4%)	1 (0.2%)
Hip Surgery	0	1 (0.4%)	1 (0.2%)
Intestinal Adhesion Lysis	0	1 (0.4%)	1 (0.2%)
Jejunostomy	1 (0.4%)	0	1 (0.2%)
Knee Operation	1 (0.4%)	0	1 (0.2%)
Ligament Operation	1 (0.4%)	0	1 (0.2%)
Mastectomy	1 (0.4%)	0	1 (0.2%)
Meniscus Operation	0	1 (0.4%)	1 (0.2%)
Meniscus Removal	1 (0.4%)	0	1 (0.2%)
Nephrostomy	1 (0.4%)	0	1 (0.2%)
Oesophageal Fistula Repair	0	1 (0.4%)	1 (0.2%)
Oesophagogastric Fundoplasty	0	1 (0.4%)	1 (0.2%)

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Omentectomy	1 (0.4%)	0	1 (0.2%)
Orchidectomy	0	1 (0.4%)	1 (0.2%)
Peritoneal Lavage	1 (0.4%)	0	1 (0.2%)
Peritonectomy	1 (0.4%)	0	1 (0.2%)
Prophylaxis Of Nausea And Vomiting	0	1 (0.4%)	1 (0.2%)
Prostatectomy	1 (0.4%)	0	1 (0.2%)
Prostatic Operation	0	1 (0.4%)	1 (0.2%)
Renal Stone Removal	1 (0.4%)	0	1 (0.2%)
Rhinoplasty	1 (0.4%)	0	1 (0.2%)
Salpingo-Oophorectomy Unilateral	1 (0.4%)	0	1 (0.2%)
Sinus Operation	0	1 (0.4%)	1 (0.2%)
Stent Placement	1 (0.4%)	0	1 (0.2%)
Umbilical Hernia Repair	0	1 (0.4%)	1 (0.2%)
Urinary Incontinence Surgery	1 (0.4%)	0	1 (0.2%)
Vascular Disorders	77 (30.3%)	58 (22.9%)	135 (26.6%)
Hypertension	68 (26.8%)	55 (21.7%)	123 (24.3%)
Aortic Arteriosclerosis	4 (1.6%)	0	4 (0.8%)
Varicose Vein	3 (1.2%)	0	3 (0.6%)
Peripheral Venous Disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Angiopathy	1 (0.4%)	0	1 (0.2%)
Deep Vein Thrombosis	1 (0.4%)	0	1 (0.2%)
Essential Hypertension	1 (0.4%)	0	1 (0.2%)
Hypotension	1 (0.4%)	0	1 (0.2%)
Leriche Syndrome	0	1 (0.4%)	1 (0.2%)
Subclavian Vein Thrombosis	1 (0.4%)	0	1 (0.2%)
Thrombosis	0	1 (0.4%)	1 (0.2%)
Venous Thrombosis	1 (0.4%)	0	1 (0.2%)
Venous Thrombosis Limb	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024

Anhang 4-G1 Gesamtüberleben und Progressionsfreies Überleben

Anhang 4-G1 Gesamtüberleben

1. Time-to-Event-Analyse

Table 302.3.1002.1.1: Summary of Overall Survival - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	180 (70.9%)	207 (81.8%)	
Number of patients censored	74 (29.1%)	46 (18.2%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 6	82.1 [76.6, 86.4]	76.3 [70.4, 81.1]	5.8 [-1.4, 13.0], p=0.1135
Month 12	56.7 [50.1, 62.7]	50.4 [43.9, 56.6]	6.2 [-2.8, 15.3], p=0.1739
Month 18	39.3 [33.0, 45.6]	30.1 [24.3, 36.1]	9.2 [0.5, 17.9], p=0.0380
Month 24	29.0 [23.2, 35.1]	18.8 [14.0, 24.2]	10.2 [2.4, 18.1], p=0.0108
Month 30	22.2 [16.8, 28.2]	13.0 [8.9, 17.9]	9.2 [1.9, 16.6], p=0.0137
Month 36	18.3 [12.9, 24.4]	7.9 [4.4, 12.6]	10.4 [3.3, 17.5], p=0.0039
Month 42	16.8 [11.3, 23.2]	7.9 [4.4, 12.6]	8.9 [1.6, 16.2], p=0.0166
Month 48	16.8 [11.3, 23.2]	7.9 [4.4, 12.6]	8.9 [1.6, 16.2], p=0.0166
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI (c)			
50%	14.3 [12.1, 16.4]	12.2 [10.3, 13.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.763 [0.622, 0.936]
Log-rank test			
Two-sided stratified log-rank p-value			0.0094

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) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.1002.1.2: Type of Events and Censoring of Overall Survival - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Number of patients at risk	254 (100.0%)	253 (100.0%)
Number of patients with events	180 (70.9%)	207 (81.8%)
Death Before Analysis Cutoff Date	180 (70.9%)	207 (81.8%)
Number of patients censored	74 (29.1%)	46 (18.2%)
Last Known Alive Date Is Before Cutoff Date	65 (25.6%)	44 (17.4%)
Censored At Cutoff Date	9 (3.5%)	2 (0.8%)

Abbreviations: N=number of patients.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.1002.1.3: Summary of Overall Survival by Subgroups - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	115 (65.3)	14.3 [12.1, 17.2]	180	149 (82.8)	11.9 [9.7, 13.7]	0.650 [0.509, 0.830]	0.0005	0.0314
>65 years	78	65 (83.3)	13.9 [9.1, 17.4]	73	58 (79.5)	12.3 [9.4, 16.6]	1.044 [0.732, 1.490]	0.8066	
Age Group2									
<=75 years	242	172 (71.1)	13.7 [11.9, 16.4]	239	196 (82.0)	11.9 [9.9, 13.2]	0.749 [0.610, 0.920]	0.0057	0.8699
>75 years	12	8 (66.7)	25.5 [2.7, 30.1]	14	11 (78.6)	17.4 [5.1, 18.9]	0.653 [0.259, 1.642]	0.3738	
Sex									
Male	159	119 (74.8)	12.5 [10.3, 15.5]	156	133 (85.3)	11.5 [9.2, 13.2]	0.772 [0.602, 0.989]	0.0400	0.6537
Female	95	61 (64.2)	16.5 [12.6, 19.4]	97	74 (76.3)	13.2 [10.5, 15.4]	0.698 [0.497, 0.981]	0.0376	
Race									
White	94	66 (70.2)	12.6 [10.3, 17.2]	90	78 (86.7)	13.7 [10.6, 17.4]	0.805 [0.579, 1.120]	0.1966	0.4557
Asian	158	112 (70.9)	15.0 [12.5, 17.8]	158	124 (78.5)	11.2 [9.4, 13.2]	0.710 [0.549, 0.917]	0.0084	
Tobacco History									
Current	32	22 (68.8)	12.3 [9.3, 21.7]	33	27 (81.8)	15.0 [9.3, 19.4]	0.904 [0.513, 1.591]	0.7248	0.7010
Former	90	65 (72.2)	13.9 [10.8, 17.8]	84	72 (85.7)	12.6 [9.7, 14.5]	0.720 [0.514, 1.009]	0.0556	
Never	128	91 (71.1)	15.0 [11.7, 17.9]	132	107 (81.1)	10.9 [8.7, 13.9]	0.699 [0.528, 0.925]	0.0119	
Region									
Asia	157	111 (70.7)	15.0 [12.5, 17.8]	158	124 (78.5)	11.2 [9.4, 13.2]	0.706 [0.546, 0.913]	0.0076	0.4194
Non-Asia	97	69 (71.1)	12.3 [10.3, 16.0]	95	83 (87.4)	13.2 [9.9, 17.1]	0.814 [0.591, 1.122]	0.2076	
Number of Organs with Metastatic Sites									
0-2	189	129 (68.3)	15.7 [13.6, 18.7]	188	153 (81.4)	12.9 [10.7, 14.9]	0.705 [0.558, 0.892]	0.0034	0.3477
>=3	65	51 (78.5)	10.8 [8.1, 12.5]	65	54 (83.1)	9.8 [7.5, 13.2]	0.881 [0.601, 1.292]	0.5174	
Prior Gastrectomy (total or partial)									
Yes	75	51 (68.0)	15.5 [11.1, 22.6]	75	58 (77.3)	12.9 [9.1, 17.3]	0.760 [0.521, 1.109]	0.1535	0.8765
No	179	129 (72.1)	13.6 [11.8, 16.4]	178	149 (83.7)	11.8 [9.8, 13.7]	0.737 [0.582, 0.933]	0.0111	

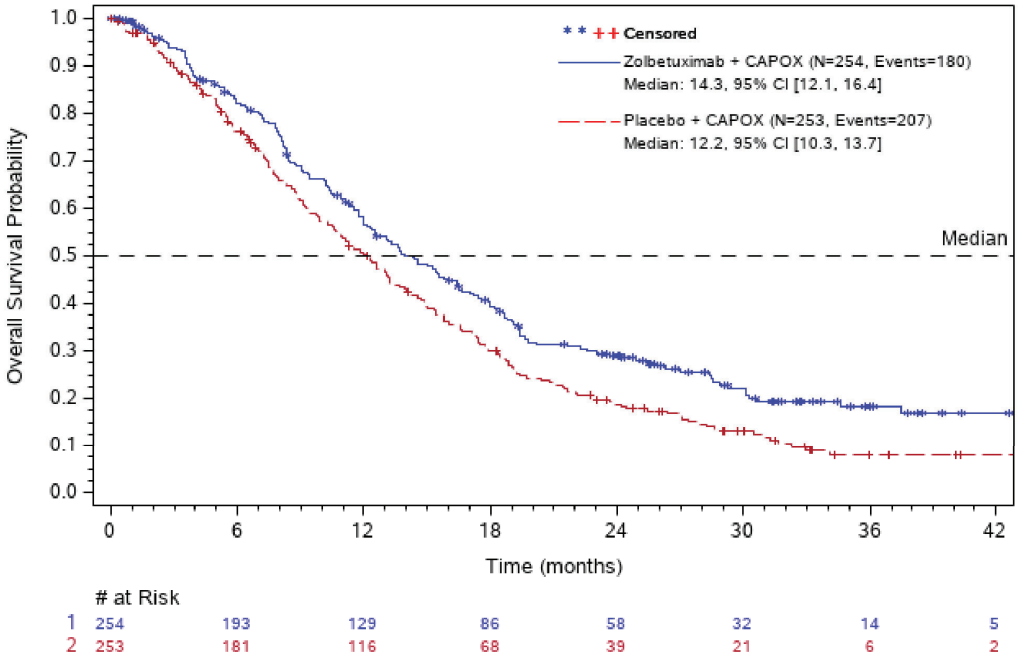
	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Histology (Tumor Type)									
Diffuse	87	57 (65.5)	14.3 [12.0, 18.7]	100	78 (78.0)	12.6 [9.3, 15.8]	0.723 [0.513, 1.018]	0.0619	0.7119
Intestinal	36	27 (75.0)	18.8 [12.3, 25.5]	41	33 (80.5)	12.9 [8.3, 17.3]	0.818 [0.491, 1.363]	0.4436	
Mixed/Other	54	39 (72.2)	11.7 [8.7, 16.6]	48	41 (85.4)	13.3 [11.2, 16.0]	0.888 [0.570, 1.383]	0.5981	
Tumor Location 1									
Gastric	219	153 (69.9)	14.3 [12.0, 16.6]	209	170 (81.3)	11.8 [9.7, 13.3]	0.713 [0.573, 0.888]	0.0024	0.1936
GEJ	35	27 (77.1)	13.3 [9.4, 17.9]	44	37 (84.1)	12.9 [9.2, 20.4]	1.046 [0.634, 1.726]	0.8627	
Tumor Location 2									
Gastric Proximal	73	50 (68.5)	15.2 [11.9, 18.7]	73	60 (82.2)	10.9 [8.3, 15.8]	0.662 [0.455, 0.965]	0.0309	0.4110
Gastric Distal	90	62 (68.9)	13.3 [10.1, 17.0]	83	63 (75.9)	12.6 [9.7, 15.0]	0.841 [0.592, 1.196]	0.3360	
Tumor Location 3									
GEJ Proximal	15	11 (73.3)	15.4 [8.3, 25.9]	21	16 (76.2)	11.9 [6.8, 20.4]	0.602 [0.264, 1.371]	0.2219	0.0734
GEJ Distal	10	7 (70.0)	13.1 [3.6, 19.6]	13	12 (92.3)	15.3 [8.9, 24.2]	2.118 [0.745, 6.020]	0.1509	

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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G1 Gesamtüberleben

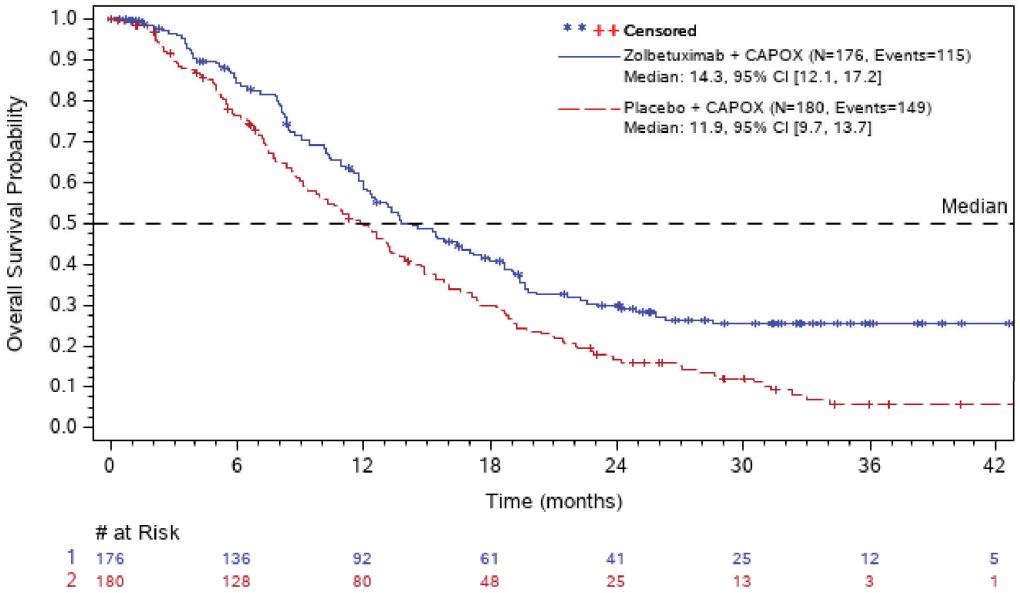
2. Kaplan-Meier-Plots

Figure 302.3.1002.1: 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: 12JAN24

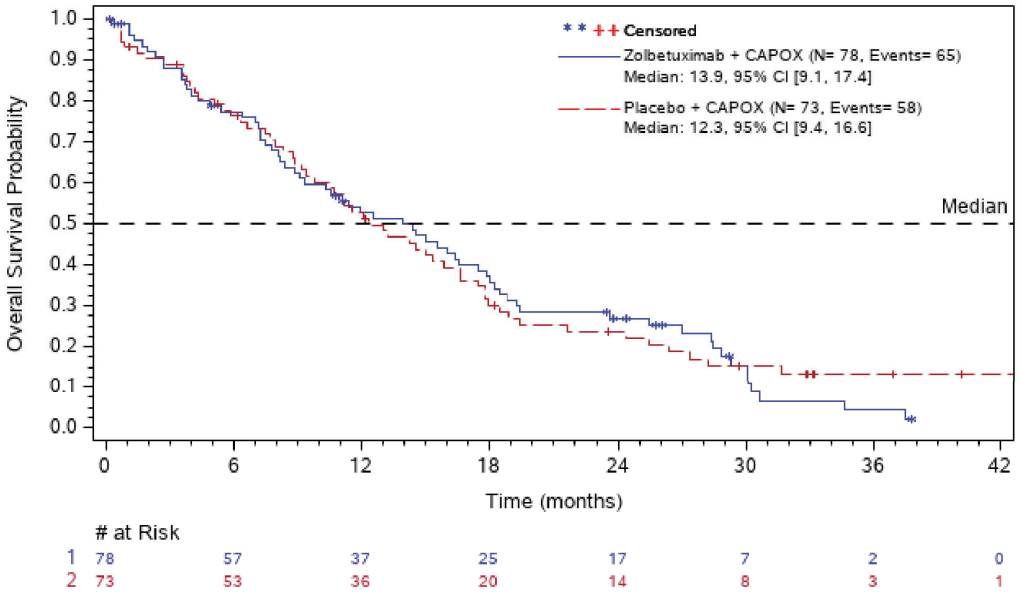
Figure 302.3.1002.1.1: Kaplan-Meier Plot of Overall Survival by Age Group 1 - Full Analysis Set
Pooled Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.1002.1.1: Kaplan-Meier Plot of Overall Survival by Age Group 1 - Full Analysis Set

Pooled Age Group 1: >65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G1 Progressionsfreies Überleben (IRC und INV)

1. Time-to-Event-Analysen

Table 302.3.1002.2.1: Summary of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	153 (60.2%)	182 (71.9%)	
Number of patients censored	101 (39.8%)	71 (28.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.2 [7.3, 8.8]	6.8 [6.1, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.689 [0.552, 0.860]
Log-rank test			
Two-sided stratified log-rank p-value			0.0009

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: 12JAN24

Table 302.3.1002.2.2: Type of Events and Censoring of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Number of patients at risk	254 (100.0%)	253 (100.0%)
Number of patients with events	153 (60.2%)	182 (71.9%)
rPD	85 (33.5%)	108 (42.7%)
No rPD, but death recorded on eCRF	68 (26.8%)	74 (29.2%)
Number of patients censored	101 (39.8%)	71 (28.1%)

Abbreviations: eCRF=electronic case report form; IRC=independent review committee; N=number of patients; rPD=radiological progressive disease.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.1002.2.3: Summary of Progression-Free Survival (IRC) by Subgroups - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	106 (60.2)	8.3 [7.9, 9.4]	180	136 (75.6)	6.4 [6.0, 8.1]	0.621 [0.480, 0.803]	0.0003	0.0611
>65 years	78	47 (60.3)	7.1 [6.1, 9.3]	73	46 (63.0)	8.2 [6.0, 10.3]	0.984 [0.655, 1.479]	0.9363	
Age Group2									
<=75 years	242	149 (61.6)	8.2 [7.1, 8.8]	239	175 (73.2)	6.5 [6.1, 8.1]	0.703 [0.564, 0.877]	0.0016	0.9119
>75 years	12	4 (33.3)	17.8 [1.1, 17.8]	14	7 (50.0)	10.3 [4.1, 14.2]	0.692 [0.202, 2.373]	0.5625	
Sex									
Male	159	104 (65.4)	8.2 [6.7, 8.8]	156	116 (74.4)	6.2 [5.8, 7.7]	0.686 [0.525, 0.896]	0.0054	0.8428
Female	95	49 (51.6)	8.3 [6.4, 12.7]	97	66 (68.0)	8.1 [6.5, 8.5]	0.735 [0.507, 1.067]	0.1037	
Race									
White	94	59 (62.8)	8.0 [6.4, 8.4]	90	62 (68.9)	8.1 [6.3, 8.7]	0.891 [0.622, 1.276]	0.5235	0.0808
Asian	158	92 (58.2)	8.4 [7.1, 10.4]	158	115 (72.8)	6.3 [6.0, 8.0]	0.616 [0.467, 0.813]	0.0006	
Tobacco History									
Current	32	20 (62.5)	8.1 [6.1, 9.3]	33	25 (75.8)	8.0 [4.3, 8.4]	0.753 [0.418, 1.360]	0.3497	0.8554
Former	90	51 (56.7)	8.5 [6.5, 12.0]	84	64 (76.2)	6.5 [6.1, 8.2]	0.589 [0.400, 0.866]	0.0068	
Never	128	80 (62.5)	8.1 [6.4, 9.2]	132	92 (69.7)	6.5 [5.3, 8.3]	0.732 [0.541, 0.989]	0.0399	
Region									
Asia	157	91 (58.0)	8.5 [7.3, 10.4]	158	115 (72.8)	6.3 [6.0, 8.0]	0.612 [0.464, 0.809]	0.0005	0.0658
Non-Asia	97	62 (63.9)	8.0 [6.2, 8.4]	95	67 (70.5)	8.1 [6.2, 8.7]	0.900 [0.635, 1.275]	0.5464	
Number of Organs with Metastatic Sites									
0-2	189	111 (58.7)	8.3 [7.8, 9.4]	188	134 (71.3)	7.7 [6.3, 8.2]	0.707 [0.548, 0.911]	0.0070	0.9490
>=3	65	42 (64.6)	7.9 [6.1, 8.8]	65	48 (73.8)	6.0 [4.1, 8.0]	0.676 [0.444, 1.029]	0.0667	
Prior Gastrectomy (total or partial)									
Yes	75	49 (65.3)	8.2 [6.2, 13.0]	75	53 (70.7)	7.8 [6.0, 8.3]	0.794 [0.537, 1.173]	0.2441	0.5342
No	179	104 (58.1)	8.2 [7.3, 8.8]	178	129 (72.5)	6.5 [6.0, 8.1]	0.680 [0.524, 0.883]	0.0036	

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [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	87	43 (49.4)	10.4 [7.9, 15.1]	100	69 (69.0)	8.1 [6.4, 8.8]	0.602 [0.410, 0.883]	0.0087	0.6450
Intestinal	36	23 (63.9)	8.1 [6.1, 17.8]	41	26 (63.4)	6.1 [5.8, 8.3]	0.769 [0.436, 1.357]	0.3658	
Mixed/Other	54	31 (57.4)	7.5 [4.2, 8.8]	48	37 (77.1)	6.4 [5.3, 8.5]	0.845 [0.523, 1.366]	0.4931	
Tumor Location 1									
Gastric	219	131 (59.8)	8.3 [7.9, 9.4]	209	158 (75.6)	6.4 [6.0, 8.1]	0.640 [0.507, 0.808]	0.0002	0.0178
GEJ	35	22 (62.9)	6.2 [4.2, 8.4]	44	24 (54.5)	9.2 [6.4, 11.5]	1.275 [0.701, 2.320]	0.4322	
Tumor Location 2									
Gastric Proximal	73	43 (58.9)	10.3 [7.9, 12.1]	73	56 (76.7)	6.5 [4.4, 8.3]	0.576 [0.386, 0.861]	0.0065	0.2732
Gastric Distal	90	52 (57.8)	8.1 [6.1, 9.3]	83	57 (68.7)	6.3 [5.2, 8.3]	0.813 [0.557, 1.186]	0.2822	
Tumor Location 3									
GEJ Proximal	15	10 (66.7)	6.2 [4.2, 19.1]	21	12 (57.1)	6.2 [4.3, 10.2]	0.776 [0.315, 1.913]	0.5761	0.1867
GEJ Distal	10	4 (40.0)	8.1 [2.2, NC]	13	9 (69.2)	10.4 [6.4, 15.8]	2.614 [0.632, 10.816]	0.1699	

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.
[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: 12JAN24

Table 302.3.1002.3.1: Summary of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	173 (68.1%)	210 (83.0%)	
Number of patients censored	81 (31.9%)	43 (17.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.8 [6.3, 8.3]	6.0 [5.3, 6.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.671 [0.544, 0.828]
Log-rank test			
Two-sided stratified log-rank p-value			0.0002

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: 12JAN24

Table 302.3.1002.3.2: Type of Events and Censoring of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Number of patients at risk	254 (100.0%)	253 (100.0%)
Number of patients with events	173 (68.1%)	210 (83.0%)
rPD	126 (49.6%)	173 (68.4%)
No rPD, but death recorded on eCRF	47 (18.5%)	37 (14.6%)
Number of patients censored	81 (31.9%)	43 (17.0%)

Abbreviations: eCRF= electronic case report form; INV=investigator; N=number of patients; rPD=radiological progressive disease.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.1002.3.3: Summary of Progression-Free Survival (INV) by Subgroups - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	124 (70.5)	8.0 [6.3, 8.4]	180	152 (84.4)	6.1 [5.2, 6.4]	0.631 [0.496, 0.804]	0.0002	0.2741
>65 years	78	49 (62.8)	6.4 [4.9, 8.4]	73	58 (79.5)	6.0 [4.3, 6.8]	0.824 [0.563, 1.206]	0.3195	
Age Group2									
<=75 years	242	168 (69.4)	7.8 [6.3, 8.3]	239	203 (84.9)	6.0 [5.3, 6.3]	0.669 [0.544, 0.823]	0.0001	0.4314
>75 years	12	5 (41.7)	10.4 [1.1, 17.8]	14	7 (50.0)	9.8 [2.6, NC]	0.946 [0.299, 2.996]	0.9337	
Sex									
Male	159	114 (71.7)	7.3 [6.2, 8.3]	156	132 (84.6)	6.1 [5.2, 6.4]	0.681 [0.528, 0.877]	0.0028	0.9129
Female	95	59 (62.1)	8.1 [6.2, 9.2]	97	78 (80.4)	6.0 [4.4, 7.2]	0.681 [0.483, 0.959]	0.0265	
Race									
White	94	65 (69.1)	7.3 [6.2, 8.3]	90	79 (87.8)	6.2 [5.2, 8.1]	0.734 [0.526, 1.026]	0.0697	0.3878
Asian	158	106 (67.1)	8.1 [6.2, 8.5]	158	126 (79.7)	6.0 [5.2, 6.3]	0.651 [0.501, 0.845]	0.0012	
Tobacco History									
Current	32	23 (71.9)	7.9 [4.8, 8.4]	33	27 (81.8)	6.4 [5.3, 8.1]	0.931 [0.533, 1.627]	0.7990	0.5322
Former	90	57 (63.3)	8.0 [5.6, 9.0]	84	72 (85.7)	6.2 [5.3, 7.3]	0.630 [0.440, 0.902]	0.0115	
Never	128	91 (71.1)	7.3 [6.2, 8.4]	132	109 (82.6)	5.4 [4.2, 6.2]	0.659 [0.497, 0.873]	0.0033	
Region									
Asia	157	105 (66.9)	8.1 [6.2, 8.6]	158	126 (79.7)	6.0 [5.2, 6.3]	0.650 [0.500, 0.845]	0.0012	0.3649
Non-Asia	97	68 (70.1)	7.3 [6.2, 8.2]	95	84 (88.4)	6.1 [4.4, 8.1]	0.742 [0.536, 1.027]	0.0710	
Number of Organs with Metastatic Sites									
0-2	189	124 (65.6)	7.9 [6.3, 8.6]	188	154 (81.9)	6.1 [5.3, 6.4]	0.679 [0.535, 0.862]	0.0014	0.7772
>=3	65	49 (75.4)	7.1 [4.5, 8.3]	65	56 (86.2)	6.0 [4.2, 6.4]	0.688 [0.465, 1.017]	0.0580	
Prior Gastrectomy (total or partial)									
Yes	75	50 (66.7)	7.3 [6.1, 9.0]	75	55 (73.3)	6.2 [5.4, 8.0]	0.732 [0.498, 1.077]	0.1125	0.8382
No	179	123 (68.7)	7.8 [6.3, 8.3]	178	155 (87.1)	6.0 [4.4, 6.3]	0.670 [0.527, 0.851]	0.0010	

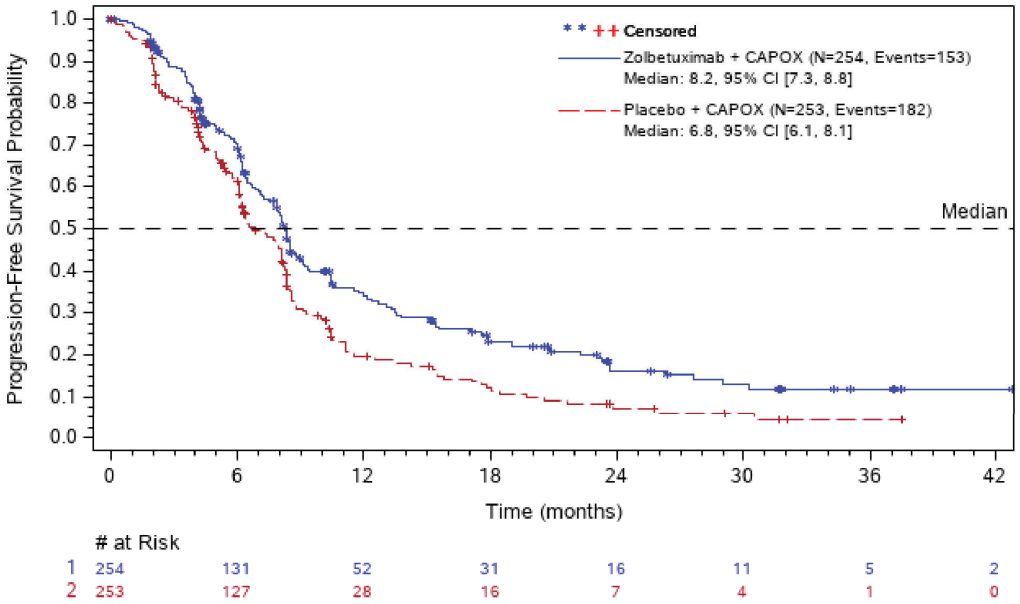
	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Histology (Tumor Type)									
Diffuse	87	54 (62.1)	8.4 [6.2, 12.4]	100	79 (79.0)	6.3 [5.5, 7.8]	0.659 [0.464, 0.936]	0.0189	0.5917
Intestinal	36	26 (72.2)	7.3 [4.3, 10.4]	41	31 (75.6)	6.0 [4.2, 6.2]	0.752 [0.444, 1.274]	0.2949	
Mixed/Other	54	36 (66.7)	6.3 [4.2, 8.2]	48	42 (87.5)	6.4 [5.3, 8.1]	0.876 [0.559, 1.373]	0.5628	
Tumor Location 1									
Gastric	219	149 (68.0)	7.9 [6.4, 8.4]	209	177 (84.7)	6.0 [5.0, 6.2]	0.640 [0.513, 0.797]	<.0001	0.0743
GEJ	35	24 (68.6)	6.2 [4.0, 8.1]	44	33 (75.0)	6.8 [5.4, 8.3]	1.053 [0.615, 1.803]	0.8487	
Tumor Location 2									
Gastric Proximal	73	51 (69.9)	8.4 [6.6, 10.4]	73	62 (84.9)	6.0 [4.3, 6.4]	0.596 [0.409, 0.868]	0.0063	0.5068
Gastric Distal	90	59 (65.6)	7.0 [5.4, 8.5]	83	70 (84.3)	6.0 [4.3, 6.3]	0.730 [0.515, 1.034]	0.0777	
Tumor Location 3									
GEJ Proximal	15	11 (73.3)	6.3 [3.9, 9.2]	21	16 (76.2)	6.8 [2.6, 8.3]	0.739 [0.324, 1.685]	0.4679	0.2476
GEJ Distal	10	5 (50.0)	5.1 [2.2, NC]	13	13 (100.0)	6.4 [4.4, 10.4]	1.703 [0.562, 5.155]	0.3412	

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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G1 Progressionsfreies Überleben (IRC und INV)

2. Kaplan-Meier-Plots

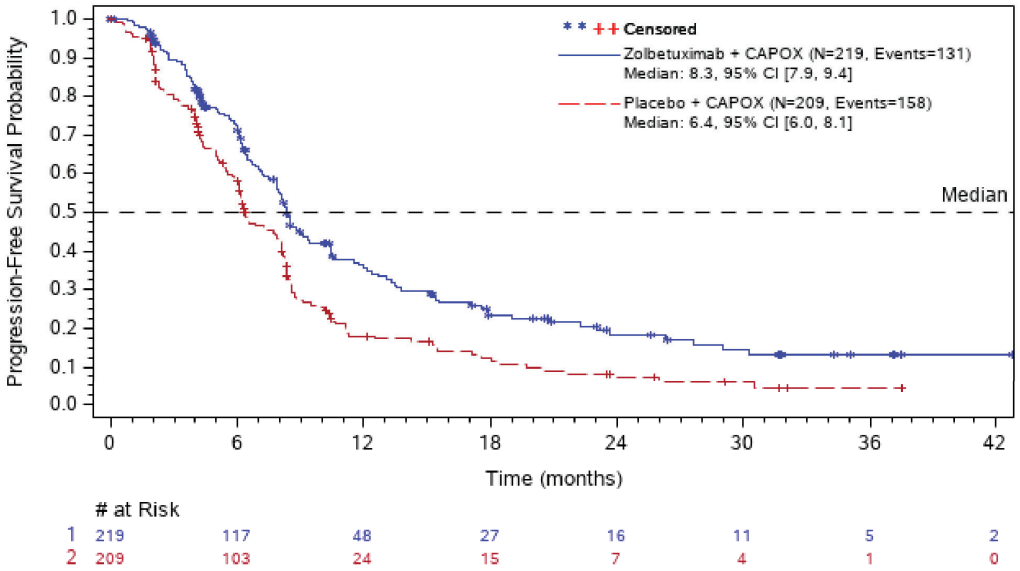
Figure 302.3.1002.2: Kaplan-Meier Plot of Progression-Free Survival (IRC) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; IRC=independent review committee; N=number of patients.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.1002.2.10: Kaplan-Meier Plot of Progression-Free Survival (IRC) by Tumor Location 1 - Full Analysis Set

Tumor Location 1: Gastric

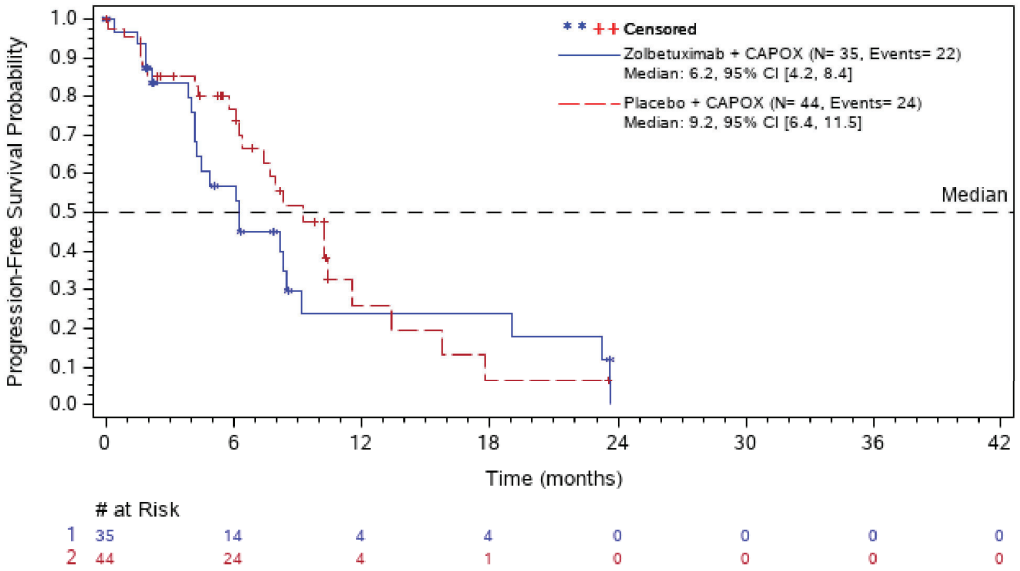


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; GEJ=gastro-esophageal junction; IRC=independent review committee; N=number of patients.

ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.1002.2.10: Kaplan-Meier Plot of Progression-Free Survival (IRC) by Tumor Location 1 - Full Analysis Set

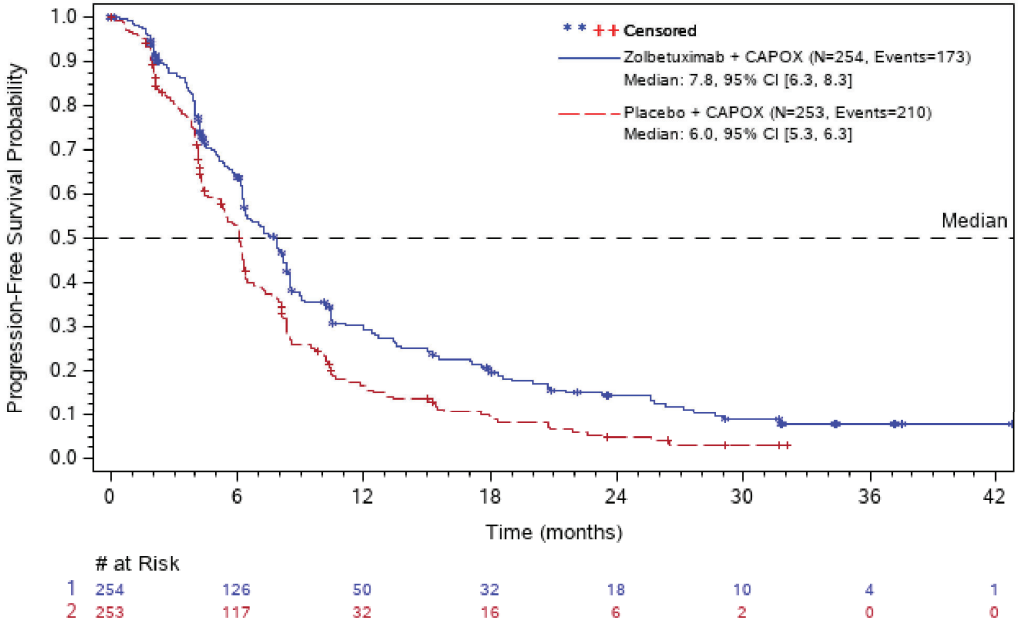
Tumor Location 1: GEJ



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: 12JAN24

Figure 302.3.1002.3: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024

Anhang 4-G1 Patientenberichtete Endpunkte

Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

1. Rücklaufquoten

Table 302.3.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	242/250 (96.8%)	242/252 (96.0%)	242/253 (95.7%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	182/197 (92.4%)	186/221 (84.2%)	187/254 (73.6%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	113/128 (88.3%)	122/199 (61.3%)	122/254 (48.0%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	166/229 (72.5%)	166/231 (71.9%)	166/253 (65.6%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

Table 302.3.3002.5: 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 + CAPOX (N=254)												
Baseline	243	68.83	18.94	0.0	66.67	100.0						
Cycle 2 Day 1	209	69.06	17.50	0.0	66.67	100.0	208	0.04	17.35	-83.3	0.00	58.3
Cycle 3 Day 1	187	70.99	17.18	0.0	66.67	100.0	182	1.47	17.15	-66.7	0.00	58.3
Cycle 4 Day 1	172	72.14	17.44	8.3	79.17	100.0	169	2.61	18.79	-50.0	0.00	75.0
Cycle 5 Day 1	163	70.35	20.44	0.0	75.00	100.0	159	0.89	20.96	-91.7	0.00	75.0
Cycle 6 Day 1	151	71.08	19.93	0.0	75.00	100.0	149	0.84	19.32	-83.3	0.00	58.3
Cycle 7 Day 1	122	73.22	16.29	16.7	83.33	100.0	120	1.94	18.29	-50.0	0.00	66.7
Cycle 8 Day 1	114	73.17	18.14	0.0	79.17	100.0	108	0.77	16.96	-50.0	0.00	50.0
Cycle 9 Day 1	107	72.98	17.16	16.7	75.00	100.0	102	1.88	20.91	-50.0	0.00	83.3
Cycle 10 Day 1	88	74.15	18.00	25.0	83.33	100.0	85	2.65	20.38	-41.7	0.00	75.0
Cycle 11 Day 1	84	74.90	16.18	41.7	83.33	100.0	81	1.23	21.89	-41.7	0.00	75.0
Cycle 12 Day 1	77	76.19	18.86	0.0	83.33	100.0	75	2.44	23.44	-83.3	0.00	75.0
Cycle 13 Day 1	62	77.02	16.37	41.7	83.33	100.0	60	3.47	24.22	-41.7	0.00	91.7
Cycle 14 Day 1	57	77.34	15.09	41.7	83.33	100.0	55	1.52	18.08	-33.3	0.00	50.0
Cycle 15 Day 1	53	77.83	16.09	33.3	83.33	100.0	51	2.94	22.78	-33.3	0.00	91.7
Cycle 16 Day 1	50	76.83	15.36	33.3	83.33	100.0	48	3.65	22.67	-41.7	0.00	75.0
Cycle 17 Day 1	45	80.00	13.69	50.0	83.33	100.0	43	6.01	19.36	-33.3	0.00	58.3
Cycle 18 Day 1	43	78.10	13.49	50.0	83.33	100.0	41	3.66	21.33	-33.3	0.00	75.0
Cycle 19 Day 1	42	79.37	14.64	50.0	83.33	100.0	40	4.17	17.50	-33.3	0.00	41.7
Cycle 20 Day 1	41	77.03	15.90	25.0	83.33	100.0	39	1.50	17.72	-25.0	0.00	41.7
Cycle 21 Day 1	38	78.51	15.09	41.7	83.33	100.0	36	4.17	18.53	-25.0	0.00	50.0
Cycle 22 Day 1	33	80.05	16.66	50.0	83.33	100.0	31	4.03	19.71	-33.3	0.00	50.0
Cycle 23 Day 1	33	79.80	15.31	50.0	83.33	100.0	31	4.03	16.92	-25.0	0.00	50.0
Cycle 24 Day 1	31	79.30	13.76	50.0	83.33	100.0	29	2.87	19.32	-33.3	0.00	50.0
Cycle 25 Day 1	30	78.06	17.02	41.7	83.33	100.0	28	1.79	18.75	-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: 12JAN24

Table 302.3.3002.5: 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 26 Day 1	28	81.25	12.34	50.0	83.33	100.0	26	4.81	16.36	-16.7	0.00	33.3
Cycle 27 Day 1	27	80.25	17.92	50.0	83.33	100.0	25	4.00	18.18	-16.7	0.00	50.0
Cycle 28 Day 1	23	80.07	15.23	50.0	83.33	100.0	21	1.98	18.62	-16.7	0.00	50.0
Cycle 29 Day 1	24	80.56	12.69	50.0	83.33	100.0	22	3.03	14.21	-16.7	0.00	33.3
Cycle 30 Day 1	22	81.44	14.98	50.0	83.33	100.0	20	2.92	14.12	-16.7	0.00	33.3
Cycle 31 Day 1	22	81.44	15.20	50.0	83.33	100.0	20	2.08	19.28	-33.3	0.00	33.3
Cycle 32 Day 1	20	80.00	14.66	50.0	83.33	100.0	18	2.78	16.17	-25.0	0.00	33.3
Cycle 33 Day 1	17	84.31	11.37	50.0	83.33	100.0	15	5.56	17.72	-25.0	0.00	33.3
Cycle 34 Day 1	14	84.52	15.28	50.0	83.33	100.0	12	8.33	20.72	-16.7	8.33	50.0
Cycle 35 Day 1	15	80.56	12.86	58.3	83.33	100.0	13	4.49	17.88	-16.7	0.00	41.7
Cycle 36 Day 1	14	82.14	16.62	50.0	83.33	100.0	12	2.78	17.16	-16.7	0.00	33.3
Cycle 37 Day 1	12	84.72	11.70	58.3	83.33	100.0	11	10.61	15.85	-16.7	16.67	33.3
Cycle 38 Day 1	11	81.82	12.81	58.3	83.33	100.0	10	8.33	21.15	-25.0	12.50	41.7
Cycle 39 Day 1	10	80.00	15.32	50.0	83.33	100.0	9	3.70	13.89	-16.7	0.00	16.7
Study Disc 1	135	63.15	22.68	0.0	66.67	100.0	133	-8.58	24.10	-100.0	0.00	50.0
30 D SFU Z/P	58	65.09	23.90	0.0	66.67	100.0	57	-8.63	25.10	-75.0	0.00	50.0
90 D SFU Z/P	62	71.91	19.22	0.0	66.67	100.0	61	-5.46	21.19	-83.3	0.00	50.0
Placebo + CAPOX (N=253)												
Baseline	242	66.15	19.40	0.0	66.67	100.0						
Cycle 2 Day 1	222	69.71	17.70	0.0	66.67	100.0	217	2.96	18.89	-100.0	0.00	50.0
Cycle 3 Day 1	200	70.12	18.96	8.3	66.67	100.0	197	3.68	20.69	-83.3	0.00	58.3
Cycle 4 Day 1	171	71.54	17.02	8.3	66.67	100.0	169	4.54	20.59	-58.3	0.00	58.3
Cycle 5 Day 1	166	70.48	18.18	0.0	70.83	100.0	165	3.48	19.57	-50.0	0.00	58.3
Cycle 6 Day 1	147	71.83	17.83	0.0	75.00	100.0	146	3.94	20.51	-58.3	0.00	58.3
Cycle 7 Day 1	127	69.69	17.62	33.3	66.67	100.0	126	2.12	19.69	-50.0	0.00	58.3
Cycle 8 Day 1	111	71.10	18.83	0.0	75.00	100.0	110	4.32	20.31	-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: 12JAN24

Table 302.3.3002.5: 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 9 Day 1	104	72.04	16.74	33.3	66.67	100.0	103	3.32	20.89	-50.0	0.00	66.7
Cycle 10 Day 1	81	73.15	16.56	33.3	66.67	100.0	79	3.48	22.23	-50.0	0.00	66.7
Cycle 11 Day 1	72	72.57	17.72	25.0	75.00	100.0	71	3.99	23.18	-50.0	0.00	75.0
Cycle 12 Day 1	59	73.45	18.60	33.3	75.00	100.0	57	2.63	22.06	-50.0	0.00	75.0
Cycle 13 Day 1	50	72.50	17.44	25.0	75.00	100.0	48	3.30	20.82	-41.7	0.00	58.3
Cycle 14 Day 1	46	75.36	20.18	16.7	83.33	100.0	44	3.79	21.15	-66.7	0.00	50.0
Cycle 15 Day 1	38	74.34	22.21	8.3	83.33	100.0	36	2.08	21.02	-66.7	0.00	58.3
Cycle 16 Day 1	33	77.02	20.84	0.0	83.33	100.0	31	5.65	17.40	-25.0	0.00	41.7
Cycle 17 Day 1	28	77.08	18.65	33.3	83.33	100.0	25	3.33	20.41	-33.3	0.00	58.3
Cycle 18 Day 1	23	77.90	21.85	0.0	83.33	100.0	21	3.97	31.36	-100.0	8.33	66.7
Cycle 19 Day 1	21	86.51	13.30	50.0	83.33	100.0	20	10.42	15.97	-8.3	4.17	50.0
Cycle 20 Day 1	20	79.17	14.68	50.0	83.33	100.0	19	3.95	19.71	-33.3	0.00	58.3
Cycle 21 Day 1	21	78.57	17.39	50.0	83.33	100.0	20	2.92	18.98	-16.7	0.00	66.7
Cycle 22 Day 1	18	81.48	14.16	50.0	83.33	100.0	17	9.31	22.99	-16.7	0.00	58.3
Cycle 23 Day 1	17	79.90	12.86	50.0	83.33	100.0	16	9.38	19.69	-16.7	0.00	66.7
Cycle 24 Day 1	13	82.69	9.90	66.7	83.33	100.0	12	9.72	21.86	-16.7	4.17	66.7
Cycle 25 Day 1	13	85.26	12.80	66.7	83.33	100.0	12	10.42	24.39	-25.0	0.00	66.7
Cycle 26 Day 1	10	83.33	17.57	41.7	83.33	100.0	9	3.70	19.59	-33.3	8.33	41.7
Cycle 27 Day 1	11	87.88	10.11	75.0	83.33	100.0	10	6.67	11.65	-8.3	4.17	33.3
Cycle 28 Day 1	11	81.82	11.07	66.7	83.33	100.0	11	5.30	14.08	-8.3	0.00	33.3
Cycle 29 Day 1	12	80.56	14.79	58.3	83.33	100.0	12	4.86	14.42	-16.7	0.00	33.3
Study Disc 1	157	54.46	23.52	0.0	50.00	100.0	151	-12.20	22.81	-83.3	-8.33	41.7
30 D SFU Z/P	80	57.29	22.00	0.0	54.17	100.0	78	-10.68	24.65	-83.3	-8.33	41.7
90 D SFU Z/P	81	62.55	21.97	0.0	66.67	100.0	79	-4.96	22.86	-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: 12JAN24

Table 302.3.3002.6: 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 + CAPOX (N=254)												
Baseline	243	83.79	16.85	13.3	86.67	100.0						
Cycle 2 Day 1	209	83.09	17.53	0.0	86.67	100.0	208	-0.93	14.62	-60.0	0.00	40.0
Cycle 3 Day 1	187	82.50	17.93	0.0	86.67	100.0	182	-1.76	14.13	-66.7	0.00	40.0
Cycle 4 Day 1	172	84.07	17.08	13.3	86.67	100.0	169	-0.16	14.25	-53.3	0.00	33.3
Cycle 5 Day 1	163	83.48	16.86	6.7	86.67	100.0	159	-0.67	15.32	-46.7	0.00	46.7
Cycle 6 Day 1	151	83.00	18.68	6.7	86.67	100.0	149	-0.89	15.47	-53.3	0.00	40.0
Cycle 7 Day 1	122	82.46	18.78	6.7	86.67	100.0	120	-1.78	16.05	-80.0	0.00	46.7
Cycle 8 Day 1	114	82.40	17.09	13.3	86.67	100.0	108	-3.27	15.51	-33.3	0.00	60.0
Cycle 9 Day 1	107	81.81	19.42	0.0	86.67	100.0	102	-3.20	17.84	-66.7	0.00	46.7
Cycle 10 Day 1	88	82.58	19.51	0.0	86.67	100.0	85	-2.75	17.13	-66.7	0.00	46.7
Cycle 11 Day 1	84	86.43	12.94	40.0	86.67	100.0	81	-0.82	15.00	-33.3	0.00	46.7
Cycle 12 Day 1	77	86.49	12.56	46.7	86.67	100.0	75	-0.89	17.31	-26.7	0.00	46.7
Cycle 13 Day 1	62	85.81	11.03	60.0	86.67	100.0	60	-0.56	18.59	-33.3	0.00	60.0
Cycle 14 Day 1	57	87.13	12.21	60.0	86.67	100.0	55	0.12	15.95	-26.7	0.00	46.7
Cycle 15 Day 1	53	87.67	12.84	60.0	93.33	100.0	51	0.39	14.20	-20.0	0.00	40.0
Cycle 16 Day 1	50	86.53	11.62	53.3	86.67	100.0	48	-0.42	14.77	-26.7	0.00	40.0
Cycle 17 Day 1	45	89.93	12.11	53.3	93.33	100.0	43	2.33	14.61	-26.7	0.00	53.3
Cycle 18 Day 1	43	85.27	14.88	26.7	86.67	100.0	41	-2.93	17.32	-73.3	0.00	33.3
Cycle 19 Day 1	42	88.89	12.02	53.3	93.33	100.0	40	1.33	10.48	-13.3	0.00	33.3
Cycle 20 Day 1	41	87.80	12.37	53.3	86.67	100.0	39	-0.85	11.96	-20.0	0.00	33.3
Cycle 21 Day 1	38	87.89	13.14	53.3	90.00	100.0	36	-0.74	13.31	-26.7	0.00	33.3
Cycle 22 Day 1	33	89.09	12.89	53.3	86.67	100.0	31	-0.22	12.11	-20.0	0.00	26.7
Cycle 23 Day 1	33	90.10	11.68	60.0	93.33	100.0	31	-0.22	14.35	-20.0	0.00	53.3
Cycle 24 Day 1	31	92.47	9.39	66.7	93.33	100.0	29	2.30	14.61	-20.0	0.00	53.3
Cycle 25 Day 1	30	90.44	11.96	60.0	96.67	100.0	28	0.48	17.40	-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: 12JAN24

Table 302.3.3002.6: 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 26 Day 1	28	91.67	10.20	66.7	96.67	100.0	26	1.28	17.28	-26.7	0.00	66.7
Cycle 27 Day 1	27	91.11	11.09	66.7	93.33	100.0	25	1.07	16.52	-26.7	0.00	60.0
Cycle 28 Day 1	23	87.54	13.53	60.0	93.33	100.0	21	-1.27	16.55	-26.7	0.00	46.7
Cycle 29 Day 1	24	86.94	21.58	0.0	93.33	100.0	22	-3.33	23.25	-73.3	0.00	60.0
Cycle 30 Day 1	22	91.21	9.51	73.3	93.33	100.0	20	1.67	16.17	-26.7	0.00	60.0
Cycle 31 Day 1	22	90.61	10.62	66.7	93.33	100.0	20	2.00	16.91	-26.7	0.00	60.0
Cycle 32 Day 1	20	87.33	14.65	46.7	93.33	100.0	18	-1.11	19.97	-40.0	0.00	60.0
Cycle 33 Day 1	17	91.37	10.48	66.7	93.33	100.0	15	2.22	18.11	-13.3	0.00	60.0
Cycle 34 Day 1	14	94.29	8.21	80.0	100.00	100.0	12	6.67	17.98	-13.3	0.00	60.0
Cycle 35 Day 1	15	95.56	9.97	66.7	100.00	100.0	13	7.18	18.55	-13.3	0.00	60.0
Cycle 36 Day 1	14	95.71	6.72	80.0	100.00	100.0	12	6.67	17.98	-13.3	0.00	60.0
Cycle 37 Day 1	12	93.89	8.74	80.0	100.00	100.0	11	7.27	17.24	-13.3	0.00	53.3
Cycle 38 Day 1	11	92.73	10.94	66.7	100.00	100.0	10	6.67	21.55	-13.3	0.00	60.0
Cycle 39 Day 1	10	94.67	9.84	73.3	100.00	100.0	9	2.96	10.06	-13.3	0.00	20.0
Study Disc 1	135	75.36	24.55	0.0	80.00	100.0	133	-10.38	22.48	-100.0	-6.67	46.7
30 D SFU Z/P	58	77.24	21.05	6.7	80.00	100.0	57	-8.65	22.36	-66.7	-6.67	46.7
90 D SFU Z/P	62	79.78	21.05	6.7	83.33	100.0	61	-10.16	20.28	-86.7	-6.67	33.3
Placebo + CAPOX (N=253)												
Baseline	242	83.55	17.22	0.0	86.67	100.0						
Cycle 2 Day 1	222	83.27	17.17	0.0	86.67	100.0	217	-0.77	13.70	-73.3	0.00	33.3
Cycle 3 Day 1	200	84.43	17.96	13.3	86.67	100.0	197	-0.07	14.94	-80.0	0.00	46.7
Cycle 4 Day 1	171	85.11	16.35	6.7	86.67	100.0	169	1.07	15.38	-93.3	0.00	46.7
Cycle 5 Day 1	166	84.82	17.50	13.3	86.67	100.0	165	0.24	16.29	-66.7	0.00	53.3
Cycle 6 Day 1	147	83.90	19.64	0.0	86.67	100.0	146	-0.96	17.94	-86.7	0.00	53.3
Cycle 7 Day 1	127	85.51	17.03	6.7	86.67	100.0	126	0.21	17.69	-93.3	0.00	46.7
Cycle 8 Day 1	111	83.78	19.36	6.7	86.67	100.0	110	-1.33	17.08	-93.3	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: 12JAN24

Table 302.3.3002.6: 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 9 Day 1	104	84.94	18.83	6.7	86.67	100.0	103	-0.84	18.26	-93.3	0.00	46.7
Cycle 10 Day 1	81	85.02	17.78	13.3	86.67	100.0	79	-2.28	18.76	-86.7	0.00	40.0
Cycle 11 Day 1	72	86.76	15.76	20.0	93.33	100.0	71	-0.09	17.11	-80.0	0.00	33.3
Cycle 12 Day 1	59	87.34	16.92	20.0	93.33	100.0	57	-0.70	19.18	-80.0	0.00	46.7
Cycle 13 Day 1	50	88.53	13.20	33.3	90.00	100.0	48	0.97	13.89	-46.7	0.00	40.0
Cycle 14 Day 1	46	88.55	15.18	6.7	86.67	100.0	44	1.21	13.04	-26.7	0.00	33.3
Cycle 15 Day 1	38	86.67	17.40	6.7	86.67	100.0	36	0.00	13.62	-40.0	0.00	33.3
Cycle 16 Day 1	33	87.88	16.87	13.3	93.33	100.0	31	0.86	12.14	-20.0	0.00	33.3
Cycle 17 Day 1	28	88.57	15.59	40.0	93.33	100.0	25	2.13	16.75	-40.0	0.00	33.3
Cycle 18 Day 1	23	92.46	10.88	60.0	93.33	100.0	21	3.49	15.44	-40.0	0.00	46.7
Cycle 19 Day 1	21	94.29	7.08	80.0	100.00	100.0	20	4.00	13.40	-20.0	0.00	46.7
Cycle 20 Day 1	20	90.67	11.73	60.0	93.33	100.0	19	2.81	16.68	-40.0	0.00	46.7
Cycle 21 Day 1	21	91.75	8.14	73.3	93.33	100.0	20	3.33	12.89	-20.0	0.00	40.0
Cycle 22 Day 1	18	92.22	10.29	60.0	93.33	100.0	17	5.49	17.52	-40.0	0.00	46.7
Cycle 23 Day 1	17	91.76	10.68	60.0	93.33	100.0	16	5.83	19.30	-33.3	0.00	46.7
Cycle 24 Day 1	13	92.31	9.75	66.7	93.33	100.0	12	5.56	17.71	-33.3	0.00	33.3
Cycle 25 Day 1	13	90.26	13.23	53.3	93.33	100.0	12	3.89	23.35	-46.7	0.00	46.7
Cycle 26 Day 1	10	92.00	9.32	73.3	93.33	100.0	9	2.96	17.36	-20.0	0.00	40.0
Cycle 27 Day 1	11	92.12	6.54	86.7	86.67	100.0	10	2.00	13.72	-13.3	0.00	33.3
Cycle 28 Day 1	11	87.88	11.08	66.7	86.67	100.0	11	-1.82	19.80	-26.7	-6.67	46.7
Cycle 29 Day 1	12	88.89	9.98	73.3	86.67	100.0	12	1.11	18.16	-20.0	0.00	46.7
Study Disc 1	157	70.40	28.97	0.0	80.00	100.0	151	-14.08	26.22	-100.0	-6.67	33.3
30 D SFU Z/P	80	76.58	22.00	0.0	80.00	100.0	78	-9.91	20.29	-66.7	-6.67	26.7
90 D SFU Z/P	81	77.37	24.65	0.0	86.67	100.0	79	-10.63	22.28	-86.7	0.00	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: 12JAN24

Table 302.3.3002.7: 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 + CAPOX (N=254)												
Baseline	243	83.20	22.52	0.0	100.00	100.0						
Cycle 2 Day 1	209	80.78	24.16	0.0	83.33	100.0	208	-2.64	20.52	-66.7	0.00	66.7
Cycle 3 Day 1	187	81.28	23.19	0.0	100.00	100.0	182	-2.38	21.82	-83.3	0.00	50.0
Cycle 4 Day 1	172	80.81	23.91	0.0	100.00	100.0	169	-2.37	20.36	-66.7	0.00	33.3
Cycle 5 Day 1	163	82.52	22.13	0.0	100.00	100.0	159	-0.94	20.73	-66.7	0.00	66.7
Cycle 6 Day 1	151	79.25	25.96	0.0	83.33	100.0	149	-3.69	22.91	-100.0	0.00	66.7
Cycle 7 Day 1	122	82.24	22.03	0.0	83.33	100.0	120	-2.08	20.68	-66.7	0.00	50.0
Cycle 8 Day 1	114	78.22	24.50	0.0	83.33	100.0	108	-5.25	21.57	-66.7	0.00	66.7
Cycle 9 Day 1	107	77.88	25.78	0.0	83.33	100.0	102	-5.39	23.71	-83.3	0.00	66.7
Cycle 10 Day 1	88	81.63	25.78	0.0	100.00	100.0	85	-3.92	24.89	-83.3	0.00	50.0
Cycle 11 Day 1	84	84.52	16.32	50.0	83.33	100.0	81	-3.50	19.31	-33.3	0.00	66.7
Cycle 12 Day 1	77	85.28	17.72	33.3	100.00	100.0	75	-3.33	23.89	-66.7	0.00	66.7
Cycle 13 Day 1	62	87.10	16.64	50.0	100.00	100.0	60	-0.83	24.44	-50.0	0.00	66.7
Cycle 14 Day 1	57	86.26	17.00	50.0	100.00	100.0	55	-1.21	21.48	-50.0	0.00	66.7
Cycle 15 Day 1	53	87.74	17.03	33.3	100.00	100.0	51	-0.65	21.07	-33.3	0.00	66.7
Cycle 16 Day 1	50	88.00	15.45	66.7	100.00	100.0	48	1.74	23.12	-33.3	0.00	66.7
Cycle 17 Day 1	45	90.00	15.65	50.0	100.00	100.0	43	3.10	22.50	-33.3	0.00	66.7
Cycle 18 Day 1	43	84.88	16.19	66.7	100.00	100.0	41	-3.25	20.49	-33.3	0.00	33.3
Cycle 19 Day 1	42	86.90	17.47	33.3	100.00	100.0	40	-0.42	20.50	-33.3	0.00	33.3
Cycle 20 Day 1	41	89.02	16.92	33.3	100.00	100.0	39	1.28	20.37	-33.3	0.00	33.3
Cycle 21 Day 1	38	86.40	17.70	33.3	100.00	100.0	36	-0.93	20.29	-33.3	0.00	33.3
Cycle 22 Day 1	33	88.89	17.51	33.3	100.00	100.0	31	0.54	19.48	-33.3	0.00	33.3
Cycle 23 Day 1	33	90.40	15.04	66.7	100.00	100.0	31	0.00	18.76	-33.3	0.00	33.3
Cycle 24 Day 1	31	90.32	13.45	66.7	100.00	100.0	29	0.00	18.37	-33.3	0.00	33.3
Cycle 25 Day 1	30	91.67	14.35	66.7	100.00	100.0	28	1.79	20.95	-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: 12JAN24

Table 302.3.3002.7: 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 26 Day 1	28	88.69	15.75	66.7	100.00	100.0	26	-0.64	20.81	-33.3	0.00	33.3
Cycle 27 Day 1	27	90.12	14.81	66.7	100.00	100.0	25	0.00	17.35	-33.3	0.00	33.3
Cycle 28 Day 1	23	89.13	13.86	66.7	100.00	100.0	21	1.59	18.18	-33.3	0.00	33.3
Cycle 29 Day 1	24	86.81	23.56	0.0	100.00	100.0	22	-1.52	24.62	-66.7	0.00	50.0
Cycle 30 Day 1	22	91.67	14.32	66.7	100.00	100.0	20	3.33	19.19	-33.3	0.00	50.0
Cycle 31 Day 1	22	93.94	13.16	66.7	100.00	100.0	20	7.50	21.27	-33.3	0.00	50.0
Cycle 32 Day 1	20	90.83	14.78	66.7	100.00	100.0	18	5.56	23.57	-33.3	0.00	50.0
Cycle 33 Day 1	17	92.16	13.33	66.7	100.00	100.0	15	6.67	20.70	-33.3	0.00	50.0
Cycle 34 Day 1	14	92.86	12.60	66.7	100.00	100.0	12	9.72	24.06	-33.3	0.00	50.0
Cycle 35 Day 1	15	92.22	13.90	66.7	100.00	100.0	13	7.69	21.10	-33.3	0.00	50.0
Cycle 36 Day 1	14	95.24	10.19	66.7	100.00	100.0	12	9.72	21.86	-33.3	0.00	50.0
Cycle 37 Day 1	12	93.06	13.22	66.7	100.00	100.0	11	12.12	23.68	-33.3	0.00	50.0
Cycle 38 Day 1	11	92.42	11.46	66.7	100.00	100.0	10	13.33	21.94	-33.3	16.67	33.3
Cycle 39 Day 1	10	90.00	16.10	66.7	100.00	100.0	9	7.41	22.22	-33.3	0.00	33.3
Study Disc 1	135	72.35	30.21	0.0	83.33	100.0	133	-14.41	26.89	-100.0	0.00	66.7
30 D SFU Z/P	58	73.85	24.80	0.0	66.67	100.0	57	-13.16	27.95	-100.0	-16.67	33.3
90 D SFU Z/P	62	80.38	24.98	0.0	100.00	100.0	61	-10.93	27.03	-100.0	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	242	82.23	23.59	0.0	100.00	100.0						
Cycle 2 Day 1	222	80.71	23.98	0.0	83.33	100.0	217	-1.92	19.97	-83.3	0.00	66.7
Cycle 3 Day 1	200	80.92	25.31	0.0	100.00	100.0	197	-2.28	24.38	-100.0	0.00	66.7
Cycle 4 Day 1	171	81.77	25.32	0.0	100.00	100.0	169	-0.79	24.65	-100.0	0.00	66.7
Cycle 5 Day 1	166	82.73	23.42	0.0	100.00	100.0	165	-0.40	25.03	-83.3	0.00	83.3
Cycle 6 Day 1	147	80.39	24.50	0.0	83.33	100.0	146	-3.08	24.68	-100.0	0.00	66.7
Cycle 7 Day 1	127	83.33	22.12	0.0	100.00	100.0	126	-0.79	23.74	-100.0	0.00	66.7
Cycle 8 Day 1	111	78.68	27.36	0.0	100.00	100.0	110	-5.61	26.16	-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: 12JAN24

Table 302.3.3002.7: 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 9 Day 1	104	81.57	23.45	0.0	83.33	100.0	103	-2.59	23.89	-100.0	0.00	50.0
Cycle 10 Day 1	81	82.10	24.83	0.0	100.00	100.0	79	-3.59	26.91	-100.0	0.00	50.0
Cycle 11 Day 1	72	81.94	25.45	0.0	100.00	100.0	71	-3.29	28.40	-100.0	0.00	66.7
Cycle 12 Day 1	59	84.18	23.86	0.0	100.00	100.0	57	-2.63	26.69	-100.0	0.00	33.3
Cycle 13 Day 1	50	84.67	23.29	0.0	100.00	100.0	48	-0.35	27.39	-66.7	0.00	66.7
Cycle 14 Day 1	46	85.14	20.85	0.0	100.00	100.0	44	0.76	21.25	-50.0	0.00	66.7
Cycle 15 Day 1	38	84.21	23.55	0.0	100.00	100.0	36	-0.46	24.72	-100.0	0.00	50.0
Cycle 16 Day 1	33	83.33	22.44	0.0	100.00	100.0	31	0.00	21.08	-33.3	0.00	50.0
Cycle 17 Day 1	28	85.12	21.91	33.3	100.00	100.0	25	2.67	28.74	-66.7	0.00	66.7
Cycle 18 Day 1	23	88.41	17.72	33.3	100.00	100.0	21	6.35	21.39	-33.3	0.00	33.3
Cycle 19 Day 1	21	92.86	12.44	66.7	100.00	100.0	20	6.67	17.44	-16.7	0.00	33.3
Cycle 20 Day 1	20	90.83	13.76	66.7	100.00	100.0	19	10.53	22.37	-16.7	0.00	66.7
Cycle 21 Day 1	21	89.68	15.34	66.7	100.00	100.0	20	6.67	23.82	-33.3	0.00	66.7
Cycle 22 Day 1	18	88.89	15.12	66.7	100.00	100.0	17	8.82	24.38	-33.3	0.00	66.7
Cycle 23 Day 1	17	88.24	15.33	66.7	100.00	100.0	16	9.37	30.41	-33.3	0.00	83.3
Cycle 24 Day 1	13	89.74	14.50	66.7	100.00	100.0	12	6.94	27.02	-33.3	0.00	66.7
Cycle 25 Day 1	13	88.46	18.49	50.0	100.00	100.0	12	8.33	28.87	-33.3	0.00	66.7
Cycle 26 Day 1	10	85.00	27.72	16.7	100.00	100.0	9	-3.70	27.36	-50.0	0.00	33.3
Cycle 27 Day 1	11	86.36	16.36	66.7	100.00	100.0	10	-3.33	23.31	-33.3	0.00	33.3
Cycle 28 Day 1	11	84.85	17.41	50.0	83.33	100.0	11	-4.55	21.20	-33.3	-16.67	33.3
Cycle 29 Day 1	12	87.50	17.59	50.0	100.00	100.0	12	2.78	19.89	-16.7	0.00	33.3
Study Disc 1	157	67.09	32.19	0.0	66.67	100.0	151	-15.01	32.07	-100.0	0.00	66.7
30 D SFU Z/P	80	67.50	30.34	0.0	66.67	100.0	78	-16.88	31.38	-100.0	-16.67	50.0
90 D SFU Z/P	81	75.51	27.65	0.0	83.33	100.0	79	-9.49	30.39	-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: 12JAN24

Table 302.3.3002.8: 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 + CAPOX (N=254)												
Baseline	243	80.42	19.13	8.3	83.33	100.0						
Cycle 2 Day 1	209	82.22	19.08	16.7	83.33	100.0	208	1.32	15.92	-50.0	0.00	58.3
Cycle 3 Day 1	187	82.13	18.36	0.0	83.33	100.0	182	0.05	16.21	-91.7	0.00	66.7
Cycle 4 Day 1	172	83.62	17.45	8.3	91.67	100.0	169	2.42	15.52	-50.0	0.00	58.3
Cycle 5 Day 1	163	83.69	17.55	0.0	91.67	100.0	159	2.46	17.35	-100.0	0.00	58.3
Cycle 6 Day 1	151	83.00	18.25	8.3	83.33	100.0	149	1.79	15.96	-58.3	0.00	50.0
Cycle 7 Day 1	122	84.63	16.18	33.3	91.67	100.0	120	3.54	17.90	-50.0	0.00	91.7
Cycle 8 Day 1	114	80.70	21.71	8.3	83.33	100.0	108	0.77	19.15	-50.0	0.00	91.7
Cycle 9 Day 1	107	80.84	19.06	0.0	83.33	100.0	102	2.53	19.19	-58.3	0.00	91.7
Cycle 10 Day 1	88	83.52	19.24	0.0	91.67	100.0	85	5.20	21.13	-41.7	0.00	91.7
Cycle 11 Day 1	84	84.72	15.94	41.7	91.67	100.0	81	5.35	20.47	-33.3	0.00	91.7
Cycle 12 Day 1	77	87.23	14.28	41.7	91.67	100.0	75	6.44	19.93	-33.3	0.00	91.7
Cycle 13 Day 1	62	86.69	16.35	41.7	91.67	100.0	60	6.11	20.40	-33.3	0.00	91.7
Cycle 14 Day 1	57	85.53	16.48	33.3	91.67	100.0	55	3.94	19.96	-41.7	0.00	91.7
Cycle 15 Day 1	53	85.85	15.81	41.7	91.67	100.0	51	4.25	16.61	-33.3	0.00	41.7
Cycle 16 Day 1	50	85.50	15.87	41.7	91.67	100.0	48	3.99	15.75	-33.3	0.00	41.7
Cycle 17 Day 1	45	86.30	16.59	41.7	91.67	100.0	43	5.81	15.16	-25.0	8.33	41.7
Cycle 18 Day 1	43	82.56	17.04	41.7	91.67	100.0	41	2.24	15.59	-25.0	0.00	41.7
Cycle 19 Day 1	42	85.71	15.10	41.7	91.67	100.0	40	5.00	15.07	-33.3	4.17	41.7
Cycle 20 Day 1	41	84.55	16.20	33.3	83.33	100.0	39	3.85	15.40	-41.7	8.33	41.7
Cycle 21 Day 1	38	84.21	18.56	25.0	91.67	100.0	36	3.94	18.31	-50.0	0.00	41.7
Cycle 22 Day 1	33	85.61	16.31	41.7	91.67	100.0	31	4.30	14.25	-25.0	8.33	33.3
Cycle 23 Day 1	33	85.61	16.31	41.7	91.67	100.0	31	2.42	11.42	-25.0	0.00	33.3
Cycle 24 Day 1	31	85.75	17.24	41.7	91.67	100.0	29	2.59	14.79	-33.3	0.00	41.7
Cycle 25 Day 1	30	86.67	17.99	25.0	95.83	100.0	28	2.68	16.36	-50.0	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: 12JAN24

Table 302.3.3002.8: 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 26 Day 1	28	86.31	18.17	33.3	100.00	100.0	26	4.17	16.37	-41.7	4.17	41.7
Cycle 27 Day 1	27	86.11	20.15	25.0	91.67	100.0	25	3.00	18.30	-50.0	8.33	41.7
Cycle 28 Day 1	23	81.88	19.73	25.0	91.67	100.0	21	0.79	19.53	-50.0	0.00	41.7
Cycle 29 Day 1	24	84.38	17.26	41.7	91.67	100.0	22	2.65	17.33	-25.0	4.17	41.7
Cycle 30 Day 1	22	82.20	17.69	41.7	87.50	100.0	20	-0.42	17.41	-33.3	0.00	25.0
Cycle 31 Day 1	22	83.33	18.00	41.7	87.50	100.0	20	1.25	17.16	-25.0	0.00	41.7
Cycle 32 Day 1	20	83.33	18.34	50.0	91.67	100.0	18	3.70	16.96	-25.0	4.17	41.7
Cycle 33 Day 1	17	89.22	16.07	50.0	91.67	100.0	15	5.56	18.81	-25.0	0.00	41.7
Cycle 34 Day 1	14	94.64	11.14	58.3	100.00	100.0	12	11.81	12.03	-8.3	8.33	33.3
Cycle 35 Day 1	15	87.78	15.06	50.0	91.67	100.0	13	5.13	15.79	-16.7	0.00	41.7
Cycle 36 Day 1	14	90.48	16.62	41.7	95.83	100.0	12	9.03	15.27	-25.0	8.33	33.3
Cycle 37 Day 1	12	90.97	16.46	50.0	100.00	100.0	11	11.36	15.93	-16.7	8.33	41.7
Cycle 38 Day 1	11	90.15	11.07	66.7	91.67	100.0	10	10.83	14.72	-8.3	8.33	41.7
Cycle 39 Day 1	10	79.17	20.13	50.0	75.00	100.0	9	-1.85	21.15	-25.0	-8.33	41.7
Study Disc 1	135	75.25	23.85	0.0	83.33	100.0	133	-6.77	22.94	-100.0	0.00	91.7
30 D SFU Z/P	58	75.57	23.72	0.0	75.00	100.0	57	-5.99	26.01	-75.0	-8.33	91.7
90 D SFU Z/P	62	81.32	18.95	33.3	83.33	100.0	61	-4.37	15.34	-50.0	0.00	41.7
Placebo + CAPOX (N=253)												
Baseline	242	78.79	19.41	0.0	83.33	100.0						
Cycle 2 Day 1	222	82.96	18.47	0.0	83.33	100.0	217	4.42	16.49	-58.3	0.00	58.3
Cycle 3 Day 1	200	81.46	19.35	0.0	83.33	100.0	197	3.00	18.84	-66.7	0.00	66.7
Cycle 4 Day 1	171	81.63	18.70	0.0	83.33	100.0	169	2.51	19.52	-50.0	0.00	66.7
Cycle 5 Day 1	166	83.23	17.31	33.3	83.33	100.0	165	3.69	17.81	-58.3	0.00	50.0
Cycle 6 Day 1	147	82.60	19.43	0.0	91.67	100.0	146	3.77	19.18	-58.3	0.00	66.7
Cycle 7 Day 1	127	81.50	20.27	0.0	83.33	100.0	126	2.12	21.24	-66.7	0.00	58.3
Cycle 8 Day 1	111	80.93	20.46	0.0	83.33	100.0	110	2.20	18.08	-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.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.8: 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 9 Day 1	104	82.45	18.76	0.0	83.33	100.0	103	2.59	19.07	-50.0	0.00	41.7
Cycle 10 Day 1	81	81.38	20.04	8.3	83.33	100.0	79	1.79	20.62	-50.0	0.00	50.0
Cycle 11 Day 1	72	83.68	22.53	0.0	91.67	100.0	71	2.58	20.97	-50.0	0.00	58.3
Cycle 12 Day 1	59	83.05	22.05	8.3	91.67	100.0	57	2.05	21.49	-50.0	0.00	50.0
Cycle 13 Day 1	50	83.33	19.56	25.0	91.67	100.0	48	1.91	21.42	-50.0	0.00	50.0
Cycle 14 Day 1	46	83.33	19.25	25.0	91.67	100.0	44	-1.33	18.76	-50.0	0.00	41.7
Cycle 15 Day 1	38	84.65	20.46	25.0	91.67	100.0	36	-1.85	21.19	-50.0	0.00	50.0
Cycle 16 Day 1	33	86.11	19.51	33.3	91.67	100.0	31	-0.27	23.22	-58.3	0.00	50.0
Cycle 17 Day 1	28	92.26	10.38	66.7	100.00	100.0	25	5.33	16.12	-16.7	0.00	50.0
Cycle 18 Day 1	23	90.94	12.03	58.3	91.67	100.0	21	3.97	19.65	-33.3	0.00	58.3
Cycle 19 Day 1	21	95.24	8.96	66.7	100.00	100.0	20	4.58	13.10	-25.0	0.00	33.3
Cycle 20 Day 1	20	89.17	12.42	66.7	91.67	100.0	19	1.75	19.95	-33.3	0.00	58.3
Cycle 21 Day 1	21	92.46	10.51	66.7	100.00	100.0	20	5.00	18.22	-33.3	0.00	50.0
Cycle 22 Day 1	18	88.43	11.83	66.7	91.67	100.0	17	2.45	18.58	-25.0	0.00	58.3
Cycle 23 Day 1	17	90.69	12.46	66.7	100.00	100.0	16	3.65	23.56	-25.0	0.00	58.3
Cycle 24 Day 1	13	87.82	15.45	58.3	91.67	100.0	12	-0.69	23.96	-33.3	0.00	58.3
Cycle 25 Day 1	13	89.74	15.65	58.3	100.00	100.0	12	-0.69	20.24	-33.3	0.00	50.0
Cycle 26 Day 1	10	90.83	16.41	50.0	100.00	100.0	9	-3.70	18.69	-41.7	0.00	25.0
Cycle 27 Day 1	11	89.39	17.52	50.0	100.00	100.0	10	-5.83	19.66	-41.7	0.00	25.0
Cycle 28 Day 1	11	87.88	16.82	50.0	91.67	100.0	11	-3.79	19.85	-41.7	0.00	25.0
Cycle 29 Day 1	12	87.50	22.89	25.0	100.00	100.0	12	-3.47	27.17	-66.7	0.00	33.3
Study Disc 1	157	70.17	24.33	0.0	66.67	100.0	151	-6.84	22.67	-66.7	0.00	41.7
30 D SFU Z/P	80	71.56	25.32	0.0	75.00	100.0	78	-5.02	24.15	-75.0	0.00	41.7
90 D SFU Z/P	81	76.54	23.61	0.0	83.33	100.0	79	0.21	21.88	-58.3	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: 12JAN24

Table 302.3.3002.9: 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 + CAPOX (N=254)												
Baseline	243	90.95	14.86	33.3	100.00	100.0						
Cycle 2 Day 1	209	90.51	15.47	33.3	100.00	100.0	208	-0.24	13.36	-66.7	0.00	66.7
Cycle 3 Day 1	187	89.75	15.37	0.0	100.00	100.0	182	-1.47	14.90	-83.3	0.00	50.0
Cycle 4 Day 1	172	90.99	14.46	16.7	100.00	100.0	169	-0.59	13.47	-50.0	0.00	50.0
Cycle 5 Day 1	163	89.57	16.47	0.0	100.00	100.0	159	-1.89	15.80	-83.3	0.00	50.0
Cycle 6 Day 1	151	90.07	15.54	16.7	100.00	100.0	149	-1.45	14.87	-50.0	0.00	50.0
Cycle 7 Day 1	122	91.26	13.92	33.3	100.00	100.0	120	0.00	16.31	-66.7	0.00	66.7
Cycle 8 Day 1	114	88.45	15.85	16.7	100.00	100.0	108	-2.16	15.13	-50.0	0.00	50.0
Cycle 9 Day 1	107	88.47	16.73	16.7	100.00	100.0	102	-1.96	14.70	-50.0	0.00	33.3
Cycle 10 Day 1	88	89.96	14.85	33.3	100.00	100.0	85	-0.59	17.15	-50.0	0.00	66.7
Cycle 11 Day 1	84	90.28	13.98	50.0	100.00	100.0	81	-1.23	14.86	-33.3	0.00	50.0
Cycle 12 Day 1	77	91.34	12.27	66.7	100.00	100.0	75	-0.22	13.83	-33.3	0.00	50.0
Cycle 13 Day 1	62	90.59	13.02	66.7	100.00	100.0	60	-0.28	15.19	-33.3	0.00	66.7
Cycle 14 Day 1	57	92.69	11.79	66.7	100.00	100.0	55	0.61	15.70	-33.3	0.00	66.7
Cycle 15 Day 1	53	91.51	12.50	66.7	100.00	100.0	51	-0.98	15.06	-33.3	0.00	50.0
Cycle 16 Day 1	50	92.67	11.74	66.7	100.00	100.0	48	1.39	16.43	-16.7	0.00	66.7
Cycle 17 Day 1	45	92.59	12.08	66.7	100.00	100.0	43	0.78	12.57	-16.7	0.00	50.0
Cycle 18 Day 1	43	91.86	11.13	66.7	100.00	100.0	41	1.63	13.85	-16.7	0.00	50.0
Cycle 19 Day 1	42	90.48	11.72	66.7	100.00	100.0	40	0.42	16.66	-33.3	0.00	50.0
Cycle 20 Day 1	41	90.65	12.39	66.7	100.00	100.0	39	0.85	17.91	-33.3	0.00	66.7
Cycle 21 Day 1	38	91.23	13.83	50.0	100.00	100.0	36	0.93	19.08	-33.3	0.00	50.0
Cycle 22 Day 1	33	92.42	11.85	66.7	100.00	100.0	31	2.69	18.31	-33.3	0.00	50.0
Cycle 23 Day 1	33	93.43	11.74	66.7	100.00	100.0	31	1.61	17.93	-33.3	0.00	66.7
Cycle 24 Day 1	31	94.62	10.88	66.7	100.00	100.0	29	2.30	18.75	-33.3	0.00	66.7
Cycle 25 Day 1	30	94.44	9.11	66.7	100.00	100.0	28	1.79	18.89	-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: 12JAN24

Table 302.3.3002.9: 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 26 Day 1	28	93.45	12.29	50.0	100.00	100.0	26	1.92	19.05	-33.3	0.00	66.7
Cycle 27 Day 1	27	93.83	10.49	66.7	100.00	100.0	25	2.67	17.13	-16.7	0.00	66.7
Cycle 28 Day 1	23	93.48	10.94	66.7	100.00	100.0	21	3.17	18.72	-16.7	0.00	66.7
Cycle 29 Day 1	24	90.97	12.98	66.7	100.00	100.0	22	0.76	21.50	-33.3	0.00	66.7
Cycle 30 Day 1	22	92.42	13.34	50.0	100.00	100.0	20	0.00	18.73	-33.3	0.00	66.7
Cycle 31 Day 1	22	90.91	12.31	66.7	100.00	100.0	20	0.00	18.73	-16.7	0.00	66.7
Cycle 32 Day 1	20	92.50	12.65	66.7	100.00	100.0	18	2.78	21.58	-33.3	0.00	66.7
Cycle 33 Day 1	17	95.10	7.83	83.3	100.00	100.0	15	5.56	20.57	-16.7	0.00	66.7
Cycle 34 Day 1	14	96.43	7.10	83.3	100.00	100.0	12	6.94	21.86	-16.7	0.00	66.7
Cycle 35 Day 1	15	95.56	9.89	66.7	100.00	100.0	13	6.41	24.09	-33.3	0.00	66.7
Cycle 36 Day 1	14	96.43	7.10	83.3	100.00	100.0	12	8.33	19.46	0.0	0.00	66.7
Cycle 37 Day 1	12	97.22	6.49	83.3	100.00	100.0	11	9.09	21.56	0.0	0.00	66.7
Cycle 38 Day 1	11	95.45	7.78	83.3	100.00	100.0	10	8.33	23.90	-16.7	0.00	66.7
Cycle 39 Day 1	10	95.00	8.05	83.3	100.00	100.0	9	1.85	13.03	-16.7	0.00	33.3
Study Disc 1	135	85.06	19.13	0.0	100.00	100.0	133	-6.27	18.87	-100.0	0.00	50.0
30 D SFU Z/P	58	89.37	18.12	16.7	100.00	100.0	57	-2.63	18.84	-83.3	0.00	50.0
90 D SFU Z/P	62	87.10	17.45	33.3	100.00	100.0	61	-7.65	17.37	-66.7	0.00	16.7
Placebo + CAPOX (N=253)												
Baseline	242	87.81	18.01	0.0	100.00	100.0						
Cycle 2 Day 1	222	88.51	17.28	0.0	100.00	100.0	217	0.54	15.50	-50.0	0.00	66.7
Cycle 3 Day 1	200	88.75	16.79	0.0	100.00	100.0	197	0.51	15.51	-50.0	0.00	50.0
Cycle 4 Day 1	171	89.28	16.53	16.7	100.00	100.0	169	1.87	15.58	-50.0	0.00	50.0
Cycle 5 Day 1	166	90.16	15.25	16.7	100.00	100.0	165	2.22	15.13	-50.0	0.00	50.0
Cycle 6 Day 1	147	88.66	17.12	0.0	100.00	100.0	146	0.91	16.81	-66.7	0.00	66.7
Cycle 7 Day 1	127	86.48	17.91	33.3	100.00	100.0	126	-1.19	17.02	-66.7	0.00	50.0
Cycle 8 Day 1	111	87.24	18.66	16.7	100.00	100.0	110	0.15	18.27	-83.3	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: 12JAN24

Table 302.3.3002.9: 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 9 Day 1	104	88.14	17.94	0.0	100.00	100.0	103	0.97	18.05	-100.0	0.00	33.3
Cycle 10 Day 1	81	87.24	18.12	16.7	100.00	100.0	79	-0.42	19.61	-83.3	0.00	50.0
Cycle 11 Day 1	72	86.81	16.77	33.3	100.00	100.0	71	-1.41	18.42	-66.7	0.00	50.0
Cycle 12 Day 1	59	88.42	16.74	16.7	100.00	100.0	57	1.17	16.62	-50.0	0.00	33.3
Cycle 13 Day 1	50	88.00	17.51	16.7	100.00	100.0	48	0.69	22.00	-50.0	0.00	83.3
Cycle 14 Day 1	46	88.04	19.14	16.7	100.00	100.0	44	0.00	19.02	-66.7	0.00	50.0
Cycle 15 Day 1	38	87.28	16.64	33.3	100.00	100.0	36	-1.39	19.67	-50.0	0.00	66.7
Cycle 16 Day 1	33	84.34	20.39	16.7	100.00	100.0	31	-2.69	20.68	-50.0	0.00	50.0
Cycle 17 Day 1	28	88.69	18.17	33.3	100.00	100.0	25	2.67	14.97	-33.3	0.00	50.0
Cycle 18 Day 1	23	91.30	13.17	66.7	100.00	100.0	21	2.38	16.06	-33.3	0.00	50.0
Cycle 19 Day 1	21	94.44	12.17	66.7	100.00	100.0	20	3.33	11.60	-33.3	0.00	16.7
Cycle 20 Day 1	20	88.33	13.36	66.7	91.67	100.0	19	1.75	21.44	-33.3	0.00	66.7
Cycle 21 Day 1	21	93.65	12.33	66.7	100.00	100.0	20	6.67	18.26	-33.3	0.00	66.7
Cycle 22 Day 1	18	90.74	14.26	66.7	100.00	100.0	17	4.90	20.21	-33.3	0.00	66.7
Cycle 23 Day 1	17	92.16	13.33	66.7	100.00	100.0	16	6.25	17.08	-33.3	0.00	50.0
Cycle 24 Day 1	13	88.46	17.19	50.0	100.00	100.0	12	0.00	15.89	-33.3	0.00	33.3
Cycle 25 Day 1	13	88.46	15.79	66.7	100.00	100.0	12	1.39	19.41	-33.3	0.00	50.0
Cycle 26 Day 1	10	91.67	14.16	66.7	100.00	100.0	9	0.00	16.67	-33.3	0.00	16.7
Cycle 27 Day 1	11	90.91	13.67	66.7	100.00	100.0	10	-1.67	14.59	-33.3	0.00	16.7
Cycle 28 Day 1	11	92.42	11.46	66.7	100.00	100.0	11	-3.03	14.56	-33.3	0.00	16.7
Cycle 29 Day 1	12	91.67	13.30	66.7	100.00	100.0	12	0.00	14.21	-33.3	0.00	16.7
Study Disc 1	157	80.68	24.06	0.0	83.33	100.0	151	-5.85	20.75	-83.3	0.00	66.7
30 D SFU Z/P	80	82.08	23.83	0.0	91.67	100.0	78	-4.27	20.18	-100.0	0.00	50.0
90 D SFU Z/P	81	83.95	21.15	0.0	83.33	100.0	79	-2.32	20.28	-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: 12JAN24

Table 302.3.3002.10: 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 + CAPOX (N=254)												
Baseline	243	79.42	22.16	0.0	83.33	100.0						
Cycle 2 Day 1	209	80.70	20.99	16.7	83.33	100.0	208	0.88	21.31	-66.7	0.00	66.7
Cycle 3 Day 1	187	77.63	22.73	0.0	83.33	100.0	182	-1.47	23.65	-66.7	0.00	66.7
Cycle 4 Day 1	172	80.33	21.15	0.0	83.33	100.0	169	0.79	23.77	-66.7	0.00	66.7
Cycle 5 Day 1	163	80.67	22.22	0.0	83.33	100.0	159	2.20	25.58	-100.0	0.00	66.7
Cycle 6 Day 1	151	78.70	22.78	0.0	83.33	100.0	149	-0.78	25.29	-83.3	0.00	66.7
Cycle 7 Day 1	122	78.96	22.45	0.0	83.33	100.0	120	-0.97	26.22	-100.0	0.00	66.7
Cycle 8 Day 1	114	78.80	23.18	0.0	83.33	100.0	108	-0.93	27.33	-100.0	0.00	66.7
Cycle 9 Day 1	107	77.26	22.94	0.0	83.33	100.0	102	-0.98	24.01	-66.7	0.00	66.7
Cycle 10 Day 1	88	81.06	23.19	0.0	83.33	100.0	85	2.55	25.39	-66.7	0.00	66.7
Cycle 11 Day 1	84	83.93	17.63	33.3	91.67	100.0	81	3.29	23.19	-66.7	0.00	66.7
Cycle 12 Day 1	77	84.20	18.12	33.3	83.33	100.0	75	3.33	23.09	-66.7	0.00	66.7
Cycle 13 Day 1	62	84.14	18.46	33.3	100.00	100.0	60	3.89	24.43	-66.7	0.00	66.7
Cycle 14 Day 1	57	83.92	16.66	50.0	83.33	100.0	55	2.12	20.80	-33.3	0.00	66.7
Cycle 15 Day 1	53	83.96	17.89	33.3	100.00	100.0	51	1.63	22.42	-66.7	0.00	66.7
Cycle 16 Day 1	50	85.67	18.75	16.7	100.00	100.0	48	4.86	20.03	-50.0	0.00	50.0
Cycle 17 Day 1	45	86.67	16.51	50.0	100.00	100.0	43	5.43	18.45	-33.3	0.00	66.7
Cycle 18 Day 1	43	82.17	19.04	33.3	83.33	100.0	41	0.81	22.96	-66.7	0.00	66.7
Cycle 19 Day 1	42	84.92	15.96	50.0	83.33	100.0	40	5.42	19.02	-33.3	0.00	66.7
Cycle 20 Day 1	41	82.93	18.06	50.0	83.33	100.0	39	2.56	21.81	-50.0	0.00	66.7
Cycle 21 Day 1	38	83.33	20.87	33.3	100.00	100.0	36	2.31	21.88	-33.3	0.00	66.7
Cycle 22 Day 1	33	87.37	17.19	33.3	100.00	100.0	31	5.91	21.32	-33.3	0.00	66.7
Cycle 23 Day 1	33	87.88	17.32	33.3	100.00	100.0	31	4.30	24.33	-66.7	0.00	66.7
Cycle 24 Day 1	31	89.78	14.71	66.7	100.00	100.0	29	4.02	23.84	-33.3	0.00	66.7
Cycle 25 Day 1	30	89.44	14.17	66.7	100.00	100.0	28	4.76	21.21	-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: 12JAN24

Table 302.3.3002.10: 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 26 Day 1	28	91.07	13.97	66.7	100.00	100.0	26	5.77	23.54	-33.3	0.00	66.7
Cycle 27 Day 1	27	90.12	17.46	33.3	100.00	100.0	25	4.00	25.59	-66.7	0.00	66.7
Cycle 28 Day 1	23	86.96	19.43	33.3	100.00	100.0	21	4.76	29.88	-66.7	0.00	66.7
Cycle 29 Day 1	24	86.11	18.82	33.3	100.00	100.0	22	3.03	26.55	-66.7	0.00	66.7
Cycle 30 Day 1	22	87.88	18.67	33.3	100.00	100.0	20	3.33	28.41	-66.7	0.00	66.7
Cycle 31 Day 1	22	86.36	19.68	33.3	100.00	100.0	20	3.33	27.36	-66.7	0.00	66.7
Cycle 32 Day 1	20	84.17	21.27	33.3	100.00	100.0	18	0.93	29.41	-66.7	0.00	66.7
Cycle 33 Day 1	17	88.24	20.21	33.3	100.00	100.0	15	3.33	34.04	-66.7	0.00	66.7
Cycle 34 Day 1	14	90.48	20.37	33.3	100.00	100.0	12	5.56	35.06	-66.7	0.00	66.7
Cycle 35 Day 1	15	88.89	20.57	33.3	100.00	100.0	13	2.56	32.52	-66.7	0.00	66.7
Cycle 36 Day 1	14	92.86	19.30	33.3	100.00	100.0	12	5.56	33.58	-66.7	0.00	66.7
Cycle 37 Day 1	12	88.89	21.71	33.3	100.00	100.0	11	6.06	36.72	-66.7	0.00	66.7
Cycle 38 Day 1	11	93.94	13.48	66.7	100.00	100.0	10	13.33	31.23	-33.3	16.67	66.7
Cycle 39 Day 1	10	85.00	25.40	33.3	100.00	100.0	9	0.00	33.33	-66.7	16.67	33.3
Study Disc 1	135	73.33	27.10	0.0	66.67	100.0	133	-8.02	28.91	-100.0	0.00	66.7
30 D SFU Z/P	58	78.16	24.82	0.0	83.33	100.0	57	-4.09	28.22	-100.0	0.00	66.7
90 D SFU Z/P	62	84.14	21.00	33.3	100.00	100.0	61	0.27	24.05	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	79.55	23.48	0.0	83.33	100.0						
Cycle 2 Day 1	222	78.45	24.87	0.0	83.33	100.0	217	-1.61	20.88	-100.0	0.00	50.0
Cycle 3 Day 1	200	79.00	22.24	0.0	83.33	100.0	197	-1.44	22.70	-83.3	0.00	66.7
Cycle 4 Day 1	171	82.55	21.83	0.0	83.33	100.0	169	1.97	21.73	-100.0	0.00	66.7
Cycle 5 Day 1	166	81.43	21.27	0.0	83.33	100.0	165	0.20	22.31	-66.7	0.00	83.3
Cycle 6 Day 1	147	79.82	23.10	0.0	83.33	100.0	146	-1.37	22.53	-100.0	0.00	66.7
Cycle 7 Day 1	127	80.31	22.16	0.0	83.33	100.0	126	-0.66	24.71	-100.0	0.00	66.7
Cycle 8 Day 1	111	77.93	24.53	0.0	83.33	100.0	110	-2.12	23.58	-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: 12JAN24

Table 302.3.3002.10: 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 9 Day 1	104	80.13	23.00	0.0	83.33	100.0	103	-0.32	24.47	-100.0	0.00	66.7
Cycle 10 Day 1	81	81.48	24.72	0.0	100.00	100.0	79	-0.84	27.20	-100.0	0.00	66.7
Cycle 11 Day 1	72	79.40	24.94	0.0	83.33	100.0	71	-2.58	25.14	-100.0	0.00	33.3
Cycle 12 Day 1	59	80.79	26.77	0.0	100.00	100.0	57	-1.75	28.12	-100.0	0.00	66.7
Cycle 13 Day 1	50	84.00	23.32	0.0	100.00	100.0	48	-0.35	23.19	-100.0	0.00	33.3
Cycle 14 Day 1	46	85.87	23.30	0.0	100.00	100.0	44	1.52	24.86	-100.0	0.00	66.7
Cycle 15 Day 1	38	82.89	23.72	0.0	100.00	100.0	36	-2.78	23.06	-100.0	0.00	33.3
Cycle 16 Day 1	33	85.35	20.31	16.7	100.00	100.0	31	1.08	19.21	-33.3	0.00	33.3
Cycle 17 Day 1	28	86.90	18.35	33.3	100.00	100.0	25	3.33	15.96	-33.3	0.00	33.3
Cycle 18 Day 1	23	89.86	13.98	66.7	100.00	100.0	21	2.38	16.90	-33.3	0.00	50.0
Cycle 19 Day 1	21	94.44	10.97	66.7	100.00	100.0	20	8.33	20.59	-33.3	0.00	66.7
Cycle 20 Day 1	20	92.50	12.65	66.7	100.00	100.0	19	7.02	20.27	-33.3	0.00	66.7
Cycle 21 Day 1	21	92.06	12.49	66.7	100.00	100.0	20	4.17	17.83	-33.3	0.00	50.0
Cycle 22 Day 1	18	90.74	14.26	66.7	100.00	100.0	17	4.90	15.33	-16.7	0.00	33.3
Cycle 23 Day 1	17	93.14	11.87	66.7	100.00	100.0	16	8.33	18.26	-16.7	0.00	50.0
Cycle 24 Day 1	13	88.46	15.79	66.7	100.00	100.0	12	-1.39	15.01	-33.3	0.00	33.3
Cycle 25 Day 1	13	87.18	16.88	66.7	100.00	100.0	12	-2.78	15.62	-33.3	0.00	33.3
Cycle 26 Day 1	10	90.00	21.08	33.3	100.00	100.0	9	3.70	24.69	-50.0	0.00	33.3
Cycle 27 Day 1	11	92.42	13.67	66.7	100.00	100.0	10	5.00	15.81	-16.7	0.00	33.3
Cycle 28 Day 1	11	90.91	15.57	66.7	100.00	100.0	11	3.03	16.36	-16.7	0.00	33.3
Cycle 29 Day 1	12	83.33	21.32	33.3	91.67	100.0	12	0.00	21.32	-50.0	0.00	33.3
Study Disc 1	157	66.56	31.38	0.0	66.67	100.0	151	-12.36	28.96	-100.0	0.00	66.7
30 D SFU Z/P	80	68.33	28.88	0.0	66.67	100.0	78	-12.82	26.03	-100.0	0.00	33.3
90 D SFU Z/P	81	74.49	27.14	0.0	66.67	100.0	79	-8.23	26.40	-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: 12JAN24

Table 302.3.3002.11: 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 + CAPOX (N=254)												
Baseline	243	26.29	22.00	0.0	22.22	100.0						
Cycle 2 Day 1	209	27.91	19.92	0.0	33.33	100.0	208	1.66	19.69	-66.7	0.00	66.7
Cycle 3 Day 1	187	29.41	21.04	0.0	33.33	100.0	182	3.17	21.71	-66.7	0.00	66.7
Cycle 4 Day 1	172	26.94	21.33	0.0	33.33	100.0	169	1.05	21.93	-77.8	0.00	55.6
Cycle 5 Day 1	163	27.06	21.84	0.0	33.33	100.0	159	1.40	23.21	-66.7	0.00	88.9
Cycle 6 Day 1	151	29.21	22.02	0.0	33.33	100.0	149	2.83	21.07	-55.6	0.00	55.6
Cycle 7 Day 1	122	26.41	20.57	0.0	22.22	100.0	120	1.11	20.99	-55.6	0.00	66.7
Cycle 8 Day 1	114	28.85	21.71	0.0	33.33	100.0	108	4.94	20.34	-66.7	0.00	55.6
Cycle 9 Day 1	107	28.25	25.82	0.0	33.33	100.0	102	1.96	24.94	-66.7	0.00	77.8
Cycle 10 Day 1	88	26.01	24.11	0.0	22.22	100.0	85	1.57	25.67	-77.8	0.00	66.7
Cycle 11 Day 1	84	21.69	16.71	0.0	22.22	66.7	81	-0.14	22.53	-66.7	0.00	44.4
Cycle 12 Day 1	77	20.06	18.74	0.0	22.22	66.7	75	-0.89	24.08	-66.7	0.00	66.7
Cycle 13 Day 1	62	18.46	16.46	0.0	16.67	44.4	60	-3.70	25.03	-77.8	0.00	33.3
Cycle 14 Day 1	57	17.74	16.78	0.0	11.11	66.7	55	-2.22	19.99	-66.7	0.00	33.3
Cycle 15 Day 1	53	17.19	16.82	0.0	11.11	55.6	51	-3.27	21.12	-66.7	0.00	44.4
Cycle 16 Day 1	50	16.89	15.75	0.0	22.22	55.6	48	-4.63	21.60	-66.7	0.00	33.3
Cycle 17 Day 1	45	18.27	17.43	0.0	11.11	55.6	43	-2.07	18.98	-55.6	0.00	33.3
Cycle 18 Day 1	43	19.90	16.72	0.0	22.22	55.6	41	-0.81	17.10	-44.4	0.00	33.3
Cycle 19 Day 1	42	18.52	17.64	0.0	16.67	66.7	40	-1.11	17.93	-55.6	0.00	44.4
Cycle 20 Day 1	41	19.78	17.66	0.0	22.22	66.7	39	0.57	16.51	-22.2	0.00	33.3
Cycle 21 Day 1	38	20.47	18.36	0.0	22.22	66.7	36	1.23	16.75	-22.2	0.00	44.4
Cycle 22 Day 1	33	15.82	16.20	0.0	11.11	66.7	31	-2.87	19.02	-44.4	0.00	33.3
Cycle 23 Day 1	33	15.49	16.88	0.0	11.11	44.4	31	-1.43	17.62	-33.3	0.00	44.4
Cycle 24 Day 1	31	15.41	15.63	0.0	11.11	44.4	29	-1.15	17.65	-33.3	0.00	33.3
Cycle 25 Day 1	30	12.96	16.00	0.0	0.00	44.4	28	-3.17	18.36	-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: 12JAN24

Table 302.3.3002.11: 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 26 Day 1	28	15.48	16.93	0.0	11.11	55.6	26	-1.71	21.70	-44.4	0.00	44.4
Cycle 27 Day 1	27	13.99	16.19	0.0	0.00	44.4	25	-3.11	14.17	-22.2	0.00	22.2
Cycle 28 Day 1	23	17.39	17.99	0.0	22.22	55.6	21	-2.65	16.06	-44.4	0.00	33.3
Cycle 29 Day 1	24	17.13	17.64	0.0	11.11	66.7	22	-3.54	14.70	-22.2	-5.56	33.3
Cycle 30 Day 1	22	16.16	18.38	0.0	11.11	55.6	20	-2.78	13.90	-22.2	0.00	22.2
Cycle 31 Day 1	22	18.18	18.32	0.0	16.67	55.6	20	-2.22	17.14	-44.4	0.00	22.2
Cycle 32 Day 1	20	17.78	16.28	0.0	16.67	55.6	18	-5.56	18.77	-44.4	-5.56	22.2
Cycle 33 Day 1	17	13.73	15.48	0.0	11.11	44.4	15	-8.15	19.91	-33.3	-11.11	22.2
Cycle 34 Day 1	14	12.70	17.89	0.0	5.56	55.6	12	-12.04	18.63	-44.4	-11.11	22.2
Cycle 35 Day 1	15	16.30	17.25	0.0	11.11	55.6	13	-10.26	12.39	-33.3	-11.11	11.1
Cycle 36 Day 1	14	11.90	17.14	0.0	0.00	55.6	12	-12.04	10.00	-22.2	-11.11	0.0
Cycle 37 Day 1	12	12.96	18.85	0.0	0.00	55.6	11	-12.12	14.45	-33.3	-11.11	11.1
Cycle 38 Day 1	11	14.14	15.78	0.0	11.11	33.3	10	-12.22	21.24	-33.3	-22.22	22.2
Cycle 39 Day 1	10	14.44	20.32	0.0	0.00	55.6	9	-7.41	19.25	-33.3	0.00	22.2
Study Disc 1	135	33.58	26.65	0.0	33.33	100.0	133	10.19	25.33	-66.7	11.11	100.0
30 D SFU Z/P	58	33.33	23.91	0.0	33.33	88.9	57	11.50	23.09	-44.4	0.00	66.7
90 D SFU Z/P	62	28.67	23.60	0.0	33.33	100.0	61	11.84	21.55	-22.2	0.00	77.8
Placebo + CAPOX (N=253)												
Baseline	242	27.55	22.43	0.0	22.22	100.0						
Cycle 2 Day 1	222	27.43	20.21	0.0	33.33	100.0	217	0.15	19.11	-77.8	0.00	44.4
Cycle 3 Day 1	200	27.28	22.90	0.0	33.33	100.0	197	0.96	21.26	-66.7	0.00	77.8
Cycle 4 Day 1	171	25.93	21.32	0.0	22.22	100.0	169	-0.46	22.03	-66.7	0.00	77.8
Cycle 5 Day 1	166	25.57	22.24	0.0	22.22	100.0	165	-0.81	23.52	-77.8	0.00	66.7
Cycle 6 Day 1	147	26.00	23.17	0.0	22.22	100.0	146	0.91	25.25	-77.8	0.00	77.8
Cycle 7 Day 1	127	24.23	20.74	0.0	22.22	100.0	126	-1.06	23.11	-66.7	0.00	66.7
Cycle 8 Day 1	111	25.83	22.33	0.0	22.22	100.0	110	0.10	23.05	-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.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.11: 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 9 Day 1	104	23.93	20.93	0.0	22.22	100.0	103	-0.86	23.06	-77.8	0.00	66.7
Cycle 10 Day 1	81	21.95	22.70	0.0	22.22	100.0	79	-0.42	24.81	-55.6	0.00	66.7
Cycle 11 Day 1	72	22.84	23.87	0.0	22.22	100.0	71	-0.31	24.34	-55.6	0.00	77.8
Cycle 12 Day 1	59	19.96	22.96	0.0	11.11	100.0	57	0.00	23.19	-44.4	0.00	66.7
Cycle 13 Day 1	50	21.33	19.81	0.0	22.22	88.9	48	0.00	20.76	-44.4	0.00	44.4
Cycle 14 Day 1	46	20.29	22.01	0.0	16.67	100.0	44	-0.76	19.82	-44.4	0.00	66.7
Cycle 15 Day 1	38	20.47	21.23	0.0	22.22	100.0	36	-0.62	17.20	-33.3	0.00	44.4
Cycle 16 Day 1	33	18.52	18.56	0.0	11.11	88.9	31	-2.15	17.55	-33.3	0.00	33.3
Cycle 17 Day 1	28	18.65	17.12	0.0	22.22	66.7	25	-1.78	18.61	-44.4	0.00	33.3
Cycle 18 Day 1	23	12.08	12.50	0.0	11.11	33.3	21	-7.94	17.26	-44.4	0.00	22.2
Cycle 19 Day 1	21	13.76	13.57	0.0	11.11	33.3	20	-4.44	15.46	-33.3	0.00	22.2
Cycle 20 Day 1	20	16.11	15.91	0.0	11.11	55.6	19	-4.68	18.64	-44.4	0.00	22.2
Cycle 21 Day 1	21	13.76	14.45	0.0	11.11	44.4	20	-3.33	18.77	-33.3	0.00	44.4
Cycle 22 Day 1	18	14.81	12.64	0.0	16.67	33.3	17	-3.27	18.33	-44.4	0.00	22.2
Cycle 23 Day 1	17	16.34	16.72	0.0	11.11	66.7	16	-4.17	22.18	-44.4	-5.56	33.3
Cycle 24 Day 1	13	13.68	15.15	0.0	11.11	33.3	12	-3.70	19.73	-33.3	0.00	33.3
Cycle 25 Day 1	13	16.24	16.11	0.0	11.11	44.4	12	-0.93	17.38	-33.3	0.00	22.2
Cycle 26 Day 1	10	13.33	11.48	0.0	11.11	33.3	9	0.00	11.11	-11.1	0.00	22.2
Cycle 27 Day 1	11	13.13	13.89	0.0	11.11	33.3	10	2.22	15.54	-22.2	0.00	22.2
Cycle 28 Day 1	11	19.19	17.28	0.0	22.22	55.6	11	8.08	13.23	-11.1	11.11	22.2
Cycle 29 Day 1	12	18.52	14.47	0.0	16.67	33.3	12	5.56	18.65	-22.2	5.56	33.3
Study Disc 1	157	39.70	29.08	0.0	33.33	100.0	151	12.21	26.16	-44.4	11.11	100.0
30 D SFU Z/P	80	36.53	26.23	0.0	33.33	100.0	78	13.68	27.15	-44.4	11.11	100.0
90 D SFU Z/P	81	30.59	24.69	0.0	33.33	100.0	79	7.31	22.00	-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: 12JAN24

Table 302.3.3002.12: 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 + CAPOX (N=254)												
Baseline	243	10.49	18.08	0.0	0.00	100.0						
Cycle 2 Day 1	209	16.03	19.67	0.0	0.00	83.3	208	6.41	19.77	-50.0	0.00	83.3
Cycle 3 Day 1	187	15.15	19.07	0.0	16.67	100.0	182	5.86	19.88	-50.0	0.00	83.3
Cycle 4 Day 1	172	13.76	17.88	0.0	0.00	66.7	169	4.73	20.67	-66.7	0.00	66.7
Cycle 5 Day 1	163	14.21	18.72	0.0	0.00	100.0	159	4.93	21.01	-66.7	0.00	66.7
Cycle 6 Day 1	151	15.01	20.71	0.0	0.00	100.0	149	6.04	20.25	-66.7	0.00	66.7
Cycle 7 Day 1	122	9.29	12.50	0.0	0.00	66.7	120	1.25	19.94	-83.3	0.00	50.0
Cycle 8 Day 1	114	11.26	15.44	0.0	0.00	66.7	108	3.09	20.14	-83.3	0.00	50.0
Cycle 9 Day 1	107	10.90	14.50	0.0	0.00	66.7	102	1.80	20.83	-83.3	0.00	50.0
Cycle 10 Day 1	88	7.20	12.58	0.0	0.00	50.0	85	0.39	20.25	-83.3	0.00	50.0
Cycle 11 Day 1	84	5.36	11.32	0.0	0.00	50.0	81	-1.65	19.65	-83.3	0.00	33.3
Cycle 12 Day 1	77	5.84	10.74	0.0	0.00	33.3	75	-1.11	19.82	-83.3	0.00	33.3
Cycle 13 Day 1	62	4.57	10.53	0.0	0.00	66.7	60	-3.33	20.54	-83.3	0.00	66.7
Cycle 14 Day 1	57	4.97	10.43	0.0	0.00	50.0	55	-1.21	19.73	-83.3	0.00	50.0
Cycle 15 Day 1	53	3.14	8.04	0.0	0.00	33.3	51	-2.94	18.17	-83.3	0.00	33.3
Cycle 16 Day 1	50	5.67	11.47	0.0	0.00	33.3	48	-1.04	20.17	-83.3	0.00	33.3
Cycle 17 Day 1	45	4.44	8.26	0.0	0.00	33.3	43	-1.94	18.62	-83.3	0.00	16.7
Cycle 18 Day 1	43	7.36	12.23	0.0	0.00	33.3	41	0.81	20.40	-83.3	0.00	33.3
Cycle 19 Day 1	42	6.75	11.08	0.0	0.00	33.3	40	0.00	20.32	-83.3	0.00	33.3
Cycle 20 Day 1	41	6.10	10.38	0.0	0.00	33.3	39	-0.85	19.10	-83.3	0.00	33.3
Cycle 21 Day 1	38	7.02	11.38	0.0	0.00	33.3	36	0.00	19.92	-83.3	0.00	33.3
Cycle 22 Day 1	33	5.05	9.76	0.0	0.00	33.3	31	-2.69	20.23	-83.3	0.00	33.3
Cycle 23 Day 1	33	3.03	8.79	0.0	0.00	33.3	31	-3.76	21.39	-83.3	0.00	33.3
Cycle 24 Day 1	31	3.76	7.08	0.0	0.00	16.7	29	-3.45	20.11	-83.3	0.00	16.7
Cycle 25 Day 1	30	3.33	8.07	0.0	0.00	33.3	28	-4.17	20.60	-83.3	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: 12JAN24

Table 302.3.3002.12: 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 26 Day 1	28	3.57	8.31	0.0	0.00	33.3	26	-4.49	20.85	-83.3	0.00	16.7
Cycle 27 Day 1	27	3.09	6.60	0.0	0.00	16.7	25	-4.67	20.14	-83.3	0.00	16.7
Cycle 28 Day 1	23	5.80	12.92	0.0	0.00	33.3	21	-0.79	23.85	-83.3	0.00	33.3
Cycle 29 Day 1	24	2.78	10.62	0.0	0.00	50.0	22	-3.79	21.78	-83.3	0.00	50.0
Cycle 30 Day 1	22	3.03	8.35	0.0	0.00	33.3	20	-3.33	21.36	-83.3	0.00	33.3
Cycle 31 Day 1	22	3.03	11.07	0.0	0.00	50.0	20	-4.17	23.49	-83.3	0.00	50.0
Cycle 32 Day 1	20	5.00	12.21	0.0	0.00	50.0	18	-2.78	25.72	-83.3	0.00	50.0
Cycle 33 Day 1	17	0.98	4.04	0.0	0.00	16.7	15	-8.89	21.70	-83.3	0.00	0.0
Cycle 34 Day 1	14	2.38	6.05	0.0	0.00	16.7	12	-8.33	25.13	-83.3	0.00	16.7
Cycle 35 Day 1	15	5.56	10.29	0.0	0.00	33.3	13	-6.41	25.04	-83.3	0.00	16.7
Cycle 36 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-6.94	25.08	-83.3	0.00	16.7
Cycle 37 Day 1	12	2.78	6.49	0.0	0.00	16.7	11	-9.09	20.23	-66.7	0.00	0.0
Cycle 38 Day 1	11	6.06	15.41	0.0	0.00	50.0	10	-6.67	14.05	-33.3	0.00	16.7
Cycle 39 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	-5.56	8.33	-16.7	0.00	0.0
Study Disc 1	135	15.93	24.17	0.0	0.00	100.0	133	6.52	24.86	-50.0	0.00	100.0
30 D SFU Z/P	58	12.07	21.58	0.0	0.00	100.0	57	4.39	19.80	-50.0	0.00	50.0
90 D SFU Z/P	62	13.17	19.82	0.0	0.00	100.0	61	7.38	21.20	-33.3	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	242	15.08	23.20	0.0	0.00	100.0						
Cycle 2 Day 1	222	12.31	17.25	0.0	0.00	100.0	217	-0.92	20.77	-100.0	0.00	83.3
Cycle 3 Day 1	200	12.33	17.14	0.0	0.00	83.3	197	0.17	22.21	-100.0	0.00	83.3
Cycle 4 Day 1	171	9.94	15.82	0.0	0.00	100.0	169	-2.76	22.98	-100.0	0.00	100.0
Cycle 5 Day 1	166	9.54	14.49	0.0	0.00	66.7	165	-3.74	25.06	-100.0	0.00	50.0
Cycle 6 Day 1	147	12.02	17.20	0.0	0.00	66.7	146	-1.60	24.71	-100.0	0.00	66.7
Cycle 7 Day 1	127	10.24	16.27	0.0	0.00	100.0	126	-2.91	24.59	-100.0	0.00	100.0
Cycle 8 Day 1	111	6.31	12.32	0.0	0.00	66.7	110	-6.97	23.83	-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: 12JAN24

Table 302.3.3002.12: 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 9 Day 1	104	7.21	12.46	0.0	0.00	50.0	103	-6.15	20.74	-100.0	0.00	50.0
Cycle 10 Day 1	81	5.97	14.75	0.0	0.00	83.3	79	-7.17	24.99	-100.0	0.00	50.0
Cycle 11 Day 1	72	6.25	12.33	0.0	0.00	50.0	71	-6.81	24.17	-100.0	0.00	33.3
Cycle 12 Day 1	59	7.91	17.60	0.0	0.00	66.7	57	-2.34	25.48	-100.0	0.00	66.7
Cycle 13 Day 1	50	4.67	10.67	0.0	0.00	50.0	48	-7.99	23.82	-100.0	0.00	33.3
Cycle 14 Day 1	46	7.61	16.74	0.0	0.00	66.7	44	-4.17	21.00	-66.7	0.00	33.3
Cycle 15 Day 1	38	6.58	19.96	0.0	0.00	100.0	36	-5.56	20.31	-50.0	0.00	66.7
Cycle 16 Day 1	33	4.04	10.23	0.0	0.00	33.3	31	-5.91	20.43	-66.7	0.00	33.3
Cycle 17 Day 1	28	6.55	13.10	0.0	0.00	33.3	25	2.67	13.33	-33.3	0.00	33.3
Cycle 18 Day 1	23	0.72	3.48	0.0	0.00	16.7	21	-4.76	11.95	-33.3	0.00	16.7
Cycle 19 Day 1	21	1.59	5.01	0.0	0.00	16.7	20	-4.17	11.94	-33.3	0.00	16.7
Cycle 20 Day 1	20	0.83	3.73	0.0	0.00	16.7	19	-4.39	12.22	-33.3	0.00	16.7
Cycle 21 Day 1	21	2.38	5.98	0.0	0.00	16.7	20	-3.33	11.60	-33.3	0.00	16.7
Cycle 22 Day 1	18	0.93	3.93	0.0	0.00	16.7	17	-5.88	13.10	-33.3	0.00	16.7
Cycle 23 Day 1	17	0.00	0.00	0.0	0.00	0.0	16	-7.29	12.12	-33.3	0.00	0.0
Cycle 24 Day 1	13	2.56	6.26	0.0	0.00	16.7	12	-1.39	11.14	-33.3	0.00	16.7
Cycle 25 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-6.94	13.22	-33.3	0.00	0.0
Cycle 26 Day 1	10	6.67	21.08	0.0	0.00	66.7	9	-1.85	24.22	-33.3	0.00	50.0
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	-5.00	15.81	-33.3	0.00	16.7
Cycle 28 Day 1	11	6.06	11.24	0.0	0.00	33.3	11	-3.03	14.56	-33.3	0.00	16.7
Cycle 29 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-9.72	13.22	-33.3	0.00	0.0
Study Disc 1	157	18.58	26.62	0.0	0.00	100.0	151	5.96	28.63	-100.0	0.00	100.0
30 D SFU Z/P	80	13.75	22.78	0.0	0.00	100.0	78	0.21	24.25	-83.3	0.00	100.0
90 D SFU Z/P	81	12.55	23.35	0.0	0.00	100.0	79	-1.05	26.06	-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: 12JAN24

Table 302.3.3002.13: 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 + CAPOX (N=254)												
Baseline	243	21.67	22.14	0.0	16.67	100.0						
Cycle 2 Day 1	209	16.99	19.74	0.0	16.67	100.0	208	-4.17	22.43	-83.3	0.00	66.7
Cycle 3 Day 1	187	15.69	19.64	0.0	0.00	83.3	182	-5.40	21.16	-83.3	0.00	50.0
Cycle 4 Day 1	172	15.12	19.93	0.0	0.00	100.0	169	-7.10	21.18	-66.7	0.00	50.0
Cycle 5 Day 1	163	15.13	19.67	0.0	0.00	100.0	159	-4.82	22.06	-83.3	0.00	83.3
Cycle 6 Day 1	151	17.88	20.83	0.0	16.67	83.3	149	-3.13	19.79	-66.7	0.00	50.0
Cycle 7 Day 1	122	13.52	17.45	0.0	0.00	66.7	120	-6.39	22.16	-100.0	0.00	50.0
Cycle 8 Day 1	114	16.81	21.32	0.0	16.67	100.0	108	-4.17	22.22	-100.0	0.00	50.0
Cycle 9 Day 1	107	16.67	19.56	0.0	16.67	83.3	102	-5.07	21.72	-100.0	0.00	50.0
Cycle 10 Day 1	88	15.34	19.45	0.0	0.00	83.3	85	-4.12	22.11	-100.0	0.00	33.3
Cycle 11 Day 1	84	11.90	16.07	0.0	0.00	66.7	81	-6.38	21.01	-100.0	0.00	33.3
Cycle 12 Day 1	77	13.64	19.07	0.0	0.00	100.0	75	-4.44	22.48	-100.0	0.00	50.0
Cycle 13 Day 1	62	11.29	16.74	0.0	0.00	66.7	60	-6.39	23.98	-100.0	0.00	33.3
Cycle 14 Day 1	57	10.23	14.35	0.0	0.00	50.0	55	-5.76	22.27	-100.0	0.00	33.3
Cycle 15 Day 1	53	9.12	13.70	0.0	0.00	33.3	51	-6.54	19.17	-66.7	0.00	33.3
Cycle 16 Day 1	50	10.67	14.97	0.0	0.00	50.0	48	-6.25	19.64	-66.7	0.00	33.3
Cycle 17 Day 1	45	11.85	14.49	0.0	0.00	50.0	43	-5.04	19.43	-66.7	0.00	33.3
Cycle 18 Day 1	43	14.73	15.94	0.0	16.67	50.0	41	-1.63	18.18	-50.0	0.00	33.3
Cycle 19 Day 1	42	13.10	16.68	0.0	0.00	66.7	40	-2.50	18.32	-66.7	0.00	33.3
Cycle 20 Day 1	41	13.82	16.63	0.0	0.00	66.7	39	-0.85	16.64	-66.7	0.00	33.3
Cycle 21 Day 1	38	11.40	14.55	0.0	0.00	50.0	36	-2.31	19.58	-66.7	0.00	33.3
Cycle 22 Day 1	33	10.61	16.57	0.0	0.00	66.7	31	-2.69	18.31	-66.7	0.00	33.3
Cycle 23 Day 1	33	7.58	12.56	0.0	0.00	33.3	31	-3.76	18.11	-66.7	0.00	33.3
Cycle 24 Day 1	31	6.99	12.00	0.0	0.00	33.3	29	-4.02	18.18	-66.7	0.00	33.3
Cycle 25 Day 1	30	9.44	14.96	0.0	0.00	50.0	28	-1.19	21.24	-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: 12JAN24

Table 302.3.3002.13: 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 26 Day 1	28	7.74	12.41	0.0	0.00	33.3	26	-3.85	19.61	-66.7	0.00	33.3
Cycle 27 Day 1	27	7.41	12.52	0.0	0.00	33.3	25	-4.00	20.57	-66.7	0.00	33.3
Cycle 28 Day 1	23	10.14	13.98	0.0	0.00	50.0	21	-4.76	21.18	-66.7	0.00	33.3
Cycle 29 Day 1	24	9.72	13.83	0.0	0.00	50.0	22	-3.79	21.16	-66.7	0.00	33.3
Cycle 30 Day 1	22	6.82	13.27	0.0	0.00	50.0	20	-6.67	19.79	-66.7	0.00	16.7
Cycle 31 Day 1	22	8.33	14.32	0.0	0.00	50.0	20	-6.67	21.90	-66.7	-8.33	33.3
Cycle 32 Day 1	20	9.17	16.64	0.0	0.00	50.0	18	-6.48	22.97	-66.7	-8.33	33.3
Cycle 33 Day 1	17	4.90	11.43	0.0	0.00	33.3	15	-10.00	22.54	-66.7	0.00	16.7
Cycle 34 Day 1	14	3.57	9.65	0.0	0.00	33.3	12	-13.89	21.12	-66.7	-16.67	16.7
Cycle 35 Day 1	15	5.56	10.29	0.0	0.00	33.3	13	-10.26	22.09	-66.7	0.00	16.7
Cycle 36 Day 1	14	4.76	10.19	0.0	0.00	33.3	12	-12.50	21.47	-66.7	-8.33	16.7
Cycle 37 Day 1	12	5.56	10.86	0.0	0.00	33.3	11	-12.12	23.68	-66.7	-16.67	16.7
Cycle 38 Day 1	11	12.12	21.20	0.0	0.00	50.0	10	-5.00	24.91	-33.3	-8.33	50.0
Cycle 39 Day 1	10	5.00	11.25	0.0	0.00	33.3	9	-9.26	16.90	-33.3	0.00	16.7
Study Disc 1	135	27.41	27.50	0.0	16.67	100.0	133	7.39	25.41	-83.3	0.00	100.0
30 D SFU Z/P	58	24.14	24.81	0.0	16.67	100.0	57	4.97	27.45	-100.0	0.00	66.7
90 D SFU Z/P	62	18.82	21.01	0.0	16.67	66.7	61	4.37	22.55	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	24.10	23.71	0.0	16.67	100.0						
Cycle 2 Day 1	222	18.69	19.47	0.0	16.67	100.0	217	-4.61	20.08	-66.7	0.00	50.0
Cycle 3 Day 1	200	18.33	22.04	0.0	16.67	100.0	197	-3.38	22.77	-66.7	0.00	83.3
Cycle 4 Day 1	171	14.33	18.46	0.0	0.00	83.3	169	-7.40	22.41	-83.3	0.00	66.7
Cycle 5 Day 1	166	15.86	22.00	0.0	0.00	100.0	165	-6.26	26.05	-83.3	0.00	83.3
Cycle 6 Day 1	147	14.40	21.60	0.0	0.00	100.0	146	-6.85	26.09	-83.3	0.00	66.7
Cycle 7 Day 1	127	13.65	17.37	0.0	0.00	66.7	126	-7.67	22.57	-66.7	0.00	50.0
Cycle 8 Day 1	111	15.77	22.34	0.0	0.00	100.0	110	-5.61	24.96	-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: 12JAN24

Table 302.3.3002.13: 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 9 Day 1	104	12.50	20.48	0.0	0.00	83.3	103	-8.09	24.46	-83.3	0.00	66.7
Cycle 10 Day 1	81	14.40	20.88	0.0	0.00	83.3	79	-6.33	25.50	-66.7	0.00	66.7
Cycle 11 Day 1	72	13.89	19.58	0.0	0.00	66.7	71	-6.34	26.78	-83.3	0.00	66.7
Cycle 12 Day 1	59	11.30	17.35	0.0	0.00	66.7	57	-7.02	24.99	-66.7	0.00	66.7
Cycle 13 Day 1	50	12.67	18.31	0.0	0.00	83.3	48	-7.64	24.54	-83.3	0.00	66.7
Cycle 14 Day 1	46	14.13	22.21	0.0	0.00	100.0	44	-6.06	24.14	-66.7	0.00	66.7
Cycle 15 Day 1	38	13.60	22.55	0.0	0.00	100.0	36	-7.41	21.25	-66.7	0.00	50.0
Cycle 16 Day 1	33	13.13	18.52	0.0	0.00	66.7	31	-6.45	23.04	-66.7	0.00	33.3
Cycle 17 Day 1	28	10.71	19.36	0.0	0.00	66.7	25	-7.33	25.95	-83.3	0.00	33.3
Cycle 18 Day 1	23	5.80	9.55	0.0	0.00	33.3	21	-11.90	27.96	-83.3	0.00	33.3
Cycle 19 Day 1	21	6.35	15.34	0.0	0.00	66.7	20	-7.50	26.20	-66.7	0.00	66.7
Cycle 20 Day 1	20	10.00	16.58	0.0	0.00	66.7	19	-8.77	30.11	-83.3	0.00	50.0
Cycle 21 Day 1	21	7.14	16.31	0.0	0.00	66.7	20	-11.67	29.17	-83.3	0.00	66.7
Cycle 22 Day 1	18	8.33	11.79	0.0	0.00	33.3	17	-12.75	30.35	-83.3	-16.67	33.3
Cycle 23 Day 1	17	5.88	16.61	0.0	0.00	66.7	16	-15.63	30.10	-83.3	-8.33	33.3
Cycle 24 Day 1	13	8.97	12.94	0.0	0.00	33.3	12	-8.33	29.73	-83.3	0.00	33.3
Cycle 25 Day 1	13	10.26	14.50	0.0	0.00	33.3	12	-11.11	29.59	-83.3	0.00	33.3
Cycle 26 Day 1	10	8.33	21.15	0.0	0.00	66.7	9	-9.26	18.84	-50.0	0.00	16.7
Cycle 27 Day 1	11	9.09	13.67	0.0	0.00	33.3	10	-6.67	23.83	-50.0	0.00	33.3
Cycle 28 Day 1	11	13.64	22.13	0.0	0.00	66.7	11	-3.03	19.46	-50.0	0.00	16.7
Cycle 29 Day 1	12	6.94	11.14	0.0	0.00	33.3	12	-11.11	23.92	-50.0	-16.67	33.3
Study Disc 1	157	32.70	29.29	0.0	33.33	100.0	151	8.83	25.30	-50.0	0.00	83.3
30 D SFU Z/P	80	28.33	28.61	0.0	25.00	100.0	78	8.76	26.42	-66.7	0.00	100.0
90 D SFU Z/P	81	22.22	25.14	0.0	16.67	83.3	79	2.11	22.70	-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: 12JAN24

Table 302.3.3002.14: 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 + CAPOX (N=254)												
Baseline	243	9.74	17.96	0.0	0.00	100.0						
Cycle 2 Day 1	209	11.96	18.79	0.0	0.00	100.0	208	2.24	15.89	-33.3	0.00	66.7
Cycle 3 Day 1	187	9.09	17.81	0.0	0.00	100.0	182	-0.37	16.80	-66.7	0.00	66.7
Cycle 4 Day 1	172	8.72	16.37	0.0	0.00	100.0	169	0.00	16.67	-33.3	0.00	66.7
Cycle 5 Day 1	163	9.20	16.27	0.0	0.00	66.7	159	-0.42	19.48	-66.7	0.00	66.7
Cycle 6 Day 1	151	8.61	17.83	0.0	0.00	100.0	149	1.12	19.54	-33.3	0.00	100.0
Cycle 7 Day 1	122	9.02	16.06	0.0	0.00	66.7	120	1.67	20.20	-66.7	0.00	66.7
Cycle 8 Day 1	114	8.77	16.62	0.0	0.00	100.0	108	1.85	19.25	-66.7	0.00	100.0
Cycle 9 Day 1	107	7.48	14.70	0.0	0.00	66.7	102	0.65	18.15	-66.7	0.00	33.3
Cycle 10 Day 1	88	8.33	15.37	0.0	0.00	66.7	85	1.18	20.86	-66.7	0.00	66.7
Cycle 11 Day 1	84	7.54	15.82	0.0	0.00	66.7	81	0.41	20.07	-66.7	0.00	66.7
Cycle 12 Day 1	77	5.63	13.68	0.0	0.00	66.7	75	-1.33	20.09	-66.7	0.00	66.7
Cycle 13 Day 1	62	6.99	16.12	0.0	0.00	66.7	60	-0.56	23.36	-66.7	0.00	66.7
Cycle 14 Day 1	57	6.43	14.69	0.0	0.00	66.7	55	-0.61	20.78	-66.7	0.00	66.7
Cycle 15 Day 1	53	6.92	13.65	0.0	0.00	33.3	51	0.00	17.64	-33.3	0.00	33.3
Cycle 16 Day 1	50	6.00	12.94	0.0	0.00	33.3	48	-0.69	16.11	-33.3	0.00	33.3
Cycle 17 Day 1	45	5.93	12.89	0.0	0.00	33.3	43	0.00	16.27	-33.3	0.00	33.3
Cycle 18 Day 1	43	7.75	14.25	0.0	0.00	33.3	41	1.63	16.59	-33.3	0.00	33.3
Cycle 19 Day 1	42	6.35	13.25	0.0	0.00	33.3	40	0.00	16.88	-33.3	0.00	33.3
Cycle 20 Day 1	41	8.94	14.95	0.0	0.00	33.3	39	2.56	19.32	-33.3	0.00	33.3
Cycle 21 Day 1	38	7.89	14.36	0.0	0.00	33.3	36	0.93	16.88	-33.3	0.00	33.3
Cycle 22 Day 1	33	8.08	14.51	0.0	0.00	33.3	31	1.08	20.15	-33.3	0.00	33.3
Cycle 23 Day 1	33	7.07	13.84	0.0	0.00	33.3	31	0.00	14.91	-33.3	0.00	33.3
Cycle 24 Day 1	31	7.53	14.17	0.0	0.00	33.3	29	0.00	17.82	-33.3	0.00	33.3
Cycle 25 Day 1	30	7.78	14.34	0.0	0.00	33.3	28	0.00	20.29	-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: 12JAN24

Table 302.3.3002.14: 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 26 Day 1	28	4.76	11.88	0.0	0.00	33.3	26	-3.85	14.38	-33.3	0.00	33.3
Cycle 27 Day 1	27	9.88	18.06	0.0	0.00	66.7	25	2.67	16.44	-33.3	0.00	33.3
Cycle 28 Day 1	23	7.25	14.06	0.0	0.00	33.3	21	-1.59	16.59	-33.3	0.00	33.3
Cycle 29 Day 1	24	15.28	24.04	0.0	0.00	100.0	22	7.58	27.08	-33.3	0.00	100.0
Cycle 30 Day 1	22	7.58	14.30	0.0	0.00	33.3	20	0.00	18.73	-33.3	0.00	33.3
Cycle 31 Day 1	22	7.58	14.30	0.0	0.00	33.3	20	-1.67	22.88	-33.3	0.00	33.3
Cycle 32 Day 1	20	8.33	14.81	0.0	0.00	33.3	18	0.00	22.87	-33.3	0.00	33.3
Cycle 33 Day 1	17	9.80	15.66	0.0	0.00	33.3	15	2.22	23.46	-33.3	0.00	33.3
Cycle 34 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-8.33	20.72	-33.3	0.00	33.3
Cycle 35 Day 1	15	6.67	13.80	0.0	0.00	33.3	13	-2.56	21.35	-33.3	0.00	33.3
Cycle 36 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
Cycle 37 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-9.09	21.56	-33.3	0.00	33.3
Cycle 38 Day 1	11	9.09	15.57	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 39 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3
Study Disc 1	135	12.35	19.84	0.0	0.00	100.0	133	5.01	20.72	-66.7	0.00	66.7
30 D SFU Z/P	58	8.62	15.99	0.0	0.00	66.7	57	3.51	16.29	-66.7	0.00	33.3
90 D SFU Z/P	62	6.99	13.68	0.0	0.00	33.3	61	2.73	15.27	-33.3	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	242	10.88	19.35	0.0	0.00	100.0						
Cycle 2 Day 1	222	10.36	19.23	0.0	0.00	100.0	217	-0.77	17.99	-66.7	0.00	66.7
Cycle 3 Day 1	200	10.67	18.83	0.0	0.00	100.0	197	0.51	22.20	-100.0	0.00	100.0
Cycle 4 Day 1	171	10.33	19.57	0.0	0.00	100.0	169	-0.39	23.28	-66.7	0.00	100.0
Cycle 5 Day 1	166	7.83	17.18	0.0	0.00	100.0	165	-2.22	23.03	-100.0	0.00	66.7
Cycle 6 Day 1	147	8.39	17.38	0.0	0.00	100.0	146	0.00	21.80	-66.7	0.00	100.0
Cycle 7 Day 1	127	9.45	17.26	0.0	0.00	100.0	126	-0.53	22.70	-66.7	0.00	100.0
Cycle 8 Day 1	111	11.71	22.31	0.0	0.00	100.0	110	2.12	23.58	-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: 12JAN24

Table 302.3.3002.14: 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 9 Day 1	104	8.33	17.22	0.0	0.00	66.7	103	-2.27	20.49	-66.7	0.00	66.7
Cycle 10 Day 1	81	8.64	17.30	0.0	0.00	100.0	79	-0.42	24.16	-66.7	0.00	100.0
Cycle 11 Day 1	72	7.41	15.03	0.0	0.00	66.7	71	-3.29	21.20	-66.7	0.00	33.3
Cycle 12 Day 1	59	6.78	14.88	0.0	0.00	66.7	57	-2.92	19.19	-33.3	0.00	66.7
Cycle 13 Day 1	50	6.67	15.06	0.0	0.00	66.7	48	-2.78	21.56	-66.7	0.00	66.7
Cycle 14 Day 1	46	6.52	15.10	0.0	0.00	66.7	44	-4.55	19.81	-66.7	0.00	33.3
Cycle 15 Day 1	38	7.02	15.80	0.0	0.00	66.7	36	-4.63	16.24	-33.3	0.00	33.3
Cycle 16 Day 1	33	9.09	20.87	0.0	0.00	100.0	31	-3.23	21.70	-66.7	0.00	33.3
Cycle 17 Day 1	28	4.76	11.88	0.0	0.00	33.3	25	-6.67	21.52	-66.7	0.00	33.3
Cycle 18 Day 1	23	2.90	9.60	0.0	0.00	33.3	21	-9.52	18.69	-33.3	0.00	33.3
Cycle 19 Day 1	21	0.00	0.00	0.0	0.00	0.0	20	-11.67	19.57	-66.7	0.00	0.0
Cycle 20 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	-10.53	22.37	-66.7	0.00	33.3
Cycle 21 Day 1	21	1.59	7.27	0.0	0.00	33.3	20	-10.00	19.04	-66.7	0.00	0.0
Cycle 22 Day 1	18	1.85	7.86	0.0	0.00	33.3	17	-9.80	22.87	-66.7	0.00	33.3
Cycle 23 Day 1	17	3.92	11.07	0.0	0.00	33.3	16	-8.33	22.77	-66.7	0.00	33.3
Cycle 24 Day 1	13	2.56	9.25	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
Cycle 25 Day 1	13	7.69	14.62	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
Cycle 26 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	-7.41	14.70	-33.3	0.00	0.0
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	-6.67	14.05	-33.3	0.00	0.0
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-9.09	21.56	-66.7	0.00	0.0
Cycle 29 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-11.11	21.71	-66.7	0.00	0.0
Study Disc 1	157	19.96	26.92	0.0	0.00	100.0	151	9.05	27.47	-66.7	0.00	100.0
30 D SFU Z/P	80	13.33	20.95	0.0	0.00	100.0	78	4.27	23.02	-66.7	0.00	66.7
90 D SFU Z/P	81	13.17	23.38	0.0	0.00	100.0	79	2.53	24.33	-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: 12JAN24

Table 302.3.3002.15: 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 + CAPOX (N=254)												
Baseline	243	20.99	27.16	0.0	0.00	100.0						
Cycle 2 Day 1	209	19.94	26.58	0.0	0.00	100.0	208	-1.44	27.47	-100.0	0.00	100.0
Cycle 3 Day 1	187	18.72	23.45	0.0	0.00	100.0	182	-0.55	28.14	-100.0	0.00	100.0
Cycle 4 Day 1	172	15.12	21.72	0.0	0.00	100.0	169	-4.73	28.47	-66.7	0.00	66.7
Cycle 5 Day 1	163	15.95	22.33	0.0	0.00	100.0	159	-2.73	28.06	-100.0	0.00	66.7
Cycle 6 Day 1	151	15.01	22.99	0.0	0.00	100.0	149	-5.15	28.40	-66.7	0.00	100.0
Cycle 7 Day 1	122	13.93	20.48	0.0	0.00	100.0	120	-5.28	28.34	-100.0	0.00	66.7
Cycle 8 Day 1	114	18.13	21.79	0.0	0.00	100.0	108	0.31	29.00	-100.0	0.00	66.7
Cycle 9 Day 1	107	15.26	19.58	0.0	0.00	100.0	102	-4.90	29.44	-100.0	0.00	66.7
Cycle 10 Day 1	88	13.26	20.55	0.0	0.00	100.0	85	-5.49	29.48	-100.0	0.00	66.7
Cycle 11 Day 1	84	15.08	18.22	0.0	0.00	66.7	81	-2.47	29.71	-100.0	0.00	33.3
Cycle 12 Day 1	77	15.58	19.93	0.0	0.00	100.0	75	-0.89	27.39	-100.0	0.00	66.7
Cycle 13 Day 1	62	11.83	19.18	0.0	0.00	66.7	60	-3.33	24.32	-66.7	0.00	66.7
Cycle 14 Day 1	57	13.45	17.66	0.0	0.00	66.7	55	0.61	27.59	-100.0	0.00	33.3
Cycle 15 Day 1	53	16.35	19.20	0.0	0.00	66.7	51	5.23	23.45	-66.7	0.00	33.3
Cycle 16 Day 1	50	14.00	20.30	0.0	0.00	100.0	48	0.00	25.73	-66.7	0.00	66.7
Cycle 17 Day 1	45	14.07	21.89	0.0	0.00	100.0	43	1.55	25.15	-66.7	0.00	66.7
Cycle 18 Day 1	43	13.95	20.87	0.0	0.00	100.0	41	0.00	24.72	-33.3	0.00	66.7
Cycle 19 Day 1	42	11.90	20.59	0.0	0.00	100.0	40	0.00	21.35	-33.3	0.00	66.7
Cycle 20 Day 1	41	11.38	19.16	0.0	0.00	66.7	39	-0.85	17.91	-33.3	0.00	33.3
Cycle 21 Day 1	38	12.28	16.30	0.0	0.00	33.3	36	0.00	19.52	-33.3	0.00	33.3
Cycle 22 Day 1	33	7.07	13.84	0.0	0.00	33.3	31	-5.38	17.42	-33.3	0.00	33.3
Cycle 23 Day 1	33	7.07	13.84	0.0	0.00	33.3	31	-3.23	15.76	-33.3	0.00	33.3
Cycle 24 Day 1	31	9.68	15.38	0.0	0.00	33.3	29	0.00	17.82	-33.3	0.00	33.3
Cycle 25 Day 1	30	5.56	12.63	0.0	0.00	33.3	28	-2.38	20.14	-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: 12JAN24

Table 302.3.3002.15: 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 26 Day 1	28	7.14	13.93	0.0	0.00	33.3	26	-2.56	18.67	-33.3	0.00	33.3
Cycle 27 Day 1	27	6.17	13.19	0.0	0.00	33.3	25	-4.00	17.53	-33.3	0.00	33.3
Cycle 28 Day 1	23	10.14	18.63	0.0	0.00	66.7	21	-1.59	19.65	-33.3	0.00	33.3
Cycle 29 Day 1	24	12.50	19.19	0.0	0.00	66.7	22	1.52	21.77	-33.3	0.00	33.3
Cycle 30 Day 1	22	7.58	14.30	0.0	0.00	33.3	20	-1.67	17.01	-33.3	0.00	33.3
Cycle 31 Day 1	22	12.12	16.41	0.0	0.00	33.3	20	1.67	17.01	-33.3	0.00	33.3
Cycle 32 Day 1	20	11.67	16.31	0.0	0.00	33.3	18	0.00	22.87	-33.3	0.00	33.3
Cycle 33 Day 1	17	5.88	13.10	0.0	0.00	33.3	15	-2.22	19.79	-33.3	0.00	33.3
Cycle 34 Day 1	14	4.76	12.10	0.0	0.00	33.3	12	-2.78	22.29	-33.3	0.00	33.3
Cycle 35 Day 1	15	8.89	15.26	0.0	0.00	33.3	13	0.00	23.57	-33.3	0.00	33.3
Cycle 36 Day 1	14	7.14	14.19	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
Cycle 37 Day 1	12	11.11	16.41	0.0	0.00	33.3	11	3.03	23.35	-33.3	0.00	33.3
Cycle 38 Day 1	11	15.15	27.34	0.0	0.00	66.7	10	6.67	34.43	-33.3	0.00	66.7
Cycle 39 Day 1	10	13.33	17.21	0.0	0.00	33.3	9	7.41	22.22	-33.3	0.00	33.3
Study Disc 1	135	24.44	27.68	0.0	33.33	100.0	133	6.52	33.70	-100.0	0.00	100.0
30 D SFU Z/P	58	21.84	24.62	0.0	16.67	66.7	57	6.43	30.50	-100.0	0.00	66.7
90 D SFU Z/P	62	18.28	19.72	0.0	16.67	66.7	61	6.56	22.62	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	24.79	26.66	0.0	33.33	100.0						
Cycle 2 Day 1	222	22.82	25.95	0.0	33.33	100.0	217	-1.54	27.55	-66.7	0.00	100.0
Cycle 3 Day 1	200	21.50	26.29	0.0	0.00	100.0	197	-2.54	28.56	-66.7	0.00	100.0
Cycle 4 Day 1	171	19.10	24.23	0.0	0.00	100.0	169	-5.13	27.94	-66.7	0.00	66.7
Cycle 5 Day 1	166	18.88	22.44	0.0	0.00	66.7	165	-4.44	28.16	-66.7	0.00	66.7
Cycle 6 Day 1	147	20.41	27.16	0.0	0.00	100.0	146	-2.51	30.35	-100.0	0.00	100.0
Cycle 7 Day 1	127	19.69	24.25	0.0	0.00	100.0	126	-2.91	31.28	-100.0	0.00	100.0
Cycle 8 Day 1	111	19.22	24.02	0.0	0.00	100.0	110	-4.85	25.48	-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: 12JAN24

Table 302.3.3002.15: 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 9 Day 1	104	17.95	26.24	0.0	0.00	100.0	103	-4.21	27.88	-66.7	0.00	66.7
Cycle 10 Day 1	81	20.99	24.41	0.0	0.00	100.0	79	-0.42	28.49	-66.7	0.00	66.7
Cycle 11 Day 1	72	21.76	25.73	0.0	16.67	100.0	71	0.94	30.33	-66.7	0.00	100.0
Cycle 12 Day 1	59	18.64	23.38	0.0	0.00	100.0	57	-0.58	29.87	-66.7	0.00	66.7
Cycle 13 Day 1	50	20.67	25.99	0.0	0.00	100.0	48	1.39	33.66	-66.7	0.00	66.7
Cycle 14 Day 1	46	16.67	23.04	0.0	0.00	66.7	44	-0.76	33.32	-66.7	0.00	66.7
Cycle 15 Day 1	38	18.42	20.06	0.0	16.67	66.7	36	1.85	30.80	-66.7	0.00	66.7
Cycle 16 Day 1	33	21.21	21.76	0.0	33.33	66.7	31	6.45	24.97	-33.3	0.00	66.7
Cycle 17 Day 1	28	22.62	30.16	0.0	0.00	100.0	25	12.00	31.74	-33.3	0.00	100.0
Cycle 18 Day 1	23	14.49	22.08	0.0	0.00	66.7	21	4.76	24.23	-33.3	0.00	66.7
Cycle 19 Day 1	21	17.46	30.95	0.0	0.00	100.0	20	6.67	38.39	-33.3	0.00	100.0
Cycle 20 Day 1	20	18.33	22.88	0.0	0.00	66.7	19	7.02	23.78	-33.3	0.00	66.7
Cycle 21 Day 1	21	17.46	22.65	0.0	0.00	66.7	20	8.33	30.35	-33.3	0.00	66.7
Cycle 22 Day 1	18	20.37	28.33	0.0	0.00	100.0	17	9.80	34.89	-33.3	0.00	100.0
Cycle 23 Day 1	17	15.69	23.91	0.0	0.00	66.7	16	4.17	34.16	-33.3	0.00	66.7
Cycle 24 Day 1	13	12.82	21.68	0.0	0.00	66.7	12	0.00	24.62	-33.3	0.00	33.3
Cycle 25 Day 1	13	12.82	16.88	0.0	0.00	33.3	12	2.78	22.29	-33.3	0.00	33.3
Cycle 26 Day 1	10	13.33	17.21	0.0	0.00	33.3	9	3.70	20.03	-33.3	0.00	33.3
Cycle 27 Day 1	11	15.15	17.41	0.0	0.00	33.3	10	6.67	21.08	-33.3	0.00	33.3
Cycle 28 Day 1	11	24.24	26.21	0.0	33.33	66.7	11	15.15	27.34	-33.3	0.00	66.7
Cycle 29 Day 1	12	19.44	22.29	0.0	16.67	66.7	12	8.33	25.13	-33.3	0.00	33.3
Study Disc 1	157	32.48	30.42	0.0	33.33	100.0	151	9.05	34.20	-66.7	0.00	100.0
30 D SFU Z/P	80	28.75	29.41	0.0	33.33	100.0	78	8.55	36.21	-66.7	0.00	100.0
90 D SFU Z/P	81	23.87	27.00	0.0	33.33	100.0	79	0.42	28.99	-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: 12JAN24

Table 302.3.3002.16: 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 + CAPOX (N=254)												
Baseline	243	26.20	29.91	0.0	33.33	100.0						
Cycle 2 Day 1	209	28.23	28.97	0.0	33.33	100.0	208	3.69	31.97	-66.7	0.00	100.0
Cycle 3 Day 1	187	26.56	29.15	0.0	33.33	100.0	182	0.73	34.86	-100.0	0.00	100.0
Cycle 4 Day 1	172	22.09	26.79	0.0	0.00	100.0	169	-3.55	34.32	-100.0	0.00	100.0
Cycle 5 Day 1	163	22.90	28.33	0.0	0.00	100.0	159	-2.94	36.24	-100.0	0.00	100.0
Cycle 6 Day 1	151	26.71	29.32	0.0	33.33	100.0	149	-0.22	34.55	-66.7	0.00	100.0
Cycle 7 Day 1	122	19.95	24.11	0.0	0.00	100.0	120	-4.44	37.41	-100.0	0.00	100.0
Cycle 8 Day 1	114	23.10	26.28	0.0	33.33	100.0	108	-1.23	31.55	-100.0	0.00	66.7
Cycle 9 Day 1	107	20.87	30.55	0.0	0.00	100.0	102	-3.92	36.72	-100.0	0.00	100.0
Cycle 10 Day 1	88	18.94	26.65	0.0	0.00	100.0	85	-3.92	31.04	-100.0	0.00	66.7
Cycle 11 Day 1	84	13.10	21.35	0.0	0.00	100.0	81	-7.82	31.30	-100.0	0.00	66.7
Cycle 12 Day 1	77	13.85	21.19	0.0	0.00	100.0	75	-8.00	31.40	-100.0	0.00	66.7
Cycle 13 Day 1	62	14.52	23.08	0.0	0.00	100.0	60	-9.44	36.36	-100.0	0.00	66.7
Cycle 14 Day 1	57	9.94	18.86	0.0	0.00	100.0	55	-12.12	31.01	-100.0	0.00	66.7
Cycle 15 Day 1	53	12.58	19.86	0.0	0.00	100.0	51	-9.80	30.03	-100.0	0.00	66.7
Cycle 16 Day 1	50	13.33	19.05	0.0	0.00	66.7	48	-9.72	32.22	-100.0	0.00	66.7
Cycle 17 Day 1	45	14.07	23.02	0.0	0.00	100.0	43	-8.53	32.61	-100.0	0.00	100.0
Cycle 18 Day 1	43	12.40	20.60	0.0	0.00	100.0	41	-12.20	32.28	-100.0	0.00	100.0
Cycle 19 Day 1	42	11.11	17.53	0.0	0.00	66.7	40	-14.17	30.09	-100.0	0.00	66.7
Cycle 20 Day 1	41	14.63	23.63	0.0	0.00	100.0	39	-7.69	33.74	-100.0	0.00	100.0
Cycle 21 Day 1	38	17.54	20.12	0.0	0.00	66.7	36	-4.63	33.00	-100.0	0.00	66.7
Cycle 22 Day 1	33	11.11	19.84	0.0	0.00	66.7	31	-10.75	32.65	-100.0	0.00	33.3
Cycle 23 Day 1	33	10.10	22.80	0.0	0.00	100.0	31	-10.75	30.29	-100.0	0.00	33.3
Cycle 24 Day 1	31	6.45	15.91	0.0	0.00	66.7	29	-13.79	28.89	-100.0	0.00	33.3
Cycle 25 Day 1	30	10.00	17.83	0.0	0.00	66.7	28	-10.71	30.16	-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: 12JAN24

Table 302.3.3002.16: 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 26 Day 1	28	8.33	21.52	0.0	0.00	100.0	26	-12.82	35.37	-100.0	0.00	66.7
Cycle 27 Day 1	27	11.11	18.49	0.0	0.00	66.7	25	-8.00	30.85	-100.0	0.00	33.3
Cycle 28 Day 1	23	8.70	18.03	0.0	0.00	66.7	21	-14.29	32.61	-100.0	0.00	33.3
Cycle 29 Day 1	24	4.17	11.26	0.0	0.00	33.3	22	-16.67	28.64	-100.0	0.00	33.3
Cycle 30 Day 1	22	9.09	15.19	0.0	0.00	33.3	20	-10.00	32.62	-100.0	0.00	33.3
Cycle 31 Day 1	22	4.55	15.59	0.0	0.00	66.7	20	-16.67	31.53	-100.0	0.00	33.3
Cycle 32 Day 1	20	8.33	18.34	0.0	0.00	66.7	18	-14.81	36.55	-100.0	0.00	33.3
Cycle 33 Day 1	17	5.88	13.10	0.0	0.00	33.3	15	-17.78	37.52	-100.0	0.00	33.3
Cycle 34 Day 1	14	4.76	12.10	0.0	0.00	33.3	12	-27.78	34.33	-100.0	-16.67	0.0
Cycle 35 Day 1	15	11.11	20.57	0.0	0.00	66.7	13	-17.95	35.00	-100.0	0.00	33.3
Cycle 36 Day 1	14	7.14	14.19	0.0	0.00	33.3	12	-19.44	36.12	-100.0	0.00	33.3
Cycle 37 Day 1	12	13.89	17.16	0.0	0.00	33.3	11	-18.18	37.61	-66.7	0.00	33.3
Cycle 38 Day 1	11	12.12	26.97	0.0	0.00	66.7	10	-23.33	41.72	-66.7	-33.33	66.7
Cycle 39 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	-18.52	37.68	-66.7	-33.33	33.3
Study Disc 1	135	27.65	31.69	0.0	33.33	100.0	133	5.76	35.65	-100.0	0.00	100.0
30 D SFU Z/P	58	27.01	33.89	0.0	0.00	100.0	57	4.68	38.03	-100.0	0.00	100.0
90 D SFU Z/P	62	22.04	29.53	0.0	0.00	100.0	61	3.28	38.83	-66.7	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	242	24.66	29.17	0.0	33.33	100.0						
Cycle 2 Day 1	222	21.47	24.45	0.0	33.33	100.0	217	-2.61	27.37	-100.0	0.00	100.0
Cycle 3 Day 1	200	19.83	25.47	0.0	0.00	100.0	197	-2.71	27.43	-100.0	0.00	66.7
Cycle 4 Day 1	171	18.91	25.31	0.0	0.00	100.0	169	-5.13	33.13	-100.0	0.00	100.0
Cycle 5 Day 1	166	19.28	24.41	0.0	0.00	100.0	165	-4.44	33.03	-100.0	0.00	66.7
Cycle 6 Day 1	147	21.09	25.31	0.0	0.00	100.0	146	-2.51	33.47	-100.0	0.00	100.0
Cycle 7 Day 1	127	16.27	22.95	0.0	0.00	100.0	126	-6.88	31.36	-100.0	0.00	100.0
Cycle 8 Day 1	111	16.82	22.42	0.0	0.00	100.0	110	-6.36	32.71	-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: 12JAN24

Table 302.3.3002.16: 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 9 Day 1	104	16.35	25.01	0.0	0.00	100.0	103	-7.12	34.51	-100.0	0.00	100.0
Cycle 10 Day 1	81	12.35	20.03	0.0	0.00	66.7	79	-10.13	32.62	-100.0	0.00	66.7
Cycle 11 Day 1	72	11.57	21.05	0.0	0.00	100.0	71	-12.21	33.92	-100.0	0.00	66.7
Cycle 12 Day 1	59	9.04	19.41	0.0	0.00	100.0	57	-11.11	30.43	-66.7	0.00	66.7
Cycle 13 Day 1	50	9.33	16.55	0.0	0.00	66.7	48	-12.50	31.23	-100.0	0.00	66.7
Cycle 14 Day 1	46	10.14	18.42	0.0	0.00	66.7	44	-11.36	30.45	-100.0	0.00	66.7
Cycle 15 Day 1	38	10.53	20.66	0.0	0.00	100.0	36	-11.11	29.81	-100.0	0.00	66.7
Cycle 16 Day 1	33	11.11	18.00	0.0	0.00	66.7	31	-8.60	32.17	-100.0	0.00	66.7
Cycle 17 Day 1	28	11.90	20.72	0.0	0.00	66.7	25	-6.67	36.00	-100.0	0.00	66.7
Cycle 18 Day 1	23	11.59	19.09	0.0	0.00	66.7	21	-9.52	35.19	-100.0	0.00	66.7
Cycle 19 Day 1	21	3.17	10.03	0.0	0.00	33.3	20	-15.00	20.16	-66.7	0.00	0.0
Cycle 20 Day 1	20	8.33	14.81	0.0	0.00	33.3	19	-15.79	30.16	-100.0	0.00	33.3
Cycle 21 Day 1	21	12.70	19.65	0.0	0.00	66.7	20	-10.00	34.37	-66.7	0.00	66.7
Cycle 22 Day 1	18	9.26	19.15	0.0	0.00	66.7	17	-17.65	31.44	-100.0	0.00	33.3
Cycle 23 Day 1	17	13.73	29.01	0.0	0.00	100.0	16	-14.58	40.31	-100.0	-16.67	66.7
Cycle 24 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	-16.67	33.33	-100.0	0.00	33.3
Cycle 25 Day 1	13	10.26	16.01	0.0	0.00	33.3	12	-16.67	33.33	-100.0	0.00	33.3
Cycle 26 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	-14.81	17.57	-33.3	0.00	0.0
Cycle 27 Day 1	11	9.09	15.57	0.0	0.00	33.3	10	-10.00	31.62	-66.7	0.00	33.3
Cycle 28 Day 1	11	18.18	22.92	0.0	0.00	66.7	11	0.00	29.81	-33.3	0.00	66.7
Cycle 29 Day 1	12	13.89	22.29	0.0	0.00	66.7	12	-11.11	29.59	-66.7	0.00	33.3
Study Disc 1	157	32.06	33.31	0.0	33.33	100.0	151	7.51	33.59	-100.0	0.00	100.0
30 D SFU Z/P	80	26.67	28.26	0.0	33.33	100.0	78	6.41	29.94	-66.7	0.00	100.0
90 D SFU Z/P	81	22.22	27.39	0.0	0.00	100.0	79	0.84	32.46	-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: 12JAN24

Table 302.3.3002.17: 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 + CAPOX (N=254)												
Baseline	243	18.11	26.09	0.0	0.00	100.0						
Cycle 2 Day 1	209	16.43	22.67	0.0	0.00	100.0	208	-0.64	24.94	-66.7	0.00	100.0
Cycle 3 Day 1	187	15.15	24.49	0.0	0.00	100.0	182	-2.38	26.23	-100.0	0.00	100.0
Cycle 4 Day 1	172	12.98	21.46	0.0	0.00	100.0	169	-4.73	26.30	-100.0	0.00	66.7
Cycle 5 Day 1	163	14.11	24.54	0.0	0.00	100.0	159	-2.73	25.97	-66.7	0.00	100.0
Cycle 6 Day 1	151	12.36	21.98	0.0	0.00	100.0	149	-5.82	26.77	-100.0	0.00	100.0
Cycle 7 Day 1	122	10.93	17.90	0.0	0.00	66.7	120	-7.78	26.19	-66.7	0.00	66.7
Cycle 8 Day 1	114	13.16	22.00	0.0	0.00	100.0	108	-4.63	27.14	-100.0	0.00	66.7
Cycle 9 Day 1	107	14.64	21.56	0.0	0.00	100.0	102	-4.25	22.82	-66.7	0.00	66.7
Cycle 10 Day 1	88	11.74	20.86	0.0	0.00	100.0	85	-6.27	26.97	-66.7	0.00	100.0
Cycle 11 Day 1	84	10.32	20.02	0.0	0.00	100.0	81	-4.94	28.44	-100.0	0.00	100.0
Cycle 12 Day 1	77	10.39	18.14	0.0	0.00	100.0	75	-6.22	25.52	-100.0	0.00	33.3
Cycle 13 Day 1	62	9.14	17.25	0.0	0.00	66.7	60	-7.78	25.58	-66.7	0.00	66.7
Cycle 14 Day 1	57	10.53	19.06	0.0	0.00	66.7	55	-6.06	25.73	-66.7	0.00	66.7
Cycle 15 Day 1	53	11.95	18.60	0.0	0.00	66.7	51	-4.58	27.50	-66.7	0.00	66.7
Cycle 16 Day 1	50	12.00	18.76	0.0	0.00	66.7	48	-2.78	26.48	-66.7	0.00	66.7
Cycle 17 Day 1	45	11.11	20.10	0.0	0.00	100.0	43	-3.88	27.42	-66.7	0.00	100.0
Cycle 18 Day 1	43	9.30	16.79	0.0	0.00	66.7	41	-5.69	25.71	-66.7	0.00	66.7
Cycle 19 Day 1	42	9.52	18.46	0.0	0.00	66.7	40	-5.83	23.74	-66.7	0.00	66.7
Cycle 20 Day 1	41	13.82	24.69	0.0	0.00	100.0	39	0.00	31.53	-66.7	0.00	100.0
Cycle 21 Day 1	38	14.04	22.77	0.0	0.00	100.0	36	0.00	26.43	-33.3	0.00	100.0
Cycle 22 Day 1	33	12.12	23.30	0.0	0.00	100.0	31	-2.15	32.13	-66.7	0.00	100.0
Cycle 23 Day 1	33	9.09	20.87	0.0	0.00	100.0	31	-3.23	27.70	-66.7	0.00	100.0
Cycle 24 Day 1	31	9.68	17.62	0.0	0.00	66.7	29	-3.45	22.44	-66.7	0.00	33.3
Cycle 25 Day 1	30	10.00	17.83	0.0	0.00	66.7	28	-3.57	24.58	-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: 12JAN24

Table 302.3.3002.17: 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 26 Day 1	28	8.33	17.27	0.0	0.00	66.7	26	-5.13	26.15	-100.0	0.00	33.3
Cycle 27 Day 1	27	6.17	16.11	0.0	0.00	66.7	25	-6.67	25.46	-100.0	0.00	33.3
Cycle 28 Day 1	23	7.25	17.28	0.0	0.00	66.7	21	-4.76	19.11	-33.3	0.00	33.3
Cycle 29 Day 1	24	9.72	18.33	0.0	0.00	66.7	22	0.00	20.57	-66.7	0.00	33.3
Cycle 30 Day 1	22	7.58	17.61	0.0	0.00	66.7	20	-3.33	21.36	-33.3	0.00	33.3
Cycle 31 Day 1	22	10.61	18.93	0.0	0.00	66.7	20	0.00	18.73	-33.3	0.00	33.3
Cycle 32 Day 1	20	11.67	19.57	0.0	0.00	66.7	18	1.85	17.98	-33.3	0.00	33.3
Cycle 33 Day 1	17	5.88	13.10	0.0	0.00	33.3	15	-6.67	18.69	-33.3	0.00	33.3
Cycle 34 Day 1	14	4.76	12.10	0.0	0.00	33.3	12	-8.33	15.08	-33.3	0.00	0.0
Cycle 35 Day 1	15	4.44	11.73	0.0	0.00	33.3	13	-7.69	14.62	-33.3	0.00	0.0
Cycle 36 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-8.33	15.08	-33.3	0.00	0.0
Cycle 37 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-12.12	16.82	-33.3	0.00	0.0
Cycle 38 Day 1	11	6.06	20.10	0.0	0.00	66.7	10	-6.67	14.05	-33.3	0.00	0.0
Cycle 39 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	-3.70	11.11	-33.3	0.00	0.0
Study Disc 1	135	16.54	24.39	0.0	0.00	100.0	133	-1.25	27.95	-66.7	0.00	100.0
30 D SFU Z/P	58	15.52	25.91	0.0	0.00	100.0	57	-2.34	30.12	-66.7	0.00	100.0
90 D SFU Z/P	62	16.13	23.95	0.0	0.00	100.0	61	1.09	27.19	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	17.63	27.02	0.0	0.00	100.0						
Cycle 2 Day 1	222	14.56	22.93	0.0	0.00	100.0	217	-2.76	25.10	-100.0	0.00	66.7
Cycle 3 Day 1	200	11.17	20.13	0.0	0.00	100.0	197	-5.25	23.58	-100.0	0.00	66.7
Cycle 4 Day 1	171	10.33	20.86	0.0	0.00	100.0	169	-6.90	29.07	-100.0	0.00	100.0
Cycle 5 Day 1	166	11.85	19.77	0.0	0.00	100.0	165	-4.65	26.77	-100.0	0.00	66.7
Cycle 6 Day 1	147	13.15	22.26	0.0	0.00	100.0	146	-4.34	29.36	-100.0	0.00	100.0
Cycle 7 Day 1	127	14.70	24.00	0.0	0.00	100.0	126	-2.12	32.32	-100.0	0.00	100.0
Cycle 8 Day 1	111	13.81	23.12	0.0	0.00	100.0	110	-3.03	31.13	-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: 12JAN24

Table 302.3.3002.17: 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 9 Day 1	104	10.90	21.00	0.0	0.00	100.0	103	-5.50	29.19	-100.0	0.00	66.7
Cycle 10 Day 1	81	8.64	20.26	0.0	0.00	100.0	79	-7.17	30.97	-100.0	0.00	100.0
Cycle 11 Day 1	72	12.50	24.67	0.0	0.00	100.0	71	-3.29	33.88	-100.0	0.00	100.0
Cycle 12 Day 1	59	11.86	23.78	0.0	0.00	100.0	57	-1.17	26.70	-66.7	0.00	100.0
Cycle 13 Day 1	50	12.00	23.09	0.0	0.00	100.0	48	-3.47	33.85	-100.0	0.00	100.0
Cycle 14 Day 1	46	13.77	22.85	0.0	0.00	100.0	44	-2.27	28.21	-100.0	0.00	66.7
Cycle 15 Day 1	38	11.40	19.42	0.0	0.00	66.7	36	-3.70	32.64	-100.0	0.00	66.7
Cycle 16 Day 1	33	12.12	24.75	0.0	0.00	100.0	31	-2.15	33.26	-66.7	0.00	66.7
Cycle 17 Day 1	28	9.52	23.76	0.0	0.00	100.0	25	-1.33	26.32	-66.7	0.00	66.7
Cycle 18 Day 1	23	5.80	12.92	0.0	0.00	33.3	21	-6.35	29.10	-100.0	0.00	33.3
Cycle 19 Day 1	21	1.59	7.27	0.0	0.00	33.3	20	-6.67	17.44	-66.7	0.00	0.0
Cycle 20 Day 1	20	5.00	12.21	0.0	0.00	33.3	19	-7.02	26.24	-66.7	0.00	33.3
Cycle 21 Day 1	21	6.35	17.06	0.0	0.00	66.7	20	-5.00	31.11	-100.0	0.00	33.3
Cycle 22 Day 1	18	12.96	20.26	0.0	0.00	66.7	17	1.96	24.92	-66.7	0.00	33.3
Cycle 23 Day 1	17	11.76	26.20	0.0	0.00	100.0	16	0.00	34.43	-100.0	0.00	66.7
Cycle 24 Day 1	13	12.82	21.68	0.0	0.00	66.7	12	5.56	31.25	-66.7	0.00	66.7
Cycle 25 Day 1	13	7.69	14.62	0.0	0.00	33.3	12	0.00	24.62	-66.7	0.00	33.3
Cycle 26 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	7.41	14.70	0.0	0.00	33.3
Cycle 27 Day 1	11	9.09	21.56	0.0	0.00	66.7	10	10.00	22.50	0.0	0.00	66.7
Cycle 28 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 29 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	5.56	19.25	-33.3	0.00	33.3
Study Disc 1	157	20.17	26.89	0.0	0.00	100.0	151	4.19	30.62	-100.0	0.00	66.7
30 D SFU Z/P	80	18.33	24.25	0.0	0.00	100.0	78	4.70	28.29	-66.7	0.00	100.0
90 D SFU Z/P	81	19.34	25.75	0.0	0.00	100.0	79	5.91	31.01	-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: 12JAN24

Table 302.3.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 + CAPOX (N=157)												
	Baseline	155	14.62	22.82	0.0	0.00	100.0						
	Cycle 2 Day 1	138	14.98	22.09	0.0	0.00	100.0	138	0.72	22.23	-66.7	0.00	66.7
	Cycle 3 Day 1	121	13.22	22.56	0.0	0.00	100.0	120	-1.11	21.14	-66.7	0.00	100.0
	Cycle 4 Day 1	110	13.03	19.73	0.0	0.00	66.7	110	-1.21	22.09	-100.0	0.00	66.7
	Cycle 5 Day 1	106	13.21	21.42	0.0	0.00	100.0	106	-0.94	21.31	-66.7	0.00	66.7
	Cycle 6 Day 1	95	10.88	19.11	0.0	0.00	66.7	95	-3.51	22.53	-100.0	0.00	33.3
	Cycle 7 Day 1	80	9.17	15.89	0.0	0.00	66.7	80	-7.50	22.49	-66.7	0.00	33.3
	Cycle 8 Day 1	70	12.86	20.69	0.0	0.00	100.0	69	-2.90	22.68	-100.0	0.00	33.3
	Cycle 9 Day 1	70	13.33	18.30	0.0	0.00	66.7	69	-2.42	20.06	-66.7	0.00	33.3
	Cycle 10 Day 1	55	10.91	19.30	0.0	0.00	100.0	54	-4.94	20.89	-66.7	0.00	33.3
	Cycle 11 Day 1	56	12.50	19.66	0.0	0.00	100.0	55	-1.82	22.61	-66.7	0.00	33.3
	Cycle 12 Day 1	53	12.58	19.86	0.0	0.00	100.0	52	-2.56	22.72	-66.7	0.00	33.3
	Cycle 13 Day 1	44	9.09	16.65	0.0	0.00	66.7	43	-6.98	20.00	-66.7	0.00	33.3
	Cycle 14 Day 1	40	10.83	17.52	0.0	0.00	66.7	39	-4.27	21.87	-66.7	0.00	33.3
	Cycle 15 Day 1	35	10.48	15.70	0.0	0.00	33.3	34	-4.90	21.92	-66.7	0.00	33.3
	Cycle 16 Day 1	34	10.78	15.83	0.0	0.00	33.3	33	-5.05	20.62	-66.7	0.00	33.3
	Cycle 17 Day 1	30	10.00	15.54	0.0	0.00	33.3	29	-5.75	20.06	-66.7	0.00	33.3
	Cycle 18 Day 1	28	8.33	14.70	0.0	0.00	33.3	27	-7.41	21.35	-66.7	0.00	33.3
	Cycle 19 Day 1	27	9.88	18.06	0.0	0.00	66.7	26	-6.41	18.90	-33.3	0.00	33.3
	Cycle 20 Day 1	28	8.33	14.70	0.0	0.00	33.3	27	-7.41	19.25	-66.7	0.00	33.3
	Cycle 21 Day 1	25	12.00	18.95	0.0	0.00	66.7	24	-4.17	17.89	-33.3	0.00	33.3
	Cycle 22 Day 1	22	12.12	19.37	0.0	0.00	66.7	21	-4.76	26.43	-66.7	0.00	33.3
	Cycle 23 Day 1	21	7.94	14.55	0.0	0.00	33.3	20	-8.33	21.29	-66.7	0.00	33.3
	Cycle 24 Day 1	21	11.11	19.25	0.0	0.00	66.7	20	-5.00	24.84	-66.7	0.00	33.3
	Cycle 25 Day 1	20	11.67	19.57	0.0	0.00	66.7	19	-5.26	27.81	-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: 12JAN24

Table 302.3.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 26 Day 1	19	10.53	19.41	0.0	0.00	66.7	18	-7.41	29.27	-100.0	0.00	33.3
	Cycle 27 Day 1	18	7.41	18.28	0.0	0.00	66.7	17	-7.84	30.11	-100.0	0.00	33.3
	Cycle 28 Day 1	13	12.82	21.68	0.0	0.00	66.7	12	-2.78	22.29	-33.3	0.00	33.3
	Cycle 29 Day 1	15	11.11	20.57	0.0	0.00	66.7	14	-2.38	24.33	-66.7	0.00	33.3
	Cycle 30 Day 1	14	9.52	20.37	0.0	0.00	66.7	13	-5.13	22.96	-33.3	0.00	33.3
	Cycle 31 Day 1	15	11.11	20.57	0.0	0.00	66.7	14	-2.38	20.52	-33.3	0.00	33.3
	Cycle 32 Day 1	13	12.82	21.68	0.0	0.00	66.7	12	0.00	20.10	-33.3	0.00	33.3
	Cycle 33 Day 1	13	7.69	14.62	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
	Cycle 35 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	-7.41	14.70	-33.3	0.00	0.0
	Study Disc 1	90	16.30	25.11	0.0	0.00	100.0	90	-0.74	27.36	-66.7	0.00	100.0
	30 D SFU Z/P	38	15.79	26.55	0.0	0.00	100.0	38	0.00	24.51	-66.7	0.00	66.7
	90 D SFU Z/P	38	20.18	25.16	0.0	16.67	100.0	38	5.26	22.63	-33.3	0.00	66.7
	Placebo + CAPOX (N=158)												
	Baseline	155	16.34	23.53	0.0	0.00	100.0						
	Cycle 2 Day 1	140	12.38	20.52	0.0	0.00	100.0	139	-3.60	20.73	-100.0	0.00	66.7
	Cycle 3 Day 1	127	9.97	17.97	0.0	0.00	66.7	126	-4.76	20.96	-66.7	0.00	66.7
	Cycle 4 Day 1	108	8.64	18.44	0.0	0.00	100.0	107	-7.48	25.62	-100.0	0.00	100.0
	Cycle 5 Day 1	104	10.90	18.83	0.0	0.00	66.7	104	-4.81	25.62	-100.0	0.00	66.7
	Cycle 6 Day 1	88	11.36	19.50	0.0	0.00	66.7	88	-6.06	26.04	-100.0	0.00	66.7
	Cycle 7 Day 1	79	13.50	21.03	0.0	0.00	66.7	79	-2.95	24.57	-100.0	0.00	66.7
	Cycle 8 Day 1	68	13.24	20.88	0.0	0.00	66.7	68	-3.92	26.72	-100.0	0.00	66.7
	Cycle 9 Day 1	63	10.05	19.52	0.0	0.00	66.7	63	-5.82	26.46	-100.0	0.00	66.7
	Cycle 10 Day 1	47	5.67	14.44	0.0	0.00	66.7	47	-8.51	28.21	-100.0	0.00	66.7
	Cycle 11 Day 1	45	9.63	23.16	0.0	0.00	100.0	45	-2.96	29.15	-100.0	0.00	100.0
	Cycle 12 Day 1	34	7.84	18.46	0.0	0.00	66.7	34	-3.92	21.34	-66.7	0.00	66.7
	Cycle 13 Day 1	28	10.71	24.09	0.0	0.00	100.0	28	2.38	25.55	-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.
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: 12JAN24

Table 302.3.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 14 Day 1	25	10.67	18.56	0.0	0.00	66.7	25	2.67	23.41	-66.7	0.00	66.7
	Cycle 15 Day 1	19	12.28	19.91	0.0	0.00	66.7	19	3.51	26.98	-66.7	0.00	66.7
	Cycle 16 Day 1	18	14.81	28.52	0.0	0.00	100.0	18	5.56	28.58	-66.7	0.00	66.7
	Cycle 17 Day 1	15	13.33	30.34	0.0	0.00	100.0	15	4.44	27.79	-66.7	0.00	66.7
	Cycle 18 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	20.10	-66.7	0.00	0.0
	Cycle 19 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 20 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-9.09	21.56	-66.7	0.00	0.0
	Cycle 21 Day 1	11	6.06	20.10	0.0	0.00	66.7	11	-3.03	23.35	-66.7	0.00	33.3
	Study Disc 1	102	18.95	25.48	0.0	0.00	66.7	101	3.96	30.29	-100.0	0.00	66.7
	30 D SFU Z/P	50	16.00	19.33	0.0	0.00	66.7	50	2.67	24.13	-66.7	0.00	66.7
	90 D SFU Z/P	49	17.69	25.55	0.0	0.00	100.0	49	5.44	28.34	-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: 12JAN24

Table 302.3.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 + CAPOX (N= 97)												
	Baseline	88	24.24	30.21	0.0	0.00	100.0						
	Cycle 2 Day 1	71	19.25	23.68	0.0	0.00	100.0	70	-3.33	29.57	-66.7	0.00	100.0
	Cycle 3 Day 1	66	18.69	27.51	0.0	0.00	100.0	62	-4.84	34.06	-100.0	0.00	100.0
	Cycle 4 Day 1	62	12.90	24.41	0.0	0.00	100.0	59	-11.30	31.93	-100.0	0.00	66.7
	Cycle 5 Day 1	57	15.79	29.62	0.0	0.00	100.0	53	-6.29	33.37	-66.7	0.00	100.0
	Cycle 6 Day 1	56	14.88	26.15	0.0	0.00	100.0	54	-9.88	32.78	-66.7	0.00	100.0
	Cycle 7 Day 1	42	14.29	21.01	0.0	0.00	66.7	40	-8.33	32.69	-66.7	0.00	66.7
	Cycle 8 Day 1	44	13.64	24.19	0.0	0.00	100.0	39	-7.69	33.74	-100.0	0.00	66.7
	Cycle 9 Day 1	37	17.12	26.78	0.0	0.00	100.0	33	-8.08	27.68	-66.7	0.00	66.7
	Cycle 10 Day 1	33	13.13	23.48	0.0	0.00	100.0	31	-8.60	35.45	-66.7	0.00	100.0
	Cycle 11 Day 1	28	5.95	20.39	0.0	0.00	100.0	26	-11.54	37.64	-100.0	0.00	100.0
	Cycle 12 Day 1	24	5.56	12.69	0.0	0.00	33.3	23	-14.49	29.86	-100.0	0.00	33.3
	Cycle 13 Day 1	18	9.26	19.15	0.0	0.00	66.7	17	-9.80	36.83	-66.7	0.00	66.7
	Cycle 14 Day 1	17	9.80	22.87	0.0	0.00	66.7	16	-10.42	33.82	-66.7	0.00	66.7
	Cycle 15 Day 1	18	14.81	23.49	0.0	0.00	66.7	17	-3.92	37.05	-66.7	0.00	66.7
	Cycle 16 Day 1	16	14.58	24.25	0.0	0.00	66.7	15	2.22	36.66	-66.7	0.00	66.7
	Cycle 17 Day 1	15	13.33	27.60	0.0	0.00	100.0	14	0.00	39.22	-66.7	0.00	100.0
	Cycle 18 Day 1	15	11.11	20.57	0.0	0.00	66.7	14	-2.38	33.24	-66.7	0.00	66.7
	Cycle 19 Day 1	15	8.89	19.79	0.0	0.00	66.7	14	-4.76	31.64	-66.7	0.00	66.7
	Cycle 20 Day 1	13	25.64	36.40	0.0	0.00	100.0	12	16.67	46.06	-33.3	0.00	100.0
	Cycle 21 Day 1	13	17.95	29.24	0.0	0.00	100.0	12	8.33	37.94	-33.3	0.00	100.0
	Cycle 22 Day 1	11	12.12	30.81	0.0	0.00	100.0	10	3.33	42.89	-66.7	0.00	100.0
	Cycle 23 Day 1	12	11.11	29.59	0.0	0.00	100.0	11	6.06	35.96	-33.3	0.00	100.0
	Cycle 24 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Cycle 25 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	0.00	16.67	-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.
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: 12JAN24

Table 302.3.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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 28 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	-7.41	14.70	-33.3	0.00	0.0
	Study Disc 1	45	17.04	23.16	0.0	0.00	100.0	43	-2.33	29.45	-66.7	0.00	100.0
	30 D SFU Z/P	20	15.00	25.31	0.0	0.00	100.0	19	-7.02	39.41	-66.7	0.00	100.0
	90 D SFU Z/P	24	9.72	20.80	0.0	0.00	66.7	23	-5.80	32.80	-66.7	0.00	66.7
	Placebo + CAPOX (N= 95)												
	Baseline	87	19.92	32.33	0.0	0.00	100.0						
	Cycle 2 Day 1	82	18.29	26.27	0.0	0.00	100.0	78	-1.28	31.53	-100.0	0.00	66.7
	Cycle 3 Day 1	73	13.24	23.40	0.0	0.00	100.0	71	-6.10	27.78	-100.0	0.00	66.7
	Cycle 4 Day 1	63	13.23	24.35	0.0	0.00	100.0	62	-5.91	34.42	-100.0	0.00	100.0
	Cycle 5 Day 1	62	13.44	21.31	0.0	0.00	100.0	61	-4.37	28.85	-100.0	0.00	33.3
	Cycle 6 Day 1	59	15.82	25.79	0.0	0.00	100.0	58	-1.72	33.87	-100.0	0.00	100.0
	Cycle 7 Day 1	48	16.67	28.35	0.0	0.00	100.0	47	-0.71	42.56	-100.0	0.00	100.0
	Cycle 8 Day 1	43	14.73	26.53	0.0	0.00	100.0	42	-1.59	37.51	-100.0	0.00	100.0
	Cycle 9 Day 1	41	12.20	23.28	0.0	0.00	100.0	40	-5.00	33.38	-100.0	0.00	66.7
	Cycle 10 Day 1	34	12.75	25.97	0.0	0.00	100.0	32	-5.21	35.02	-100.0	0.00	100.0
	Cycle 11 Day 1	27	17.28	26.75	0.0	0.00	100.0	26	-3.85	41.45	-100.0	0.00	100.0
	Cycle 12 Day 1	25	17.33	29.06	0.0	0.00	100.0	23	2.90	33.20	-33.3	0.00	100.0
	Cycle 13 Day 1	22	13.64	22.20	0.0	0.00	66.7	20	-11.67	42.27	-100.0	0.00	66.7
	Cycle 14 Day 1	21	17.46	27.12	0.0	0.00	100.0	19	-8.77	33.04	-100.0	0.00	33.3
	Cycle 15 Day 1	19	10.53	19.41	0.0	0.00	66.7	17	-11.76	37.16	-100.0	0.00	33.3
	Cycle 16 Day 1	15	8.89	19.79	0.0	0.00	66.7	13	-12.82	37.36	-66.7	0.00	66.7
	Cycle 17 Day 1	13	5.13	12.52	0.0	0.00	33.3	10	-10.00	22.50	-66.7	0.00	0.0
	Cycle 18 Day 1	12	8.33	15.08	0.0	0.00	33.3	10	-6.67	37.84	-100.0	0.00	33.3
	Cycle 21 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	-7.41	40.06	-100.0	0.00	33.3
	Cycle 22 Day 1	10	13.33	17.21	0.0	0.00	33.3	9	-3.70	30.93	-66.7	0.00	33.3
	Study Disc 1	55	22.42	29.44	0.0	0.00	100.0	50	4.67	31.59	-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.
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: 12JAN24

Table 302.3.3002.17.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation 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
	30 D SFU Z/P	30	22.22	30.74	0.0	0.00	100.0	28	8.33	34.69	-66.7	0.00	100.0
	90 D SFU Z/P	32	21.87	26.25	0.0	0.00	66.7	30	6.67	35.45	-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.
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: 12JAN24

Table 302.3.3002.18: 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 + CAPOX (N=254)												
Baseline	243	8.09	16.41	0.0	0.00	100.0						
Cycle 2 Day 1	209	10.37	18.60	0.0	0.00	100.0	208	2.56	20.56	-66.7	0.00	66.7
Cycle 3 Day 1	187	10.70	20.56	0.0	0.00	100.0	182	2.93	21.40	-66.7	0.00	66.7
Cycle 4 Day 1	172	9.30	17.77	0.0	0.00	66.7	169	1.38	21.00	-66.7	0.00	66.7
Cycle 5 Day 1	163	9.41	18.34	0.0	0.00	100.0	159	1.47	20.66	-66.7	0.00	66.7
Cycle 6 Day 1	151	11.04	21.68	0.0	0.00	100.0	149	2.91	24.79	-66.7	0.00	100.0
Cycle 7 Day 1	122	10.38	20.14	0.0	0.00	100.0	120	1.94	24.17	-33.3	0.00	100.0
Cycle 8 Day 1	114	9.94	18.78	0.0	0.00	100.0	108	1.23	21.82	-33.3	0.00	100.0
Cycle 9 Day 1	107	10.59	19.21	0.0	0.00	100.0	102	1.31	23.42	-66.7	0.00	100.0
Cycle 10 Day 1	88	8.33	18.40	0.0	0.00	100.0	85	1.18	19.55	-33.3	0.00	66.7
Cycle 11 Day 1	84	4.76	17.27	0.0	0.00	100.0	81	-3.29	21.48	-66.7	0.00	100.0
Cycle 12 Day 1	77	5.63	14.71	0.0	0.00	66.7	75	-1.33	17.71	-33.3	0.00	66.7
Cycle 13 Day 1	62	4.30	12.78	0.0	0.00	66.7	60	-3.89	16.34	-33.3	0.00	33.3
Cycle 14 Day 1	57	4.68	11.68	0.0	0.00	33.3	55	-3.03	17.30	-33.3	0.00	33.3
Cycle 15 Day 1	53	6.92	17.73	0.0	0.00	100.0	51	-1.31	19.96	-33.3	0.00	33.3
Cycle 16 Day 1	50	6.67	17.82	0.0	0.00	100.0	48	-1.39	16.78	-33.3	0.00	33.3
Cycle 17 Day 1	45	7.41	15.71	0.0	0.00	66.7	43	-0.78	19.91	-33.3	0.00	66.7
Cycle 18 Day 1	43	6.20	18.19	0.0	0.00	100.0	41	-1.63	16.59	-33.3	0.00	33.3
Cycle 19 Day 1	42	5.56	14.57	0.0	0.00	66.7	40	-2.50	15.81	-33.3	0.00	33.3
Cycle 20 Day 1	41	6.50	17.03	0.0	0.00	66.7	39	-1.71	17.01	-33.3	0.00	33.3
Cycle 21 Day 1	38	7.02	15.80	0.0	0.00	66.7	36	-0.93	18.66	-33.3	0.00	33.3
Cycle 22 Day 1	33	7.07	21.66	0.0	0.00	100.0	31	0.00	14.91	-33.3	0.00	33.3
Cycle 23 Day 1	33	7.07	20.00	0.0	0.00	100.0	31	1.08	16.06	-33.3	0.00	33.3
Cycle 24 Day 1	31	6.45	13.39	0.0	0.00	33.3	29	2.30	12.38	-33.3	0.00	33.3
Cycle 25 Day 1	30	4.44	11.52	0.0	0.00	33.3	28	0.00	15.71	-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: 12JAN24

Table 302.3.3002.18: 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 26 Day 1	28	4.76	11.88	0.0	0.00	33.3	26	0.00	13.33	-33.3	0.00	33.3
Cycle 27 Day 1	27	6.17	13.19	0.0	0.00	33.3	25	1.33	15.15	-33.3	0.00	33.3
Cycle 28 Day 1	23	5.80	21.68	0.0	0.00	100.0	21	0.00	14.91	-33.3	0.00	33.3
Cycle 29 Day 1	24	9.72	23.01	0.0	0.00	100.0	22	3.03	17.55	-33.3	0.00	33.3
Cycle 30 Day 1	22	7.58	22.84	0.0	0.00	100.0	20	1.67	17.01	-33.3	0.00	33.3
Cycle 31 Day 1	22	6.06	22.15	0.0	0.00	100.0	20	-1.67	13.13	-33.3	0.00	33.3
Cycle 32 Day 1	20	13.33	25.13	0.0	0.00	100.0	18	5.56	17.15	-33.3	0.00	33.3
Cycle 33 Day 1	17	7.84	14.57	0.0	0.00	33.3	15	0.00	17.82	-33.3	0.00	33.3
Cycle 34 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
Cycle 35 Day 1	15	13.33	21.08	0.0	0.00	66.7	13	2.56	16.45	-33.3	0.00	33.3
Cycle 36 Day 1	14	7.14	14.19	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
Cycle 37 Day 1	12	8.33	15.08	0.0	0.00	33.3	11	0.00	21.08	-33.3	0.00	33.3
Cycle 38 Day 1	11	15.15	22.92	0.0	0.00	66.7	10	6.67	21.08	-33.3	0.00	33.3
Cycle 39 Day 1	10	13.33	17.21	0.0	0.00	33.3	9	3.70	20.03	-33.3	0.00	33.3
Study Disc 1	135	8.15	17.02	0.0	0.00	66.7	133	-1.00	20.08	-66.7	0.00	66.7
30 D SFU Z/P	58	7.47	16.57	0.0	0.00	66.7	57	-0.58	18.36	-33.3	0.00	66.7
90 D SFU Z/P	62	8.60	18.04	0.0	0.00	100.0	61	2.73	20.45	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	7.71	15.34	0.0	0.00	66.7						
Cycle 2 Day 1	222	12.76	22.47	0.0	0.00	100.0	217	5.68	22.98	-66.7	0.00	100.0
Cycle 3 Day 1	200	10.83	20.58	0.0	0.00	100.0	197	4.06	20.63	-66.7	0.00	100.0
Cycle 4 Day 1	171	10.92	21.03	0.0	0.00	100.0	169	3.94	22.07	-66.7	0.00	100.0
Cycle 5 Day 1	166	10.84	21.47	0.0	0.00	100.0	165	4.44	20.34	-33.3	0.00	100.0
Cycle 6 Day 1	147	9.75	20.35	0.0	0.00	100.0	146	3.65	21.49	-66.7	0.00	100.0
Cycle 7 Day 1	127	11.29	20.67	0.0	0.00	100.0	126	5.29	19.51	-33.3	0.00	66.7
Cycle 8 Day 1	111	8.71	18.37	0.0	0.00	100.0	110	2.12	18.77	-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: 12JAN24

Table 302.3.3002.18: 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 9 Day 1	104	7.05	15.87	0.0	0.00	66.7	103	0.65	19.79	-66.7	0.00	66.7
Cycle 10 Day 1	81	4.53	14.68	0.0	0.00	100.0	79	-2.53	17.52	-66.7	0.00	66.7
Cycle 11 Day 1	72	5.56	15.82	0.0	0.00	100.0	71	-0.94	18.66	-66.7	0.00	66.7
Cycle 12 Day 1	59	5.65	14.05	0.0	0.00	66.7	57	-2.92	20.20	-66.7	0.00	66.7
Cycle 13 Day 1	50	4.67	11.68	0.0	0.00	33.3	48	-4.17	17.70	-66.7	0.00	33.3
Cycle 14 Day 1	46	5.80	12.77	0.0	0.00	33.3	44	-2.27	20.83	-66.7	0.00	33.3
Cycle 15 Day 1	38	5.26	14.55	0.0	0.00	66.7	36	-2.78	20.12	-66.7	0.00	66.7
Cycle 16 Day 1	33	5.05	12.14	0.0	0.00	33.3	31	-3.23	13.21	-33.3	0.00	33.3
Cycle 17 Day 1	28	5.95	13.00	0.0	0.00	33.3	25	-4.00	11.06	-33.3	0.00	0.0
Cycle 18 Day 1	23	4.35	11.48	0.0	0.00	33.3	21	-4.76	19.11	-66.7	0.00	33.3
Cycle 19 Day 1	21	6.35	13.41	0.0	0.00	33.3	20	-3.33	14.91	-33.3	0.00	33.3
Cycle 20 Day 1	20	5.00	12.21	0.0	0.00	33.3	19	-3.51	15.29	-33.3	0.00	33.3
Cycle 21 Day 1	21	6.35	13.41	0.0	0.00	33.3	20	-3.33	14.91	-33.3	0.00	33.3
Cycle 22 Day 1	18	5.56	12.78	0.0	0.00	33.3	17	-5.88	21.20	-66.7	0.00	33.3
Cycle 23 Day 1	17	3.92	11.07	0.0	0.00	33.3	16	-8.33	14.91	-33.3	0.00	0.0
Cycle 24 Day 1	13	2.56	9.25	0.0	0.00	33.3	12	-2.78	9.62	-33.3	0.00	0.0
Cycle 25 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
Cycle 26 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
Cycle 27 Day 1	11	6.06	13.48	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 28 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	20.10	-33.3	0.00	33.3
Cycle 29 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	-8.33	25.13	-66.7	0.00	33.3
Study Disc 1	157	8.49	19.21	0.0	0.00	100.0	151	2.21	20.97	-66.7	0.00	100.0
30 D SFU Z/P	80	9.17	17.57	0.0	0.00	66.7	78	1.71	19.29	-33.3	0.00	66.7
90 D SFU Z/P	81	9.47	17.67	0.0	0.00	100.0	79	-1.27	23.54	-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: 12JAN24

Table 302.3.3002.19: 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 + CAPOX (N=254)												
Baseline	243	20.71	25.99	0.0	0.00	100.0						
Cycle 2 Day 1	209	19.78	24.51	0.0	0.00	100.0	208	-0.64	25.58	-66.7	0.00	100.0
Cycle 3 Day 1	187	19.43	24.13	0.0	0.00	100.0	182	-0.92	25.13	-66.7	0.00	100.0
Cycle 4 Day 1	172	17.64	21.15	0.0	0.00	66.7	169	-2.17	23.33	-66.7	0.00	66.7
Cycle 5 Day 1	163	20.25	26.82	0.0	0.00	100.0	159	-0.63	28.92	-100.0	0.00	100.0
Cycle 6 Day 1	151	18.54	24.54	0.0	0.00	100.0	149	-0.89	27.66	-66.7	0.00	100.0
Cycle 7 Day 1	122	19.40	22.61	0.0	0.00	100.0	120	0.56	24.05	-66.7	0.00	66.7
Cycle 8 Day 1	114	19.59	23.80	0.0	0.00	100.0	108	-0.62	26.95	-66.7	0.00	100.0
Cycle 9 Day 1	107	21.81	25.12	0.0	33.33	100.0	102	2.29	24.94	-66.7	0.00	66.7
Cycle 10 Day 1	88	15.15	22.55	0.0	0.00	100.0	85	-2.75	27.80	-100.0	0.00	66.7
Cycle 11 Day 1	84	18.65	23.91	0.0	0.00	100.0	81	0.00	27.39	-66.7	0.00	66.7
Cycle 12 Day 1	77	17.75	23.93	0.0	0.00	100.0	75	-0.89	30.00	-66.7	0.00	100.0
Cycle 13 Day 1	62	16.67	23.18	0.0	0.00	100.0	60	-3.33	27.92	-66.7	0.00	100.0
Cycle 14 Day 1	57	18.13	22.77	0.0	0.00	100.0	55	-0.61	29.04	-66.7	0.00	66.7
Cycle 15 Day 1	53	19.50	25.68	0.0	0.00	100.0	51	0.00	29.06	-66.7	0.00	66.7
Cycle 16 Day 1	50	16.67	23.57	0.0	0.00	100.0	48	-2.08	25.18	-66.7	0.00	66.7
Cycle 17 Day 1	45	16.30	23.16	0.0	0.00	100.0	43	-2.33	23.45	-66.7	0.00	66.7
Cycle 18 Day 1	43	19.38	27.44	0.0	0.00	100.0	41	3.25	22.12	-33.3	0.00	66.7
Cycle 19 Day 1	42	15.08	22.33	0.0	0.00	100.0	40	-2.50	21.86	-66.7	0.00	33.3
Cycle 20 Day 1	41	17.07	23.71	0.0	0.00	100.0	39	0.00	24.18	-33.3	0.00	66.7
Cycle 21 Day 1	38	15.79	20.12	0.0	0.00	66.7	36	1.85	25.13	-66.7	0.00	66.7
Cycle 22 Day 1	33	10.10	17.65	0.0	0.00	66.7	31	-3.23	21.70	-66.7	0.00	33.3
Cycle 23 Day 1	33	15.15	22.19	0.0	0.00	66.7	31	3.23	23.34	-33.3	0.00	66.7
Cycle 24 Day 1	31	9.68	15.38	0.0	0.00	33.3	29	1.15	22.68	-66.7	0.00	33.3
Cycle 25 Day 1	30	10.00	15.54	0.0	0.00	33.3	28	0.00	22.22	-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: 12JAN24

Table 302.3.3002.19: 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 26 Day 1	28	5.95	13.00	0.0	0.00	33.3	26	-2.56	20.92	-66.7	0.00	33.3
Cycle 27 Day 1	27	9.88	18.06	0.0	0.00	66.7	25	1.33	17.95	-33.3	0.00	33.3
Cycle 28 Day 1	23	10.14	18.63	0.0	0.00	66.7	21	-4.76	21.82	-66.7	0.00	33.3
Cycle 29 Day 1	24	16.67	26.01	0.0	0.00	100.0	22	3.03	17.55	-33.3	0.00	33.3
Cycle 30 Day 1	22	13.64	22.20	0.0	0.00	66.7	20	0.00	24.18	-33.3	0.00	66.7
Cycle 31 Day 1	22	15.15	24.62	0.0	0.00	66.7	20	0.00	21.63	-33.3	0.00	66.7
Cycle 32 Day 1	20	10.00	21.90	0.0	0.00	66.7	18	-5.56	17.15	-33.3	0.00	33.3
Cycle 33 Day 1	17	7.84	18.74	0.0	0.00	66.7	15	-6.67	13.80	-33.3	0.00	0.0
Cycle 34 Day 1	14	7.14	19.30	0.0	0.00	66.7	12	-5.56	12.97	-33.3	0.00	0.0
Cycle 35 Day 1	15	8.89	19.79	0.0	0.00	66.7	13	-2.56	16.45	-33.3	0.00	33.3
Cycle 36 Day 1	14	9.52	20.37	0.0	0.00	66.7	12	-2.78	17.16	-33.3	0.00	33.3
Cycle 37 Day 1	12	8.33	20.72	0.0	0.00	66.7	11	-6.06	13.48	-33.3	0.00	0.0
Cycle 38 Day 1	11	9.09	21.56	0.0	0.00	66.7	10	-6.67	14.05	-33.3	0.00	0.0
Cycle 39 Day 1	10	13.33	23.31	0.0	0.00	66.7	9	-3.70	20.03	-33.3	0.00	33.3
Study Disc 1	135	24.69	27.91	0.0	33.33	100.0	133	5.26	32.00	-66.7	0.00	100.0
30 D SFU Z/P	58	22.41	26.04	0.0	33.33	100.0	57	4.09	26.03	-66.7	0.00	66.7
90 D SFU Z/P	62	17.74	25.41	0.0	0.00	100.0	61	3.28	24.87	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	242	19.42	25.30	0.0	0.00	100.0						
Cycle 2 Day 1	222	18.02	24.88	0.0	0.00	100.0	217	-0.92	18.68	-66.7	0.00	100.0
Cycle 3 Day 1	200	20.50	25.82	0.0	0.00	100.0	197	1.18	22.43	-66.7	0.00	100.0
Cycle 4 Day 1	171	18.13	25.10	0.0	0.00	100.0	169	-1.58	22.07	-100.0	0.00	100.0
Cycle 5 Day 1	166	19.28	24.13	0.0	0.00	100.0	165	0.81	19.81	-66.7	0.00	66.7
Cycle 6 Day 1	147	20.18	25.45	0.0	0.00	100.0	146	0.00	21.80	-66.7	0.00	66.7
Cycle 7 Day 1	127	20.47	27.23	0.0	0.00	100.0	126	0.26	24.76	-100.0	0.00	66.7
Cycle 8 Day 1	111	23.12	28.35	0.0	0.00	100.0	110	3.33	23.87	-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.
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Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.19: 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 9 Day 1	104	20.83	27.55	0.0	0.00	100.0	103	1.94	21.30	-33.3	0.00	66.7
Cycle 10 Day 1	81	19.34	28.80	0.0	0.00	100.0	79	1.27	24.13	-33.3	0.00	66.7
Cycle 11 Day 1	72	23.15	28.33	0.0	33.33	100.0	71	4.69	22.04	-33.3	0.00	66.7
Cycle 12 Day 1	59	20.90	28.97	0.0	0.00	100.0	57	3.51	22.44	-33.3	0.00	66.7
Cycle 13 Day 1	50	18.67	27.90	0.0	0.00	100.0	48	4.17	25.38	-33.3	0.00	66.7
Cycle 14 Day 1	46	13.04	22.75	0.0	0.00	100.0	44	0.00	23.84	-33.3	0.00	66.7
Cycle 15 Day 1	38	16.67	26.57	0.0	0.00	100.0	36	4.63	24.11	-33.3	0.00	66.7
Cycle 16 Day 1	33	18.18	23.70	0.0	0.00	66.7	31	6.45	26.41	-33.3	0.00	66.7
Cycle 17 Day 1	28	13.10	20.96	0.0	0.00	66.7	25	1.33	20.37	-33.3	0.00	66.7
Cycle 18 Day 1	23	13.04	21.88	0.0	0.00	66.7	21	4.76	24.23	-33.3	0.00	66.7
Cycle 19 Day 1	21	6.35	13.41	0.0	0.00	33.3	20	-3.33	18.42	-33.3	0.00	33.3
Cycle 20 Day 1	20	8.33	18.34	0.0	0.00	66.7	19	-1.75	20.71	-33.3	0.00	66.7
Cycle 21 Day 1	21	11.11	19.25	0.0	0.00	66.7	20	3.33	21.36	-33.3	0.00	66.7
Cycle 22 Day 1	18	12.96	23.26	0.0	0.00	66.7	17	3.92	26.04	-33.3	0.00	66.7
Cycle 23 Day 1	17	13.73	20.61	0.0	0.00	66.7	16	4.17	23.96	-33.3	0.00	66.7
Cycle 24 Day 1	13	10.26	21.01	0.0	0.00	66.7	12	2.78	26.43	-33.3	0.00	66.7
Cycle 25 Day 1	13	12.82	21.68	0.0	0.00	66.7	12	8.33	20.72	0.0	0.00	66.7
Cycle 26 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	-7.41	14.70	-33.3	0.00	0.0
Cycle 27 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	-6.67	14.05	-33.3	0.00	0.0
Cycle 28 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 29 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
Study Disc 1	157	28.66	30.54	0.0	33.33	100.0	151	9.27	27.53	-33.3	0.00	100.0
30 D SFU Z/P	80	27.50	32.16	0.0	33.33	100.0	78	9.40	24.56	-33.3	0.00	100.0
90 D SFU Z/P	81	19.75	25.70	0.0	0.00	100.0	79	3.80	20.66	-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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

Table 302.3.3004.5.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	132 (52.0%)	147 (58.1%)	
Number of patients censored	122 (48.0%)	106 (41.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.6 [3.7, 7.2]	4.4 [3.5, 5.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.969 [0.761, 1.234]
Log-rank test			
Two-sided stratified log-rank p-value			0.7925

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: 12JAN24

Table 302.3.3004.5.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	92 (52.3)	6.6 [4.0, 7.9]	180	100 (55.6)	4.6 [3.7, 6.8]	0.958 [0.721, 1.272]	0.7624	0.9522
>65 years	78	40 (51.3)	3.8 [2.6, 6.0]	73	47 (64.4)	3.8 [2.8, 5.1]	0.959 [0.628, 1.465]	0.8449	
Sex									
Male	159	80 (50.3)	6.0 [4.1, 9.1]	156	94 (60.3)	4.4 [3.0, 5.3]	0.822 [0.610, 1.109]	0.2008	0.0708
Female	95	52 (54.7)	3.5 [2.3, 6.7]	97	53 (54.6)	4.2 [3.0, 7.2]	1.262 [0.861, 1.851]	0.2351	
Region									
Asia	157	80 (51.0)	6.7 [3.7, 9.2]	158	95 (60.1)	4.4 [3.4, 5.3]	0.816 [0.605, 1.100]	0.1783	0.0799
Non-Asia	97	52 (53.6)	4.0 [2.6, 6.3]	95	52 (54.7)	4.4 [2.8, 8.5]	1.262 [0.858, 1.857]	0.2308	
Number of Organs with Metastatic Sites									
0-2	189	102 (54.0)	4.2 [3.3, 6.7]	188	110 (58.5)	4.2 [3.1, 5.3]	0.975 [0.744, 1.277]	0.8572	0.7274
>=3	65	30 (46.2)	7.2 [3.2, 10.6]	65	37 (56.9)	5.0 [3.0, 6.7]	0.871 [0.537, 1.413]	0.5665	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.6.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	140 (55.1%)	142 (56.1%)	
Number of patients censored	114 (44.9%)	111 (43.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.2 [3.2, 5.0]	4.9 [4.2, 6.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.100 [0.867, 1.396]
Log-rank test			
Two-sided stratified log-rank p-value			0.4321

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: 12JAN24

Table 302.3.3004.6.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	97 (55.1)	4.6 [3.2, 7.1]	180	102 (56.7)	5.6 [4.2, 6.9]	1.007 [0.762, 1.332]	0.9478	0.3794
>65 years	78	43 (55.1)	3.5 [1.9, 4.5]	73	40 (54.8)	4.8 [3.1, 6.2]	1.316 [0.851, 2.034]	0.2140	
Sex									
Male	159	89 (56.0)	4.2 [3.0, 5.0]	156	91 (58.3)	4.8 [3.4, 5.6]	0.993 [0.741, 1.332]	0.9665	0.3510
Female	95	51 (53.7)	4.0 [2.3, 6.7]	97	51 (52.6)	6.7 [4.1, 8.8]	1.231 [0.831, 1.824]	0.2946	
Region									
Asia	157	83 (52.9)	4.7 [3.3, 7.6]	158	87 (55.1)	5.2 [4.2, 6.7]	0.965 [0.712, 1.306]	0.8203	0.1885
Non-Asia	97	57 (58.8)	3.5 [1.9, 4.4]	95	55 (57.9)	4.8 [3.0, 7.7]	1.342 [0.924, 1.948]	0.1181	
Number of Organs with Metastatic Sites									
0-2	189	105 (55.6)	4.4 [3.2, 6.7]	188	105 (55.9)	4.9 [4.1, 6.7]	1.079 [0.823, 1.416]	0.5756	0.9119
>=3	65	35 (53.8)	4.0 [1.9, 5.1]	65	37 (56.9)	5.3 [2.3, 7.0]	1.106 [0.692, 1.766]	0.6745	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.7.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	146 (57.5%)	156 (61.7%)	
Number of patients censored	108 (42.5%)	97 (38.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.7 [2.3, 4.7]	2.9 [2.3, 4.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.884 [0.703, 1.112]
Log-rank test			
Two-sided stratified log-rank p-value			0.3007

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: 12JAN24

Table 302.3.3004.7.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	105 (59.7)	4.2 [2.3, 5.1]	180	114 (63.3)	2.8 [2.0, 4.4]	0.878 [0.672, 1.146]	0.3465	0.7492
>65 years	78	41 (52.6)	3.1 [1.6, 6.7]	73	42 (57.5)	3.2 [1.6, 4.9]	0.955 [0.620, 1.470]	0.8407	
Sex									
Male	159	92 (57.9)	4.0 [2.2, 5.6]	156	103 (66.0)	2.5 [1.6, 4.1]	0.802 [0.604, 1.064]	0.1280	0.2077
Female	95	54 (56.8)	3.3 [2.1, 4.8]	97	53 (54.6)	3.9 [2.3, 6.9]	1.084 [0.740, 1.588]	0.6754	
Region									
Asia	157	90 (57.3)	4.2 [3.1, 5.3]	158	97 (61.4)	3.1 [2.3, 4.9]	0.848 [0.635, 1.132]	0.2676	0.4992
Non-Asia	97	56 (57.7)	2.3 [1.7, 5.1]	95	59 (62.1)	2.8 [1.5, 4.8]	0.989 [0.686, 1.426]	0.9686	
Number of Organs with Metastatic Sites									
0-2	189	109 (57.7)	4.0 [2.3, 5.6]	188	120 (63.8)	3.3 [2.4, 4.8]	0.861 [0.663, 1.117]	0.2633	0.5113
>=3	65	37 (56.9)	3.0 [1.7, 4.4]	65	36 (55.4)	2.1 [1.4, 4.8]	1.008 [0.635, 1.600]	0.9592	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.8.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	118 (46.5%)	114 (45.1%)	
Number of patients censored	136 (53.5%)	139 (54.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.1 [5.5, 9.1]	6.7 [5.5, 8.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.073 [0.826, 1.395]
Log-rank test			
Two-sided stratified log-rank p-value			0.5883

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: 12JAN24

Table 302.3.3004.8.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	84 (47.7)	7.9 [5.7, 10.9]	180	85 (47.2)	6.4 [4.4, 8.8]	0.923 [0.681, 1.251]	0.6095	0.1082
>65 years	78	34 (43.6)	5.4 [3.1, 8.3]	73	29 (39.7)	7.9 [5.7, NC]	1.527 [0.928, 2.514]	0.0932	
Sex									
Male	159	73 (45.9)	7.2 [5.7, 10.0]	156	68 (43.6)	6.4 [4.5, 16.8]	0.978 [0.701, 1.363]	0.9064	0.4557
Female	95	45 (47.4)	5.5 [3.0, 11.7]	97	46 (47.4)	6.7 [5.0, 10.2]	1.195 [0.791, 1.805]	0.3975	
Region									
Asia	157	72 (45.9)	8.3 [5.4, 10.9]	158	70 (44.3)	6.7 [5.7, 8.8]	0.981 [0.705, 1.366]	0.9079	0.3417
Non-Asia	97	46 (47.4)	6.3 [3.3, 7.3]	95	44 (46.3)	6.3 [4.1, 16.8]	1.263 [0.832, 1.918]	0.2640	
Number of Organs with Metastatic Sites									
0-2	189	89 (47.1)	7.3 [5.5, 10.0]	188	80 (42.6)	7.2 [6.3, 11.6]	1.143 [0.844, 1.546]	0.3851	0.3942
>=3	65	29 (44.6)	6.3 [3.5, 10.9]	65	34 (52.3)	4.9 [3.1, 6.7]	0.867 [0.525, 1.432]	0.5776	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.9.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	135 (53.1%)	130 (51.4%)	
Number of patients censored	119 (46.9%)	123 (48.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.9 [3.4, 5.8]	5.0 [4.1, 7.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.136 [0.890, 1.450]
Log-rank test			
Two-sided stratified log-rank p-value			0.2983

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: 12JAN24

Table 302.3.3004.9.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	92 (52.3)	5.6 [4.1, 6.9]	180	96 (53.3)	4.7 [3.9, 7.7]	0.963 [0.724, 1.283]	0.8106	0.0577
>65 years	78	43 (55.1)	3.3 [1.6, 5.3]	73	34 (46.6)	6.0 [3.6, 10.8]	1.643 [1.045, 2.582]	0.0296	
Sex									
Male	159	84 (52.8)	5.2 [3.6, 8.2]	156	80 (51.3)	4.7 [3.3, 8.0]	1.049 [0.772, 1.425]	0.7540	0.4513
Female	95	51 (53.7)	4.3 [2.3, 5.8]	97	50 (51.5)	5.1 [3.9, 7.9]	1.274 [0.860, 1.888]	0.2201	
Region									
Asia	157	89 (56.7)	4.2 [3.0, 6.5]	158	84 (53.2)	4.4 [3.3, 7.8]	1.092 [0.811, 1.472]	0.5550	0.8221
Non-Asia	97	46 (47.4)	5.8 [3.4, 6.9]	95	46 (48.4)	6.5 [4.2, 8.9]	1.174 [0.779, 1.771]	0.4443	
Number of Organs with Metastatic Sites									
0-2	189	101 (53.4)	5.4 [3.7, 6.7]	188	95 (50.5)	5.1 [4.1, 8.0]	1.100 [0.831, 1.456]	0.4961	0.8047
>=3	65	34 (52.3)	3.6 [2.1, 5.6]	65	35 (53.8)	4.5 [2.8, 7.7]	1.241 [0.772, 1.994]	0.3734	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.10.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	133 (52.4%)	139 (54.9%)	
Number of patients censored	121 (47.6%)	114 (45.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.0 [2.8, 6.7]	4.2 [2.8, 5.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.970 [0.762, 1.234]
Log-rank test			
Two-sided stratified log-rank p-value			0.8229

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: 12JAN24

Table 302.3.3004.10.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	94 (53.4)	5.6 [2.8, 7.4]	180	105 (58.3)	4.2 [2.8, 5.1]	0.877 [0.663, 1.158]	0.3626	0.1440
>65 years	78	39 (50.0)	3.3 [1.6, 7.6]	73	34 (46.6)	5.8 [2.3, NC]	1.306 [0.824, 2.071]	0.2527	
Sex									
Male	159	86 (54.1)	4.4 [2.1, 7.6]	156	88 (56.4)	4.5 [2.7, 6.9]	0.948 [0.703, 1.278]	0.7392	0.8439
Female	95	47 (49.5)	5.6 [1.6, 8.1]	97	51 (52.6)	4.2 [2.3, 7.7]	1.013 [0.681, 1.507]	0.9407	
Region									
Asia	157	81 (51.6)	6.1 [2.8, 9.0]	158	77 (48.7)	6.9 [3.1, 10.2]	1.095 [0.801, 1.496]	0.5708	0.2655
Non-Asia	97	52 (53.6)	3.3 [1.6, 5.8]	95	62 (65.3)	2.8 [1.5, 4.4]	0.825 [0.570, 1.193]	0.3210	
Number of Organs with Metastatic Sites									
0-2	189	98 (51.9)	5.6 [2.9, 8.5]	188	103 (54.8)	4.2 [2.7, 6.9]	0.927 [0.703, 1.222]	0.6023	0.3672
>=3	65	35 (53.8)	2.8 [1.4, 5.8]	65	36 (55.4)	4.5 [2.4, 7.3]	1.195 [0.746, 1.913]	0.4487	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.11.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	169 (66.5%)	171 (67.6%)	
Number of patients censored	85 (33.5%)	82 (32.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.9 [1.5, 2.4]	2.6 [1.6, 3.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.076 [0.867, 1.337]
Log-rank test			
Two-sided stratified log-rank p-value			0.4940

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: 12JAN24

Table 302.3.3004.11.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	117 (66.5)	1.9 [1.4, 2.4]	180	124 (68.9)	2.5 [1.6, 3.4]	1.015 [0.787, 1.308]	0.8972	0.4989
>65 years	78	52 (66.7)	2.1 [1.5, 3.3]	73	47 (64.4)	2.6 [1.5, 3.7]	1.214 [0.816, 1.807]	0.3329	
Sex									
Male	159	107 (67.3)	1.7 [1.4, 3.3]	156	108 (69.2)	2.3 [1.5, 3.3]	0.972 [0.744, 1.270]	0.8468	0.1815
Female	95	62 (65.3)	1.9 [1.0, 2.4]	97	63 (64.9)	2.6 [1.4, 4.1]	1.312 [0.920, 1.873]	0.1257	
Region									
Asia	157	106 (67.5)	1.6 [1.4, 2.6]	158	105 (66.5)	3.0 [1.7, 4.2]	1.158 [0.884, 1.518]	0.2908	0.4423
Non-Asia	97	63 (64.9)	2.1 [1.5, 3.4]	95	66 (69.5)	1.6 [0.9, 2.9]	0.965 [0.682, 1.367]	0.8894	
Number of Organs with Metastatic Sites									
0-2	189	128 (67.7)	1.7 [1.5, 2.8]	188	131 (69.7)	2.3 [1.5, 3.0]	1.044 [0.818, 1.332]	0.7076	0.5635
>=3	65	41 (63.1)	1.9 [1.1, 3.7]	65	40 (61.5)	3.5 [1.4, 5.8]	1.193 [0.768, 1.853]	0.4476	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.12.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	164 (64.6%)	144 (56.9%)	
Number of patients censored	90 (35.4%)	109 (43.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.7 [1.5, 2.5]	3.9 [3.0, 4.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.575 [1.248, 1.986]
Log-rank test			
Two-sided stratified log-rank p-value			0.0001

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: 12JAN24

Table 302.3.3004.12.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	120 (68.2)	1.6 [1.4, 2.3]	180	107 (59.4)	4.0 [2.8, 5.3]	1.575 [1.212, 2.047]	0.0006	0.4930
>65 years	78	44 (56.4)	3.0 [1.5, 3.8]	73	37 (50.7)	3.6 [2.3, 6.0]	1.338 [0.863, 2.074]	0.1903	
Sex									
Male	159	101 (63.5)	2.3 [1.5, 3.3]	156	90 (57.7)	3.7 [3.0, 4.5]	1.371 [1.031, 1.823]	0.0301	0.2586
Female	95	63 (66.3)	1.4 [0.9, 2.1]	97	54 (55.7)	3.9 [2.3, 6.0]	1.775 [1.228, 2.564]	0.0019	
Region									
Asia	157	101 (64.3)	2.2 [1.5, 3.0]	158	85 (53.8)	4.1 [2.8, 5.3]	1.425 [1.067, 1.903]	0.0174	0.3991
Non-Asia	97	63 (64.9)	1.5 [1.0, 2.3]	95	59 (62.1)	3.6 [2.8, 5.4]	1.900 [1.309, 2.759]	0.0005	
Number of Organs with Metastatic Sites									
0-2	189	124 (65.6)	1.7 [1.5, 2.4]	188	109 (58.0)	3.7 [2.8, 4.5]	1.466 [1.132, 1.899]	0.0033	0.8144
>=3	65	40 (61.5)	2.3 [1.0, 3.7]	65	35 (53.8)	4.3 [2.6, 7.0]	1.693 [1.069, 2.681]	0.0253	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.13.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	136 (53.5%)	149 (58.9%)	
Number of patients censored	118 (46.5%)	104 (41.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.3 [3.6, 5.7]	5.0 [3.6, 5.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.948 [0.746, 1.204]
Log-rank test			
Two-sided stratified log-rank p-value			0.6603

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: 12JAN24

Table 302.3.3004.13.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	95 (54.0)	4.4 [3.2, 7.9]	180	103 (57.2)	5.6 [4.2, 6.7]	1.005 [0.759, 1.330]	0.9695	0.3909
>65 years	78	41 (52.6)	4.2 [2.9, 7.0]	73	46 (63.0)	3.5 [2.1, 5.3]	0.842 [0.551, 1.287]	0.4266	
Sex									
Male	159	88 (55.3)	4.3 [3.4, 7.0]	156	95 (60.9)	5.0 [3.1, 6.0]	0.874 [0.653, 1.170]	0.3701	0.3895
Female	95	48 (50.5)	4.2 [2.7, 7.7]	97	54 (55.7)	5.6 [3.4, 7.7]	1.107 [0.748, 1.639]	0.6145	
Region									
Asia	157	86 (54.8)	4.6 [3.3, 8.8]	158	91 (57.6)	5.6 [3.8, 6.1]	0.908 [0.673, 1.225]	0.5209	0.7304
Non-Asia	97	50 (51.5)	4.1 [2.8, 5.6]	95	58 (61.1)	4.1 [2.1, 5.8]	0.985 [0.673, 1.442]	0.9471	
Number of Organs with Metastatic Sites									
0-2	189	103 (54.5)	4.2 [3.3, 7.5]	188	117 (62.2)	4.6 [3.1, 5.8]	0.902 [0.691, 1.177]	0.4497	0.3997
>=3	65	33 (50.8)	4.4 [3.0, 8.8]	65	32 (49.2)	5.3 [3.4, 7.9]	1.120 [0.685, 1.831]	0.6509	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.14.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	97 (38.2%)	108 (42.7%)	
Number of patients censored	157 (61.8%)	145 (57.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.8 [6.7, 19.5]	7.2 [6.0, 10.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.906 [0.686, 1.197]
Log-rank test			
Two-sided stratified log-rank p-value			0.4804

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: 12JAN24

Table 302.3.3004.14.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	68 (38.6)	10.9 [8.0, 19.6]	180	85 (47.2)	6.7 [5.0, 8.8]	0.773 [0.562, 1.065]	0.1143	0.0878
>65 years	78	29 (37.2)	6.2 [4.4, 23.0]	73	23 (31.5)	NC [5.8, NC]	1.355 [0.781, 2.351]	0.2750	
Sex									
Male	159	65 (40.9)	10.4 [5.3, 19.5]	156	64 (41.0)	6.8 [5.3, 28.7]	0.975 [0.690, 1.379]	0.8883	0.3724
Female	95	32 (33.7)	9.8 [6.7, NC]	97	44 (45.4)	7.2 [5.0, 10.8]	0.763 [0.483, 1.204]	0.2495	
Region									
Asia	157	65 (41.4)	8.5 [6.3, 19.5]	158	69 (43.7)	7.2 [5.3, 11.9]	0.936 [0.666, 1.314]	0.6975	0.7405
Non-Asia	97	32 (33.0)	10.4 [6.2, 19.8]	95	39 (41.1)	7.7 [5.0, 28.7]	0.826 [0.517, 1.320]	0.4302	
Number of Organs with Metastatic Sites									
0-2	189	73 (38.6)	10.4 [7.4, 19.8]	188	72 (38.3)	10.8 [6.0, 28.7]	0.989 [0.714, 1.371]	0.9547	0.2926
>=3	65	24 (36.9)	6.3 [3.9, 19.5]	65	36 (55.4)	5.1 [4.1, 7.2]	0.715 [0.426, 1.200]	0.2010	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.15.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	122 (48.0%)	121 (47.8%)	
Number of patients censored	132 (52.0%)	132 (52.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.4 [3.8, 7.6]	5.2 [4.0, 7.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.015 [0.786, 1.310]
Log-rank test			
Two-sided stratified log-rank p-value			0.9026

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: 12JAN24

Table 302.3.3004.15.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	88 (50.0)	5.4 [3.7, 7.9]	180	87 (48.3)	6.0 [4.0, 8.0]	1.020 [0.757, 1.374]	0.8889	0.8930
>65 years	78	34 (43.6)	6.1 [2.4, 10.8]	73	34 (46.6)	4.6 [2.3, 15.0]	1.017 [0.632, 1.638]	0.9497	
Sex									
Male	159	84 (52.8)	4.4 [3.7, 7.2]	156	79 (50.6)	5.1 [3.7, 6.5]	1.055 [0.774, 1.437]	0.7256	0.5968
Female	95	38 (40.0)	6.7 [2.9, NC]	97	42 (43.3)	7.3 [3.0, 11.6]	0.954 [0.614, 1.484]	0.8305	
Region									
Asia	157	81 (51.6)	6.1 [3.8, 8.2]	158	76 (48.1)	5.7 [4.2, 10.2]	1.090 [0.796, 1.493]	0.5927	0.4413
Non-Asia	97	41 (42.3)	4.4 [3.0, 20.8]	95	45 (47.4)	3.9 [2.3, 10.3]	0.893 [0.583, 1.368]	0.6117	
Number of Organs with Metastatic Sites									
0-2	189	92 (48.7)	5.4 [3.8, 7.9]	188	86 (45.7)	6.7 [4.2, 11.6]	1.122 [0.835, 1.507]	0.4398	0.1989
>=3	65	30 (46.2)	6.0 [1.6, 13.9]	65	35 (53.8)	2.8 [1.5, 5.3]	0.759 [0.461, 1.249]	0.2675	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.16.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	143 (56.3%)	137 (54.2%)	
Number of patients censored	111 (43.7%)	116 (45.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.8 [1.6, 3.5]	4.3 [3.0, 5.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.251 [0.986, 1.586]
Log-rank test			
Two-sided stratified log-rank p-value			0.0657

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: 12JAN24

Table 302.3.3004.16.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	99 (56.3)	3.3 [1.6, 4.2]	180	95 (52.8)	5.0 [3.0, 6.3]	1.187 [0.895, 1.575]	0.2362	0.8307
>65 years	78	44 (56.4)	2.0 [1.4, 3.3]	73	42 (57.5)	3.3 [2.1, 5.7]	1.282 [0.838, 1.963]	0.2531	
Sex									
Male	159	91 (57.2)	2.8 [1.6, 3.6]	156	88 (56.4)	3.5 [2.8, 5.4]	1.111 [0.829, 1.490]	0.4822	0.3499
Female	95	52 (54.7)	3.0 [1.0, 3.9]	97	49 (50.5)	5.3 [2.9, 7.8]	1.383 [0.934, 2.048]	0.1056	
Region									
Asia	157	102 (65.0)	2.3 [1.4, 3.3]	158	85 (53.8)	3.5 [2.8, 5.6]	1.393 [1.044, 1.859]	0.0244	0.1383
Non-Asia	97	41 (42.3)	4.1 [1.5, 7.9]	95	52 (54.7)	5.1 [2.8, 7.0]	0.925 [0.613, 1.396]	0.7128	
Number of Organs with Metastatic Sites									
0-2	189	114 (60.3)	2.3 [1.5, 3.4]	188	104 (55.3)	3.5 [2.9, 5.7]	1.251 [0.958, 1.633]	0.0974	0.5318
>=3	65	29 (44.6)	3.6 [1.4, NC]	65	33 (50.8)	5.0 [2.8, 7.0]	1.107 [0.672, 1.826]	0.6963	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.17.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	93 (36.6%)	102 (40.3%)	
Number of patients censored	161 (63.4%)	151 (59.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.1 [6.6, 13.9]	7.4 [5.3, 13.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.956 [0.719, 1.273]
Log-rank test			
Two-sided stratified log-rank p-value			0.7446

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: 12JAN24

Table 302.3.3004.17.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	71 (40.3)	9.0 [5.4, 13.9]	180	75 (41.7)	7.2 [4.9, 10.8]	0.952 [0.687, 1.319]	0.7546	0.8984
>65 years	78	22 (28.2)	9.6 [5.5, NC]	73	27 (37.0)	8.0 [4.5, NC]	0.935 [0.531, 1.647]	0.8143	
Sex									
Male	159	61 (38.4)	9.0 [5.5, NC]	156	65 (41.7)	6.5 [4.4, NC]	0.902 [0.635, 1.280]	0.5551	0.6095
Female	95	32 (33.7)	10.1 [5.5, NC]	97	37 (38.1)	8.6 [6.4, NC]	1.044 [0.650, 1.678]	0.8588	
Region									
Asia	157	64 (40.8)	8.5 [6.0, 13.9]	158	57 (36.1)	9.0 [6.4, NC]	1.187 [0.830, 1.697]	0.3530	0.0356
Non-Asia	97	29 (29.9)	13.6 [5.2, NC]	95	45 (47.4)	4.9 [2.9, 8.0]	0.627 [0.393, 1.001]	0.0479	
Number of Organs with Metastatic Sites									
0-2	189	72 (38.1)	9.1 [6.0, NC]	188	71 (37.8)	9.0 [6.4, NC]	1.031 [0.743, 1.432]	0.8546	0.3234
>=3	65	21 (32.3)	7.0 [3.5, NC]	65	31 (47.7)	4.9 [2.5, 8.3]	0.740 [0.425, 1.288]	0.2711	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.18.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhoea (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	98 (38.6%)	123 (48.6%)	
Number of patients censored	156 (61.4%)	130 (51.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.1 [5.3, 26.0]	5.0 [3.3, 8.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.765 [0.584, 1.001]
Log-rank test			
Two-sided stratified log-rank p-value			0.0519

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: 12JAN24

Table 302.3.3004.18.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhoea by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	69 (39.2)	13.4 [5.3, NC]	180	84 (46.7)	6.2 [3.1, 10.1]	0.774 [0.563, 1.065]	0.1183	0.8908
>65 years	78	29 (37.2)	9.1 [3.3, NC]	73	39 (53.4)	4.1 [2.9, 6.8]	0.713 [0.436, 1.168]	0.1771	
Sex									
Male	159	60 (37.7)	9.1 [5.3, NC]	156	74 (47.4)	4.9 [3.3, 9.0]	0.759 [0.540, 1.067]	0.1134	0.8909
Female	95	38 (40.0)	13.4 [4.0, 26.0]	97	49 (50.5)	5.0 [2.6, 10.7]	0.754 [0.491, 1.159]	0.1975	
Region									
Asia	157	63 (40.1)	22.4 [5.3, 27.2]	158	80 (50.6)	5.0 [3.5, 8.3]	0.730 [0.524, 1.017]	0.0616	0.7053
Non-Asia	97	35 (36.1)	6.9 [4.4, NC]	95	43 (45.3)	4.5 [2.8, NC]	0.822 [0.526, 1.284]	0.4043	
Number of Organs with Metastatic Sites									
0-2	189	76 (40.2)	9.1 [5.3, 26.0]	188	91 (48.4)	6.2 [3.7, 9.3]	0.787 [0.580, 1.069]	0.1266	0.6793
>=3	65	22 (33.8)	NC [3.5, NC]	65	32 (49.2)	3.7 [2.8, 8.3]	0.692 [0.402, 1.191]	0.1830	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3004.19.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	99 (39.0%)	96 (37.9%)	
Number of patients censored	155 (61.0%)	157 (62.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.0 [6.6, 11.5]	10.9 [5.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.063 [0.802, 1.410]
Log-rank test			
Two-sided stratified log-rank p-value			0.6699

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: 12JAN24

Table 302.3.3004.19.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	72 (40.9)	8.8 [6.0, 12.7]	180	67 (37.2)	10.9 [5.0, NC]	1.084 [0.777, 1.511]	0.6360	0.9868
>65 years	78	27 (34.6)	9.2 [3.3, NC]	73	29 (39.7)	7.6 [4.1, NC]	1.080 [0.639, 1.828]	0.7716	
Sex									
Male	159	64 (40.3)	9.1 [6.0, 20.3]	156	63 (40.4)	7.6 [4.5, NC]	0.973 [0.687, 1.378]	0.8722	0.3446
Female	95	35 (36.8)	8.8 [5.6, NC]	97	33 (34.0)	NC [5.0, NC]	1.297 [0.805, 2.088]	0.2853	
Region									
Asia	157	64 (40.8)	9.1 [6.2, 26.0]	158	60 (38.0)	10.9 [5.1, NC]	1.071 [0.753, 1.524]	0.7064	0.9591
Non-Asia	97	35 (36.1)	7.8 [4.4, 11.4]	95	36 (37.9)	NC [3.7, NC]	1.085 [0.681, 1.729]	0.7302	
Number of Organs with Metastatic Sites									
0-2	189	75 (39.7)	9.1 [6.7, 12.7]	188	64 (34.0)	NC [7.6, NC]	1.218 [0.873, 1.701]	0.2460	0.1952
>=3	65	24 (36.9)	6.0 [2.8, NC]	65	32 (49.2)	4.5 [3.3, 7.8]	0.817 [0.481, 1.388]	0.4529	

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 and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

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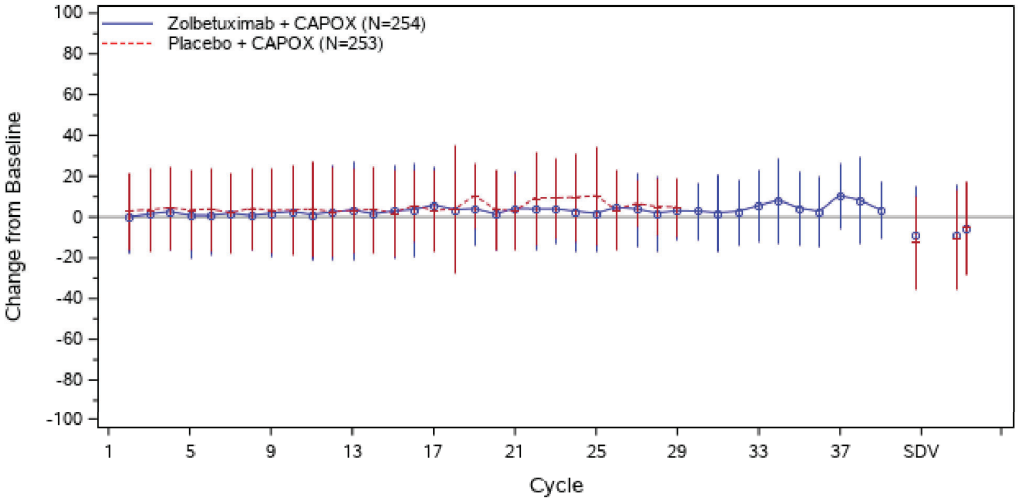
Figure 302.3.3002.5: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Global Health Status - Full Analysis Set



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: 12JAN24

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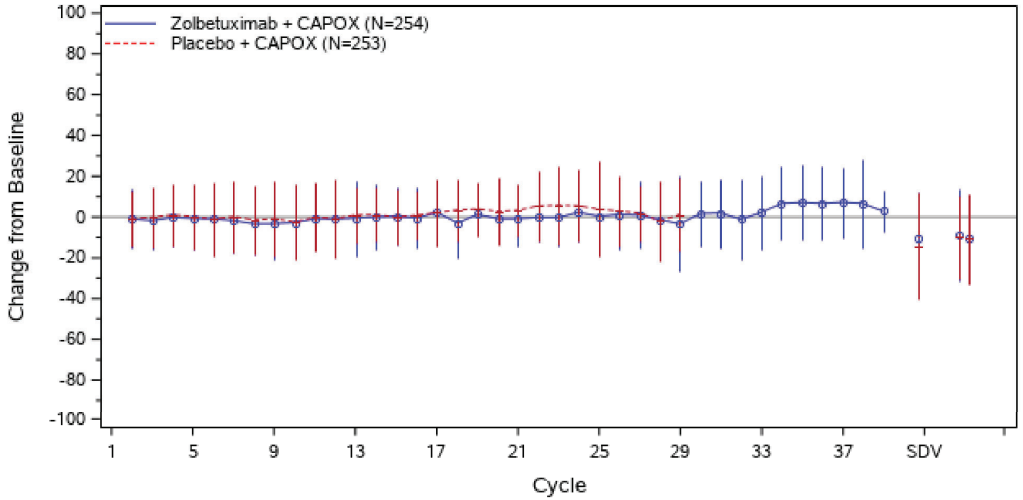
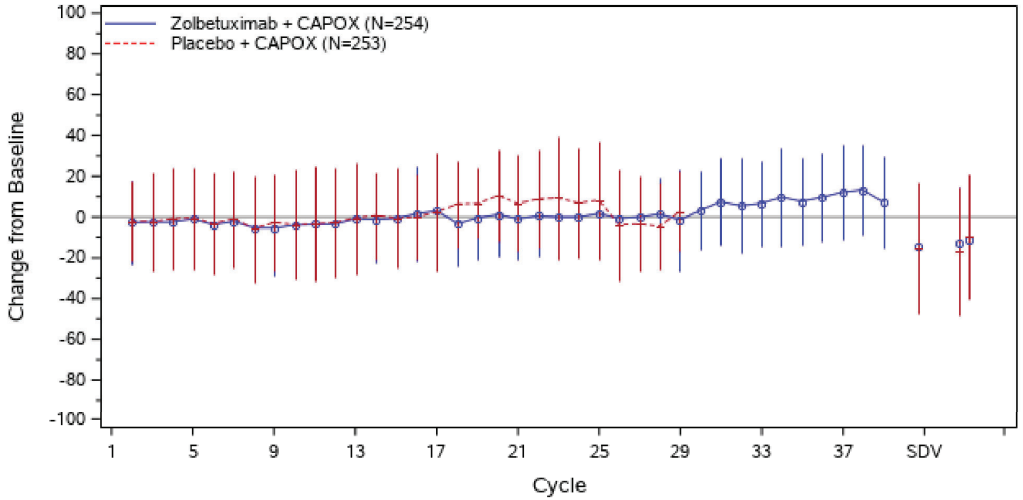
Figure 302.3.3002.6: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Physical Functioning - Full Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.3002.7: 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: 12JAN24

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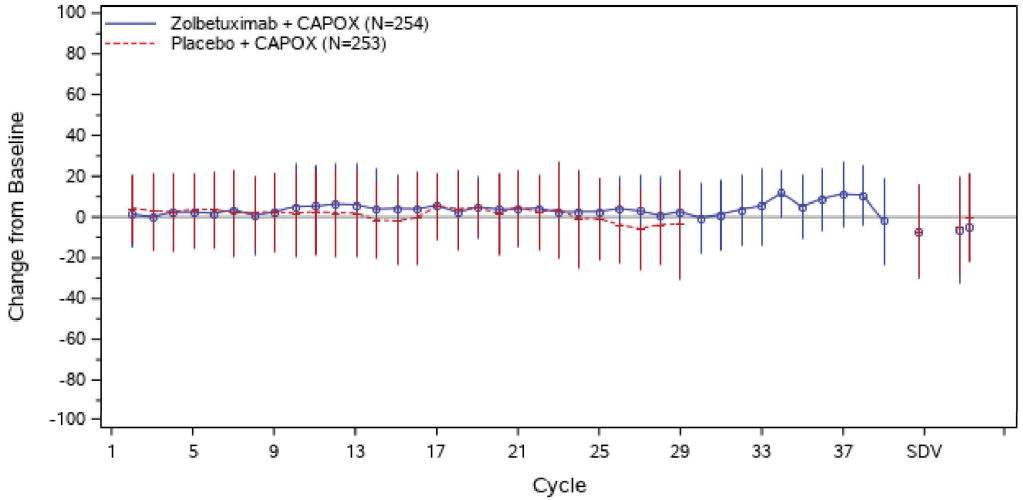
Figure 302.3.3002.8: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Emotional Functioning - Full Analysis Set



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: 12JAN24

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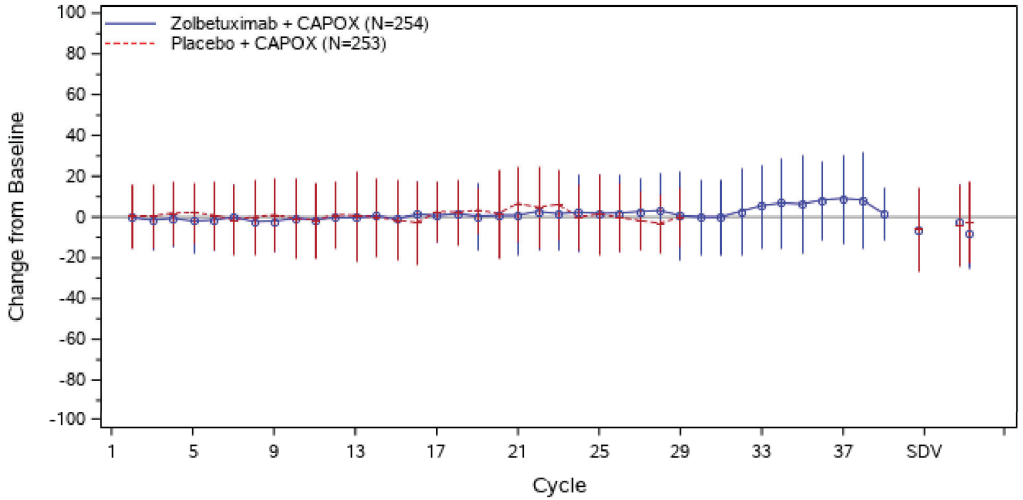
Figure 302.3.3002.9: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Cognitive Functioning - Full Analysis Set



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: 12JAN24

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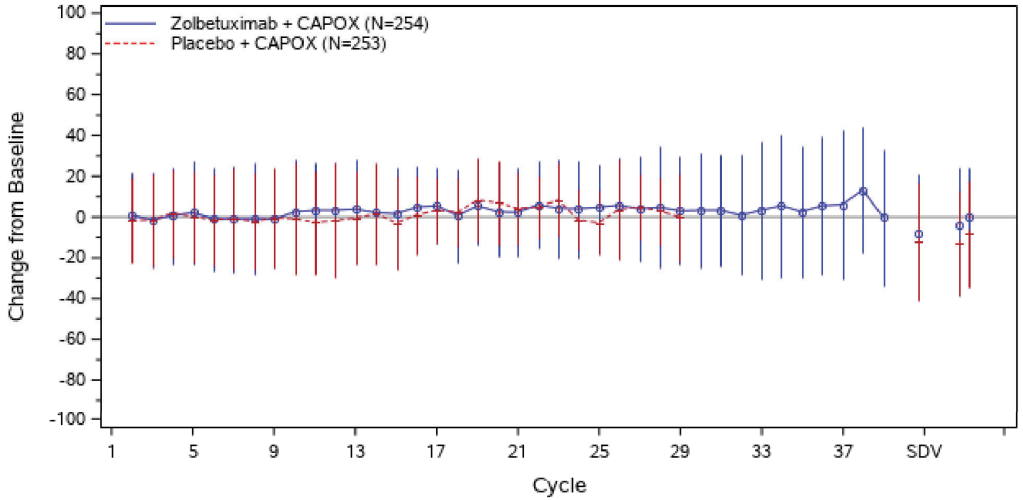
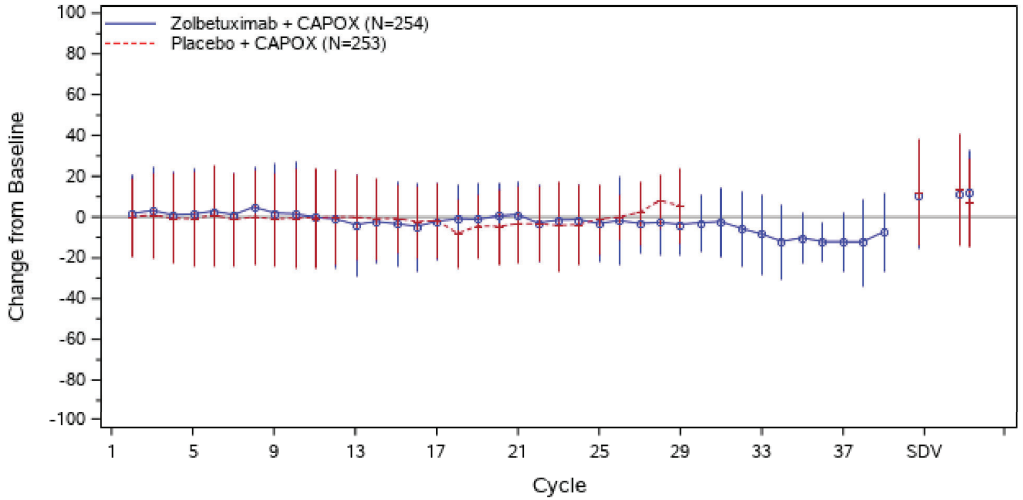
Figure 302.3.3002.10: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Social Functioning - Full Analysis Set



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: 12JAN24

The SAS System

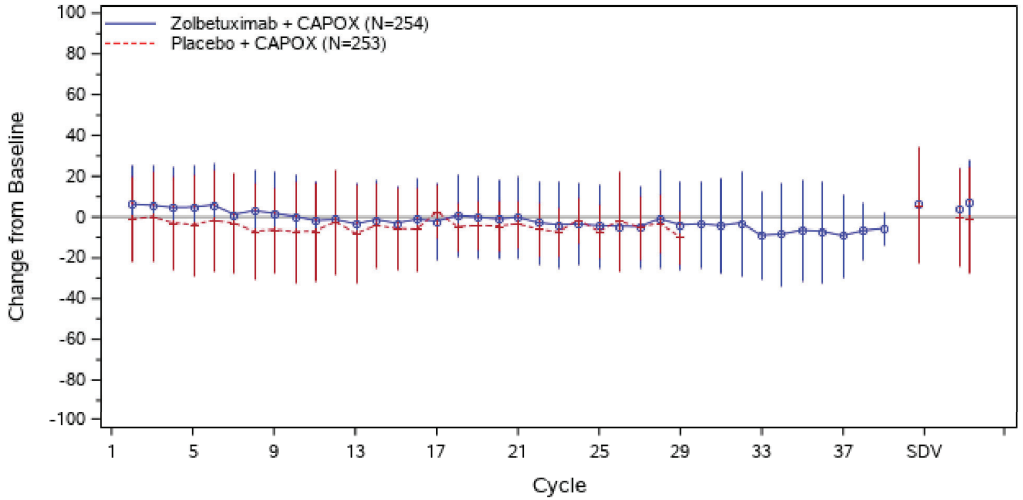
Figure 302.3.3002.11: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Fatigue - Full Analysis Set



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: 12JAN24

The SAS System

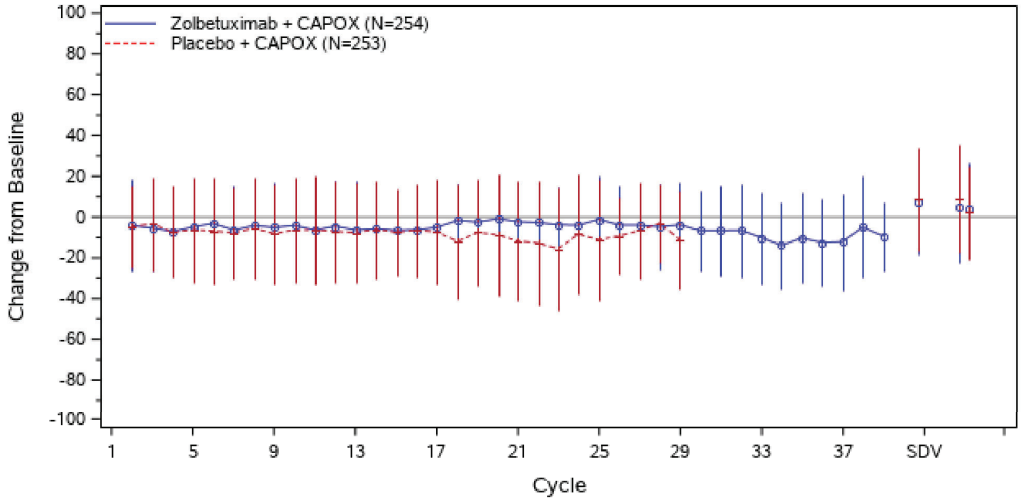
Figure 302.3.3002.12: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Nausea and Vomiting - Full Analysis Set



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: 12JAN24

The SAS System

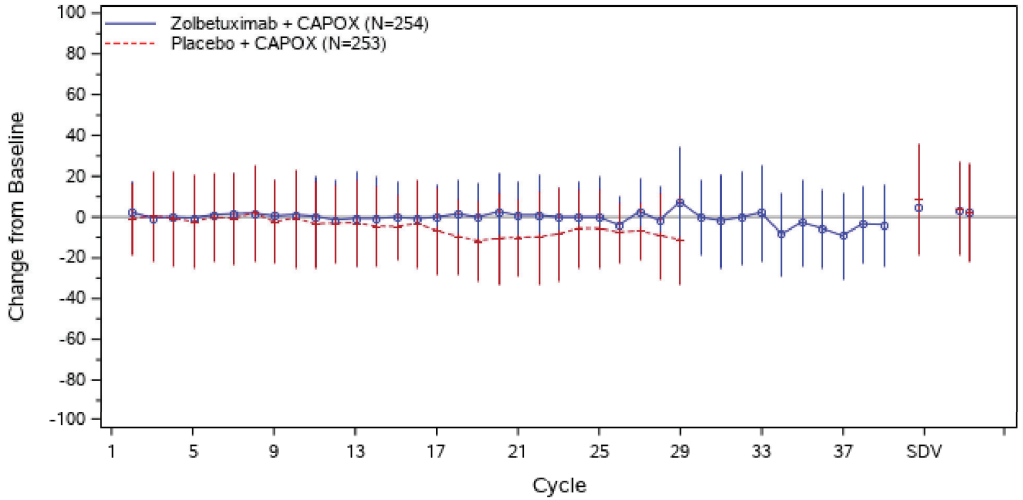
Figure 302.3.3002.13: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Pain - Full Analysis Set



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: 12JAN24

The SAS System

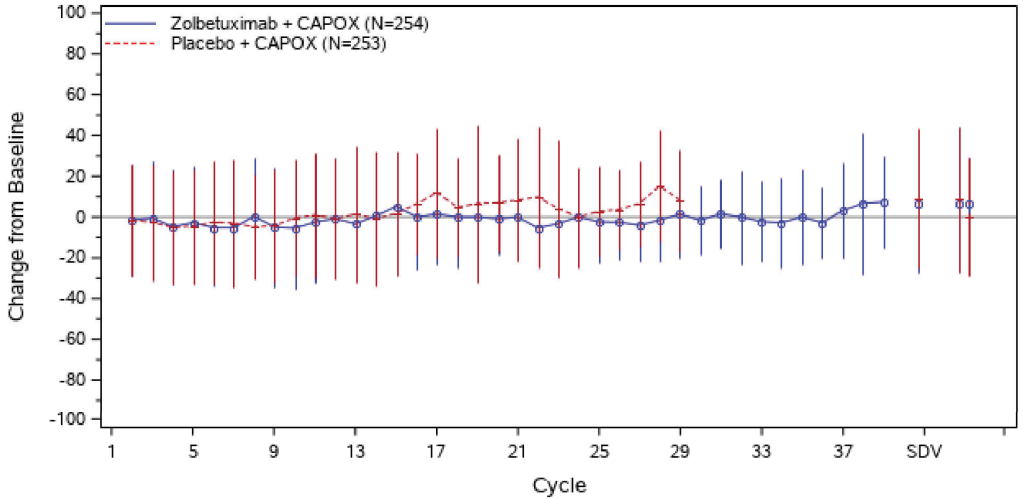
Figure 302.3.3002.14: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Dyspnoea - Full Analysis Set



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: 12JAN24

The SAS System

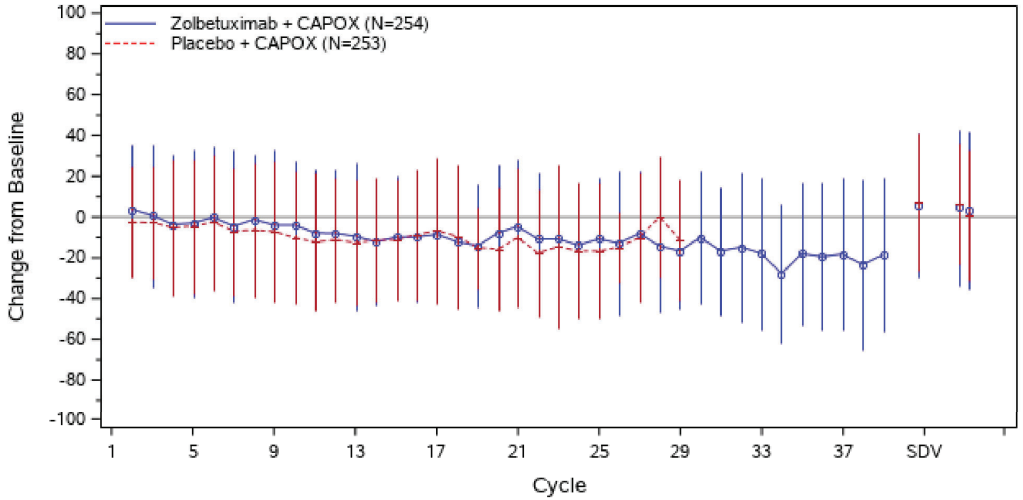
Figure 302.3.3002.15: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Insomnia - Full Analysis Set



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: 12JAN24

The SAS System

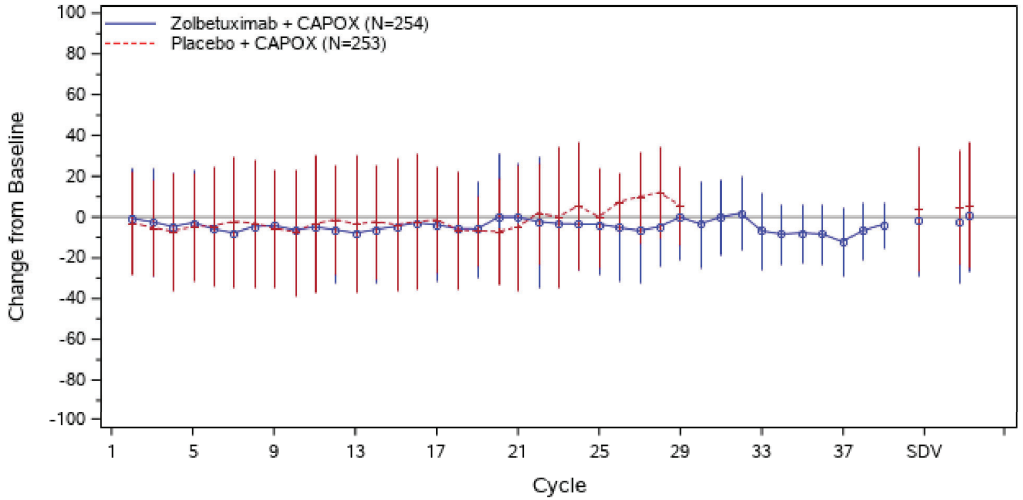
Figure 302.3.3002.16: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Appetite Loss - Full Analysis Set



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: 12JAN24

The SAS System

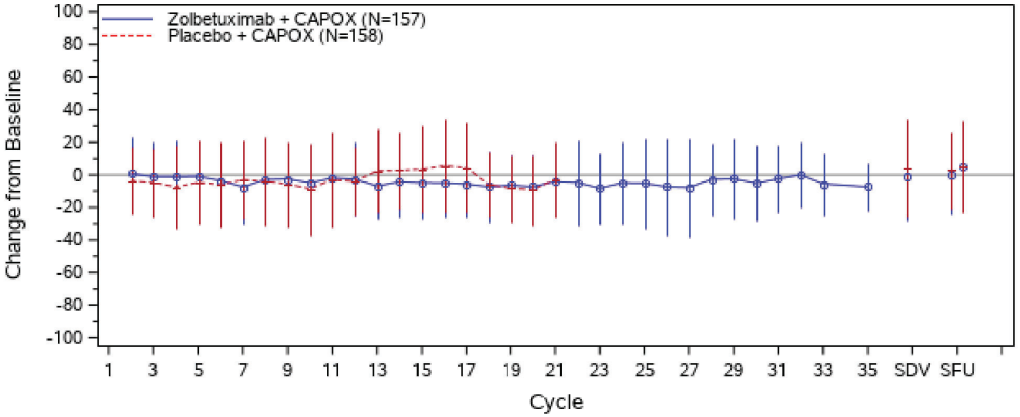
Figure 302.3.3002.17: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Constipation - Full Analysis Set



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: 12JAN24

The SAS System

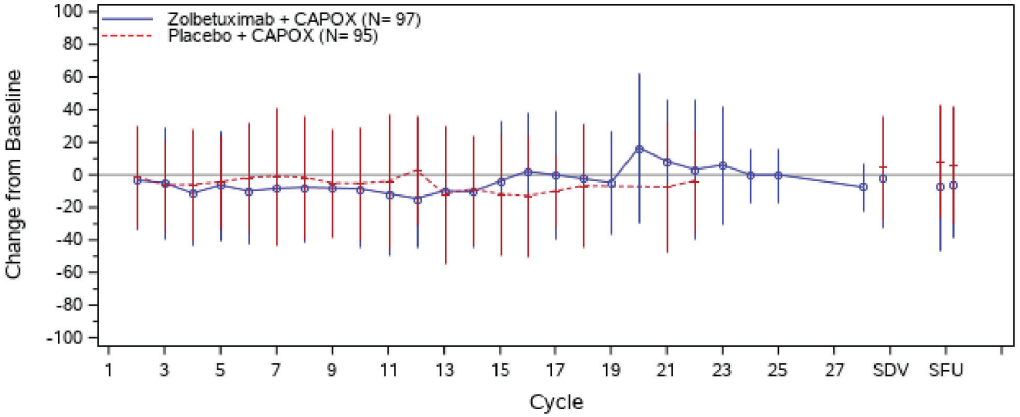
Figure 302.3.3002.17.3: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Constipation by Region - Full Analysis Set
Region: Asia



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: 12JAN24

The SAS System

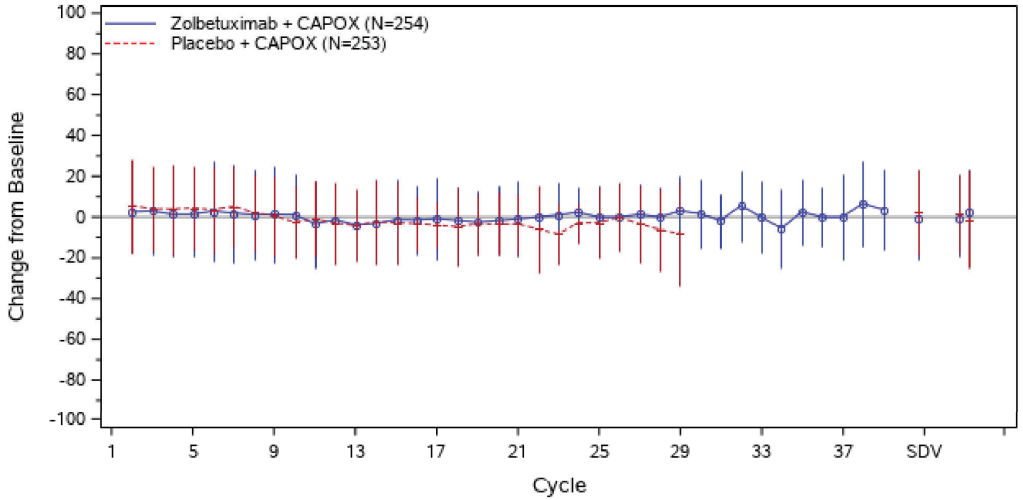
Figure 302.3.3002.17.3: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Constipation by Region - Full Analysis Set
Region: Non-Asia



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: 12JAN24

The SAS System

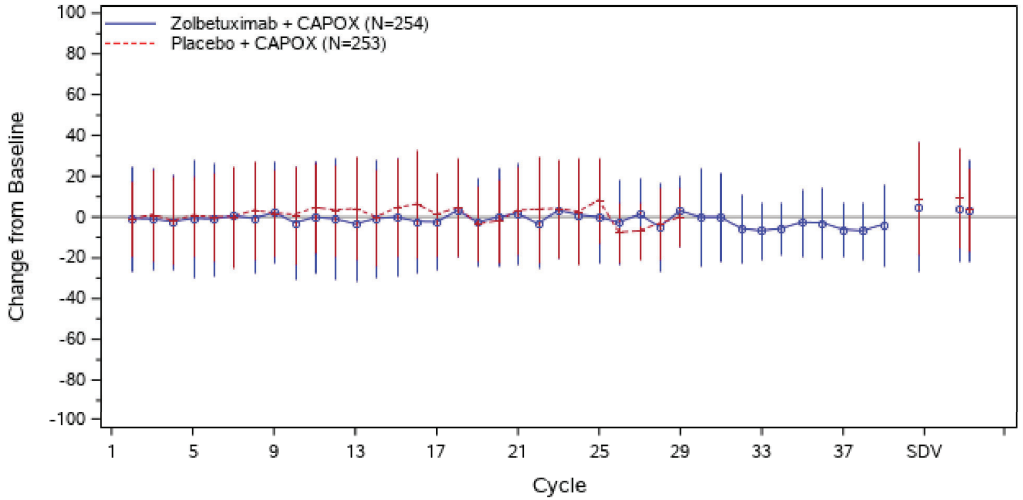
Figure 302.3.3002.18: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Diarrhoea - Full Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.3002.19: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Financial Difficulties - Full Analysis Set



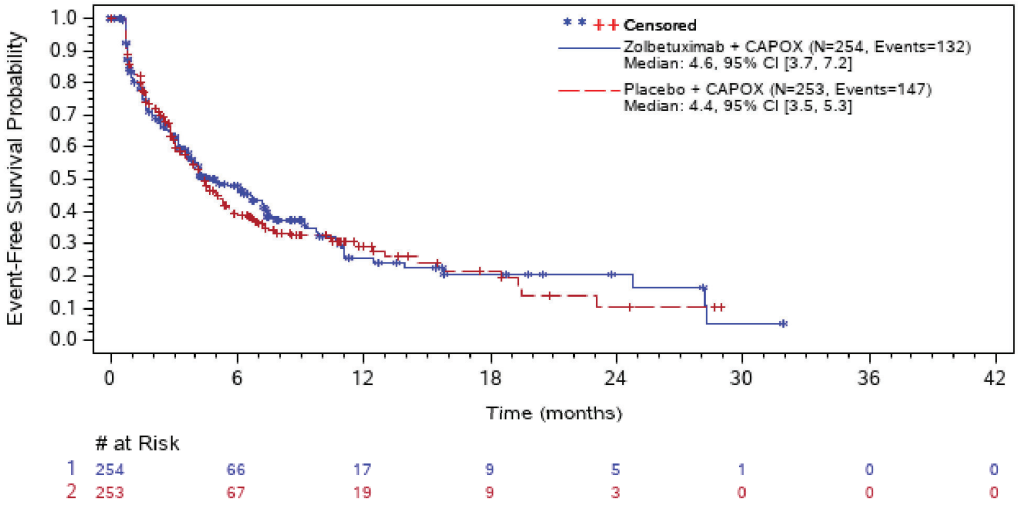
Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

5. Kaplan-Meier-Plots

The SAS System

Figure 302.3.3004.5: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Global Health Status (MID=10) - Full Analysis Set



# at Risk							
1	254	66	17	9	5	1	0	0
2	253	67	19	9	3	0	0	0

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.

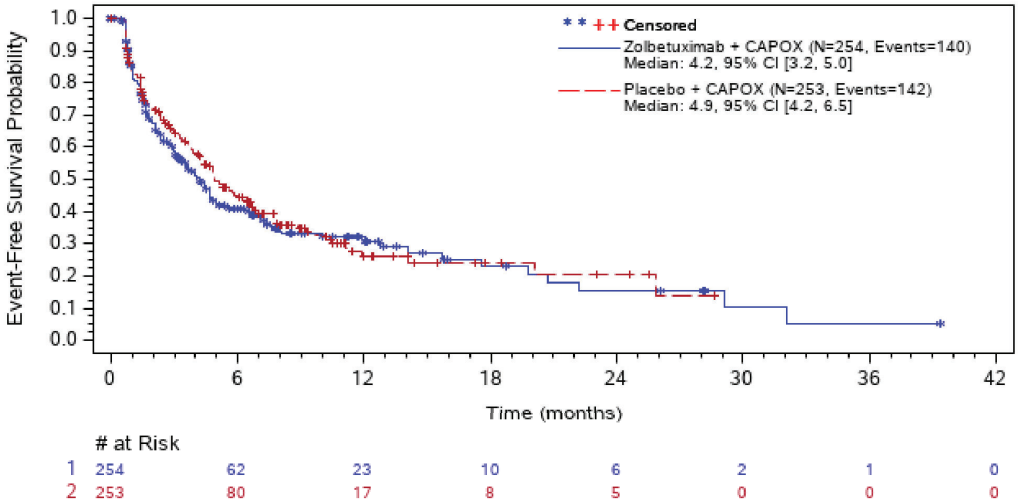
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.6: 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.

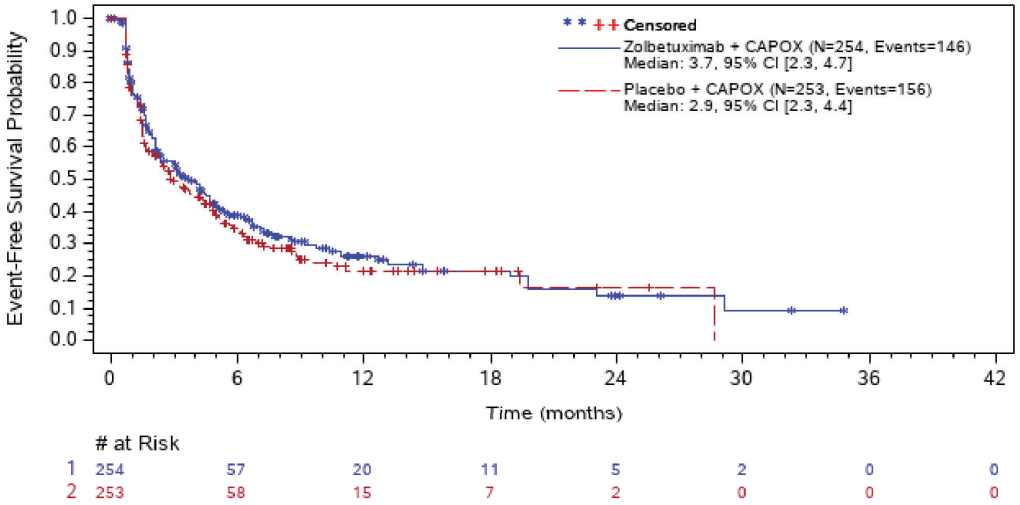
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.7: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Role Functioning (MID=10) - Full Analysis Set



# at Risk							
1	254	57	20	11	5	2	0	0
2	253	58	15	7	2	0	0	0

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.

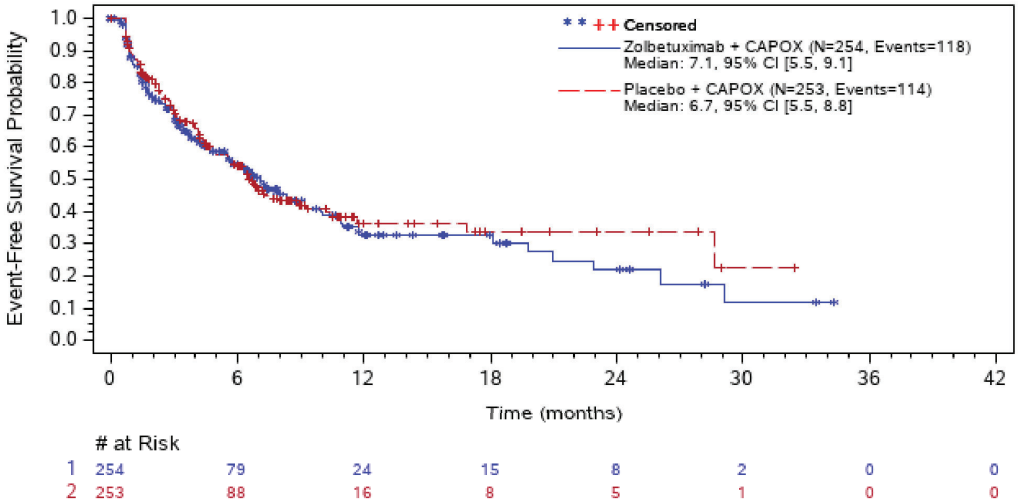
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.8: 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.

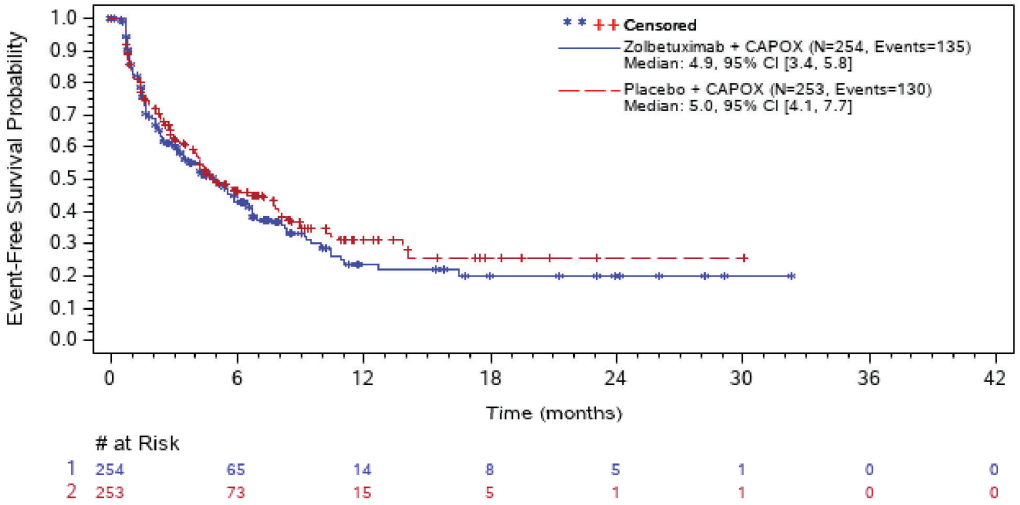
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.9: 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.

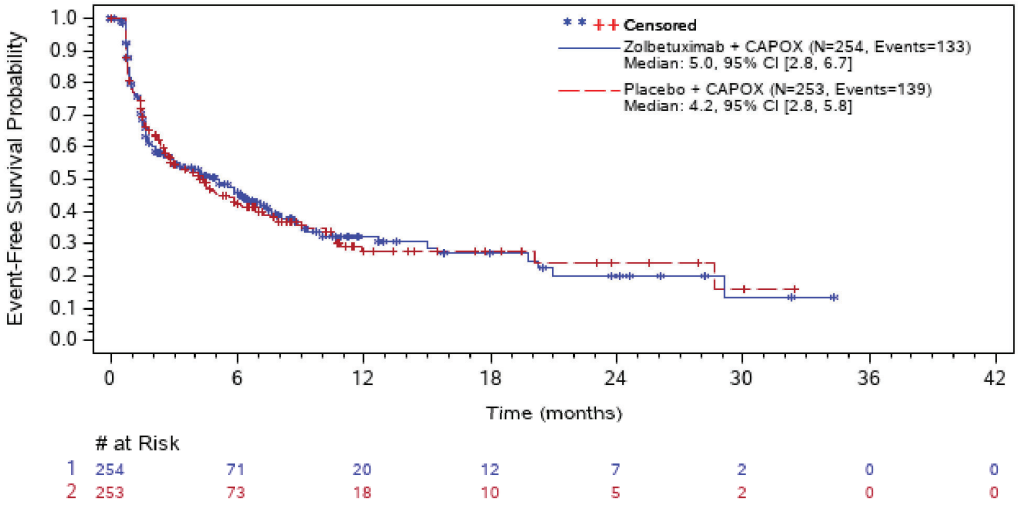
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.10: 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.

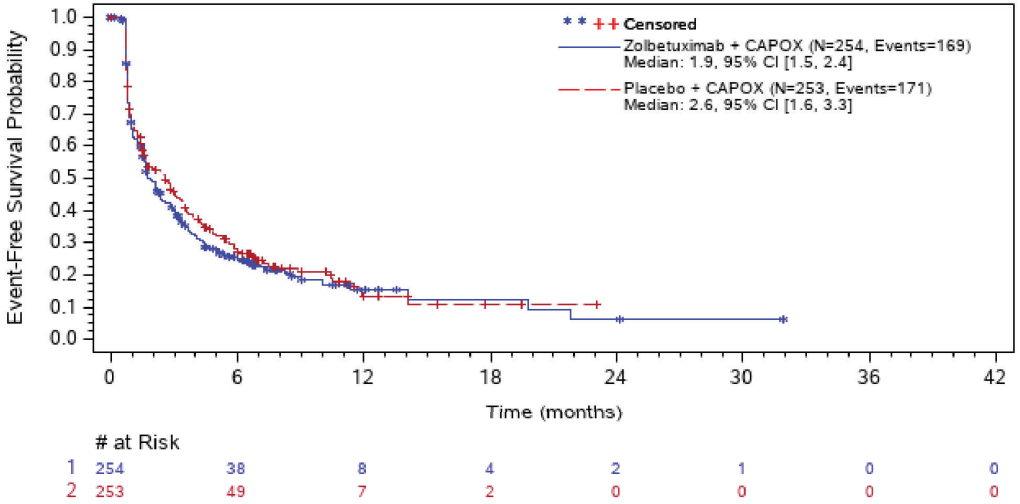
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.11: 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.

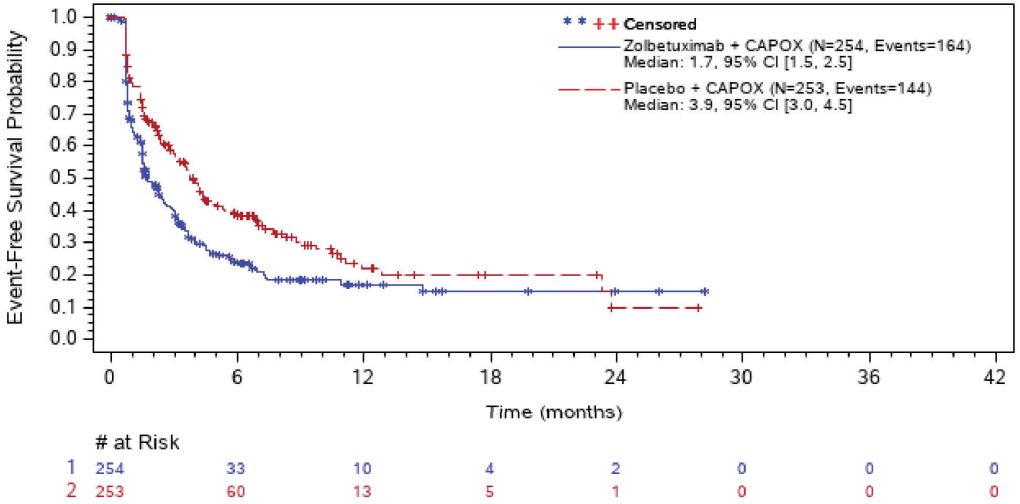
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.12: 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.

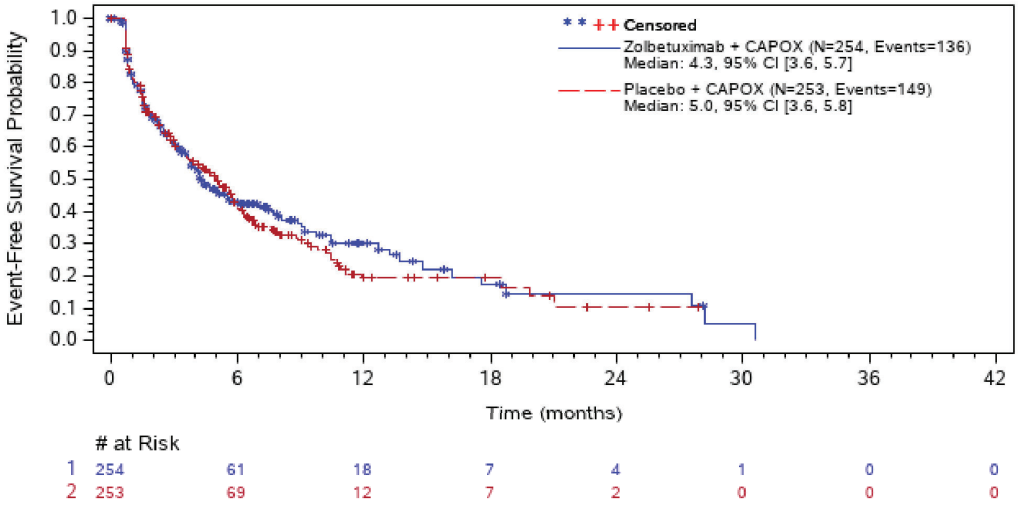
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.13: 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.

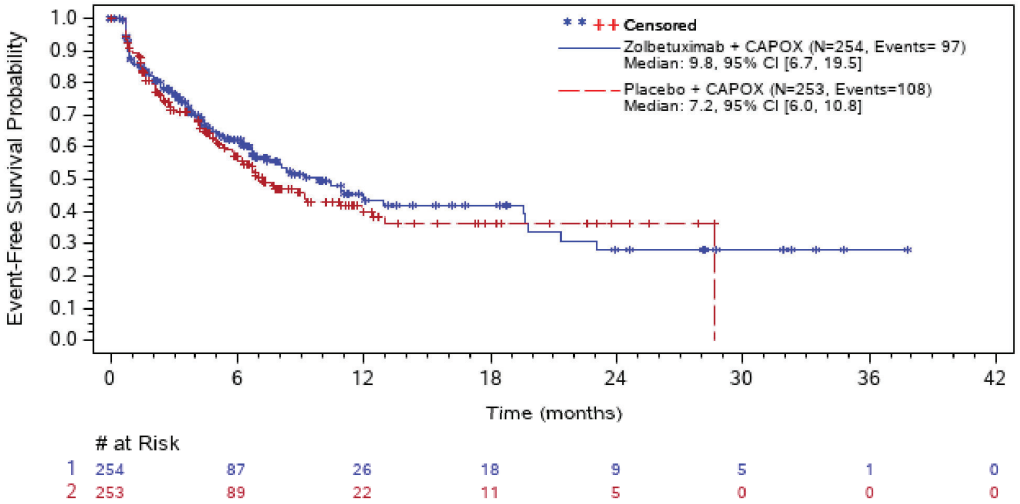
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.14: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Dyspnoea (MID=10) - Full Analysis Set



	# at Risk							
1	254	87	26	18	9	5	1	0
2	253	89	22	11	5	0	0	0

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.

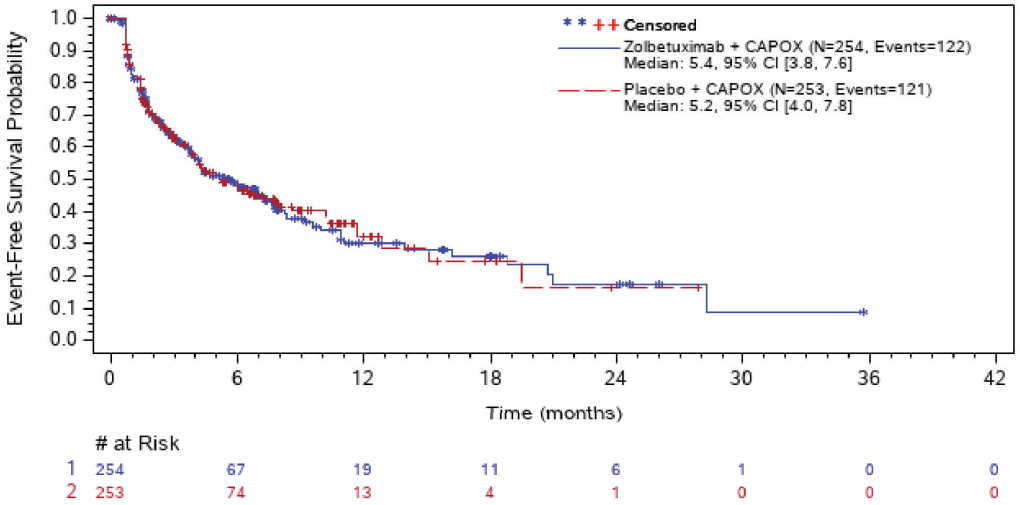
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.15: 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.

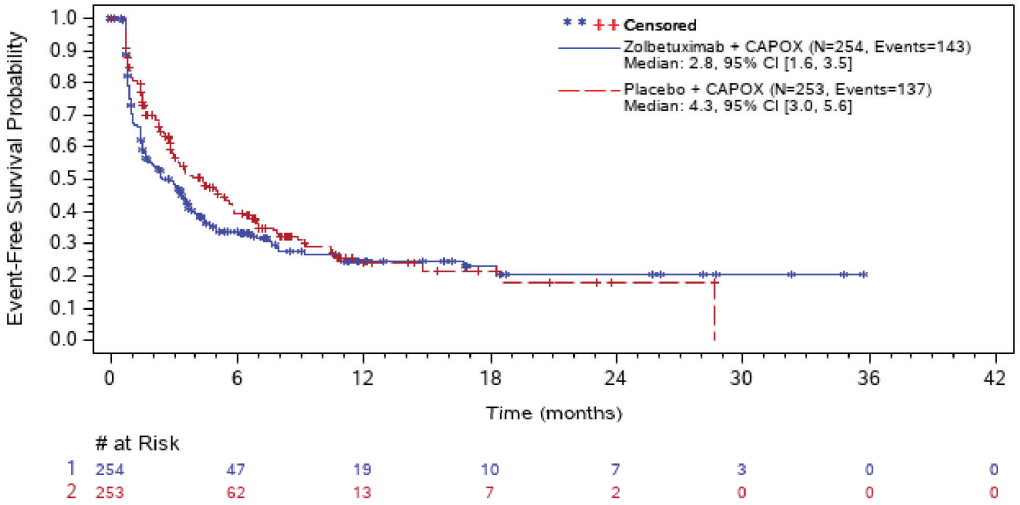
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.16: 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.

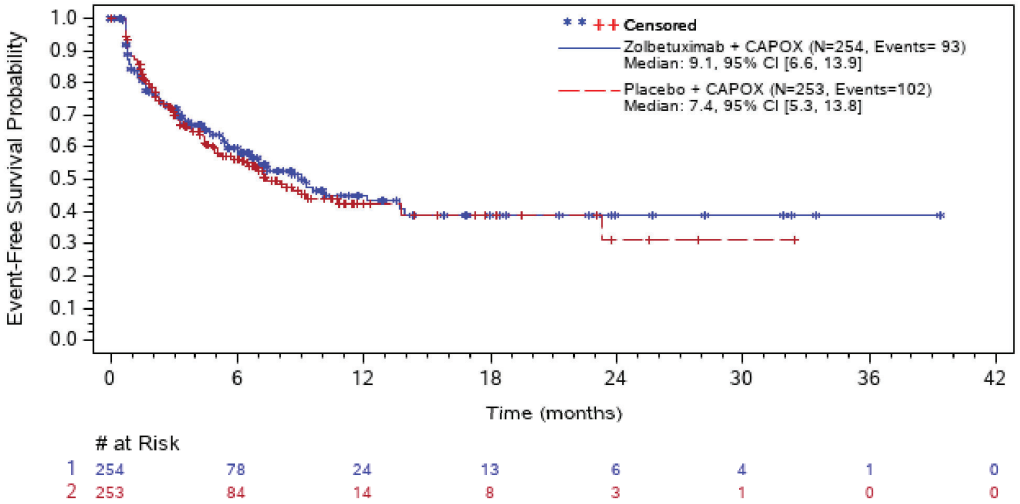
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.17: 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.

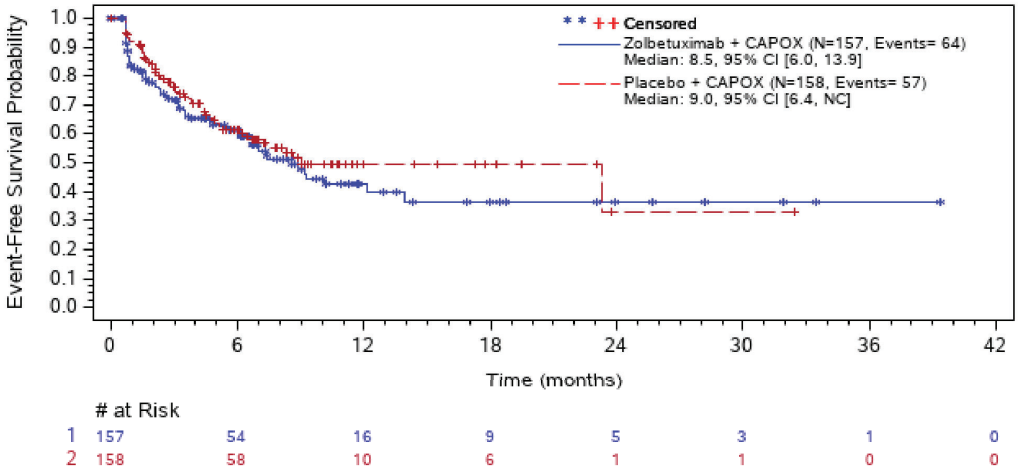
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

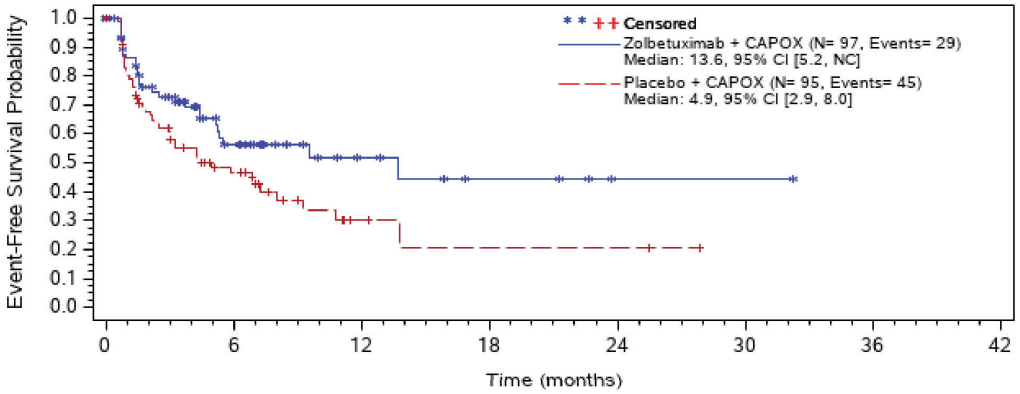
Figure 302.3.3004.17.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Constipation by Region (MID=10) - Full Analysis Set
Region: Asia



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: 12JAN24

The SAS System

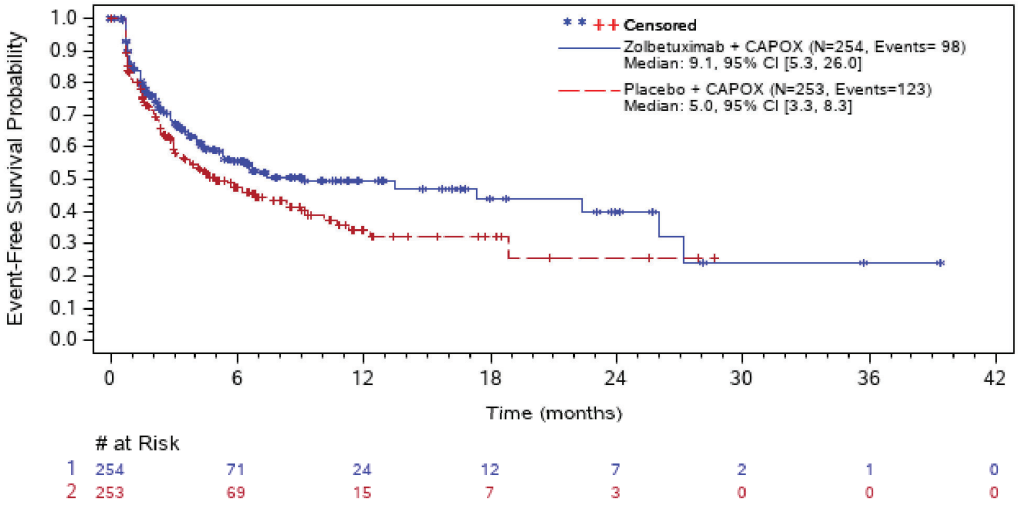
Figure 302.3.3004.17.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Constipation by Region (MID=10) - Full Analysis Set
Region: Non-Asia



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: 12JAN24

The SAS System

Figure 302.3.3004.18: 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.

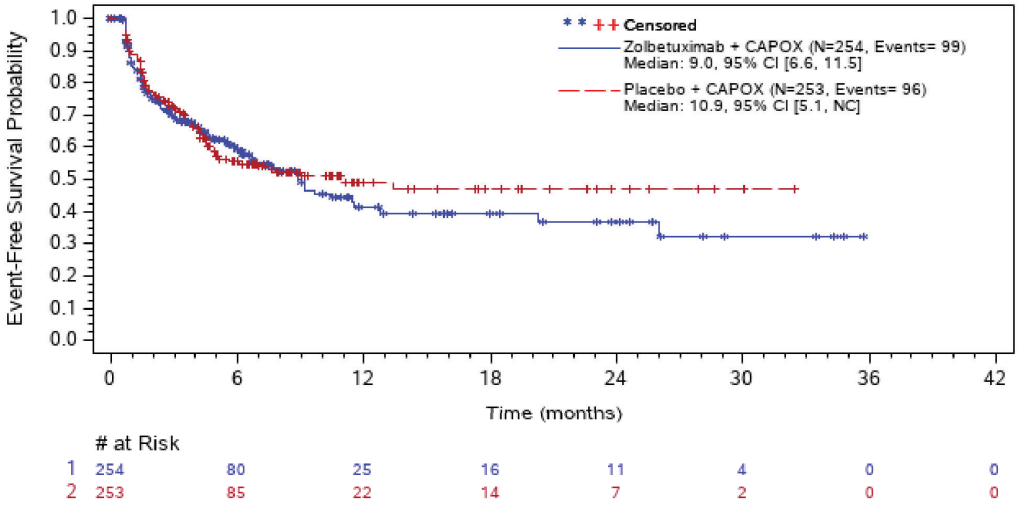
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.19: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Financial Difficulties (MID=10) - Full Analysis Set



	# at Risk							
1	254	80	25	16	11	4	0	0
2	253	85	22	14	7	2	0	0

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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

1. Rücklaufquoten

Table 302.3.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Table 302.3.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	91/253 (36.0%)	91/253 (36.0%)	91/254 (35.8%)	85/250 (34.0%)	85/252 (33.7%)	85/253 (33.6%)
Cycle 2 Day 1	100/224 (44.6%)	100/235 (42.6%)	100/254 (39.4%)	90/229 (39.3%)	91/237 (38.4%)	91/253 (36.0%)
Cycle 3 Day 1	102/197 (51.8%)	102/221 (46.2%)	103/254 (40.6%)	78/215 (36.3%)	78/232 (33.6%)	78/253 (30.8%)
Cycle 4 Day 1	90/182 (49.5%)	90/218 (41.3%)	90/254 (35.4%)	69/192 (35.9%)	70/228 (30.7%)	70/253 (27.7%)
Cycle 5 Day 1	71/172 (41.3%)	72/212 (34.0%)	74/254 (29.1%)	69/181 (38.1%)	69/227 (30.4%)	69/253 (27.3%)
Cycle 6 Day 1	68/155 (43.9%)	71/205 (34.6%)	72/254 (28.3%)	61/165 (37.0%)	61/220 (27.7%)	61/253 (24.1%)
Cycle 7 Day 1	52/128 (40.6%)	53/199 (26.6%)	53/254 (20.9%)	57/141 (40.4%)	57/217 (26.3%)	57/253 (22.5%)
Cycle 8 Day 1	52/119 (43.7%)	52/196 (26.5%)	53/254 (20.9%)	53/125 (42.4%)	53/217 (24.4%)	53/253 (20.9%)
Cycle 9 Day 1	52/108 (48.1%)	52/192 (27.1%)	52/254 (20.5%)	42/110 (38.2%)	44/214 (20.6%)	44/253 (17.4%)
Cycle 10 Day 1	35/ 90 (38.9%)	37/188 (19.7%)	37/254 (14.6%)	40/ 91 (44.0%)	40/213 (18.8%)	40/253 (15.8%)
Cycle 11 Day 1	36/ 84 (42.9%)	37/187 (19.8%)	37/254 (14.6%)	32/ 78 (41.0%)	32/212 (15.1%)	32/253 (12.6%)
Cycle 12 Day 1	36/ 77 (46.8%)	38/187 (20.3%)	38/254 (15.0%)	27/ 68 (39.7%)	28/211 (13.3%)	28/253 (11.1%)
Cycle 13 Day 1	30/ 67 (44.8%)	31/187 (16.6%)	31/254 (12.2%)	20/ 57 (35.1%)	20/210 (9.5%)	20/253 (7.9%)
Cycle 14 Day 1	23/ 62 (37.1%)	23/187 (12.3%)	23/254 (9.1%)	18/ 49 (36.7%)	18/210 (8.6%)	18/253 (7.1%)
Cycle 15 Day 1	19/ 55 (34.5%)	20/184 (10.9%)	21/254 (8.3%)	13/ 43 (30.2%)	13/207 (6.3%)	13/253 (5.1%)
Cycle 16 Day 1	22/ 50 (44.0%)	23/184 (12.5%)	23/254 (9.1%)	13/ 34 (38.2%)	13/207 (6.3%)	13/253 (5.1%)
Cycle 17 Day 1	22/ 47 (46.8%)	23/183 (12.6%)	23/254 (9.1%)	10/ 29 (34.5%)	10/206 (4.9%)	10/253 (4.0%)
Cycle 18 Day 1	20/ 44 (45.5%)	21/183 (11.5%)	21/254 (8.3%)	9/ 25 (36.0%)	9/206 (4.4%)	9/253 (3.6%)
Cycle 19 Day 1	16/ 44 (36.4%)	16/183 (8.7%)	16/254 (6.3%)	10/ 23 (43.5%)	10/206 (4.9%)	10/253 (4.0%)
Cycle 20 Day 1	15/ 41 (36.6%)	15/181 (8.3%)	15/254 (5.9%)	10/ 23 (43.5%)	10/206 (4.9%)	10/253 (4.0%)
Cycle 21 Day 1	14/ 39 (35.9%)	14/181 (7.7%)	14/254 (5.5%)	9/ 22 (40.9%)	9/206 (4.4%)	9/253 (3.6%)
Cycle 22 Day 1	11/ 35 (31.4%)	11/180 (6.1%)	11/254 (4.3%)	7/ 20 (35.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 23 Day 1	10/ 34 (29.4%)	10/180 (5.6%)	10/254 (3.9%)	8/ 19 (42.1%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 24 Day 1	12/ 33 (36.4%)	12/180 (6.7%)	12/254 (4.7%)	5/ 18 (27.8%)	5/206 (2.4%)	5/253 (2.0%)
Cycle 25 Day 1	10/ 33 (30.3%)	10/180 (5.6%)	10/254 (3.9%)	5/ 16 (31.3%)	5/206 (2.4%)	5/253 (2.0%)
Cycle 26 Day 1	9/ 32 (28.1%)	9/180 (5.0%)	9/254 (3.5%)	3/ 13 (23.1%)	3/206 (1.5%)	3/253 (1.2%)

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: 12JAN24

Table 302.3.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	7/ 28 (25.0%)	9/180 (5.0%)	9/254 (3.5%)	3/ 13 (23.1%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 28 Day 1	7/ 26 (26.9%)	7/180 (3.9%)	7/254 (2.8%)	3/ 13 (23.1%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 29 Day 1	7/ 25 (28.0%)	7/180 (3.9%)	7/254 (2.8%)	2/ 12 (16.7%)	2/206 (1.0%)	2/253 (0.8%)
Cycle 30 Day 1	7/ 23 (30.4%)	7/180 (3.9%)	7/254 (2.8%)	3/ 9 (33.3%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 31 Day 1	8/ 22 (36.4%)	8/180 (4.4%)	8/254 (3.1%)	1/ 8 (12.5%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 32 Day 1	6/ 20 (30.0%)	6/179 (3.4%)	6/254 (2.4%)	2/ 7 (28.6%)	2/206 (1.0%)	2/253 (0.8%)
Cycle 33 Day 1	7/ 18 (38.9%)	7/179 (3.9%)	7/254 (2.8%)	0/ 7 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 34 Day 1	5/ 15 (33.3%)	5/179 (2.8%)	5/254 (2.0%)	1/ 7 (14.3%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 35 Day 1	5/ 15 (33.3%)	5/179 (2.8%)	5/254 (2.0%)	1/ 6 (16.7%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 36 Day 1	5/ 15 (33.3%)	5/179 (2.8%)	5/254 (2.0%)	0/ 4 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 37 Day 1	4/ 13 (30.8%)	4/179 (2.2%)	4/254 (1.6%)	0/ 4 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 38 Day 1	4/ 12 (33.3%)	4/179 (2.2%)	4/254 (1.6%)	0/ 3 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 39 Day 1	1/ 10 (10.0%)	2/179 (1.1%)	2/254 (0.8%)	0/ 2 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 40 Day 1	1/ 10 (10.0%)	1/179 (0.6%)	1/254 (0.4%)	0/ 1 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 41 Day 1	2/ 10 (20.0%)	2/179 (1.1%)	2/254 (0.8%)	0/ 1 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 42 Day 1	3/ 9 (33.3%)	4/179 (2.2%)	4/254 (1.6%)	0/ 1 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 43 Day 1	1/ 8 (12.5%)	1/179 (0.6%)	1/254 (0.4%)	0/ 1 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 44 Day 1	1/ 8 (12.5%)	1/179 (0.6%)	1/254 (0.4%)	0/ 1 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 45 Day 1	1/ 8 (12.5%)	1/179 (0.6%)	1/254 (0.4%)	0/ 1 (0.0%)	0/206 (0.0%)	0/253 (0.0%)
Cycle 46 Day 1	1/ 8 (12.5%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	2/ 7 (28.6%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	1/ 6 (16.7%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	1/ 4 (25.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	0/ 3 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	0/ 3 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	0/ 3 (0.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	0/ 3 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	0/ 3 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	0/ 2 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	0/ 2 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	0/ 1 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	0/ 1 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	0/ 1 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	0/ 1 (0.0%)	0/179 (0.0%)	0/254 (0.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	61/218 (28.0%)	61/227 (26.9%)	61/254 (24.0%)	63/229 (27.5%)	63/231 (27.3%)	63/253 (24.9%)
30 D SFU Z/P	23/210 (11.0%)	23/219 (10.5%)	23/254 (9.1%)	34/217 (15.7%)	34/219 (15.5%)	34/253 (13.4%)
90 D SFU Z/P	36/192 (18.8%)	36/203 (17.7%)	36/254 (14.2%)	60/178 (33.7%)	60/180 (33.3%)	60/253 (23.7%)

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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

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

Table 302.3.3002.20: 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 + CAPOX (N=254)												
Baseline	243	12.12	18.27	0.0	0.00	77.8						
Cycle 2 Day 1	209	11.38	17.41	0.0	0.00	88.9	208	-0.37	17.07	-55.6	0.00	66.7
Cycle 3 Day 1	186	10.22	16.17	0.0	0.00	88.9	182	-0.92	15.22	-55.6	0.00	66.7
Cycle 4 Day 1	169	8.02	14.34	0.0	0.00	88.9	166	-2.68	17.13	-77.8	0.00	66.7
Cycle 5 Day 1	163	9.54	16.28	0.0	0.00	100.0	159	-1.05	20.30	-77.8	0.00	100.0
Cycle 6 Day 1	151	9.49	15.47	0.0	0.00	77.8	149	-1.42	16.81	-66.7	0.00	66.7
Cycle 7 Day 1	121	6.61	11.53	0.0	0.00	55.6	119	-2.61	16.28	-55.6	0.00	55.6
Cycle 8 Day 1	114	7.89	14.84	0.0	0.00	66.7	108	-2.88	18.81	-77.8	0.00	55.6
Cycle 9 Day 1	107	8.62	14.90	0.0	0.00	77.8	102	-2.83	17.67	-55.6	0.00	44.4
Cycle 10 Day 1	88	6.69	13.64	0.0	0.00	77.8	85	-3.27	16.61	-55.6	0.00	44.4
Cycle 11 Day 1	83	6.02	11.93	0.0	0.00	44.4	80	-3.33	16.90	-66.7	0.00	44.4
Cycle 12 Day 1	77	5.63	12.44	0.0	0.00	77.8	75	-3.70	17.07	-66.7	0.00	33.3
Cycle 13 Day 1	62	3.58	8.48	0.0	0.00	33.3	60	-6.30	17.64	-66.7	0.00	33.3
Cycle 14 Day 1	57	4.29	9.33	0.0	0.00	44.4	55	-4.24	15.49	-55.6	0.00	44.4
Cycle 15 Day 1	53	5.03	10.58	0.0	0.00	44.4	51	-3.49	14.82	-44.4	0.00	33.3
Cycle 16 Day 1	50	7.11	11.17	0.0	0.00	33.3	48	-2.31	14.85	-44.4	0.00	33.3
Cycle 17 Day 1	45	5.68	11.27	0.0	0.00	44.4	43	-3.10	13.13	-44.4	0.00	33.3
Cycle 18 Day 1	43	5.68	10.11	0.0	0.00	33.3	41	-3.25	14.96	-44.4	0.00	33.3
Cycle 19 Day 1	42	5.03	8.92	0.0	0.00	33.3	40	-4.17	13.48	-44.4	0.00	33.3
Cycle 20 Day 1	41	4.61	9.61	0.0	0.00	44.4	39	-4.56	11.60	-44.4	0.00	11.1
Cycle 21 Day 1	38	5.56	10.88	0.0	0.00	33.3	36	-3.40	15.22	-44.4	0.00	33.3
Cycle 22 Day 1	33	4.04	8.25	0.0	0.00	33.3	31	-5.38	15.94	-44.4	0.00	33.3
Cycle 23 Day 1	33	3.70	8.18	0.0	0.00	33.3	31	-4.30	14.54	-44.4	0.00	33.3
Cycle 24 Day 1	31	2.15	6.68	0.0	0.00	33.3	29	-4.98	13.80	-44.4	0.00	33.3
Cycle 25 Day 1	30	2.96	7.68	0.0	0.00	33.3	28	-4.37	12.95	-44.4	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: 12JAN24

Table 302.3.3002.20: 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 26 Day 1	28	4.76	14.00	0.0	0.00	66.7	26	-2.99	18.21	-44.4	0.00	66.7
Cycle 27 Day 1	27	2.47	5.63	0.0	0.00	22.2	25	-5.33	12.88	-44.4	0.00	22.2
Cycle 28 Day 1	23	5.31	9.40	0.0	0.00	33.3	21	-4.76	14.30	-44.4	0.00	33.3
Cycle 29 Day 1	24	2.78	6.75	0.0	0.00	22.2	22	-7.07	13.95	-44.4	0.00	22.2
Cycle 30 Day 1	22	4.04	10.02	0.0	0.00	33.3	20	-5.00	15.07	-44.4	0.00	33.3
Cycle 31 Day 1	22	4.04	10.59	0.0	0.00	44.4	20	-6.11	13.72	-44.4	0.00	22.2
Cycle 32 Day 1	20	3.89	6.52	0.0	0.00	22.2	18	-7.41	14.76	-55.6	0.00	11.1
Cycle 33 Day 1	17	3.92	8.73	0.0	0.00	33.3	15	-3.70	16.08	-44.4	0.00	33.3
Cycle 34 Day 1	14	3.97	9.35	0.0	0.00	33.3	12	-8.33	19.03	-44.4	-11.11	33.3
Cycle 35 Day 1	15	4.44	8.19	0.0	0.00	22.2	13	-6.84	19.53	-55.6	0.00	22.2
Cycle 36 Day 1	14	2.38	6.43	0.0	0.00	22.2	12	-9.26	19.44	-55.6	-5.56	22.2
Cycle 37 Day 1	12	2.78	5.03	0.0	0.00	11.1	11	-8.08	14.13	-44.4	-11.11	11.1
Cycle 38 Day 1	11	5.05	7.64	0.0	0.00	22.2	10	-6.67	16.73	-44.4	-5.56	22.2
Cycle 39 Day 1	10	3.33	7.50	0.0	0.00	22.2	9	-4.94	12.56	-22.2	-11.11	22.2
Study Disc 1	135	15.23	23.26	0.0	0.00	100.0	133	3.84	22.35	-55.6	0.00	88.9
30 D SFU Z/P	58	13.03	22.43	0.0	0.00	100.0	57	4.48	22.60	-44.4	0.00	100.0
90 D SFU Z/P	62	6.45	12.00	0.0	0.00	55.6	61	0.36	12.33	-44.4	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	241	12.59	19.27	0.0	0.00	100.0						
Cycle 2 Day 1	222	8.46	14.73	0.0	0.00	100.0	216	-3.86	15.69	-66.7	0.00	77.8
Cycle 3 Day 1	200	7.22	13.54	0.0	0.00	66.7	196	-4.59	16.22	-66.7	0.00	44.4
Cycle 4 Day 1	171	6.89	13.04	0.0	0.00	77.8	169	-5.00	17.23	-66.7	0.00	44.4
Cycle 5 Day 1	166	6.02	11.05	0.0	0.00	55.6	165	-5.66	17.07	-55.6	0.00	44.4
Cycle 6 Day 1	146	7.61	14.81	0.0	0.00	77.8	145	-3.45	19.00	-66.7	0.00	66.7
Cycle 7 Day 1	126	6.00	12.14	0.0	0.00	66.7	125	-5.16	17.02	-77.8	0.00	33.3
Cycle 8 Day 1	110	6.87	12.23	0.0	0.00	66.7	109	-4.28	17.88	-77.8	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: 12JAN24

Table 302.3.3002.20: 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 9 Day 1	104	4.81	10.24	0.0	0.00	55.6	103	-5.93	17.17	-77.8	0.00	44.4
Cycle 10 Day 1	81	4.66	10.81	0.0	0.00	55.6	79	-6.75	18.70	-77.8	0.00	55.6
Cycle 11 Day 1	72	4.48	11.14	0.0	0.00	66.7	71	-5.95	19.41	-44.4	0.00	66.7
Cycle 12 Day 1	59	3.77	8.66	0.0	0.00	44.4	57	-5.65	16.15	-44.4	0.00	44.4
Cycle 13 Day 1	50	4.22	8.37	0.0	0.00	33.3	48	-4.40	14.81	-44.4	0.00	33.3
Cycle 14 Day 1	46	4.35	10.07	0.0	0.00	44.4	44	-3.03	14.25	-44.4	0.00	44.4
Cycle 15 Day 1	38	6.14	12.84	0.0	0.00	55.6	36	-1.54	17.24	-44.4	0.00	55.6
Cycle 16 Day 1	33	6.40	11.80	0.0	0.00	44.4	31	0.00	12.83	-33.3	0.00	33.3
Cycle 17 Day 1	28	3.97	9.66	0.0	0.00	33.3	25	-1.78	11.86	-33.3	0.00	22.2
Cycle 18 Day 1	23	1.93	7.23	0.0	0.00	33.3	21	-4.23	10.82	-33.3	0.00	11.1
Cycle 19 Day 1	21	2.12	4.47	0.0	0.00	11.1	20	-2.78	7.10	-22.2	0.00	11.1
Cycle 20 Day 1	20	3.89	9.03	0.0	0.00	33.3	19	-2.92	11.01	-33.3	0.00	22.2
Cycle 21 Day 1	21	3.17	6.23	0.0	0.00	22.2	20	-3.33	13.05	-33.3	0.00	22.2
Cycle 22 Day 1	18	2.47	6.09	0.0	0.00	22.2	17	-5.23	9.72	-33.3	0.00	0.0
Cycle 23 Day 1	17	2.61	6.25	0.0	0.00	22.2	16	-5.56	10.73	-33.3	0.00	11.1
Cycle 24 Day 1	13	4.27	9.66	0.0	0.00	33.3	12	-2.78	11.73	-33.3	0.00	11.1
Cycle 25 Day 1	13	3.42	7.00	0.0	0.00	22.2	12	-3.70	10.94	-33.3	0.00	11.1
Cycle 26 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	2.47	9.26	-11.1	0.00	22.2
Cycle 27 Day 1	11	4.04	10.27	0.0	0.00	33.3	10	0.00	5.24	-11.1	0.00	11.1
Cycle 28 Day 1	11	5.05	10.38	0.0	0.00	33.3	11	1.01	5.99	-11.1	0.00	11.1
Cycle 29 Day 1	12	8.33	15.08	0.0	0.00	44.4	12	1.85	13.26	-22.2	0.00	33.3
Study Disc 1	156	16.52	25.26	0.0	0.00	100.0	150	4.15	25.73	-77.8	0.00	100.0
30 D SFU Z/P	78	13.11	23.60	0.0	0.00	100.0	76	0.73	24.63	-55.6	0.00	100.0
90 D SFU Z/P	81	10.70	17.34	0.0	0.00	66.7	79	-1.83	19.28	-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: 12JAN24

Table 302.3.3002.21: 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 + CAPOX (N=254)												
Baseline	243	22.67	25.20	0.0	16.67	100.0						
Cycle 2 Day 1	209	20.41	21.59	0.0	16.67	100.0	208	-1.24	21.39	-66.7	0.00	83.3
Cycle 3 Day 1	186	17.11	20.86	0.0	8.33	100.0	182	-4.12	20.26	-83.3	0.00	66.7
Cycle 4 Day 1	169	15.29	20.04	0.0	8.33	100.0	166	-5.52	21.76	-75.0	0.00	75.0
Cycle 5 Day 1	163	16.10	19.80	0.0	8.33	100.0	159	-5.14	23.77	-83.3	0.00	100.0
Cycle 6 Day 1	151	17.49	21.75	0.0	8.33	100.0	149	-3.97	21.24	-75.0	0.00	66.7
Cycle 7 Day 1	121	14.60	18.17	0.0	8.33	100.0	119	-4.69	21.03	-66.7	0.00	66.7
Cycle 8 Day 1	114	16.37	21.00	0.0	8.33	100.0	108	-3.70	21.87	-100.0	0.00	66.7
Cycle 9 Day 1	107	17.37	20.06	0.0	8.33	91.7	102	-3.59	22.75	-100.0	0.00	58.3
Cycle 10 Day 1	88	15.44	20.82	0.0	8.33	100.0	85	-4.80	24.03	-100.0	0.00	66.7
Cycle 11 Day 1	83	11.95	19.40	0.0	0.00	100.0	80	-5.83	25.96	-100.0	0.00	66.7
Cycle 12 Day 1	77	11.58	19.88	0.0	0.00	100.0	75	-6.22	27.47	-100.0	0.00	66.7
Cycle 13 Day 1	62	10.75	17.23	0.0	0.00	91.7	60	-9.31	28.04	-100.0	0.00	58.3
Cycle 14 Day 1	57	11.26	17.57	0.0	0.00	100.0	55	-6.97	25.45	-100.0	0.00	66.7
Cycle 15 Day 1	53	11.79	18.01	0.0	0.00	100.0	51	-7.03	24.46	-75.0	0.00	66.7
Cycle 16 Day 1	50	11.33	13.96	0.0	4.17	41.7	48	-8.68	22.41	-75.0	-8.33	33.3
Cycle 17 Day 1	45	12.41	14.28	0.0	8.33	50.0	43	-7.75	22.67	-66.7	0.00	33.3
Cycle 18 Day 1	43	12.98	15.57	0.0	0.00	41.7	41	-7.11	23.68	-75.0	0.00	33.3
Cycle 19 Day 1	42	11.71	14.26	0.0	0.00	41.7	40	-7.92	20.06	-66.7	-8.33	33.3
Cycle 20 Day 1	41	13.01	17.78	0.0	8.33	58.3	39	-6.41	22.98	-66.7	0.00	50.0
Cycle 21 Day 1	38	13.82	16.81	0.0	8.33	58.3	36	-5.32	20.52	-66.7	0.00	41.7
Cycle 22 Day 1	33	11.11	16.75	0.0	0.00	66.7	31	-7.26	23.93	-66.7	0.00	50.0
Cycle 23 Day 1	33	10.35	16.54	0.0	0.00	66.7	31	-6.18	20.07	-66.7	0.00	50.0
Cycle 24 Day 1	31	8.87	13.77	0.0	0.00	50.0	29	-6.03	21.12	-66.7	0.00	25.0
Cycle 25 Day 1	30	9.44	14.64	0.0	0.00	58.3	28	-5.95	23.34	-66.7	0.00	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: 12JAN24

Table 302.3.3002.21: 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 26 Day 1	28	8.63	16.89	0.0	0.00	75.0	26	-7.37	25.31	-66.7	-4.17	58.3
Cycle 27 Day 1	27	7.72	14.60	0.0	0.00	50.0	25	-7.67	22.30	-66.7	0.00	33.3
Cycle 28 Day 1	23	10.87	16.17	0.0	0.00	58.3	21	-6.35	24.71	-66.7	0.00	41.7
Cycle 29 Day 1	24	6.25	10.78	0.0	0.00	33.3	22	-10.23	19.57	-66.7	-4.17	16.7
Cycle 30 Day 1	22	10.98	14.18	0.0	0.00	33.3	20	-5.42	22.01	-66.7	0.00	33.3
Cycle 31 Day 1	22	7.58	12.31	0.0	0.00	41.7	20	-10.42	20.75	-66.7	-8.33	25.0
Cycle 32 Day 1	20	10.00	16.58	0.0	0.00	66.7	18	-9.26	23.90	-66.7	-8.33	25.0
Cycle 33 Day 1	17	7.35	13.14	0.0	0.00	41.7	15	-7.78	13.90	-33.3	-8.33	16.7
Cycle 34 Day 1	14	5.36	10.65	0.0	0.00	33.3	12	-17.36	25.74	-66.7	-8.33	8.3
Cycle 35 Day 1	15	8.89	14.25	0.0	0.00	33.3	13	-11.54	26.25	-66.7	0.00	16.7
Cycle 36 Day 1	14	4.17	9.67	0.0	0.00	33.3	12	-15.97	25.24	-66.7	-8.33	8.3
Cycle 37 Day 1	12	6.94	10.56	0.0	0.00	25.0	11	-12.12	15.08	-41.7	-8.33	8.3
Cycle 38 Day 1	11	3.03	4.20	0.0	0.00	8.3	10	-17.50	21.68	-66.7	-12.50	8.3
Cycle 39 Day 1	10	8.33	12.42	0.0	0.00	33.3	9	-7.41	13.47	-25.0	-8.33	16.7
Study Disc 1	135	24.38	27.78	0.0	16.67	100.0	133	3.07	27.30	-100.0	0.00	75.0
30 D SFU Z/P	58	19.97	25.07	0.0	8.33	100.0	57	0.15	27.57	-100.0	0.00	58.3
90 D SFU Z/P	62	15.19	18.45	0.0	8.33	91.7	61	-2.19	22.77	-50.0	0.00	75.0
Placebo + CAPOX (N=253)												
Baseline	241	22.51	24.22	0.0	16.67	100.0						
Cycle 2 Day 1	222	18.02	21.01	0.0	8.33	100.0	216	-4.55	20.82	-83.3	0.00	83.3
Cycle 3 Day 1	200	15.25	19.33	0.0	8.33	91.7	196	-6.08	20.52	-100.0	0.00	58.3
Cycle 4 Day 1	171	14.23	18.41	0.0	8.33	83.3	169	-8.19	21.18	-91.7	0.00	58.3
Cycle 5 Day 1	166	14.41	17.99	0.0	8.33	75.0	165	-7.22	22.12	-91.7	0.00	50.0
Cycle 6 Day 1	146	15.30	19.35	0.0	8.33	75.0	145	-6.03	23.04	-83.3	0.00	58.3
Cycle 7 Day 1	126	14.09	18.87	0.0	4.17	75.0	125	-5.07	22.32	-91.7	0.00	58.3
Cycle 8 Day 1	110	14.39	19.09	0.0	8.33	91.7	109	-6.27	24.35	-91.7	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: 12JAN24

Table 302.3.3002.21: 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 9 Day 1	104	12.42	17.18	0.0	0.00	83.3	103	-7.52	22.25	-91.7	0.00	58.3
Cycle 10 Day 1	81	12.14	18.45	0.0	0.00	75.0	79	-8.54	26.75	-91.7	0.00	75.0
Cycle 11 Day 1	72	10.42	16.65	0.0	0.00	66.7	71	-9.39	27.17	-91.7	0.00	66.7
Cycle 12 Day 1	59	9.75	16.61	0.0	0.00	83.3	57	-9.36	22.33	-75.0	0.00	50.0
Cycle 13 Day 1	50	9.50	15.61	0.0	0.00	58.3	48	-10.59	21.59	-75.0	-4.17	25.0
Cycle 14 Day 1	46	11.96	20.91	0.0	0.00	100.0	44	-7.39	22.17	-66.7	0.00	58.3
Cycle 15 Day 1	38	12.94	20.57	0.0	0.00	91.7	36	-6.25	21.02	-58.3	0.00	50.0
Cycle 16 Day 1	33	12.12	15.88	0.0	8.33	66.7	31	-6.72	20.23	-66.7	0.00	25.0
Cycle 17 Day 1	28	13.39	18.47	0.0	4.17	66.7	25	-3.33	21.52	-66.7	0.00	25.0
Cycle 18 Day 1	23	7.25	12.64	0.0	0.00	50.0	21	-10.32	21.23	-66.7	0.00	25.0
Cycle 19 Day 1	21	5.95	10.25	0.0	0.00	33.3	20	-9.17	14.02	-50.0	0.00	0.0
Cycle 20 Day 1	20	9.58	13.04	0.0	8.33	41.7	19	-9.21	20.95	-58.3	0.00	16.7
Cycle 21 Day 1	21	7.94	10.03	0.0	0.00	33.3	20	-10.00	19.61	-58.3	0.00	16.7
Cycle 22 Day 1	18	8.33	14.85	0.0	0.00	50.0	17	-12.25	22.46	-66.7	0.00	25.0
Cycle 23 Day 1	17	9.31	15.28	0.0	0.00	50.0	16	-12.50	19.95	-58.3	-4.17	16.7
Cycle 24 Day 1	13	10.26	14.09	0.0	8.33	41.7	12	-6.25	20.45	-58.3	0.00	16.7
Cycle 25 Day 1	13	9.62	12.66	0.0	8.33	33.3	12	-8.33	18.46	-58.3	0.00	8.3
Cycle 26 Day 1	10	10.83	15.24	0.0	4.17	41.7	9	-2.78	17.68	-33.3	0.00	25.0
Cycle 27 Day 1	11	9.85	10.42	0.0	8.33	33.3	10	-3.33	13.72	-33.3	0.00	16.7
Cycle 28 Day 1	11	14.39	12.96	0.0	8.33	33.3	11	2.27	7.54	-8.3	0.00	16.7
Cycle 29 Day 1	12	13.89	17.16	0.0	8.33	50.0	12	-3.47	19.29	-41.7	0.00	33.3
Study Disc 1	156	26.12	28.78	0.0	16.67	100.0	150	4.39	26.31	-83.3	0.00	100.0
30 D SFU Z/P	78	21.37	25.71	0.0	12.50	100.0	76	0.88	23.47	-75.0	0.00	75.0
90 D SFU Z/P	81	19.44	22.59	0.0	8.33	75.0	79	-0.42	23.19	-66.7	0.00	58.3

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: 12JAN24

Table 302.3.3002.22: 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 + CAPOX (N=254)												
Baseline	243	13.17	20.28	0.0	0.00	100.0						
Cycle 2 Day 1	209	12.12	18.47	0.0	0.00	100.0	208	-1.04	20.79	-66.7	0.00	100.0
Cycle 3 Day 1	186	12.19	19.70	0.0	0.00	100.0	182	-0.09	21.71	-66.7	0.00	66.7
Cycle 4 Day 1	169	12.03	18.63	0.0	0.00	100.0	166	-0.70	22.80	-66.7	0.00	100.0
Cycle 5 Day 1	163	11.35	15.68	0.0	0.00	66.7	159	-0.84	22.17	-83.3	0.00	50.0
Cycle 6 Day 1	151	12.25	18.83	0.0	0.00	100.0	149	-0.11	22.39	-66.7	0.00	100.0
Cycle 7 Day 1	121	9.37	15.65	0.0	0.00	100.0	119	-1.68	20.40	-66.7	0.00	50.0
Cycle 8 Day 1	114	10.82	18.68	0.0	0.00	100.0	108	-1.08	23.04	-83.3	0.00	66.7
Cycle 9 Day 1	107	12.62	20.96	0.0	0.00	100.0	102	-0.82	27.49	-83.3	0.00	100.0
Cycle 10 Day 1	88	9.85	20.32	0.0	0.00	100.0	85	-1.57	23.80	-83.3	0.00	66.7
Cycle 11 Day 1	83	7.03	15.43	0.0	0.00	100.0	80	-3.13	21.23	-83.3	0.00	66.7
Cycle 12 Day 1	77	6.49	12.73	0.0	0.00	50.0	75	-4.44	22.48	-83.3	0.00	33.3
Cycle 13 Day 1	62	8.87	16.45	0.0	0.00	83.3	60	-3.33	28.26	-83.3	0.00	83.3
Cycle 14 Day 1	57	8.19	13.77	0.0	0.00	50.0	55	-1.82	22.38	-83.3	0.00	50.0
Cycle 15 Day 1	53	5.66	11.30	0.0	0.00	33.3	51	-3.92	18.13	-66.7	0.00	33.3
Cycle 16 Day 1	50	8.33	13.15	0.0	0.00	33.3	48	-3.13	23.23	-66.7	0.00	33.3
Cycle 17 Day 1	45	5.19	11.69	0.0	0.00	33.3	43	-5.81	22.09	-66.7	0.00	33.3
Cycle 18 Day 1	43	7.75	15.15	0.0	0.00	50.0	41	-3.25	23.04	-66.7	0.00	50.0
Cycle 19 Day 1	42	7.14	14.32	0.0	0.00	66.7	40	-2.92	22.61	-66.7	0.00	66.7
Cycle 20 Day 1	41	9.76	15.80	0.0	0.00	66.7	39	0.00	20.94	-66.7	0.00	50.0
Cycle 21 Day 1	38	10.09	21.06	0.0	0.00	100.0	36	0.46	24.07	-50.0	0.00	100.0
Cycle 22 Day 1	33	5.05	11.40	0.0	0.00	50.0	31	-5.38	17.94	-66.7	0.00	33.3
Cycle 23 Day 1	33	5.56	15.40	0.0	0.00	83.3	31	-4.30	18.74	-66.7	0.00	33.3
Cycle 24 Day 1	31	5.38	10.88	0.0	0.00	33.3	29	-2.30	19.78	-66.7	0.00	33.3
Cycle 25 Day 1	30	6.11	11.97	0.0	0.00	50.0	28	-1.19	19.74	-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: 12JAN24

Table 302.3.3002.22: 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 26 Day 1	28	5.36	11.16	0.0	0.00	33.3	26	-1.28	16.95	-50.0	0.00	33.3
Cycle 27 Day 1	27	6.79	13.28	0.0	0.00	50.0	25	-1.33	17.29	-50.0	0.00	33.3
Cycle 28 Day 1	23	7.97	21.83	0.0	0.00	100.0	21	0.00	17.48	-50.0	0.00	50.0
Cycle 29 Day 1	24	4.17	8.86	0.0	0.00	33.3	22	-3.03	14.21	-50.0	0.00	16.7
Cycle 30 Day 1	22	7.58	13.34	0.0	0.00	50.0	20	-0.83	13.76	-33.3	0.00	33.3
Cycle 31 Day 1	22	6.82	13.27	0.0	0.00	50.0	20	-1.67	16.13	-50.0	0.00	33.3
Cycle 32 Day 1	20	8.33	14.81	0.0	0.00	50.0	18	0.00	18.96	-50.0	0.00	33.3
Cycle 33 Day 1	17	4.90	9.80	0.0	0.00	33.3	15	-3.33	14.36	-33.3	0.00	33.3
Cycle 34 Day 1	14	3.57	9.65	0.0	0.00	33.3	12	-4.17	18.97	-50.0	0.00	33.3
Cycle 35 Day 1	15	8.89	10.67	0.0	0.00	33.3	13	1.28	19.79	-50.0	0.00	33.3
Cycle 36 Day 1	14	4.76	10.19	0.0	0.00	33.3	12	-4.17	21.47	-50.0	0.00	33.3
Cycle 37 Day 1	12	4.17	7.54	0.0	0.00	16.7	11	-4.55	18.40	-50.0	0.00	16.7
Cycle 38 Day 1	11	7.58	13.67	0.0	0.00	33.3	10	0.00	20.79	-50.0	0.00	33.3
Cycle 39 Day 1	10	8.33	11.79	0.0	0.00	33.3	9	7.41	12.11	0.0	0.00	33.3
Study Disc 1	135	14.44	22.47	0.0	0.00	100.0	133	2.38	24.37	-83.3	0.00	100.0
30 D SFU Z/P	58	12.36	24.30	0.0	0.00	100.0	57	1.46	26.03	-83.3	0.00	100.0
90 D SFU Z/P	62	10.22	19.87	0.0	0.00	100.0	61	2.19	19.83	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	16.11	22.25	0.0	0.00	100.0						
Cycle 2 Day 1	222	10.74	18.38	0.0	0.00	100.0	216	-4.01	18.66	-83.3	0.00	66.7
Cycle 3 Day 1	200	10.08	17.19	0.0	0.00	100.0	196	-4.17	18.36	-66.7	0.00	50.0
Cycle 4 Day 1	171	8.48	15.59	0.0	0.00	66.7	169	-5.82	21.53	-83.3	0.00	50.0
Cycle 5 Day 1	166	6.93	13.12	0.0	0.00	66.7	165	-7.88	19.87	-83.3	0.00	33.3
Cycle 6 Day 1	146	8.45	15.19	0.0	0.00	66.7	145	-7.01	20.57	-83.3	0.00	33.3
Cycle 7 Day 1	126	8.60	13.78	0.0	0.00	66.7	125	-6.67	21.48	-83.3	0.00	33.3
Cycle 8 Day 1	110	6.97	15.21	0.0	0.00	66.7	109	-9.17	21.81	-83.3	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: 12JAN24

Table 302.3.3002.22: 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 9 Day 1	104	5.45	11.48	0.0	0.00	66.7	103	-11.00	20.82	-83.3	0.00	33.3
Cycle 10 Day 1	81	7.20	13.16	0.0	0.00	50.0	79	-10.34	22.69	-83.3	0.00	33.3
Cycle 11 Day 1	72	5.32	11.47	0.0	0.00	33.3	71	-11.03	24.23	-83.3	0.00	33.3
Cycle 12 Day 1	59	6.50	13.14	0.0	0.00	50.0	57	-8.48	23.60	-100.0	0.00	33.3
Cycle 13 Day 1	50	7.33	13.95	0.0	0.00	50.0	48	-9.03	24.78	-83.3	0.00	50.0
Cycle 14 Day 1	46	5.07	11.58	0.0	0.00	33.3	44	-8.71	20.80	-83.3	0.00	33.3
Cycle 15 Day 1	38	5.70	13.01	0.0	0.00	50.0	36	-7.41	24.70	-83.3	0.00	33.3
Cycle 16 Day 1	33	6.06	14.32	0.0	0.00	50.0	31	-4.84	20.27	-66.7	0.00	50.0
Cycle 17 Day 1	28	5.36	11.16	0.0	0.00	33.3	25	-2.67	21.34	-83.3	0.00	33.3
Cycle 18 Day 1	23	5.80	12.92	0.0	0.00	50.0	21	-3.17	23.93	-83.3	0.00	50.0
Cycle 19 Day 1	21	4.76	10.73	0.0	0.00	33.3	20	-1.67	13.13	-16.7	0.00	33.3
Cycle 20 Day 1	20	5.83	14.58	0.0	0.00	50.0	19	-4.39	24.75	-83.3	0.00	50.0
Cycle 21 Day 1	21	7.14	17.14	0.0	0.00	66.7	20	-2.50	27.72	-83.3	0.00	66.7
Cycle 22 Day 1	18	8.33	14.29	0.0	0.00	50.0	17	-1.96	26.93	-83.3	0.00	50.0
Cycle 23 Day 1	17	5.88	13.10	0.0	0.00	33.3	16	-4.17	24.72	-83.3	0.00	33.3
Cycle 24 Day 1	13	3.85	9.99	0.0	0.00	33.3	12	-6.94	26.07	-83.3	0.00	16.7
Cycle 25 Day 1	13	6.41	18.68	0.0	0.00	66.7	12	-4.17	25.75	-66.7	0.00	50.0
Cycle 26 Day 1	10	6.67	21.08	0.0	0.00	66.7	9	3.70	18.22	-16.7	0.00	50.0
Cycle 27 Day 1	11	4.55	15.08	0.0	0.00	50.0	10	1.67	12.30	-16.7	0.00	33.3
Cycle 28 Day 1	11	6.06	20.10	0.0	0.00	66.7	11	3.03	16.36	-16.7	0.00	50.0
Cycle 29 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-1.39	8.58	-16.7	0.00	16.7
Study Disc 1	156	16.77	24.86	0.0	0.00	100.0	150	2.33	27.31	-66.7	0.00	100.0
30 D SFU Z/P	78	14.53	25.11	0.0	0.00	100.0	76	0.44	26.10	-100.0	0.00	100.0
90 D SFU Z/P	81	10.29	19.47	0.0	0.00	100.0	79	-1.69	21.28	-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: 12JAN24

Table 302.3.3002.23: 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 + CAPOX (N=254)												
Baseline	243	15.64	22.78	0.0	0.00	100.0						
Cycle 2 Day 1	209	13.16	18.66	0.0	0.00	100.0	208	-2.80	21.46	-83.3	0.00	66.7
Cycle 3 Day 1	186	10.75	16.00	0.0	0.00	66.7	182	-3.94	19.38	-66.7	0.00	50.0
Cycle 4 Day 1	169	9.07	16.16	0.0	0.00	66.7	166	-5.22	21.93	-66.7	0.00	66.7
Cycle 5 Day 1	163	10.53	15.38	0.0	0.00	100.0	159	-4.19	22.58	-66.7	0.00	100.0
Cycle 6 Day 1	151	11.59	20.37	0.0	0.00	100.0	149	-2.80	20.54	-66.7	0.00	83.3
Cycle 7 Day 1	121	8.68	14.92	0.0	0.00	83.3	119	-3.92	19.73	-50.0	0.00	83.3
Cycle 8 Day 1	114	9.94	17.56	0.0	0.00	83.3	108	-4.32	21.54	-100.0	0.00	66.7
Cycle 9 Day 1	107	11.68	17.91	0.0	0.00	83.3	102	-2.94	22.30	-100.0	0.00	66.7
Cycle 10 Day 1	88	9.85	17.26	0.0	0.00	100.0	85	-5.10	24.26	-100.0	0.00	66.7
Cycle 11 Day 1	83	9.64	18.43	0.0	0.00	100.0	80	-4.17	25.78	-100.0	0.00	66.7
Cycle 12 Day 1	77	7.58	14.94	0.0	0.00	66.7	75	-6.67	25.70	-100.0	0.00	66.7
Cycle 13 Day 1	62	8.06	12.71	0.0	0.00	33.3	60	-8.06	26.66	-100.0	0.00	33.3
Cycle 14 Day 1	57	6.43	12.10	0.0	0.00	50.0	55	-7.58	24.18	-100.0	0.00	50.0
Cycle 15 Day 1	53	6.92	14.03	0.0	0.00	66.7	51	-7.84	23.18	-66.7	0.00	66.7
Cycle 16 Day 1	50	8.00	12.71	0.0	0.00	33.3	48	-9.37	21.99	-66.7	0.00	33.3
Cycle 17 Day 1	45	6.30	11.94	0.0	0.00	33.3	43	-11.63	21.37	-66.7	0.00	33.3
Cycle 18 Day 1	43	8.53	13.79	0.0	0.00	33.3	41	-9.76	22.66	-66.7	0.00	33.3
Cycle 19 Day 1	42	7.54	15.27	0.0	0.00	66.7	40	-9.58	18.45	-66.7	0.00	33.3
Cycle 20 Day 1	41	8.54	15.42	0.0	0.00	66.7	39	-7.26	21.56	-66.7	0.00	33.3
Cycle 21 Day 1	38	10.53	17.51	0.0	0.00	66.7	36	-5.09	18.61	-66.7	0.00	50.0
Cycle 22 Day 1	33	9.60	17.19	0.0	0.00	66.7	31	-5.91	19.51	-66.7	0.00	33.3
Cycle 23 Day 1	33	6.57	13.14	0.0	0.00	50.0	31	-7.53	21.01	-66.7	0.00	50.0
Cycle 24 Day 1	31	5.91	13.30	0.0	0.00	50.0	29	-6.90	21.14	-66.7	0.00	50.0
Cycle 25 Day 1	30	5.56	11.01	0.0	0.00	33.3	28	-7.14	18.39	-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: 12JAN24

Table 302.3.3002.23: 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 26 Day 1	28	5.36	13.65	0.0	0.00	50.0	26	-7.69	23.68	-66.7	0.00	50.0
Cycle 27 Day 1	27	6.79	11.56	0.0	0.00	33.3	25	-7.33	18.05	-66.7	0.00	16.7
Cycle 28 Day 1	23	7.97	15.79	0.0	0.00	66.7	21	-9.52	17.93	-66.7	0.00	16.7
Cycle 29 Day 1	24	5.56	14.47	0.0	0.00	66.7	22	-10.61	18.22	-66.7	0.00	16.7
Cycle 30 Day 1	22	7.58	13.34	0.0	0.00	50.0	20	-9.17	21.95	-66.7	0.00	33.3
Cycle 31 Day 1	22	5.30	14.90	0.0	0.00	66.7	20	-12.50	19.40	-66.7	0.00	16.7
Cycle 32 Day 1	20	6.67	16.58	0.0	0.00	66.7	18	-11.11	19.80	-50.0	0.00	16.7
Cycle 33 Day 1	17	2.94	6.55	0.0	0.00	16.7	15	-10.00	15.17	-33.3	0.00	16.7
Cycle 34 Day 1	14	3.57	7.10	0.0	0.00	16.7	12	-16.67	20.10	-66.7	-16.67	0.0
Cycle 35 Day 1	15	2.22	5.86	0.0	0.00	16.7	13	-17.95	20.93	-66.7	-16.67	0.0
Cycle 36 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-18.06	24.06	-66.7	-16.67	16.7
Cycle 37 Day 1	12	5.56	10.86	0.0	0.00	33.3	11	-10.61	15.41	-33.3	-16.67	16.7
Cycle 38 Day 1	11	4.55	7.78	0.0	0.00	16.7	10	-11.67	15.81	-33.3	-16.67	16.7
Cycle 39 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	-16.67	14.43	-33.3	-16.67	0.0
Study Disc 1	135	16.54	24.98	0.0	0.00	100.0	133	2.13	25.16	-100.0	0.00	83.3
30 D SFU Z/P	58	15.23	25.61	0.0	0.00	100.0	57	1.75	29.66	-100.0	0.00	83.3
90 D SFU Z/P	62	9.68	17.48	0.0	0.00	100.0	61	-0.27	18.63	-50.0	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	17.29	24.69	0.0	0.00	100.0						
Cycle 2 Day 1	222	12.61	19.12	0.0	0.00	100.0	216	-4.63	22.20	-83.3	0.00	66.7
Cycle 3 Day 1	200	10.17	18.74	0.0	0.00	100.0	196	-6.04	20.37	-83.3	0.00	66.7
Cycle 4 Day 1	171	8.87	15.79	0.0	0.00	100.0	169	-8.19	21.14	-100.0	0.00	33.3
Cycle 5 Day 1	166	8.73	15.32	0.0	0.00	83.3	165	-7.58	23.75	-100.0	0.00	50.0
Cycle 6 Day 1	146	10.27	17.75	0.0	0.00	83.3	145	-5.98	22.96	-100.0	0.00	66.7
Cycle 7 Day 1	126	10.19	15.49	0.0	0.00	66.7	125	-5.33	24.19	-100.0	0.00	50.0
Cycle 8 Day 1	110	9.55	16.04	0.0	0.00	66.7	109	-7.19	23.83	-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: 12JAN24

Table 302.3.3002.23: 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 9 Day 1	104	8.01	14.68	0.0	0.00	83.3	103	-7.93	24.35	-100.0	0.00	50.0
Cycle 10 Day 1	81	8.85	17.89	0.0	0.00	100.0	79	-8.02	28.35	-100.0	0.00	100.0
Cycle 11 Day 1	72	6.48	14.14	0.0	0.00	66.7	71	-9.62	27.26	-100.0	0.00	66.7
Cycle 12 Day 1	59	6.21	12.34	0.0	0.00	50.0	57	-7.60	22.29	-83.3	0.00	50.0
Cycle 13 Day 1	50	7.33	13.95	0.0	0.00	50.0	48	-7.99	25.50	-100.0	0.00	50.0
Cycle 14 Day 1	46	8.33	17.48	0.0	0.00	66.7	44	-5.68	24.10	-100.0	0.00	33.3
Cycle 15 Day 1	38	10.09	20.33	0.0	0.00	100.0	36	-3.24	27.55	-100.0	0.00	66.7
Cycle 16 Day 1	33	10.10	17.15	0.0	0.00	66.7	31	0.00	23.17	-83.3	0.00	50.0
Cycle 17 Day 1	28	7.14	14.65	0.0	0.00	66.7	25	-2.67	24.38	-100.0	0.00	33.3
Cycle 18 Day 1	23	5.07	10.58	0.0	0.00	33.3	21	-5.56	23.77	-100.0	0.00	16.7
Cycle 19 Day 1	21	3.97	11.67	0.0	0.00	50.0	20	-2.50	13.55	-33.3	0.00	33.3
Cycle 20 Day 1	20	5.00	9.52	0.0	0.00	33.3	19	-7.02	25.65	-100.0	0.00	16.7
Cycle 21 Day 1	21	3.97	8.98	0.0	0.00	33.3	20	-7.50	22.60	-83.3	0.00	33.3
Cycle 22 Day 1	18	7.41	14.26	0.0	0.00	50.0	17	-5.88	27.60	-100.0	0.00	33.3
Cycle 23 Day 1	17	6.86	17.74	0.0	0.00	66.7	16	-7.29	29.17	-100.0	0.00	50.0
Cycle 24 Day 1	13	3.85	9.99	0.0	0.00	33.3	12	-11.11	29.59	-100.0	0.00	16.7
Cycle 25 Day 1	13	5.13	10.51	0.0	0.00	33.3	12	-9.72	30.53	-100.0	0.00	16.7
Cycle 26 Day 1	10	5.00	8.05	0.0	0.00	16.7	9	-1.85	13.03	-16.7	0.00	16.7
Cycle 27 Day 1	11	4.55	10.78	0.0	0.00	33.3	10	-1.67	14.59	-16.7	0.00	33.3
Cycle 28 Day 1	11	4.55	7.78	0.0	0.00	16.7	11	-1.52	11.68	-16.7	0.00	16.7
Cycle 29 Day 1	12	6.94	13.22	0.0	0.00	33.3	12	-1.39	8.58	-16.7	0.00	16.7
Study Disc 1	156	19.87	26.58	0.0	0.00	100.0	150	4.11	27.24	-100.0	0.00	83.3
30 D SFU Z/P	78	18.80	28.35	0.0	0.00	100.0	76	2.19	27.53	-100.0	0.00	66.7
90 D SFU Z/P	81	14.40	21.04	0.0	0.00	100.0	79	-0.21	23.19	-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: 12JAN24

Table 302.3.3002.24: 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 + CAPOX (N=254)												
Baseline	243	23.53	23.88	0.0	16.67	100.0						
Cycle 2 Day 1	209	18.98	20.12	0.0	16.67	100.0	208	-4.25	23.38	-100.0	0.00	66.7
Cycle 3 Day 1	186	16.94	18.62	0.0	16.67	66.7	182	-6.59	22.14	-100.0	0.00	33.3
Cycle 4 Day 1	169	15.98	18.75	0.0	0.00	83.3	166	-7.33	24.99	-100.0	0.00	50.0
Cycle 5 Day 1	163	14.93	17.72	0.0	0.00	83.3	159	-7.44	20.43	-83.3	0.00	33.3
Cycle 6 Day 1	151	16.78	23.77	0.0	0.00	100.0	149	-5.82	25.48	-100.0	0.00	66.7
Cycle 7 Day 1	121	13.77	17.83	0.0	0.00	66.7	119	-8.54	23.95	-100.0	0.00	66.7
Cycle 8 Day 1	114	15.79	20.06	0.0	8.33	100.0	108	-7.10	23.04	-100.0	0.00	33.3
Cycle 9 Day 1	107	19.16	23.66	0.0	16.67	100.0	102	-5.07	24.57	-100.0	0.00	66.7
Cycle 10 Day 1	88	15.53	21.41	0.0	0.00	100.0	85	-8.24	26.80	-100.0	0.00	66.7
Cycle 11 Day 1	83	13.86	21.44	0.0	0.00	100.0	80	-7.71	30.00	-100.0	0.00	83.3
Cycle 12 Day 1	77	14.72	19.86	0.0	0.00	100.0	75	-6.44	27.52	-100.0	0.00	66.7
Cycle 13 Day 1	62	11.29	15.90	0.0	0.00	66.7	60	-11.39	27.19	-100.0	0.00	33.3
Cycle 14 Day 1	57	10.53	13.96	0.0	0.00	33.3	55	-9.39	25.21	-100.0	0.00	33.3
Cycle 15 Day 1	53	12.26	15.38	0.0	0.00	50.0	51	-8.82	24.12	-83.3	0.00	50.0
Cycle 16 Day 1	50	10.67	14.97	0.0	0.00	50.0	48	-12.15	24.73	-83.3	-8.33	33.3
Cycle 17 Day 1	45	12.96	15.03	0.0	0.00	33.3	43	-9.69	25.00	-66.7	0.00	33.3
Cycle 18 Day 1	43	11.63	16.07	0.0	0.00	66.7	41	-11.79	22.44	-83.3	0.00	33.3
Cycle 19 Day 1	42	15.08	16.38	0.0	16.67	66.7	40	-5.83	22.82	-66.7	0.00	33.3
Cycle 20 Day 1	41	15.04	18.56	0.0	0.00	66.7	39	-5.56	19.99	-66.7	0.00	33.3
Cycle 21 Day 1	38	13.16	18.65	0.0	0.00	66.7	36	-7.41	20.10	-66.7	0.00	33.3
Cycle 22 Day 1	33	13.64	22.99	0.0	0.00	100.0	31	-8.06	21.89	-66.7	0.00	33.3
Cycle 23 Day 1	33	9.60	17.19	0.0	0.00	66.7	31	-10.22	20.04	-66.7	0.00	33.3
Cycle 24 Day 1	31	9.14	14.17	0.0	0.00	50.0	29	-8.62	21.19	-66.7	0.00	33.3
Cycle 25 Day 1	30	5.56	11.85	0.0	0.00	33.3	28	-11.90	23.07	-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: 12JAN24

Table 302.3.3002.24: 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 26 Day 1	28	10.71	17.69	0.0	0.00	66.7	26	-7.69	26.76	-66.7	0.00	66.7
Cycle 27 Day 1	27	8.02	12.55	0.0	0.00	33.3	25	-12.00	21.79	-66.7	0.00	33.3
Cycle 28 Day 1	23	10.87	19.85	0.0	0.00	66.7	21	-11.90	22.45	-66.7	-16.67	33.3
Cycle 29 Day 1	24	9.03	17.01	0.0	0.00	66.7	22	-12.88	21.16	-66.7	-8.33	33.3
Cycle 30 Day 1	22	10.61	18.22	0.0	0.00	66.7	20	-10.83	24.35	-66.7	-8.33	33.3
Cycle 31 Day 1	22	9.09	17.61	0.0	0.00	66.7	20	-15.00	22.23	-66.7	-16.67	33.3
Cycle 32 Day 1	20	7.50	17.50	0.0	0.00	66.7	18	-17.59	18.50	-66.7	-16.67	0.0
Cycle 33 Day 1	17	4.90	9.80	0.0	0.00	33.3	15	-13.33	21.08	-33.3	-16.67	33.3
Cycle 34 Day 1	14	3.57	7.10	0.0	0.00	16.7	12	-20.83	23.70	-66.7	-16.67	16.7
Cycle 35 Day 1	15	3.33	6.90	0.0	0.00	16.7	13	-21.79	21.93	-66.7	-33.33	16.7
Cycle 36 Day 1	14	7.14	12.60	0.0	0.00	33.3	12	-19.44	17.16	-33.3	-25.00	16.7
Cycle 37 Day 1	12	6.94	13.22	0.0	0.00	33.3	11	-13.64	20.84	-33.3	-16.67	33.3
Cycle 38 Day 1	11	7.58	20.23	0.0	0.00	66.7	10	-13.33	33.15	-50.0	-25.00	66.7
Cycle 39 Day 1	10	1.67	5.27	0.0	0.00	16.7	9	-22.22	18.63	-50.0	-33.33	0.0
Study Disc 1	135	25.68	27.53	0.0	33.33	100.0	133	4.64	26.06	-66.7	0.00	100.0
30 D SFU Z/P	58	19.54	26.33	0.0	0.00	100.0	57	0.88	29.45	-100.0	0.00	66.7
90 D SFU Z/P	62	15.86	23.07	0.0	0.00	100.0	61	-1.37	26.75	-66.7	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	241	25.38	25.42	0.0	33.33	100.0						
Cycle 2 Day 1	222	18.47	20.04	0.0	16.67	100.0	216	-6.94	24.18	-83.3	0.00	66.7
Cycle 3 Day 1	200	16.00	20.72	0.0	0.00	100.0	196	-8.25	21.97	-100.0	0.00	66.7
Cycle 4 Day 1	171	14.04	18.02	0.0	0.00	100.0	169	-11.34	24.08	-100.0	0.00	66.7
Cycle 5 Day 1	166	13.86	18.50	0.0	0.00	83.3	165	-11.41	26.21	-100.0	0.00	66.7
Cycle 6 Day 1	146	15.07	19.51	0.0	0.00	100.0	145	-9.31	27.28	-100.0	0.00	66.7
Cycle 7 Day 1	126	14.29	17.73	0.0	0.00	100.0	125	-9.20	24.54	-100.0	0.00	50.0
Cycle 8 Day 1	110	13.03	17.97	0.0	0.00	66.7	109	-9.94	25.87	-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: 12JAN24

Table 302.3.3002.24: 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 9 Day 1	104	13.94	19.31	0.0	0.00	100.0	103	-8.09	26.08	-100.0	0.00	66.7
Cycle 10 Day 1	81	13.99	21.16	0.0	0.00	100.0	79	-8.23	28.48	-83.3	0.00	100.0
Cycle 11 Day 1	72	13.89	18.34	0.0	0.00	66.7	71	-8.22	28.99	-100.0	0.00	66.7
Cycle 12 Day 1	59	12.99	18.84	0.0	0.00	66.7	57	-5.85	25.49	-83.3	0.00	66.7
Cycle 13 Day 1	50	13.33	16.84	0.0	0.00	66.7	48	-8.33	29.97	-100.0	0.00	50.0
Cycle 14 Day 1	46	14.86	21.72	0.0	0.00	100.0	44	-3.79	27.81	-66.7	0.00	66.7
Cycle 15 Day 1	38	15.35	23.05	0.0	0.00	100.0	36	-4.17	29.11	-83.3	0.00	66.7
Cycle 16 Day 1	33	12.12	20.53	0.0	0.00	66.7	31	-5.38	28.35	-83.3	0.00	66.7
Cycle 17 Day 1	28	7.74	15.37	0.0	0.00	66.7	25	-6.00	28.41	-100.0	0.00	66.7
Cycle 18 Day 1	23	9.42	14.06	0.0	0.00	33.3	21	-6.35	28.61	-100.0	0.00	33.3
Cycle 19 Day 1	21	5.56	12.17	0.0	0.00	33.3	20	-5.00	17.18	-33.3	0.00	33.3
Cycle 20 Day 1	20	9.17	13.76	0.0	0.00	33.3	19	-7.02	26.83	-83.3	0.00	33.3
Cycle 21 Day 1	21	5.56	12.17	0.0	0.00	33.3	20	-10.00	23.82	-66.7	-8.33	33.3
Cycle 22 Day 1	18	10.19	14.16	0.0	0.00	33.3	17	-5.88	31.70	-100.0	0.00	33.3
Cycle 23 Day 1	17	10.78	18.58	0.0	0.00	66.7	16	-8.33	29.81	-100.0	0.00	33.3
Cycle 24 Day 1	13	8.97	12.94	0.0	0.00	33.3	12	-8.33	29.73	-83.3	0.00	33.3
Cycle 25 Day 1	13	7.69	16.12	0.0	0.00	50.0	12	-9.72	32.14	-83.3	0.00	50.0
Cycle 26 Day 1	10	6.67	21.08	0.0	0.00	66.7	9	-1.85	28.19	-33.3	0.00	66.7
Cycle 27 Day 1	11	4.55	10.78	0.0	0.00	33.3	10	-3.33	15.32	-16.7	0.00	33.3
Cycle 28 Day 1	11	10.61	20.10	0.0	0.00	66.7	11	3.03	22.13	-16.7	0.00	66.7
Cycle 29 Day 1	12	8.33	13.30	0.0	0.00	33.3	12	-1.39	11.14	-16.7	0.00	16.7
Study Disc 1	156	26.18	28.02	0.0	25.00	100.0	150	0.89	30.88	-100.0	0.00	100.0
30 D SFU Z/P	78	25.43	28.64	0.0	16.67	100.0	76	1.32	27.99	-66.7	0.00	66.7
90 D SFU Z/P	81	19.55	23.83	0.0	16.67	100.0	79	-2.95	23.08	-66.7	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: 12JAN24

Table 302.3.3002.25: 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 + CAPOX (N=254)												
Baseline	243	38.96	28.31	0.0	33.33	100.0						
Cycle 2 Day 1	209	34.21	28.18	0.0	33.33	100.0	208	-3.93	25.15	-66.7	0.00	83.3
Cycle 3 Day 1	186	35.04	25.79	0.0	33.33	100.0	182	-3.02	24.93	-66.7	0.00	66.7
Cycle 4 Day 1	169	33.14	25.72	0.0	33.33	100.0	166	-4.12	24.65	-83.3	0.00	83.3
Cycle 5 Day 1	163	34.56	28.66	0.0	33.33	100.0	159	-2.73	26.24	-83.3	0.00	83.3
Cycle 6 Day 1	151	31.35	24.94	0.0	33.33	100.0	149	-6.04	23.43	-100.0	0.00	66.7
Cycle 7 Day 1	121	31.54	27.37	0.0	33.33	100.0	119	-3.64	23.28	-66.7	0.00	66.7
Cycle 8 Day 1	114	33.19	28.18	0.0	33.33	100.0	108	-4.32	25.21	-83.3	0.00	66.7
Cycle 9 Day 1	107	32.71	28.50	0.0	33.33	100.0	102	-5.23	25.80	-100.0	0.00	66.7
Cycle 10 Day 1	88	30.11	26.24	0.0	33.33	100.0	85	-7.45	28.11	-100.0	0.00	66.7
Cycle 11 Day 1	83	28.31	23.68	0.0	33.33	100.0	80	-7.29	28.54	-100.0	0.00	66.7
Cycle 12 Day 1	77	26.19	23.17	0.0	33.33	100.0	75	-10.00	29.38	-100.0	0.00	66.7
Cycle 13 Day 1	62	28.23	25.17	0.0	33.33	100.0	60	-7.78	30.76	-100.0	0.00	66.7
Cycle 14 Day 1	57	26.90	24.95	0.0	33.33	100.0	55	-7.88	28.30	-100.0	0.00	66.7
Cycle 15 Day 1	53	28.93	22.21	0.0	33.33	100.0	51	-8.50	28.55	-83.3	0.00	66.7
Cycle 16 Day 1	50	20.67	21.44	0.0	25.00	100.0	48	-15.62	27.38	-83.3	-16.67	66.7
Cycle 17 Day 1	45	31.85	24.05	0.0	33.33	100.0	43	-6.98	24.19	-66.7	0.00	66.7
Cycle 18 Day 1	43	31.01	23.73	0.0	33.33	100.0	41	-7.32	28.64	-83.3	0.00	66.7
Cycle 19 Day 1	42	29.76	24.57	0.0	33.33	100.0	40	-8.33	25.88	-66.7	0.00	66.7
Cycle 20 Day 1	41	27.24	23.79	0.0	33.33	100.0	39	-9.83	24.99	-66.7	0.00	66.7
Cycle 21 Day 1	38	28.51	24.48	0.0	33.33	100.0	36	-9.26	29.93	-83.3	0.00	66.7
Cycle 22 Day 1	33	31.82	32.37	0.0	33.33	100.0	31	-4.84	27.28	-66.7	0.00	66.7
Cycle 23 Day 1	33	25.25	25.39	0.0	33.33	100.0	31	-10.22	26.76	-66.7	0.00	66.7
Cycle 24 Day 1	31	22.58	23.78	0.0	33.33	100.0	29	-9.77	28.00	-66.7	0.00	66.7
Cycle 25 Day 1	30	22.78	24.17	0.0	33.33	100.0	28	-10.71	24.52	-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: 12JAN24

Table 302.3.3002.25: 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 26 Day 1	28	23.81	25.43	0.0	33.33	100.0	26	-7.69	25.49	-66.7	0.00	66.7
Cycle 27 Day 1	27	23.46	29.33	0.0	16.67	100.0	25	-9.33	30.08	-66.7	0.00	66.7
Cycle 28 Day 1	23	29.71	28.41	0.0	33.33	100.0	21	-10.32	31.83	-66.7	-16.67	66.7
Cycle 29 Day 1	24	29.17	24.20	0.0	33.33	100.0	22	-6.82	33.20	-100.0	0.00	66.7
Cycle 30 Day 1	22	28.79	23.67	0.0	33.33	100.0	20	-5.00	26.55	-33.3	-8.33	66.7
Cycle 31 Day 1	22	31.06	27.84	0.0	33.33	100.0	20	-7.50	28.34	-66.7	0.00	66.7
Cycle 32 Day 1	20	28.33	24.84	0.0	33.33	100.0	18	-10.19	32.91	-66.7	-16.67	66.7
Cycle 33 Day 1	17	30.39	26.51	0.0	33.33	100.0	15	-4.44	30.52	-66.7	0.00	66.7
Cycle 34 Day 1	14	26.19	29.03	0.0	25.00	100.0	12	-13.89	27.37	-66.7	-8.33	33.3
Cycle 35 Day 1	15	26.67	25.04	0.0	33.33	66.7	13	-10.26	25.04	-50.0	0.00	50.0
Cycle 36 Day 1	14	25.00	23.34	0.0	33.33	66.7	12	-12.50	26.71	-66.7	-8.33	33.3
Cycle 37 Day 1	12	16.67	26.59	0.0	0.00	66.7	11	-25.76	20.23	-66.7	-33.33	0.0
Cycle 38 Day 1	11	27.27	25.03	0.0	33.33	66.7	10	-18.33	22.84	-66.7	-8.33	0.0
Cycle 39 Day 1	10	31.67	27.72	0.0	33.33	83.3	9	-14.81	34.81	-100.0	0.00	16.7
Study Disc 1	135	38.89	31.08	0.0	33.33	100.0	133	1.63	31.37	-100.0	0.00	100.0
30 D SFU Z/P	58	40.80	30.13	0.0	33.33	100.0	57	2.34	31.25	-100.0	0.00	83.3
90 D SFU Z/P	62	33.06	27.41	0.0	33.33	100.0	61	0.27	27.47	-66.7	0.00	83.3
Placebo + CAPOX (N=253)												
Baseline	241	42.05	28.30	0.0	33.33	100.0						
Cycle 2 Day 1	222	35.96	27.40	0.0	33.33	100.0	216	-7.02	25.23	-66.7	0.00	66.7
Cycle 3 Day 1	200	36.25	26.91	0.0	33.33	100.0	196	-6.04	25.63	-83.3	0.00	66.7
Cycle 4 Day 1	171	34.21	28.48	0.0	33.33	100.0	169	-7.20	26.96	-66.7	0.00	66.7
Cycle 5 Day 1	166	33.84	26.11	0.0	33.33	100.0	165	-6.77	27.66	-66.7	0.00	66.7
Cycle 6 Day 1	146	32.19	26.67	0.0	33.33	100.0	145	-8.51	29.14	-66.7	0.00	100.0
Cycle 7 Day 1	126	30.03	26.42	0.0	33.33	100.0	125	-8.80	26.23	-66.7	0.00	66.7
Cycle 8 Day 1	110	33.64	27.74	0.0	33.33	100.0	109	-8.87	29.79	-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: 12JAN24

Table 302.3.3002.25: 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 9 Day 1	104	33.49	26.53	0.0	33.33	100.0	103	-6.96	26.04	-66.7	0.00	66.7
Cycle 10 Day 1	81	30.86	28.52	0.0	33.33	100.0	79	-11.60	32.40	-100.0	0.00	66.7
Cycle 11 Day 1	72	31.02	26.58	0.0	33.33	100.0	71	-8.69	31.35	-100.0	0.00	66.7
Cycle 12 Day 1	59	31.36	26.82	0.0	33.33	100.0	57	-8.19	31.67	-100.0	0.00	66.7
Cycle 13 Day 1	50	32.33	25.51	0.0	33.33	100.0	48	-6.60	31.08	-66.7	0.00	66.7
Cycle 14 Day 1	46	29.71	25.56	0.0	33.33	100.0	44	-5.68	31.53	-66.7	0.00	66.7
Cycle 15 Day 1	38	28.51	28.71	0.0	33.33	100.0	36	-6.02	33.13	-66.7	0.00	66.7
Cycle 16 Day 1	33	27.78	26.24	0.0	33.33	100.0	31	-3.76	37.44	-66.7	0.00	66.7
Cycle 17 Day 1	28	25.60	22.90	0.0	33.33	66.7	25	-6.67	34.69	-83.3	0.00	66.7
Cycle 18 Day 1	23	23.91	22.38	0.0	16.67	66.7	21	-10.32	37.07	-83.3	0.00	50.0
Cycle 19 Day 1	21	26.19	22.71	0.0	33.33	66.7	20	-2.50	27.72	-66.7	0.00	66.7
Cycle 20 Day 1	20	25.00	23.88	0.0	25.00	66.7	19	-8.77	35.73	-83.3	0.00	66.7
Cycle 21 Day 1	21	19.05	21.27	0.0	16.67	66.7	20	-11.67	35.91	-83.3	0.00	66.7
Cycle 22 Day 1	18	27.78	22.14	0.0	33.33	66.7	17	-7.84	40.45	-83.3	0.00	66.7
Cycle 23 Day 1	17	20.59	26.04	0.0	0.00	66.7	16	-10.42	35.42	-66.7	-8.33	66.7
Cycle 24 Day 1	13	23.08	25.04	0.0	33.33	66.7	12	-9.72	41.72	-66.7	0.00	66.7
Cycle 25 Day 1	13	23.08	25.04	0.0	33.33	66.7	12	-11.11	40.41	-66.7	0.00	66.7
Cycle 26 Day 1	10	26.67	29.61	0.0	25.00	83.3	9	3.70	34.13	-33.3	0.00	66.7
Cycle 27 Day 1	11	30.30	22.13	0.0	33.33	66.7	10	6.67	29.61	-50.0	0.00	66.7
Cycle 28 Day 1	11	24.24	25.13	0.0	16.67	66.7	11	1.52	29.30	-50.0	0.00	66.7
Cycle 29 Day 1	12	25.00	32.18	0.0	16.67	100.0	12	1.39	37.24	-66.7	0.00	66.7
Study Disc 1	156	46.15	29.20	0.0	33.33	100.0	150	2.89	29.20	-66.7	0.00	83.3
30 D SFU Z/P	78	47.86	30.55	0.0	33.33	100.0	76	3.51	26.15	-50.0	0.00	66.7
90 D SFU Z/P	81	39.71	29.65	0.0	33.33	100.0	79	-4.22	31.29	-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: 12JAN24

Table 302.3.3002.26: 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 + CAPOX (N=254)												
Baseline	243	10.70	21.53	0.0	0.00	100.0						
Cycle 2 Day 1	209	7.18	15.56	0.0	0.00	66.7	208	-3.21	18.25	-100.0	0.00	66.7
Cycle 3 Day 1	186	6.27	13.95	0.0	0.00	66.7	182	-2.01	18.26	-100.0	0.00	66.7
Cycle 4 Day 1	169	5.92	14.70	0.0	0.00	100.0	166	-3.01	16.34	-66.7	0.00	33.3
Cycle 5 Day 1	163	7.16	15.60	0.0	0.00	100.0	159	-1.68	15.82	-66.7	0.00	33.3
Cycle 6 Day 1	151	8.61	18.24	0.0	0.00	100.0	149	-0.22	15.25	-33.3	0.00	33.3
Cycle 7 Day 1	121	6.89	14.86	0.0	0.00	66.7	119	-0.84	18.13	-66.7	0.00	66.7
Cycle 8 Day 1	114	7.60	15.38	0.0	0.00	66.7	108	-2.47	18.63	-66.7	0.00	33.3
Cycle 9 Day 1	107	8.41	18.93	0.0	0.00	100.0	102	-1.63	21.69	-66.7	0.00	66.7
Cycle 10 Day 1	88	7.20	18.53	0.0	0.00	100.0	85	-2.35	23.45	-66.7	0.00	100.0
Cycle 11 Day 1	83	6.02	15.74	0.0	0.00	100.0	80	-2.92	19.98	-66.7	0.00	66.7
Cycle 12 Day 1	77	6.06	15.03	0.0	0.00	66.7	75	-3.11	20.63	-66.7	0.00	66.7
Cycle 13 Day 1	62	4.84	11.84	0.0	0.00	33.3	60	-5.56	21.41	-66.7	0.00	33.3
Cycle 14 Day 1	57	4.68	13.27	0.0	0.00	66.7	55	-4.85	20.71	-66.7	0.00	66.7
Cycle 15 Day 1	53	1.89	7.78	0.0	0.00	33.3	51	-8.50	21.95	-66.7	0.00	33.3
Cycle 16 Day 1	50	4.00	10.94	0.0	0.00	33.3	48	-6.94	18.14	-66.7	0.00	33.3
Cycle 17 Day 1	45	5.19	12.22	0.0	0.00	33.3	43	-6.20	19.59	-66.7	0.00	33.3
Cycle 18 Day 1	43	3.88	10.81	0.0	0.00	33.3	41	-8.13	19.41	-66.7	0.00	33.3
Cycle 19 Day 1	42	2.38	8.69	0.0	0.00	33.3	40	-10.83	21.86	-66.7	0.00	33.3
Cycle 20 Day 1	41	4.07	11.04	0.0	0.00	33.3	39	-8.55	19.82	-66.7	0.00	33.3
Cycle 21 Day 1	38	4.39	11.42	0.0	0.00	33.3	36	-8.33	20.12	-66.7	0.00	33.3
Cycle 22 Day 1	33	6.06	13.06	0.0	0.00	33.3	31	-6.45	18.09	-66.7	0.00	33.3
Cycle 23 Day 1	33	3.03	9.73	0.0	0.00	33.3	31	-7.53	18.68	-66.7	0.00	0.0
Cycle 24 Day 1	31	5.38	15.15	0.0	0.00	66.7	29	-3.45	18.57	-66.7	0.00	33.3
Cycle 25 Day 1	30	6.67	13.56	0.0	0.00	33.3	28	-2.38	20.14	-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: 12JAN24

Table 302.3.3002.26: 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 26 Day 1	28	3.57	10.50	0.0	0.00	33.3	26	-6.41	18.90	-66.7	0.00	33.3
Cycle 27 Day 1	27	6.17	13.19	0.0	0.00	33.3	25	-2.67	19.05	-66.7	0.00	33.3
Cycle 28 Day 1	23	7.25	17.28	0.0	0.00	66.7	21	-4.76	26.43	-66.7	0.00	66.7
Cycle 29 Day 1	24	2.78	9.41	0.0	0.00	33.3	22	-9.09	21.04	-66.7	0.00	0.0
Cycle 30 Day 1	22	4.55	11.71	0.0	0.00	33.3	20	-6.67	23.20	-66.7	0.00	33.3
Cycle 31 Day 1	22	3.03	9.81	0.0	0.00	33.3	20	-10.00	21.90	-66.7	0.00	33.3
Cycle 32 Day 1	20	6.67	13.68	0.0	0.00	33.3	18	-7.41	24.40	-66.7	0.00	33.3
Cycle 33 Day 1	17	1.96	8.08	0.0	0.00	33.3	15	-8.89	23.46	-66.7	0.00	33.3
Cycle 34 Day 1	14	0.00	0.00	0.0	0.00	0.0	12	-16.67	22.47	-66.7	0.00	0.0
Cycle 35 Day 1	15	8.89	15.26	0.0	0.00	33.3	13	-5.13	22.96	-66.7	0.00	33.3
Cycle 36 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-11.11	21.71	-66.7	0.00	0.0
Cycle 37 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-12.12	22.47	-66.7	0.00	0.0
Cycle 38 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	-16.67	23.57	-66.7	0.00	0.0
Cycle 39 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	-7.41	14.70	-33.3	0.00	0.0
Study Disc 1	135	12.35	25.99	0.0	0.00	100.0	133	2.76	23.23	-66.7	0.00	100.0
30 D SFU Z/P	58	10.92	24.49	0.0	0.00	100.0	57	2.92	23.81	-66.7	0.00	100.0
90 D SFU Z/P	62	8.06	17.79	0.0	0.00	66.7	61	3.28	18.96	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	10.51	22.36	0.0	0.00	100.0						
Cycle 2 Day 1	222	6.91	16.24	0.0	0.00	100.0	216	-3.09	19.04	-100.0	0.00	33.3
Cycle 3 Day 1	200	7.33	18.05	0.0	0.00	100.0	196	-3.06	19.15	-100.0	0.00	66.7
Cycle 4 Day 1	171	4.09	13.14	0.0	0.00	100.0	169	-7.10	21.57	-100.0	0.00	33.3
Cycle 5 Day 1	166	5.42	13.39	0.0	0.00	66.7	165	-5.45	23.37	-100.0	0.00	66.7
Cycle 6 Day 1	146	5.48	15.18	0.0	0.00	100.0	145	-4.83	21.51	-100.0	0.00	33.3
Cycle 7 Day 1	126	5.56	16.19	0.0	0.00	100.0	125	-4.53	20.45	-100.0	0.00	66.7
Cycle 8 Day 1	110	5.15	13.69	0.0	0.00	66.7	109	-5.81	21.20	-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: 12JAN24

Table 302.3.3002.26: 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 9 Day 1	104	4.81	13.48	0.0	0.00	66.7	103	-5.50	21.44	-100.0	0.00	66.7
Cycle 10 Day 1	81	3.70	10.54	0.0	0.00	33.3	79	-6.33	20.03	-100.0	0.00	33.3
Cycle 11 Day 1	72	3.70	10.55	0.0	0.00	33.3	71	-4.69	19.76	-100.0	0.00	33.3
Cycle 12 Day 1	59	2.26	8.45	0.0	0.00	33.3	57	-4.09	14.18	-33.3	0.00	33.3
Cycle 13 Day 1	50	6.67	15.06	0.0	0.00	66.7	48	0.00	16.84	-33.3	0.00	66.7
Cycle 14 Day 1	46	2.17	8.32	0.0	0.00	33.3	44	-4.55	13.62	-66.7	0.00	0.0
Cycle 15 Day 1	38	4.39	11.42	0.0	0.00	33.3	36	-0.93	9.71	-33.3	0.00	33.3
Cycle 16 Day 1	33	6.06	15.49	0.0	0.00	66.7	31	-1.08	16.06	-66.7	0.00	33.3
Cycle 17 Day 1	28	5.95	15.85	0.0	0.00	66.7	25	0.00	16.67	-66.7	0.00	33.3
Cycle 18 Day 1	23	2.90	9.60	0.0	0.00	33.3	21	-3.17	14.55	-66.7	0.00	0.0
Cycle 19 Day 1	21	1.59	7.27	0.0	0.00	33.3	20	-1.67	7.45	-33.3	0.00	0.0
Cycle 20 Day 1	20	6.67	13.68	0.0	0.00	33.3	19	0.00	19.25	-66.7	0.00	33.3
Cycle 21 Day 1	21	3.17	10.03	0.0	0.00	33.3	20	-3.33	14.91	-66.7	0.00	0.0
Cycle 22 Day 1	18	3.70	10.78	0.0	0.00	33.3	17	-3.92	16.17	-66.7	0.00	0.0
Cycle 23 Day 1	17	1.96	8.08	0.0	0.00	33.3	16	-6.25	18.13	-66.7	0.00	0.0
Cycle 24 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	-5.56	19.25	-66.7	0.00	0.0
Cycle 25 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	-5.56	19.25	-66.7	0.00	0.0
Cycle 26 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	-3.70	11.11	-33.3	0.00	0.0
Cycle 27 Day 1	11	6.06	13.48	0.0	0.00	33.3	10	0.00	0.00	0.0	0.00	0.0
Cycle 28 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	10.05	-33.3	0.00	0.0
Cycle 29 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
Study Disc 1	156	13.89	25.95	0.0	0.00	100.0	150	3.11	24.83	-100.0	0.00	100.0
30 D SFU Z/P	78	12.82	28.54	0.0	0.00	100.0	76	1.75	24.28	-100.0	0.00	100.0
90 D SFU Z/P	81	10.70	22.25	0.0	0.00	100.0	79	2.53	16.69	-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: 12JAN24

Table 302.3.3002.27: 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 + CAPOX (N=254)												
Baseline	243	19.20	24.74	0.0	0.00	100.0						
Cycle 2 Day 1	209	20.73	23.47	0.0	33.33	100.0	208	-0.32	23.40	-66.7	0.00	100.0
Cycle 3 Day 1	186	19.71	24.38	0.0	0.00	100.0	182	-0.55	23.89	-66.7	0.00	100.0
Cycle 4 Day 1	169	18.34	24.10	0.0	0.00	100.0	166	-2.01	25.08	-66.7	0.00	100.0
Cycle 5 Day 1	163	19.63	25.85	0.0	0.00	100.0	159	-1.05	26.89	-66.7	0.00	100.0
Cycle 6 Day 1	151	21.41	26.48	0.0	0.00	100.0	149	0.89	27.93	-100.0	0.00	100.0
Cycle 7 Day 1	121	20.66	27.30	0.0	0.00	100.0	119	-0.28	27.62	-66.7	0.00	100.0
Cycle 8 Day 1	114	18.42	24.33	0.0	0.00	100.0	108	-1.85	25.71	-100.0	0.00	66.7
Cycle 9 Day 1	107	20.56	26.16	0.0	0.00	100.0	102	0.00	28.92	-66.7	0.00	100.0
Cycle 10 Day 1	88	14.02	25.13	0.0	0.00	100.0	85	-5.88	28.72	-66.7	0.00	100.0
Cycle 11 Day 1	83	13.25	22.66	0.0	0.00	100.0	80	-4.58	26.38	-66.7	0.00	66.7
Cycle 12 Day 1	77	9.96	18.78	0.0	0.00	100.0	75	-5.78	26.49	-66.7	0.00	66.7
Cycle 13 Day 1	62	12.37	17.32	0.0	0.00	66.7	60	-5.00	26.63	-66.7	0.00	66.7
Cycle 14 Day 1	57	9.36	16.37	0.0	0.00	66.7	55	-7.27	26.21	-66.7	0.00	66.7
Cycle 15 Day 1	53	12.58	18.75	0.0	0.00	66.7	51	-5.88	24.68	-66.7	0.00	66.7
Cycle 16 Day 1	50	12.00	19.93	0.0	0.00	100.0	48	-7.64	25.02	-66.7	0.00	33.3
Cycle 17 Day 1	45	11.85	20.30	0.0	0.00	100.0	43	-6.20	19.59	-66.7	0.00	33.3
Cycle 18 Day 1	43	12.40	20.60	0.0	0.00	100.0	41	-5.69	19.58	-33.3	0.00	33.3
Cycle 19 Day 1	42	8.73	20.90	0.0	0.00	100.0	40	-9.17	25.02	-66.7	0.00	33.3
Cycle 20 Day 1	41	9.76	20.06	0.0	0.00	100.0	39	-8.55	21.24	-66.7	0.00	33.3
Cycle 21 Day 1	38	13.16	21.28	0.0	0.00	100.0	36	-5.56	24.56	-66.7	0.00	33.3
Cycle 22 Day 1	33	7.07	13.84	0.0	0.00	33.3	31	-9.68	23.08	-66.7	0.00	33.3
Cycle 23 Day 1	33	9.09	15.08	0.0	0.00	33.3	31	-7.53	23.90	-66.7	0.00	33.3
Cycle 24 Day 1	31	9.68	15.38	0.0	0.00	33.3	29	-6.90	24.20	-66.7	0.00	33.3
Cycle 25 Day 1	30	5.56	12.63	0.0	0.00	33.3	28	-10.71	22.32	-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: 12JAN24

Table 302.3.3002.27: 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 26 Day 1	28	7.14	13.93	0.0	0.00	33.3	26	-8.97	27.58	-66.7	0.00	33.3
Cycle 27 Day 1	27	9.88	15.51	0.0	0.00	33.3	25	-6.67	21.52	-33.3	0.00	33.3
Cycle 28 Day 1	23	11.59	16.23	0.0	0.00	33.3	21	-4.76	26.43	-66.7	0.00	33.3
Cycle 29 Day 1	24	11.11	16.05	0.0	0.00	33.3	22	-6.06	28.43	-66.7	0.00	33.3
Cycle 30 Day 1	22	12.12	16.41	0.0	0.00	33.3	20	-5.00	24.84	-33.3	0.00	33.3
Cycle 31 Day 1	22	10.61	15.89	0.0	0.00	33.3	20	-8.33	28.36	-66.7	0.00	33.3
Cycle 32 Day 1	20	10.00	15.67	0.0	0.00	33.3	18	-11.11	30.25	-66.7	0.00	33.3
Cycle 33 Day 1	17	5.88	13.10	0.0	0.00	33.3	15	-15.56	21.33	-66.7	0.00	0.0
Cycle 34 Day 1	14	4.76	12.10	0.0	0.00	33.3	12	-22.22	21.71	-66.7	-33.33	0.0
Cycle 35 Day 1	15	8.89	15.26	0.0	0.00	33.3	13	-17.95	25.88	-66.7	-33.33	33.3
Cycle 36 Day 1	14	7.14	14.19	0.0	0.00	33.3	12	-16.67	17.41	-33.3	-16.67	0.0
Cycle 37 Day 1	12	5.56	12.97	0.0	0.00	33.3	11	-18.18	31.14	-66.7	0.00	33.3
Cycle 38 Day 1	11	6.06	13.48	0.0	0.00	33.3	10	-20.00	32.20	-66.7	-16.67	33.3
Cycle 39 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	-22.22	33.33	-66.7	-33.33	33.3
Study Disc 1	135	19.75	28.30	0.0	0.00	100.0	133	-0.25	29.73	-100.0	0.00	100.0
30 D SFU Z/P	58	12.07	25.51	0.0	0.00	100.0	57	-4.68	26.31	-66.7	0.00	100.0
90 D SFU Z/P	62	19.35	29.29	0.0	0.00	100.0	61	3.83	25.16	-33.3	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	241	16.87	23.79	0.0	0.00	100.0						
Cycle 2 Day 1	222	18.17	22.09	0.0	0.00	100.0	216	2.16	23.30	-100.0	0.00	66.7
Cycle 3 Day 1	200	19.83	23.65	0.0	0.00	100.0	196	4.93	26.44	-100.0	0.00	100.0
Cycle 4 Day 1	171	19.69	22.48	0.0	0.00	100.0	169	4.34	28.30	-100.0	0.00	66.7
Cycle 5 Day 1	166	17.07	21.32	0.0	0.00	66.7	165	1.41	27.88	-100.0	0.00	66.7
Cycle 6 Day 1	146	18.26	24.78	0.0	0.00	100.0	145	3.91	27.64	-100.0	0.00	100.0
Cycle 7 Day 1	126	15.87	21.38	0.0	0.00	100.0	125	0.53	28.08	-100.0	0.00	100.0
Cycle 8 Day 1	110	19.09	24.92	0.0	0.00	100.0	109	3.98	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: 12JAN24

Table 302.3.3002.27: 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 9 Day 1	104	16.67	25.01	0.0	0.00	100.0	103	2.27	28.49	-100.0	0.00	100.0
Cycle 10 Day 1	81	12.35	18.59	0.0	0.00	66.7	79	-2.11	27.39	-66.7	0.00	66.7
Cycle 11 Day 1	72	11.57	16.93	0.0	0.00	66.7	71	-2.35	26.02	-66.7	0.00	66.7
Cycle 12 Day 1	59	14.12	19.77	0.0	0.00	66.7	57	1.17	25.17	-66.7	0.00	66.7
Cycle 13 Day 1	50	12.00	17.51	0.0	0.00	66.7	48	-2.08	27.85	-100.0	0.00	66.7
Cycle 14 Day 1	46	11.59	22.46	0.0	0.00	100.0	44	-2.27	26.31	-66.7	0.00	66.7
Cycle 15 Day 1	38	14.04	22.77	0.0	0.00	100.0	36	0.00	21.08	-66.7	0.00	33.3
Cycle 16 Day 1	33	13.13	18.52	0.0	0.00	66.7	31	1.08	16.06	-33.3	0.00	33.3
Cycle 17 Day 1	28	11.90	16.27	0.0	0.00	33.3	25	4.00	17.53	-33.3	0.00	33.3
Cycle 18 Day 1	23	11.59	16.23	0.0	0.00	33.3	21	4.76	15.94	-33.3	0.00	33.3
Cycle 19 Day 1	21	11.11	16.10	0.0	0.00	33.3	20	3.33	14.91	-33.3	0.00	33.3
Cycle 20 Day 1	20	11.67	16.31	0.0	0.00	33.3	19	3.51	24.58	-66.7	0.00	33.3
Cycle 21 Day 1	21	11.11	16.10	0.0	0.00	33.3	20	3.33	18.42	-33.3	0.00	33.3
Cycle 22 Day 1	18	14.81	17.04	0.0	0.00	33.3	17	7.84	18.74	-33.3	0.00	33.3
Cycle 23 Day 1	17	9.80	15.66	0.0	0.00	33.3	16	2.08	14.75	-33.3	0.00	33.3
Cycle 24 Day 1	13	15.38	17.30	0.0	0.00	33.3	12	5.56	27.83	-66.7	0.00	33.3
Cycle 25 Day 1	13	10.26	16.01	0.0	0.00	33.3	12	2.78	17.16	-33.3	0.00	33.3
Cycle 26 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
Cycle 27 Day 1	11	12.12	16.82	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3
Cycle 28 Day 1	11	9.09	15.57	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 29 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
Study Disc 1	156	21.37	27.29	0.0	0.00	100.0	150	4.44	29.58	-100.0	0.00	100.0
30 D SFU Z/P	78	21.37	25.18	0.0	16.67	100.0	76	5.70	26.88	-66.7	0.00	100.0
90 D SFU Z/P	81	19.75	25.70	0.0	0.00	100.0	79	6.75	28.43	-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: 12JAN24

Table 302.3.3002.28: 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 + CAPOX (N=254)												
Baseline	243	9.47	21.58	0.0	0.00	100.0						
Cycle 2 Day 1	209	12.92	23.07	0.0	0.00	100.0	208	3.85	22.85	-100.0	0.00	100.0
Cycle 3 Day 1	186	16.49	25.05	0.0	0.00	100.0	182	7.33	25.41	-100.0	0.00	100.0
Cycle 4 Day 1	169	15.19	24.66	0.0	0.00	100.0	166	5.62	24.24	-66.7	0.00	100.0
Cycle 5 Day 1	163	17.18	25.49	0.0	0.00	100.0	159	8.18	26.71	-100.0	0.00	100.0
Cycle 6 Day 1	151	21.85	26.96	0.0	0.00	100.0	149	12.30	27.77	-66.7	0.00	100.0
Cycle 7 Day 1	121	19.01	27.16	0.0	0.00	100.0	119	10.92	28.82	-66.7	0.00	100.0
Cycle 8 Day 1	114	20.47	29.25	0.0	0.00	100.0	108	10.49	25.23	-66.7	0.00	100.0
Cycle 9 Day 1	107	19.63	27.83	0.0	0.00	100.0	102	8.17	29.83	-100.0	0.00	100.0
Cycle 10 Day 1	88	17.80	26.24	0.0	0.00	100.0	85	7.06	29.59	-66.7	0.00	100.0
Cycle 11 Day 1	83	11.65	21.10	0.0	0.00	100.0	80	2.92	27.14	-66.7	0.00	100.0
Cycle 12 Day 1	77	11.69	20.78	0.0	0.00	100.0	75	2.22	26.47	-66.7	0.00	100.0
Cycle 13 Day 1	62	11.29	20.86	0.0	0.00	100.0	60	0.56	32.18	-100.0	0.00	100.0
Cycle 14 Day 1	57	9.94	17.78	0.0	0.00	66.7	55	1.82	25.99	-66.7	0.00	66.7
Cycle 15 Day 1	53	10.69	21.46	0.0	0.00	100.0	51	0.00	27.49	-100.0	0.00	100.0
Cycle 16 Day 1	50	12.67	23.22	0.0	0.00	100.0	48	1.39	25.69	-66.7	0.00	66.7
Cycle 17 Day 1	45	13.33	21.79	0.0	0.00	66.7	43	1.55	24.07	-66.7	0.00	66.7
Cycle 18 Day 1	43	13.18	21.99	0.0	0.00	66.7	41	0.81	24.14	-66.7	0.00	66.7
Cycle 19 Day 1	42	11.90	21.87	0.0	0.00	100.0	40	0.83	21.99	-66.7	0.00	33.3
Cycle 20 Day 1	41	13.01	24.58	0.0	0.00	100.0	39	2.56	22.14	-66.7	0.00	66.7
Cycle 21 Day 1	38	10.53	20.66	0.0	0.00	100.0	36	-0.93	24.54	-66.7	0.00	33.3
Cycle 22 Day 1	33	8.08	20.46	0.0	0.00	100.0	31	-1.08	26.50	-66.7	0.00	33.3
Cycle 23 Day 1	33	9.09	20.87	0.0	0.00	100.0	31	2.15	24.24	-66.7	0.00	33.3
Cycle 24 Day 1	31	7.53	20.57	0.0	0.00	100.0	29	0.00	19.92	-66.7	0.00	33.3
Cycle 25 Day 1	30	10.00	17.83	0.0	0.00	66.7	28	2.38	20.14	-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: 12JAN24

Table 302.3.3002.28: 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 26 Day 1	28	7.14	21.00	0.0	0.00	100.0	26	-1.28	19.96	-66.7	0.00	33.3
Cycle 27 Day 1	27	4.94	12.07	0.0	0.00	33.3	25	0.00	19.25	-66.7	0.00	33.3
Cycle 28 Day 1	23	7.25	14.06	0.0	0.00	33.3	21	3.17	23.34	-66.7	0.00	33.3
Cycle 29 Day 1	24	8.33	14.74	0.0	0.00	33.3	22	4.55	21.32	-66.7	0.00	33.3
Cycle 30 Day 1	22	6.06	13.16	0.0	0.00	33.3	20	1.67	20.16	-66.7	0.00	33.3
Cycle 31 Day 1	22	6.06	13.16	0.0	0.00	33.3	20	1.67	22.88	-66.7	0.00	33.3
Cycle 32 Day 1	20	5.00	12.21	0.0	0.00	33.3	18	0.00	22.87	-66.7	0.00	33.3
Cycle 33 Day 1	17	3.92	11.07	0.0	0.00	33.3	15	-2.22	23.46	-66.7	0.00	33.3
Cycle 34 Day 1	14	0.00	0.00	0.0	0.00	0.0	12	-8.33	20.72	-66.7	0.00	0.0
Cycle 35 Day 1	15	4.44	11.73	0.0	0.00	33.3	13	-2.56	21.35	-66.7	0.00	33.3
Cycle 36 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-2.78	22.29	-66.7	0.00	33.3
Cycle 37 Day 1	12	5.56	12.97	0.0	0.00	33.3	11	-3.03	27.71	-66.7	0.00	33.3
Cycle 38 Day 1	11	6.06	13.48	0.0	0.00	33.3	10	-3.33	29.19	-66.7	0.00	33.3
Cycle 39 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
Study Disc 1	135	19.51	28.91	0.0	0.00	100.0	133	8.77	30.95	-100.0	0.00	100.0
30 D SFU Z/P	58	13.22	24.93	0.0	0.00	100.0	57	4.09	23.63	-66.7	0.00	100.0
90 D SFU Z/P	62	12.37	23.56	0.0	0.00	100.0	61	7.65	25.38	-66.7	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	241	7.47	18.50	0.0	0.00	100.0						
Cycle 2 Day 1	222	10.06	20.15	0.0	0.00	100.0	216	2.47	20.69	-100.0	0.00	100.0
Cycle 3 Day 1	200	11.00	19.23	0.0	0.00	100.0	196	5.27	20.55	-66.7	0.00	100.0
Cycle 4 Day 1	171	12.28	21.05	0.0	0.00	100.0	169	5.52	24.31	-66.7	0.00	100.0
Cycle 5 Day 1	166	14.46	23.03	0.0	0.00	100.0	165	8.08	25.01	-66.7	0.00	100.0
Cycle 6 Day 1	146	18.04	25.41	0.0	0.00	100.0	145	11.72	27.65	-66.7	0.00	100.0
Cycle 7 Day 1	126	15.61	23.73	0.0	0.00	100.0	125	9.33	25.96	-66.7	0.00	100.0
Cycle 8 Day 1	110	16.67	24.21	0.0	0.00	100.0	109	10.40	28.58	-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: 12JAN24

Table 302.3.3002.28: 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 9 Day 1	104	12.18	19.74	0.0	0.00	100.0	103	6.47	25.16	-66.7	0.00	100.0
Cycle 10 Day 1	81	8.64	18.84	0.0	0.00	100.0	79	2.95	26.25	-66.7	0.00	100.0
Cycle 11 Day 1	72	9.26	18.74	0.0	0.00	100.0	71	4.23	26.39	-66.7	0.00	100.0
Cycle 12 Day 1	59	5.08	12.09	0.0	0.00	33.3	57	0.00	21.82	-66.7	0.00	33.3
Cycle 13 Day 1	50	8.00	14.38	0.0	0.00	33.3	48	3.47	19.74	-66.7	0.00	33.3
Cycle 14 Day 1	46	5.80	14.58	0.0	0.00	66.7	44	1.52	22.68	-66.7	0.00	66.7
Cycle 15 Day 1	38	7.02	13.77	0.0	0.00	33.3	36	1.85	23.83	-66.7	0.00	33.3
Cycle 16 Day 1	33	7.07	13.84	0.0	0.00	33.3	31	3.23	15.76	-33.3	0.00	33.3
Cycle 17 Day 1	28	8.33	14.70	0.0	0.00	33.3	25	8.00	14.53	0.0	0.00	33.3
Cycle 18 Day 1	23	4.35	11.48	0.0	0.00	33.3	21	4.76	11.95	0.0	0.00	33.3
Cycle 19 Day 1	21	1.59	7.27	0.0	0.00	33.3	20	1.67	7.45	0.0	0.00	33.3
Cycle 20 Day 1	20	6.67	13.68	0.0	0.00	33.3	19	7.02	13.96	0.0	0.00	33.3
Cycle 21 Day 1	21	9.52	15.43	0.0	0.00	33.3	20	10.00	15.67	0.0	0.00	33.3
Cycle 22 Day 1	18	5.56	12.78	0.0	0.00	33.3	17	5.88	13.10	0.0	0.00	33.3
Cycle 23 Day 1	17	7.84	18.74	0.0	0.00	66.7	16	8.33	19.25	0.0	0.00	66.7
Cycle 24 Day 1	13	2.56	9.25	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
Cycle 25 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	5.56	12.97	0.0	0.00	33.3
Cycle 26 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	11.11	16.67	0.0	0.00	33.3
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
Cycle 28 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 29 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	8.33	15.08	0.0	0.00	33.3
Study Disc 1	156	14.53	25.73	0.0	0.00	100.0	150	7.11	29.81	-100.0	0.00	100.0
30 D SFU Z/P	78	15.38	26.69	0.0	0.00	100.0	76	9.21	29.11	-66.7	0.00	100.0
90 D SFU Z/P	81	12.76	20.12	0.0	0.00	66.7	79	7.59	22.61	-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: 12JAN24

Table 302.3.3002.29: 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 + CAPOX (N=254)												
Baseline	243	17.97	25.75	0.0	0.00	100.0						
Cycle 2 Day 1	209	17.38	23.59	0.0	0.00	100.0	208	-0.80	22.80	-100.0	0.00	66.7
Cycle 3 Day 1	186	18.10	25.25	0.0	0.00	100.0	182	1.47	24.48	-100.0	0.00	66.7
Cycle 4 Day 1	169	18.15	25.19	0.0	0.00	100.0	166	1.00	26.32	-100.0	0.00	100.0
Cycle 5 Day 1	163	20.04	28.82	0.0	0.00	100.0	159	2.52	28.45	-100.0	0.00	100.0
Cycle 6 Day 1	151	21.19	28.41	0.0	0.00	100.0	149	3.58	24.55	-100.0	0.00	100.0
Cycle 7 Day 1	121	18.73	25.78	0.0	0.00	100.0	119	0.28	25.85	-66.7	0.00	66.7
Cycle 8 Day 1	114	22.51	28.22	0.0	0.00	100.0	108	2.78	26.62	-100.0	0.00	100.0
Cycle 9 Day 1	107	23.36	27.17	0.0	33.33	100.0	102	1.31	24.34	-100.0	0.00	66.7
Cycle 10 Day 1	88	21.21	26.35	0.0	0.00	100.0	85	-1.57	29.95	-100.0	0.00	100.0
Cycle 11 Day 1	83	14.86	20.99	0.0	0.00	100.0	80	-5.00	26.57	-100.0	0.00	33.3
Cycle 12 Day 1	77	16.88	23.95	0.0	0.00	100.0	75	-3.56	29.29	-100.0	0.00	66.7
Cycle 13 Day 1	62	14.52	23.08	0.0	0.00	100.0	60	-7.22	30.12	-100.0	0.00	33.3
Cycle 14 Day 1	57	14.04	22.67	0.0	0.00	100.0	55	-6.06	27.29	-100.0	0.00	33.3
Cycle 15 Day 1	53	15.72	24.11	0.0	0.00	100.0	51	-5.88	28.83	-100.0	0.00	66.7
Cycle 16 Day 1	50	16.67	23.57	0.0	0.00	100.0	48	-7.64	27.71	-100.0	0.00	33.3
Cycle 17 Day 1	45	18.52	26.17	0.0	0.00	100.0	43	-6.20	27.46	-100.0	0.00	33.3
Cycle 18 Day 1	43	15.50	23.40	0.0	0.00	100.0	41	-8.13	25.58	-100.0	0.00	33.3
Cycle 19 Day 1	42	16.67	24.69	0.0	0.00	100.0	40	-6.67	24.11	-66.7	0.00	33.3
Cycle 20 Day 1	41	19.51	27.86	0.0	0.00	100.0	39	-3.42	23.93	-33.3	0.00	66.7
Cycle 21 Day 1	38	14.04	22.77	0.0	0.00	100.0	36	-9.26	20.49	-66.7	0.00	33.3
Cycle 22 Day 1	33	19.19	30.08	0.0	0.00	100.0	31	-5.38	24.49	-66.7	0.00	33.3
Cycle 23 Day 1	33	13.13	24.92	0.0	0.00	100.0	31	-8.60	19.18	-66.7	0.00	33.3
Cycle 24 Day 1	31	11.83	23.65	0.0	0.00	100.0	29	-8.05	17.03	-33.3	0.00	33.3
Cycle 25 Day 1	30	13.33	24.13	0.0	0.00	100.0	28	-8.33	23.35	-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.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.29: 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 26 Day 1	28	14.29	24.73	0.0	0.00	100.0	26	-6.41	23.13	-33.3	0.00	33.3
Cycle 27 Day 1	27	14.81	28.24	0.0	0.00	100.0	25	-6.67	19.25	-33.3	0.00	33.3
Cycle 28 Day 1	23	15.94	28.19	0.0	0.00	100.0	21	-9.52	21.46	-66.7	0.00	33.3
Cycle 29 Day 1	24	15.28	31.05	0.0	0.00	100.0	22	-9.09	25.58	-66.7	0.00	33.3
Cycle 30 Day 1	22	21.21	33.41	0.0	0.00	100.0	20	-3.33	21.36	-33.3	0.00	33.3
Cycle 31 Day 1	22	18.18	30.39	0.0	0.00	100.0	20	-10.00	21.90	-33.3	0.00	33.3
Cycle 32 Day 1	20	16.67	27.57	0.0	0.00	100.0	18	-11.11	22.87	-66.7	0.00	33.3
Cycle 33 Day 1	17	11.76	26.20	0.0	0.00	100.0	15	-15.56	24.77	-66.7	0.00	33.3
Cycle 34 Day 1	14	11.90	21.11	0.0	0.00	66.7	12	-13.89	17.16	-33.3	0.00	0.0
Cycle 35 Day 1	15	13.33	21.08	0.0	0.00	66.7	13	-10.26	16.01	-33.3	0.00	0.0
Cycle 36 Day 1	14	11.90	21.11	0.0	0.00	66.7	12	-11.11	16.41	-33.3	0.00	0.0
Cycle 37 Day 1	12	13.89	22.29	0.0	0.00	66.7	11	-15.15	17.41	-33.3	0.00	0.0
Cycle 38 Day 1	11	15.15	22.92	0.0	0.00	66.7	10	-16.67	17.57	-33.3	-16.67	0.0
Cycle 39 Day 1	10	16.67	23.57	0.0	0.00	66.7	9	-11.11	16.67	-33.3	0.00	0.0
Study Disc 1	135	23.46	28.53	0.0	0.00	100.0	133	7.77	30.67	-100.0	0.00	100.0
30 D SFU Z/P	58	19.54	27.95	0.0	0.00	100.0	57	3.51	30.00	-100.0	0.00	100.0
90 D SFU Z/P	62	17.20	26.82	0.0	0.00	100.0	61	7.10	20.29	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	19.64	23.99	0.0	0.00	100.0						
Cycle 2 Day 1	222	16.52	24.10	0.0	0.00	100.0	216	-2.31	22.04	-66.7	0.00	66.7
Cycle 3 Day 1	200	17.33	26.09	0.0	0.00	100.0	196	-1.53	23.94	-100.0	0.00	66.7
Cycle 4 Day 1	171	17.35	22.39	0.0	0.00	100.0	169	-0.99	22.25	-66.7	0.00	66.7
Cycle 5 Day 1	166	16.67	22.25	0.0	0.00	100.0	165	0.61	22.83	-100.0	0.00	66.7
Cycle 6 Day 1	146	15.75	24.51	0.0	0.00	100.0	145	-1.38	26.61	-100.0	0.00	100.0
Cycle 7 Day 1	126	15.08	23.70	0.0	0.00	100.0	125	-0.80	25.56	-100.0	0.00	66.7
Cycle 8 Day 1	110	15.76	23.34	0.0	0.00	100.0	109	0.00	24.43	-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: 12JAN24

Table 302.3.3002.29: 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 9 Day 1	104	14.42	22.16	0.0	0.00	100.0	103	-0.97	24.01	-100.0	0.00	66.7
Cycle 10 Day 1	81	14.40	22.94	0.0	0.00	100.0	79	-0.42	26.95	-100.0	0.00	66.7
Cycle 11 Day 1	72	15.74	23.05	0.0	0.00	100.0	71	0.94	26.41	-100.0	0.00	66.7
Cycle 12 Day 1	59	11.30	21.09	0.0	0.00	100.0	57	-2.34	22.59	-66.7	0.00	66.7
Cycle 13 Day 1	50	13.33	22.34	0.0	0.00	100.0	48	0.00	26.63	-100.0	0.00	66.7
Cycle 14 Day 1	46	8.70	20.41	0.0	0.00	66.7	44	-2.27	25.31	-100.0	0.00	66.7
Cycle 15 Day 1	38	10.53	20.66	0.0	0.00	100.0	36	-0.93	28.16	-100.0	0.00	100.0
Cycle 16 Day 1	33	11.11	19.84	0.0	0.00	66.7	31	1.08	26.50	-100.0	0.00	33.3
Cycle 17 Day 1	28	7.14	16.62	0.0	0.00	66.7	25	-2.67	23.41	-100.0	0.00	33.3
Cycle 18 Day 1	23	4.35	11.48	0.0	0.00	33.3	21	-4.76	26.43	-100.0	0.00	33.3
Cycle 19 Day 1	21	3.17	10.03	0.0	0.00	33.3	20	-1.67	13.13	-33.3	0.00	33.3
Cycle 20 Day 1	20	6.67	13.68	0.0	0.00	33.3	19	-3.51	29.18	-100.0	0.00	33.3
Cycle 21 Day 1	21	1.59	7.27	0.0	0.00	33.3	20	-8.33	23.88	-100.0	0.00	0.0
Cycle 22 Day 1	18	7.41	14.26	0.0	0.00	33.3	17	-3.92	30.92	-100.0	0.00	33.3
Cycle 23 Day 1	17	3.92	11.07	0.0	0.00	33.3	16	-8.33	28.54	-100.0	0.00	33.3
Cycle 24 Day 1	13	7.69	14.62	0.0	0.00	33.3	12	-5.56	34.33	-100.0	0.00	33.3
Cycle 25 Day 1	13	7.69	14.62	0.0	0.00	33.3	12	-2.78	33.21	-100.0	0.00	33.3
Cycle 26 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
Cycle 27 Day 1	11	6.06	13.48	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
Cycle 28 Day 1	11	9.09	15.57	0.0	0.00	33.3	11	6.06	13.48	0.0	0.00	33.3
Cycle 29 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	5.56	12.97	0.0	0.00	33.3
Study Disc 1	156	26.28	31.00	0.0	33.33	100.0	150	4.22	30.24	-66.7	0.00	100.0
30 D SFU Z/P	78	26.92	34.00	0.0	0.00	100.0	76	5.26	26.70	-33.3	0.00	100.0
90 D SFU Z/P	81	26.34	29.68	0.0	33.33	100.0	79	6.75	29.42	-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: 12JAN24

Table 302.3.3002.30: 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 + CAPOX (N=254)												
Baseline	243	3.84	12.64	0.0	0.00	66.7						
Cycle 2 Day 1	209	4.31	11.67	0.0	0.00	66.7	208	0.48	13.70	-66.7	0.00	33.3
Cycle 3 Day 1	186	4.30	13.62	0.0	0.00	100.0	182	0.00	13.57	-66.7	0.00	33.3
Cycle 4 Day 1	169	4.34	14.35	0.0	0.00	100.0	166	0.20	16.20	-66.7	0.00	100.0
Cycle 5 Day 1	163	3.89	12.50	0.0	0.00	66.7	159	0.21	15.23	-66.7	0.00	66.7
Cycle 6 Day 1	151	6.62	18.06	0.0	0.00	100.0	149	2.91	18.96	-66.7	0.00	100.0
Cycle 7 Day 1	121	5.23	14.91	0.0	0.00	100.0	119	1.40	18.61	-66.7	0.00	100.0
Cycle 8 Day 1	114	4.97	14.86	0.0	0.00	100.0	108	-0.62	15.77	-66.7	0.00	33.3
Cycle 9 Day 1	107	5.61	15.52	0.0	0.00	100.0	102	0.65	15.54	-66.7	0.00	66.7
Cycle 10 Day 1	88	5.68	15.35	0.0	0.00	66.7	85	0.78	17.04	-66.7	0.00	66.7
Cycle 11 Day 1	83	3.61	13.79	0.0	0.00	100.0	80	-0.42	13.52	-66.7	0.00	33.3
Cycle 12 Day 1	77	3.03	11.06	0.0	0.00	66.7	75	0.00	10.96	-33.3	0.00	33.3
Cycle 13 Day 1	62	2.69	9.15	0.0	0.00	33.3	60	0.00	12.27	-33.3	0.00	33.3
Cycle 14 Day 1	57	1.75	7.51	0.0	0.00	33.3	55	-1.21	11.04	-33.3	0.00	33.3
Cycle 15 Day 1	53	1.89	7.78	0.0	0.00	33.3	51	-1.96	14.00	-66.7	0.00	33.3
Cycle 16 Day 1	50	4.00	10.94	0.0	0.00	33.3	48	0.00	16.84	-66.7	0.00	33.3
Cycle 17 Day 1	45	2.22	8.41	0.0	0.00	33.3	43	-2.33	13.40	-66.7	0.00	33.3
Cycle 18 Day 1	43	2.33	8.59	0.0	0.00	33.3	41	-2.44	13.72	-66.7	0.00	33.3
Cycle 19 Day 1	42	3.97	10.93	0.0	0.00	33.3	40	-0.83	15.99	-66.7	0.00	33.3
Cycle 20 Day 1	41	1.63	7.27	0.0	0.00	33.3	39	-3.42	16.75	-66.7	0.00	33.3
Cycle 21 Day 1	38	4.39	11.42	0.0	0.00	33.3	36	0.00	17.82	-66.7	0.00	33.3
Cycle 22 Day 1	33	2.02	8.08	0.0	0.00	33.3	31	0.00	12.17	-33.3	0.00	33.3
Cycle 23 Day 1	33	2.02	8.08	0.0	0.00	33.3	31	0.00	12.17	-33.3	0.00	33.3
Cycle 24 Day 1	31	2.15	8.32	0.0	0.00	33.3	29	0.00	12.60	-33.3	0.00	33.3
Cycle 25 Day 1	30	3.33	10.17	0.0	0.00	33.3	28	1.19	14.29	-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.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.30: 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 26 Day 1	28	1.19	6.30	0.0	0.00	33.3	26	-1.28	11.47	-33.3	0.00	33.3
Cycle 27 Day 1	27	2.47	8.90	0.0	0.00	33.3	25	0.00	13.61	-33.3	0.00	33.3
Cycle 28 Day 1	23	1.45	6.95	0.0	0.00	33.3	21	0.00	10.54	-33.3	0.00	33.3
Cycle 29 Day 1	24	2.78	9.41	0.0	0.00	33.3	22	1.52	12.50	-33.3	0.00	33.3
Cycle 30 Day 1	22	1.52	7.11	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
Cycle 31 Day 1	22	1.52	7.11	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
Cycle 32 Day 1	20	0.00	0.00	0.0	0.00	0.0	18	-1.85	7.86	-33.3	0.00	0.0
Cycle 33 Day 1	17	0.00	0.00	0.0	0.00	0.0	15	-2.22	8.61	-33.3	0.00	0.0
Cycle 34 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
Cycle 35 Day 1	15	2.22	8.61	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
Cycle 36 Day 1	14	0.00	0.00	0.0	0.00	0.0	12	-2.78	9.62	-33.3	0.00	0.0
Cycle 37 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 38 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 39 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	0.00	0.00	0.0	0.00	0.0
Study Disc 1	135	8.15	19.73	0.0	0.00	100.0	133	4.01	20.94	-66.7	0.00	100.0
30 D SFU Z/P	58	5.75	17.81	0.0	0.00	100.0	57	1.75	20.34	-66.7	0.00	100.0
90 D SFU Z/P	62	4.30	14.13	0.0	0.00	66.7	61	1.64	16.58	-66.7	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	5.26	15.52	0.0	0.00	100.0						
Cycle 2 Day 1	222	3.15	11.65	0.0	0.00	100.0	216	-1.85	14.62	-66.7	0.00	66.7
Cycle 3 Day 1	200	3.50	12.23	0.0	0.00	100.0	196	-1.19	15.97	-100.0	0.00	100.0
Cycle 4 Day 1	171	4.48	13.98	0.0	0.00	100.0	169	-0.59	16.05	-66.7	0.00	100.0
Cycle 5 Day 1	166	2.61	9.70	0.0	0.00	66.7	165	-2.63	16.04	-66.7	0.00	66.7
Cycle 6 Day 1	146	5.02	13.18	0.0	0.00	66.7	145	0.00	18.84	-66.7	0.00	66.7
Cycle 7 Day 1	126	4.50	12.19	0.0	0.00	66.7	125	-1.33	18.16	-66.7	0.00	66.7
Cycle 8 Day 1	110	2.73	9.18	0.0	0.00	33.3	109	-3.06	16.06	-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: 12JAN24

Table 302.3.3002.30: 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 9 Day 1	104	2.88	11.48	0.0	0.00	66.7	103	-3.56	19.75	-66.7	0.00	66.7
Cycle 10 Day 1	81	2.47	12.67	0.0	0.00	100.0	79	-4.22	20.23	-66.7	0.00	100.0
Cycle 11 Day 1	72	2.78	9.28	0.0	0.00	33.3	71	-4.69	18.94	-66.7	0.00	33.3
Cycle 12 Day 1	59	1.69	9.64	0.0	0.00	66.7	57	-4.68	19.35	-66.7	0.00	66.7
Cycle 13 Day 1	50	2.67	11.35	0.0	0.00	66.7	48	-2.78	19.25	-66.7	0.00	66.7
Cycle 14 Day 1	46	2.90	15.44	0.0	0.00	100.0	44	-3.79	25.13	-66.7	0.00	100.0
Cycle 15 Day 1	38	2.63	11.96	0.0	0.00	66.7	36	-6.48	23.66	-66.7	0.00	66.7
Cycle 16 Day 1	33	2.02	8.08	0.0	0.00	33.3	31	-4.30	20.62	-66.7	0.00	33.3
Cycle 17 Day 1	28	0.00	0.00	0.0	0.00	0.0	25	-6.67	19.25	-66.7	0.00	0.0
Cycle 18 Day 1	23	1.45	6.95	0.0	0.00	33.3	21	-6.35	22.65	-66.7	0.00	33.3
Cycle 19 Day 1	21	0.00	0.00	0.0	0.00	0.0	20	-5.00	16.31	-66.7	0.00	0.0
Cycle 20 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	-7.02	23.78	-66.7	0.00	33.3
Cycle 21 Day 1	21	3.17	14.55	0.0	0.00	66.7	20	-5.00	27.09	-66.7	0.00	66.7
Cycle 22 Day 1	18	3.70	10.78	0.0	0.00	33.3	17	-5.88	24.25	-66.7	0.00	33.3
Cycle 23 Day 1	17	0.00	0.00	0.0	0.00	0.0	16	-10.42	23.47	-66.7	0.00	0.0
Cycle 24 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-8.33	20.72	-66.7	0.00	0.0
Cycle 25 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-13.89	26.43	-66.7	0.00	0.0
Cycle 26 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	-11.11	23.57	-66.7	0.00	0.0
Cycle 27 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	-10.00	22.50	-66.7	0.00	0.0
Cycle 28 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-9.09	21.56	-66.7	0.00	0.0
Cycle 29 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-8.33	20.72	-66.7	0.00	0.0
Study Disc 1	156	10.04	20.54	0.0	0.00	100.0	150	4.22	25.70	-100.0	0.00	100.0
30 D SFU Z/P	78	4.27	12.44	0.0	0.00	66.7	76	-1.75	17.12	-66.7	0.00	66.7
90 D SFU Z/P	81	4.12	12.23	0.0	0.00	66.7	79	-2.95	21.48	-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: 12JAN24

Table 302.3.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
0-2	Zolbetuximab + CAPOX (N=189)												
	Baseline	184	3.26	12.13	0.0	0.00	66.7						
	Cycle 2 Day 1	158	4.22	11.74	0.0	0.00	66.7	158	0.63	13.81	-66.7	0.00	33.3
	Cycle 3 Day 1	142	3.76	11.97	0.0	0.00	66.7	140	0.00	13.26	-66.7	0.00	33.3
	Cycle 4 Day 1	127	3.94	14.92	0.0	0.00	100.0	126	0.00	17.38	-66.7	0.00	100.0
	Cycle 5 Day 1	123	3.52	11.93	0.0	0.00	66.7	122	0.55	15.44	-66.7	0.00	66.7
	Cycle 6 Day 1	110	7.27	19.88	0.0	0.00	100.0	110	3.94	21.05	-66.7	0.00	100.0
	Cycle 7 Day 1	93	5.38	15.77	0.0	0.00	100.0	93	2.51	20.40	-66.7	0.00	100.0
	Cycle 8 Day 1	90	3.70	13.63	0.0	0.00	100.0	87	-0.77	16.06	-66.7	0.00	33.3
	Cycle 9 Day 1	80	6.25	16.85	0.0	0.00	100.0	78	1.28	16.51	-66.7	0.00	66.7
	Cycle 10 Day 1	67	5.47	14.90	0.0	0.00	66.7	66	1.01	16.51	-66.7	0.00	66.7
	Cycle 11 Day 1	64	4.17	15.14	0.0	0.00	100.0	63	0.00	14.66	-66.7	0.00	33.3
	Cycle 12 Day 1	60	3.33	11.81	0.0	0.00	66.7	59	0.56	11.57	-33.3	0.00	33.3
	Cycle 13 Day 1	48	2.78	9.31	0.0	0.00	33.3	47	0.71	12.98	-33.3	0.00	33.3
	Cycle 14 Day 1	46	1.45	6.87	0.0	0.00	33.3	45	-0.74	11.21	-33.3	0.00	33.3
	Cycle 15 Day 1	42	1.59	7.18	0.0	0.00	33.3	41	-1.63	14.82	-66.7	0.00	33.3
	Cycle 16 Day 1	42	3.17	9.90	0.0	0.00	33.3	41	0.00	16.67	-66.7	0.00	33.3
	Cycle 17 Day 1	36	1.85	7.74	0.0	0.00	33.3	35	-1.90	13.87	-66.7	0.00	33.3
	Cycle 18 Day 1	34	1.96	7.96	0.0	0.00	33.3	33	-2.02	14.29	-66.7	0.00	33.3
	Cycle 19 Day 1	34	2.94	9.60	0.0	0.00	33.3	33	-1.01	15.56	-66.7	0.00	33.3
	Cycle 20 Day 1	34	1.96	7.96	0.0	0.00	33.3	33	-2.02	16.54	-66.7	0.00	33.3
	Cycle 21 Day 1	33	5.05	12.14	0.0	0.00	33.3	32	1.04	17.93	-66.7	0.00	33.3
	Cycle 22 Day 1	30	2.22	8.46	0.0	0.00	33.3	29	1.15	10.85	-33.3	0.00	33.3
	Cycle 23 Day 1	30	2.22	8.46	0.0	0.00	33.3	29	1.15	10.85	-33.3	0.00	33.3
	Cycle 24 Day 1	28	2.38	8.74	0.0	0.00	33.3	27	1.23	11.25	-33.3	0.00	33.3
	Cycle 25 Day 1	27	3.70	10.68	0.0	0.00	33.3	26	2.56	13.07	-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: 12JAN24

Table 302.3.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - 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 26 Day 1	26	1.28	6.54	0.0	0.00	33.3	25	0.00	9.62	-33.3	0.00	33.3
	Cycle 27 Day 1	24	2.78	9.41	0.0	0.00	33.3	23	1.45	12.22	-33.3	0.00	33.3
	Cycle 28 Day 1	22	1.52	7.11	0.0	0.00	33.3	21	0.00	10.54	-33.3	0.00	33.3
	Cycle 29 Day 1	23	2.90	9.60	0.0	0.00	33.3	22	1.52	12.50	-33.3	0.00	33.3
	Cycle 30 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	0.00	11.11	-33.3	0.00	33.3
	Cycle 31 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	0.00	11.11	-33.3	0.00	33.3
	Cycle 32 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 33 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 34 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Cycle 35 Day 1	13	2.56	9.25	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
	Cycle 36 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
	Cycle 37 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	107	9.03	21.27	0.0	0.00	100.0	106	4.72	22.27	-66.7	0.00	100.0
	30 D SFU Z/P	47	7.09	19.58	0.0	0.00	100.0	46	2.90	22.03	-66.7	0.00	100.0
	90 D SFU Z/P	48	4.86	15.36	0.0	0.00	66.7	47	2.13	18.91	-66.7	0.00	66.7
	Placebo + CAPOX (N=188)												
	Baseline	181	4.79	14.54	0.0	0.00	100.0						
	Cycle 2 Day 1	169	3.35	12.41	0.0	0.00	100.0	165	-1.41	14.42	-66.7	0.00	66.7
	Cycle 3 Day 1	152	3.29	12.58	0.0	0.00	100.0	149	-1.12	15.21	-100.0	0.00	100.0
	Cycle 4 Day 1	130	4.36	14.01	0.0	0.00	100.0	128	-0.26	14.18	-66.7	0.00	100.0
	Cycle 5 Day 1	125	2.93	10.38	0.0	0.00	66.7	124	-2.15	15.76	-66.7	0.00	66.7
	Cycle 6 Day 1	114	4.39	12.16	0.0	0.00	66.7	113	-0.88	18.61	-66.7	0.00	66.7
	Cycle 7 Day 1	95	4.21	12.15	0.0	0.00	66.7	94	-1.42	17.57	-66.7	0.00	66.7
	Cycle 8 Day 1	86	2.33	8.54	0.0	0.00	33.3	85	-3.14	16.76	-66.7	0.00	33.3
	Cycle 9 Day 1	80	3.33	12.55	0.0	0.00	66.7	79	-2.53	19.81	-66.7	0.00	66.7
	Cycle 10 Day 1	65	3.08	14.10	0.0	0.00	100.0	64	-3.65	21.51	-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: 12JAN24

Table 302.3.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - 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 11 Day 1	58	2.87	9.44	0.0	0.00	33.3	57	-4.09	17.90	-66.7	0.00	33.3
	Cycle 12 Day 1	48	2.08	10.67	0.0	0.00	66.7	47	-2.84	18.16	-66.7	0.00	66.7
	Cycle 13 Day 1	41	2.44	11.52	0.0	0.00	66.7	40	-2.50	19.08	-66.7	0.00	66.7
	Cycle 14 Day 1	38	2.63	16.22	0.0	0.00	100.0	37	-2.70	24.06	-66.7	0.00	100.0
	Cycle 15 Day 1	31	1.08	5.99	0.0	0.00	33.3	30	-6.67	18.36	-66.7	0.00	0.0
	Cycle 16 Day 1	27	0.00	0.00	0.0	0.00	0.0	26	-5.13	15.47	-66.7	0.00	0.0
	Cycle 17 Day 1	25	0.00	0.00	0.0	0.00	0.0	23	-4.35	15.26	-66.7	0.00	0.0
	Cycle 18 Day 1	20	1.67	7.45	0.0	0.00	33.3	19	-3.51	18.90	-66.7	0.00	33.3
	Cycle 19 Day 1	19	0.00	0.00	0.0	0.00	0.0	18	-1.85	7.86	-33.3	0.00	0.0
	Cycle 20 Day 1	19	1.75	7.65	0.0	0.00	33.3	18	-3.70	19.43	-66.7	0.00	33.3
	Cycle 21 Day 1	19	3.51	15.29	0.0	0.00	66.7	18	-1.85	24.18	-66.7	0.00	66.7
	Cycle 22 Day 1	16	2.08	8.33	0.0	0.00	33.3	15	-4.44	17.21	-66.7	0.00	0.0
	Cycle 23 Day 1	15	0.00	0.00	0.0	0.00	0.0	14	-7.14	19.30	-66.7	0.00	0.0
	Cycle 24 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-8.33	20.72	-66.7	0.00	0.0
	Cycle 25 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-9.09	21.56	-66.7	0.00	0.0
	Cycle 27 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	-3.70	11.11	-33.3	0.00	0.0
	Cycle 29 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	118	7.34	17.51	0.0	0.00	100.0	114	1.17	23.85	-100.0	0.00	100.0
	30 D SFU Z/P	63	3.17	9.86	0.0	0.00	33.3	61	-1.64	14.18	-66.7	0.00	33.3
	90 D SFU Z/P	65	3.08	11.37	0.0	0.00	66.7	63	-2.12	20.63	-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: 12JAN24

Table 302.3.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>=3	Zolbetuximab + CAPOX (N= 65)												
	Baseline	59	5.65	14.05	0.0	0.00	66.7						
	Cycle 2 Day 1	51	4.58	11.58	0.0	0.00	33.3	50	0.00	13.47	-33.3	0.00	33.3
	Cycle 3 Day 1	44	6.06	18.00	0.0	0.00	100.0	42	0.00	14.72	-33.3	0.00	33.3
	Cycle 4 Day 1	42	5.56	12.57	0.0	0.00	33.3	40	0.83	11.91	-33.3	0.00	33.3
	Cycle 5 Day 1	40	5.00	14.22	0.0	0.00	66.7	37	-0.90	14.67	-33.3	0.00	33.3
	Cycle 6 Day 1	41	4.88	11.93	0.0	0.00	33.3	39	0.00	10.81	-33.3	0.00	33.3
	Cycle 7 Day 1	28	4.76	11.88	0.0	0.00	33.3	26	-2.56	9.06	-33.3	0.00	0.0
	Cycle 8 Day 1	24	9.72	18.33	0.0	0.00	66.7	21	0.00	14.91	-33.3	0.00	33.3
	Cycle 9 Day 1	27	3.70	10.68	0.0	0.00	33.3	24	-1.39	11.95	-33.3	0.00	33.3
	Cycle 10 Day 1	21	6.35	17.06	0.0	0.00	66.7	19	0.00	19.25	-33.3	0.00	66.7
	Cycle 11 Day 1	19	1.75	7.65	0.0	0.00	33.3	17	-1.96	8.08	-33.3	0.00	0.0
	Cycle 12 Day 1	17	1.96	8.08	0.0	0.00	33.3	16	-2.08	8.33	-33.3	0.00	0.0
	Cycle 13 Day 1	14	2.38	8.91	0.0	0.00	33.3	13	-2.56	9.25	-33.3	0.00	0.0
	Cycle 14 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Cycle 15 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Study Disc 1	28	4.76	11.88	0.0	0.00	33.3	27	1.23	14.56	-33.3	0.00	33.3
	30 D SFU Z/P	11	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
	90 D SFU Z/P	14	2.38	8.91	0.0	0.00	33.3	14	0.00	0.00	0.0	0.00	0.0
	Placebo + CAPOX (N= 65)												
	Baseline	60	6.67	18.21	0.0	0.00	100.0						
	Cycle 2 Day 1	53	2.52	8.89	0.0	0.00	33.3	51	-3.27	15.28	-66.7	0.00	33.3
	Cycle 3 Day 1	48	4.17	11.14	0.0	0.00	33.3	47	-1.42	18.33	-66.7	0.00	33.3
	Cycle 4 Day 1	41	4.88	14.07	0.0	0.00	66.7	41	-1.63	21.02	-66.7	0.00	66.7
	Cycle 5 Day 1	41	1.63	7.27	0.0	0.00	33.3	41	-4.07	16.99	-66.7	0.00	33.3
	Cycle 6 Day 1	32	7.29	16.36	0.0	0.00	66.7	32	3.13	19.60	-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: 12JAN24

Table 302.3.3002.30.4: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - 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	31	5.38	12.46	0.0	0.00	33.3	31	-1.08	20.15	-66.7	0.00	33.3
	Cycle 8 Day 1	24	4.17	11.26	0.0	0.00	33.3	24	-2.78	13.61	-33.3	0.00	33.3
	Cycle 9 Day 1	24	1.39	6.80	0.0	0.00	33.3	24	-6.94	19.61	-66.7	0.00	33.3
	Cycle 10 Day 1	16	0.00	0.00	0.0	0.00	0.0	15	-6.67	13.80	-33.3	0.00	0.0
	Cycle 11 Day 1	14	2.38	8.91	0.0	0.00	33.3	14	-7.14	23.31	-66.7	0.00	33.3
	Cycle 12 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	-13.33	23.31	-66.7	0.00	0.0
	Study Disc 1	38	18.42	26.51	0.0	0.00	100.0	36	13.89	29.14	-33.3	0.00	100.0
	30 D SFU Z/P	15	8.89	19.79	0.0	0.00	66.7	15	-2.22	26.63	-33.3	0.00	66.7
	90 D SFU Z/P	16	8.33	14.91	0.0	0.00	33.3	16	-6.25	25.00	-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: 12JAN24

Table 302.3.3002.31: 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 + CAPOX (N=254)												
Baseline	243	5.35	14.01	0.0	0.00	100.0						
Cycle 2 Day 1	209	3.99	11.33	0.0	0.00	66.7	208	-1.60	13.81	-66.7	0.00	33.3
Cycle 3 Day 1	186	4.48	13.79	0.0	0.00	100.0	182	-1.10	12.09	-66.7	0.00	33.3
Cycle 4 Day 1	169	3.55	12.09	0.0	0.00	100.0	166	-2.01	14.07	-66.7	0.00	66.7
Cycle 5 Day 1	163	3.89	11.94	0.0	0.00	66.7	159	-1.68	15.82	-66.7	0.00	66.7
Cycle 6 Day 1	151	3.75	13.63	0.0	0.00	100.0	149	-1.12	15.70	-33.3	0.00	66.7
Cycle 7 Day 1	121	5.79	17.57	0.0	0.00	100.0	119	0.56	19.40	-33.3	0.00	100.0
Cycle 8 Day 1	114	5.26	13.73	0.0	0.00	66.7	108	-0.31	14.76	-33.3	0.00	66.7
Cycle 9 Day 1	107	4.67	12.50	0.0	0.00	66.7	102	-0.65	14.82	-33.3	0.00	33.3
Cycle 10 Day 1	88	4.17	13.19	0.0	0.00	66.7	85	-1.96	14.87	-33.3	0.00	66.7
Cycle 11 Day 1	83	4.82	14.85	0.0	0.00	100.0	80	-0.83	14.98	-33.3	0.00	66.7
Cycle 12 Day 1	77	3.46	11.58	0.0	0.00	66.7	75	-2.22	14.84	-33.3	0.00	33.3
Cycle 13 Day 1	62	2.69	9.15	0.0	0.00	33.3	60	-3.33	14.65	-33.3	0.00	33.3
Cycle 14 Day 1	57	3.51	10.32	0.0	0.00	33.3	55	-3.03	11.61	-33.3	0.00	33.3
Cycle 15 Day 1	53	2.52	8.89	0.0	0.00	33.3	51	-3.92	12.73	-33.3	0.00	33.3
Cycle 16 Day 1	50	4.67	11.68	0.0	0.00	33.3	48	-2.08	12.69	-33.3	0.00	33.3
Cycle 17 Day 1	45	5.19	12.22	0.0	0.00	33.3	43	-1.55	7.10	-33.3	0.00	0.0
Cycle 18 Day 1	43	6.20	13.12	0.0	0.00	33.3	41	-0.81	11.76	-33.3	0.00	33.3
Cycle 19 Day 1	42	5.56	12.57	0.0	0.00	33.3	40	-1.67	10.54	-33.3	0.00	33.3
Cycle 20 Day 1	41	4.07	11.04	0.0	0.00	33.3	39	-2.56	11.81	-33.3	0.00	33.3
Cycle 21 Day 1	38	4.39	11.42	0.0	0.00	33.3	36	-1.85	15.83	-33.3	0.00	33.3
Cycle 22 Day 1	33	4.04	11.05	0.0	0.00	33.3	31	-2.15	11.97	-33.3	0.00	33.3
Cycle 23 Day 1	33	3.03	9.73	0.0	0.00	33.3	31	-2.15	14.75	-33.3	0.00	33.3
Cycle 24 Day 1	31	4.30	11.36	0.0	0.00	33.3	29	-1.15	14.04	-33.3	0.00	33.3
Cycle 25 Day 1	30	2.22	8.46	0.0	0.00	33.3	28	-3.57	13.88	-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: 12JAN24

Table 302.3.3002.31: 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 26 Day 1	28	3.57	10.50	0.0	0.00	33.3	26	-2.56	13.07	-33.3	0.00	33.3
Cycle 27 Day 1	27	3.70	14.12	0.0	0.00	66.7	25	-1.33	17.95	-33.3	0.00	66.7
Cycle 28 Day 1	23	4.35	11.48	0.0	0.00	33.3	21	0.00	18.26	-33.3	0.00	33.3
Cycle 29 Day 1	24	5.56	12.69	0.0	0.00	33.3	22	1.52	16.19	-33.3	0.00	33.3
Cycle 30 Day 1	22	6.06	13.16	0.0	0.00	33.3	20	3.33	18.42	-33.3	0.00	33.3
Cycle 31 Day 1	22	6.06	13.16	0.0	0.00	33.3	20	1.67	17.01	-33.3	0.00	33.3
Cycle 32 Day 1	20	5.00	12.21	0.0	0.00	33.3	18	0.00	19.80	-33.3	0.00	33.3
Cycle 33 Day 1	17	1.96	8.08	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
Cycle 34 Day 1	14	4.76	12.10	0.0	0.00	33.3	12	0.00	20.10	-33.3	0.00	33.3
Cycle 35 Day 1	15	6.67	13.80	0.0	0.00	33.3	13	2.56	21.35	-33.3	0.00	33.3
Cycle 36 Day 1	14	7.14	14.19	0.0	0.00	33.3	12	2.78	17.16	-33.3	0.00	33.3
Cycle 37 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 38 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 39 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
Study Disc 1	135	7.41	17.59	0.0	0.00	100.0	133	2.01	17.29	-66.7	0.00	66.7
30 D SFU Z/P	58	9.77	24.19	0.0	0.00	100.0	57	4.09	21.89	-33.3	0.00	100.0
90 D SFU Z/P	62	4.30	12.78	0.0	0.00	66.7	61	0.00	14.91	-33.3	0.00	66.7
Placebo + CAPOX (N=253)												
Baseline	241	6.64	17.00	0.0	0.00	100.0						
Cycle 2 Day 1	222	4.65	13.20	0.0	0.00	100.0	216	-1.54	15.00	-66.7	0.00	66.7
Cycle 3 Day 1	200	4.17	13.75	0.0	0.00	100.0	196	-1.87	17.92	-100.0	0.00	100.0
Cycle 4 Day 1	171	4.87	12.87	0.0	0.00	66.7	169	-1.38	16.41	-66.7	0.00	33.3
Cycle 5 Day 1	166	3.61	11.62	0.0	0.00	66.7	165	-2.42	17.09	-66.7	0.00	66.7
Cycle 6 Day 1	146	4.57	12.76	0.0	0.00	66.7	145	-1.84	18.33	-66.7	0.00	66.7
Cycle 7 Day 1	126	3.70	12.09	0.0	0.00	66.7	125	-2.93	19.41	-66.7	0.00	66.7
Cycle 8 Day 1	110	3.94	10.81	0.0	0.00	33.3	109	-3.67	18.89	-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: 12JAN24

Table 302.3.3002.31: 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 9 Day 1	104	5.13	15.24	0.0	0.00	100.0	103	-2.27	19.95	-66.7	0.00	66.7
Cycle 10 Day 1	81	4.12	11.03	0.0	0.00	33.3	79	-2.95	19.39	-66.7	0.00	33.3
Cycle 11 Day 1	72	3.70	10.55	0.0	0.00	33.3	71	-2.82	18.47	-66.7	0.00	33.3
Cycle 12 Day 1	59	3.95	10.87	0.0	0.00	33.3	57	-1.75	15.96	-66.7	0.00	33.3
Cycle 13 Day 1	50	3.33	10.10	0.0	0.00	33.3	48	-4.17	18.99	-66.7	0.00	33.3
Cycle 14 Day 1	46	3.62	16.07	0.0	0.00	100.0	44	-1.52	21.51	-66.7	0.00	100.0
Cycle 15 Day 1	38	6.14	18.75	0.0	0.00	100.0	36	0.93	24.54	-66.7	0.00	100.0
Cycle 16 Day 1	33	6.06	15.49	0.0	0.00	66.7	31	1.08	21.92	-66.7	0.00	66.7
Cycle 17 Day 1	28	2.38	8.74	0.0	0.00	33.3	25	-4.00	22.19	-66.7	0.00	33.3
Cycle 18 Day 1	23	1.45	6.95	0.0	0.00	33.3	21	-3.17	17.97	-66.7	0.00	33.3
Cycle 19 Day 1	21	0.00	0.00	0.0	0.00	0.0	20	-1.67	7.45	-33.3	0.00	0.0
Cycle 20 Day 1	20	3.33	10.26	0.0	0.00	33.3	19	-3.51	18.90	-66.7	0.00	33.3
Cycle 21 Day 1	21	0.00	0.00	0.0	0.00	0.0	20	-5.00	16.31	-66.7	0.00	0.0
Cycle 22 Day 1	18	1.85	7.86	0.0	0.00	33.3	17	-3.92	20.01	-66.7	0.00	33.3
Cycle 23 Day 1	17	1.96	8.08	0.0	0.00	33.3	16	-4.17	20.64	-66.7	0.00	33.3
Cycle 24 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-5.56	19.25	-66.7	0.00	0.0
Cycle 25 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-5.56	19.25	-66.7	0.00	0.0
Cycle 26 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	0.00	0.00	0.0	0.00	0.0
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	0.00	0.00	0.0	0.00	0.0
Cycle 28 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 29 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-2.78	9.62	-33.3	0.00	0.0
Study Disc 1	156	6.84	16.81	0.0	0.00	66.7	150	0.00	21.50	-100.0	0.00	66.7
30 D SFU Z/P	78	3.85	15.18	0.0	0.00	100.0	76	-3.07	19.00	-66.7	0.00	66.7
90 D SFU Z/P	81	5.76	14.71	0.0	0.00	66.7	79	-1.69	21.94	-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: 12JAN24

Table 302.3.3002.32: 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 + CAPOX (N=254)												
Baseline	243	10.56	17.49	0.0	0.00	100.0						
Cycle 2 Day 1	209	9.41	16.40	0.0	0.00	66.7	208	-0.48	16.86	-100.0	0.00	66.7
Cycle 3 Day 1	186	7.53	15.21	0.0	0.00	66.7	182	-2.01	17.92	-100.0	0.00	66.7
Cycle 4 Day 1	169	8.28	16.58	0.0	0.00	100.0	166	-1.61	19.00	-100.0	0.00	100.0
Cycle 5 Day 1	163	9.61	16.03	0.0	0.00	66.7	159	0.21	19.30	-100.0	0.00	66.7
Cycle 6 Day 1	151	9.49	18.21	0.0	0.00	100.0	149	0.22	23.41	-100.0	0.00	100.0
Cycle 7 Day 1	121	6.89	16.05	0.0	0.00	100.0	119	-2.24	19.76	-100.0	0.00	66.7
Cycle 8 Day 1	114	7.60	14.73	0.0	0.00	66.7	108	-0.31	17.94	-33.3	0.00	66.7
Cycle 9 Day 1	107	7.17	15.21	0.0	0.00	66.7	102	-3.92	20.06	-66.7	0.00	66.7
Cycle 10 Day 1	88	6.82	15.30	0.0	0.00	66.7	85	-3.53	22.43	-100.0	0.00	66.7
Cycle 11 Day 1	83	6.43	16.01	0.0	0.00	100.0	80	-4.17	22.73	-100.0	0.00	100.0
Cycle 12 Day 1	77	7.36	14.93	0.0	0.00	66.7	75	-2.67	23.09	-100.0	0.00	66.7
Cycle 13 Day 1	62	5.91	16.56	0.0	0.00	100.0	60	-5.00	25.91	-100.0	0.00	100.0
Cycle 14 Day 1	57	1.75	7.51	0.0	0.00	33.3	55	-6.06	15.83	-33.3	0.00	33.3
Cycle 15 Day 1	53	3.14	11.81	0.0	0.00	66.7	51	-7.19	20.35	-100.0	0.00	33.3
Cycle 16 Day 1	50	6.00	12.94	0.0	0.00	33.3	48	-4.17	23.44	-100.0	0.00	33.3
Cycle 17 Day 1	45	3.70	10.59	0.0	0.00	33.3	43	-7.75	22.81	-100.0	0.00	33.3
Cycle 18 Day 1	43	6.20	13.12	0.0	0.00	33.3	41	-6.50	21.37	-66.7	0.00	33.3
Cycle 19 Day 1	42	4.76	11.81	0.0	0.00	33.3	40	-5.00	17.78	-33.3	0.00	33.3
Cycle 20 Day 1	41	6.50	13.37	0.0	0.00	33.3	39	-3.42	19.93	-33.3	0.00	33.3
Cycle 21 Day 1	38	5.26	12.32	0.0	0.00	33.3	36	-4.63	19.76	-33.3	0.00	33.3
Cycle 22 Day 1	33	3.03	12.81	0.0	0.00	66.7	31	-5.38	17.42	-33.3	0.00	33.3
Cycle 23 Day 1	33	4.04	11.05	0.0	0.00	33.3	31	-4.30	18.74	-33.3	0.00	33.3
Cycle 24 Day 1	31	3.23	10.02	0.0	0.00	33.3	29	-3.45	18.57	-33.3	0.00	33.3
Cycle 25 Day 1	30	3.33	10.17	0.0	0.00	33.3	28	-2.38	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: 12JAN24

Table 302.3.3002.32: 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 26 Day 1	28	4.76	11.88	0.0	0.00	33.3	26	-1.28	17.59	-33.3	0.00	33.3
Cycle 27 Day 1	27	2.47	8.90	0.0	0.00	33.3	25	-4.00	17.53	-33.3	0.00	33.3
Cycle 28 Day 1	23	2.90	9.60	0.0	0.00	33.3	21	-1.59	12.81	-33.3	0.00	33.3
Cycle 29 Day 1	24	8.33	22.52	0.0	0.00	100.0	22	3.03	22.79	-33.3	0.00	66.7
Cycle 30 Day 1	22	9.09	18.35	0.0	0.00	66.7	20	1.67	17.01	-33.3	0.00	33.3
Cycle 31 Day 1	22	10.61	23.87	0.0	0.00	100.0	20	3.33	21.36	-33.3	0.00	66.7
Cycle 32 Day 1	20	13.33	19.94	0.0	0.00	66.7	18	3.70	19.43	-33.3	0.00	33.3
Cycle 33 Day 1	17	3.92	11.07	0.0	0.00	33.3	15	-4.44	11.73	-33.3	0.00	0.0
Cycle 34 Day 1	14	7.14	14.19	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
Cycle 35 Day 1	15	4.44	11.73	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
Cycle 36 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-5.56	12.97	-33.3	0.00	0.0
Cycle 37 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-6.06	13.48	-33.3	0.00	0.0
Cycle 38 Day 1	11	6.06	13.48	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 39 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
Study Disc 1	135	10.37	19.30	0.0	0.00	100.0	133	1.25	22.25	-33.3	0.00	100.0
30 D SFU Z/P	58	8.62	18.27	0.0	0.00	100.0	57	1.17	21.79	-33.3	0.00	100.0
90 D SFU Z/P	62	9.14	14.99	0.0	0.00	33.3	61	2.19	15.95	-33.3	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	241	9.82	19.49	0.0	0.00	100.0						
Cycle 2 Day 1	222	9.01	17.34	0.0	0.00	100.0	216	-0.77	18.59	-66.7	0.00	66.7
Cycle 3 Day 1	200	9.50	16.50	0.0	0.00	100.0	196	-0.68	19.08	-100.0	0.00	33.3
Cycle 4 Day 1	171	8.38	17.75	0.0	0.00	100.0	169	-0.99	20.39	-100.0	0.00	100.0
Cycle 5 Day 1	166	7.03	15.49	0.0	0.00	100.0	165	-2.63	18.03	-100.0	0.00	33.3
Cycle 6 Day 1	146	7.31	14.90	0.0	0.00	66.7	145	-1.38	16.61	-66.7	0.00	33.3
Cycle 7 Day 1	126	7.67	14.70	0.0	0.00	66.7	125	-1.87	19.54	-66.7	0.00	33.3
Cycle 8 Day 1	110	8.18	15.10	0.0	0.00	66.7	109	-1.22	20.75	-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: 12JAN24

Table 302.3.3002.32: 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 9 Day 1	104	7.37	15.38	0.0	0.00	66.7	103	-2.91	21.44	-100.0	0.00	66.7
Cycle 10 Day 1	81	9.05	19.01	0.0	0.00	100.0	79	-2.11	25.79	-100.0	0.00	100.0
Cycle 11 Day 1	72	7.87	17.24	0.0	0.00	100.0	71	-4.23	25.15	-100.0	0.00	100.0
Cycle 12 Day 1	59	5.08	13.58	0.0	0.00	66.7	57	-8.19	22.96	-100.0	0.00	66.7
Cycle 13 Day 1	50	6.67	16.50	0.0	0.00	66.7	48	-6.94	22.76	-66.7	0.00	66.7
Cycle 14 Day 1	46	7.25	15.58	0.0	0.00	66.7	44	-6.82	23.38	-100.0	0.00	66.7
Cycle 15 Day 1	38	7.02	13.77	0.0	0.00	33.3	36	-7.41	21.25	-66.7	0.00	33.3
Cycle 16 Day 1	33	5.05	12.14	0.0	0.00	33.3	31	-8.60	19.18	-66.7	0.00	0.0
Cycle 17 Day 1	28	9.52	15.33	0.0	0.00	33.3	25	1.33	17.95	-33.3	0.00	33.3
Cycle 18 Day 1	23	4.35	11.48	0.0	0.00	33.3	21	-4.76	19.11	-33.3	0.00	33.3
Cycle 19 Day 1	21	7.94	17.97	0.0	0.00	66.7	20	-1.67	7.45	-33.3	0.00	0.0
Cycle 20 Day 1	20	5.00	12.21	0.0	0.00	33.3	19	-5.26	22.94	-66.7	0.00	33.3
Cycle 21 Day 1	21	7.94	14.55	0.0	0.00	33.3	20	-1.67	20.16	-66.7	0.00	33.3
Cycle 22 Day 1	18	5.56	12.78	0.0	0.00	33.3	17	-5.88	21.20	-66.7	0.00	33.3
Cycle 23 Day 1	17	5.88	13.10	0.0	0.00	33.3	16	-6.25	21.84	-66.7	0.00	33.3
Cycle 24 Day 1	13	2.56	9.25	0.0	0.00	33.3	12	-5.56	23.92	-66.7	0.00	33.3
Cycle 25 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
Cycle 26 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3
Cycle 27 Day 1	11	9.09	21.56	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 28 Day 1	11	12.12	22.47	0.0	0.00	66.7	11	0.00	21.08	-33.3	0.00	33.3
Cycle 29 Day 1	12	11.11	16.41	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
Study Disc 1	156	9.62	19.68	0.0	0.00	100.0	150	0.22	25.18	-100.0	0.00	100.0
30 D SFU Z/P	78	11.97	22.13	0.0	0.00	100.0	76	1.32	28.51	-66.7	0.00	100.0
90 D SFU Z/P	81	11.52	19.12	0.0	0.00	66.7	79	1.27	25.29	-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: 12JAN24

Table 302.3.3002.32.3: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing 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 + CAPOX (N=157)												
	Baseline	155	9.89	16.63	0.0	0.00	100.0						
	Cycle 2 Day 1	138	8.94	14.82	0.0	0.00	33.3	138	-1.21	15.29	-100.0	0.00	33.3
	Cycle 3 Day 1	121	6.06	12.91	0.0	0.00	33.3	120	-3.61	16.62	-100.0	0.00	33.3
	Cycle 4 Day 1	110	8.18	15.10	0.0	0.00	66.7	110	-2.12	17.65	-100.0	0.00	33.3
	Cycle 5 Day 1	106	8.81	15.47	0.0	0.00	66.7	106	-0.31	18.68	-100.0	0.00	66.7
	Cycle 6 Day 1	95	8.77	15.54	0.0	0.00	66.7	95	-0.35	20.91	-100.0	0.00	66.7
	Cycle 7 Day 1	79	6.75	13.48	0.0	0.00	33.3	79	-4.22	20.23	-100.0	0.00	33.3
	Cycle 8 Day 1	70	6.19	13.06	0.0	0.00	33.3	69	-2.90	16.90	-33.3	0.00	33.3
	Cycle 9 Day 1	70	6.19	13.06	0.0	0.00	33.3	69	-5.80	18.92	-66.7	0.00	33.3
	Cycle 10 Day 1	55	3.64	10.49	0.0	0.00	33.3	54	-8.64	20.67	-100.0	0.00	33.3
	Cycle 11 Day 1	55	6.06	12.97	0.0	0.00	33.3	54	-5.56	22.20	-100.0	0.00	33.3
	Cycle 12 Day 1	53	8.18	14.48	0.0	0.00	33.3	52	-3.21	24.04	-100.0	0.00	33.3
	Cycle 13 Day 1	44	6.82	18.44	0.0	0.00	100.0	43	-6.20	30.22	-100.0	0.00	100.0
	Cycle 14 Day 1	40	2.50	8.89	0.0	0.00	33.3	39	-6.84	17.40	-33.3	0.00	33.3
	Cycle 15 Day 1	35	1.90	7.85	0.0	0.00	33.3	34	-9.80	22.52	-100.0	0.00	33.3
	Cycle 16 Day 1	34	7.84	14.35	0.0	0.00	33.3	33	-3.03	26.83	-100.0	0.00	33.3
	Cycle 17 Day 1	30	3.33	10.17	0.0	0.00	33.3	29	-9.20	25.03	-100.0	0.00	33.3
	Cycle 18 Day 1	28	5.95	13.00	0.0	0.00	33.3	27	-8.64	23.74	-66.7	0.00	33.3
	Cycle 19 Day 1	27	4.94	12.07	0.0	0.00	33.3	26	-5.13	20.42	-33.3	0.00	33.3
	Cycle 20 Day 1	28	4.76	11.88	0.0	0.00	33.3	27	-4.94	20.05	-33.3	0.00	33.3
	Cycle 21 Day 1	25	5.33	12.47	0.0	0.00	33.3	24	-2.78	21.80	-33.3	0.00	33.3
	Cycle 22 Day 1	22	1.52	7.11	0.0	0.00	33.3	21	-6.35	17.06	-33.3	0.00	33.3
	Cycle 23 Day 1	21	4.76	11.95	0.0	0.00	33.3	20	-3.33	21.36	-33.3	0.00	33.3
	Cycle 24 Day 1	21	3.17	10.03	0.0	0.00	33.3	20	-5.00	19.57	-33.3	0.00	33.3
	Cycle 25 Day 1	20	3.33	10.26	0.0	0.00	33.3	19	-3.51	18.90	-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: 12JAN24

Table 302.3.3002.32.3: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing 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 26 Day 1	19	5.26	12.49	0.0	0.00	33.3	18	-1.85	21.30	-33.3	0.00	33.3
	Cycle 27 Day 1	18	3.70	10.78	0.0	0.00	33.3	17	-5.88	21.20	-33.3	0.00	33.3
	Cycle 28 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-5.56	12.97	-33.3	0.00	0.0
	Cycle 29 Day 1	15	6.67	13.80	0.0	0.00	33.3	14	0.00	22.65	-33.3	0.00	33.3
	Cycle 30 Day 1	14	9.52	15.63	0.0	0.00	33.3	13	0.00	19.25	-33.3	0.00	33.3
	Cycle 31 Day 1	15	6.67	13.80	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3
	Cycle 32 Day 1	13	12.82	16.88	0.0	0.00	33.3	12	2.78	22.29	-33.3	0.00	33.3
	Cycle 33 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	-5.56	12.97	-33.3	0.00	0.0
	Cycle 35 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3
	Study Disc 1	90	10.74	17.19	0.0	0.00	66.7	90	0.74	19.97	-33.3	0.00	66.7
	30 D SFU Z/P	38	7.89	14.36	0.0	0.00	33.3	38	0.00	18.98	-33.3	0.00	33.3
	90 D SFU Z/P	38	11.40	16.03	0.0	0.00	33.3	38	2.63	16.22	-33.3	0.00	33.3
	Placebo + CAPOX (N=158)												
	Baseline	155	8.82	17.02	0.0	0.00	66.7						
	Cycle 2 Day 1	140	8.33	15.03	0.0	0.00	66.7	139	0.00	19.25	-66.7	0.00	66.7
	Cycle 3 Day 1	127	8.66	14.68	0.0	0.00	33.3	126	0.00	18.86	-66.7	0.00	33.3
	Cycle 4 Day 1	108	6.48	14.74	0.0	0.00	66.7	107	-2.18	19.03	-66.7	0.00	66.7
	Cycle 5 Day 1	104	6.73	13.45	0.0	0.00	33.3	104	-2.56	16.55	-66.7	0.00	33.3
	Cycle 6 Day 1	88	5.30	12.26	0.0	0.00	33.3	88	-3.03	17.24	-66.7	0.00	33.3
	Cycle 7 Day 1	79	6.75	14.50	0.0	0.00	66.7	79	-2.53	19.08	-66.7	0.00	33.3
	Cycle 8 Day 1	68	5.88	14.04	0.0	0.00	66.7	68	-2.94	20.55	-66.7	0.00	66.7
	Cycle 9 Day 1	63	4.76	13.19	0.0	0.00	66.7	63	-4.76	17.82	-33.3	0.00	33.3
	Cycle 10 Day 1	47	8.51	20.23	0.0	0.00	100.0	47	-0.71	24.56	-33.3	0.00	100.0
	Cycle 11 Day 1	45	6.67	18.26	0.0	0.00	100.0	45	-2.22	22.92	-33.3	0.00	100.0
	Cycle 12 Day 1	34	3.92	13.64	0.0	0.00	66.7	34	-5.88	19.19	-33.3	0.00	66.7
	Cycle 13 Day 1	28	3.57	13.88	0.0	0.00	66.7	28	-4.76	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.
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: 12JAN24

Table 302.3.3002.32.3: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing 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 14 Day 1	25	2.67	9.23	0.0	0.00	33.3	25	-5.33	12.47	-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	18	5.56	12.78	0.0	0.00	33.3	18	-1.85	7.86	-33.3	0.00	0.0
	Cycle 17 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 18 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 19 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-2.78	9.62	-33.3	0.00	0.0
	Cycle 20 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3
	Cycle 21 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
	Study Disc 1	102	8.82	19.30	0.0	0.00	100.0	101	0.00	25.82	-66.7	0.00	100.0
	30 D SFU Z/P	50	12.00	24.06	0.0	0.00	100.0	50	0.67	31.22	-66.7	0.00	100.0
	90 D SFU Z/P	49	9.52	18.00	0.0	0.00	66.7	49	0.00	26.35	-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: 12JAN24

Table 302.3.3002.32.3: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing 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 + CAPOX (N= 97)												
	Baseline	88	11.74	18.94	0.0	0.00	66.7						
	Cycle 2 Day 1	71	10.33	19.18	0.0	0.00	66.7	70	0.95	19.64	-33.3	0.00	66.7
	Cycle 3 Day 1	65	10.26	18.56	0.0	0.00	66.7	62	1.08	19.99	-33.3	0.00	66.7
	Cycle 4 Day 1	59	8.47	19.17	0.0	0.00	100.0	56	-0.60	21.55	-33.3	0.00	100.0
	Cycle 5 Day 1	57	11.11	17.06	0.0	0.00	66.7	53	1.26	20.63	-33.3	0.00	66.7
	Cycle 6 Day 1	56	10.71	22.12	0.0	0.00	100.0	54	1.23	27.44	-66.7	0.00	100.0
	Cycle 7 Day 1	42	7.14	20.21	0.0	0.00	100.0	40	1.67	18.41	-33.3	0.00	66.7
	Cycle 8 Day 1	44	9.85	16.98	0.0	0.00	66.7	39	4.27	19.01	-33.3	0.00	66.7
	Cycle 9 Day 1	37	9.01	18.67	0.0	0.00	66.7	33	0.00	22.05	-33.3	0.00	66.7
	Cycle 10 Day 1	33	12.12	20.10	0.0	0.00	66.7	31	5.38	22.93	-33.3	0.00	66.7
	Cycle 11 Day 1	28	7.14	21.00	0.0	0.00	100.0	26	-1.28	24.00	-33.3	0.00	100.0
	Cycle 12 Day 1	24	5.56	16.05	0.0	0.00	66.7	23	-1.45	21.27	-33.3	0.00	66.7
	Cycle 13 Day 1	18	3.70	10.78	0.0	0.00	33.3	17	-1.96	8.08	-33.3	0.00	0.0
	Cycle 14 Day 1	17	0.00	0.00	0.0	0.00	0.0	16	-4.17	11.39	-33.3	0.00	0.0
	Cycle 15 Day 1	18	5.56	17.15	0.0	0.00	66.7	17	-1.96	14.29	-33.3	0.00	33.3
	Cycle 16 Day 1	16	2.08	8.33	0.0	0.00	33.3	15	-6.67	13.80	-33.3	0.00	0.0
	Cycle 17 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	-4.76	17.82	-33.3	0.00	33.3
	Cycle 18 Day 1	15	6.67	13.80	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3
	Cycle 19 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	-4.76	12.10	-33.3	0.00	0.0
	Cycle 20 Day 1	13	10.26	16.01	0.0	0.00	33.3	12	0.00	20.10	-33.3	0.00	33.3
	Cycle 21 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	-8.33	15.08	-33.3	0.00	0.0
	Cycle 22 Day 1	11	6.06	20.10	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
	Cycle 23 Day 1	12	2.78	9.62	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Cycle 24 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Cycle 25 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	0.00	16.67	-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: 12JAN24

Table 302.3.3002.32.3: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing 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 28 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
	Study Disc 1	45	9.63	23.16	0.0	0.00	100.0	43	2.33	26.62	-33.3	0.00	100.0
	30 D SFU Z/P	20	10.00	24.42	0.0	0.00	100.0	19	3.51	26.98	-33.3	0.00	100.0
	90 D SFU Z/P	24	5.56	12.69	0.0	0.00	33.3	23	1.45	15.82	-33.3	0.00	33.3
	Placebo + CAPOX (N= 95)												
	Baseline	86	11.63	23.30	0.0	0.00	100.0						
	Cycle 2 Day 1	82	10.16	20.75	0.0	0.00	100.0	77	-2.16	17.39	-66.7	0.00	33.3
	Cycle 3 Day 1	73	10.96	19.29	0.0	0.00	100.0	70	-1.90	19.57	-100.0	0.00	33.3
	Cycle 4 Day 1	63	11.64	21.72	0.0	0.00	100.0	62	1.08	22.56	-100.0	0.00	100.0
	Cycle 5 Day 1	62	7.53	18.52	0.0	0.00	100.0	61	-2.73	20.45	-100.0	0.00	33.3
	Cycle 6 Day 1	58	10.34	17.89	0.0	0.00	66.7	57	1.17	15.39	-33.3	0.00	33.3
	Cycle 7 Day 1	47	9.22	15.07	0.0	0.00	33.3	46	-0.72	20.47	-66.7	0.00	33.3
	Cycle 8 Day 1	42	11.90	16.17	0.0	0.00	33.3	41	1.63	21.02	-66.7	0.00	33.3
	Cycle 9 Day 1	41	11.38	17.65	0.0	0.00	66.7	40	0.00	26.15	-100.0	0.00	66.7
	Cycle 10 Day 1	34	9.80	17.46	0.0	0.00	66.7	32	-4.17	27.76	-100.0	0.00	66.7
	Cycle 11 Day 1	27	9.88	15.51	0.0	0.00	33.3	26	-7.69	28.76	-100.0	0.00	33.3
	Cycle 12 Day 1	25	6.67	13.61	0.0	0.00	33.3	23	-11.59	27.72	-100.0	0.00	33.3
	Cycle 13 Day 1	22	10.61	18.93	0.0	0.00	66.7	20	-10.00	26.71	-66.7	0.00	66.7
	Cycle 14 Day 1	21	12.70	19.65	0.0	0.00	66.7	19	-8.77	33.04	-100.0	0.00	66.7
	Cycle 15 Day 1	19	8.77	15.08	0.0	0.00	33.3	17	-11.76	26.20	-66.7	0.00	33.3
	Cycle 16 Day 1	15	4.44	11.73	0.0	0.00	33.3	13	-17.95	25.88	-66.7	0.00	0.0
	Cycle 17 Day 1	13	12.82	16.88	0.0	0.00	33.3	10	0.00	22.22	-33.3	0.00	33.3
	Cycle 18 Day 1	12	5.56	12.97	0.0	0.00	33.3	10	-10.00	22.50	-33.3	0.00	33.3
	Cycle 21 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	-7.41	27.78	-66.7	0.00	33.3
	Cycle 22 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	-11.11	23.57	-66.7	0.00	0.0
	Study Disc 1	54	11.11	20.48	0.0	0.00	100.0	49	0.68	24.05	-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: 12JAN24

Table 302.3.3002.32.3: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing 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
	30 D SFU Z/P	28	11.90	18.62	0.0	0.00	66.7	26	2.56	22.95	-66.7	0.00	66.7
	90 D SFU Z/P	32	14.58	20.63	0.0	0.00	66.7	30	3.33	23.73	-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: 12JAN24

Table 302.3.3002.33: 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 + CAPOX (N=254)												
Baseline	243	3.84	14.34	0.0	0.00	100.0						
Cycle 2 Day 1	209	3.99	12.23	0.0	0.00	66.7	208	0.96	13.07	-66.7	0.00	66.7
Cycle 3 Day 1	186	2.87	10.58	0.0	0.00	66.7	182	-0.18	11.35	-66.7	0.00	66.7
Cycle 4 Day 1	169	2.76	11.74	0.0	0.00	100.0	166	-0.40	12.71	-66.7	0.00	66.7
Cycle 5 Day 1	163	4.09	12.16	0.0	0.00	66.7	159	1.68	11.74	-33.3	0.00	33.3
Cycle 6 Day 1	151	3.97	13.29	0.0	0.00	66.7	149	0.67	13.68	-33.3	0.00	66.7
Cycle 7 Day 1	121	4.13	13.99	0.0	0.00	100.0	119	0.84	15.32	-66.7	0.00	100.0
Cycle 8 Day 1	114	5.26	13.73	0.0	0.00	66.7	108	0.93	12.45	-66.7	0.00	33.3
Cycle 9 Day 1	107	4.98	14.34	0.0	0.00	66.7	102	0.65	15.54	-66.7	0.00	66.7
Cycle 10 Day 1	88	4.17	12.18	0.0	0.00	66.7	85	0.39	14.08	-66.7	0.00	33.3
Cycle 11 Day 1	83	3.61	11.65	0.0	0.00	66.7	80	0.42	12.43	-66.7	0.00	33.3
Cycle 12 Day 1	77	2.16	9.88	0.0	0.00	66.7	75	-1.33	11.55	-66.7	0.00	33.3
Cycle 13 Day 1	62	0.54	4.23	0.0	0.00	33.3	60	-2.78	12.71	-66.7	0.00	33.3
Cycle 14 Day 1	57	0.00	0.00	0.0	0.00	0.0	55	-3.03	11.61	-66.7	0.00	0.0
Cycle 15 Day 1	53	0.63	4.58	0.0	0.00	33.3	51	-3.27	13.75	-66.7	0.00	33.3
Cycle 16 Day 1	50	4.00	10.94	0.0	0.00	33.3	48	0.00	16.84	-66.7	0.00	33.3
Cycle 17 Day 1	45	0.00	0.00	0.0	0.00	0.0	43	-4.65	13.77	-66.7	0.00	0.0
Cycle 18 Day 1	43	1.55	7.10	0.0	0.00	33.3	41	-3.25	12.48	-33.3	0.00	33.3
Cycle 19 Day 1	42	3.97	10.93	0.0	0.00	33.3	40	0.00	15.10	-33.3	0.00	33.3
Cycle 20 Day 1	41	1.63	7.27	0.0	0.00	33.3	39	-2.56	14.07	-66.7	0.00	33.3
Cycle 21 Day 1	38	3.51	10.37	0.0	0.00	33.3	36	-0.93	18.66	-66.7	0.00	33.3
Cycle 22 Day 1	33	1.01	5.80	0.0	0.00	33.3	31	-3.23	13.21	-66.7	0.00	0.0
Cycle 23 Day 1	33	2.02	8.08	0.0	0.00	33.3	31	-1.08	13.56	-66.7	0.00	33.3
Cycle 24 Day 1	31	1.08	5.99	0.0	0.00	33.3	29	-2.30	12.38	-66.7	0.00	0.0
Cycle 25 Day 1	30	2.22	8.46	0.0	0.00	33.3	28	-1.19	14.29	-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: 12JAN24

Table 302.3.3002.33: 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 26 Day 1	28	2.38	8.74	0.0	0.00	33.3	26	-1.28	14.85	-66.7	0.00	33.3
Cycle 27 Day 1	27	0.00	0.00	0.0	0.00	0.0	25	-2.67	13.33	-66.7	0.00	0.0
Cycle 28 Day 1	23	0.00	0.00	0.0	0.00	0.0	21	-3.17	14.55	-66.7	0.00	0.0
Cycle 29 Day 1	24	1.39	6.80	0.0	0.00	33.3	22	-1.52	16.19	-66.7	0.00	33.3
Cycle 30 Day 1	22	1.52	7.11	0.0	0.00	33.3	20	-1.67	17.01	-66.7	0.00	33.3
Cycle 31 Day 1	22	3.03	9.81	0.0	0.00	33.3	20	0.00	18.73	-66.7	0.00	33.3
Cycle 32 Day 1	20	1.67	7.45	0.0	0.00	33.3	18	-1.85	17.98	-66.7	0.00	33.3
Cycle 33 Day 1	17	0.00	0.00	0.0	0.00	0.0	15	-4.44	17.21	-66.7	0.00	0.0
Cycle 34 Day 1	14	0.00	0.00	0.0	0.00	0.0	12	-5.56	19.25	-66.7	0.00	0.0
Cycle 35 Day 1	15	0.00	0.00	0.0	0.00	0.0	13	-5.13	18.49	-66.7	0.00	0.0
Cycle 36 Day 1	14	0.00	0.00	0.0	0.00	0.0	12	-5.56	19.25	-66.7	0.00	0.0
Cycle 37 Day 1	12	0.00	0.00	0.0	0.00	0.0	11	-6.06	20.10	-66.7	0.00	0.0
Cycle 38 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	-6.67	21.08	-66.7	0.00	0.0
Cycle 39 Day 1	10	0.00	0.00	0.0	0.00	0.0	9	0.00	0.00	0.0	0.00	0.0
Study Disc 1	135	7.16	17.46	0.0	0.00	100.0	133	4.01	18.82	-66.7	0.00	66.7
30 D SFU Z/P	58	8.05	21.91	0.0	0.00	100.0	57	4.68	18.30	-33.3	0.00	100.0
90 D SFU Z/P	62	4.30	11.27	0.0	0.00	33.3	61	3.83	10.71	0.0	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	241	3.60	12.40	0.0	0.00	100.0						
Cycle 2 Day 1	222	3.15	11.65	0.0	0.00	100.0	216	-0.31	9.64	-33.3	0.00	66.7
Cycle 3 Day 1	200	1.83	7.62	0.0	0.00	33.3	196	-1.02	11.65	-100.0	0.00	33.3
Cycle 4 Day 1	171	3.70	11.68	0.0	0.00	66.7	169	0.99	14.28	-33.3	0.00	66.7
Cycle 5 Day 1	166	2.21	9.80	0.0	0.00	66.7	165	-0.81	11.01	-33.3	0.00	66.7
Cycle 6 Day 1	146	3.20	9.85	0.0	0.00	33.3	145	0.46	11.78	-33.3	0.00	33.3
Cycle 7 Day 1	126	2.65	9.05	0.0	0.00	33.3	125	-0.53	11.19	-33.3	0.00	33.3
Cycle 8 Day 1	110	2.42	8.70	0.0	0.00	33.3	109	-1.22	13.55	-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: 12JAN24

Table 302.3.3002.33: 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 9 Day 1	104	3.53	11.30	0.0	0.00	66.7	103	0.32	13.60	-33.3	0.00	33.3
Cycle 10 Day 1	81	2.88	10.80	0.0	0.00	66.7	79	-1.27	15.51	-66.7	0.00	66.7
Cycle 11 Day 1	72	1.85	7.69	0.0	0.00	33.3	71	-1.41	13.14	-66.7	0.00	33.3
Cycle 12 Day 1	59	2.26	8.45	0.0	0.00	33.3	57	0.58	7.69	-33.3	0.00	33.3
Cycle 13 Day 1	50	2.00	8.00	0.0	0.00	33.3	48	-1.39	15.31	-66.7	0.00	33.3
Cycle 14 Day 1	46	2.90	11.81	0.0	0.00	66.7	44	0.00	16.07	-66.7	0.00	66.7
Cycle 15 Day 1	38	1.75	7.54	0.0	0.00	33.3	36	-1.85	13.67	-66.7	0.00	33.3
Cycle 16 Day 1	33	3.03	9.73	0.0	0.00	33.3	31	-1.08	16.06	-66.7	0.00	33.3
Cycle 17 Day 1	28	4.76	11.88	0.0	0.00	33.3	25	2.67	13.33	-33.3	0.00	33.3
Cycle 18 Day 1	23	5.80	12.92	0.0	0.00	33.3	21	3.17	14.55	-33.3	0.00	33.3
Cycle 19 Day 1	21	1.59	7.27	0.0	0.00	33.3	20	1.67	7.45	0.0	0.00	33.3
Cycle 20 Day 1	20	5.00	12.21	0.0	0.00	33.3	19	1.75	13.49	-33.3	0.00	33.3
Cycle 21 Day 1	21	6.35	17.06	0.0	0.00	66.7	20	3.33	18.42	-33.3	0.00	66.7
Cycle 22 Day 1	18	3.70	10.78	0.0	0.00	33.3	17	0.00	20.41	-66.7	0.00	33.3
Cycle 23 Day 1	17	1.96	8.08	0.0	0.00	33.3	16	-2.08	19.12	-66.7	0.00	33.3
Cycle 24 Day 1	13	5.13	12.52	0.0	0.00	33.3	12	0.00	24.62	-66.7	0.00	33.3
Cycle 25 Day 1	13	7.69	14.62	0.0	0.00	33.3	12	2.78	17.16	-33.3	0.00	33.3
Cycle 26 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
Cycle 28 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 29 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	156	7.48	17.99	0.0	0.00	100.0	150	4.89	20.21	-66.7	0.00	100.0
30 D SFU Z/P	78	4.70	14.93	0.0	0.00	66.7	76	2.19	15.72	-33.3	0.00	66.7
90 D SFU Z/P	81	5.76	15.63	0.0	0.00	66.7	79	3.38	20.39	-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: 12JAN24

Table 302.3.3002.34: 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 + CAPOX (N=254)												
Baseline	243	23.05	27.43	0.0	33.33	100.0						
Cycle 2 Day 1	209	23.13	26.59	0.0	33.33	100.0	208	0.16	23.28	-66.7	0.00	100.0
Cycle 3 Day 1	186	23.66	28.40	0.0	16.67	100.0	182	0.92	26.78	-66.7	0.00	66.7
Cycle 4 Day 1	169	23.47	25.62	0.0	33.33	100.0	166	0.00	28.19	-66.7	0.00	100.0
Cycle 5 Day 1	163	25.36	29.59	0.0	33.33	100.0	159	2.52	32.38	-66.7	0.00	100.0
Cycle 6 Day 1	151	22.08	27.73	0.0	0.00	100.0	149	-0.45	25.99	-66.7	0.00	66.7
Cycle 7 Day 1	121	19.28	27.47	0.0	0.00	100.0	119	-2.52	27.84	-66.7	0.00	100.0
Cycle 8 Day 1	114	19.59	25.01	0.0	0.00	100.0	108	-2.47	26.46	-100.0	0.00	66.7
Cycle 9 Day 1	107	18.69	24.73	0.0	0.00	100.0	102	-5.88	29.45	-100.0	0.00	100.0
Cycle 10 Day 1	88	17.42	27.21	0.0	0.00	100.0	85	-7.06	32.57	-100.0	0.00	100.0
Cycle 11 Day 1	83	13.25	24.93	0.0	0.00	100.0	80	-9.58	30.56	-100.0	0.00	66.7
Cycle 12 Day 1	77	12.99	24.87	0.0	0.00	100.0	75	-10.22	30.50	-100.0	0.00	100.0
Cycle 13 Day 1	62	14.52	24.61	0.0	0.00	100.0	60	-11.67	28.67	-100.0	0.00	66.7
Cycle 14 Day 1	57	10.53	22.85	0.0	0.00	100.0	55	-13.94	26.21	-100.0	0.00	66.7
Cycle 15 Day 1	53	11.32	22.59	0.0	0.00	100.0	51	-12.42	26.63	-66.7	0.00	66.7
Cycle 16 Day 1	50	10.67	20.69	0.0	0.00	100.0	48	-15.97	22.79	-66.7	0.00	33.3
Cycle 17 Day 1	45	10.37	22.27	0.0	0.00	100.0	43	-14.73	19.66	-66.7	0.00	0.0
Cycle 18 Day 1	43	13.95	24.38	0.0	0.00	100.0	41	-11.38	25.40	-66.7	0.00	33.3
Cycle 19 Day 1	42	9.52	19.87	0.0	0.00	100.0	40	-16.67	22.65	-66.7	0.00	33.3
Cycle 20 Day 1	41	13.82	23.54	0.0	0.00	100.0	39	-10.26	21.84	-66.7	0.00	33.3
Cycle 21 Day 1	38	10.53	20.66	0.0	0.00	100.0	36	-12.96	22.93	-66.7	0.00	33.3
Cycle 22 Day 1	33	10.10	25.66	0.0	0.00	100.0	31	-12.90	23.85	-66.7	0.00	33.3
Cycle 23 Day 1	33	11.11	24.53	0.0	0.00	100.0	31	-10.75	19.98	-66.7	0.00	33.3
Cycle 24 Day 1	31	11.83	27.95	0.0	0.00	100.0	29	-10.34	26.88	-66.7	0.00	33.3
Cycle 25 Day 1	30	12.22	23.95	0.0	0.00	100.0	28	-10.71	20.39	-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: 12JAN24

Table 302.3.3002.34: 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 26 Day 1	28	7.14	21.00	0.0	0.00	100.0	26	-16.67	25.39	-66.7	0.00	33.3
Cycle 27 Day 1	27	11.11	27.74	0.0	0.00	100.0	25	-12.00	21.26	-66.7	0.00	33.3
Cycle 28 Day 1	23	13.04	26.09	0.0	0.00	100.0	21	-14.29	22.54	-66.7	0.00	0.0
Cycle 29 Day 1	24	11.11	25.38	0.0	0.00	100.0	22	-13.64	19.68	-66.7	0.00	0.0
Cycle 30 Day 1	22	9.09	25.58	0.0	0.00	100.0	20	-15.00	20.16	-66.7	0.00	0.0
Cycle 31 Day 1	22	13.64	26.55	0.0	0.00	100.0	20	-11.67	19.57	-66.7	0.00	0.0
Cycle 32 Day 1	20	8.33	23.88	0.0	0.00	100.0	18	-20.37	20.26	-66.7	-33.33	0.0
Cycle 33 Day 1	17	9.80	28.30	0.0	0.00	100.0	15	-15.56	24.77	-66.7	0.00	0.0
Cycle 34 Day 1	14	9.52	27.51	0.0	0.00	100.0	12	-16.67	26.59	-66.7	-16.67	33.3
Cycle 35 Day 1	15	8.89	19.79	0.0	0.00	66.7	13	-15.38	22.01	-66.7	0.00	0.0
Cycle 36 Day 1	14	7.14	19.30	0.0	0.00	66.7	12	-13.89	22.29	-66.7	0.00	0.0
Cycle 37 Day 1	12	8.33	20.72	0.0	0.00	66.7	11	-18.18	27.34	-66.7	0.00	0.0
Cycle 38 Day 1	11	9.09	21.56	0.0	0.00	66.7	10	-20.00	23.31	-66.7	-16.67	0.0
Cycle 39 Day 1	10	10.00	22.50	0.0	0.00	66.7	9	-14.81	24.22	-66.7	0.00	0.0
Study Disc 1	135	25.68	28.49	0.0	33.33	100.0	133	4.76	28.76	-100.0	0.00	66.7
30 D SFU Z/P	58	24.71	28.99	0.0	33.33	100.0	57	-1.75	30.49	-100.0	0.00	66.7
90 D SFU Z/P	62	16.67	26.14	0.0	0.00	100.0	61	-1.64	24.67	-33.3	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	241	24.07	28.25	0.0	33.33	100.0						
Cycle 2 Day 1	222	23.42	26.57	0.0	33.33	100.0	216	0.46	26.99	-100.0	0.00	100.0
Cycle 3 Day 1	200	24.00	28.39	0.0	33.33	100.0	196	1.02	27.20	-66.7	0.00	100.0
Cycle 4 Day 1	171	21.64	26.19	0.0	0.00	100.0	169	-1.18	25.69	-66.7	0.00	100.0
Cycle 5 Day 1	166	19.08	26.03	0.0	0.00	100.0	165	-2.42	26.43	-100.0	0.00	100.0
Cycle 6 Day 1	146	17.58	26.03	0.0	0.00	100.0	145	-5.29	29.05	-100.0	0.00	100.0
Cycle 7 Day 1	126	16.67	24.49	0.0	0.00	100.0	125	-3.47	28.02	-100.0	0.00	100.0
Cycle 8 Day 1	110	17.58	25.82	0.0	0.00	100.0	109	-3.67	29.17	-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: 12JAN24

Table 302.3.3002.34: 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 9 Day 1	104	15.06	25.39	0.0	0.00	100.0	103	-7.12	29.76	-66.7	0.00	100.0
Cycle 10 Day 1	81	14.81	22.97	0.0	0.00	100.0	79	-5.91	28.12	-100.0	0.00	66.7
Cycle 11 Day 1	72	13.43	24.81	0.0	0.00	100.0	71	-8.45	25.65	-100.0	0.00	66.7
Cycle 12 Day 1	59	10.17	18.83	0.0	0.00	66.7	57	-10.53	24.53	-66.7	0.00	33.3
Cycle 13 Day 1	50	10.67	20.69	0.0	0.00	66.7	48	-10.42	25.87	-66.7	0.00	66.7
Cycle 14 Day 1	46	13.04	21.63	0.0	0.00	66.7	44	-6.82	23.38	-66.7	0.00	66.7
Cycle 15 Day 1	38	14.91	27.62	0.0	0.00	100.0	36	-8.33	30.21	-66.7	0.00	66.7
Cycle 16 Day 1	33	15.15	20.57	0.0	0.00	66.7	31	-8.60	22.72	-66.7	0.00	33.3
Cycle 17 Day 1	28	11.90	20.72	0.0	0.00	66.7	25	-13.33	21.52	-66.7	0.00	33.3
Cycle 18 Day 1	23	10.14	18.63	0.0	0.00	66.7	21	-14.29	27.02	-100.0	0.00	33.3
Cycle 19 Day 1	21	7.94	14.55	0.0	0.00	33.3	20	-11.67	16.31	-33.3	0.00	0.0
Cycle 20 Day 1	20	13.33	19.94	0.0	0.00	66.7	19	-12.28	25.36	-66.7	0.00	33.3
Cycle 21 Day 1	21	7.94	14.55	0.0	0.00	33.3	20	-16.67	25.36	-66.7	0.00	33.3
Cycle 22 Day 1	18	9.26	19.15	0.0	0.00	66.7	17	-17.65	26.66	-66.7	0.00	33.3
Cycle 23 Day 1	17	3.92	11.07	0.0	0.00	33.3	16	-22.92	29.11	-100.0	-16.67	0.0
Cycle 24 Day 1	13	15.38	22.01	0.0	0.00	66.7	12	-13.89	30.01	-66.7	0.00	33.3
Cycle 25 Day 1	13	12.82	16.88	0.0	0.00	33.3	12	-11.11	25.95	-66.7	0.00	0.0
Cycle 26 Day 1	10	10.00	16.10	0.0	0.00	33.3	9	-11.11	16.67	-33.3	0.00	0.0
Cycle 27 Day 1	11	6.06	13.48	0.0	0.00	33.3	10	-13.33	23.31	-66.7	0.00	0.0
Cycle 28 Day 1	11	15.15	17.41	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
Cycle 29 Day 1	12	13.89	22.29	0.0	0.00	66.7	12	-8.33	15.08	-33.3	0.00	0.0
Study Disc 1	156	25.21	29.66	0.0	33.33	100.0	150	1.56	29.24	-66.7	0.00	100.0
30 D SFU Z/P	78	28.63	31.66	0.0	33.33	100.0	76	3.95	27.74	-66.7	0.00	66.7
90 D SFU Z/P	81	25.51	30.85	0.0	33.33	100.0	79	2.95	30.75	-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: 12JAN24

Table 302.3.3002.35: 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 + CAPOX (N=254)												
Baseline	91	12.09	20.80	0.0	0.00	100.0						
Cycle 2 Day 1	100	10.33	17.53	0.0	0.00	66.7	59	-2.26	18.43	-66.7	0.00	33.3
Cycle 3 Day 1	103	10.36	17.48	0.0	0.00	66.7	54	-3.09	19.71	-66.7	0.00	33.3
Cycle 4 Day 1	90	11.85	18.90	0.0	0.00	66.7	53	-0.63	24.01	-66.7	0.00	66.7
Cycle 5 Day 1	74	12.16	17.94	0.0	0.00	66.7	44	-3.03	20.10	-66.7	0.00	33.3
Cycle 6 Day 1	72	12.96	19.82	0.0	0.00	66.7	45	2.96	23.38	-66.7	0.00	66.7
Cycle 7 Day 1	53	12.58	18.75	0.0	0.00	66.7	30	-3.33	22.06	-66.7	0.00	33.3
Cycle 8 Day 1	53	12.58	19.86	0.0	0.00	66.7	35	-5.71	27.40	-100.0	0.00	66.7
Cycle 9 Day 1	52	12.82	18.85	0.0	0.00	66.7	30	-2.22	26.16	-100.0	0.00	33.3
Cycle 10 Day 1	37	14.41	20.09	0.0	0.00	66.7	20	-1.67	25.31	-100.0	0.00	33.3
Cycle 11 Day 1	37	9.91	15.45	0.0	0.00	33.3	20	-1.67	27.52	-100.0	0.00	33.3
Cycle 12 Day 1	38	7.89	16.32	0.0	0.00	66.7	22	-4.55	25.81	-100.0	0.00	33.3
Cycle 13 Day 1	31	7.53	16.58	0.0	0.00	66.7	19	-5.26	29.94	-100.0	0.00	33.3
Cycle 14 Day 1	23	5.80	12.92	0.0	0.00	33.3	12	-11.11	29.59	-100.0	0.00	0.0
Cycle 15 Day 1	21	12.70	19.65	0.0	0.00	66.7	11	6.06	25.03	-33.3	0.00	66.7
Cycle 16 Day 1	23	7.25	14.06	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
Cycle 17 Day 1	23	11.59	19.09	0.0	0.00	66.7	11	0.00	21.08	-33.3	0.00	33.3
Cycle 18 Day 1	21	7.94	14.55	0.0	0.00	33.3	10	0.00	22.22	-33.3	0.00	33.3
Cycle 19 Day 1	16	8.33	14.91	0.0	0.00	33.3	8	0.00	17.82	-33.3	0.00	33.3
Cycle 20 Day 1	15	8.89	15.26	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 21 Day 1	14	7.14	14.19	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 22 Day 1	11	9.09	15.57	0.0	0.00	33.3	8	0.00	17.82	-33.3	0.00	33.3
Cycle 23 Day 1	10	6.67	14.05	0.0	0.00	33.3	6	0.00	21.08	-33.3	0.00	33.3
Cycle 24 Day 1	12	2.78	9.62	0.0	0.00	33.3	7	-4.76	23.00	-33.3	0.00	33.3
Cycle 25 Day 1	10	6.67	14.05	0.0	0.00	33.3	6	0.00	21.08	-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: 12JAN24

Table 302.3.3002.35: 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
Study Disc 1	60	20.56	26.10	0.0	0.00	100.0	34	7.84	29.65	-33.3	0.00	100.0
30 D SFU Z/P	23	17.39	26.34	0.0	0.00	100.0	8	8.33	23.57	-33.3	0.00	33.3
90 D SFU Z/P	36	31.48	32.80	0.0	33.33	100.0	17	23.53	40.42	-33.3	0.00	100.0
Placebo + CAPOX (N=253)												
Baseline	85	12.55	23.56	0.0	0.00	100.0						
Cycle 2 Day 1	91	10.26	22.05	0.0	0.00	100.0	60	-1.67	15.56	-33.3	0.00	33.3
Cycle 3 Day 1	78	7.69	16.05	0.0	0.00	66.7	49	-4.76	23.57	-66.7	0.00	33.3
Cycle 4 Day 1	70	11.90	22.01	0.0	0.00	100.0	46	0.00	15.71	-33.3	0.00	66.7
Cycle 5 Day 1	69	12.08	24.23	0.0	0.00	100.0	41	-0.81	18.99	-33.3	0.00	33.3
Cycle 6 Day 1	61	9.84	20.50	0.0	0.00	100.0	36	-4.63	21.31	-66.7	0.00	66.7
Cycle 7 Day 1	57	9.94	20.86	0.0	0.00	100.0	29	-4.60	17.19	-66.7	0.00	33.3
Cycle 8 Day 1	53	6.92	15.13	0.0	0.00	66.7	26	-8.97	20.13	-66.7	0.00	33.3
Cycle 9 Day 1	44	12.88	24.08	0.0	0.00	100.0	21	-9.52	26.13	-100.0	0.00	33.3
Cycle 10 Day 1	40	11.67	24.52	0.0	0.00	100.0	16	-8.33	28.54	-100.0	0.00	33.3
Cycle 11 Day 1	32	11.46	20.05	0.0	0.00	66.7	11	3.03	17.98	-33.3	0.00	33.3
Cycle 12 Day 1	28	11.90	22.62	0.0	0.00	100.0	12	0.00	20.10	-33.3	0.00	33.3
Cycle 13 Day 1	20	13.33	25.13	0.0	0.00	100.0	10	-6.67	21.08	-33.3	0.00	33.3
Cycle 14 Day 1	18	11.11	25.57	0.0	0.00	100.0	7	4.76	12.60	0.0	0.00	33.3
Cycle 15 Day 1	13	10.26	21.01	0.0	0.00	66.7	7	-4.76	12.60	-33.3	0.00	0.0
Cycle 16 Day 1	13	5.13	12.52	0.0	0.00	33.3	5	-6.67	14.91	-33.3	0.00	0.0
Cycle 17 Day 1	10	3.33	10.54	0.0	0.00	33.3	4	0.00	0.00	0.0	0.00	0.0
Cycle 19 Day 1	10	0.00	0.00	0.0	0.00	0.0	5	-13.33	18.26	-33.3	0.00	0.0
Cycle 20 Day 1	10	3.33	10.54	0.0	0.00	33.3	4	0.00	0.00	0.0	0.00	0.0
Study Disc 1	59	12.43	24.68	0.0	0.00	100.0	31	-2.15	27.13	-100.0	0.00	66.7
30 D SFU Z/P	34	13.73	23.38	0.0	0.00	66.7	14	2.38	30.56	-33.3	0.00	66.7
90 D SFU Z/P	60	32.22	33.60	0.0	33.33	100.0	22	15.15	26.68	-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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

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

Table 302.3.3004.20.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dysphagia (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	120 (47.2%)	114 (45.1%)	
Number of patients censored	134 (52.8%)	139 (54.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.7 [3.5, 10.0]	6.9 [5.0, 10.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.105 [0.851, 1.436]
Log-rank test			
Two-sided stratified log-rank p-value			0.4622

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: 12JAN24

Table 302.3.3004.20.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dysphagia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	85 (48.3)	7.4 [3.2, 10.9]	180	87 (48.3)	6.5 [4.4, 9.0]	0.971 [0.717, 1.314]	0.8348	0.1532
>65 years	78	35 (44.9)	5.4 [1.7, 23.3]	73	27 (37.0)	14.1 [4.6, NC]	1.557 [0.937, 2.587]	0.0851	
Sex									
Male	159	80 (50.3)	4.4 [2.1, 10.0]	156	74 (47.4)	6.0 [4.6, 8.8]	1.112 [0.808, 1.531]	0.5198	0.9664
Female	95	40 (42.1)	8.8 [5.5, 18.9]	97	40 (41.2)	9.0 [4.2, NC]	1.085 [0.696, 1.691]	0.7240	
Region									
Asia	157	78 (49.7)	6.7 [2.8, 10.9]	158	66 (41.8)	7.4 [5.1, NC]	1.238 [0.888, 1.725]	0.2089	0.3883
Non-Asia	97	42 (43.3)	6.0 [2.6, 18.9]	95	48 (50.5)	6.4 [3.6, 10.8]	0.953 [0.626, 1.449]	0.8135	
Number of Organs with Metastatic Sites									
0-2	189	86 (45.5)	7.6 [3.8, 18.4]	188	81 (43.1)	8.3 [6.2, 11.7]	1.129 [0.831, 1.535]	0.4441	0.8474
>=3	65	34 (52.3)	3.6 [1.9, 8.8]	65	33 (50.8)	4.2 [1.7, 17.7]	1.044 [0.644, 1.692]	0.8666	

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: 12JAN24

Table 302.3.3004.21.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating Restrictions (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	95 (37.4%)	112 (44.3%)	
Number of patients censored	159 (62.6%)	141 (55.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	12.6 [7.6, 23.3]	7.4 [5.5, 9.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.895 [0.677, 1.185]
Log-rank test			
Two-sided stratified log-rank p-value			0.4329

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: 12JAN24

Table 302.3.3004.21.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating Restrictions by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	65 (36.9)	17.3 [7.9, 28.2]	180	81 (45.0)	7.5 [5.6, 10.4]	0.808 [0.581, 1.123]	0.2011	0.6404
>65 years	78	30 (38.5)	7.6 [3.4, NC]	73	31 (42.5)	6.4 [3.5, NC]	0.972 [0.586, 1.613]	0.9127	
Sex									
Male	159	64 (40.3)	9.7 [5.5, 28.2]	156	76 (48.7)	6.8 [4.2, 9.2]	0.809 [0.579, 1.131]	0.2122	0.7379
Female	95	31 (32.6)	22.7 [8.4, NC]	97	36 (37.1)	9.2 [6.5, NC]	0.917 [0.563, 1.492]	0.7199	
Region									
Asia	157	58 (36.9)	23.3 [8.4, 29.1]	158	61 (38.6)	9.2 [6.7, NC]	0.958 [0.666, 1.377]	0.8081	0.3626
Non-Asia	97	37 (38.1)	7.6 [3.8, 22.7]	95	51 (53.7)	5.3 [3.3, 7.9]	0.746 [0.488, 1.142]	0.1764	
Number of Organs with Metastatic Sites									
0-2	189	74 (39.2)	12.6 [6.7, 23.3]	188	81 (43.1)	8.3 [6.4, 11.7]	0.936 [0.681, 1.285]	0.6775	0.2561
>=3	65	21 (32.3)	29.1 [6.0, 29.1]	65	31 (47.7)	5.1 [2.9, 9.9]	0.627 [0.357, 1.102]	0.0982	

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: 12JAN24

Table 302.3.3004.22.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Reflux (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	124 (48.8%)	110 (43.5%)	
Number of patients censored	130 (51.2%)	143 (56.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.4 [3.3, 6.5]	6.3 [4.5, 11.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.332 [1.023, 1.734]
Log-rank test			
Two-sided stratified log-rank p-value			0.0331

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: 12JAN24

Table 302.3.3004.22.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Reflux by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	88 (50.0)	5.2 [3.0, 9.3]	180	76 (42.2)	8.3 [4.8, 12.8]	1.256 [0.922, 1.712]	0.1481	0.7425
>65 years	78	36 (46.2)	3.8 [2.7, 6.5]	73	34 (46.6)	4.4 [3.2, 14.1]	1.147 [0.717, 1.834]	0.5706	
Sex									
Male	159	82 (51.6)	4.3 [2.7, 6.3]	156	71 (45.5)	4.8 [4.0, 11.8]	1.180 [0.857, 1.624]	0.3063	0.7696
Female	95	42 (44.2)	5.3 [3.2, 17.3]	97	39 (40.2)	10.6 [4.8, NC]	1.305 [0.840, 2.027]	0.2354	
Region									
Asia	157	75 (47.8)	5.5 [3.3, 18.7]	158	69 (43.7)	5.9 [4.4, 14.1]	1.166 [0.839, 1.620]	0.3664	0.5065
Non-Asia	97	49 (50.5)	4.0 [2.2, 9.1]	95	41 (43.2)	8.3 [3.8, 12.8]	1.376 [0.905, 2.093]	0.1307	
Number of Organs with Metastatic Sites									
0-2	189	95 (50.3)	5.2 [3.3, 7.9]	188	79 (42.0)	9.2 [4.6, 12.8]	1.362 [1.009, 1.839]	0.0425	0.1948
>=3	65	29 (44.6)	3.7 [2.1, 28.2]	65	31 (47.7)	4.6 [2.5, 11.9]	0.924 [0.554, 1.543]	0.7565	

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: 12JAN24

Table 302.3.3004.23.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Odynophagia (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	107 (42.1%)	110 (43.5%)	
Number of patients censored	147 (57.9%)	143 (56.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.1 [4.6, 25.7]	7.4 [5.0, 10.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.001 [0.763, 1.314]
Log-rank test			
Two-sided stratified log-rank p-value			0.9993

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: 12JAN24

Table 302.3.3004.23.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Odynophagia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	79 (44.9)	6.6 [3.9, 25.7]	180	81 (45.0)	7.4 [5.0, 10.9]	1.018 [0.745, 1.392]	0.9169	0.6788
>65 years	78	28 (35.9)	7.6 [3.2, NC]	73	29 (39.7)	9.3 [3.3, NC]	0.935 [0.556, 1.572]	0.8002	
Sex									
Male	159	71 (44.7)	6.4 [3.6, 10.0]	156	75 (48.1)	6.5 [4.2, 9.3]	0.966 [0.697, 1.338]	0.8259	0.8180
Female	95	36 (37.9)	25.7 [3.8, NC]	97	35 (36.1)	9.6 [5.1, NC]	1.017 [0.634, 1.633]	0.9401	
Region									
Asia	157	71 (45.2)	7.2 [3.5, 28.2]	158	60 (38.0)	9.3 [6.2, 14.1]	1.229 [0.870, 1.736]	0.2454	0.0553
Non-Asia	97	36 (37.1)	7.1 [4.2, NC]	95	50 (52.6)	4.4 [2.9, 8.3]	0.694 [0.450, 1.072]	0.0977	
Number of Organs with Metastatic Sites									
0-2	189	79 (41.8)	7.4 [4.7, 30.0]	188	80 (42.6)	9.2 [5.3, 11.7]	1.001 [0.732, 1.369]	0.9991	0.9013
>=3	65	28 (43.1)	4.6 [2.6, 28.2]	65	30 (46.2)	5.0 [2.9, 11.9]	0.952 [0.565, 1.606]	0.8452	

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: 12JAN24

Table 302.3.3004.24.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Pain and Discomfort (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	108 (42.5%)	115 (45.5%)	
Number of patients censored	146 (57.5%)	138 (54.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.8 [5.1, 11.1]	6.7 [5.0, 9.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.891 [0.683, 1.164]
Log-rank test			
Two-sided stratified log-rank p-value			0.3964

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: 12JAN24

Table 302.3.3004.24.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Pain and Discomfort by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	81 (46.0)	7.2 [4.4, 11.1]	180	86 (47.8)	6.6 [4.6, 9.2]	0.883 [0.651, 1.198]	0.4310	0.9849
>65 years	78	27 (34.6)	9.8 [4.2, NC]	73	29 (39.7)	9.3 [4.4, NC]	0.954 [0.564, 1.614]	0.8560	
Sex									
Male	159	70 (44.0)	7.2 [4.4, 15.4]	156	73 (46.8)	6.5 [4.4, 9.3]	0.862 [0.620, 1.199]	0.3860	0.7205
Female	95	38 (40.0)	9.7 [4.5, 15.2]	97	42 (43.3)	7.0 [5.1, 12.2]	0.958 [0.615, 1.492]	0.8418	
Region									
Asia	157	70 (44.6)	9.2 [5.1, 15.4]	158	67 (42.4)	7.0 [5.2, 9.8]	0.951 [0.678, 1.335]	0.7737	0.6197
Non-Asia	97	38 (39.2)	7.3 [4.2, 15.2]	95	48 (50.5)	5.1 [3.5, 10.4]	0.830 [0.542, 1.271]	0.3936	
Number of Organs with Metastatic Sites									
0-2	189	83 (43.9)	9.2 [5.7, 11.1]	188	87 (46.3)	6.9 [5.2, 9.5]	0.904 [0.667, 1.224]	0.5207	0.9002
>=3	65	25 (38.5)	6.9 [3.9, 19.8]	65	28 (43.1)	5.0 [2.5, 11.9]	0.887 [0.517, 1.522]	0.6443	

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: 12JAN24

Table 302.3.3004.25.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Anxiety (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	123 (48.4%)	106 (41.9%)	
Number of patients censored	131 (51.6%)	147 (58.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.7 [2.8, 5.9]	5.1 [3.7, 9.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.145 [0.878, 1.492]
Log-rank test			
Two-sided stratified log-rank p-value			0.2975

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: 12JAN24

Table 302.3.3004.25.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Anxiety by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	87 (49.4)	4.1 [2.3, 6.7]	180	70 (38.9)	5.1 [3.4, 10.9]	1.183 [0.862, 1.622]	0.2825	0.7358
>65 years	78	36 (46.2)	3.3 [3.0, 6.6]	73	36 (49.3)	4.6 [2.3, 8.3]	1.079 [0.679, 1.717]	0.7427	
Sex									
Male	159	81 (50.9)	3.3 [2.7, 5.1]	156	64 (41.0)	5.1 [3.7, NC]	1.243 [0.895, 1.728]	0.1833	0.4646
Female	95	42 (44.2)	5.9 [2.7, 13.2]	97	42 (43.3)	5.1 [3.0, 9.0]	1.001 [0.652, 1.536]	0.9925	
Region									
Asia	157	79 (50.3)	3.7 [2.7, 8.1]	158	66 (41.8)	6.3 [4.1, 10.9]	1.165 [0.838, 1.617]	0.3578	0.8550
Non-Asia	97	44 (45.4)	3.7 [2.3, 5.9]	95	40 (42.1)	3.7 [2.1, 10.4]	1.062 [0.691, 1.632]	0.7596	
Number of Organs with Metastatic Sites									
0-2	189	94 (49.7)	3.5 [2.8, 5.9]	188	80 (42.6)	4.8 [3.3, 10.9]	1.157 [0.858, 1.560]	0.3341	0.8386
>=3	65	29 (44.6)	4.2 [2.1, 29.1]	65	26 (40.0)	5.7 [3.0, NC]	1.062 [0.622, 1.813]	0.7889	

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: 12JAN24

Table 302.3.3004.26.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating in Front of Others (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	77 (30.3%)	69 (27.3%)	
Number of patients censored	177 (69.7%)	184 (72.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	17.1 [10.4, NC]	20.3 [10.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.067 [0.767, 1.486]
Log-rank test			
Two-sided stratified log-rank p-value			0.7075

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: 12JAN24

Table 302.3.3004.26.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating in Front of Others by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	56 (31.8)	17.7 [10.4, NC]	180	52 (28.9)	20.3 [10.1, NC]	1.007 [0.688, 1.472]	0.9746	0.4313
>65 years	78	21 (26.9)	12.0 [7.6, NC]	73	17 (23.3)	NC [7.9, NC]	1.361 [0.716, 2.584]	0.3433	
Sex									
Male	159	50 (31.4)	16.1 [10.0, NC]	156	44 (28.2)	20.3 [10.1, NC]	1.077 [0.717, 1.617]	0.7195	0.9662
Female	95	27 (28.4)	17.3 [9.5, NC]	97	25 (25.8)	NC [8.2, NC]	1.085 [0.627, 1.879]	0.7719	
Region									
Asia	157	56 (35.7)	16.1 [9.5, NC]	158	46 (29.1)	11.9 [8.8, NC]	1.095 [0.737, 1.626]	0.6544	0.8240
Non-Asia	97	21 (21.6)	17.3 [9.2, NC]	95	23 (24.2)	NC [10.4, NC]	1.025 [0.566, 1.854]	0.9359	
Number of Organs with Metastatic Sites									
0-2	189	57 (30.2)	17.7 [12.0, NC]	188	50 (26.6)	20.3 [10.4, NC]	1.111 [0.758, 1.628]	0.5889	0.9456
>=3	65	20 (30.8)	15.8 [5.1, 19.8]	65	19 (29.2)	11.9 [6.0, NC]	1.034 [0.549, 1.946]	0.9175	

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: 12JAN24

Table 302.3.3004.27.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dry Mouth Score (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	103 (40.6%)	129 (51.0%)	
Number of patients censored	151 (59.4%)	124 (49.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.1 [4.3, 22.6]	4.2 [2.9, 5.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.695 [0.534, 0.906]
Log-rank test			
Two-sided stratified log-rank p-value			0.0067

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: 12JAN24

Table 302.3.3004.27.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dry Mouth Score by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	67 (38.1)	14.8 [4.6, NC]	180	89 (49.4)	4.4 [3.1, 6.6]	0.686 [0.499, 0.943]	0.0201	0.5711
>65 years	78	36 (46.2)	4.2 [2.3, 8.3]	73	40 (54.8)	2.7 [1.6, 4.4]	0.800 [0.509, 1.255]	0.3304	
Sex									
Male	159	65 (40.9)	8.1 [3.7, NC]	156	84 (53.8)	3.8 [2.2, 5.2]	0.653 [0.471, 0.905]	0.0101	0.3445
Female	95	38 (40.0)	8.1 [3.5, 22.6]	97	45 (46.4)	5.1 [2.9, 8.8]	0.855 [0.554, 1.318]	0.4743	
Region									
Asia	157	61 (38.9)	14.8 [6.5, NC]	158	74 (46.8)	4.4 [3.8, 8.8]	0.727 [0.517, 1.021]	0.0652	0.9818
Non-Asia	97	42 (43.3)	4.1 [2.8, 10.4]	95	55 (57.9)	2.8 [2.1, 3.9]	0.728 [0.487, 1.089]	0.1223	
Number of Organs with Metastatic Sites									
0-2	189	81 (42.9)	7.9 [4.1, 18.4]	188	103 (54.8)	4.1 [2.7, 5.1]	0.720 [0.537, 0.964]	0.0267	0.8768
>=3	65	22 (33.8)	14.8 [3.3, 29.1]	65	26 (40.0)	6.1 [2.1, NC]	0.724 [0.406, 1.291]	0.2718	

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: 12JAN24

Table 302.3.3004.28.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Taste (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	128 (50.4%)	133 (52.6%)	
Number of patients censored	126 (49.6%)	120 (47.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.8 [3.2, 5.1]	4.7 [3.6, 5.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.982 [0.767, 1.258]
Log-rank test			
Two-sided stratified log-rank p-value			0.8944

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: 12JAN24

Table 302.3.3004.28.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Taste by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	89 (50.6)	4.0 [3.1, 6.4]	180	98 (54.4)	4.7 [3.5, 5.1]	0.917 [0.687, 1.224]	0.5628	0.3142
>65 years	78	39 (50.0)	3.6 [2.3, 6.0]	73	35 (47.9)	4.9 [2.8, 9.0]	1.225 [0.775, 1.936]	0.3826	
Sex									
Male	159	81 (50.9)	3.6 [3.0, 5.1]	156	88 (56.4)	4.6 [3.1, 5.0]	0.881 [0.651, 1.192]	0.4143	0.1890
Female	95	47 (49.5)	3.9 [2.8, 6.7]	97	45 (46.4)	5.1 [2.8, 14.8]	1.196 [0.790, 1.810]	0.4020	
Region									
Asia	157	82 (52.2)	3.8 [3.0, 6.7]	158	76 (48.1)	4.9 [3.3, 9.2]	1.128 [0.826, 1.542]	0.4463	0.2123
Non-Asia	97	46 (47.4)	3.6 [2.8, 5.6]	95	57 (60.0)	3.8 [2.3, 5.1]	0.826 [0.558, 1.221]	0.3389	
Number of Organs with Metastatic Sites									
0-2	189	96 (50.8)	3.8 [2.9, 6.4]	188	100 (53.2)	4.9 [3.6, 5.5]	1.004 [0.757, 1.330]	0.9778	0.8267
>=3	65	32 (49.2)	3.8 [3.2, 5.6]	65	33 (50.8)	4.5 [1.6, 7.0]	0.962 [0.591, 1.566]	0.8830	

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: 12JAN24

Table 302.3.3004.29.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Body Image (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	112 (44.1%)	103 (40.7%)	
Number of patients censored	142 (55.9%)	150 (59.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.0 [4.0, 8.2]	8.8 [5.8, 14.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.237 [0.941, 1.627]
Log-rank test			
Two-sided stratified log-rank p-value			0.1232

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: 12JAN24

Table 302.3.3004.29.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Body Image by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	80 (45.5)	7.5 [4.2, 10.4]	180	71 (39.4)	10.6 [5.8, 18.5]	1.179 [0.856, 1.623]	0.3029	0.9431
>65 years	78	32 (41.0)	4.6 [3.1, 7.0]	73	32 (43.8)	7.1 [3.8, 14.5]	1.255 [0.767, 2.053]	0.3688	
Sex									
Male	159	73 (45.9)	6.7 [4.2, 10.9]	156	60 (38.5)	9.2 [6.0, 18.5]	1.234 [0.877, 1.738]	0.2253	0.8333
Female	95	39 (41.1)	4.6 [3.0, 8.1]	97	43 (44.3)	7.9 [3.2, 14.5]	1.139 [0.737, 1.760]	0.5501	
Region									
Asia	157	70 (44.6)	6.4 [3.7, 11.7]	158	65 (41.1)	8.8 [4.4, 14.1]	1.124 [0.802, 1.577]	0.4969	0.4926
Non-Asia	97	42 (43.3)	5.9 [3.0, 8.7]	95	38 (40.0)	9.2 [5.0, 18.5]	1.351 [0.869, 2.102]	0.1703	
Number of Organs with Metastatic Sites									
0-2	189	86 (45.5)	5.9 [3.5, 8.7]	188	76 (40.4)	10.6 [6.0, 18.5]	1.281 [0.941, 1.744]	0.1150	0.3405
>=3	65	26 (40.0)	6.0 [3.6, 13.2]	65	27 (41.5)	7.9 [3.9, 14.5]	0.948 [0.552, 1.628]	0.8650	

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: 12JAN24

Table 302.3.3004.30.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Swallowing Saliva (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	75 (29.5%)	66 (26.1%)	
Number of patients censored	179 (70.5%)	187 (73.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	20.6 [11.3, NC]	18.9 [14.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.250 [0.892, 1.752]
Log-rank test			
Two-sided stratified log-rank p-value			0.1934

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: 12JAN24

Table 302.3.3004.30.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Swallowing Saliva by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	52 (29.5)	20.6 [11.3, NC]	180	46 (25.6)	28.7 [14.8, NC]	1.157 [0.777, 1.724]	0.4718	0.7532
>65 years	78	23 (29.5)	12.5 [4.9, NC]	73	20 (27.4)	18.5 [14.5, NC]	1.294 [0.709, 2.364]	0.3980	
Sex									
Male	159	48 (30.2)	20.6 [10.6, NC]	156	43 (27.6)	28.7 [18.5, 28.7]	1.087 [0.719, 1.643]	0.6915	0.4938
Female	95	27 (28.4)	19.8 [8.1, NC]	97	23 (23.7)	18.9 [14.5, NC]	1.358 [0.776, 2.377]	0.2839	
Region									
Asia	157	43 (27.4)	25.9 [12.5, NC]	158	35 (22.2)	NC [14.8, NC]	1.180 [0.752, 1.850]	0.4710	0.8153
Non-Asia	97	32 (33.0)	10.4 [5.1, NC]	95	31 (32.6)	18.5 [7.7, 28.7]	1.277 [0.777, 2.098]	0.3326	
Number of Organs with Metastatic Sites									
0-2	189	63 (33.3)	14.6 [10.4, NC]	188	46 (24.5)	28.7 [18.5, NC]	1.424 [0.972, 2.087]	0.0681	0.0477
>=3	65	12 (18.5)	NC [10.6, NC]	65	20 (30.8)	14.5 [7.7, NC]	0.635 [0.309, 1.303]	0.2119	

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: 12JAN24

Table 302.3.3004.31.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Choked When Swallowing Score (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	64 (25.2%)	63 (24.9%)	
Number of patients censored	190 (74.8%)	190 (75.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [15.5, NC]	25.8 [12.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.047 [0.734, 1.493]
Log-rank test			
Two-sided stratified log-rank p-value			0.7984

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: 12JAN24

Table 302.3.3004.31.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Choked When Swallowing Score by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	44 (25.0)	NC [15.5, NC]	180	45 (25.0)	NC [11.1, NC]	0.966 [0.637, 1.467]	0.8738	0.6511
>65 years	78	20 (25.6)	17.1 [5.5, NC]	73	18 (24.7)	25.8 [NC, NC]	1.154 [0.609, 2.189]	0.6561	
Sex									
Male	159	42 (26.4)	NC [12.9, NC]	156	44 (28.2)	12.3 [10.5, NC]	0.856 [0.559, 1.309]	0.4746	0.2235
Female	95	22 (23.2)	NC [15.5, NC]	97	19 (19.6)	25.8 [25.8, NC]	1.357 [0.732, 2.514]	0.3307	
Region									
Asia	157	43 (27.4)	NC [14.3, NC]	158	36 (22.8)	NC [11.1, NC]	1.149 [0.736, 1.794]	0.5379	0.3895
Non-Asia	97	21 (21.6)	NC [8.4, NC]	95	27 (28.4)	25.8 [9.2, NC]	0.836 [0.472, 1.480]	0.5371	
Number of Organs with Metastatic Sites									
0-2	189	51 (27.0)	NC [14.3, NC]	188	41 (21.8)	NC [12.3, NC]	1.238 [0.819, 1.872]	0.3081	0.0790
>=3	65	13 (20.0)	NC [8.5, NC]	65	22 (33.8)	11.1 [5.1, 25.8]	0.610 [0.307, 1.212]	0.1537	

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: 12JAN24

Table 302.3.3004.32.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Coughing (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	87 (34.3%)	95 (37.5%)	
Number of patients censored	167 (65.7%)	158 (62.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.9 [9.5, 14.8]	11.6 [7.1, 19.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.951 [0.707, 1.279]
Log-rank test			
Two-sided stratified log-rank p-value			0.7429

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: 12JAN24

Table 302.3.3004.32.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Coughing by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	60 (34.1)	11.8 [10.4, 18.9]	180	71 (39.4)	10.4 [6.1, 19.7]	0.835 [0.592, 1.178]	0.3018	0.2411
>65 years	78	27 (34.6)	7.8 [5.1, NC]	73	24 (32.9)	14.1 [6.0, 23.1]	1.236 [0.711, 2.148]	0.4536	
Sex									
Male	159	59 (37.1)	10.6 [8.0, 14.8]	156	59 (37.8)	11.6 [6.0, NC]	0.950 [0.662, 1.364]	0.7867	0.8347
Female	95	28 (29.5)	11.8 [7.5, NC]	97	36 (37.1)	14.8 [6.5, 19.7]	0.862 [0.524, 1.417]	0.5514	
Region									
Asia	157	47 (29.9)	11.9 [10.6, NC]	158	62 (39.2)	11.6 [6.5, 19.7]	0.701 [0.479, 1.027]	0.0669	0.0246
Non-Asia	97	40 (41.2)	6.8 [4.2, 10.9]	95	33 (34.7)	10.4 [5.8, NC]	1.424 [0.897, 2.259]	0.1322	
Number of Organs with Metastatic Sites									
0-2	189	69 (36.5)	10.9 [8.0, 13.5]	188	73 (38.8)	11.6 [6.7, 23.1]	0.978 [0.703, 1.359]	0.8934	0.5112
>=3	65	18 (27.7)	15.8 [6.9, NC]	65	22 (33.8)	10.5 [5.1, 17.1]	0.770 [0.409, 1.450]	0.4173	

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: 12JAN24

Table 302.3.3004.33.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Talking (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	66 (26.0%)	63 (24.9%)	
Number of patients censored	188 (74.0%)	190 (75.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [12.6, NC]	NC [14.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.110 [0.784, 1.573]
Log-rank test			
Two-sided stratified log-rank p-value			0.5567

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: 12JAN24

Table 302.3.3004.33.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Talking by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	49 (27.8)	20.9 [12.4, NC]	180	48 (26.7)	NC [12.3, NC]	1.057 [0.709, 1.575]	0.7888	0.6407
>65 years	78	17 (21.8)	NC [12.6, NC]	73	15 (20.5)	NC [NC, NC]	1.290 [0.643, 2.588]	0.4716	
Sex									
Male	159	43 (27.0)	20.9 [10.9, NC]	156	44 (28.2)	NC [12.3, NC]	0.972 [0.638, 1.482]	0.8942	0.2902
Female	95	23 (24.2)	NC [12.4, NC]	97	19 (19.6)	NC [14.8, NC]	1.495 [0.813, 2.748]	0.1940	
Region									
Asia	157	39 (24.8)	NC [12.6, NC]	158	38 (24.1)	NC [14.8, NC]	1.007 [0.643, 1.578]	0.9770	0.4722
Non-Asia	97	27 (27.8)	14.1 [6.6, NC]	95	25 (26.3)	NC [9.2, NC]	1.312 [0.761, 2.262]	0.3280	
Number of Organs with Metastatic Sites									
0-2	189	49 (25.9)	NC [12.4, NC]	188	43 (22.9)	NC [14.8, NC]	1.203 [0.798, 1.814]	0.3766	0.5124
>=3	65	17 (26.2)	12.9 [10.3, NC]	65	20 (30.8)	11.1 [6.0, NC]	0.924 [0.483, 1.767]	0.8070	

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: 12JAN24

Table 302.3.3004.34.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Weight Loss (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	114 (44.9%)	105 (41.5%)	
Number of patients censored	140 (55.1%)	148 (58.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.4 [3.4, 9.1]	8.3 [5.1, 11.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.080 [0.825, 1.415]
Log-rank test			
Two-sided stratified log-rank p-value			0.5625

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: 12JAN24

Table 302.3.3004.34.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Weight Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	81 (46.0)	6.9 [4.0, 13.2]	180	73 (40.6)	8.7 [5.0, 22.6]	1.046 [0.761, 1.437]	0.7737	0.5626
>65 years	78	33 (42.3)	3.1 [2.0, 28.1]	73	32 (43.8)	5.8 [2.7, NC]	1.246 [0.765, 2.028]	0.3741	
Sex									
Male	159	73 (45.9)	7.2 [2.8, 16.4]	156	67 (42.9)	8.3 [4.8, 10.9]	1.007 [0.721, 1.405]	0.9583	0.5017
Female	95	41 (43.2)	5.2 [3.1, 7.4]	97	38 (39.2)	11.6 [3.8, NC]	1.254 [0.805, 1.952]	0.3103	
Region									
Asia	157	68 (43.3)	9.1 [4.6, 29.1]	158	69 (43.7)	6.3 [4.8, 11.6]	0.894 [0.638, 1.252]	0.5176	0.0675
Non-Asia	97	46 (47.4)	3.5 [2.3, 7.4]	95	36 (37.9)	9.2 [3.9, NC]	1.554 [1.002, 2.409]	0.0455	
Number of Organs with Metastatic Sites									
0-2	189	87 (46.0)	6.4 [3.3, 9.1]	188	76 (40.4)	9.2 [5.0, 22.6]	1.148 [0.843, 1.562]	0.3712	0.5467
>=3	65	27 (41.5)	5.6 [2.1, 29.1]	65	29 (44.6)	6.3 [3.6, 9.2]	0.910 [0.535, 1.548]	0.7312	

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: 12JAN24

Table 302.3.3004.35.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Hair Loss (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	28 (11.0%)	23 (9.1%)	
Number of patients censored	226 (89.0%)	230 (90.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	23.0 [5.6, NC]	9.0 [7.5, 29.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.938 [0.524, 1.680]
Log-rank test			
Two-sided stratified log-rank p-value			0.8292

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: 12JAN24

Table 302.3.3004.35.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Hair Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	21 (11.9)	NC [5.1, NC]	180	15 (8.3)	9.0 [6.7, NC]	1.031 [0.530, 2.007]	0.9263	0.6254
>65 years	78	7 (9.0)	23.0 [1.9, NC]	73	8 (11.0)	23.1 [4.9, NC]	1.491 [0.519, 4.282]	0.4549	
Sex									
Male	159	13 (8.2)	NC [8.0, NC]	156	14 (9.0)	23.1 [7.5, 23.1]	0.783 [0.363, 1.688]	0.5302	0.2483
Female	95	15 (15.8)	5.6 [3.5, NC]	97	9 (9.3)	9.0 [6.7, NC]	1.511 [0.640, 3.570]	0.3429	
Region									
Asia	157	19 (12.1)	NC [9.4, NC]	158	17 (10.8)	8.8 [6.7, NC]	0.871 [0.451, 1.682]	0.6784	0.2140
Non-Asia	97	9 (9.3)	5.1 [2.1, NC]	95	6 (6.3)	9.0 [1.4, 29.0]	1.852 [0.616, 5.569]	0.2624	
Number of Organs with Metastatic Sites									
0-2	189	19 (10.1)	23.0 [8.0, NC]	188	16 (8.5)	9.0 [7.5, NC]	0.981 [0.502, 1.918]	0.9546	0.8508
>=3	65	9 (13.8)	9.4 [2.3, NC]	65	7 (10.8)	29.0 [1.4, 29.0]	1.164 [0.413, 3.283]	0.7725	

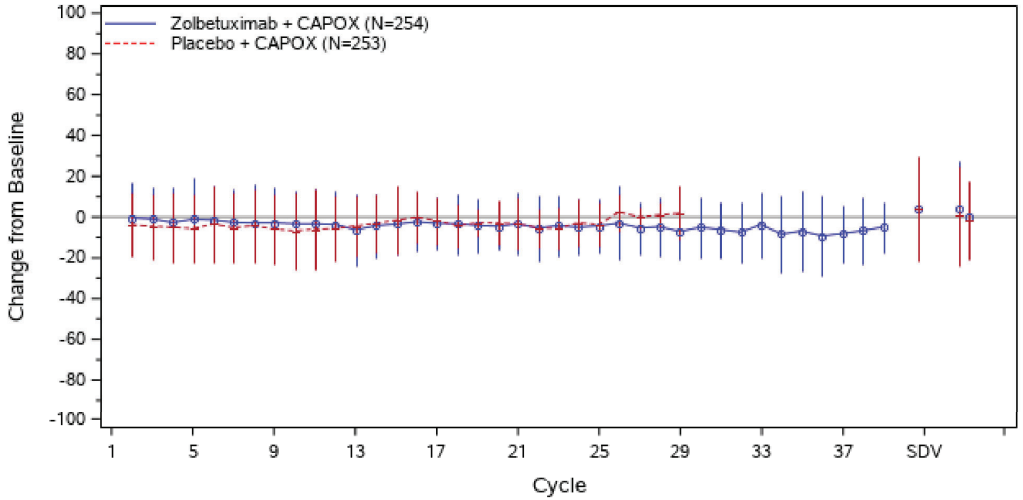
Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

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

The SAS System

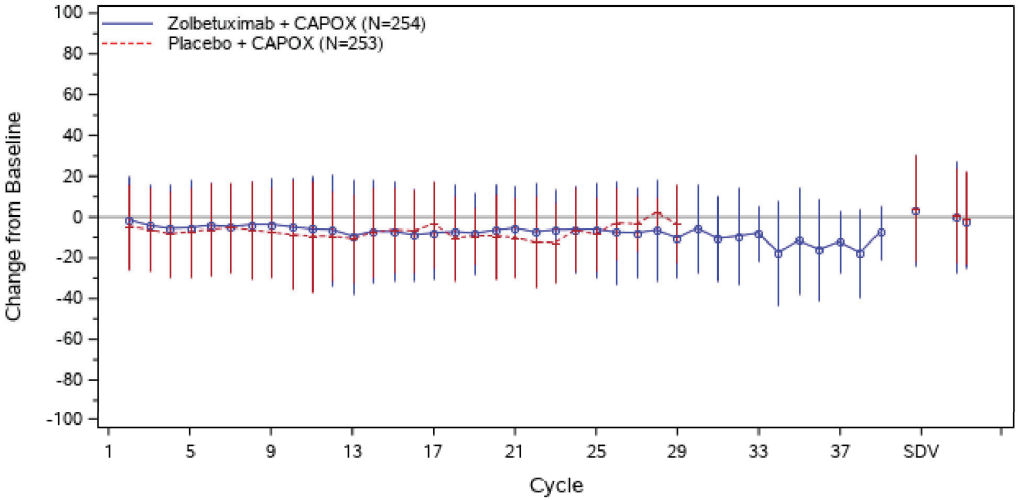
Figure 302.3.3002.20: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dysphagia - Full Analysis Set



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: 12JAN24

The SAS System

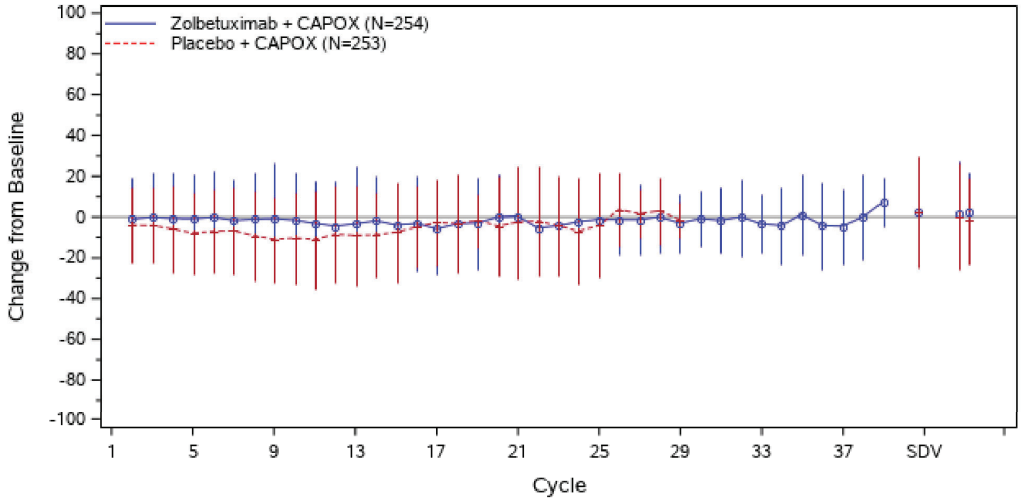
Figure 302.3.3002.21: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Eating Restrictions - Full Analysis Set



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: 12JAN24

The SAS System

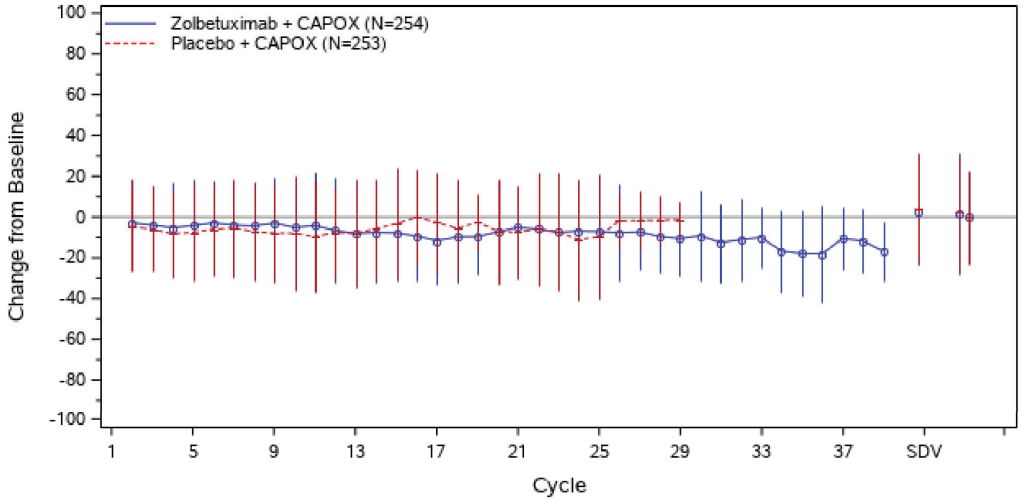
Figure 302.3.3002.22: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Reflux - Full Analysis Set



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: 12JAN24

The SAS System

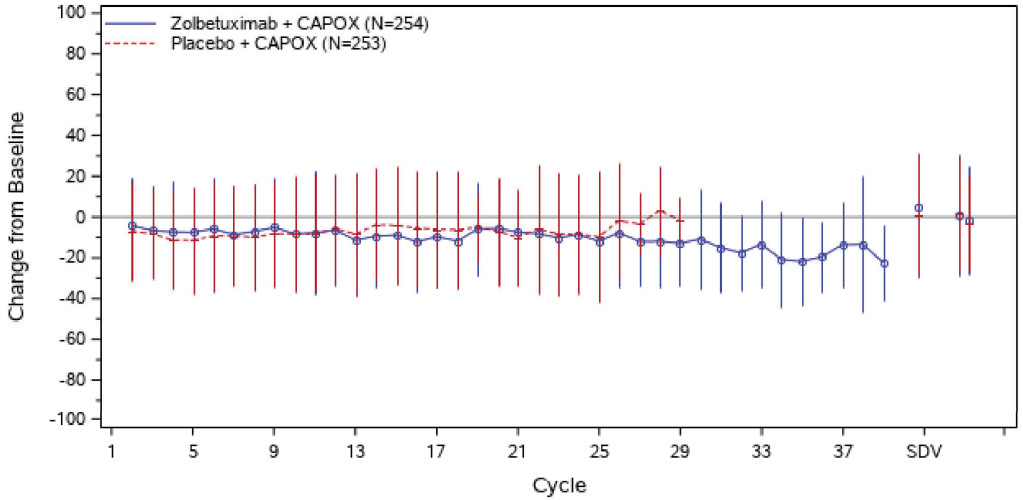
Figure 302.3.3002.23: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Odynophagia - Full Analysis Set



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: 12JAN24

The SAS System

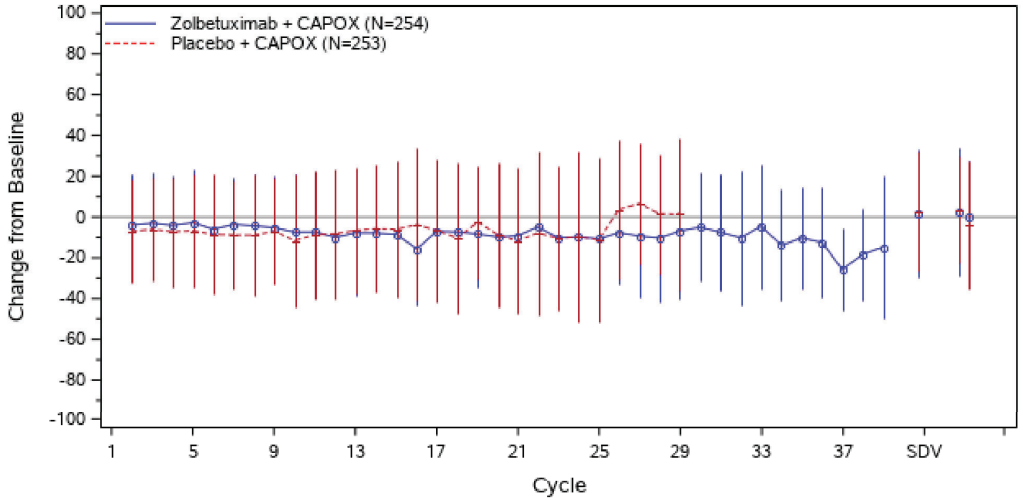
Figure 302.3.3002.24: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Pain and Discomfort - Full Analysis Set



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: 12JAN24

The SAS System

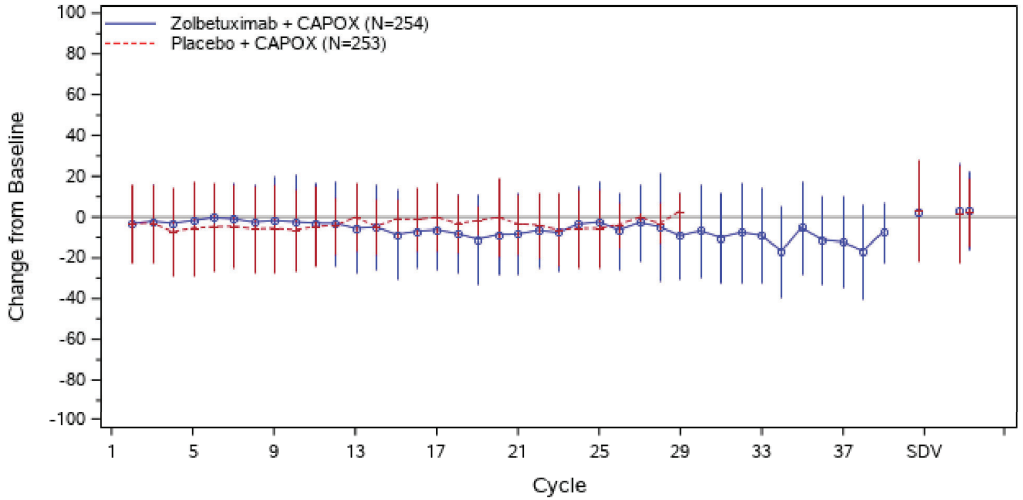
Figure 302.3.3002.25: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Anxiety - Full Analysis Set



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: 12JAN24

The SAS System

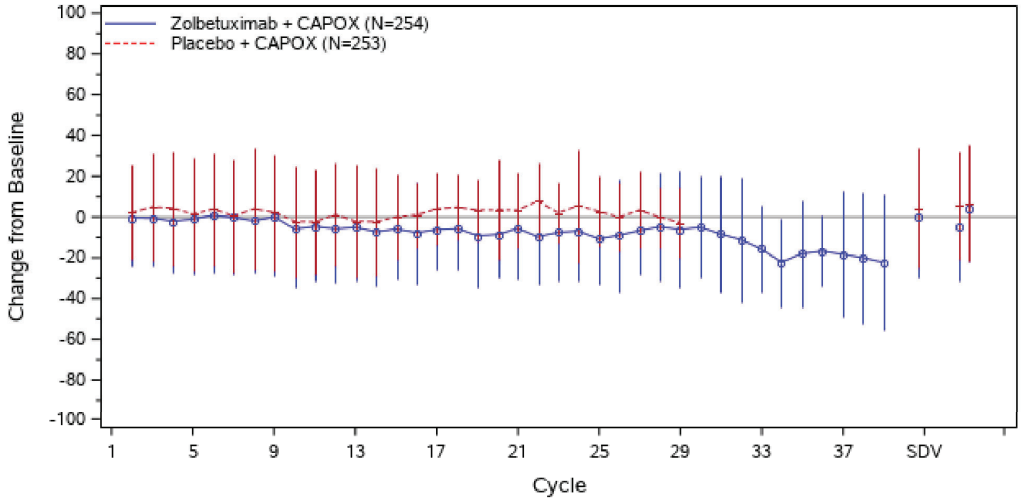
Figure 302.3.3002.26: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Eating in Front of Others - Full Analysis Set



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: 12JAN24

The SAS System

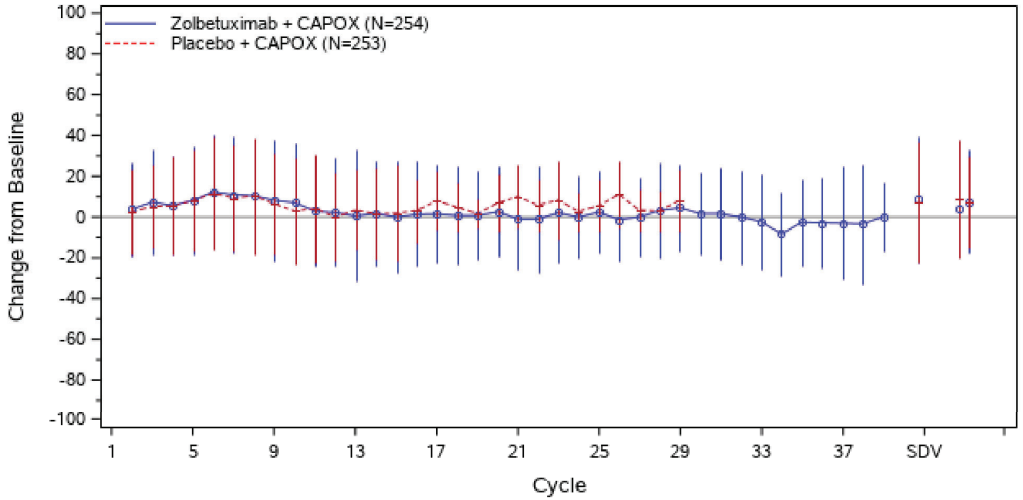
Figure 302.3.3002.27: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dry Mouth - Full Analysis Set



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: 12JAN24

The SAS System

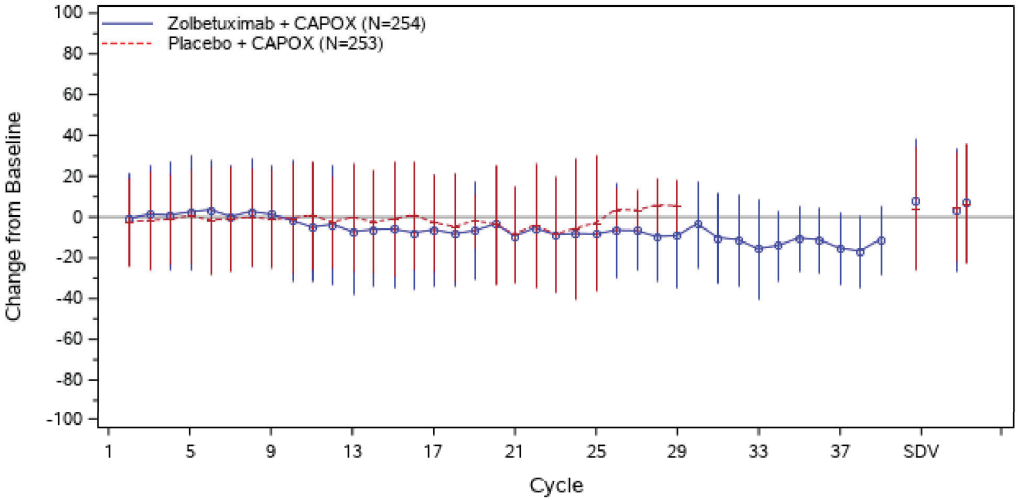
Figure 302.3.3002.28: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Taste - Full Analysis Set



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: 12JAN24

The SAS System

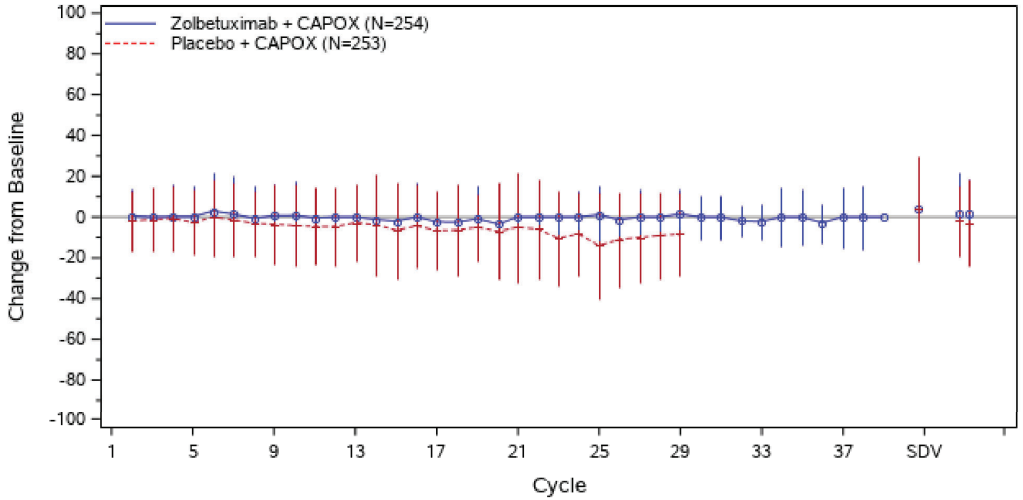
Figure 302.3.3002.29: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Body Image - Full Analysis Set



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: 12JAN24

The SAS System

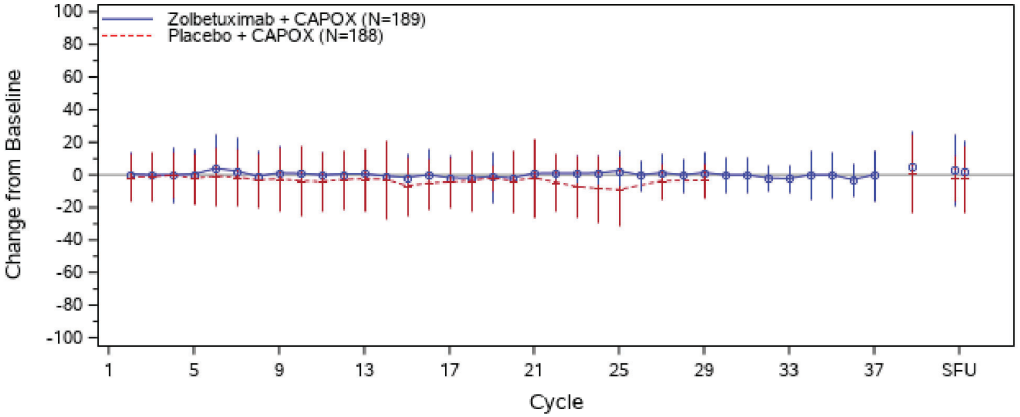
Figure 302.3.3002.30: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set



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: 12JAN24

The SAS System

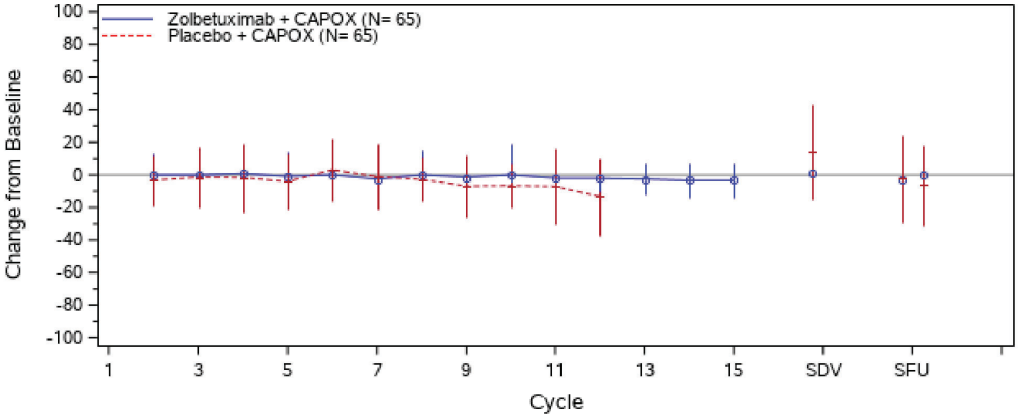
Figure 302.3.3002.30.4: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - Full Analysis Set
Number of Organs with Metastatic Sites: 0-2



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: 12JAN24

The SAS System

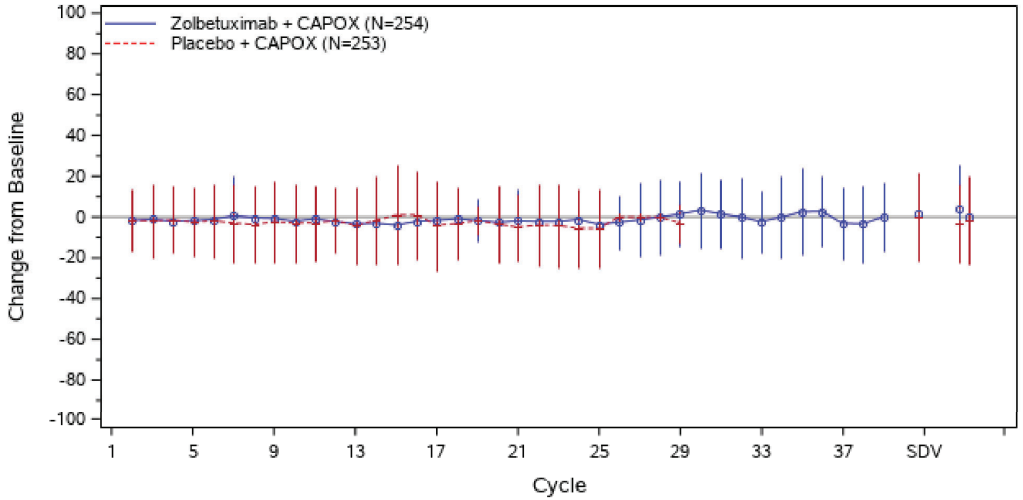
Figure 302.3.3002.30.4: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites - Full Analysis Set Number of Organs with Metastatic Sites: >=3



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: 12JAN24

The SAS System

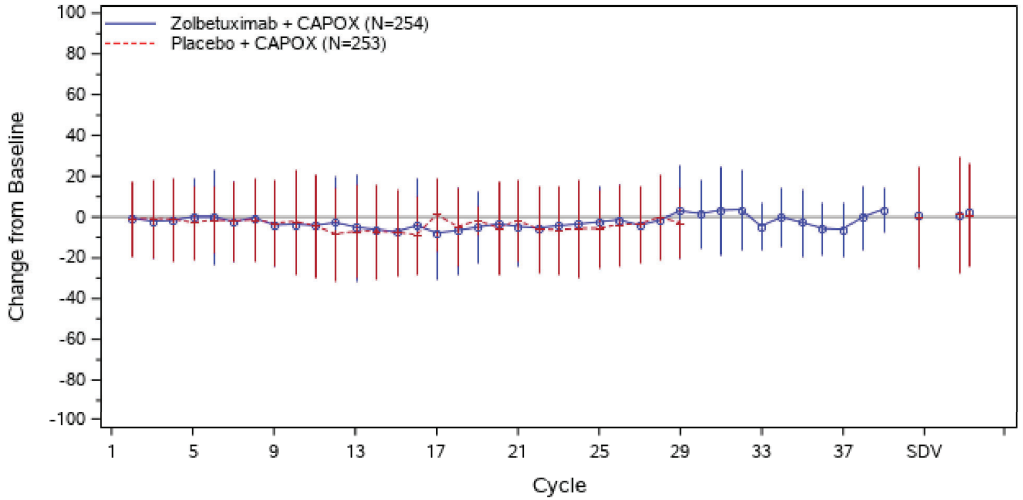
Figure 302.3.3002.31: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Choked when Swallowing Score - Full Analysis Set



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: 12JAN24

The SAS System

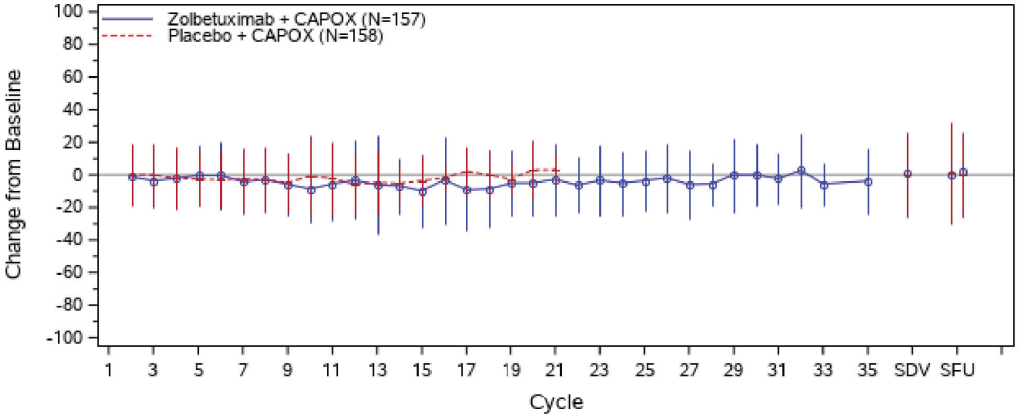
Figure 302.3.3002.32: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Coughing - Full Analysis Set



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: 12JAN24

The SAS System

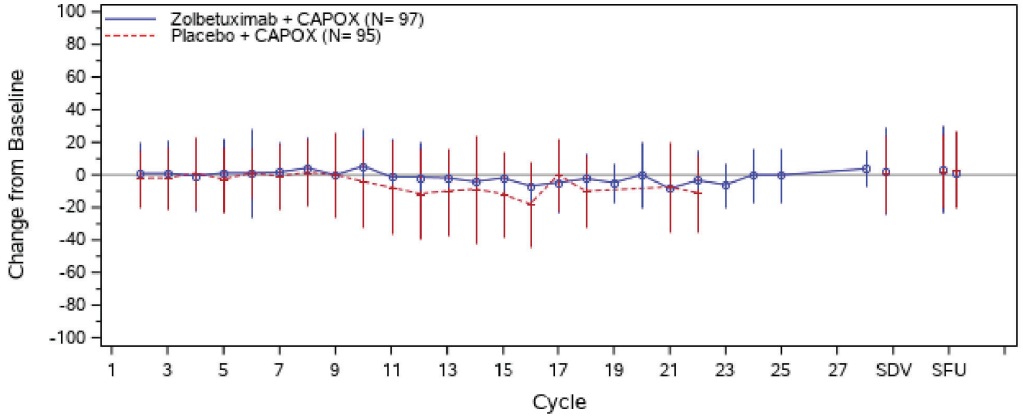
Figure 302.3.3002.32.3: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Coughing by Region - Full Analysis Set
Region: Asia



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: 12JAN24

The SAS System

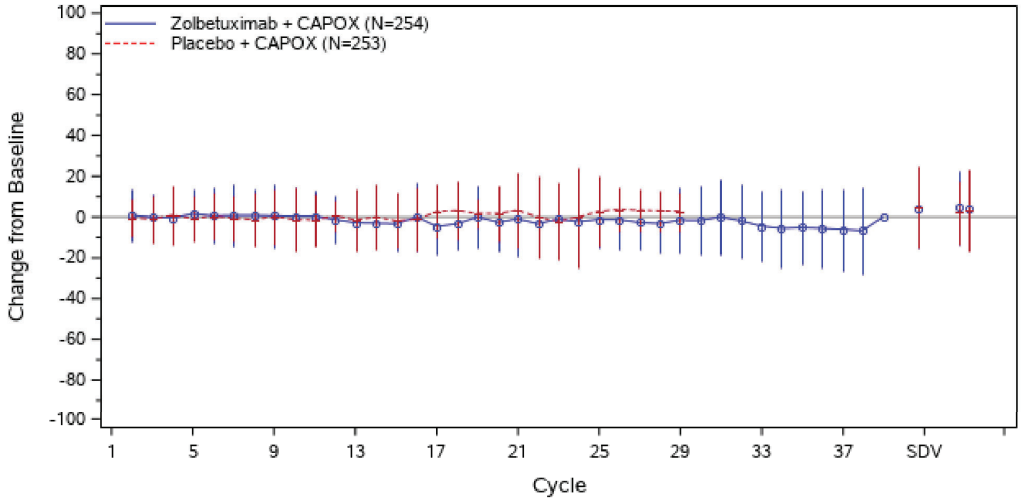
Figure 302.3.3002.32.3: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Coughing by Region - Full Analysis Set
Region: Non-Asia



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: 12JAN24

The SAS System

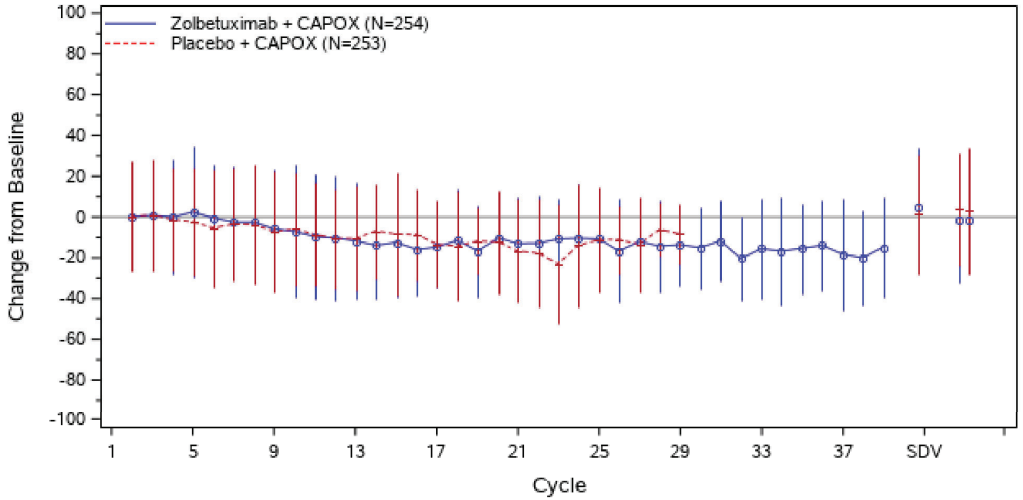
Figure 302.3.3002.33: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Talking - Full Analysis Set



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: 12JAN24

The SAS System

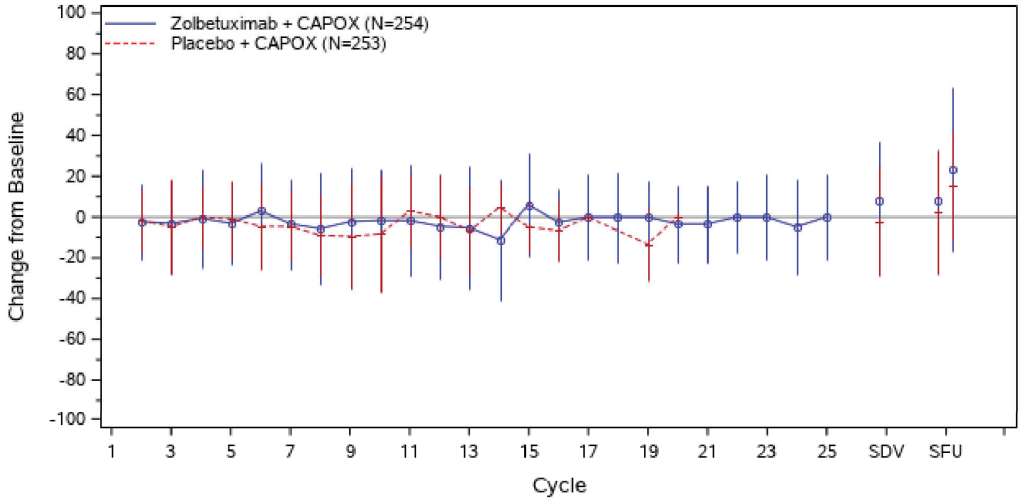
Figure 302.3.3002.34: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Weight Loss - Full Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.3002.35: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Hair Loss - Full Analysis Set



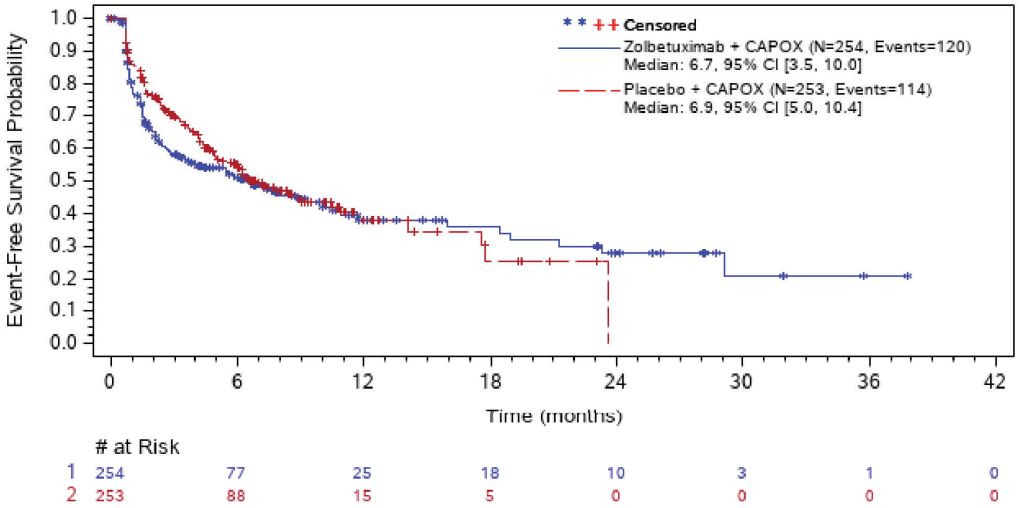
Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-OG25

5. Kaplan-Meier-Plots

The SAS System

Figure 302.3.3004.20: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia (MID=10) - Full Analysis Set



# at Risk								
1	254	77	25	18	10	3	1	0
2	253	88	15	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.

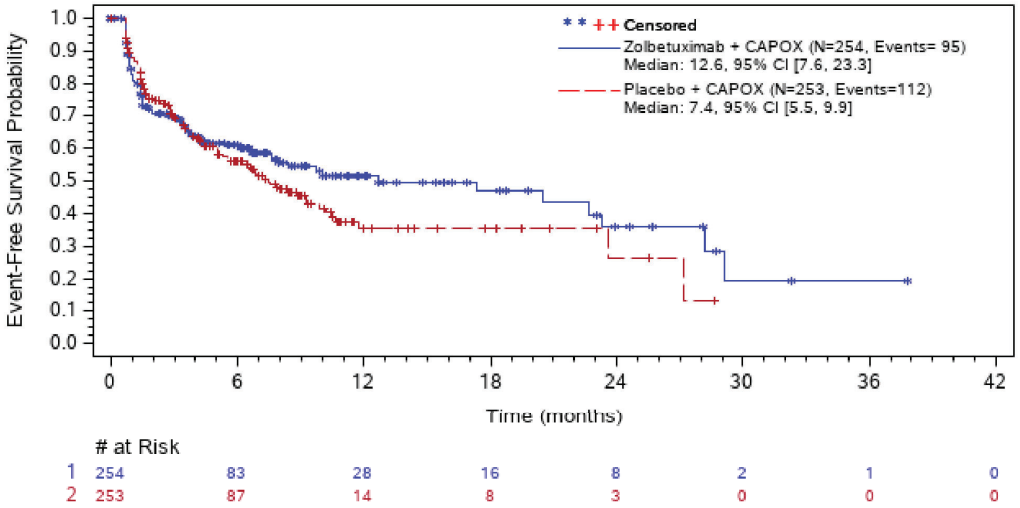
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.21: 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.

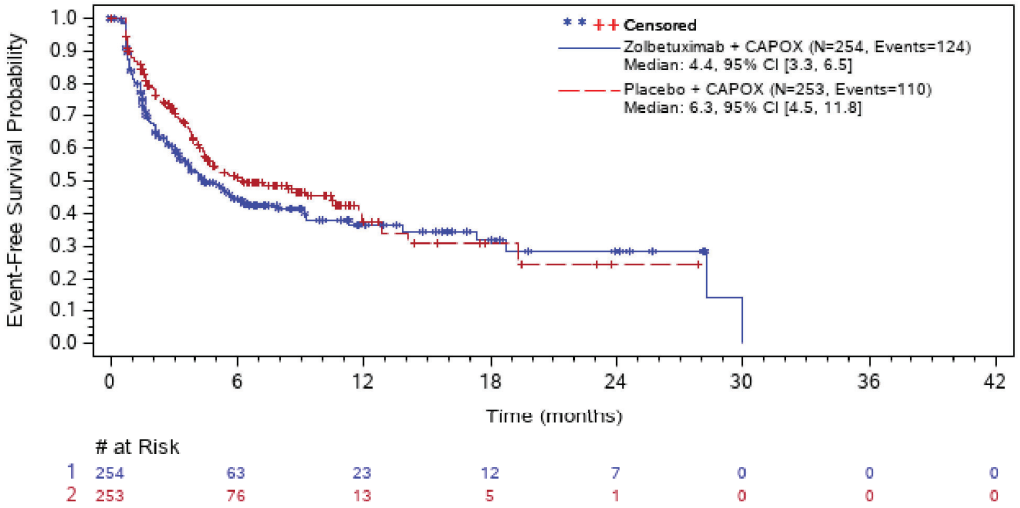
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.22: 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.

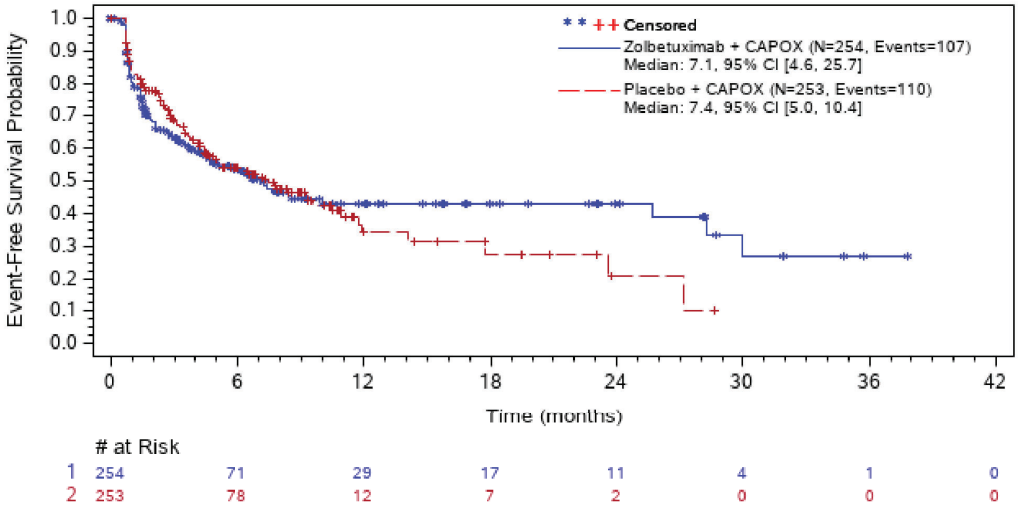
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.23: 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.

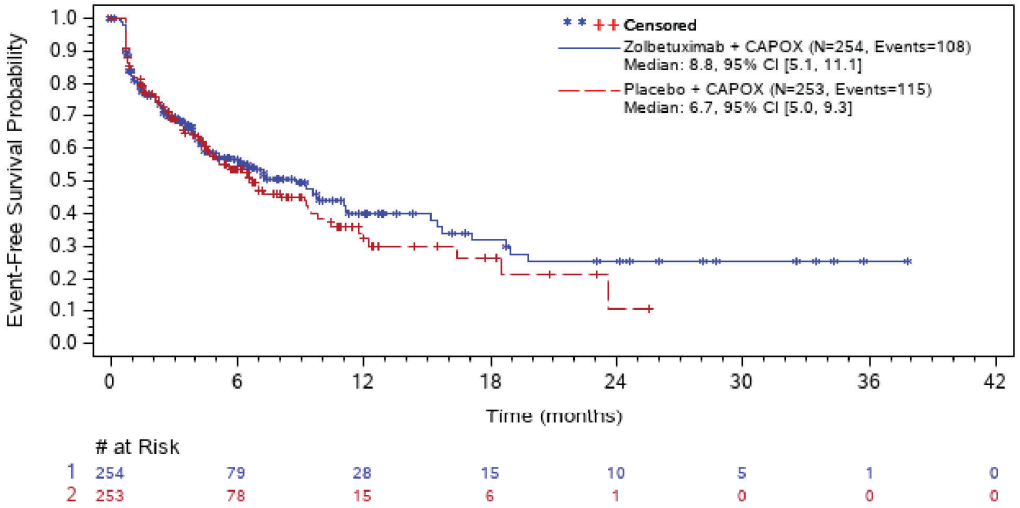
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.24: 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.

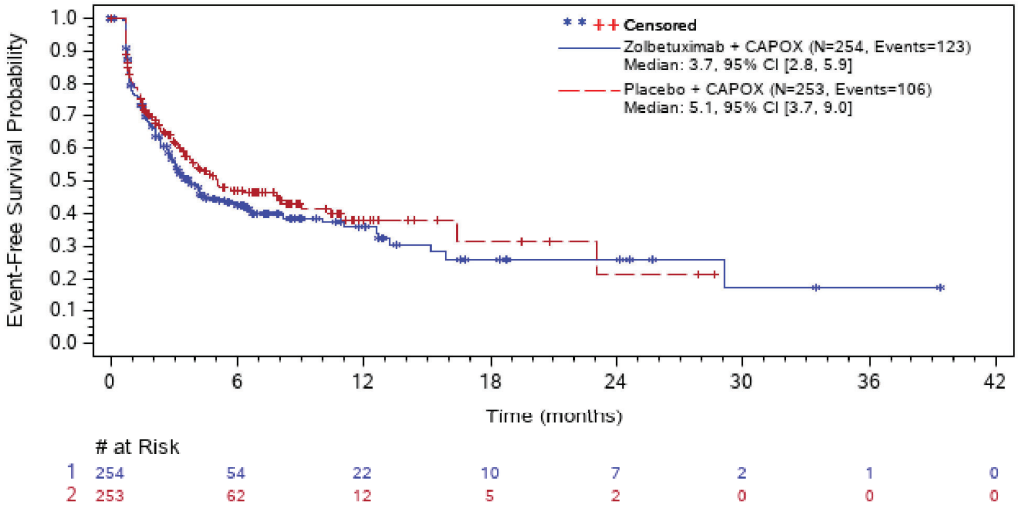
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.25: 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.

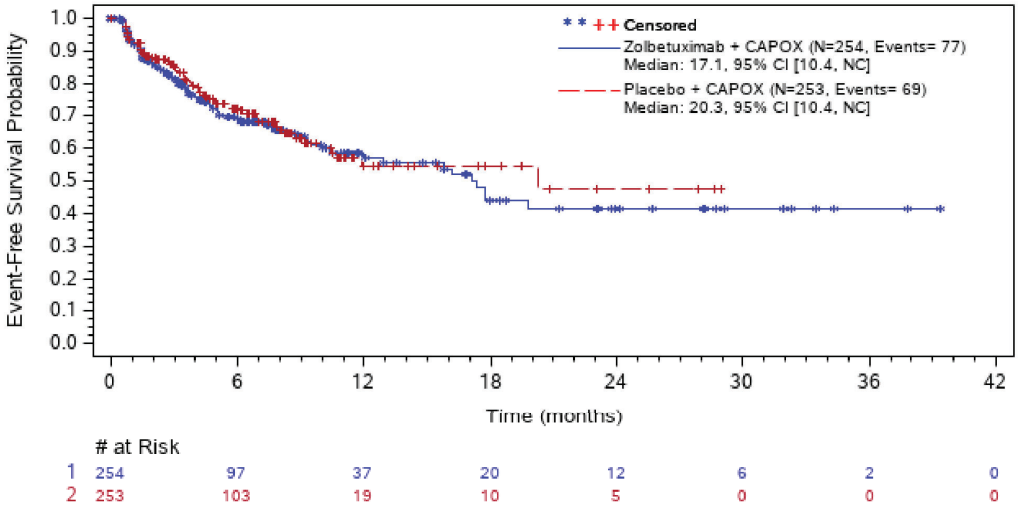
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.26: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Eating in Front of Others (MID=10) - Full Analysis Set



# at Risk								
1	254	97	37	20	12	6	2	0
2	253	103	19	10	5	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.

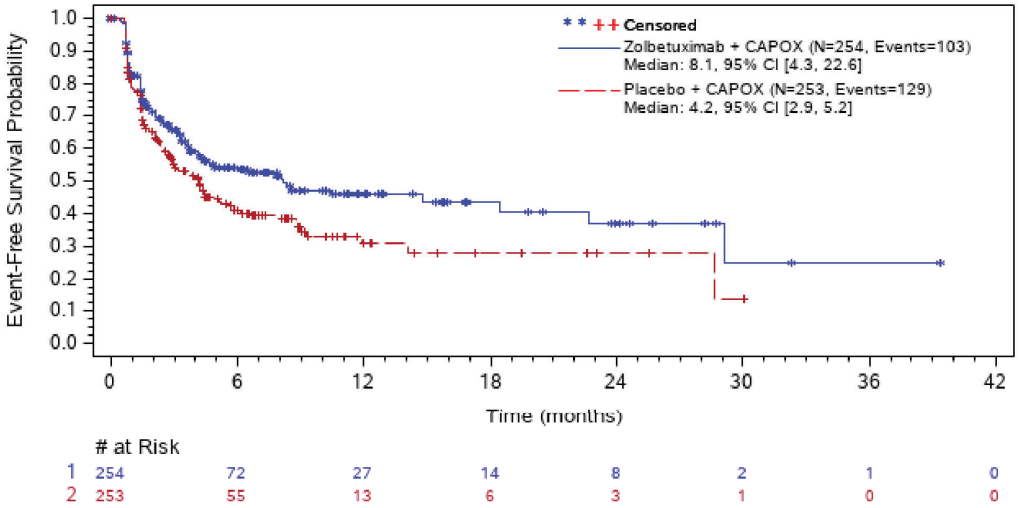
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.27: 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.

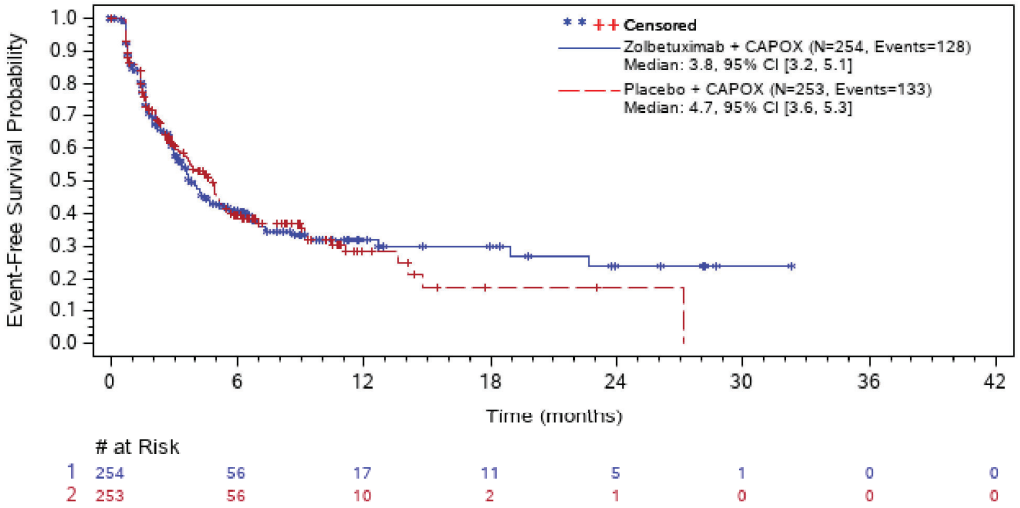
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.28: 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.

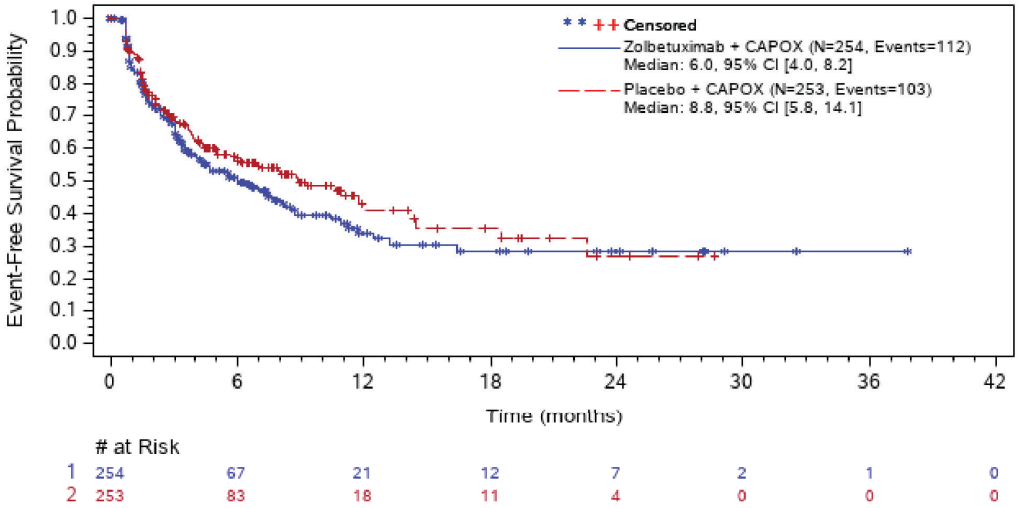
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.29: 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.

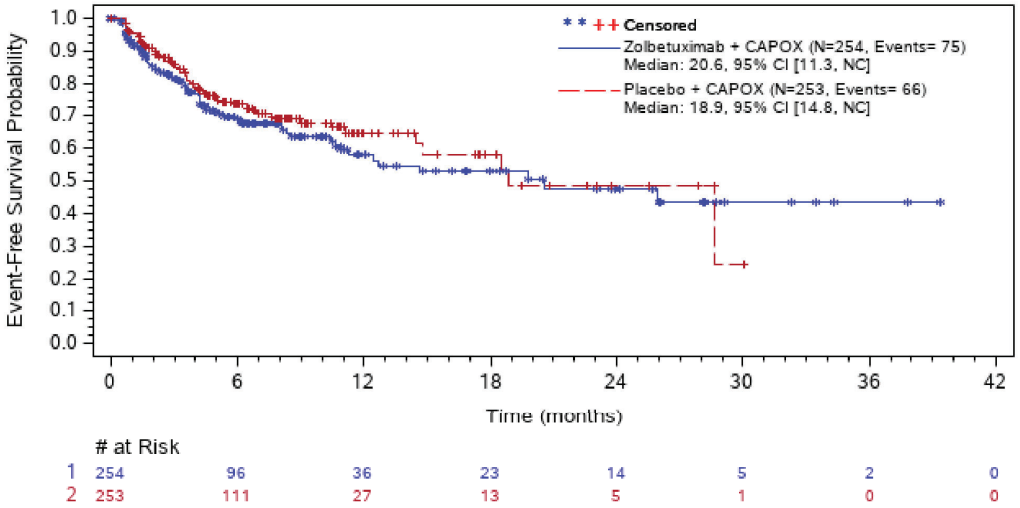
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.30: 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.

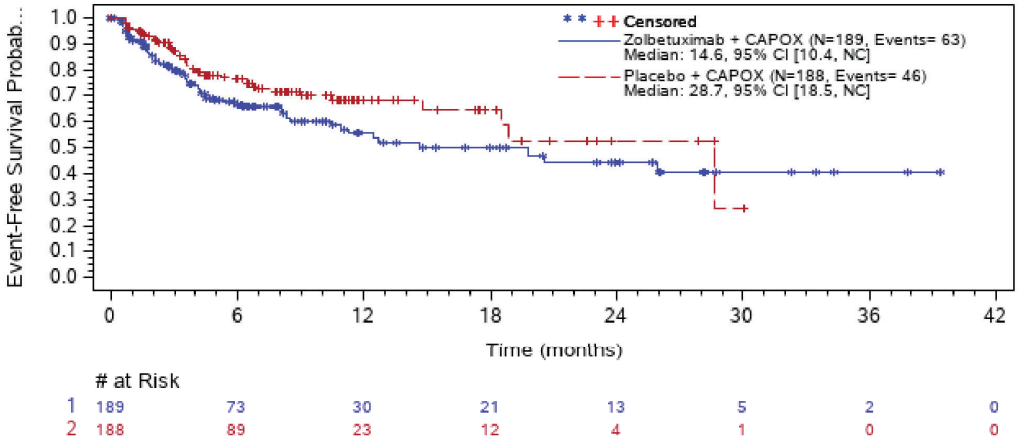
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

Figure 302.3.3004.30.4: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites (MID=10) - Full Analysis Set

Number of Organs with Metastatic Sites: 0-2



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.

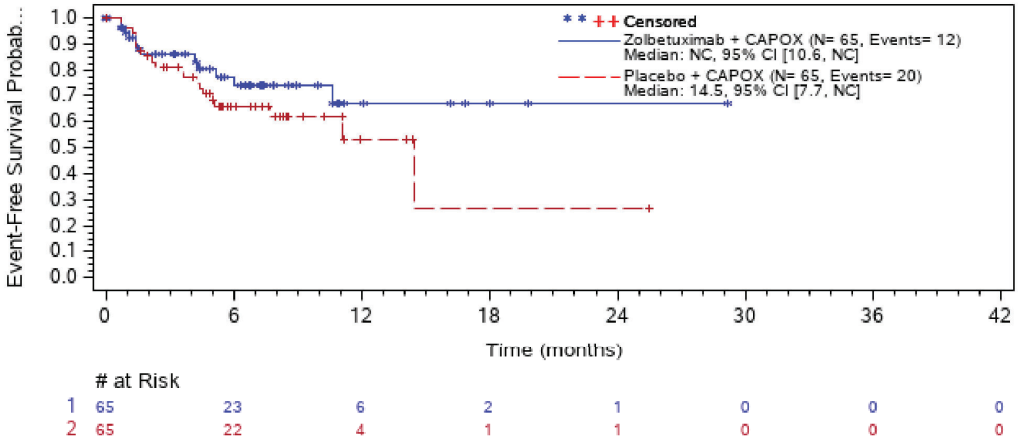
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

Figure 302.3.3004.30.4: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva by Number of Organs with Metastatic Sites (MID=10) - Full Analysis Set

Number of Organs with Metastatic Sites: >=3



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.

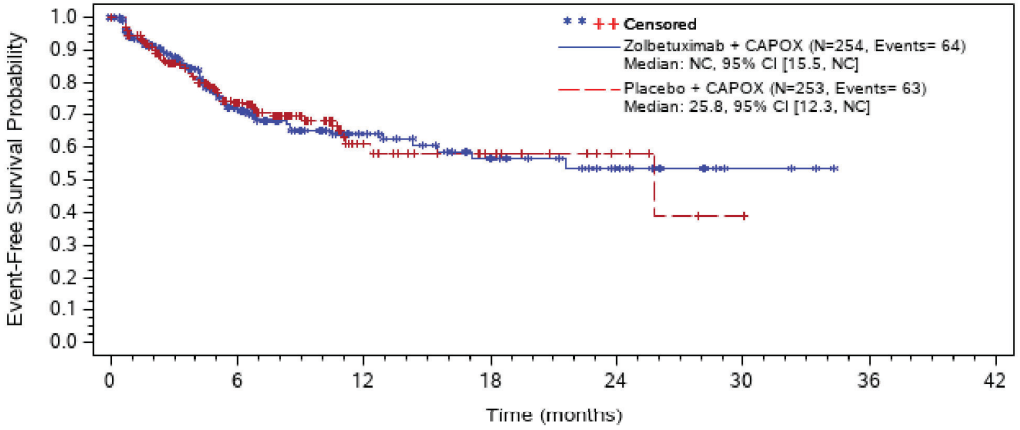
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.31: 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.

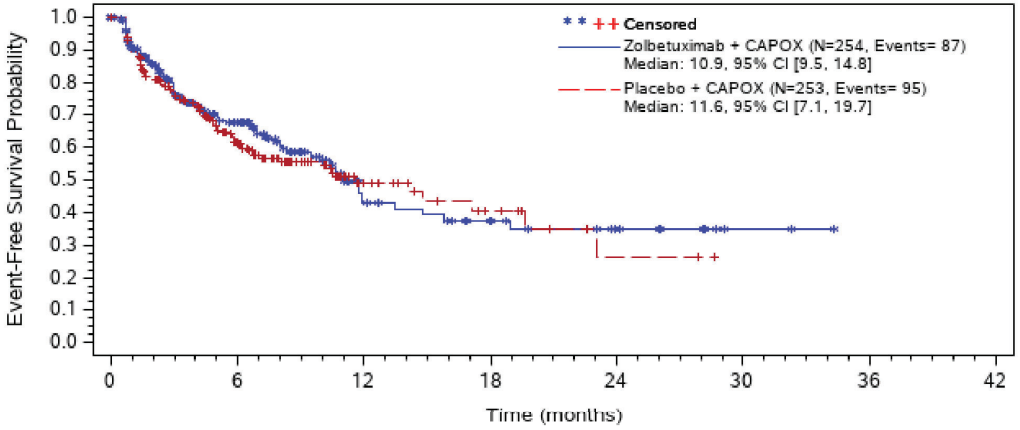
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.32: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble with Coughing (MID=10) - Full Analysis Set



# at Risk								
1	254	92	26	16	9	2	0	0
2	253	97	24	11	3	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.

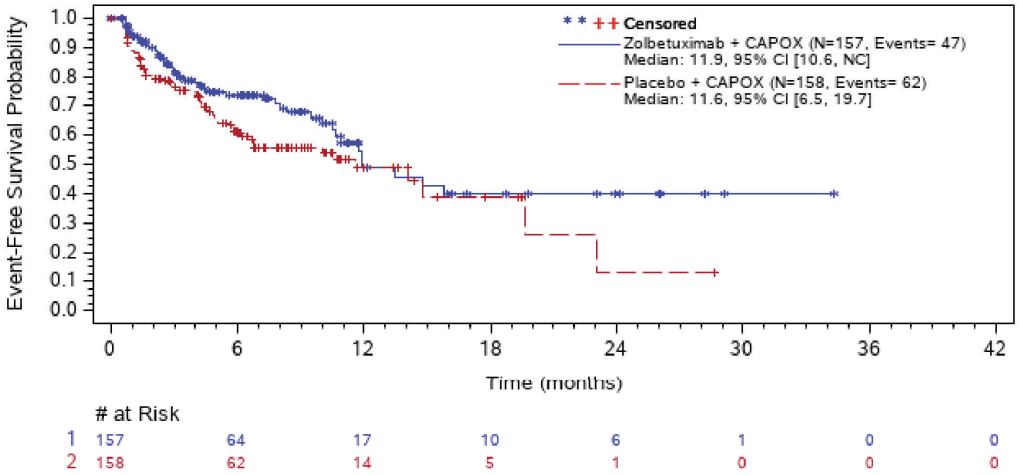
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.32.3: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble with Coughing by Region (MID=10) - Full Analysis Set Region: Asia



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.

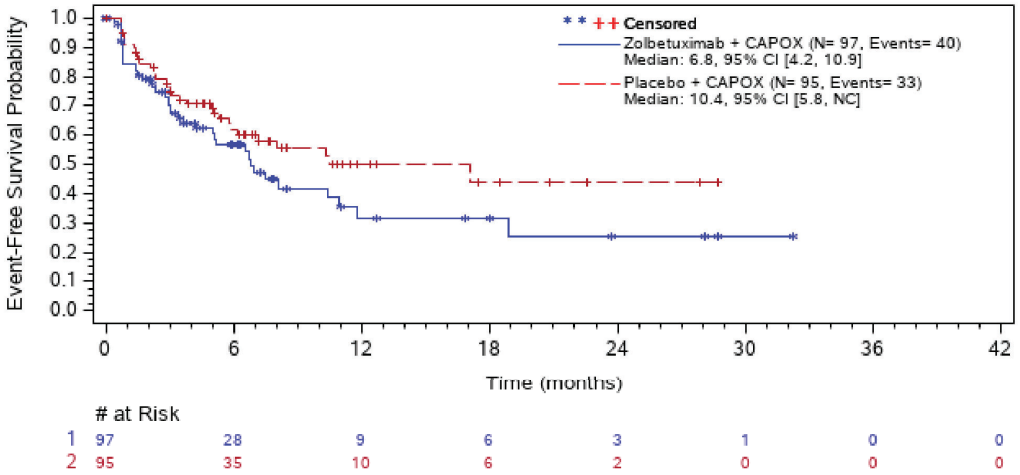
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.32.3: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble with Coughing by Region (MID=10) - Full Analysis Set Region: Non-Asia



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.

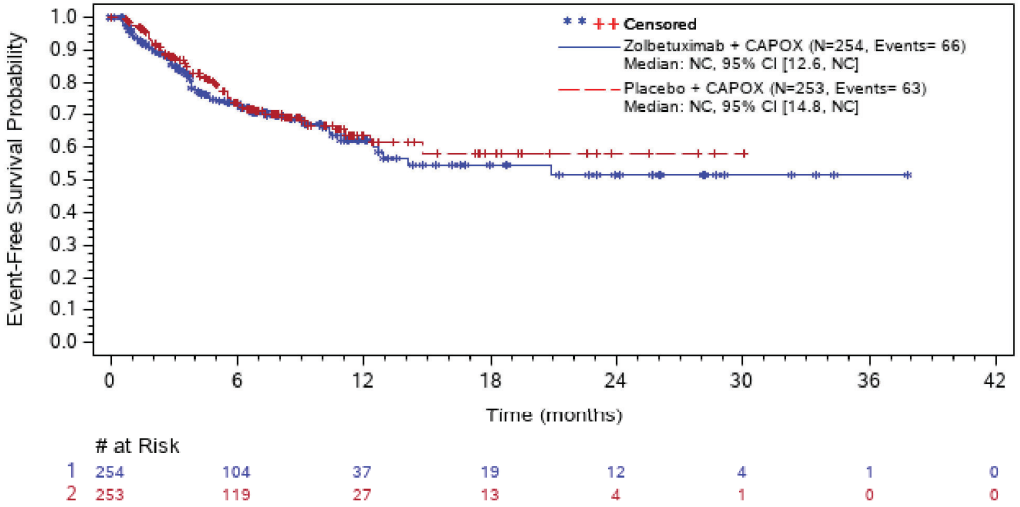
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.33: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Talking (MID=10) - Full Analysis Set



# at Risk							
1	254	104	37	19	12	4	1	0
2	253	119	27	13	4	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.

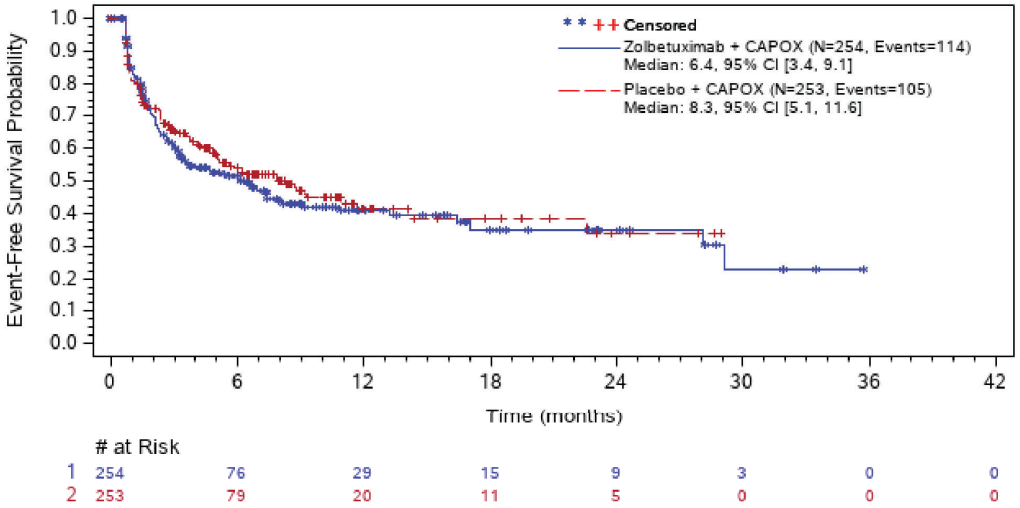
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.34: 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.

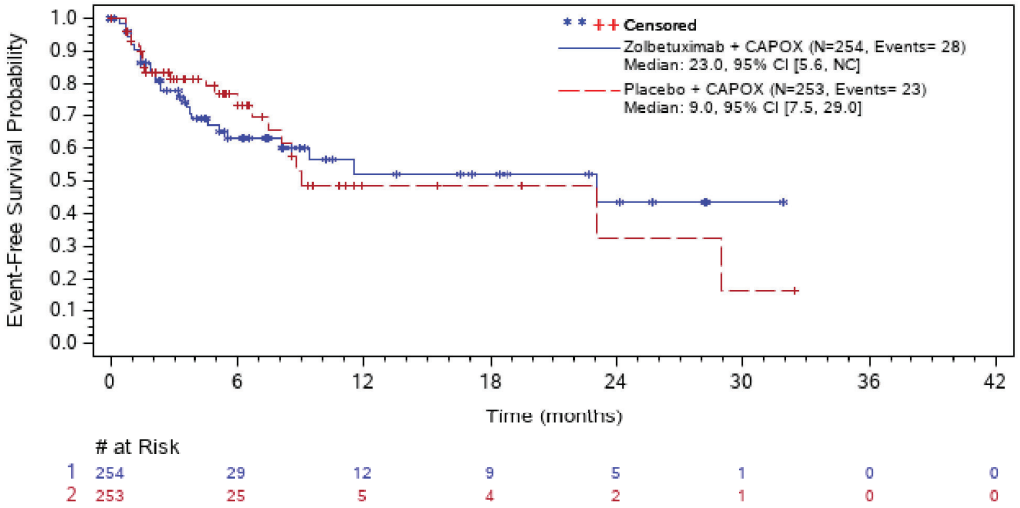
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 12JAN24

The SAS System

Figure 302.3.3004.35: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Hair Loss (MID=10) - Full Analysis Set



# at Risk								
1	254	29	12	9	5	1	0	0
2	253	25	5	4	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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024

Anhang 4-G1 Patientenberichtete Endpunkte

Anhang 4-G1 Symptomatik anhand des EORTC QLQ-STO22 (Belching subscale)

1. Rücklaufquoten

Table 302.3.3001.36: EORTC QLQ-STO22 - Completion Status of Belching - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	241/250 (96.4%)	241/252 (95.6%)	241/253 (95.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	181/197 (91.9%)	185/221 (83.7%)	186/254 (73.2%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	112/128 (87.5%)	121/199 (60.8%)	121/254 (47.6%)	125/141 (88.7%)	126/217 (58.1%)	126/253 (49.8%)
Cycle 8 Day 1	109/119 (91.6%)	113/196 (57.7%)	114/254 (44.9%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; 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: 12JAN24

Table 302.3.3001.36: EORTC QLQ-STO22 - Completion Status of Belching - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; 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: 12JAN24

Table 302.3.3001.36: EORTC QLQ-STO22 - Completion Status of Belching - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	143/218 (65.6%)	143/227 (63.0%)	143/254 (56.3%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EORTC QLQ-STO22 (Belching subscale)

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

Table 302.3.3002.36: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Belching - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + CAPOX (N=254)												
Baseline	243	12.14	18.62	0.0	0.00	83.3						
Cycle 2 Day 1	209	10.37	15.12	0.0	0.00	83.3	208	-1.52	15.68	-66.7	0.00	50.0
Cycle 3 Day 1	186	12.19	17.95	0.0	0.00	100.0	182	0.92	17.84	-66.7	0.00	100.0
Cycle 4 Day 1	169	11.54	15.21	0.0	0.00	66.7	166	0.20	16.51	-66.7	0.00	50.0
Cycle 5 Day 1	163	12.47	17.80	0.0	0.00	100.0	159	1.68	17.81	-66.7	0.00	66.7
Cycle 6 Day 1	151	11.70	16.75	0.0	0.00	83.3	149	0.00	16.67	-66.7	0.00	33.3
Cycle 7 Day 1	121	10.47	14.45	0.0	0.00	50.0	119	0.28	17.36	-66.7	0.00	33.3
Cycle 8 Day 1	114	13.30	19.98	0.0	0.00	83.3	108	1.54	20.95	-66.7	0.00	66.7
Cycle 9 Day 1	107	12.93	19.60	0.0	0.00	83.3	102	1.31	18.27	-66.7	0.00	50.0
Cycle 10 Day 1	88	10.98	18.55	0.0	0.00	83.3	85	0.39	18.54	-50.0	0.00	66.7
Cycle 11 Day 1	83	8.43	15.48	0.0	0.00	66.7	80	-2.08	17.26	-66.7	0.00	33.3
Cycle 12 Day 1	77	7.58	13.39	0.0	0.00	50.0	75	-1.78	16.11	-66.7	0.00	33.3
Cycle 13 Day 1	62	9.41	16.15	0.0	0.00	66.7	60	-0.28	20.00	-66.7	0.00	50.0
Cycle 14 Day 1	57	7.89	13.40	0.0	0.00	50.0	55	0.00	17.27	-66.7	0.00	33.3
Cycle 15 Day 1	53	8.49	15.20	0.0	0.00	50.0	51	-1.31	16.61	-66.7	0.00	33.3
Cycle 16 Day 1	50	8.67	13.98	0.0	0.00	50.0	48	-2.78	18.30	-66.7	0.00	33.3
Cycle 17 Day 1	45	7.78	13.10	0.0	0.00	50.0	43	-2.71	18.87	-66.7	0.00	33.3
Cycle 18 Day 1	43	9.69	18.27	0.0	0.00	66.7	41	-2.03	17.16	-66.7	0.00	33.3
Cycle 19 Day 1	42	10.71	19.06	0.0	0.00	83.3	40	0.42	15.33	-50.0	0.00	33.3
Cycle 20 Day 1	41	12.20	20.76	0.0	0.00	83.3	39	1.28	18.09	-66.7	0.00	33.3
Cycle 21 Day 1	38	10.09	20.70	0.0	0.00	83.3	36	-0.93	14.33	-50.0	0.00	16.7
Cycle 22 Day 1	33	9.09	16.19	0.0	0.00	66.7	31	-0.54	17.99	-66.7	0.00	33.3
Cycle 23 Day 1	33	6.57	17.15	0.0	0.00	83.3	31	-3.23	16.34	-66.7	0.00	16.7
Cycle 24 Day 1	31	7.53	13.50	0.0	0.00	50.0	29	0.00	16.67	-50.0	0.00	33.3
Cycle 25 Day 1	30	7.22	13.62	0.0	0.00	50.0	28	0.60	17.26	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.36: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Belching - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 26 Day 1	28	9.52	14.65	0.0	0.00	50.0	26	1.92	17.21	-33.3	0.00	33.3
Cycle 27 Day 1	27	8.64	14.15	0.0	0.00	50.0	25	0.00	15.21	-33.3	0.00	33.3
Cycle 28 Day 1	23	11.59	23.27	0.0	0.00	100.0	21	3.97	13.85	-33.3	0.00	33.3
Cycle 29 Day 1	24	8.33	14.74	0.0	0.00	50.0	22	0.00	15.43	-33.3	0.00	33.3
Cycle 30 Day 1	22	9.85	18.30	0.0	0.00	66.7	20	0.83	14.78	-33.3	0.00	33.3
Cycle 31 Day 1	22	11.36	19.51	0.0	0.00	66.7	20	2.50	16.47	-33.3	0.00	33.3
Cycle 32 Day 1	20	14.17	22.47	0.0	0.00	83.3	18	4.63	17.90	-33.3	0.00	33.3
Cycle 33 Day 1	17	6.86	14.50	0.0	0.00	50.0	15	-1.11	14.73	-33.3	0.00	16.7
Cycle 34 Day 1	14	3.57	7.10	0.0	0.00	16.7	12	0.00	12.31	-33.3	0.00	16.7
Cycle 35 Day 1	15	8.89	13.90	0.0	0.00	33.3	13	3.85	20.59	-33.3	0.00	33.3
Cycle 36 Day 1	14	7.14	12.60	0.0	0.00	33.3	12	1.39	19.41	-33.3	0.00	33.3
Cycle 37 Day 1	12	9.72	11.14	0.0	8.33	33.3	11	6.06	11.24	-16.7	0.00	16.7
Cycle 38 Day 1	11	6.06	13.48	0.0	0.00	33.3	10	1.67	16.57	-33.3	0.00	33.3
Cycle 39 Day 1	10	5.00	11.25	0.0	0.00	33.3	9	3.70	7.35	0.0	0.00	16.7
Study Disc 1	135	12.10	20.81	0.0	0.00	100.0	133	1.75	20.44	-66.7	0.00	66.7
30 D SFU Z/P	58	13.79	22.33	0.0	0.00	100.0	57	3.22	21.23	-50.0	0.00	100.0
90 D SFU Z/P	62	7.26	11.93	0.0	0.00	50.0	61	-0.55	15.20	-50.0	0.00	33.3
Placebo + CAPOX (N=253)												
Baseline	241	14.11	21.01	0.0	0.00	100.0						
Cycle 2 Day 1	222	10.44	15.04	0.0	0.00	100.0	216	-3.09	14.93	-66.7	0.00	33.3
Cycle 3 Day 1	200	10.75	15.93	0.0	0.00	83.3	196	-1.87	16.94	-83.3	0.00	83.3
Cycle 4 Day 1	171	9.75	13.97	0.0	0.00	66.7	169	-3.16	18.81	-83.3	0.00	33.3
Cycle 5 Day 1	166	8.33	13.70	0.0	0.00	66.7	165	-5.35	18.59	-83.3	0.00	33.3
Cycle 6 Day 1	146	10.05	15.72	0.0	0.00	66.7	145	-4.02	20.53	-66.7	0.00	50.0
Cycle 7 Day 1	126	9.79	14.65	0.0	0.00	66.7	125	-5.07	20.66	-83.3	0.00	50.0
Cycle 8 Day 1	110	9.24	16.06	0.0	0.00	66.7	109	-5.05	21.46	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.36: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Belching - 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	104	5.77	11.79	0.0	0.00	50.0	103	-9.39	20.44	-83.3	0.00	33.3
Cycle 10 Day 1	81	6.79	13.12	0.0	0.00	50.0	79	-7.38	19.93	-83.3	0.00	33.3
Cycle 11 Day 1	72	5.32	10.77	0.0	0.00	50.0	71	-9.62	21.21	-83.3	0.00	33.3
Cycle 12 Day 1	59	6.78	13.53	0.0	0.00	66.7	57	-7.60	18.65	-83.3	0.00	33.3
Cycle 13 Day 1	50	7.00	16.18	0.0	0.00	100.0	48	-7.64	22.27	-100.0	0.00	16.7
Cycle 14 Day 1	46	7.61	14.36	0.0	0.00	66.7	44	-6.06	20.99	-100.0	0.00	33.3
Cycle 15 Day 1	38	7.89	14.88	0.0	0.00	66.7	36	-5.56	19.92	-83.3	0.00	33.3
Cycle 16 Day 1	33	7.07	13.84	0.0	0.00	50.0	31	-5.91	22.17	-83.3	0.00	33.3
Cycle 17 Day 1	28	3.57	8.31	0.0	0.00	33.3	25	-5.33	22.42	-100.0	0.00	16.7
Cycle 18 Day 1	23	7.97	13.17	0.0	0.00	33.3	21	-3.17	27.19	-100.0	0.00	33.3
Cycle 19 Day 1	21	3.97	8.98	0.0	0.00	33.3	20	-2.50	11.18	-33.3	0.00	16.7
Cycle 20 Day 1	20	5.00	9.52	0.0	0.00	33.3	19	-7.02	21.74	-83.3	0.00	16.7
Cycle 21 Day 1	21	6.35	11.15	0.0	0.00	33.3	20	-5.00	23.63	-83.3	0.00	33.3
Cycle 22 Day 1	18	8.33	17.39	0.0	0.00	66.7	17	-4.90	28.73	-83.3	0.00	66.7
Cycle 23 Day 1	17	4.90	9.80	0.0	0.00	33.3	16	-9.38	23.55	-83.3	0.00	16.7
Cycle 24 Day 1	13	7.69	14.62	0.0	0.00	50.0	12	-5.56	32.05	-100.0	0.00	33.3
Cycle 25 Day 1	13	5.13	14.25	0.0	0.00	50.0	12	-8.33	31.38	-100.0	0.00	33.3
Cycle 26 Day 1	10	10.00	21.08	0.0	0.00	66.7	9	3.70	20.03	-16.7	0.00	50.0
Cycle 27 Day 1	11	6.06	15.41	0.0	0.00	50.0	10	0.00	13.61	-16.7	0.00	33.3
Cycle 28 Day 1	11	7.58	15.57	0.0	0.00	50.0	11	1.52	13.85	-16.7	0.00	33.3
Cycle 29 Day 1	12	5.56	10.86	0.0	0.00	33.3	12	-1.39	11.14	-16.7	0.00	16.7
Study Disc 1	156	13.14	20.65	0.0	0.00	100.0	150	0.56	23.99	-66.7	0.00	100.0
30 D SFU Z/P	78	13.25	21.55	0.0	0.00	100.0	76	0.66	19.52	-50.0	0.00	100.0
90 D SFU Z/P	81	9.47	17.07	0.0	0.00	100.0	79	-1.90	17.50	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 12JAN24

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

Table 302.3.3004.36.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Belching (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	122 (48.0%)	114 (45.1%)	
Number of patients censored	132 (52.0%)	139 (54.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.3 [3.4, 6.5]	7.7 [4.4, 9.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.248 [0.960, 1.623]
Log-rank test			
Two-sided stratified log-rank p-value			0.0936

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; HR=hazard ratio; MID=minimally important difference; N=number of patients.
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: 12JAN24

Table 302.3.3004.36.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Belching by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	89 (50.6)	4.8 [3.5, 7.3]	180	84 (46.7)	7.0 [4.4, 10.4]	1.159 [0.860, 1.563]	0.3216	0.6599
>65 years	78	33 (42.3)	3.8 [2.3, NC]	73	30 (41.1)	9.2 [2.8, NC]	1.253 [0.763, 2.058]	0.3751	
Sex									
Male	159	81 (50.9)	4.3 [3.2, 5.6]	156	75 (48.1)	4.7 [3.0, 9.2]	1.098 [0.801, 1.503]	0.5520	0.4550
Female	95	41 (43.2)	7.4 [3.3, 18.2]	97	39 (40.2)	9.2 [5.7, NC]	1.325 [0.852, 2.059]	0.2062	
Region									
Asia	157	82 (52.2)	4.2 [3.0, 5.6]	158	67 (42.4)	9.2 [4.4, NC]	1.374 [0.994, 1.900]	0.0515	0.1873
Non-Asia	97	40 (41.2)	6.1 [3.6, 13.8]	95	47 (49.5)	7.0 [3.0, 9.2]	0.969 [0.634, 1.480]	0.8923	
Number of Organs with Metastatic Sites									
0-2	189	95 (50.3)	4.8 [3.3, 7.3]	188	86 (45.7)	8.3 [4.2, 11.3]	1.237 [0.924, 1.658]	0.1483	0.5725
>=3	65	27 (41.5)	4.2 [3.2, NC]	65	28 (43.1)	7.7 [2.2, 23.7]	1.070 [0.627, 1.827]	0.8078	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event.
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: 12JAN24

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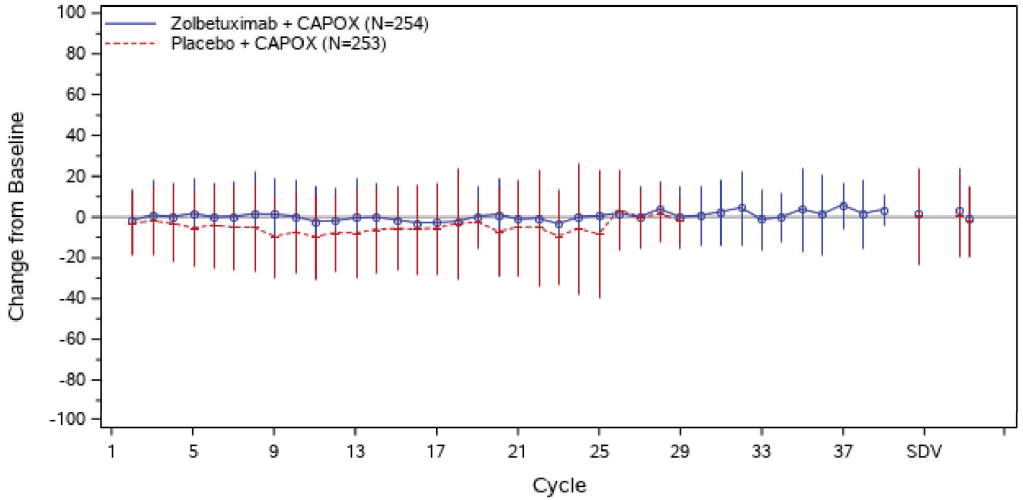
4. Graphische Darstellung des Verlaufs (Mean Change from Baseline)

The SAS System

Figure 302.3.3002.36: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Belching - Full Analysis Set



Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; 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).
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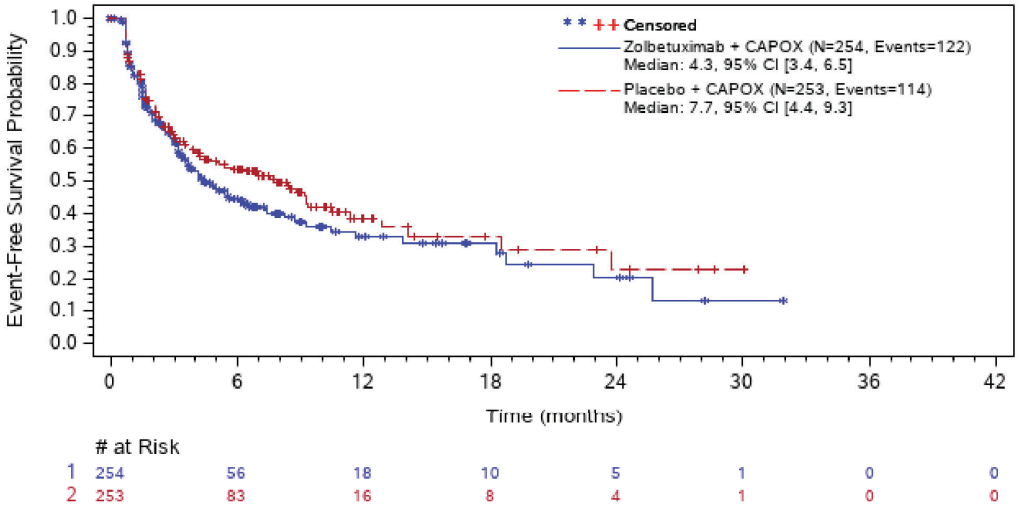
5. Kaplan-Meier-Plots

The SAS System

Figure 302.3.3004.36: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Belching (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; MID=minimally important difference; 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024

Anhang 4-G1 Patientenberichtete Endpunkte

Anhang 4-G1 Schmerzintensität anhand der NRS

1. Rücklaufquoten

Table 302.3.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	236/250 (94.4%)	236/252 (93.7%)	236/253 (93.3%)
Cycle 2 Day 1	208/224 (92.9%)	209/235 (88.9%)	209/254 (82.3%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	179/197 (90.9%)	183/221 (82.8%)	184/254 (72.4%)	198/215 (92.1%)	198/232 (85.3%)	198/253 (78.3%)
Cycle 4 Day 1	165/182 (90.7%)	169/218 (77.5%)	169/254 (66.5%)	169/192 (88.0%)	171/228 (75.0%)	171/253 (67.6%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	166/181 (91.7%)	166/227 (73.1%)	166/253 (65.6%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	146/165 (88.5%)	146/220 (66.4%)	146/253 (57.7%)
Cycle 7 Day 1	109/128 (85.2%)	118/199 (59.3%)	118/254 (46.5%)	124/141 (87.9%)	125/217 (57.6%)	125/253 (49.4%)
Cycle 8 Day 1	107/119 (89.9%)	111/196 (56.6%)	112/254 (44.1%)	109/125 (87.2%)	110/217 (50.7%)	110/253 (43.5%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	83/ 90 (92.2%)	88/188 (46.8%)	88/254 (34.6%)	78/ 91 (85.7%)	80/213 (37.6%)	80/253 (31.6%)
Cycle 11 Day 1	79/ 84 (94.0%)	83/187 (44.4%)	83/254 (32.7%)	70/ 78 (89.7%)	71/212 (33.5%)	71/253 (28.1%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	57/187 (30.5%)	57/254 (22.4%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

Abbreviations: 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: 12JAN24

Table 302.3.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)

Abbreviations: 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: 12JAN24

Table 302.3.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	142/218 (65.1%)	142/227 (62.6%)	142/254 (55.9%)	165/229 (72.1%)	165/231 (71.4%)	165/253 (65.2%)
30 D SFU Z/P	58/210 (27.6%)	58/219 (26.5%)	58/254 (22.8%)	78/217 (35.9%)	78/219 (35.6%)	78/253 (30.8%)
90 D SFU Z/P	62/192 (32.3%)	62/203 (30.5%)	62/254 (24.4%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

Abbreviations: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Schmerzintensität anhand der NRS

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

Table 302.3.3002.4: 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 + CAPOX (N=254)												
Baseline	243	2.45	2.49	0.0	2.00	10.0						
Cycle 2 Day 1	209	1.81	2.18	0.0	1.00	10.0	208	-0.60	2.61	-8.0	0.00	7.0
Cycle 3 Day 1	184	1.61	2.30	0.0	1.00	9.0	180	-0.74	2.30	-8.0	0.00	8.0
Cycle 4 Day 1	169	1.78	2.42	0.0	1.00	9.0	166	-0.63	2.58	-8.0	0.00	6.0
Cycle 5 Day 1	163	1.83	2.59	0.0	0.00	10.0	159	-0.37	2.89	-8.0	0.00	9.0
Cycle 6 Day 1	151	1.83	2.45	0.0	1.00	10.0	149	-0.51	2.61	-7.0	0.00	9.0
Cycle 7 Day 1	118	1.67	2.36	0.0	1.00	9.0	117	-0.61	2.65	-7.0	0.00	9.0
Cycle 8 Day 1	112	1.75	2.36	0.0	1.00	10.0	106	-0.59	2.45	-9.0	0.00	8.0
Cycle 9 Day 1	107	1.76	2.33	0.0	1.00	9.0	102	-0.65	2.62	-9.0	0.00	8.0
Cycle 10 Day 1	88	1.56	2.43	0.0	0.00	10.0	85	-0.71	2.67	-9.0	0.00	10.0
Cycle 11 Day 1	83	1.72	2.51	0.0	1.00	10.0	80	-0.40	2.96	-9.0	0.00	10.0
Cycle 12 Day 1	77	2.14	2.87	0.0	1.00	10.0	75	0.08	2.91	-9.0	0.00	10.0
Cycle 13 Day 1	62	2.10	2.86	0.0	0.00	9.0	60	0.05	3.40	-9.0	0.00	8.0
Cycle 14 Day 1	57	1.04	1.89	0.0	0.00	7.0	55	-0.95	2.63	-9.0	0.00	5.0
Cycle 15 Day 1	53	1.23	1.92	0.0	0.00	9.0	51	-0.80	2.62	-8.0	0.00	6.0
Cycle 16 Day 1	50	2.02	2.61	0.0	1.00	9.0	48	-0.19	3.07	-8.0	0.00	6.0
Cycle 17 Day 1	45	1.38	1.90	0.0	0.00	6.0	43	-0.74	2.46	-6.0	0.00	4.0
Cycle 18 Day 1	43	2.26	2.61	0.0	1.00	8.0	41	0.17	3.26	-6.0	0.00	8.0
Cycle 19 Day 1	42	1.69	2.11	0.0	0.50	8.0	40	-0.20	2.53	-8.0	0.00	5.0
Cycle 20 Day 1	41	1.88	2.24	0.0	1.00	8.0	39	0.05	2.72	-8.0	0.00	7.0
Cycle 21 Day 1	38	1.84	2.53	0.0	0.50	9.0	36	-0.06	2.86	-8.0	0.00	7.0
Cycle 22 Day 1	33	1.73	2.53	0.0	0.00	8.0	31	0.00	2.89	-8.0	0.00	7.0
Cycle 23 Day 1	33	1.45	2.14	0.0	0.00	7.0	31	-0.19	2.17	-5.0	0.00	5.0
Cycle 24 Day 1	31	1.23	2.32	0.0	0.00	9.0	29	-0.45	3.41	-8.0	0.00	8.0
Cycle 25 Day 1	30	0.70	1.32	0.0	0.00	5.0	28	-0.86	2.17	-8.0	0.00	2.0

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: 12JAN24

Table 302.3.3002.4: 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 26 Day 1	28	1.14	1.67	0.0	0.50	7.0	26	-0.58	2.53	-6.0	0.00	7.0
Cycle 27 Day 1	27	0.67	1.14	0.0	0.00	4.0	25	-1.08	2.25	-8.0	0.00	2.0
Cycle 28 Day 1	23	1.74	2.68	0.0	0.00	8.0	21	0.05	2.89	-5.0	0.00	8.0
Cycle 29 Day 1	24	1.38	1.93	0.0	0.50	6.0	22	-0.14	2.25	-5.0	0.00	6.0
Cycle 30 Day 1	22	1.09	2.11	0.0	0.00	8.0	20	-0.45	2.11	-5.0	0.00	6.0
Cycle 31 Day 1	22	1.14	1.67	0.0	0.00	5.0	20	-0.45	2.24	-5.0	0.00	3.0
Cycle 32 Day 1	20	1.15	1.87	0.0	0.00	6.0	18	-0.50	2.71	-6.0	0.00	6.0
Cycle 33 Day 1	17	1.00	2.65	0.0	0.00	8.0	15	0.07	3.24	-3.0	0.00	8.0
Cycle 34 Day 1	14	0.79	2.15	0.0	0.00	8.0	12	-0.67	3.20	-5.0	-1.00	8.0
Cycle 35 Day 1	15	0.73	1.79	0.0	0.00	7.0	13	-0.69	2.84	-5.0	-1.00	7.0
Cycle 36 Day 1	14	0.21	0.58	0.0	0.00	2.0	12	-1.42	1.56	-5.0	-1.00	0.0
Cycle 37 Day 1	12	1.33	2.57	0.0	0.00	8.0	11	0.18	3.06	-3.0	0.00	8.0
Cycle 38 Day 1	11	1.18	2.56	0.0	0.00	8.0	10	0.00	3.53	-3.0	-0.50	8.0
Cycle 39 Day 1	10	0.40	0.70	0.0	0.00	2.0	9	-0.89	1.27	-3.0	-1.00	1.0
Study Disc 1	134	2.99	2.90	0.0	2.00	10.0	133	0.61	3.30	-8.0	0.00	10.0
30 D SFU Z/P	58	3.09	3.21	0.0	2.00	10.0	57	0.74	3.34	-8.0	0.00	8.0
90 D SFU Z/P	62	2.26	3.07	0.0	1.00	10.0	61	0.08	3.34	-8.0	0.00	9.0
Placebo + CAPOX (N=253)												
Baseline	236	2.64	2.55	0.0	2.00	10.0						
Cycle 2 Day 1	222	1.92	2.23	0.0	1.00	10.0	211	-0.63	2.59	-10.0	0.00	9.0
Cycle 3 Day 1	198	1.73	2.34	0.0	1.00	10.0	190	-0.82	2.33	-10.0	0.00	10.0
Cycle 4 Day 1	171	1.67	2.27	0.0	0.00	9.0	167	-0.91	2.68	-10.0	-1.00	9.0
Cycle 5 Day 1	166	1.71	2.41	0.0	1.00	9.0	164	-0.79	2.84	-10.0	0.00	9.0
Cycle 6 Day 1	146	1.88	2.62	0.0	1.00	10.0	143	-0.57	3.00	-10.0	0.00	9.0
Cycle 7 Day 1	125	1.78	2.28	0.0	1.00	10.0	122	-0.38	2.74	-8.0	0.00	10.0
Cycle 8 Day 1	110	1.94	2.59	0.0	1.00	10.0	109	-0.36	2.48	-6.0	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: 12JAN24

Table 302.3.3002.4: 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 9 Day 1	104	1.86	2.57	0.0	1.00	10.0	103	-0.36	2.63	-7.0	0.00	10.0
Cycle 10 Day 1	80	1.45	2.01	0.0	0.00	7.0	78	-0.71	2.65	-7.0	-0.50	7.0
Cycle 11 Day 1	71	1.39	1.96	0.0	0.00	8.0	70	-0.61	2.55	-7.0	0.00	8.0
Cycle 12 Day 1	59	1.19	1.85	0.0	0.00	8.0	57	-0.53	2.41	-7.0	0.00	8.0
Cycle 13 Day 1	50	1.32	1.96	0.0	0.50	8.0	48	-0.63	2.44	-7.0	0.00	8.0
Cycle 14 Day 1	46	1.48	2.40	0.0	0.00	8.0	44	-0.34	2.12	-7.0	0.00	6.0
Cycle 15 Day 1	38	1.32	2.22	0.0	0.00	7.0	36	-0.44	1.81	-7.0	0.00	3.0
Cycle 16 Day 1	33	1.55	2.49	0.0	0.00	10.0	31	0.10	2.23	-3.0	0.00	10.0
Cycle 17 Day 1	28	0.68	1.56	0.0	0.00	7.0	25	-0.20	1.32	-4.0	0.00	3.0
Cycle 18 Day 1	23	0.43	1.12	0.0	0.00	5.0	21	-0.48	1.29	-4.0	0.00	2.0
Cycle 19 Day 1	21	0.38	0.74	0.0	0.00	3.0	20	-0.25	0.97	-3.0	0.00	1.0
Cycle 20 Day 1	20	1.20	2.50	0.0	0.00	10.0	19	0.21	2.90	-5.0	0.00	10.0
Cycle 21 Day 1	21	1.43	2.71	0.0	0.00	9.0	20	0.50	2.96	-4.0	0.00	9.0
Cycle 22 Day 1	18	1.06	2.24	0.0	0.00	9.0	17	0.00	2.92	-5.0	0.00	9.0
Cycle 23 Day 1	17	1.65	2.94	0.0	0.00	9.0	16	0.69	3.22	-5.0	0.00	9.0
Cycle 24 Day 1	13	0.69	1.18	0.0	0.00	4.0	12	-0.33	1.72	-5.0	0.00	2.0
Cycle 25 Day 1	13	1.15	2.48	0.0	0.00	9.0	12	0.17	3.21	-4.0	0.00	9.0
Cycle 26 Day 1	10	0.50	1.58	0.0	0.00	5.0	9	0.22	1.86	-1.0	0.00	5.0
Cycle 27 Day 1	11	1.00	3.00	0.0	0.00	10.0	10	0.80	3.29	-1.0	0.00	10.0
Cycle 28 Day 1	11	0.45	1.21	0.0	0.00	4.0	11	0.18	1.33	-1.0	0.00	4.0
Cycle 29 Day 1	12	0.17	0.39	0.0	0.00	1.0	12	-0.17	0.72	-1.0	0.00	1.0
Study Disc 1	156	3.36	2.94	0.0	3.00	10.0	147	0.71	3.02	-10.0	0.00	10.0
30 D SFU Z/P	78	2.95	2.96	0.0	2.00	9.0	73	0.56	2.63	-7.0	0.00	9.0
90 D SFU Z/P	81	2.78	3.01	0.0	2.00	10.0	77	0.62	2.81	-7.0	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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Schmerzintensität anhand der NRS

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

Table 302.3.3004.4.1: Global Pain - Summary of Time to First Deterioration of PI01 - Pain Intensity (MID=2) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	124 (48.8%)	116 (45.8%)	
Number of patients censored	130 (51.2%)	137 (54.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.6 [4.6, 8.8]	7.2 [5.2, 10.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.035 [0.799, 1.340]
Log-rank test			
Two-sided stratified log-rank p-value			0.7855

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: 12JAN24

Table 302.3.3004.4.2: Global Pain - Summary of Time to First Deterioration of PI01 - Pain Intensity by Subgroups (MID=2) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	90 (51.1)	6.0 [3.8, 8.1]	180	87 (48.3)	6.5 [4.4, 9.2]	1.045 [0.777, 1.405]	0.7608	0.9158
>65 years	78	34 (43.6)	9.2 [5.1, 13.2]	73	29 (39.7)	10.9 [4.4, 15.2]	1.064 [0.643, 1.761]	0.8147	
Sex									
Male	159	79 (49.7)	6.6 [4.1, 8.4]	156	70 (44.9)	6.4 [4.4, 10.9]	1.058 [0.765, 1.462]	0.7321	0.9432
Female	95	45 (47.4)	8.3 [4.6, 11.2]	97	46 (47.4)	7.9 [4.4, 10.2]	0.988 [0.650, 1.501]	0.9578	
Region									
Asia	157	84 (53.5)	6.6 [4.2, 8.8]	158	73 (46.2)	6.5 [4.4, 10.2]	1.132 [0.826, 1.552]	0.4398	0.4783
Non-Asia	97	40 (41.2)	6.7 [4.1, 19.6]	95	43 (45.3)	7.9 [4.4, 11.5]	0.888 [0.573, 1.377]	0.6046	
Number of Organs with Metastatic Sites									
0-2	189	90 (47.6)	7.4 [5.0, 10.2]	188	89 (47.3)	7.2 [4.8, 10.9]	0.984 [0.732, 1.323]	0.9219	0.3638
>=3	65	34 (52.3)	4.8 [3.4, 8.8]	65	27 (41.5)	7.8 [3.7, 15.7]	1.241 [0.743, 2.073]	0.4098	

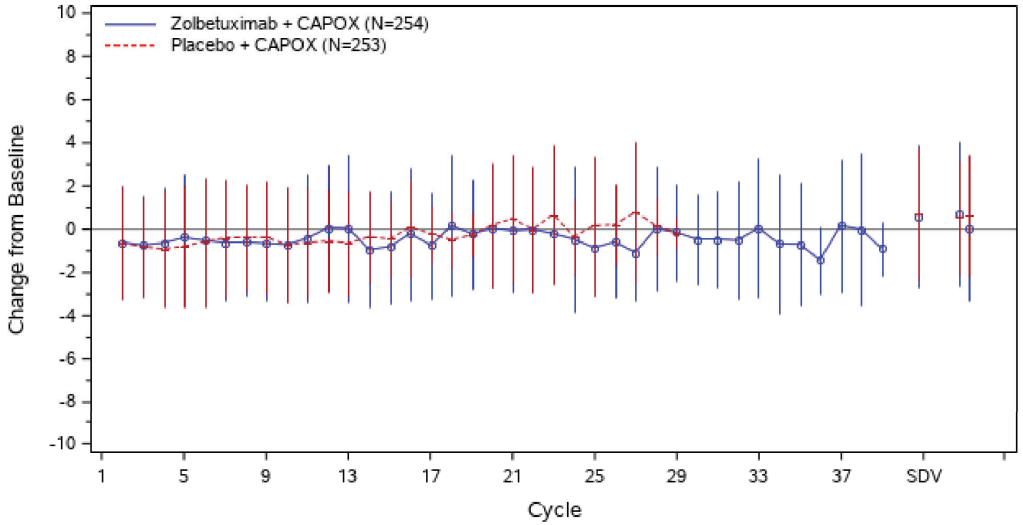
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Schmerzintensität anhand der NRS

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

The SAS System

Figure 302.3.3002.4: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
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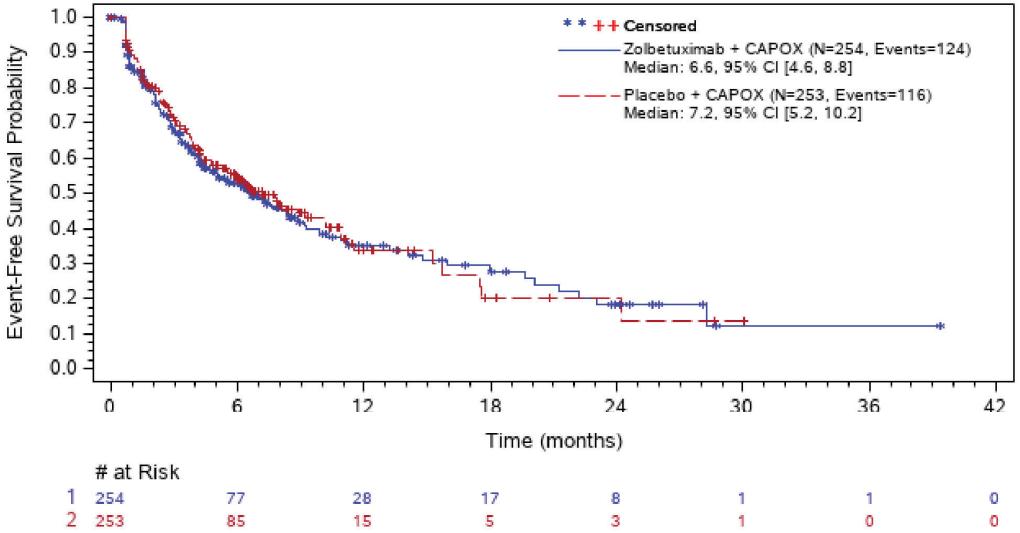
5. Kaplan-Meier-Plots

The SAS System

Figure 302.3.3004.4: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024

Anhang 4-G1 Patientenberichtete Endpunkte

Anhang 4-G1 EQ-5D VAS

1. Rücklaufquoten

Table 302.3.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	243/253 (96.0%)	243/253 (96.0%)	243/254 (95.7%)	243/250 (97.2%)	243/252 (96.4%)	243/253 (96.0%)
Cycle 2 Day 1	209/224 (93.3%)	210/235 (89.4%)	210/254 (82.7%)	220/229 (96.1%)	221/237 (93.2%)	222/253 (87.7%)
Cycle 3 Day 1	183/197 (92.9%)	187/221 (84.6%)	188/254 (74.0%)	200/215 (93.0%)	200/232 (86.2%)	200/253 (79.1%)
Cycle 4 Day 1	167/182 (91.8%)	172/218 (78.9%)	172/254 (67.7%)	170/192 (88.5%)	172/228 (75.4%)	172/253 (68.0%)
Cycle 5 Day 1	158/172 (91.9%)	161/212 (75.9%)	163/254 (64.2%)	167/181 (92.3%)	167/227 (73.6%)	167/253 (66.0%)
Cycle 6 Day 1	144/155 (92.9%)	150/205 (73.2%)	151/254 (59.4%)	147/165 (89.1%)	147/220 (66.8%)	147/253 (58.1%)
Cycle 7 Day 1	114/128 (89.1%)	123/199 (61.8%)	123/254 (48.4%)	126/141 (89.4%)	127/217 (58.5%)	127/253 (50.2%)
Cycle 8 Day 1	110/119 (92.4%)	114/196 (58.2%)	115/254 (45.3%)	110/125 (88.0%)	111/217 (51.2%)	111/253 (43.9%)
Cycle 9 Day 1	104/108 (96.3%)	107/192 (55.7%)	107/254 (42.1%)	100/110 (90.9%)	103/214 (48.1%)	104/253 (41.1%)
Cycle 10 Day 1	84/ 90 (93.3%)	89/188 (47.3%)	89/254 (35.0%)	79/ 91 (86.8%)	81/213 (38.0%)	81/253 (32.0%)
Cycle 11 Day 1	80/ 84 (95.2%)	84/187 (44.9%)	84/254 (33.1%)	71/ 78 (91.0%)	72/212 (34.0%)	72/253 (28.5%)
Cycle 12 Day 1	74/ 77 (96.1%)	77/187 (41.2%)	77/254 (30.3%)	58/ 68 (85.3%)	59/211 (28.0%)	59/253 (23.3%)
Cycle 13 Day 1	61/ 67 (91.0%)	62/187 (33.2%)	62/254 (24.4%)	50/ 57 (87.7%)	50/210 (23.8%)	50/253 (19.8%)
Cycle 14 Day 1	57/ 62 (91.9%)	58/187 (31.0%)	58/254 (22.8%)	45/ 49 (91.8%)	46/210 (21.9%)	46/253 (18.2%)
Cycle 15 Day 1	50/ 55 (90.9%)	51/184 (27.7%)	53/254 (20.9%)	37/ 43 (86.0%)	38/207 (18.4%)	38/253 (15.0%)
Cycle 16 Day 1	48/ 50 (96.0%)	49/184 (26.6%)	50/254 (19.7%)	32/ 34 (94.1%)	33/207 (15.9%)	33/253 (13.0%)
Cycle 17 Day 1	44/ 47 (93.6%)	45/183 (24.6%)	45/254 (17.7%)	28/ 29 (96.6%)	28/206 (13.6%)	28/253 (11.1%)
Cycle 18 Day 1	42/ 44 (95.5%)	43/183 (23.5%)	43/254 (16.9%)	23/ 25 (92.0%)	23/206 (11.2%)	23/253 (9.1%)
Cycle 19 Day 1	42/ 44 (95.5%)	42/183 (23.0%)	42/254 (16.5%)	20/ 23 (87.0%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 20 Day 1	40/ 41 (97.6%)	40/181 (22.1%)	41/254 (16.1%)	20/ 23 (87.0%)	20/206 (9.7%)	20/253 (7.9%)
Cycle 21 Day 1	38/ 39 (97.4%)	38/181 (21.0%)	38/254 (15.0%)	21/ 22 (95.5%)	21/206 (10.2%)	21/253 (8.3%)
Cycle 22 Day 1	33/ 35 (94.3%)	33/180 (18.3%)	33/254 (13.0%)	18/ 20 (90.0%)	18/206 (8.7%)	18/253 (7.1%)
Cycle 23 Day 1	33/ 34 (97.1%)	33/180 (18.3%)	33/254 (13.0%)	17/ 19 (89.5%)	17/206 (8.3%)	17/253 (6.7%)
Cycle 24 Day 1	31/ 33 (93.9%)	31/180 (17.2%)	31/254 (12.2%)	13/ 18 (72.2%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 25 Day 1	30/ 33 (90.9%)	30/180 (16.7%)	30/254 (11.8%)	13/ 16 (81.3%)	13/206 (6.3%)	13/253 (5.1%)
Cycle 26 Day 1	28/ 32 (87.5%)	28/180 (15.6%)	28/254 (11.0%)	10/ 13 (76.9%)	10/206 (4.9%)	10/253 (4.0%)

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: 12JAN24

Table 302.3.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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	25/ 28 (89.3%)	27/180 (15.0%)	27/254 (10.6%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 28 Day 1	23/ 26 (88.5%)	23/180 (12.8%)	23/254 (9.1%)	11/ 13 (84.6%)	11/206 (5.3%)	11/253 (4.3%)
Cycle 29 Day 1	24/ 25 (96.0%)	24/180 (13.3%)	24/254 (9.4%)	12/ 12 (100.0%)	12/206 (5.8%)	12/253 (4.7%)
Cycle 30 Day 1	22/ 23 (95.7%)	22/180 (12.2%)	22/254 (8.7%)	8/ 9 (88.9%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 31 Day 1	22/ 22 (100.0%)	22/180 (12.2%)	22/254 (8.7%)	8/ 8 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 32 Day 1	19/ 20 (95.0%)	19/179 (10.6%)	20/254 (7.9%)	7/ 7 (100.0%)	8/206 (3.9%)	8/253 (3.2%)
Cycle 33 Day 1	17/ 18 (94.4%)	17/179 (9.5%)	17/254 (6.7%)	6/ 7 (85.7%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 34 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	7/ 7 (100.0%)	7/206 (3.4%)	7/253 (2.8%)
Cycle 35 Day 1	15/ 15 (100.0%)	15/179 (8.4%)	15/254 (5.9%)	6/ 6 (100.0%)	6/206 (2.9%)	6/253 (2.4%)
Cycle 36 Day 1	14/ 15 (93.3%)	14/179 (7.8%)	14/254 (5.5%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 37 Day 1	12/ 13 (92.3%)	12/179 (6.7%)	12/254 (4.7%)	4/ 4 (100.0%)	4/206 (1.9%)	4/253 (1.6%)
Cycle 38 Day 1	11/ 12 (91.7%)	11/179 (6.1%)	11/254 (4.3%)	3/ 3 (100.0%)	3/206 (1.5%)	3/253 (1.2%)
Cycle 39 Day 1	9/ 10 (90.0%)	10/179 (5.6%)	10/254 (3.9%)	1/ 2 (50.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 40 Day 1	8/ 10 (80.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 41 Day 1	9/ 10 (90.0%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 42 Day 1	8/ 9 (88.9%)	9/179 (5.0%)	9/254 (3.5%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 43 Day 1	6/ 8 (75.0%)	7/179 (3.9%)	7/254 (2.8%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 44 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 45 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	1/ 1 (100.0%)	1/206 (0.5%)	1/253 (0.4%)
Cycle 46 Day 1	7/ 8 (87.5%)	8/179 (4.5%)	8/254 (3.1%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 47 Day 1	6/ 7 (85.7%)	7/179 (3.9%)	7/254 (2.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 48 Day 1	5/ 6 (83.3%)	6/179 (3.4%)	6/254 (2.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 49 Day 1	4/ 4 (100.0%)	5/179 (2.8%)	5/254 (2.0%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 50 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 51 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 52 Day 1	3/ 3 (100.0%)	4/179 (2.2%)	4/254 (1.6%)	0	0/206 (0.0%)	0/253 (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: 12JAN24

Table 302.3.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + CAPOX (N=254)			Placebo + CAPOX (N=253)		
	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 53 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 54 Day 1	3/ 3 (100.0%)	3/179 (1.7%)	3/254 (1.2%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 55 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 56 Day 1	2/ 2 (100.0%)	2/179 (1.1%)	2/254 (0.8%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 57 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 58 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 59 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Cycle 60 Day 1	1/ 1 (100.0%)	1/179 (0.6%)	1/254 (0.4%)	0	0/206 (0.0%)	0/253 (0.0%)
Study Disc	144/218 (66.1%)	144/227 (63.4%)	144/254 (56.7%)	168/229 (73.4%)	168/231 (72.7%)	168/253 (66.4%)
30 D SFU Z/P	59/210 (28.1%)	59/219 (26.9%)	59/254 (23.2%)	80/217 (36.9%)	80/219 (36.5%)	80/253 (31.6%)
90 D SFU Z/P	64/192 (33.3%)	64/203 (31.5%)	64/254 (25.2%)	81/178 (45.5%)	81/180 (45.0%)	81/253 (32.0%)

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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EQ-5D VAS

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

Table 302.3.3002.3: 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 + CAPOX (N=254)												
Baseline	243	71.50	19.60	0.0	77.00	100.0						
Cycle 2 Day 1	210	75.45	17.14	0.0	80.00	100.0	208	3.01	15.83	-63.0	1.00	80.0
Cycle 3 Day 1	188	74.61	17.89	1.0	79.00	100.0	183	2.17	15.19	-49.0	1.00	49.0
Cycle 4 Day 1	172	76.51	17.74	9.0	80.00	100.0	169	3.89	16.60	-52.0	2.00	97.0
Cycle 5 Day 1	163	74.10	18.96	2.0	79.00	100.0	159	1.50	17.20	-63.0	0.00	50.0
Cycle 6 Day 1	151	74.04	18.81	13.0	80.00	100.0	149	1.18	17.61	-50.0	0.00	100.0
Cycle 7 Day 1	123	77.08	16.51	4.0	80.00	100.0	121	3.21	15.60	-62.0	2.00	40.0
Cycle 8 Day 1	115	76.25	16.87	0.0	80.00	100.0	109	3.22	19.72	-50.0	0.00	100.0
Cycle 9 Day 1	107	74.31	19.46	0.0	80.00	100.0	102	0.96	17.32	-61.0	0.00	48.0
Cycle 10 Day 1	89	76.09	17.99	2.0	80.00	100.0	85	2.88	20.07	-64.0	1.00	77.0
Cycle 11 Day 1	84	72.35	20.23	0.0	75.00	100.0	81	-1.12	18.13	-61.0	0.00	42.0
Cycle 12 Day 1	77	76.45	18.71	4.0	80.00	100.0	75	2.89	21.70	-62.0	2.00	100.0
Cycle 13 Day 1	62	77.87	14.64	14.0	80.00	100.0	60	4.30	17.81	-30.0	2.00	58.0
Cycle 14 Day 1	58	78.26	16.83	1.0	80.00	100.0	56	5.68	25.25	-65.0	2.00	100.0
Cycle 15 Day 1	53	77.28	19.10	2.0	81.00	100.0	51	4.61	23.63	-64.0	1.00	100.0
Cycle 16 Day 1	50	76.32	18.39	1.0	79.00	100.0	48	2.40	18.26	-65.0	0.00	51.0
Cycle 17 Day 1	45	78.20	19.51	2.0	81.00	100.0	43	6.07	24.08	-64.0	2.00	100.0
Cycle 18 Day 1	43	80.81	11.76	59.0	80.00	100.0	41	8.49	24.62	-27.0	3.00	94.0
Cycle 19 Day 1	42	77.02	20.74	0.0	80.00	100.0	40	5.08	21.11	-47.0	1.00	89.0
Cycle 20 Day 1	41	75.51	20.63	7.0	78.00	100.0	39	2.97	25.52	-81.0	0.00	90.0
Cycle 21 Day 1	38	74.66	21.57	3.0	79.00	100.0	36	0.69	19.39	-72.0	0.50	38.0
Cycle 22 Day 1	33	78.00	19.80	8.0	79.00	100.0	31	3.55	15.24	-20.0	1.00	33.0
Cycle 23 Day 1	33	78.76	19.60	7.0	80.00	100.0	31	3.55	14.93	-20.0	0.00	34.0
Cycle 24 Day 1	31	80.74	17.08	11.0	81.00	100.0	29	5.17	16.19	-19.0	4.00	39.0
Cycle 25 Day 1	30	76.60	23.03	4.0	81.00	100.0	28	1.43	20.29	-62.0	-1.00	45.0

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;
30 D SFU 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.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.3: 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 26 Day 1	28	79.32	19.51	6.0	81.00	100.0	26	4.15	16.83	-33.0	4.50	36.0
Cycle 27 Day 1	27	75.85	23.88	1.0	80.00	100.0	25	0.20	20.58	-65.0	0.00	46.0
Cycle 28 Day 1	23	81.91	12.50	58.0	80.00	100.0	21	2.90	18.30	-30.0	3.00	44.0
Cycle 29 Day 1	24	84.25	11.92	61.0	83.50	100.0	22	3.73	15.74	-19.0	2.50	41.0
Cycle 30 Day 1	22	82.82	12.77	61.0	81.00	100.0	20	0.75	15.87	-23.0	-1.00	44.0
Cycle 31 Day 1	22	83.55	12.86	48.0	82.50	100.0	20	1.60	16.83	-26.0	-1.50	41.0
Cycle 32 Day 1	20	82.95	13.43	52.0	86.00	100.0	18	2.00	15.78	-25.0	3.00	41.0
Cycle 33 Day 1	17	87.41	11.39	57.0	92.00	100.0	15	6.80	17.07	-20.0	8.00	41.0
Cycle 34 Day 1	14	86.79	10.43	68.0	90.50	100.0	12	8.33	17.91	-18.0	8.00	45.0
Cycle 35 Day 1	15	85.67	9.07	71.0	91.00	100.0	13	5.77	16.63	-17.0	9.00	44.0
Cycle 36 Day 1	14	86.50	10.86	70.0	90.00	100.0	12	4.17	17.20	-19.0	3.00	43.0
Cycle 37 Day 1	12	87.25	9.81	70.0	91.50	100.0	11	10.73	14.55	-15.0	11.00	33.0
Cycle 38 Day 1	11	83.27	11.53	68.0	81.00	100.0	10	7.10	17.70	-29.0	10.50	32.0
Cycle 39 Day 1	10	87.40	11.74	70.0	92.50	100.0	9	10.22	11.42	-15.0	15.00	23.0
Study Disc 1	135	66.96	21.67	7.0	71.00	100.0	133	-7.50	21.73	-90.0	-5.00	41.0
30 D SFU Z/P	59	66.90	22.55	2.0	71.00	100.0	58	-7.79	23.72	-73.0	-6.50	40.0
90 D SFU Z/P	64	74.09	19.39	3.0	78.50	100.0	63	-5.24	19.73	-88.0	-3.00	34.0
Placebo + CAPOX (N=253)												
Baseline	243	72.65	18.73	0.0	75.00	100.0						
Cycle 2 Day 1	222	75.04	17.03	0.0	80.00	100.0	218	1.67	13.60	-41.0	0.00	50.0
Cycle 3 Day 1	200	74.91	17.43	0.0	79.00	100.0	198	2.07	14.70	-40.0	0.00	53.0
Cycle 4 Day 1	172	76.45	17.33	10.0	80.00	100.0	171	3.27	18.37	-80.0	2.00	95.0
Cycle 5 Day 1	167	76.82	16.63	8.0	80.00	100.0	167	3.74	17.32	-46.0	2.00	95.0
Cycle 6 Day 1	147	75.81	17.53	12.0	80.00	100.0	147	1.95	15.93	-58.0	0.00	58.0
Cycle 7 Day 1	127	76.02	18.57	2.0	80.00	100.0	127	2.73	19.74	-79.0	2.00	87.0
Cycle 8 Day 1	111	75.05	18.46	1.0	80.00	100.0	111	1.73	17.82	-73.0	2.00	60.0

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; 30 D SFU 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.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.3002.3: 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 9 Day 1	104	76.21	16.79	1.0	80.00	100.0	104	2.49	18.01	-41.0	2.00	85.0
Cycle 10 Day 1	81	77.84	14.75	4.0	79.00	100.0	80	1.48	17.73	-50.0	1.50	55.0
Cycle 11 Day 1	72	77.32	16.74	10.0	80.00	100.0	72	1.50	18.57	-51.0	1.00	55.0
Cycle 12 Day 1	59	78.61	16.91	20.0	81.00	100.0	58	1.36	24.31	-69.0	0.00	96.0
Cycle 13 Day 1	50	78.08	16.40	10.0	81.00	100.0	49	0.88	20.52	-79.0	0.00	42.0
Cycle 14 Day 1	46	78.74	17.80	10.0	81.00	100.0	45	2.20	23.17	-79.0	2.00	76.0
Cycle 15 Day 1	38	78.08	19.95	11.0	85.50	100.0	37	-1.84	19.58	-78.0	2.00	34.0
Cycle 16 Day 1	33	81.36	18.74	10.0	87.00	100.0	32	3.44	25.37	-79.0	3.50	85.0
Cycle 17 Day 1	28	84.32	13.10	47.0	87.50	100.0	26	2.35	13.65	-36.0	4.50	35.0
Cycle 18 Day 1	23	86.13	10.19	68.0	90.00	100.0	22	4.59	12.68	-20.0	3.50	42.0
Cycle 19 Day 1	21	89.33	10.19	70.0	90.00	100.0	21	5.95	10.28	-10.0	5.00	30.0
Cycle 20 Day 1	20	85.80	11.29	64.0	90.00	100.0	20	4.15	14.14	-24.0	5.50	41.0
Cycle 21 Day 1	21	88.10	11.15	60.0	90.00	100.0	21	6.29	10.93	-6.0	5.00	41.0
Cycle 22 Day 1	18	83.78	12.64	60.0	87.50	100.0	18	3.28	13.40	-20.0	1.50	36.0
Cycle 23 Day 1	17	84.18	16.49	40.0	89.00	100.0	17	4.12	16.03	-30.0	6.00	42.0
Cycle 24 Day 1	13	87.23	9.94	65.0	90.00	100.0	13	6.85	14.15	-15.0	7.00	39.0
Cycle 25 Day 1	13	89.85	7.87	75.0	90.00	100.0	13	7.15	12.08	-7.0	5.00	41.0
Cycle 26 Day 1	10	85.80	12.84	60.0	88.00	100.0	10	1.20	12.84	-30.0	5.00	13.0
Cycle 27 Day 1	11	90.73	8.40	79.0	91.00	100.0	11	4.73	4.82	-3.0	6.00	11.0
Cycle 28 Day 1	11	85.27	9.94	65.0	89.00	100.0	11	2.36	6.02	-8.0	3.00	11.0
Cycle 29 Day 1	12	87.08	9.09	72.0	87.50	100.0	12	3.58	5.95	-8.0	4.50	10.0
Study Disc 1	159	61.48	22.48	1.0	64.00	100.0	153	-10.66	21.14	-69.0	-10.00	50.0
30 D SFU Z/P	80	64.55	20.58	0.0	68.50	100.0	78	-8.63	20.32	-68.0	-6.00	30.0
90 D SFU Z/P	81	70.28	19.32	20.0	75.00	100.0	80	-4.34	19.79	-80.0	-3.50	50.0

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;
30 D SFU 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.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EQ-5D VAS

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

Table 302.3.3004.3.1: EQ-5D-5L - Summary of Time to First Deterioration of Visual Analog Scale (MID=15) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	253 (100.0%)	
Number of patients with events	100 (39.4%)	115 (45.5%)	
Number of patients censored	154 (60.6%)	138 (54.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.0 [6.9, 13.5]	6.7 [5.1, 9.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.856 [0.651, 1.125]
Log-rank test			
Two-sided stratified log-rank p-value			0.2611

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: 12JAN24

Table 302.3.3004.3.2: EQ-5D-5L - Summary of Time to First Deterioration of Visual Analog Scale by Subgroups (MID=15) - Full Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	70 (39.8)	12.4 [7.3, 14.8]	180	79 (43.9)	7.8 [5.7, 17.5]	0.833 [0.602, 1.153]	0.2708	0.8370
>65 years	78	30 (38.5)	6.6 [4.2, 12.6]	73	36 (49.3)	5.1 [3.4, 6.8]	0.908 [0.559, 1.475]	0.6937	
Sex									
Male	159	65 (40.9)	9.0 [6.9, 13.5]	156	71 (45.5)	6.7 [4.9, 10.4]	0.858 [0.612, 1.203]	0.3761	0.9459
Female	95	35 (36.8)	12.1 [6.0, 30.0]	97	44 (45.4)	6.7 [4.2, NC]	0.846 [0.540, 1.325]	0.4668	
Region									
Asia	157	65 (41.4)	12.1 [6.7, 13.9]	158	70 (44.3)	6.7 [5.0, 8.8]	0.827 [0.588, 1.161]	0.2729	0.6668
Non-Asia	97	35 (36.1)	7.3 [5.6, 21.0]	95	45 (47.4)	6.4 [4.2, 18.5]	0.898 [0.575, 1.403]	0.6360	
Number of Organs with Metastatic Sites									
0-2	189	72 (38.1)	12.4 [7.1, 16.4]	188	88 (46.8)	6.7 [5.1, 10.2]	0.797 [0.582, 1.090]	0.1546	0.3748
>=3	65	28 (43.1)	7.2 [5.5, 13.9]	65	27 (41.5)	6.1 [4.1, NC]	0.997 [0.581, 1.708]	0.9889	

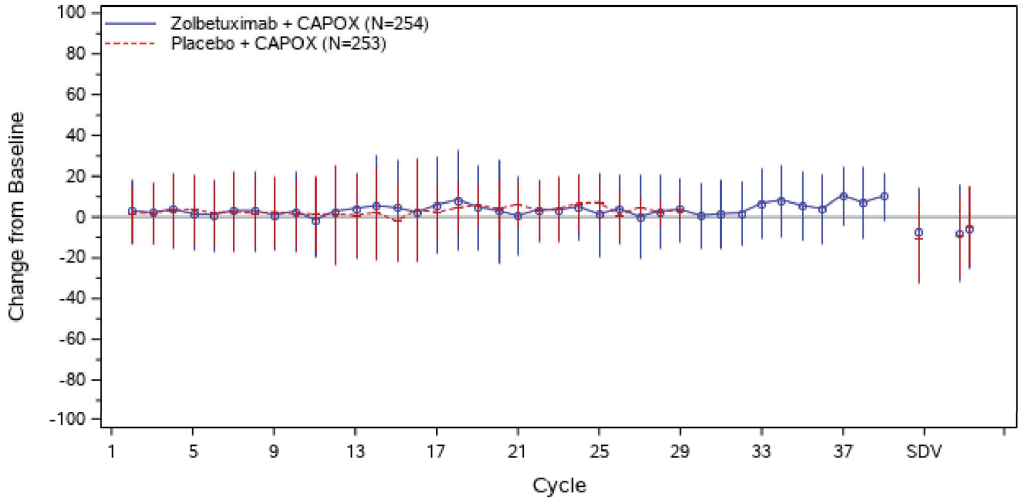
Abbreviations: CI=confidence interval; EQ-5D-5L=european quality of life 5 dimensions 5 level; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EQ-5D VAS

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

The SAS System

Figure 302.3.3002.3: EQ-5D-5L - Plot of Mean Change from Baseline of Visual Analog Scale - Full Analysis Set



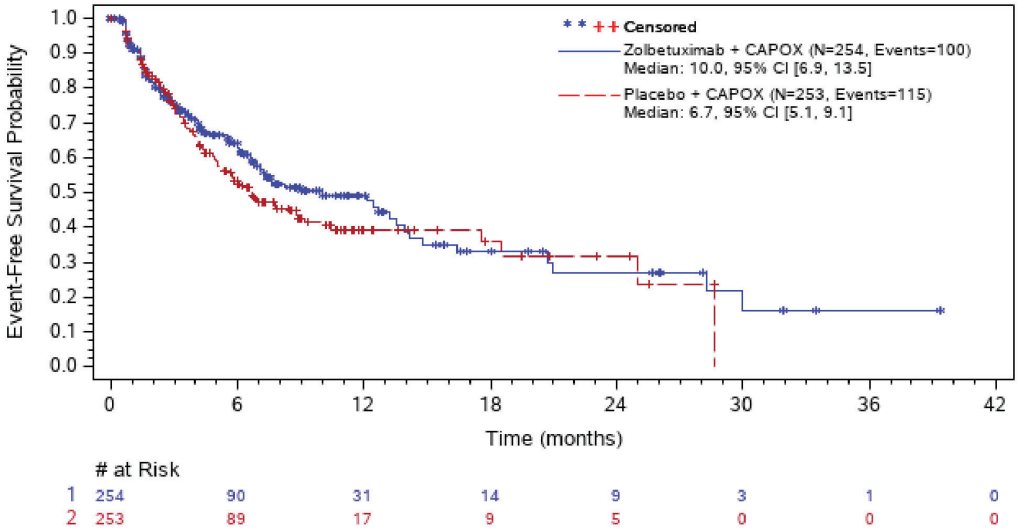
Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Patientenberichtete Endpunkte
Anhang 4-G1 Symptomatik anhand des EQ-5D VAS

5. Kaplan-Meier-Plots

The SAS System

Figure 302.3.3004.3: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024

Anhang 4-G1 Sicherheit

Anhang 4-G1 Unerwünschte Ereignisse

1. Time-to Event-Analysen

Table 302.3.2001.1.1: Summary and Results of TEAEs - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	251 (98.8%)	244 (98.0%)	
Number of patients censored	3 (1.2%)	5 (2.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.1 [0.1, 0.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.242 [1.856, 2.709]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.1.2: Summary and Results of TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	174 (98.9)	0.0 [NC, NC]	177	173 (97.7)	0.1 [0.1, 0.2]	2.117 [1.702, 2.633]	<.0001	0.8224
>65 years	78	77 (98.7)	0.0 [NC, NC]	72	71 (98.6)	0.2 [0.1, 0.5]	2.211 [1.582, 3.089]	<.0001	
Sex									
Male	160	158 (98.8)	0.0 [NC, NC]	152	149 (98.0)	0.1 [0.1, 0.2]	2.031 [1.610, 2.561]	<.0001	0.6362
Female	94	93 (98.9)	0.0 [NC, NC]	97	95 (97.9)	0.1 [0.1, 0.3]	2.449 [1.815, 3.303]	<.0001	
Region									
Asia	157	157 (100.0)	0.0 [NC, NC]	156	151 (96.8)	0.1 [0.1, 0.1]	2.357 [1.867, 2.975]	<.0001	0.4610
Non-Asia	97	94 (96.9)	0.0 [NC, NC]	93	93 (100.0)	0.2 [0.1, 0.5]	1.898 [1.411, 2.553]	0.0002	
Number of Organs with Metastatic Sites									
0-2	190	189 (99.5)	0.0 [NC, NC]	186	182 (97.8)	0.1 [0.1, 0.2]	2.036 [1.650, 2.513]	<.0001	0.4762
>=3	64	62 (96.9)	0.0 [NC, NC]	63	62 (98.4)	0.2 [0.1, 0.6]	2.507 [1.735, 3.622]	<.0001	

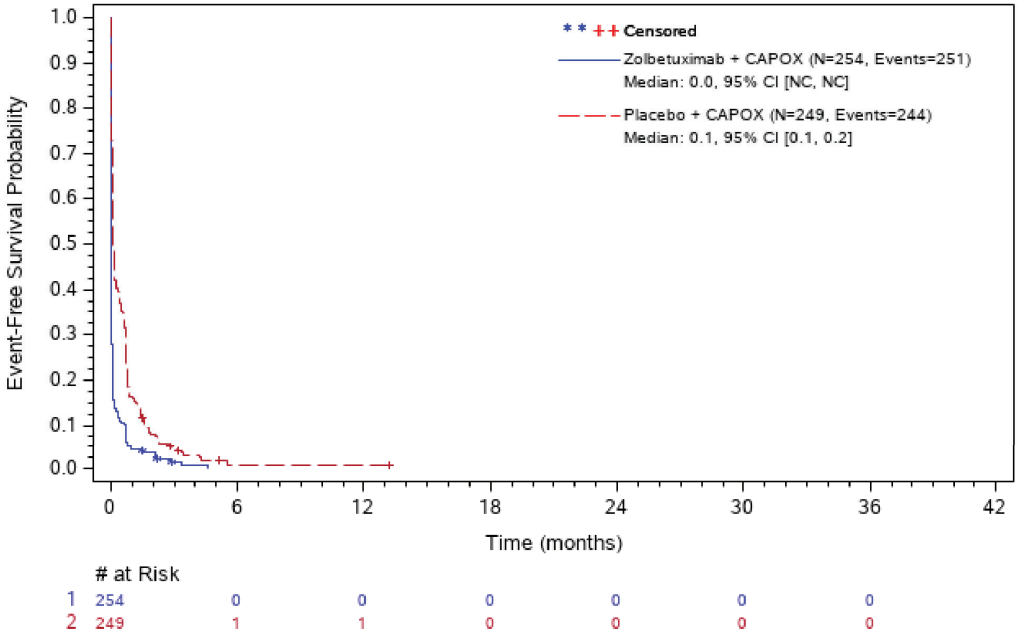
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated;
TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study
treatment + 30 days, death date). [a] Based on the Brookmeyer-Crowley Method, [b] Calculated from 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 302.3.2001.1: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwere unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table 302.3.2001.3.1: Summary and Results of Severe TEAEs - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	186 (73.2%)	175 (70.3%)	
Number of patients censored	68 (26.8%)	74 (29.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.6 [1.8, 3.3]	3.6 [3.0, 4.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.229 [0.997, 1.515]
Log-rank test			
Two-sided stratified log-rank p-value			0.0575

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.3.2: Summary and Results of Severe TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	123 (69.9)	2.3 [1.7, 3.5]	177	118 (66.7)	4.1 [3.0, 5.1]	1.226 [0.952, 1.579]	0.1252	0.8923
>65 years	78	63 (80.8)	2.9 [1.5, 3.5]	72	57 (79.2)	3.3 [2.4, 4.1]	1.183 [0.825, 1.696]	0.3649	
Sex									
Male	160	115 (71.9)	2.9 [2.1, 3.8]	152	111 (73.0)	3.6 [2.9, 4.6]	1.058 [0.815, 1.375]	0.6949	0.0734
Female	94	71 (75.5)	1.6 [1.1, 3.2]	97	64 (66.0)	3.6 [2.8, 6.0]	1.549 [1.103, 2.175]	0.0119	
Region									
Asia	157	111 (70.7)	2.8 [1.6, 3.5]	156	110 (70.5)	3.4 [2.8, 4.3]	1.104 [0.847, 1.437]	0.4854	0.1708
Non-Asia	97	75 (77.3)	2.1 [1.5, 3.7]	93	65 (69.9)	4.1 [3.0, 5.8]	1.474 [1.055, 2.058]	0.0242	
Number of Organs with Metastatic Sites									
0-2	190	134 (70.5)	2.9 [1.6, 3.5]	186	128 (68.8)	3.7 [3.0, 4.8]	1.201 [0.942, 1.531]	0.1490	0.7628
>=3	64	52 (81.3)	2.1 [1.0, 3.0]	63	47 (74.6)	3.6 [1.8, 4.9]	1.259 [0.847, 1.871]	0.2646	

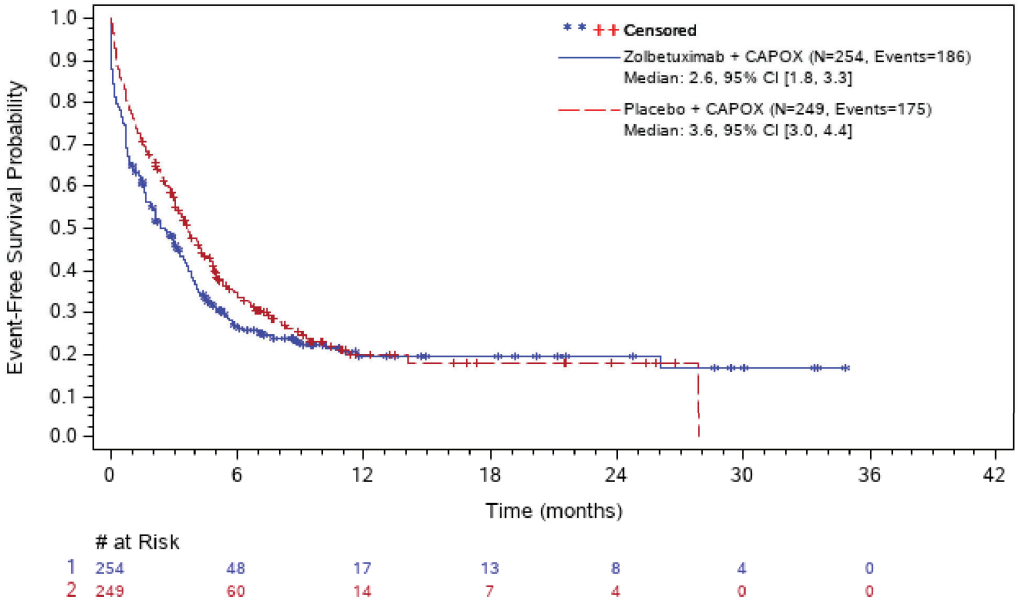
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated;
TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date). [a] Based on the Brookmeyer-Crowley Method, [b] Calculated from 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwere unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 302.3.2001.3: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwerwiegende unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table 302.3.2001.4.1: Summary and Results of TESAEs - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	123 (48.4%)	126 (50.6%)	
Number of patients censored	131 (51.6%)	123 (49.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.6 [5.8, 20.0]	8.0 [5.6, 12.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.972 [0.756, 1.251]
Log-rank test			
Two-sided stratified log-rank p-value			0.8199

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.4.2: Summary and Results of TESAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	79 (44.9)	10.7 [6.5, 23.6]	177	90 (50.8)	8.0 [5.1, 14.1]	0.839 [0.619, 1.136]	0.2500	0.1146
>65 years	78	44 (56.4)	3.9 [3.2, 8.1]	72	36 (50.0)	8.8 [4.9, 19.9]	1.333 [0.853, 2.081]	0.2057	
Sex									
Male	160	83 (51.9)	6.5 [4.0, 10.4]	152	78 (51.3)	7.8 [5.3, 14.1]	1.032 [0.757, 1.408]	0.8450	0.4341
Female	94	40 (42.6)	21.2 [6.1, NC]	97	48 (49.5)	9.0 [3.7, NC]	0.831 [0.545, 1.267]	0.3876	
Region									
Asia	157	73 (46.5)	10.4 [5.6, 25.7]	156	78 (50.0)	8.0 [5.1, 14.1]	0.889 [0.644, 1.227]	0.4675	0.4663
Non-Asia	97	50 (51.5)	6.5 [4.0, 21.2]	93	48 (51.6)	8.8 [4.3, 28.4]	1.089 [0.733, 1.619]	0.6767	
Number of Organs with Metastatic Sites									
0-2	190	84 (44.2)	15.9 [6.5, 25.7]	186	91 (48.9)	9.0 [6.2, 19.9]	0.898 [0.667, 1.210]	0.4766	0.4016
>=3	64	39 (60.9)	4.2 [3.6, 8.1]	63	35 (55.6)	5.6 [3.7, 10.8]	1.141 [0.722, 1.802]	0.5803	

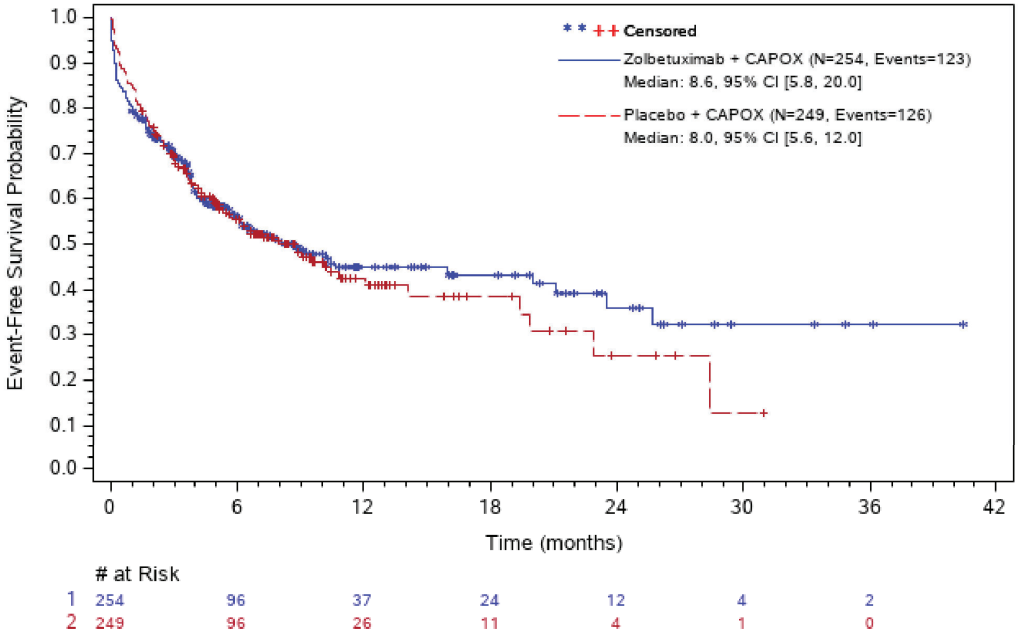
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated;
TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date). [a] Based on the Brookmeyer-Crowley Method, [b] Calculated from 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwerwiegende unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 302.3.2001.4: Kaplan-Meier Plot of Time to first TESAE - Safety Analysis Set



at Risk

1	254	96	37	24	12	4	2
2	249	96	26	11	4	1	0

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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Abbruch der Studienmedikation aufgrund unerwünschter Ereignisse

1. Time-to-Event-Analysen

Table 302.3.2001.5.1: Summary and Results of Permanent Treatment Discontinuation due to TEAEs - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	81 (31.9%)	64 (25.7%)	
Number of patients censored	173 (68.1%)	185 (74.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [10.2, NC]	NC [15.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.291 [0.928, 1.796]
Log-rank test			
Two-sided stratified log-rank p-value			0.1285

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.5.2: Summary and Results of Permanent Treatment Discontinuation due to TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	54 (30.7)	NC [11.4, NC]	177	41 (23.2)	NC [15.4, NC]	1.311 [0.872, 1.969]	0.1908	0.7207
>65 years	78	27 (34.6)	NC [6.2, NC]	72	23 (31.9)	NC [7.8, NC]	1.152 [0.660, 2.010]	0.6196	
Sex									
Male	160	55 (34.4)	11.4 [7.4, NC]	152	42 (27.6)	NC [15.4, NC]	1.262 [0.844, 1.886]	0.2561	0.9902
Female	94	26 (27.7)	NC [16.4, NC]	97	22 (22.7)	NC [NC, NC]	1.248 [0.706, 2.206]	0.4428	
Region									
Asia	157	48 (30.6)	NC [10.2, NC]	156	38 (24.4)	NC [NC, NC]	1.215 [0.793, 1.861]	0.3684	0.7423
Non-Asia	97	33 (34.0)	NC [7.4, NC]	93	26 (28.0)	NC [8.6, NC]	1.357 [0.811, 2.270]	0.2424	
Number of Organs with Metastatic Sites									
0-2	190	64 (33.7)	NC [8.6, NC]	186	44 (23.7)	NC [NC, NC]	1.479 [1.007, 2.172]	0.0447	0.1128
>=3	64	17 (26.6)	NC [10.2, NC]	63	20 (31.7)	NC [7.4, NC]	0.807 [0.422, 1.544]	0.5163	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated;
TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study
treatment + 30 days, death date). [a] Based on the Brookmeyer-Crowley Method, [b] Calculated from 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
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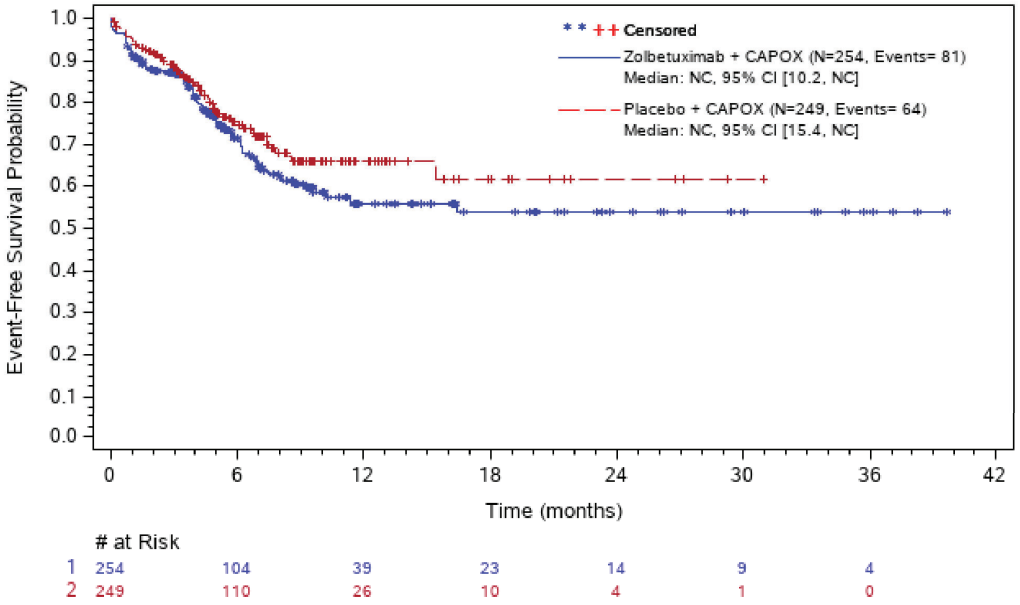
2. Kaplan-Meier-Plots

The SAS System

Figure 302.3.2001.5: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 302.3.2001.6.1: Summary and Results of TEAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	134 (52.8%)	127 (51.0%)	
Number of patients censored	120 (47.2%)	122 (49.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.2 [3.6, 5.6]	4.8 [3.6, 6.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.113 [0.872, 1.421]
Log-rank test			
Two-sided stratified log-rank p-value			0.3970

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.7.1: Summary and Results of TEAEs - Anaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	93 (36.6%)	92 (36.9%)	
Number of patients censored	161 (63.4%)	157 (63.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	13.4 [7.4, NC]	22.0 [8.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.976 [0.731, 1.303]
Log-rank test			
Two-sided stratified log-rank p-value			0.8632

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.8.1: Summary and Results of TEAEs - Leukopenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	17 (6.7%)	8 (3.2%)	
Number of patients censored	237 (93.3%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.090 [0.901, 4.852]
Log-rank test			
Two-sided stratified log-rank p-value			0.0792

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.9.1: Summary and Results of TEAEs - Neutropenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	50 (19.7%)	35 (14.1%)	
Number of patients censored	204 (80.3%)	214 (85.9%)	
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			1.491 [0.967, 2.300]
Log-rank test			
Two-sided stratified log-rank p-value			0.0693

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.10.1: Summary and Results of TEAEs - Thrombocytopenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	28 (11.0%)	31 (12.4%)	
Number of patients censored	226 (89.0%)	218 (87.6%)	
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			0.896 [0.537, 1.497]
Log-rank test			
Two-sided stratified log-rank p-value			0.6776

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.11.1: Summary and Results of TEAEs - Cardiac Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	24 (9.4%)	31 (12.4%)	
Number of patients censored	230 (90.6%)	218 (87.6%)	
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			0.701 [0.408, 1.204]
Log-rank test			
Two-sided stratified log-rank p-value			0.1991

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.12.1: Summary and Results of TEAEs - Sinus Bradycardia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	9 (3.6%)	
Number of patients censored	250 (98.4%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.433 [0.133, 1.407]
Log-rank test			
Two-sided stratified log-rank p-value			0.1538

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.13.1: Summary and Results of TEAEs - Sinus Tachycardia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	6 (2.4%)	
Number of patients censored	249 (98.0%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.853 [0.259, 2.803]
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: 12JAN24

Table 302.3.2001.14.1: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	234 (92.1%)	199 (79.9%)	
Number of patients censored	20 (7.9%)	50 (20.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.5 [0.2, 0.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.311 [1.896, 2.816]
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: 12JAN24

Table 302.3.2001.14.2: Summary and Results of TEAEs by Subgroups - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	160 (90.9)	0.0 [NC, NC]	177	145 (81.9)	0.4 [0.2, 0.7]	2.217 [1.763, 2.789]	<.0001	0.6082
>65 years	78	74 (94.9)	0.0 [0.0, 0.1]	72	54 (75.0)	0.7 [0.1, 3.3]	2.328 [1.627, 3.330]	<.0001	
Sex									
Male	160	146 (91.3)	0.0 [NC, NC]	152	119 (78.3)	0.7 [0.2, 0.9]	2.125 [1.662, 2.717]	<.0001	0.7464
Female	94	88 (93.6)	0.0 [NC, NC]	97	80 (82.5)	0.4 [0.1, 0.7]	2.454 [1.798, 3.348]	<.0001	
Region									
Asia	157	148 (94.3)	0.0 [NC, NC]	156	126 (80.8)	0.2 [0.1, 0.7]	2.454 [1.925, 3.128]	<.0001	0.4490
Non-Asia	97	86 (88.7)	0.0 [0.0, 0.1]	93	73 (78.5)	0.7 [0.4, 1.7]	1.912 [1.393, 2.623]	0.0004	
Number of Organs with Metastatic Sites									
0-2	190	177 (93.2)	0.0 [NC, NC]	186	154 (82.8)	0.4 [0.2, 0.8]	2.137 [1.715, 2.663]	<.0001	0.4715
>=3	64	57 (89.1)	0.0 [NC, NC]	63	45 (71.4)	0.6 [0.2, 1.5]	2.415 [1.620, 3.601]	<.0001	

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: 12JAN24

Table 302.3.2001.15.1: Summary and Results of TEAEs - Abdominal Discomfort (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	8 (3.2%)	
Number of patients censored	248 (97.6%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.586 [0.189, 1.820]
Log-rank test			
Two-sided stratified log-rank p-value			0.3500

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.16.1: Summary and Results of TEAEs - Abdominal Distension (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	15 (6.0%)	
Number of patients censored	239 (94.1%)	234 (94.0%)	
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			0.952 [0.464, 1.956]
Log-rank test			
Two-sided stratified log-rank p-value			0.8943

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.17.1: Summary and Results of TEAEs - Abdominal Pain (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	41 (16.1%)	56 (22.5%)	
Number of patients censored	213 (83.9%)	193 (77.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [22.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.670 [0.446, 1.008]
Log-rank test			
Two-sided stratified log-rank p-value			0.0521

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.18.1: Summary and Results of TEAEs - Abdominal Pain Upper (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	24 (9.4%)	13 (5.2%)	
Number of patients censored	230 (90.6%)	236 (94.8%)	
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			1.896 [0.946, 3.803]
Log-rank test			
Two-sided stratified log-rank p-value			0.0666

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.19.1: Summary and Results of TEAEs - Ascites (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	17 (6.8%)	
Number of patients censored	245 (96.5%)	232 (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			0.421 [0.181, 0.979]
Log-rank test			
Two-sided stratified log-rank p-value			0.0385

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.19.2: Summary and Results of TEAEs by Subgroups - Ascites (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	8 (4.5)	NC [NC, NC]	177	14 (7.9)	NC [22.3, NC]	0.512 [0.214, 1.230]	0.1276	0.7200
>65 years	78	1 (1.3)	NC [NC, NC]	72	3 (4.2)	NC [NC, NC]	0.356 [0.037, 3.431]	0.3508	
Sex									
Male	160	7 (4.4)	NC [NC, NC]	152	10 (6.6)	NC [22.3, NC]	0.588 [0.222, 1.560]	0.2812	0.4113
Female	94	2 (2.1)	NC [NC, NC]	97	7 (7.2)	NC [NC, NC]	0.312 [0.065, 1.504]	0.1249	
Region									
Asia	157	7 (4.5)	NC [NC, NC]	156	12 (7.7)	NC [NC, NC]	0.517 [0.202, 1.324]	0.1616	0.8137
Non-Asia	97	2 (2.1)	NC [NC, NC]	93	5 (5.4)	NC [22.3, NC]	0.390 [0.075, 2.015]	0.2437	
Number of Organs with Metastatic Sites									
0-2	190	2 (1.1)	NC [NC, NC]	186	8 (4.3)	NC [22.3, NC]	0.220 [0.046, 1.056]	0.0390	0.2118
>=3	64	7 (10.9)	NC [17.9, NC]	63	9 (14.3)	NC [9.2, NC]	0.720 [0.268, 1.939]	0.5145	

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: 12JAN24

Table 302.3.2001.20.1: Summary and Results of TEAEs - Constipation (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	40 (15.7%)	53 (21.3%)	
Number of patients censored	214 (84.3%)	196 (78.7%)	
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			0.736 [0.486, 1.115]
Log-rank test			
Two-sided stratified log-rank p-value			0.1462

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.21.1: Summary and Results of TEAEs - Diarrhoea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	83 (32.7%)	87 (34.9%)	
Number of patients censored	171 (67.3%)	162 (65.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [29.9, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.902 [0.667, 1.220]
Log-rank test			
Two-sided stratified log-rank p-value			0.5066

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.22.1: Summary and Results of TEAEs - Dyspepsia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	9 (3.6%)	
Number of patients censored	240 (94.5%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [24.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.496 [0.611, 3.662]
Log-rank test			
Two-sided stratified log-rank p-value			0.3755

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.23.1: Summary and Results of TEAEs - Dysphagia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	9 (3.6%)	
Number of patients censored	243 (95.7%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.168 [0.474, 2.880]
Log-rank test			
Two-sided stratified log-rank p-value			0.7358

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.24.1: Summary and Results of TEAEs - Gastrooesophageal Reflux Disease (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	5 (2.0%)	
Number of patients censored	244 (96.1%)	244 (98.0%)	
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			1.920 [0.652, 5.654]
Log-rank test			
Two-sided stratified log-rank p-value			0.2296

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.25.1: Summary and Results of TEAEs - Nausea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	175 (68.9%)	125 (50.2%)	
Number of patients censored	79 (31.1%)	124 (49.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.1, 0.4]	5.5 [2.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.961 [1.554, 2.477]
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: 12JAN24

Table 302.3.2001.25.2: Summary and Results of TEAEs by Subgroups - Nausea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	125 (71.0)	0.1 [0.0, 0.1]	177	95 (53.7)	2.9 [0.9, NC]	1.914 [1.463, 2.502]	<.0001	0.7043
>65 years	78	50 (64.1)	0.5 [0.1, 3.8]	72	30 (41.7)	12.8 [2.9, NC]	2.033 [1.289, 3.209]	0.0021	
Sex									
Male	160	108 (67.5)	0.1 [0.0, 0.7]	152	72 (47.4)	7.6 [2.3, NC]	1.946 [1.442, 2.625]	<.0001	0.8054
Female	94	67 (71.3)	0.1 [0.0, 0.7]	97	53 (54.6)	2.9 [0.8, NC]	1.891 [1.316, 2.717]	0.0011	
Region									
Asia	157	114 (72.6)	0.1 [0.0, 0.4]	156	77 (49.4)	6.3 [0.8, NC]	2.046 [1.530, 2.736]	<.0001	0.4862
Non-Asia	97	61 (62.9)	0.1 [0.1, 0.9]	93	48 (51.6)	5.5 [2.0, NC]	1.721 [1.176, 2.517]	0.0094	
Number of Organs with Metastatic Sites									
0-2	190	133 (70.0)	0.1 [0.0, 0.1]	186	101 (54.3)	2.9 [1.0, 8.3]	1.816 [1.400, 2.355]	<.0001	0.3368
>=3	64	42 (65.6)	0.7 [0.0, 2.9]	63	24 (38.1)	12.8 [2.9, 12.8]	2.281 [1.378, 3.777]	0.0014	

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: 12JAN24

Table 302.3.2001.26.1: Summary and Results of TEAEs - Stomatitis (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	7 (2.8%)	
Number of patients censored	246 (96.9%)	242 (97.2%)	
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			1.056 [0.380, 2.941]
Log-rank test			
Two-sided stratified log-rank p-value			0.9162

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.27.1: Summary and Results of TEAEs - Upper Gastrointestinal Haemorrhage (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	5 (2.0%)	
Number of patients censored	246 (96.9%)	244 (98.0%)	
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			1.695 [0.554, 5.189]
Log-rank test			
Two-sided stratified log-rank p-value			0.3514

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.28.1: Summary and Results of TEAEs - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	168 (66.1%)	79 (31.7%)	
Number of patients censored	86 (33.9%)	170 (68.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.0, 0.7]	NC [17.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.305 [2.521, 4.331]
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: 12JAN24

Table 302.3.2001.28.2: Summary and Results of TEAEs by Subgroups - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	121 (68.8)	0.0 [0.0, 0.2]	177	60 (33.9)	NC [17.3, NC]	3.356 [2.457, 4.585]	<.0001	0.9768
>65 years	78	47 (60.3)	0.9 [0.2, 6.8]	72	19 (26.4)	NC [NC, NC]	3.174 [1.858, 5.423]	<.0001	
Sex									
Male	160	101 (63.1)	0.3 [0.1, 1.4]	152	42 (27.6)	NC [17.3, NC]	3.418 [2.380, 4.907]	<.0001	0.6448
Female	94	67 (71.3)	0.0 [0.0, 0.2]	97	37 (38.1)	NC [5.5, NC]	3.200 [2.133, 4.799]	<.0001	
Region									
Asia	157	109 (69.4)	0.0 [0.0, 0.2]	156	46 (29.5)	NC [NC, NC]	3.828 [2.705, 5.416]	<.0001	0.1668
Non-Asia	97	59 (60.8)	0.7 [0.1, 2.4]	93	33 (35.5)	NC [17.3, NC]	2.550 [1.662, 3.915]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	124 (65.3)	0.2 [0.0, 0.9]	186	59 (31.7)	NC [17.3, NC]	3.131 [2.293, 4.276]	<.0001	0.6669
>=3	64	44 (68.8)	0.1 [0.0, 0.7]	63	20 (31.7)	NC [5.8, NC]	3.697 [2.166, 6.310]	<.0001	

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: 12JAN24

Table 302.3.2001.29.1: Summary and Results of TEAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	144 (56.7%)	125 (50.2%)	
Number of patients censored	110 (43.3%)	124 (49.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.9 [2.6, 6.5]	6.5 [3.1, 9.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.189 [0.933, 1.515]
Log-rank test			
Two-sided stratified log-rank p-value			0.1743

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.30.1: Summary and Results of TEAEs - Asthenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	34 (13.4%)	32 (12.9%)	
Number of patients censored	220 (86.6%)	217 (87.1%)	
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			1.068 [0.656, 1.739]
Log-rank test			
Two-sided stratified log-rank p-value			0.7958

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.31.1: Summary and Results of TEAEs - Chest Discomfort (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	7 (2.8%)	
Number of patients censored	244 (96.1%)	242 (97.2%)	
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			1.312 [0.486, 3.539]
Log-rank test			
Two-sided stratified log-rank p-value			0.5905

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.32.1: Summary and Results of TEAEs - Chills (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	5 (2.0%)	
Number of patients censored	243 (95.7%)	244 (98.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.229 [0.774, 6.421]
Log-rank test			
Two-sided stratified log-rank p-value			0.1277

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.33.1: Summary and Results of TEAEs - Fatigue (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	35 (13.8%)	42 (16.9%)	
Number of patients censored	219 (86.2%)	207 (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			0.773 [0.493, 1.212]
Log-rank test			
Two-sided stratified log-rank p-value			0.2598

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.34.1: Summary and Results of TEAEs - Malaise (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	31 (12.2%)	22 (8.8%)	
Number of patients censored	223 (87.8%)	227 (91.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.416 [0.816, 2.457]
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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.35.1: Summary and Results of TEAEs - Mucosal Inflammation (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	6 (2.4%)	
Number of patients censored	247 (97.2%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.140 [0.383, 3.393]
Log-rank test			
Two-sided stratified log-rank p-value			0.8113

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.36.1: Summary and Results of TEAEs - Oedema Peripheral (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	26 (10.2%)	6 (2.4%)	
Number of patients censored	228 (89.8%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			4.489 [1.843, 10.934]
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: 12JAN24

Table 302.3.2001.36.2: Summary and Results of TEAEs by Subgroups - Oedema Peripheral (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	16 (9.1)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	3.195 [1.168, 8.737]	0.0169	0.3335
>65 years	78	10 (12.8)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	9.978 [1.275, 78.087]	0.0068	
Sex									
Male	160	20 (12.5)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	9.776 [2.283, 41.860]	0.0002	0.0634
Female	94	6 (6.4)	NC [NC, NC]	97	4 (4.1)	NC [NC, NC]	1.636 [0.461, 5.803]	0.4423	
Region									
Asia	157	18 (11.5)	NC [NC, NC]	156	5 (3.2)	NC [NC, NC]	3.708 [1.376, 9.988]	0.0054	0.4954
Non-Asia	97	8 (8.2)	NC [NC, NC]	93	1 (1.1)	NC [NC, NC]	8.038 [1.004, 64.336]	0.0194	
Number of Organs with Metastatic Sites									
0-2	190	13 (6.8)	NC [NC, NC]	186	5 (2.7)	NC [NC, NC]	2.558 [0.910, 7.192]	0.0649	0.1523
>=3	64	13 (20.3)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	13.893 [1.817, 106.22]	0.0009	

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: 12JAN24

Table 302.3.2001.37.1: Summary and Results of TEAEs - Pyrexia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	36 (14.2%)	23 (9.2%)	
Number of patients censored	218 (85.8%)	226 (90.8%)	
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			1.526 [0.900, 2.587]
Log-rank test			
Two-sided stratified log-rank p-value			0.1141

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.38.1: Summary and Results of TEAEs - Hepatobiliary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	17 (6.7%)	15 (6.0%)	
Number of patients censored	237 (93.3%)	234 (94.0%)	
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			1.133 [0.563, 2.281]
Log-rank test			
Two-sided stratified log-rank p-value			0.7257

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.39.1: Summary and Results of TEAEs - Immune System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	7 (2.8%)	
Number of patients censored	247 (97.2%)	242 (97.2%)	
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			0.981 [0.340, 2.828]
Log-rank test			
Two-sided stratified log-rank p-value			0.9721

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.40.1: Summary and Results of TEAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	78 (30.7%)	70 (28.1%)	
Number of patients censored	176 (69.3%)	179 (71.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	15.9 [11.0, 21.4]	18.4 [11.3, 19.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.031 [0.743, 1.430]
Log-rank test			
Two-sided stratified log-rank p-value			0.8568

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.41.1: Summary and Results of TEAEs - Covid-19 (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	12 (4.8%)	
Number of patients censored	239 (94.1%)	237 (95.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [18.7, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.933 [0.412, 2.112]
Log-rank test			
Two-sided stratified log-rank p-value			0.8676

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.42.1: Summary and Results of TEAEs - Pneumonia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	11 (4.4%)	
Number of patients censored	242 (95.3%)	238 (95.6%)	
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			1.283 [0.553, 2.977]
Log-rank test			
Two-sided stratified log-rank p-value			0.5595

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.43.1: Summary and Results of TEAEs - Urinary Tract Infection (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	6 (2.4%)	
Number of patients censored	247 (97.2%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.070 [0.356, 3.212]
Log-rank test			
Two-sided stratified log-rank p-value			0.9039

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.44.1: Summary and Results of TEAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	31 (12.2%)	15 (6.0%)	
Number of patients censored	223 (87.8%)	234 (94.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [29.4, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.895 [1.015, 3.539]
Log-rank test			
Two-sided stratified log-rank p-value			0.0426

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.44.2: Summary and Results of TEAEs by Subgroups - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	20 (11.4)	NC [29.4, NC]	177	11 (6.2)	NC [NC, NC]	1.601 [0.760, 3.370]	0.2138	0.4003
>65 years	78	11 (14.1)	NC [NC, NC]	72	4 (5.6)	NC [NC, NC]	2.985 [0.949, 9.391]	0.0497	
Sex									
Male	160	19 (11.9)	NC [29.4, NC]	152	12 (7.9)	NC [NC, NC]	1.321 [0.634, 2.752]	0.4566	0.1204
Female	94	12 (12.8)	NC [NC, NC]	97	3 (3.1)	NC [NC, NC]	4.450 [1.253, 15.804]	0.0117	
Region									
Asia	157	15 (9.6)	NC [29.4, NC]	156	8 (5.1)	NC [NC, NC]	1.626 [0.682, 3.873]	0.2687	0.5969
Non-Asia	97	16 (16.5)	NC [NC, NC]	93	7 (7.5)	NC [NC, NC]	2.409 [0.991, 5.858]	0.0460	
Number of Organs with Metastatic Sites									
0-2	190	25 (13.2)	NC [29.4, NC]	186	10 (5.4)	NC [NC, NC]	2.406 [1.151, 5.030]	0.0163	0.2599
>=3	64	6 (9.4)	NC [NC, NC]	63	5 (7.9)	NC [NC, NC]	1.146 [0.349, 3.763]	0.8235	

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: 12JAN24

Table 302.3.2001.45.1: Summary and Results of TEAEs - Infusion Related Reaction (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	2 (0.8%)	
Number of patients censored	243 (95.7%)	247 (99.2%)	
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			5.357 [1.186, 24.200]
Log-rank test			
Two-sided stratified log-rank p-value			0.0146

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.45.2: Summary and Results of TEAEs by Subgroups - Infusion Related Reaction (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	7 (4.0)		177	2 (1.1)				
>65 years	78	4 (5.1)		72	0 (0.0)				
Sex									
Male	160	4 (2.5)		152	2 (1.3)				
Female	94	7 (7.4)		97	0 (0.0)				
Region									
Asia	157	5 (3.2)		156	0 (0.0)				
Non-Asia	97	6 (6.2)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	7 (3.7)		186	2 (1.1)				
>=3	64	4 (6.3)		63	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: 12JAN24

Table 302.3.2001.46.1: Summary and Results of TEAEs - Investigations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	154 (60.6%)	152 (61.0%)	
Number of patients censored	100 (39.4%)	97 (39.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.3 [1.6, 3.0]	2.8 [2.1, 3.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.035 [0.825, 1.299]
Log-rank test			
Two-sided stratified log-rank p-value			0.7649

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.47.1: Summary and Results of TEAEs - Alanine Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	48 (18.9%)	53 (21.3%)	
Number of patients censored	206 (81.1%)	196 (78.7%)	
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			0.898 [0.607, 1.330]
Log-rank test			
Two-sided stratified log-rank p-value			0.5852

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.48.1: Summary and Results of TEAEs - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	63 (24.8%)	75 (30.1%)	
Number of patients censored	191 (75.2%)	174 (69.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [25.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.811 [0.579, 1.137]
Log-rank test			
Two-sided stratified log-rank p-value			0.2216

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.49.1: Summary and Results of TEAEs - Blood Alkaline Phosphatase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	20 (8.0%)	
Number of patients censored	240 (94.5%)	229 (92.0%)	
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			0.647 [0.325, 1.288]
Log-rank test			
Two-sided stratified log-rank p-value			0.2125

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.50.1: Summary and Results of TEAEs - Blood Bilirubin Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	24 (9.4%)	23 (9.2%)	
Number of patients censored	230 (90.6%)	226 (90.8%)	
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			0.948 [0.529, 1.699]
Log-rank test			
Two-sided stratified log-rank p-value			0.8584

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.51.1: Summary and Results of TEAEs - Blood Creatinine Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	4 (1.6%)	
Number of patients censored	246 (96.9%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.779 [0.519, 6.098]
Log-rank test			
Two-sided stratified log-rank p-value			0.3525

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.52.1: Summary and Results of TEAEs - Electrocardiogram Qt Prolonged (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	6 (2.4%)	
Number of patients censored	248 (97.6%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.034 [0.331, 3.234]
Log-rank test			
Two-sided stratified log-rank p-value			0.9543

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.53.1: Summary and Results of TEAEs - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	10 (4.0%)	
Number of patients censored	245 (96.5%)	239 (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			0.887 [0.357, 2.203]
Log-rank test			
Two-sided stratified log-rank p-value			0.7962

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.54.1: Summary and Results of TEAEs - Lymphocyte Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	6 (2.4%)	
Number of patients censored	246 (96.9%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.342 [0.464, 3.882]
Log-rank test			
Two-sided stratified log-rank p-value			0.5859

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.55.1: Summary and Results of TEAEs - Neutrophil Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	71 (28.0%)	59 (23.7%)	
Number of patients censored	183 (72.0%)	190 (76.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [20.7, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.160 [0.819, 1.643]
Log-rank test			
Two-sided stratified log-rank p-value			0.4023

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.56.1: Summary and Results of TEAEs - Platelet Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	61 (24.0%)	62 (24.9%)	
Number of patients censored	193 (76.0%)	187 (75.1%)	
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			0.964 [0.676, 1.375]
Log-rank test			
Two-sided stratified log-rank p-value			0.8420

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.57.1: Summary and Results of TEAEs - Weight Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	51 (20.1%)	25 (10.0%)	
Number of patients censored	203 (79.9%)	224 (90.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.072 [1.279, 3.357]
Log-rank test			
Two-sided stratified log-rank p-value			0.0025

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.57.2: Summary and Results of TEAEs by Subgroups - Weight Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	35 (19.9)	NC [NC, NC]	177	20 (11.3)	NC [NC, NC]	1.826 [1.051, 3.172]	0.0302	0.3086
>65 years	78	16 (20.5)	NC [22.6, NC]	72	5 (6.9)	NC [NC, NC]	3.188 [1.164, 8.730]	0.0173	
Sex									
Male	160	36 (22.5)	NC [28.2, NC]	152	13 (8.6)	NC [NC, NC]	2.807 [1.485, 5.303]	0.0009	0.1316
Female	94	15 (16.0)	NC [NC, NC]	97	12 (12.4)	NC [NC, NC]	1.308 [0.610, 2.802]	0.4895	
Region									
Asia	157	34 (21.7)	NC [28.2, NC]	156	17 (10.9)	NC [NC, NC]	2.007 [1.115, 3.611]	0.0177	0.8144
Non-Asia	97	17 (17.5)	NC [NC, NC]	93	8 (8.6)	NC [NC, NC]	2.243 [0.967, 5.203]	0.0532	
Number of Organs with Metastatic Sites									
0-2	190	36 (18.9)	NC [NC, NC]	186	21 (11.3)	NC [NC, NC]	1.784 [1.040, 3.061]	0.0331	0.1791
>=3	64	15 (23.4)	28.2 [12.5, NC]	63	4 (6.3)	NC [NC, NC]	3.753 [1.234, 11.419]	0.0124	

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: 12JAN24

Table 302.3.2001.58.1: Summary and Results of TEAEs - Weight Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	5 (2.0%)	
Number of patients censored	249 (98.0%)	244 (98.0%)	
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			0.980 [0.283, 3.393]
Log-rank test			
Two-sided stratified log-rank p-value			0.9745

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.59.1: Summary and Results of TEAEs - White Blood Cell Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	51 (20.1%)	40 (16.1%)	
Number of patients censored	203 (79.9%)	209 (83.9%)	
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			1.240 [0.819, 1.878]
Log-rank test			
Two-sided stratified log-rank p-value			0.3062

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.60.1: Summary and Results of TEAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	155 (61.0%)	141 (56.6%)	
Number of patients censored	99 (39.0%)	108 (43.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.1 [1.4, 3.5]	3.7 [2.8, 6.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.252 [0.993, 1.577]
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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.61.1: Summary and Results of TEAEs - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	105 (41.3%)	86 (34.5%)	
Number of patients censored	149 (58.7%)	163 (65.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [5.9, NC]	16.5 [13.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.352 [1.013, 1.804]
Log-rank test			
Two-sided stratified log-rank p-value			0.0407

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.61.2: Summary and Results of TEAEs by Subgroups - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	71 (40.3)	NC [7.2, NC]	177	63 (35.6)	16.2 [10.3, NC]	1.249 [0.889, 1.755]	0.2153	0.5497
>65 years	78	34 (43.6)	6.8 [2.2, NC]	72	23 (31.9)	19.9 [16.5, NC]	1.481 [0.870, 2.520]	0.1425	
Sex									
Male	160	74 (46.3)	7.7 [2.6, NC]	152	52 (34.2)	19.9 [10.3, NC]	1.521 [1.066, 2.170]	0.0209	0.2005
Female	94	31 (33.0)	NC [NC, NC]	97	34 (35.1)	16.5 [11.8, NC]	1.018 [0.625, 1.658]	0.9713	
Region									
Asia	157	66 (42.0)	NC [5.2, NC]	156	58 (37.2)	19.9 [11.8, NC]	1.214 [0.852, 1.728]	0.2985	0.3786
Non-Asia	97	39 (40.2)	18.2 [4.9, NC]	93	28 (30.1)	16.5 [10.3, NC]	1.626 [0.997, 2.652]	0.0489	
Number of Organs with Metastatic Sites									
0-2	190	76 (40.0)	NC [7.2, NC]	186	70 (37.6)	19.9 [10.3, NC]	1.147 [0.828, 1.587]	0.4255	0.0839
>=3	64	29 (45.3)	6.8 [1.6, NC]	63	16 (25.4)	16.5 [11.8, NC]	2.176 [1.180, 4.014]	0.0109	

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: 12JAN24

Table 302.3.2001.62.1: Summary and Results of TEAEs - Dehydration (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	4 (1.6%)	
Number of patients censored	248 (97.6%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.509 [0.425, 5.352]
Log-rank test			
Two-sided stratified log-rank p-value			0.5215

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.63.1: Summary and Results of TEAEs - Hyperuricaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	7 (2.8%)	
Number of patients censored	250 (98.4%)	242 (97.2%)	
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			0.495 [0.139, 1.758]
Log-rank test			
Two-sided stratified log-rank p-value			0.2685

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.64.1: Summary and Results of TEAEs - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	57 (22.4%)	35 (14.1%)	
Number of patients censored	197 (77.6%)	214 (85.9%)	
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			1.767 [1.158, 2.696]
Log-rank test			
Two-sided stratified log-rank p-value			0.0076

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.64.2: Summary and Results of TEAEs by Subgroups - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	40 (22.7)	NC [NC, NC]	177	24 (13.6)	NC [NC, NC]	1.832 [1.103, 3.041]	0.0176	0.8133
>65 years	78	17 (21.8)	NC [NC, NC]	72	11 (15.3)	NC [NC, NC]	1.671 [0.781, 3.575]	0.1797	
Sex									
Male	160	37 (23.1)	NC [NC, NC]	152	26 (17.1)	NC [NC, NC]	1.467 [0.888, 2.425]	0.1322	0.2057
Female	94	20 (21.3)	NC [NC, NC]	97	9 (9.3)	NC [NC, NC]	2.687 [1.222, 5.908]	0.0105	
Region									
Asia	157	44 (28.0)	NC [NC, NC]	156	30 (19.2)	NC [NC, NC]	1.652 [1.038, 2.629]	0.0330	0.3786
Non-Asia	97	13 (13.4)	NC [NC, NC]	93	5 (5.4)	NC [NC, NC]	2.804 [0.999, 7.872]	0.0406	
Number of Organs with Metastatic Sites									
0-2	190	41 (21.6)	NC [NC, NC]	186	24 (12.9)	NC [NC, NC]	1.874 [1.132, 3.104]	0.0132	0.6793
>=3	64	16 (25.0)	NC [NC, NC]	63	11 (17.5)	NC [NC, NC]	1.577 [0.731, 3.399]	0.2400	

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: 12JAN24

Table 302.3.2001.65.1: Summary and Results of TEAEs - Hypocalcaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	13 (5.1%)	12 (4.8%)	
Number of patients censored	241 (94.9%)	237 (95.2%)	
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			1.071 [0.488, 2.351]
Log-rank test			
Two-sided stratified log-rank p-value			0.8636

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.66.1: Summary and Results of TEAEs - Hypokalaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	37 (14.6%)	38 (15.3%)	
Number of patients censored	217 (85.4%)	211 (84.7%)	
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			0.924 [0.586, 1.458]
Log-rank test			
Two-sided stratified log-rank p-value			0.7372

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.67.1: Summary and Results of TEAEs - Hyponatraemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	16 (6.3%)	18 (7.2%)	
Number of patients censored	238 (93.7%)	231 (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			0.793 [0.396, 1.589]
Log-rank test			
Two-sided stratified log-rank p-value			0.5121

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.68.1: Summary and Results of TEAEs - Hypophosphataemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	7 (2.8%)	
Number of patients censored	246 (96.9%)	242 (97.2%)	
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			1.210 [0.437, 3.352]
Log-rank test			
Two-sided stratified log-rank p-value			0.7127

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.69.1: Summary and Results of TEAEs - Hypoproteinaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	5 (2.0%)	
Number of patients censored	248 (97.6%)	244 (98.0%)	
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			1.253 [0.380, 4.127]
Log-rank test			
Two-sided stratified log-rank p-value			0.7103

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.70.1: Summary and Results of TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	37 (14.6%)	52 (20.9%)	
Number of patients censored	217 (85.4%)	197 (79.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [28.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.591 [0.383, 0.909]
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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.70.2: Summary and Results of TEAEs by Subgroups - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	32 (18.2)	NC [28.4, NC]	177	37 (20.9)	NC [NC, NC]	0.756 [0.468, 1.219]	0.2516	0.1260
>65 years	78	5 (6.4)	31.8 [NC, NC]	72	15 (20.8)	NC [11.9, NC]	0.318 [0.116, 0.876]	0.0193	
Sex									
Male	160	21 (13.1)	NC [28.5, NC]	152	34 (22.4)	NC [11.9, NC]	0.517 [0.299, 0.895]	0.0166	0.1946
Female	94	16 (17.0)	31.8 [17.1, NC]	97	18 (18.6)	NC [NC, NC]	0.871 [0.441, 1.717]	0.6893	
Region									
Asia	157	21 (13.4)	NC [28.5, NC]	156	24 (15.4)	NC [NC, NC]	0.766 [0.423, 1.386]	0.3779	0.3567
Non-Asia	97	16 (16.5)	28.4 [17.1, NC]	93	28 (30.1)	NC [10.2, NC]	0.494 [0.266, 0.916]	0.0223	
Number of Organs with Metastatic Sites									
0-2	190	27 (14.2)	NC [28.4, NC]	186	40 (21.5)	NC [NC, NC]	0.585 [0.358, 0.958]	0.0314	0.6152
>=3	64	10 (15.6)	28.5 [28.5, NC]	63	12 (19.0)	NC [9.8, NC]	0.718 [0.302, 1.704]	0.4496	

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: 12JAN24

Table 302.3.2001.71.1: Summary and Results of TEAEs - Arthralgia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	7 (2.8%)	
Number of patients censored	248 (97.6%)	242 (97.2%)	
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			0.783 [0.260, 2.359]
Log-rank test			
Two-sided stratified log-rank p-value			0.6630

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.72.1: Summary and Results of TEAEs - Back Pain (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	20 (8.0%)	
Number of patients censored	244 (96.1%)	229 (92.0%)	
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			0.418 [0.190, 0.919]
Log-rank test			
Two-sided stratified log-rank p-value			0.0252

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.72.2: Summary and Results of TEAEs by Subgroups - Back Pain (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	10 (5.7)	NC [NC, NC]	177	14 (7.9)	NC [NC, NC]	0.628 [0.275, 1.434]	0.2653	0.9872
>65 years	78	0 (0.0)	NC [NC, NC]	72	6 (8.3)	NC [NC, NC]	0.000 [0.000, NC]	0.0137	
Sex									
Male	160	5 (3.1)	NC [28.5, NC]	152	11 (7.2)	NC [NC, NC]	0.376 [0.127, 1.113]	0.0670	0.6505
Female	94	5 (5.3)	NC [NC, NC]	97	9 (9.3)	NC [NC, NC]	0.559 [0.186, 1.678]	0.2932	
Region									
Asia	157	5 (3.2)	NC [NC, NC]	156	12 (7.7)	NC [NC, NC]	0.353 [0.122, 1.020]	0.0452	0.4520
Non-Asia	97	5 (5.2)	NC [NC, NC]	93	8 (8.6)	NC [NC, NC]	0.616 [0.201, 1.889]	0.3922	
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)	NC [NC, NC]	186	14 (7.5)	NC [NC, NC]	0.402 [0.154, 1.051]	0.0545	0.5902
>=3	64	4 (6.3)	28.5 [28.5, NC]	63	6 (9.5)	NC [NC, NC]	0.487 [0.122, 1.945]	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 10% of subjects in at least 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: 12JAN24

Table 302.3.2001.73.1: Summary and Results of TEAEs - Pain In Extremity (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	6 (2.4%)	
Number of patients censored	248 (97.6%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.958 [0.309, 2.971]
Log-rank test			
Two-sided stratified log-rank p-value			0.9403

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.74.1: Summary and Results of TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	20 (8.0%)	
Number of patients censored	240 (94.5%)	229 (92.0%)	
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			0.658 [0.322, 1.345]
Log-rank test			
Two-sided stratified log-rank p-value			0.2480

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.75.1: Summary and Results of TEAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	13 (5.2%)	
Number of patients censored	244 (96.1%)	236 (94.8%)	
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			0.728 [0.306, 1.736]
Log-rank test			
Two-sided stratified log-rank p-value			0.4725

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.76.1: Summary and Results of TEAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	140 (55.1%)	144 (57.8%)	
Number of patients censored	114 (44.9%)	105 (42.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.5 [3.3, 5.3]	3.2 [2.3, 4.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.926 [0.733, 1.169]
Log-rank test			
Two-sided stratified log-rank p-value			0.4996

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.77.1: Summary and Results of TEAEs - Dizziness (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	12 (4.8%)	
Number of patients censored	240 (94.5%)	237 (95.2%)	
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			1.163 [0.537, 2.515]
Log-rank test			
Two-sided stratified log-rank p-value			0.6991

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.78.1: Summary and Results of TEAEs - Dysaesthesia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	5 (2.0%)	
Number of patients censored	247 (97.2%)	244 (98.0%)	
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			1.344 [0.426, 4.241]
Log-rank test			
Two-sided stratified log-rank p-value			0.6134

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.79.1: Summary and Results of TEAEs - Dysgeusia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	18 (7.1%)	12 (4.8%)	
Number of patients censored	236 (92.9%)	237 (95.2%)	
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			1.547 [0.743, 3.223]
Log-rank test			
Two-sided stratified log-rank p-value			0.2406

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.80.1: Summary and Results of TEAEs - Headache (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	8 (3.2%)	
Number of patients censored	246 (96.9%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.937 [0.349, 2.512]
Log-rank test			
Two-sided stratified log-rank p-value			0.8966

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.81.1: Summary and Results of TEAEs - Hypoaesthesia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	31 (12.2%)	30 (12.0%)	
Number of patients censored	223 (87.8%)	219 (88.0%)	
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			1.015 [0.614, 1.679]
Log-rank test			
Two-sided stratified log-rank p-value			0.9778

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.82.1: Summary and Results of TEAEs - Neuropathy Peripheral (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	13 (5.1%)	13 (5.2%)	
Number of patients censored	241 (94.9%)	236 (94.8%)	
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			1.000 [0.463, 2.161]
Log-rank test			
Two-sided stratified log-rank p-value			0.9954

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.83.1: Summary and Results of TEAEs - Neurotoxicity (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	19 (7.6%)	
Number of patients censored	240 (94.5%)	230 (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			0.715 [0.358, 1.426]
Log-rank test			
Two-sided stratified log-rank p-value			0.3360

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.84.1: Summary and Results of TEAEs - Paraesthesia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	13 (5.1%)	11 (4.4%)	
Number of patients censored	241 (94.9%)	238 (95.6%)	
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			1.187 [0.531, 2.652]
Log-rank test			
Two-sided stratified log-rank p-value			0.6730

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.85.1: Summary and Results of TEAEs - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	57 (22.4%)	56 (22.5%)	
Number of patients censored	197 (77.6%)	193 (77.5%)	
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			0.992 [0.685, 1.435]
Log-rank test			
Two-sided stratified log-rank p-value			0.9704

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.86.1: Summary and Results of TEAEs - Psychiatric Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	35 (13.8%)	27 (10.8%)	
Number of patients censored	219 (86.2%)	222 (89.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [22.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.255 [0.755, 2.087]
Log-rank test			
Two-sided stratified log-rank p-value			0.3800

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.87.1: Summary and Results of TEAEs - Insomnia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	28 (11.0%)	18 (7.2%)	
Number of patients censored	226 (89.0%)	231 (92.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [22.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.455 [0.801, 2.644]
Log-rank test			
Two-sided stratified log-rank p-value			0.2162

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.88.1: Summary and Results of TEAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	23 (9.1%)	21 (8.4%)	
Number of patients censored	231 (90.9%)	228 (91.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [24.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.030 [0.567, 1.871]
Log-rank test			
Two-sided stratified log-rank p-value			0.9227

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.89.1: Summary and Results of TEAEs - Proteinuria (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	4 (1.6%)	
Number of patients censored	248 (97.6%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.462 [0.410, 5.205]
Log-rank test			
Two-sided stratified log-rank p-value			0.5557

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.90.1: Summary and Results of TEAEs - Reproductive System And Breast Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	8 (3.2%)	
Number of patients censored	248 (97.6%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.663 [0.228, 1.929]
Log-rank test			
Two-sided stratified log-rank p-value			0.4477

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.91.1: Summary and Results of TEAEs - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	57 (22.4%)	63 (25.3%)	
Number of patients censored	197 (77.6%)	186 (74.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [23.6, NC]	25.5 [16.8, 28.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.846 [0.588, 1.216]
Log-rank test			
Two-sided stratified log-rank p-value			0.3633

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.92.1: Summary and Results of TEAEs - Cough (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	15 (6.0%)	
Number of patients censored	242 (95.3%)	234 (94.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [25.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.788 [0.366, 1.700]
Log-rank test			
Two-sided stratified log-rank p-value			0.5434

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.93.1: Summary and Results of TEAEs - Dyspnoea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	13 (5.2%)	
Number of patients censored	239 (94.1%)	236 (94.8%)	
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			1.136 [0.534, 2.418]
Log-rank test			
Two-sided stratified log-rank p-value			0.7396

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.94.1: Summary and Results of TEAEs - Hiccups (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	7 (2.8%)	
Number of patients censored	243 (95.7%)	242 (97.2%)	
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			1.489 [0.577, 3.845]
Log-rank test			
Two-sided stratified log-rank p-value			0.4086

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.95.1: Summary and Results of TEAEs - Pleural Effusion (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	7 (2.8%)	
Number of patients censored	249 (98.0%)	242 (97.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [28.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.718 [0.221, 2.328]
Log-rank test			
Two-sided stratified log-rank p-value			0.5791

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.96.1: Summary and Results of TEAEs - Productive Cough (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	7 (2.8%)	
Number of patients censored	250 (98.4%)	242 (97.2%)	
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			0.570 [0.155, 2.096]
Log-rank test			
Two-sided stratified log-rank p-value			0.3920

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.97.1: Summary and Results of TEAEs - Pulmonary Embolism (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	11 (4.4%)	
Number of patients censored	248 (97.6%)	238 (95.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	28.4 [28.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.502 [0.184, 1.368]
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: 12JAN24

Table 302.3.2001.98.1: Summary and Results of TEAEs - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	86 (33.9%)	74 (29.7%)	
Number of patients censored	168 (66.1%)	175 (70.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	17.1 [10.3, 25.5]	19.9 [13.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.045 [0.760, 1.437]
Log-rank test			
Two-sided stratified log-rank p-value			0.7911

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.99.1: Summary and Results of TEAEs - Alopecia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	5 (2.0%)	
Number of patients censored	247 (97.2%)	244 (98.0%)	
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			1.074 [0.316, 3.643]
Log-rank test			
Two-sided stratified log-rank p-value			0.9091

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.100.1: Summary and Results of TEAEs - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	43 (16.9%)	49 (19.7%)	
Number of patients censored	211 (83.1%)	200 (80.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [25.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.823 [0.543, 1.247]
Log-rank test			
Two-sided stratified log-rank p-value			0.3596

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.101.1: Summary and Results of TEAEs - Pruritus (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	8 (3.2%)	
Number of patients censored	244 (96.1%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.009 [0.378, 2.693]
Log-rank test			
Two-sided stratified log-rank p-value			0.9852

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.102.1: Summary and Results of TEAEs - Rash (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	6 (2.4%)	
Number of patients censored	247 (97.2%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.055 [0.352, 3.161]
Log-rank test			
Two-sided stratified log-rank p-value			0.9235

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.103.1: Summary and Results of TEAEs - Rash Maculo-Papular (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	7 (2.8%)	
Number of patients censored	249 (98.0%)	242 (97.2%)	
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			0.657 [0.207, 2.085]
Log-rank test			
Two-sided stratified log-rank p-value			0.4729

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.104.1: Summary and Results of TEAEs - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	53 (20.9%)	30 (12.0%)	
Number of patients censored	201 (79.1%)	219 (88.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	27.9 [20.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.887 [1.198, 2.972]
Log-rank test			
Two-sided stratified log-rank p-value			0.0056

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.104.2: Summary and Results of TEAEs by Subgroups - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	40 (22.7)	NC [NC, NC]	177	22 (12.4)	27.9 [27.9, NC]	1.869 [1.109, 3.150]	0.0175	0.9038
>65 years	78	13 (16.7)	NC [NC, NC]	72	8 (11.1)	20.8 [18.0, NC]	1.634 [0.674, 3.960]	0.2717	
Sex									
Male	160	33 (20.6)	NC [NC, NC]	152	19 (12.5)	27.9 [20.8, 27.9]	1.642 [0.931, 2.895]	0.0842	0.6614
Female	94	20 (21.3)	NC [NC, NC]	97	11 (11.3)	NC [18.0, NC]	2.091 [1.000, 4.374]	0.0465	
Region									
Asia	157	32 (20.4)	NC [NC, NC]	156	19 (12.2)	NC [20.8, NC]	1.738 [0.984, 3.069]	0.0549	0.7252
Non-Asia	97	21 (21.6)	NC [NC, NC]	93	11 (11.8)	27.9 [18.0, 27.9]	1.954 [0.939, 4.067]	0.0686	
Number of Organs with Metastatic Sites									
0-2	190	39 (20.5)	NC [NC, NC]	186	22 (11.8)	NC [27.9, NC]	1.821 [1.078, 3.075]	0.0234	0.9961
>=3	64	14 (21.9)	NC [NC, NC]	63	8 (12.7)	18.0 [18.0, NC]	1.802 [0.756, 4.296]	0.1796	

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: 12JAN24

Table 302.3.2001.105.1: Summary and Results of TEAEs - Hypertension (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	7 (2.8%)	
Number of patients censored	239 (94.1%)	242 (97.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [27.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.070 [0.842, 5.093]
Log-rank test			
Two-sided stratified log-rank p-value			0.1111

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.106.1: Summary and Results of TEAEs - Hypotension (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	8 (3.2%)	
Number of patients censored	239 (94.1%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.126 [0.866, 5.218]
Log-rank test			
Two-sided stratified log-rank p-value			0.0917

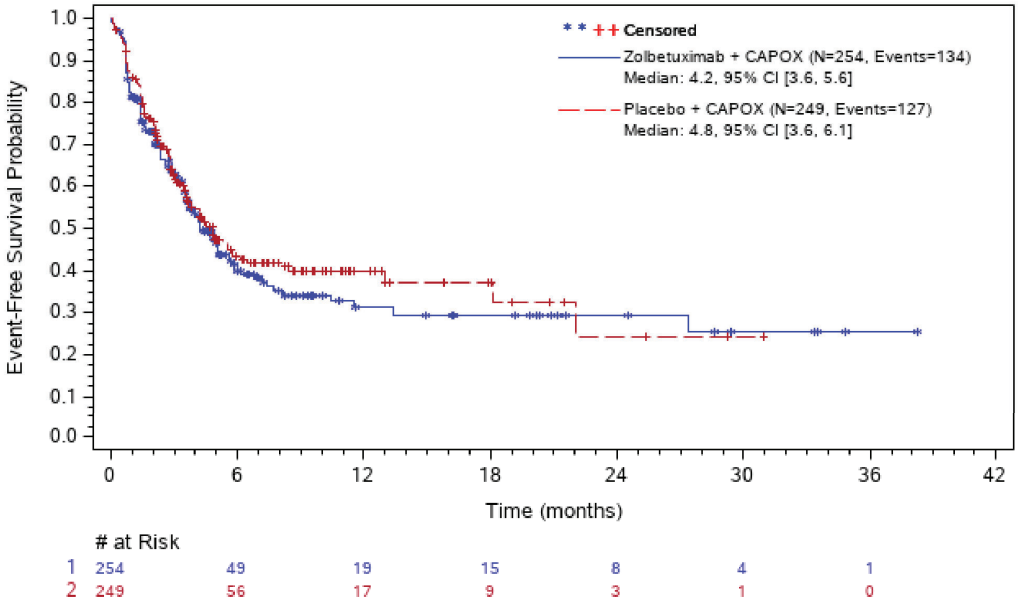
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
SOCs and PTs are reported only if events are either 1) occurring in at least 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

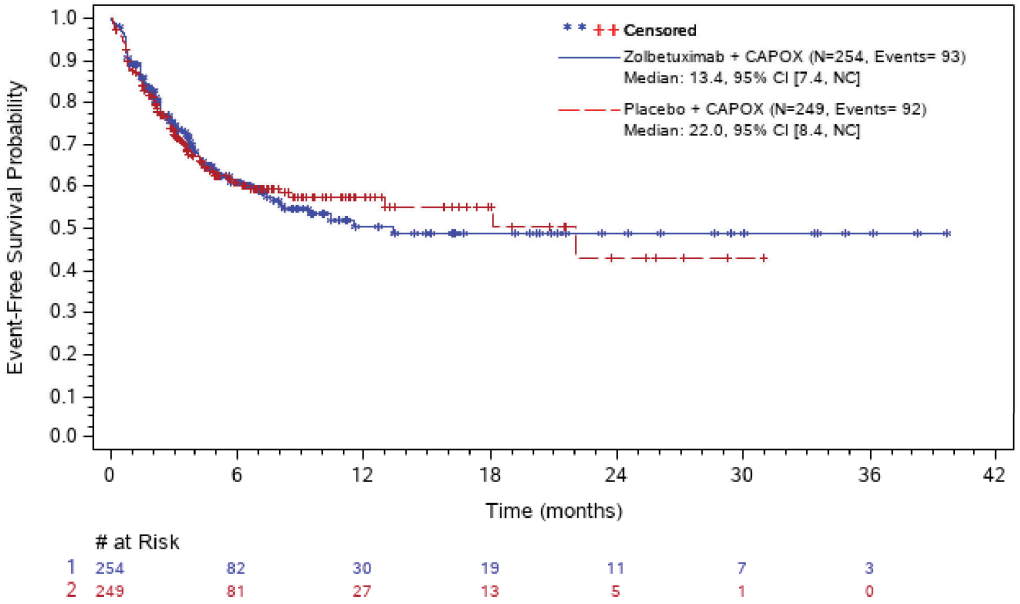
Figure 302.3.2001.6: Kaplan-Meier Plot of Time to first TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

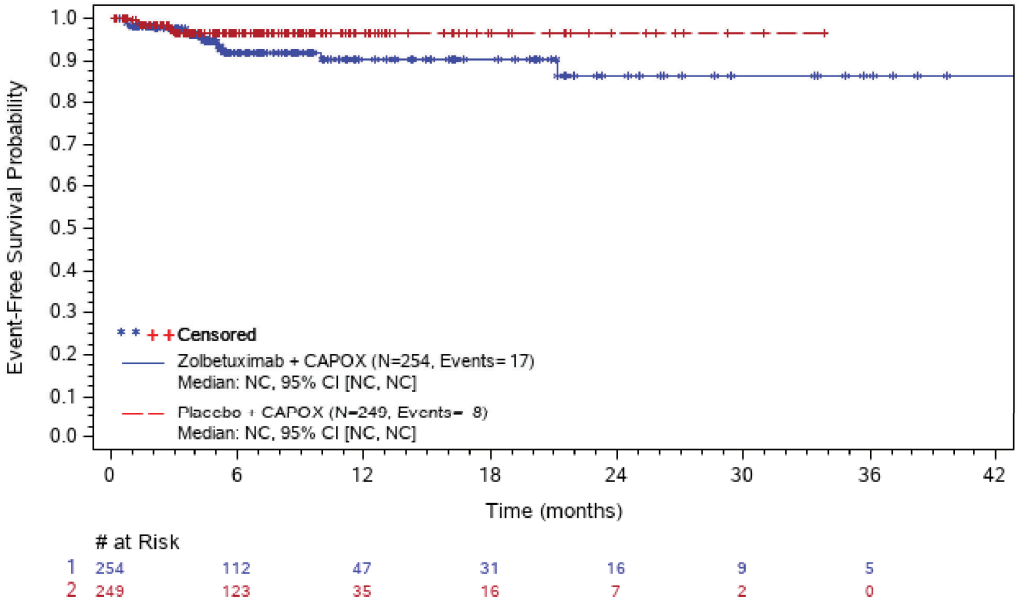
Figure 302.3.2001.7: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

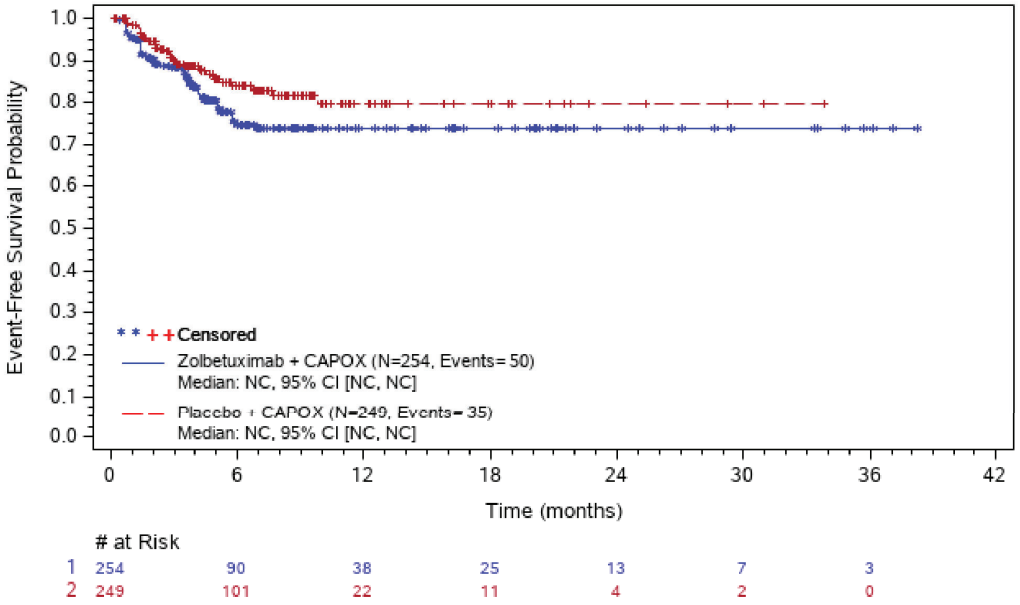
Figure 302.3.2001.8: Kaplan-Meier Plot of Time to first TEAE - Leukopenia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

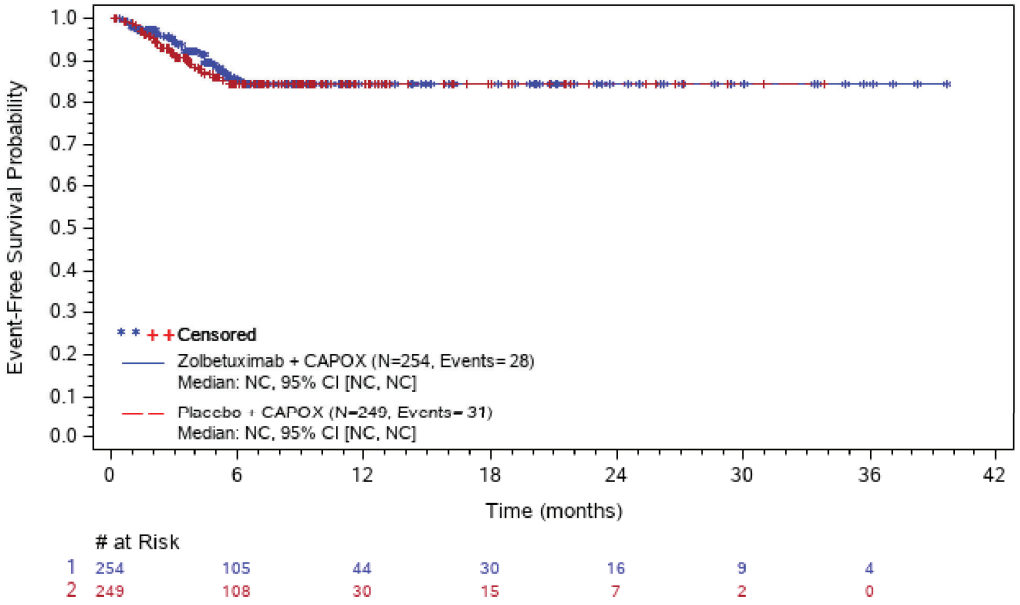
Figure 302.3.2001.9: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

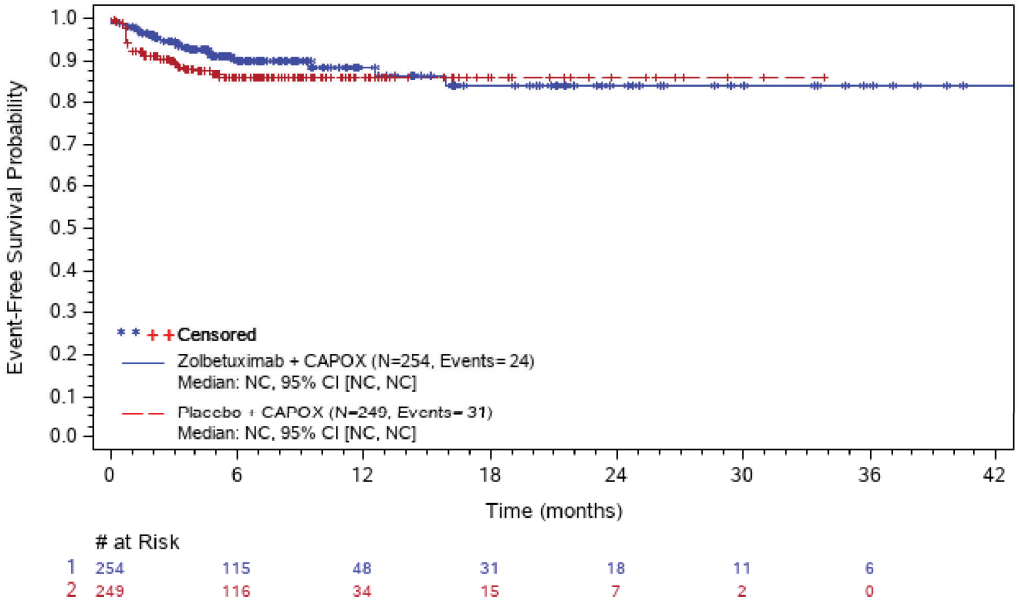
Figure 302.3.2001.10: Kaplan-Meier Plot of Time to first TEAE - Thrombocytopenia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

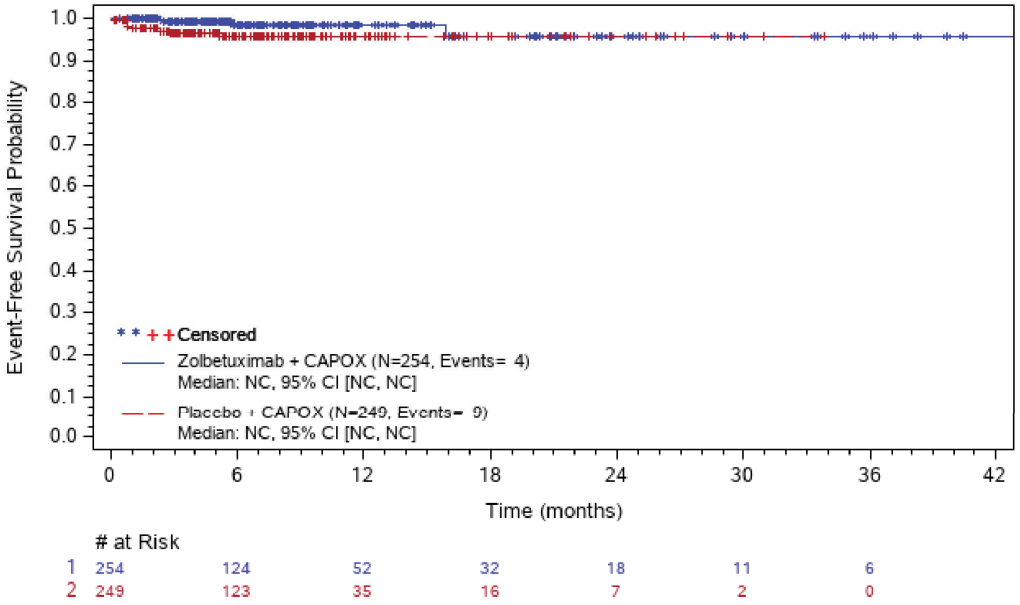
Figure 302.3.2001.11: Kaplan-Meier Plot of Time to first TEAE - Cardiac Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

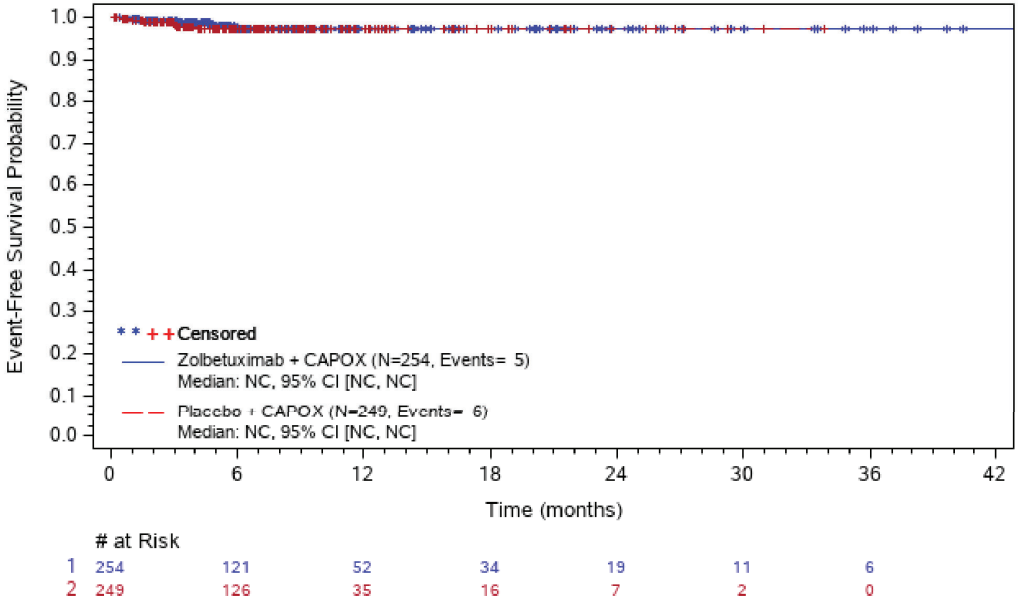
Figure 302.3.2001.12: Kaplan-Meier Plot of Time to first TEAE - Sinus Bradycardia (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

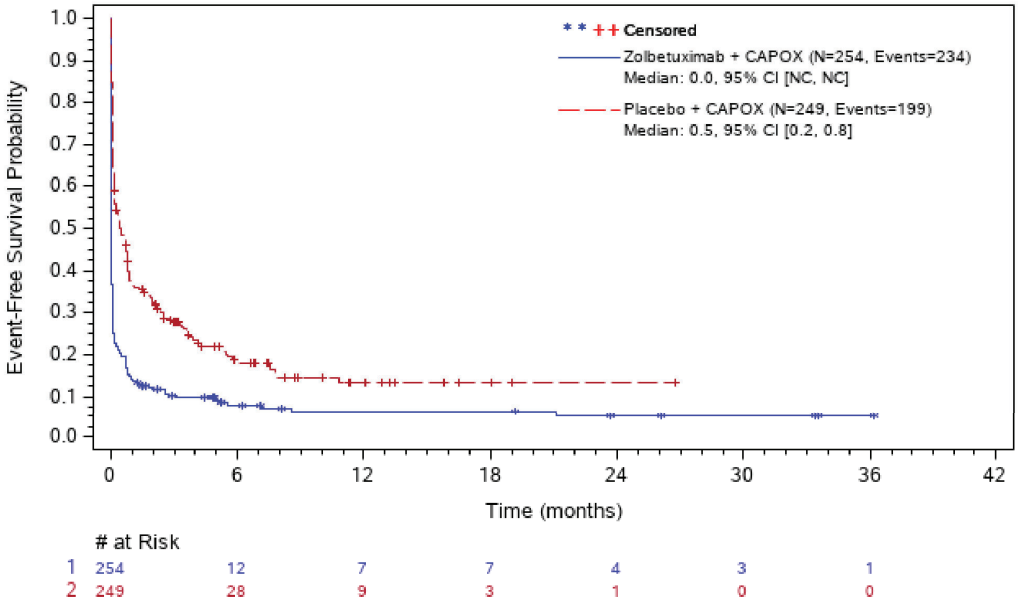
Figure 302.3.2001.13: Kaplan-Meier Plot of Time to first TEAE - Sinus Tachycardia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.14: 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: 12JAN24

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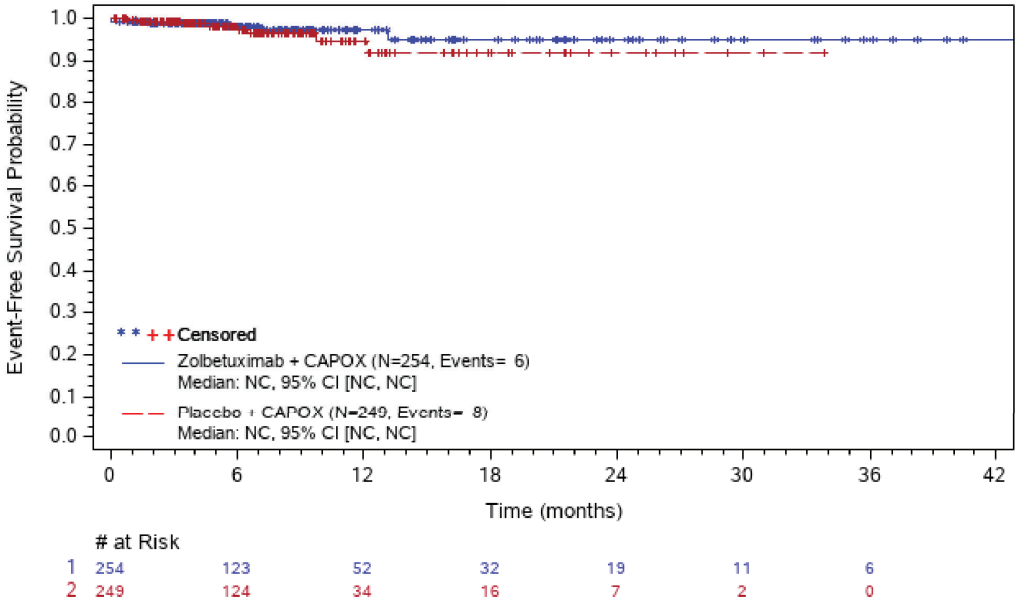
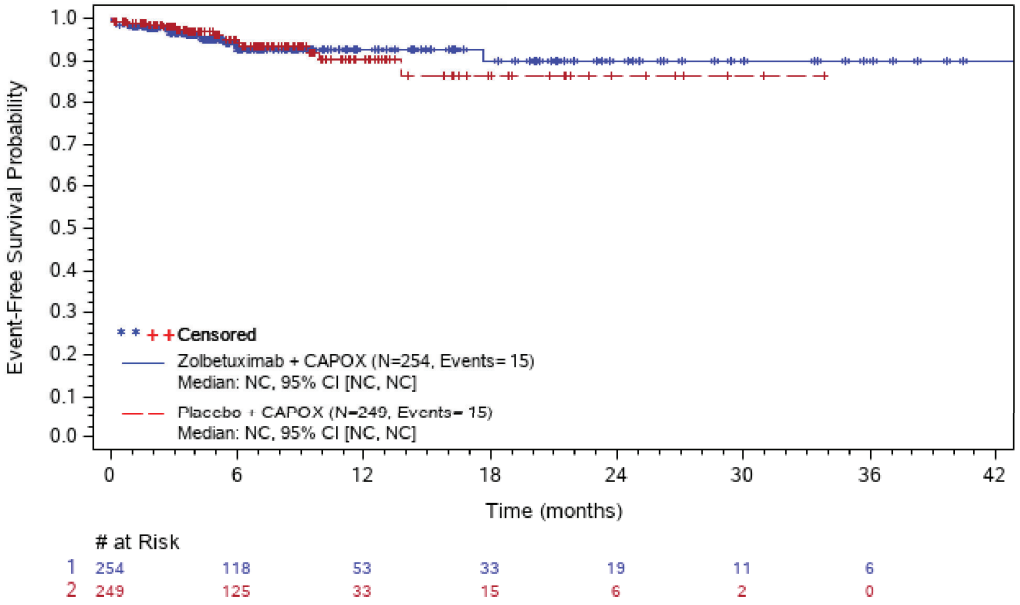
Figure 302.3.2001.15: Kaplan-Meier Plot of Time to first TEAE - Abdominal Discomfort (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.16: Kaplan-Meier Plot of Time to first TEAE - Abdominal Distension (PT) - Safety Analysis Set



# at Risk							
1	254	118	53	33	19	11	6
2	249	125	33	15	6	2	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: 12JAN24

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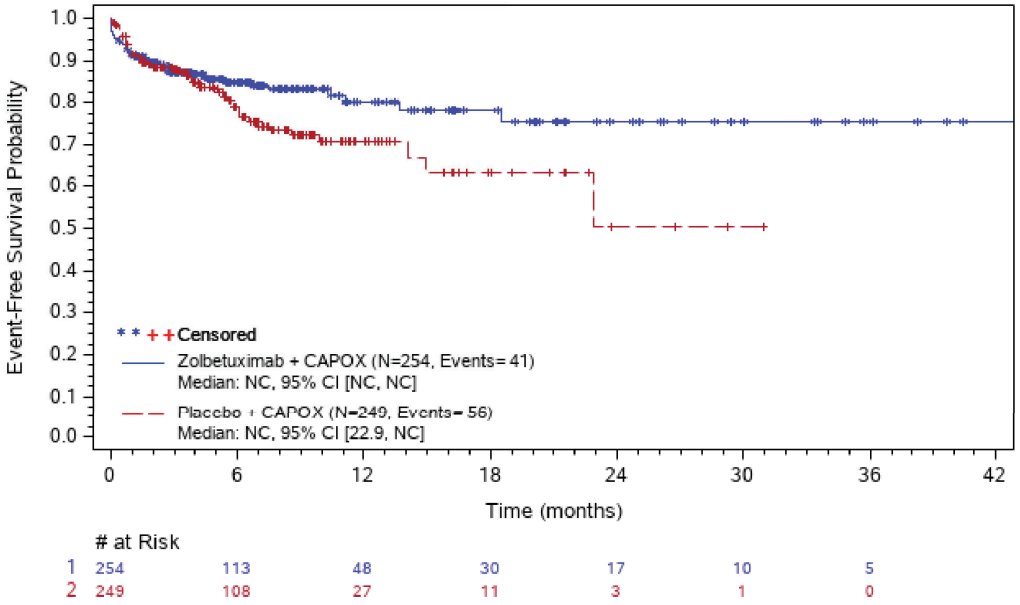
Figure 302.3.2001.17: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (PT) - Safety Analysis Set



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: 12JAN24

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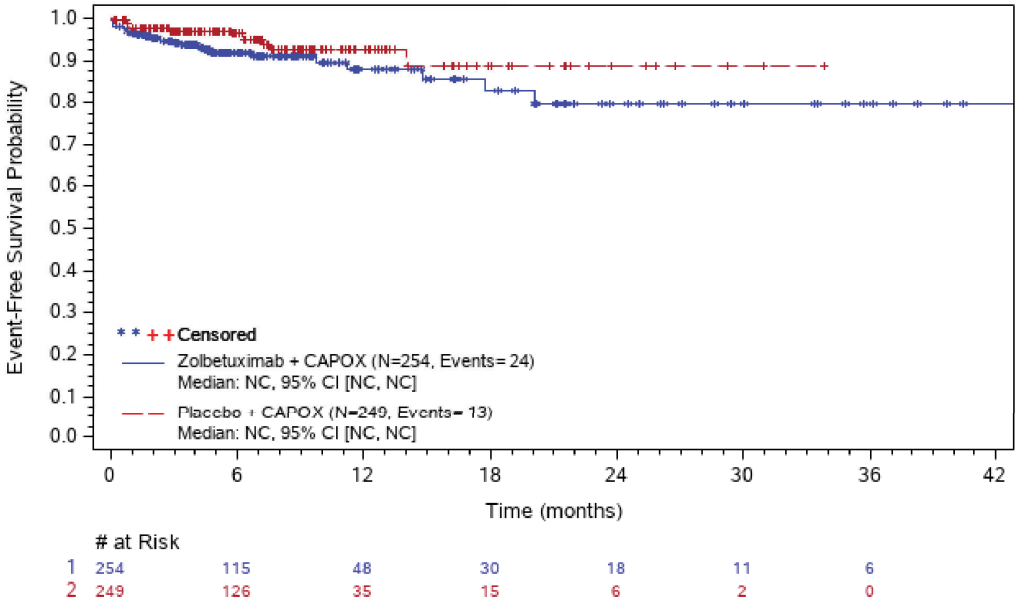
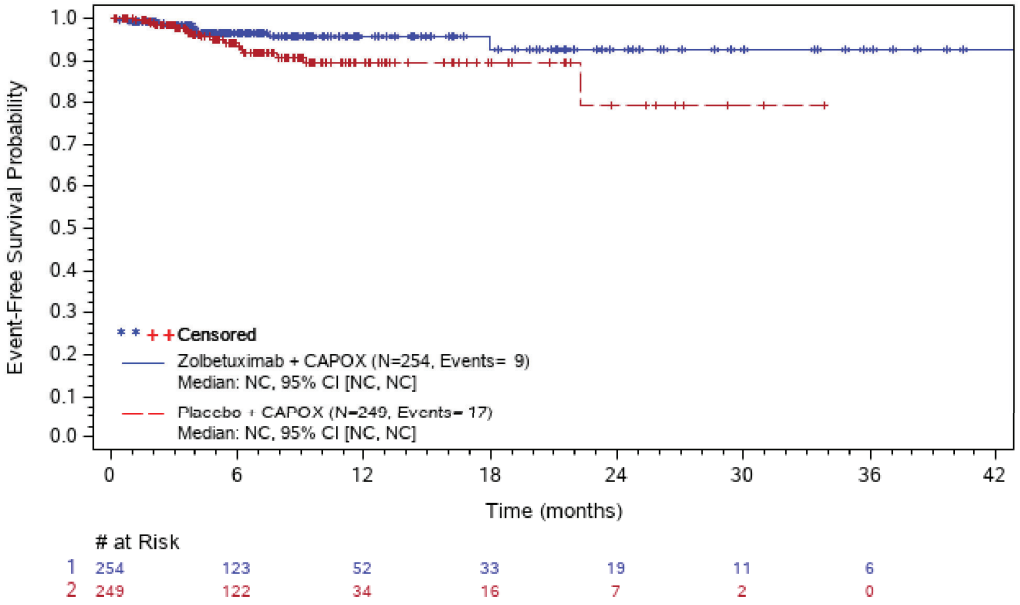
Figure 302.3.2001.18: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain Upper (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

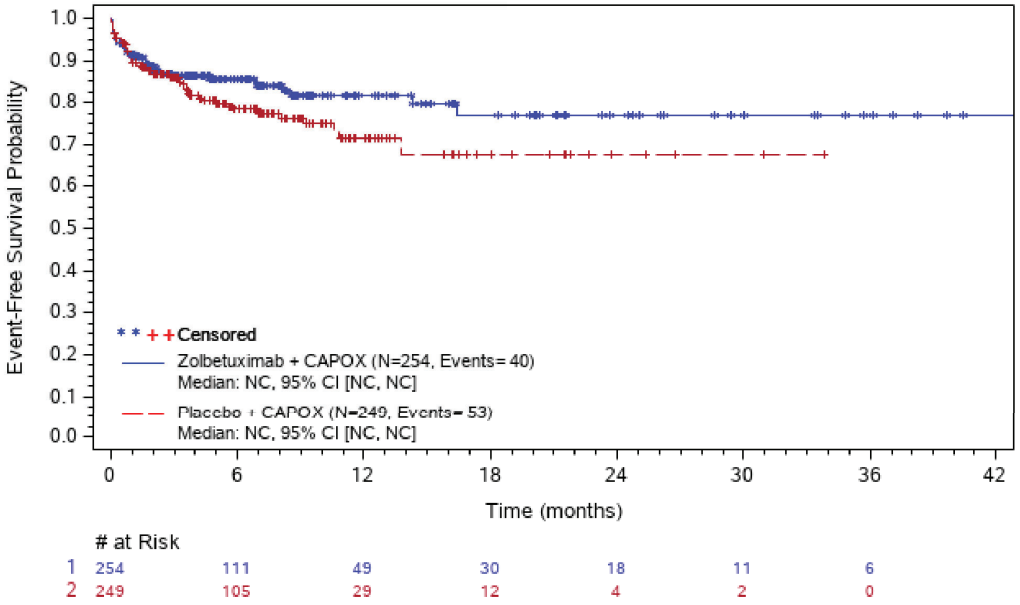
Figure 302.3.2001.19: Kaplan-Meier Plot of Time to first TEAE - Ascites (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

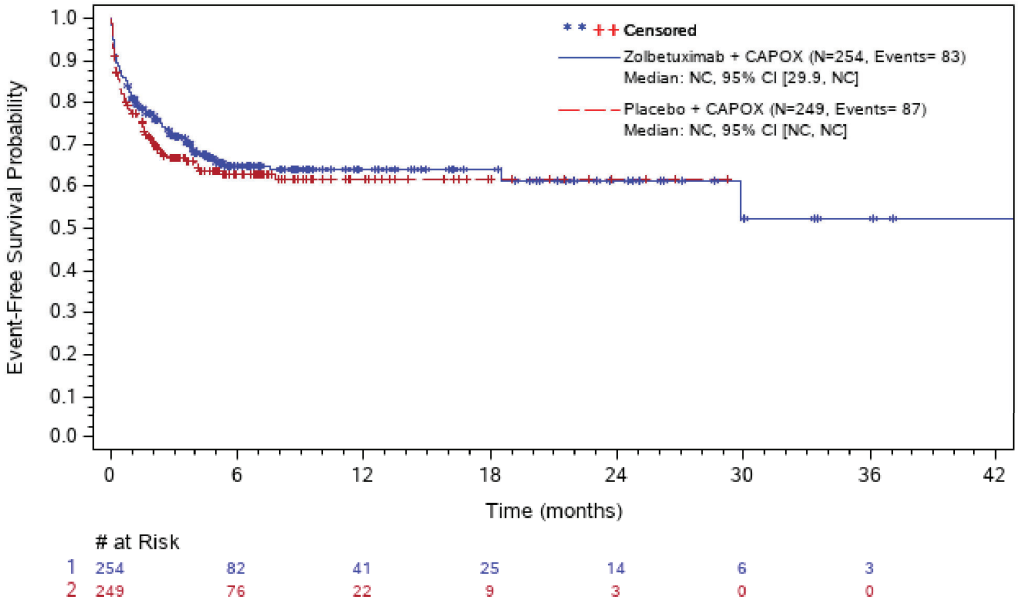
Figure 302.3.2001.20: Kaplan-Meier Plot of Time to first TEAE - Constipation (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

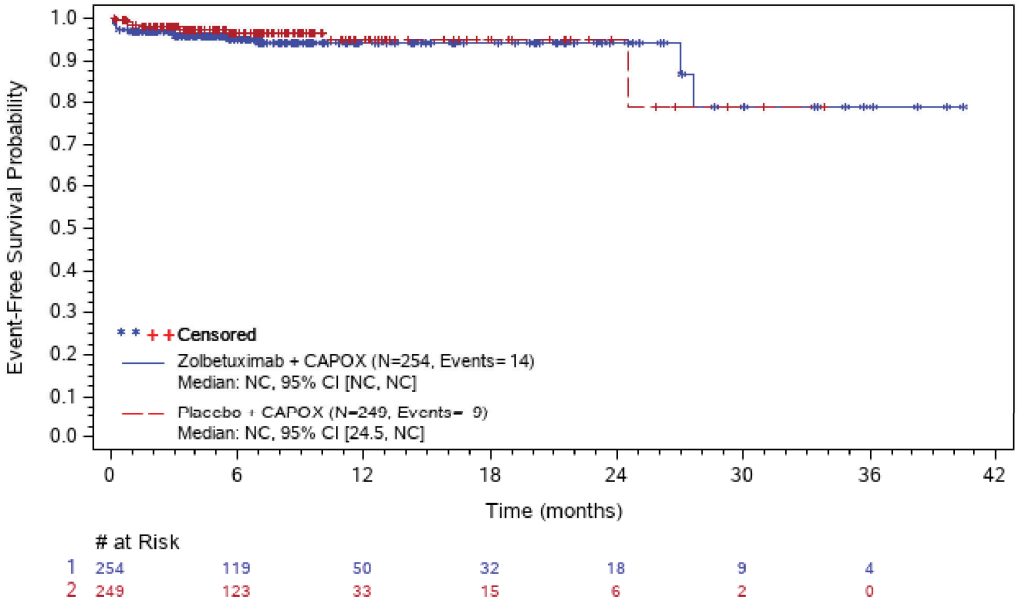
Figure 302.3.2001.21: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

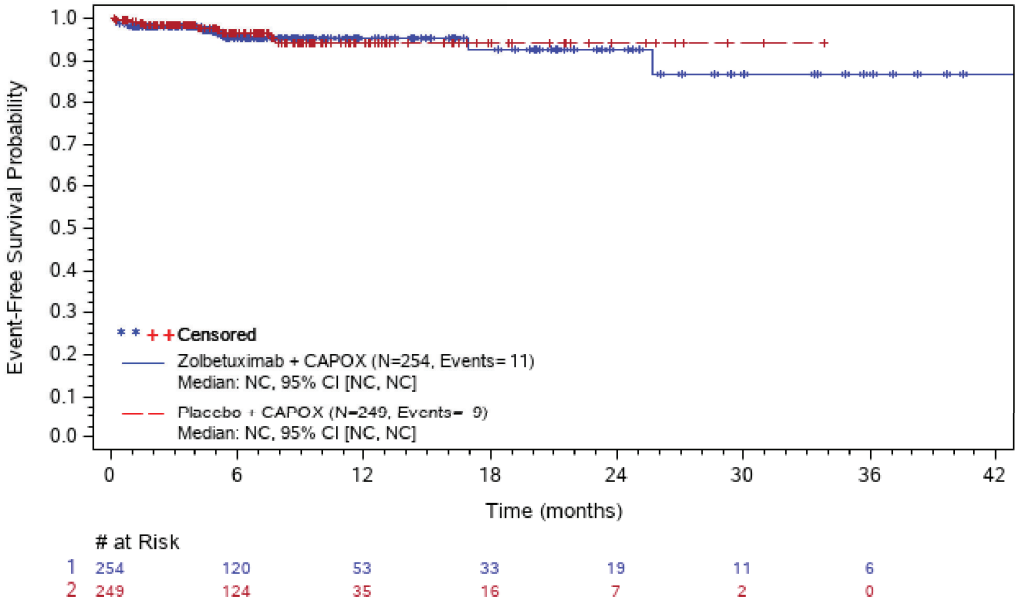
Figure 302.3.2001.22: Kaplan-Meier Plot of Time to first TEAE - Dyspepsia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

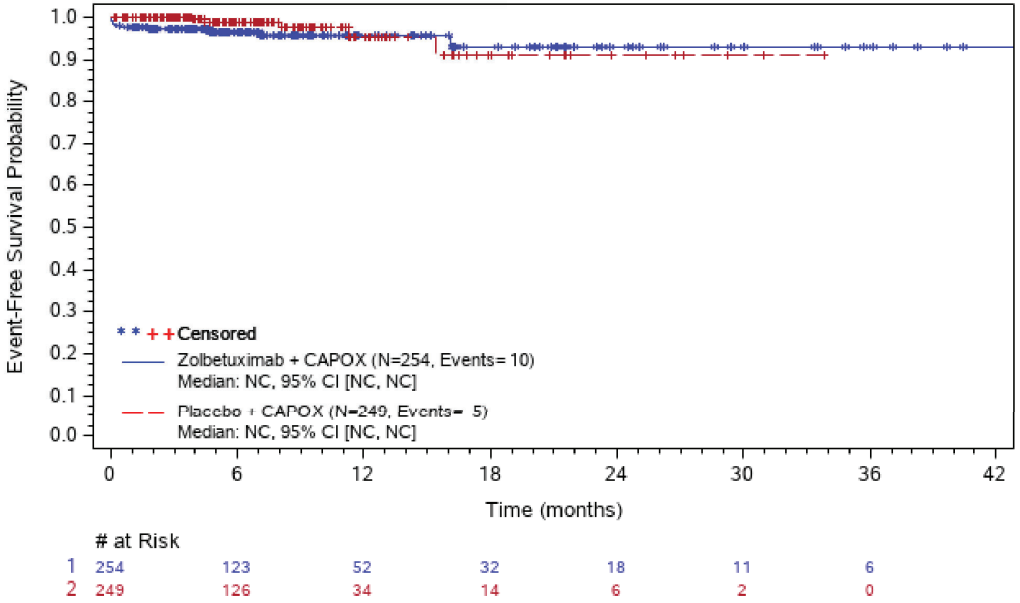
Figure 302.3.2001.23: Kaplan-Meier Plot of Time to first TEAE - Dysphagia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

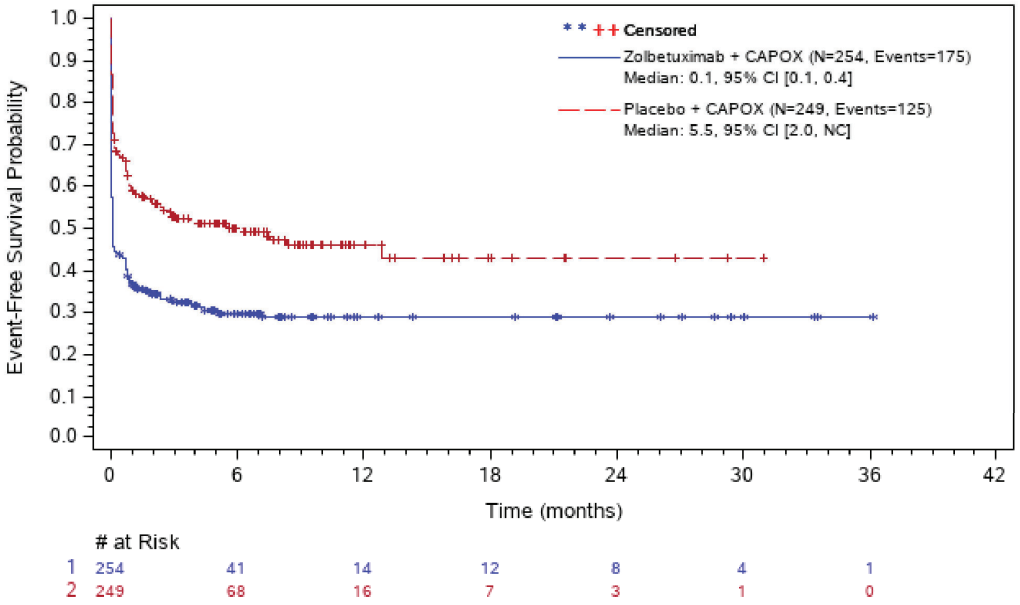
Figure 302.3.2001.24: Kaplan-Meier Plot of Time to first TEAE - Gastrooesophageal Reflux Disease (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

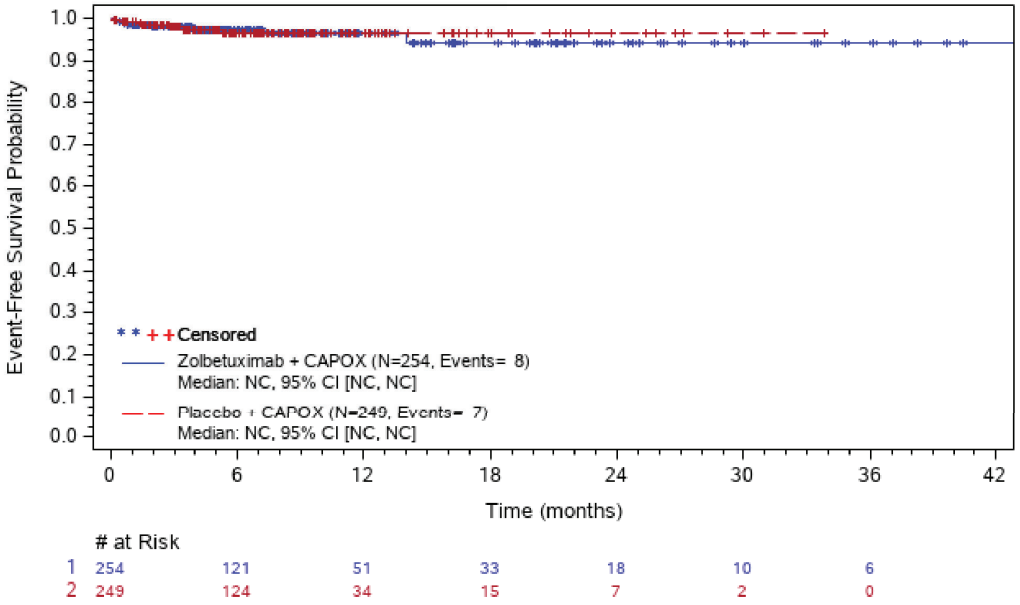
Figure 302.3.2001.25: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

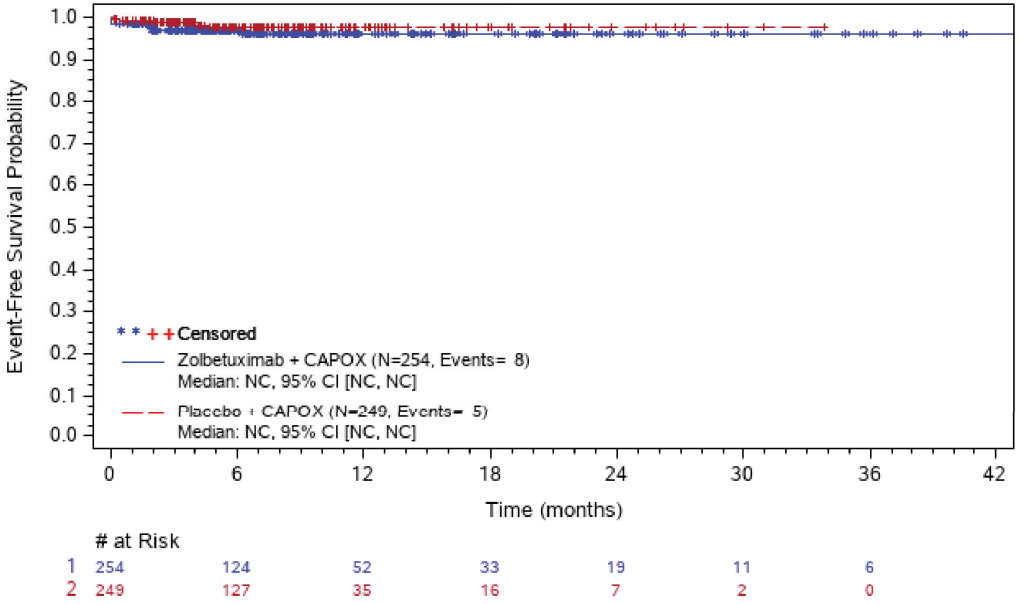
Figure 302.3.2001.26: Kaplan-Meier Plot of Time to first TEAE - Stomatitis (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

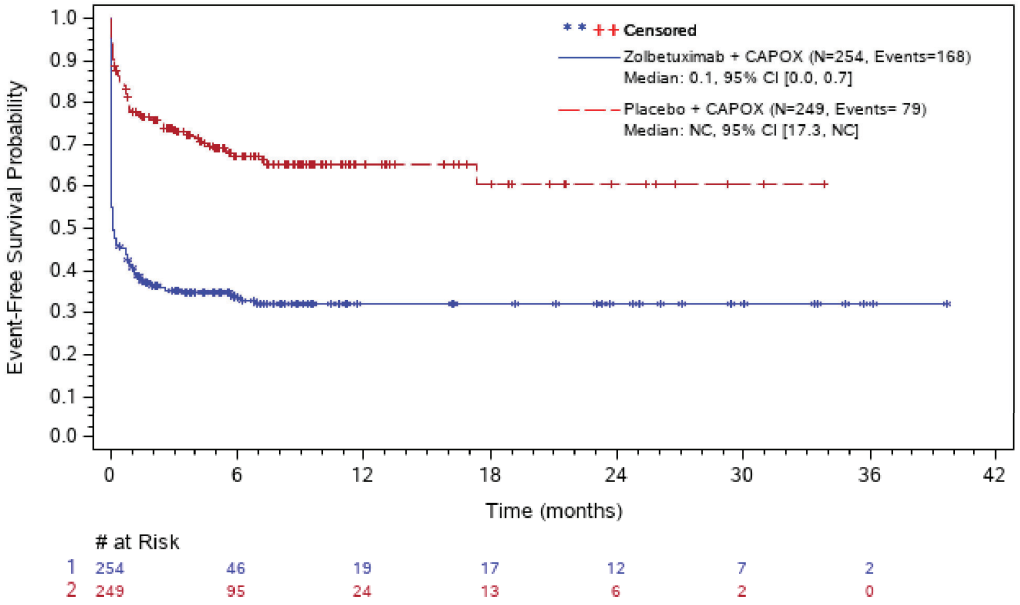
Figure 302.3.2001.27: Kaplan-Meier Plot of Time to first TEAE - Upper Gastrointestinal Haemorrhage (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

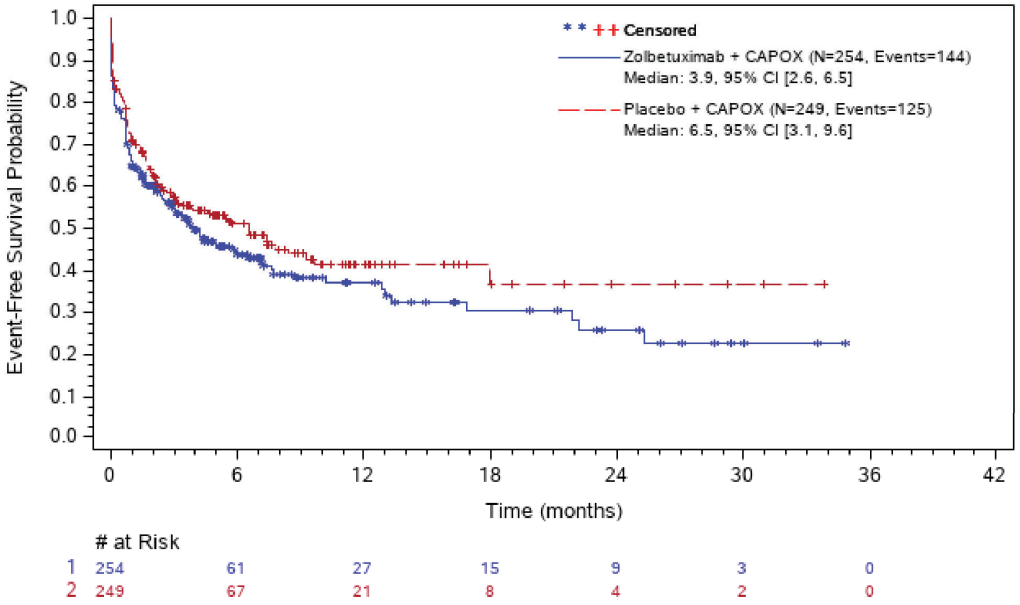
Figure 302.3.2001.28: Kaplan-Meier Plot of Time to first TEAE - Vomiting (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

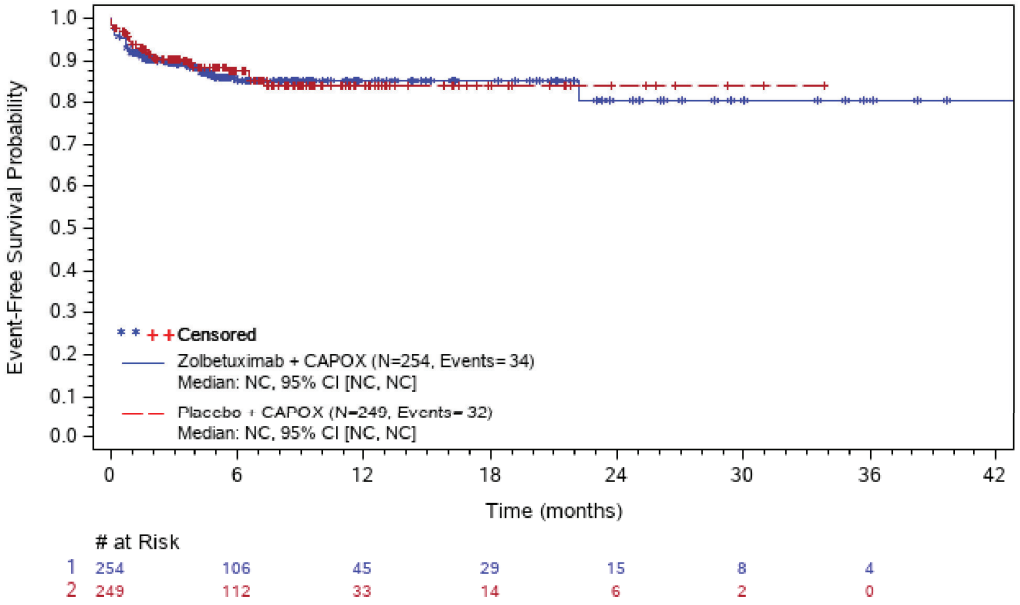
Figure 302.3.2001.29: Kaplan-Meier Plot of Time to first TEAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.30: 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: 12JAN24

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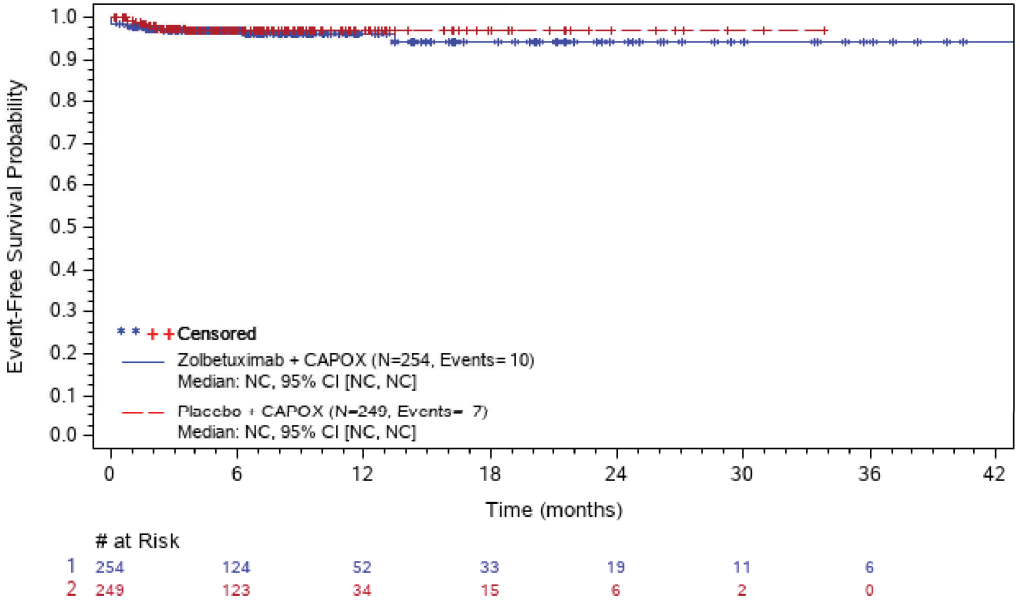
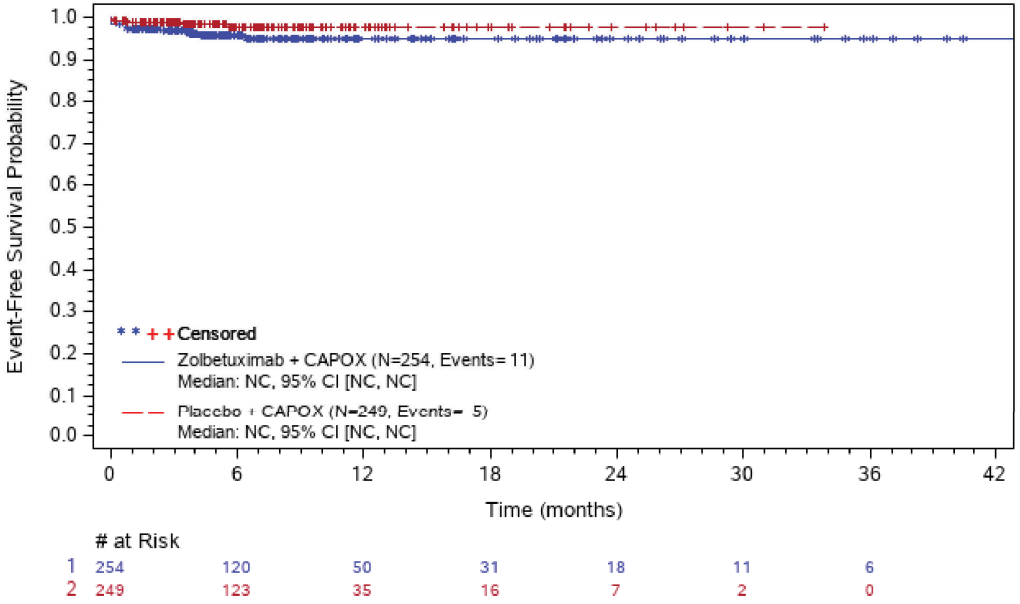
Figure 302.3.2001.31: Kaplan-Meier Plot of Time to first TEAE - Chest Discomfort (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

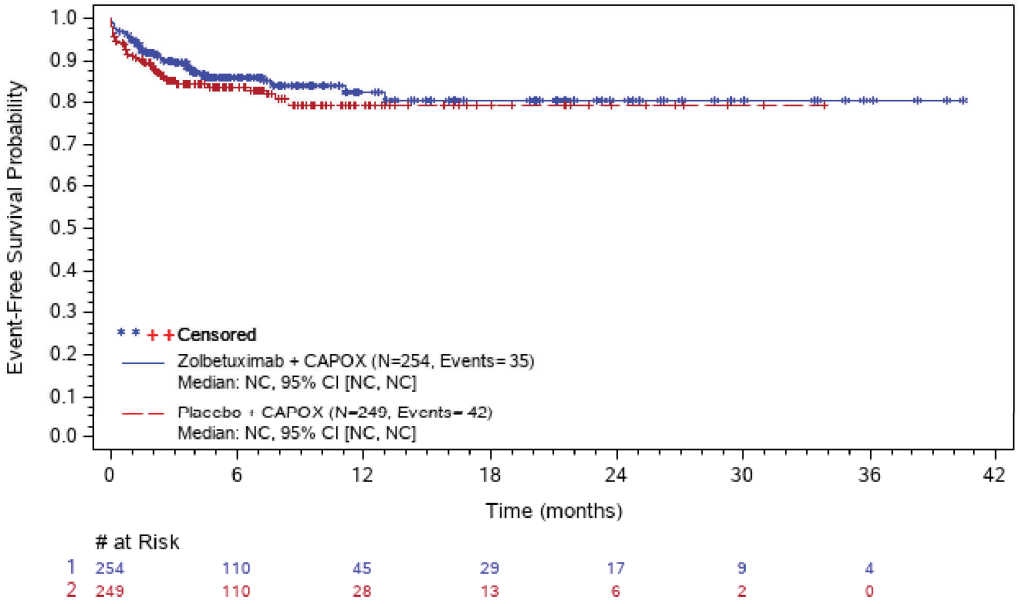
Figure 302.3.2001.32: Kaplan-Meier Plot of Time to first TEAE - Chills (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

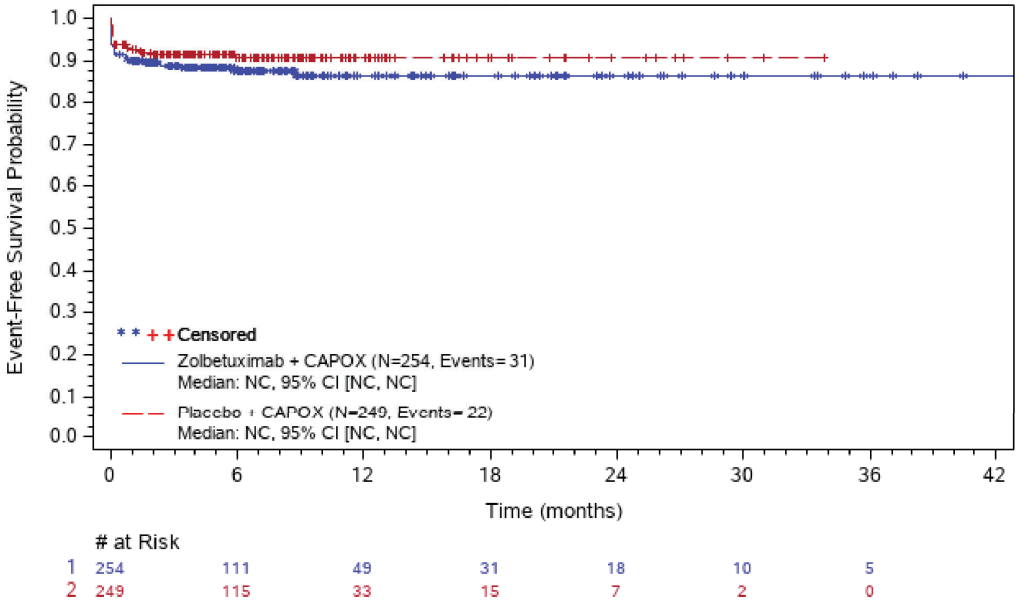
Figure 302.3.2001.33: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

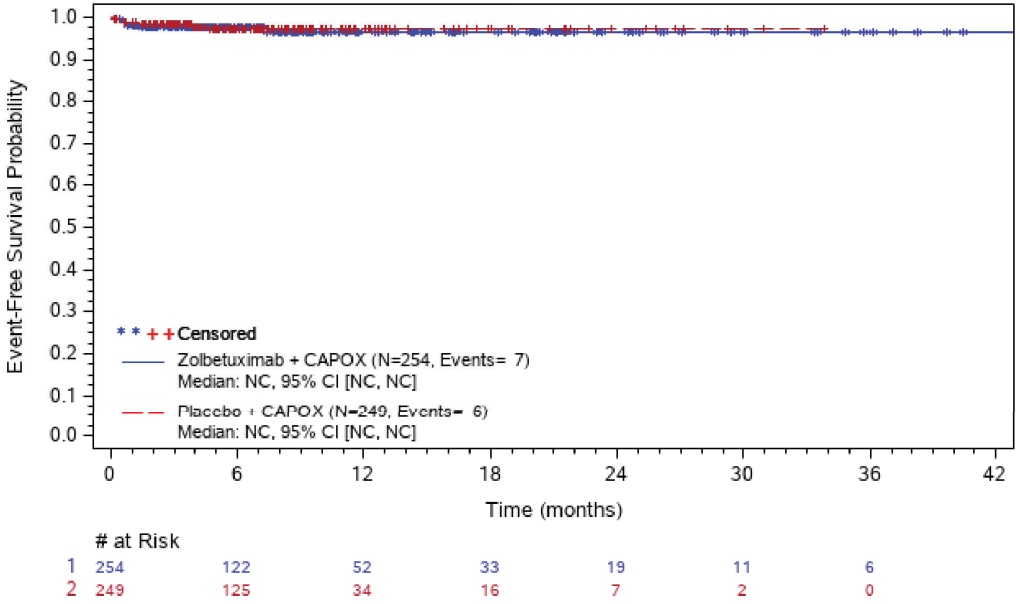
Figure 302.3.2001.34: Kaplan-Meier Plot of Time to first TEAE - Malaise (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.35: 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: 12JAN24

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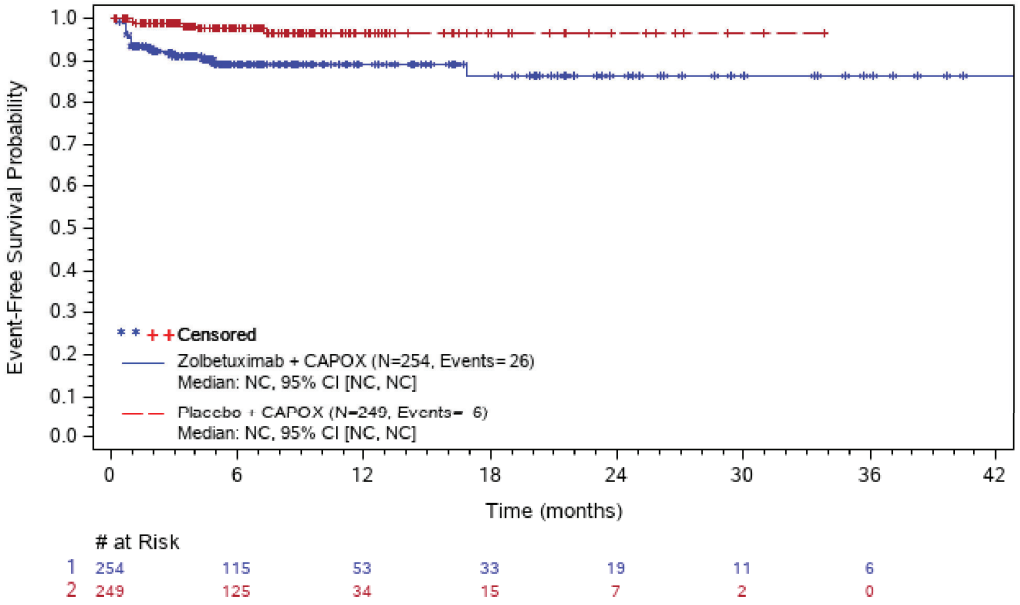
Figure 302.3.2001.36: Kaplan-Meier Plot of Time to first TEAE - Oedema Peripheral (PT) - Safety Analysis Set



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: 12JAN24

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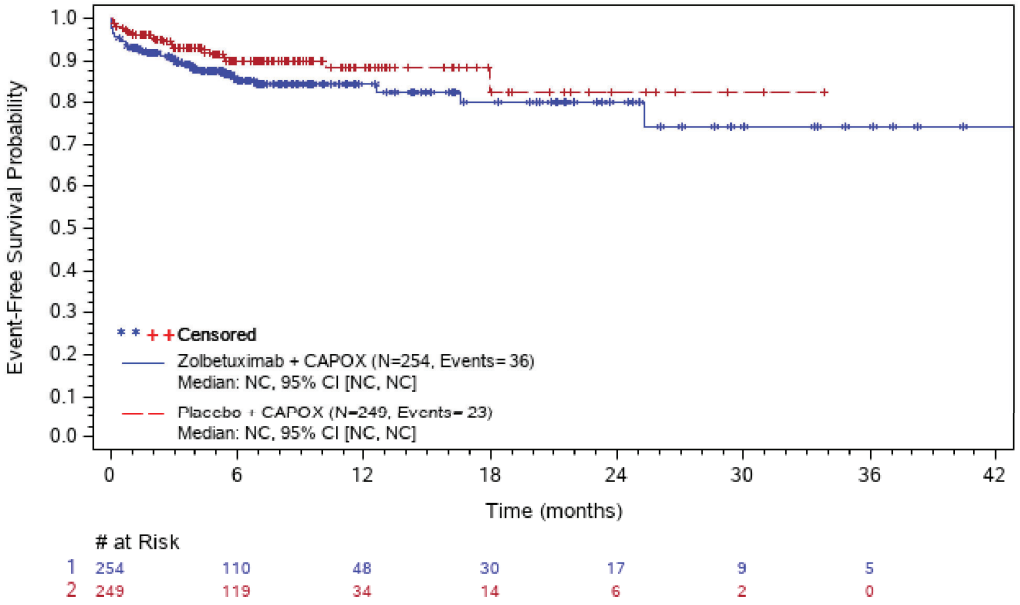
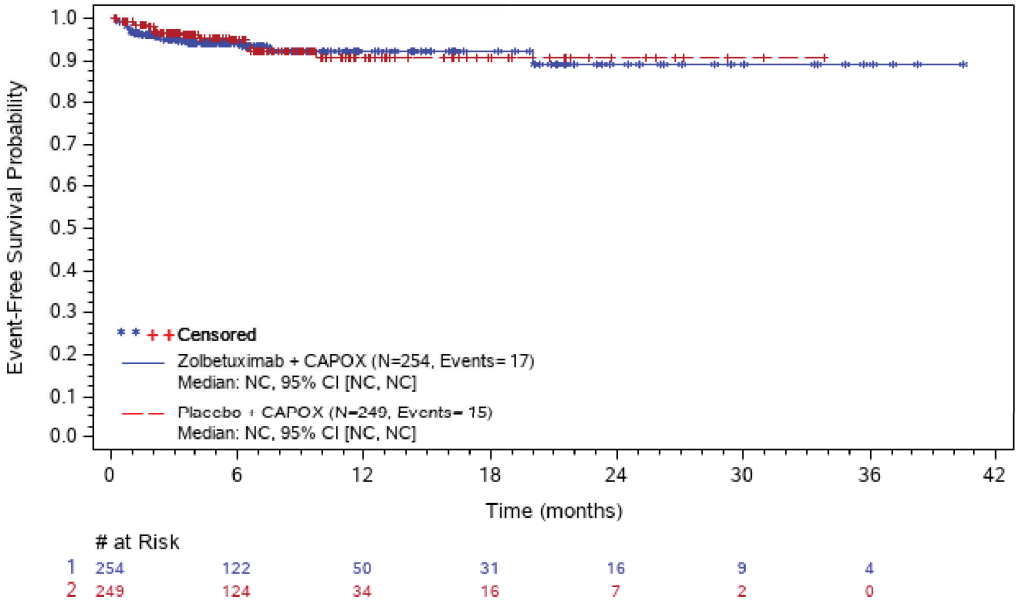
Figure 302.3.2001.37: Kaplan-Meier Plot of Time to first TEAE - Pyrexia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.38: Kaplan-Meier Plot of Time to first TEAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set

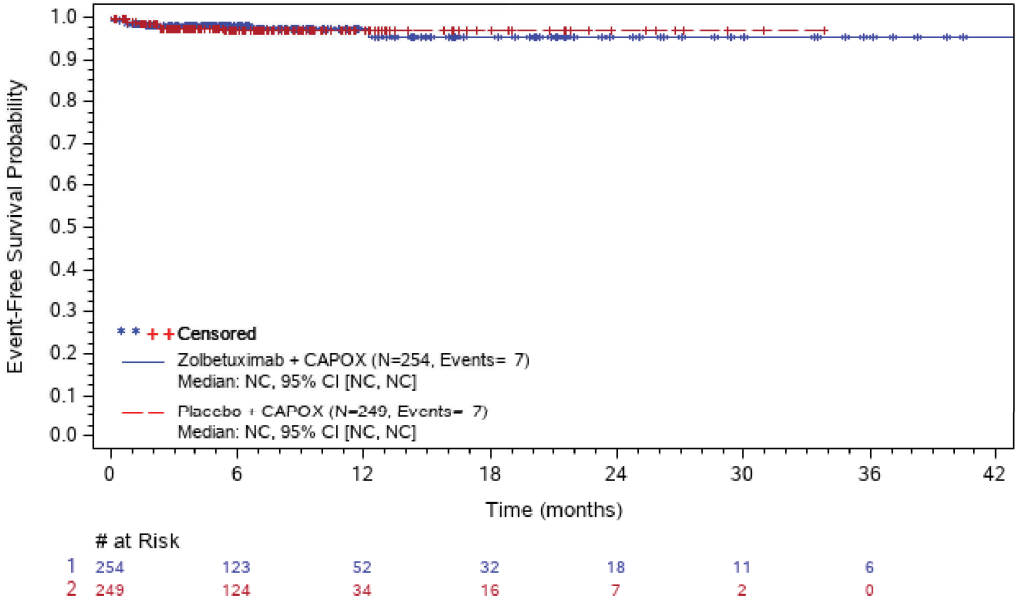


# at Risk							
1	254	122	50	31	16	9	4
2	249	124	34	16	7	2	0

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: 12JAN24

The SAS System

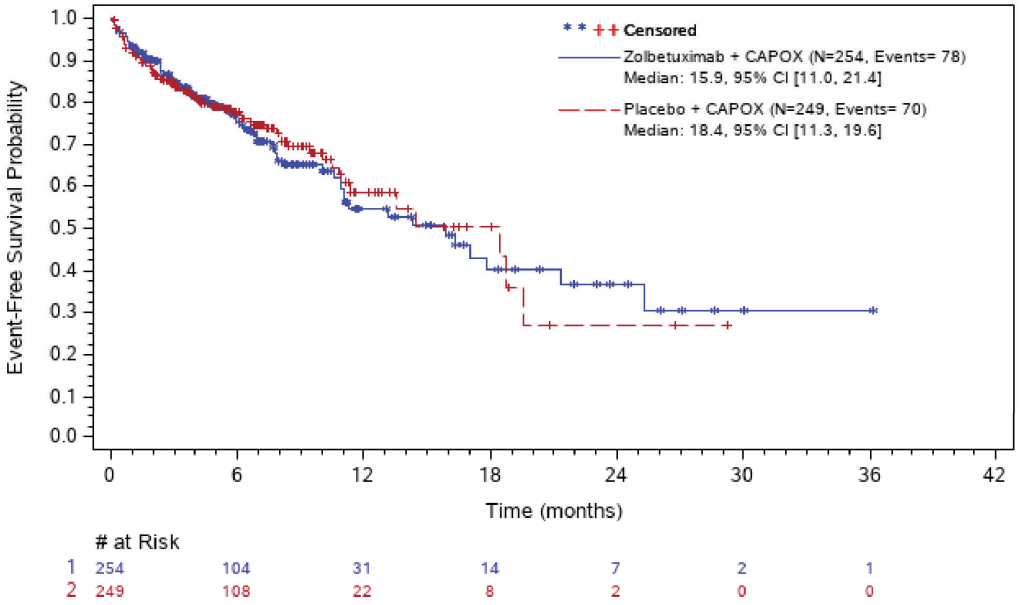
Figure 302.3.2001.39: Kaplan-Meier Plot of Time to first TEAE - Immune System Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.40: Kaplan-Meier Plot of Time to first TEAE - Infections And Infestations (SOC) - Safety Analysis Set

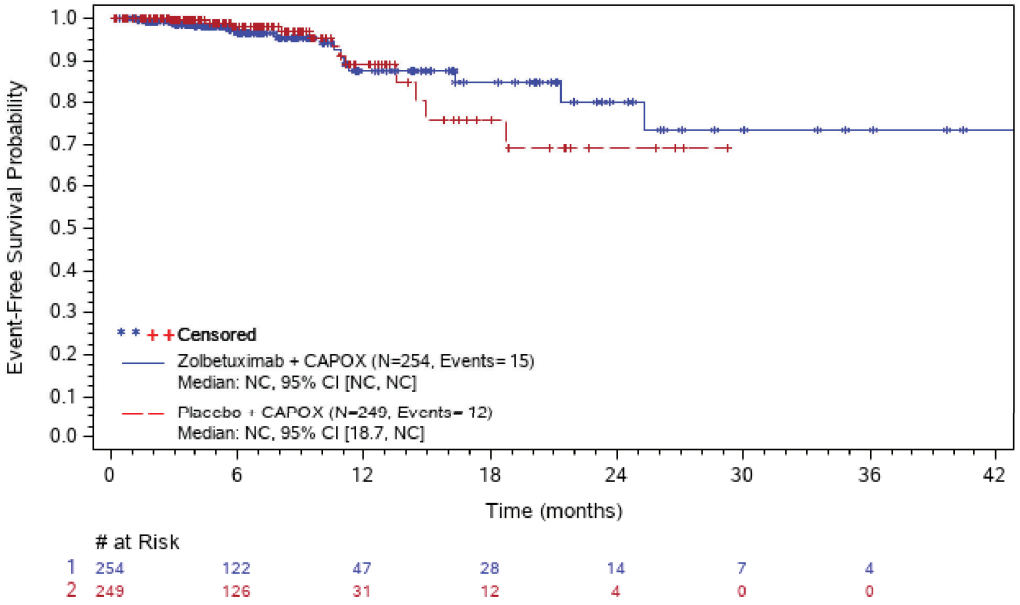


# at Risk							
1	254	104	31	14	7	2	1
2	249	108	22	8	2	0	0

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: 12JAN24

The SAS System

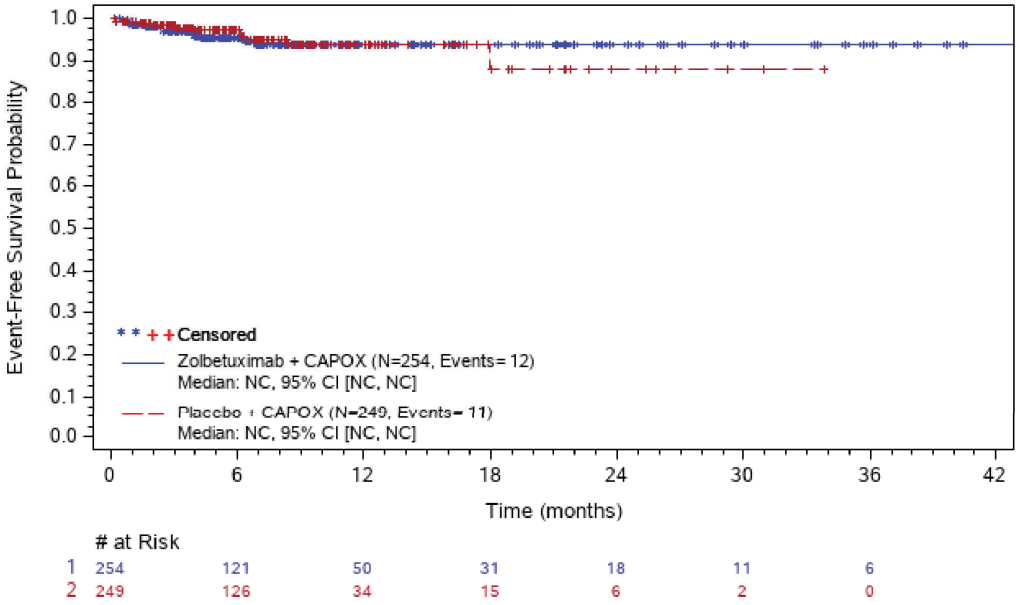
Figure 302.3.2001.41: Kaplan-Meier Plot of Time to first TEAE - Covid-19 (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

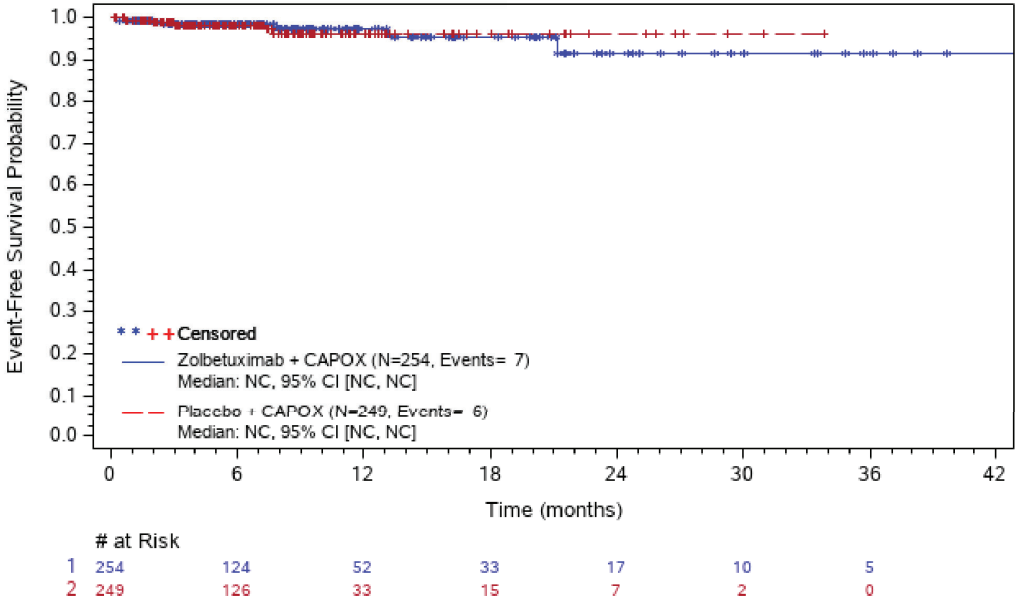
Figure 302.3.2001.42: Kaplan-Meier Plot of Time to first TEAE - Pneumonia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

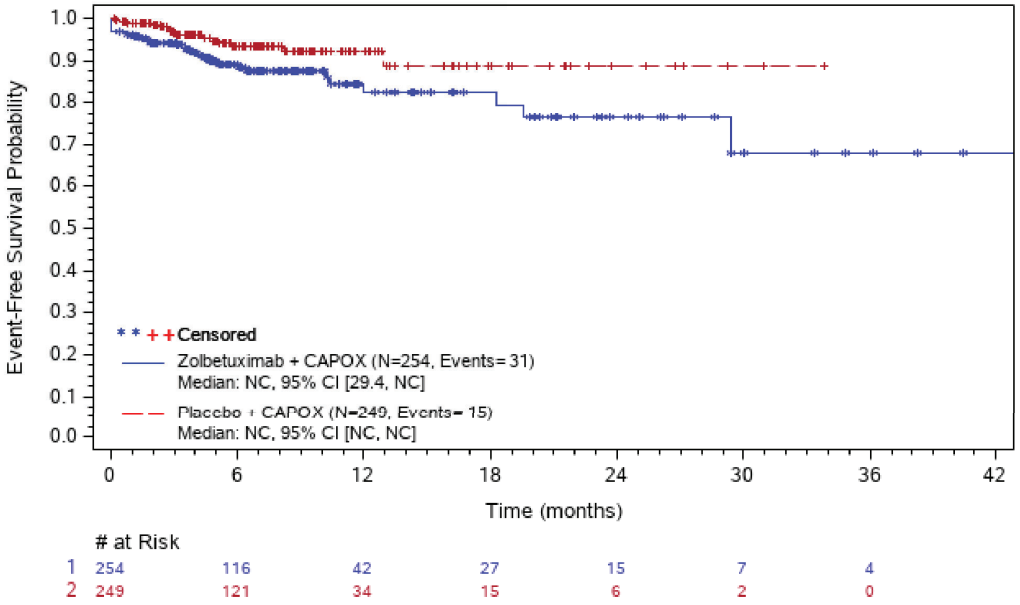
Figure 302.3.2001.43: Kaplan-Meier Plot of Time to first TEAE - Urinary Tract Infection (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

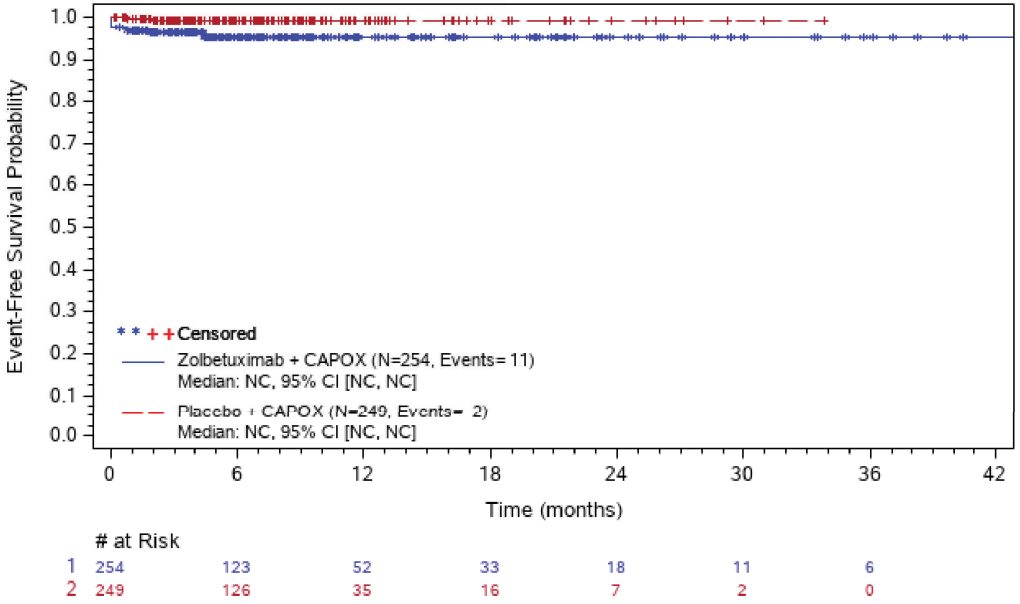
Figure 302.3.2001.44: Kaplan-Meier Plot of Time to first TEAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

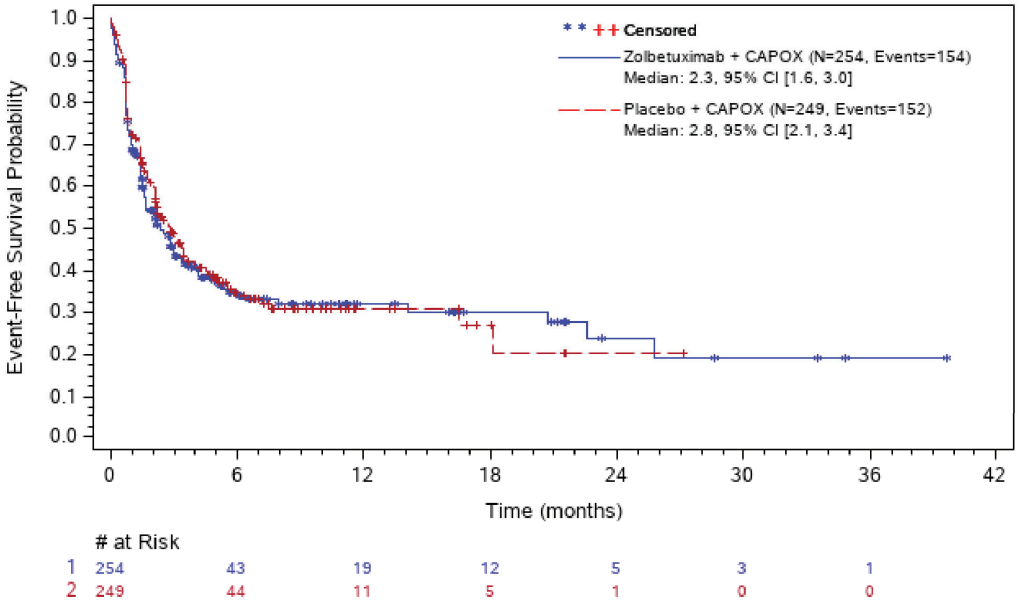
Figure 302.3.2001.45: Kaplan-Meier Plot of Time to first TEAE - Infusion Related Reaction (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

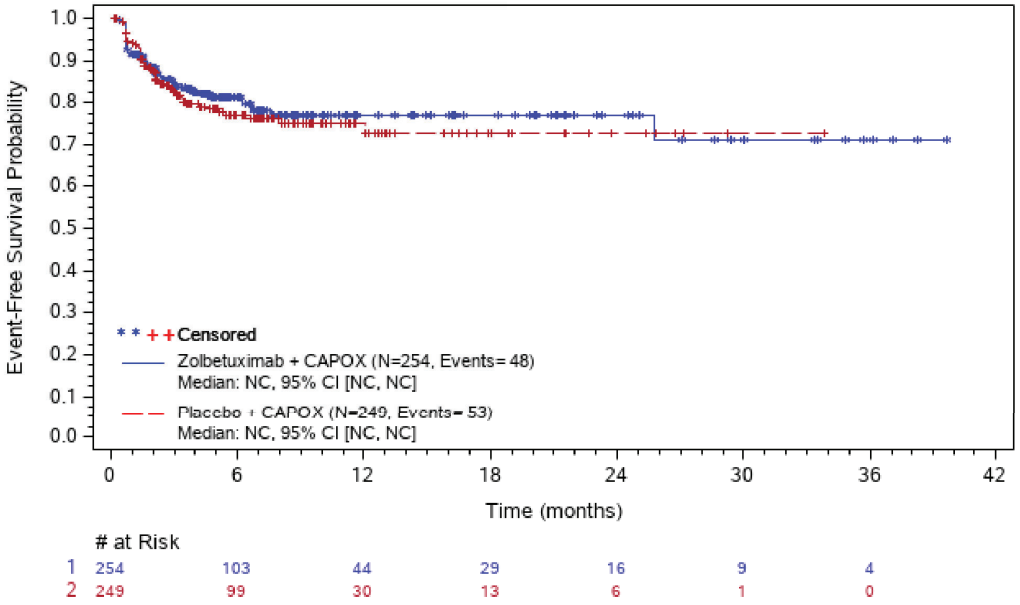
Figure 302.3.2001.46: Kaplan-Meier Plot of Time to first TEAE - Investigations (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

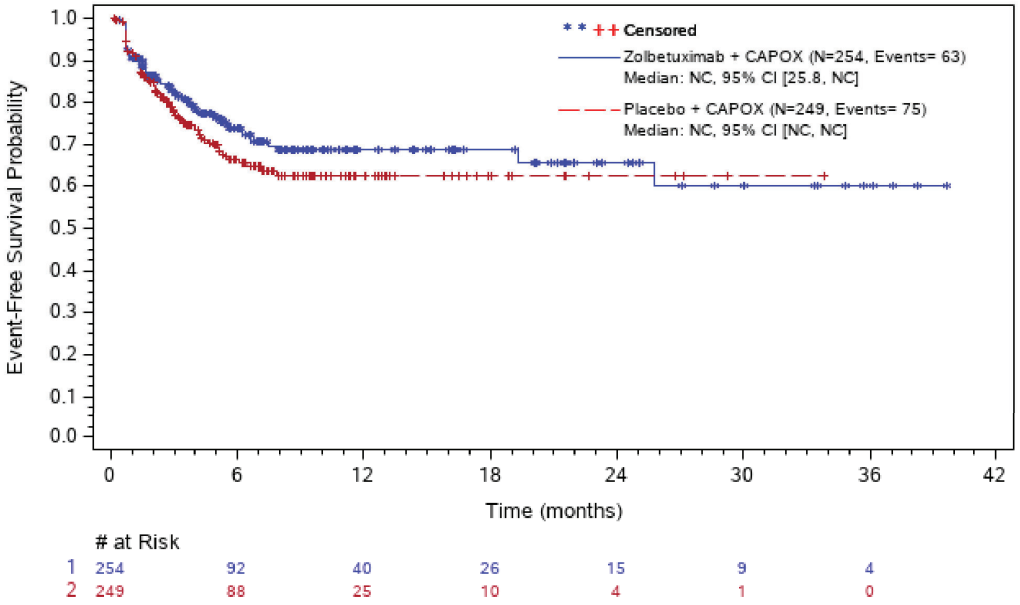
Figure 302.3.2001.47: Kaplan-Meier Plot of Time to first TEAE - Alanine Aminotransferase Increased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

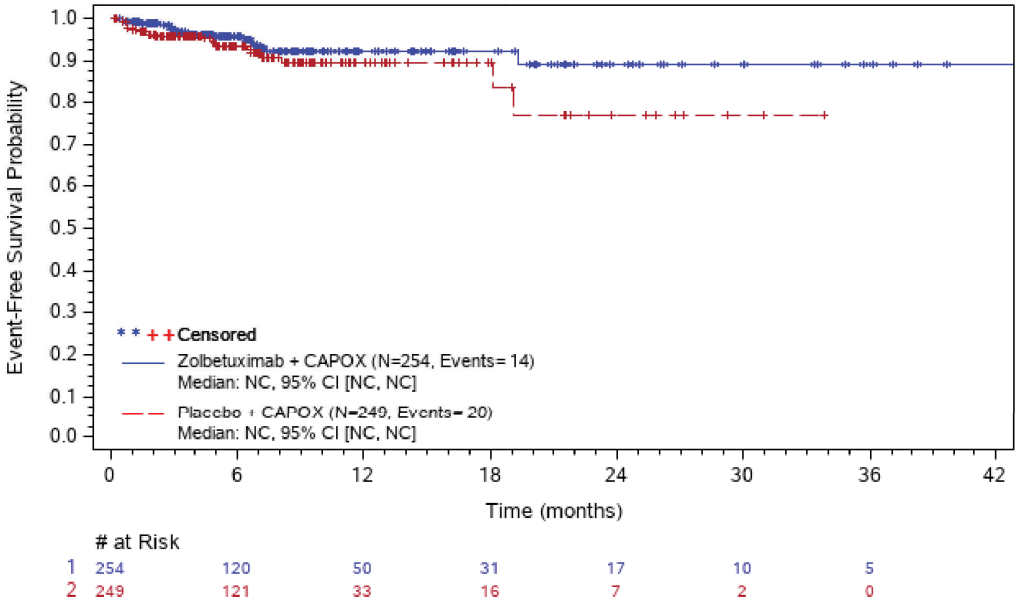
Figure 302.3.2001.48: Kaplan-Meier Plot of Time to first TEAE - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

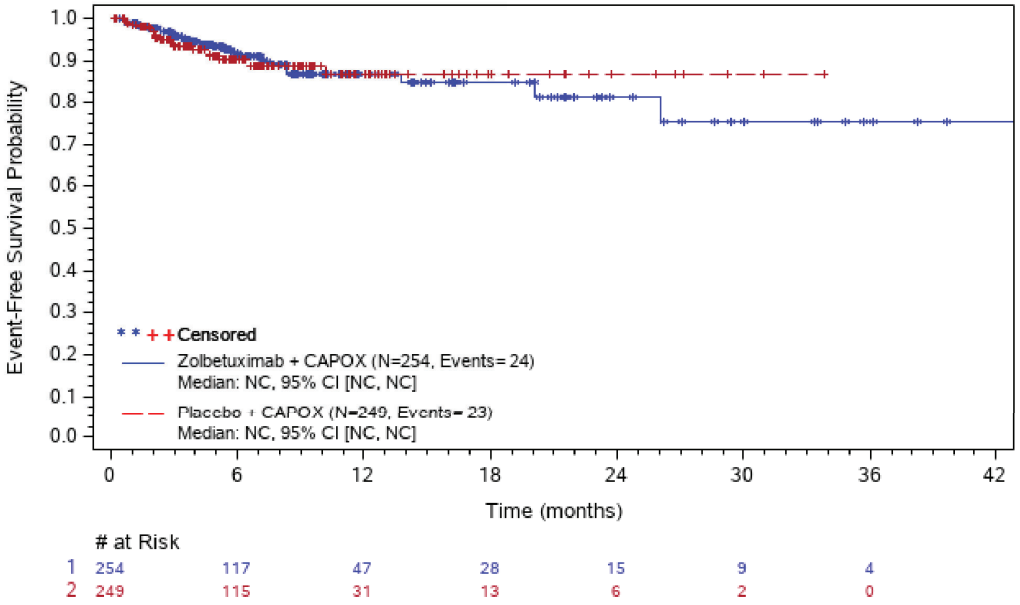
Figure 302.3.2001.49: Kaplan-Meier Plot of Time to first TEAE - Blood Alkaline Phosphatase Increased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

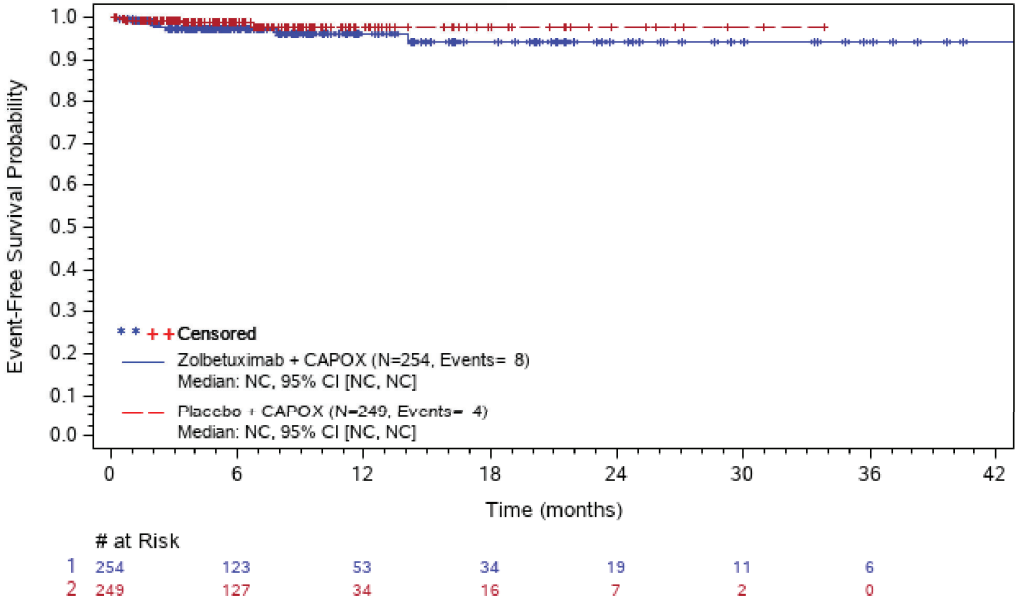
Figure 302.3.2001.50: Kaplan-Meier Plot of Time to first TEAE - Blood Bilirubin Increased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

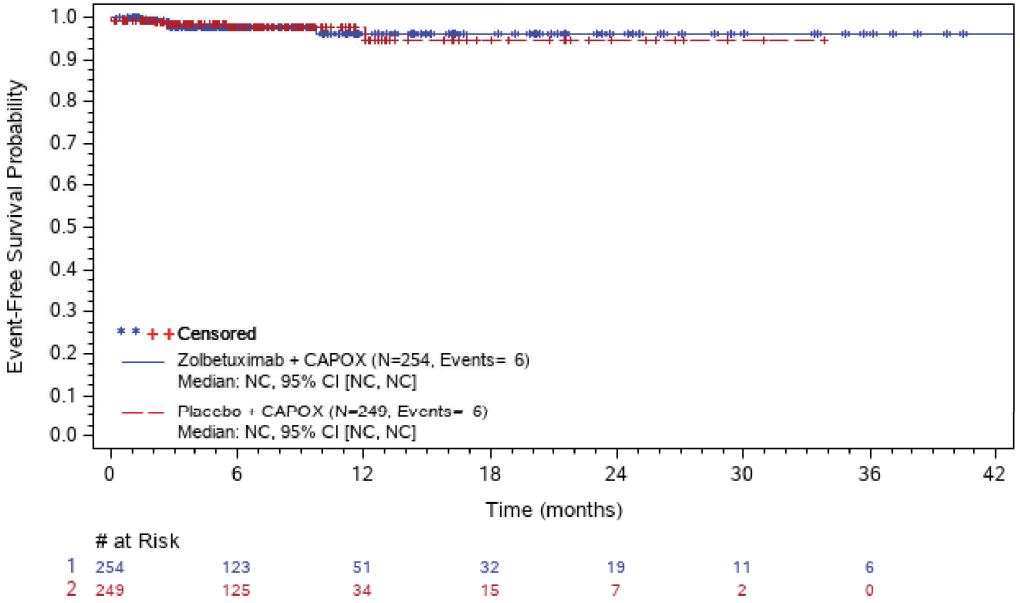
Figure 302.3.2001.51: Kaplan-Meier Plot of Time to first TEAE - Blood Creatinine Increased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

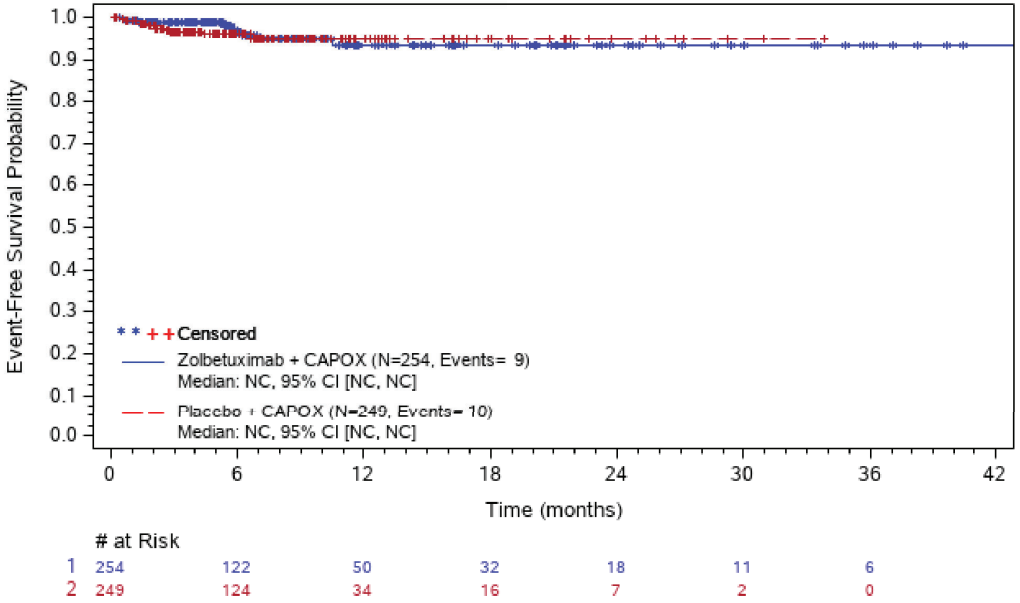
Figure 302.3.2001.52: Kaplan-Meier Plot of Time to first TEAE - Electrocardiogram Qt Prolonged (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

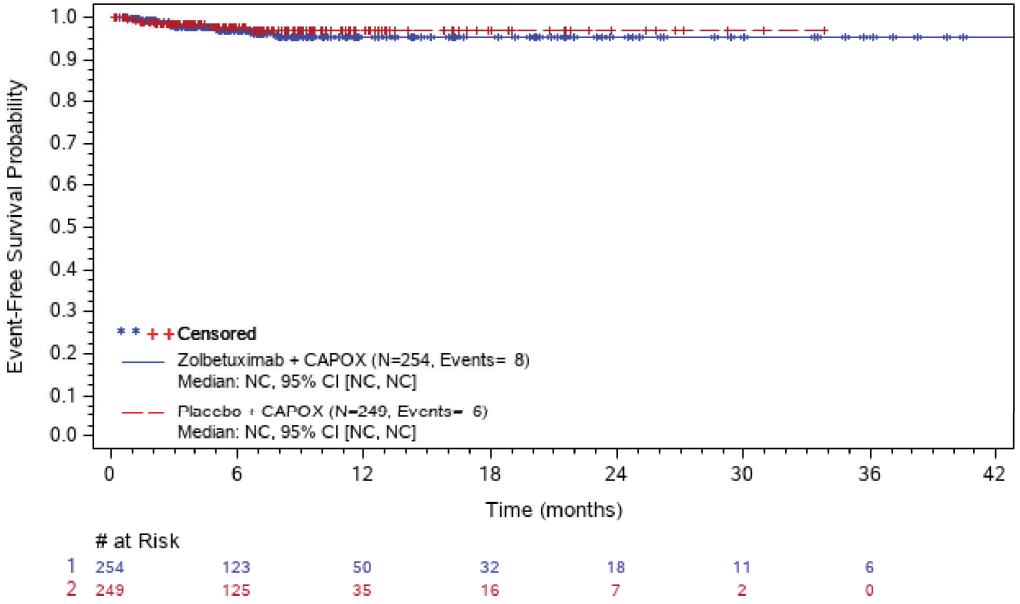
Figure 302.3.2001.53: Kaplan-Meier Plot of Time to first TEAE - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

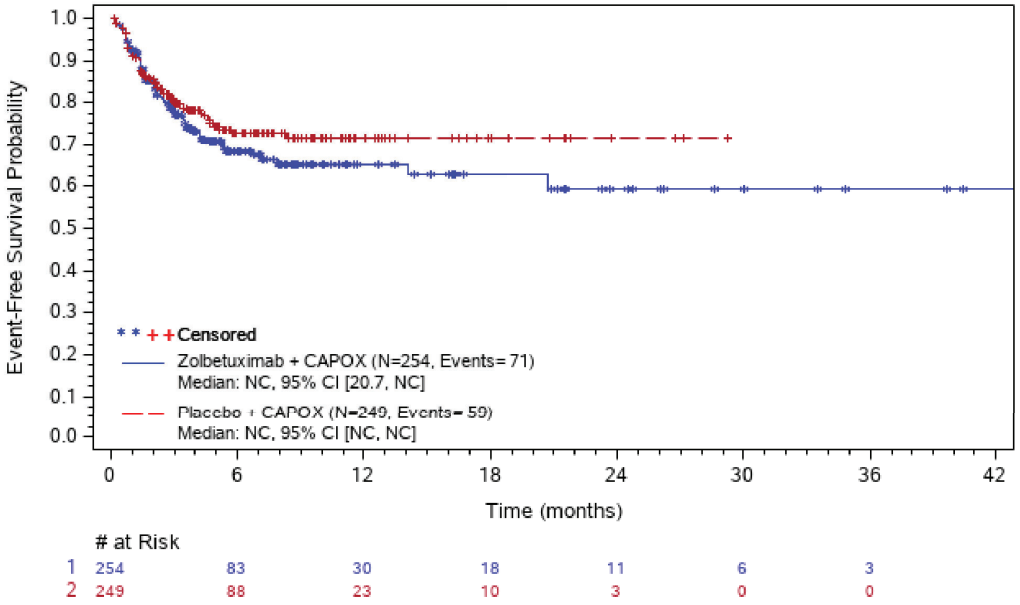
Figure 302.3.2001.54: Kaplan-Meier Plot of Time to first TEAE - Lymphocyte Count Decreased (PT) - Safety Analysis Set



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.
ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

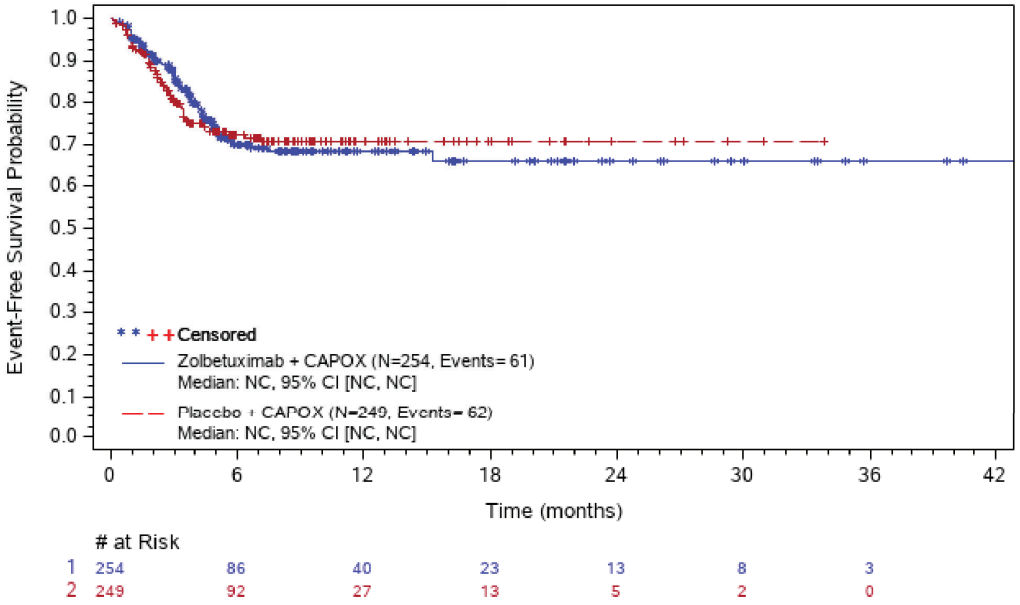
Figure 302.3.2001.55: Kaplan-Meier Plot of Time to first TEAE - Neutrophil Count Decreased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

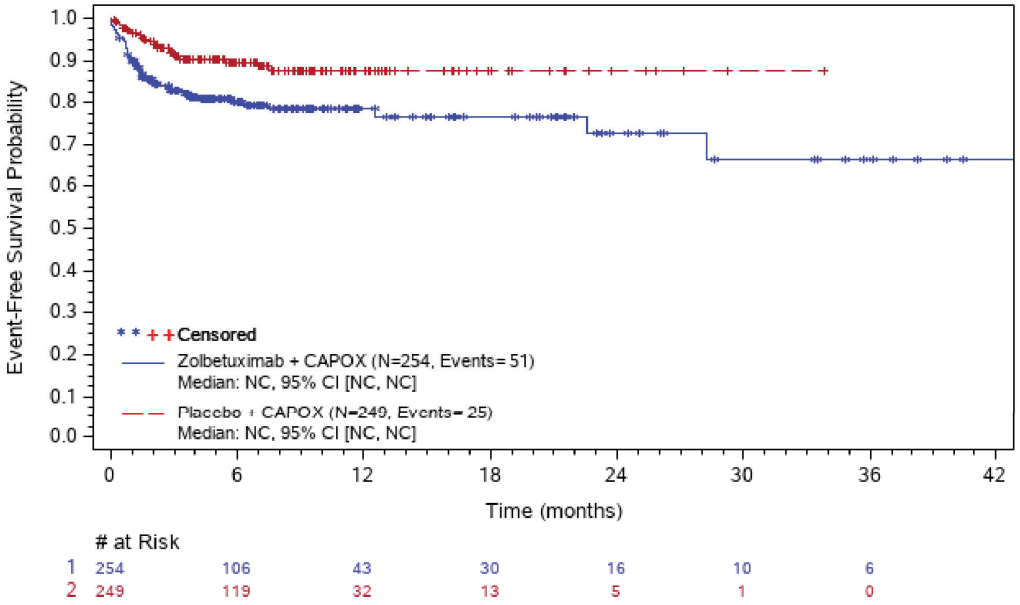
Figure 302.3.2001.56: Kaplan-Meier Plot of Time to first TEAE - Platelet Count Decreased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

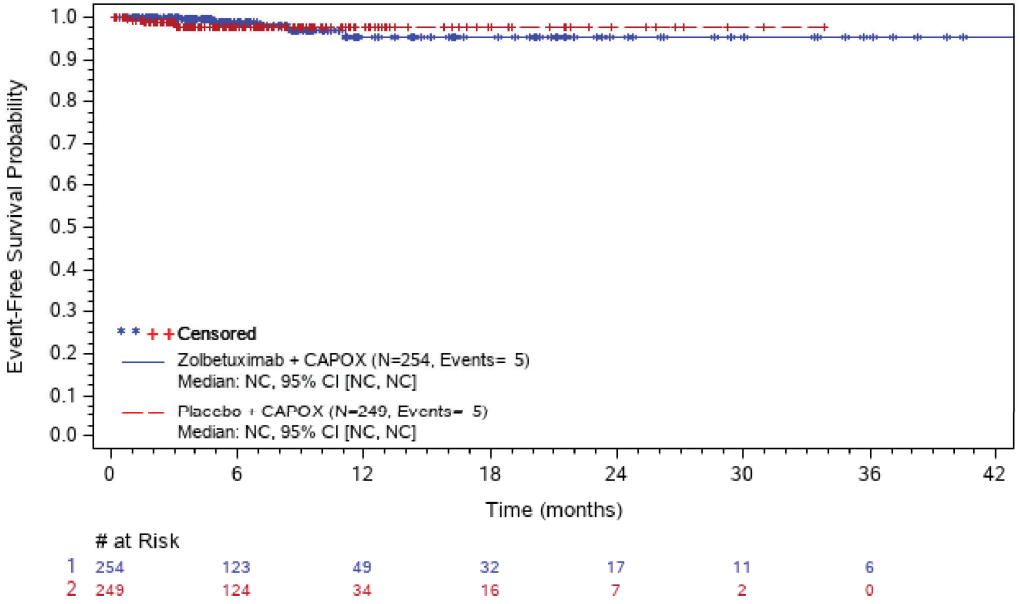
Figure 302.3.2001.57: Kaplan-Meier Plot of Time to first TEAE - Weight Decreased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

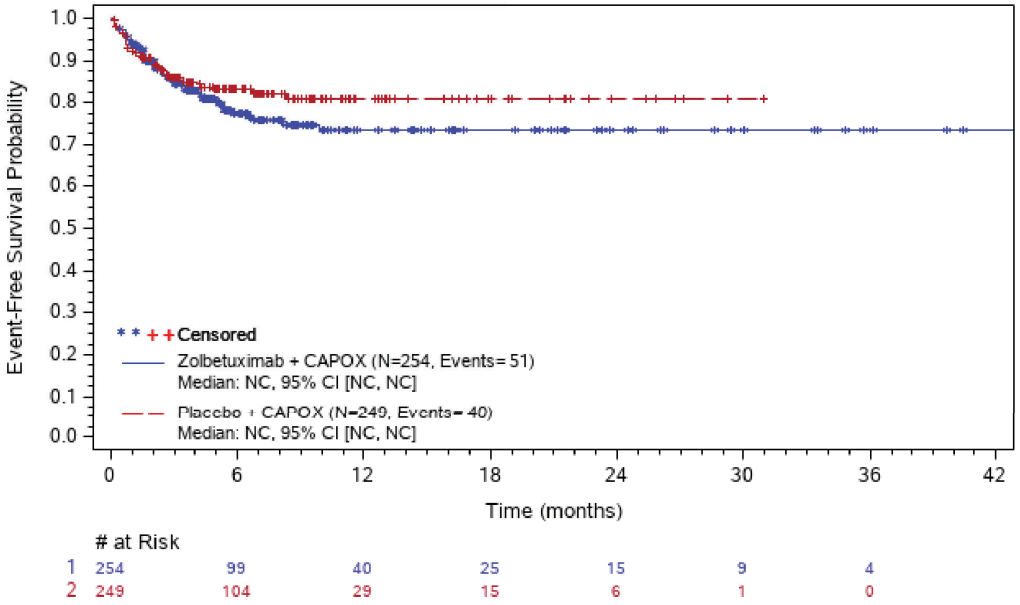
Figure 302.3.2001.58: Kaplan-Meier Plot of Time to first TEAE - Weight Increased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

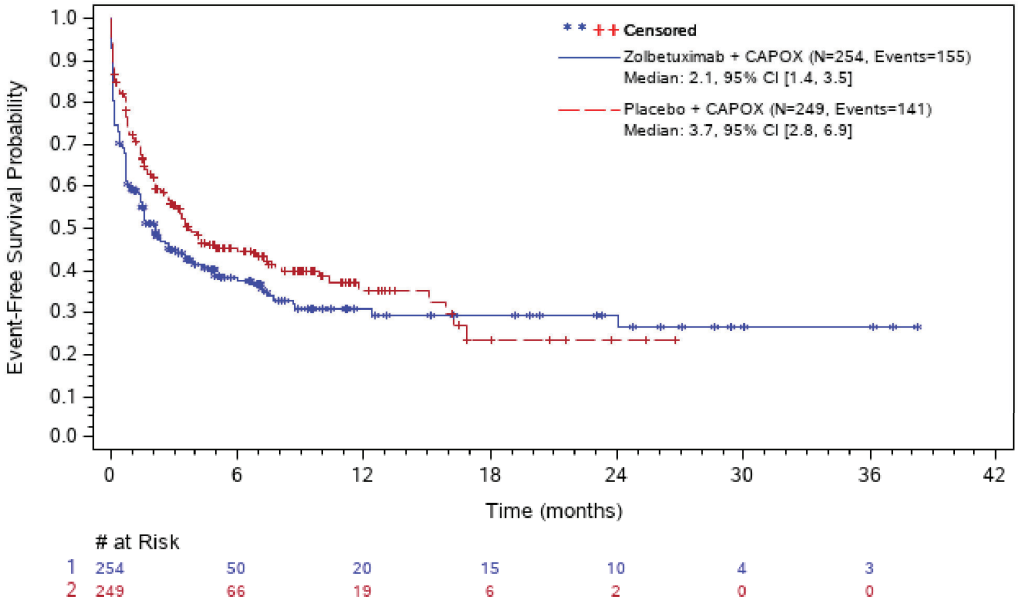
Figure 302.3.2001.59: Kaplan-Meier Plot of Time to first TEAE - White Blood Cell Count Decreased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

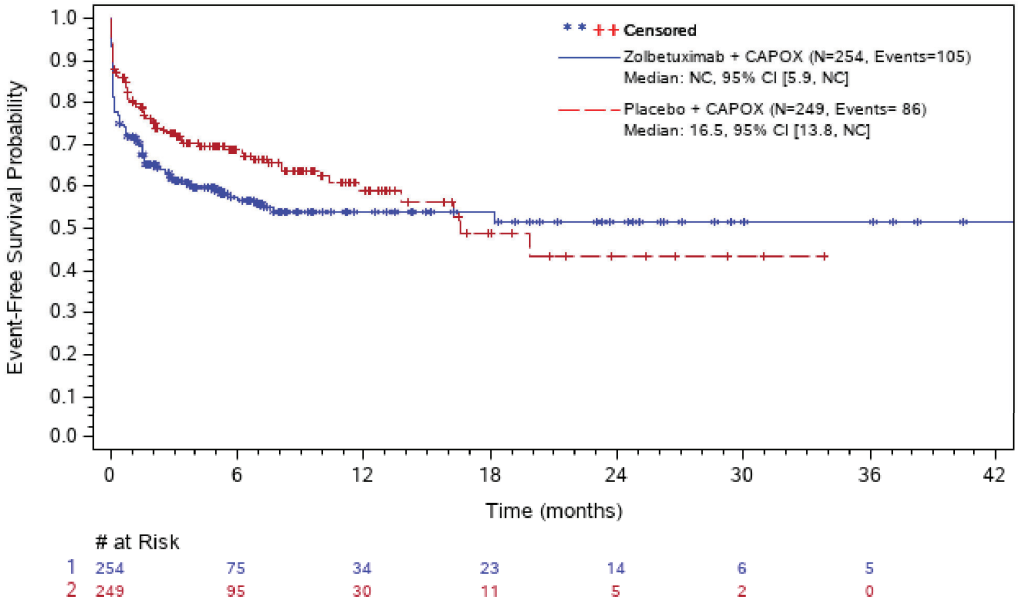
Figure 302.3.2001.60: Kaplan-Meier Plot of Time to first TEAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

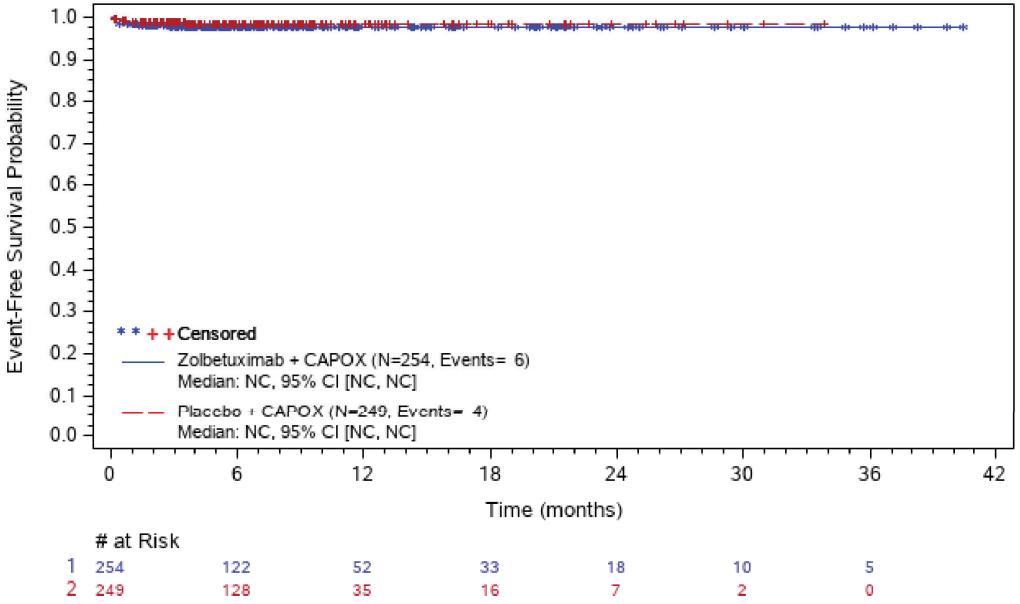
Figure 302.3.2001.61: Kaplan-Meier Plot of Time to first TEAE - Decreased Appetite (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

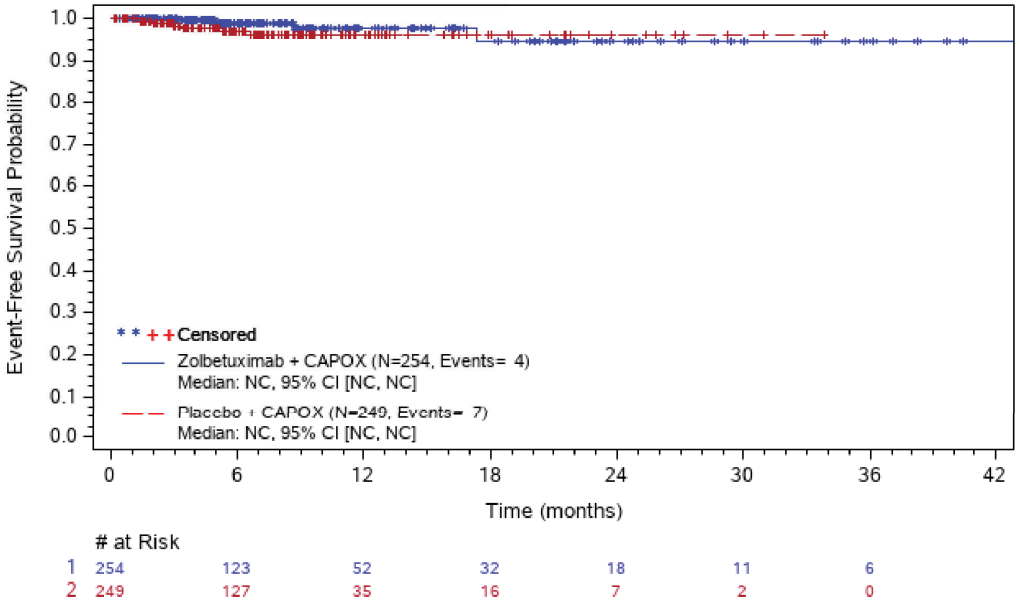
Figure 302.3.2001.62: Kaplan-Meier Plot of Time to first TEAE - Dehydration (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

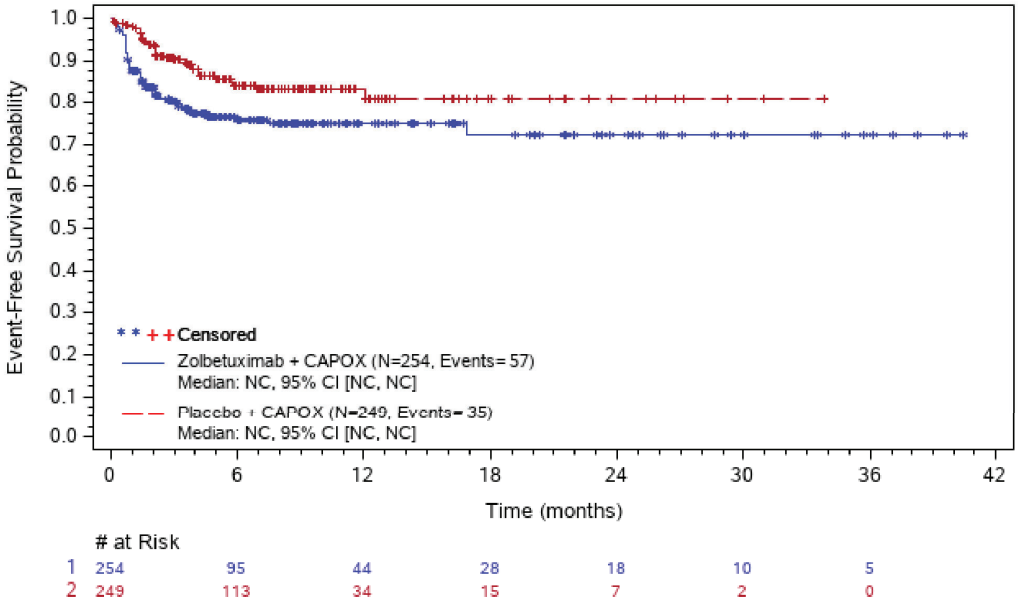
Figure 302.3.2001.63: Kaplan-Meier Plot of Time to first TEAE - Hyperuricaemia (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

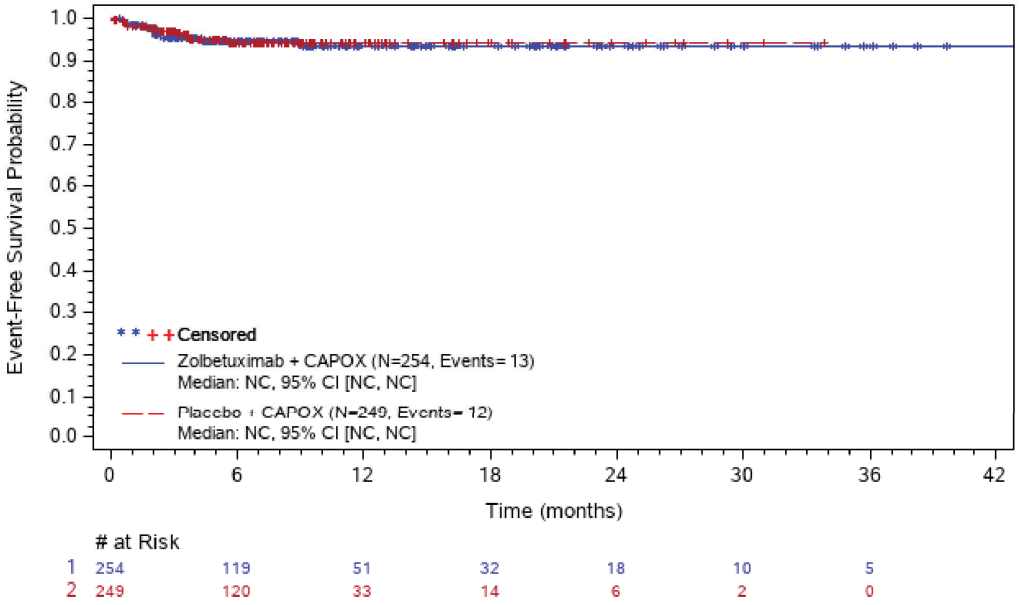
Figure 302.3.2001.64: Kaplan-Meier Plot of Time to first TEAE - Hypoalbuminaemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

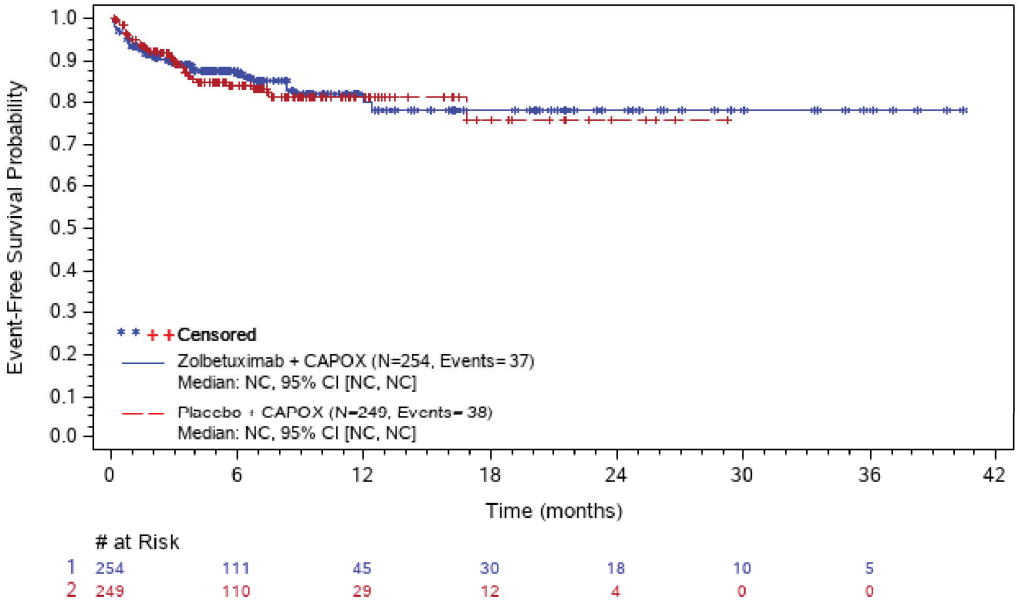
Figure 302.3.2001.65: Kaplan-Meier Plot of Time to first TEAE - Hypocalcaemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

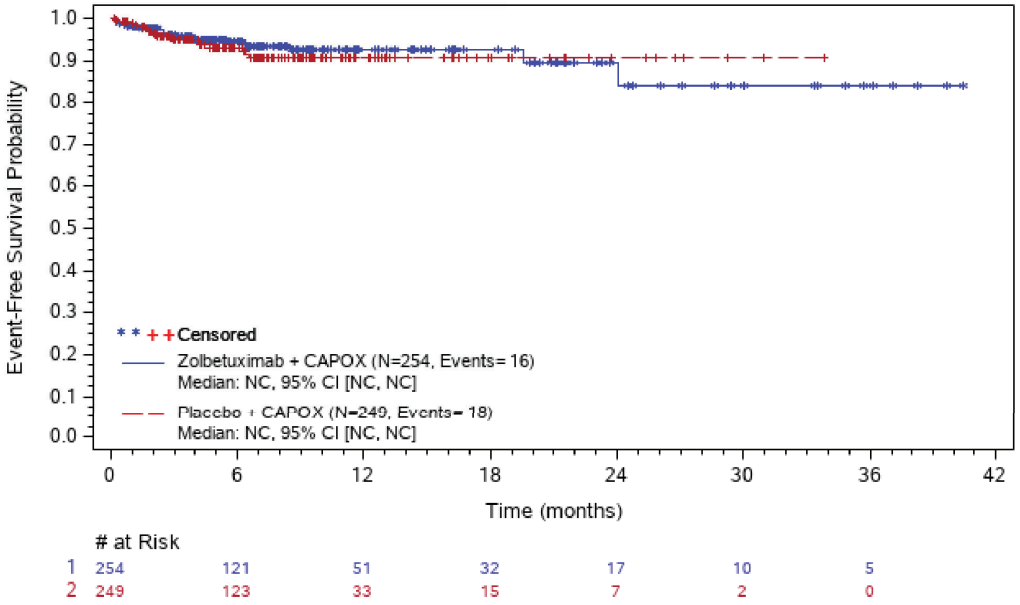
Figure 302.3.2001.66: Kaplan-Meier Plot of Time to first TEAE - Hypokalaemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.67: Kaplan-Meier Plot of Time to first TEAE - Hyponatraemia (PT) - Safety Analysis Set

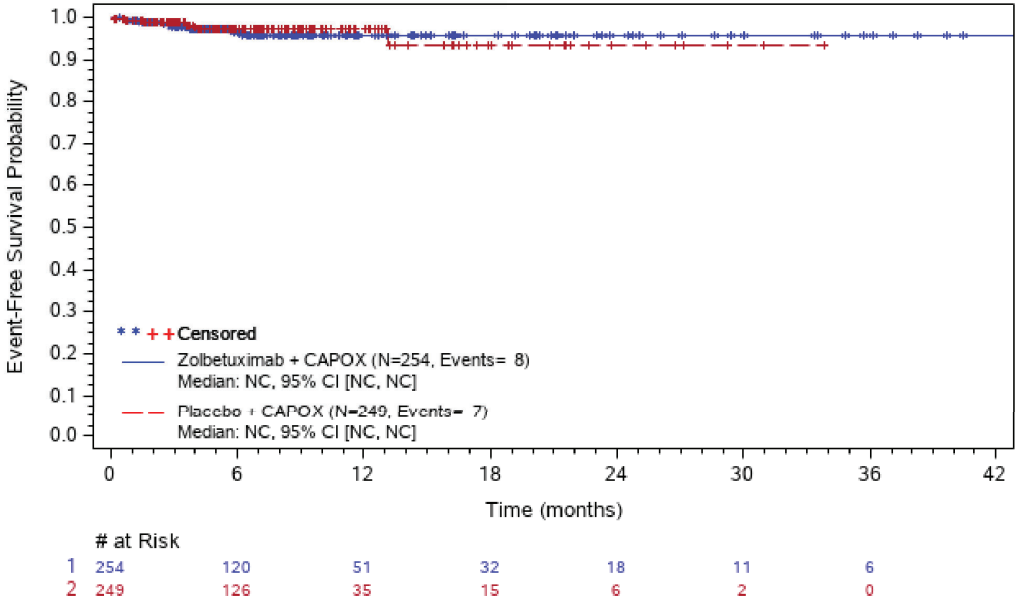


	# at Risk						
1	254	121	51	32	17	10	5
2	249	123	33	15	7	2	0

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: 12JAN24

The SAS System

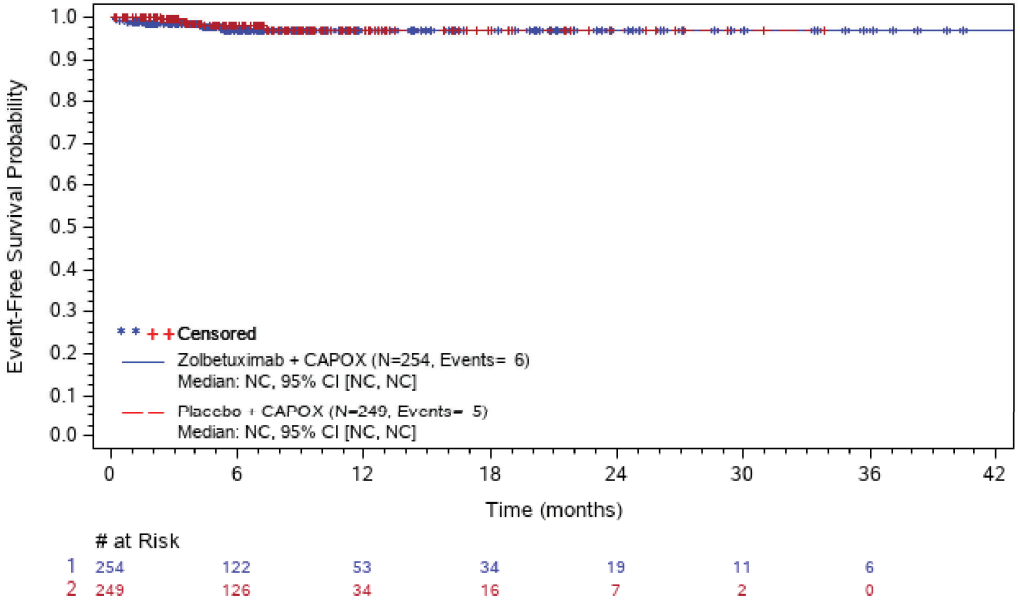
Figure 302.3.2001.68: Kaplan-Meier Plot of Time to first TEAE - Hypophosphataemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

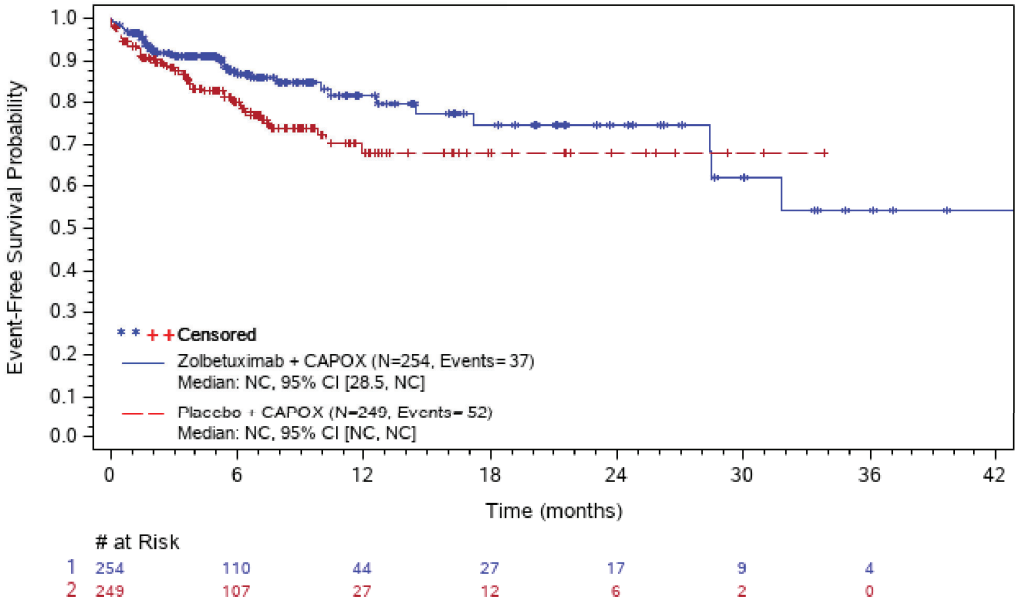
Figure 302.3.2001.69: Kaplan-Meier Plot of Time to first TEAE - Hypoproteinaemia (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

Figure 302.3.2001.70: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set

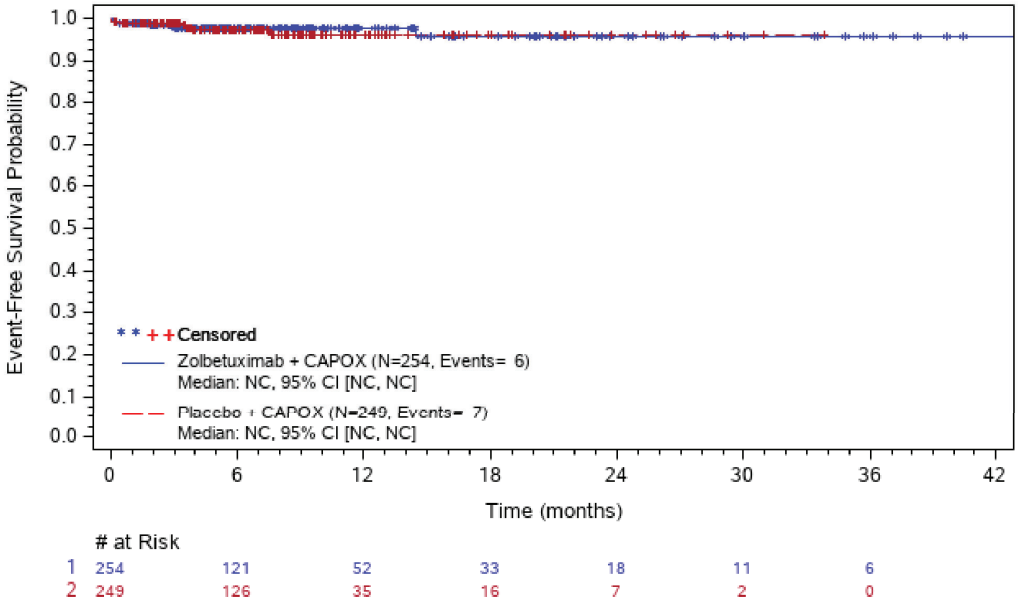


# at Risk							
1	254	110	44	27	17	9	4
2	249	107	27	12	6	2	0

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: 12JAN24

The SAS System

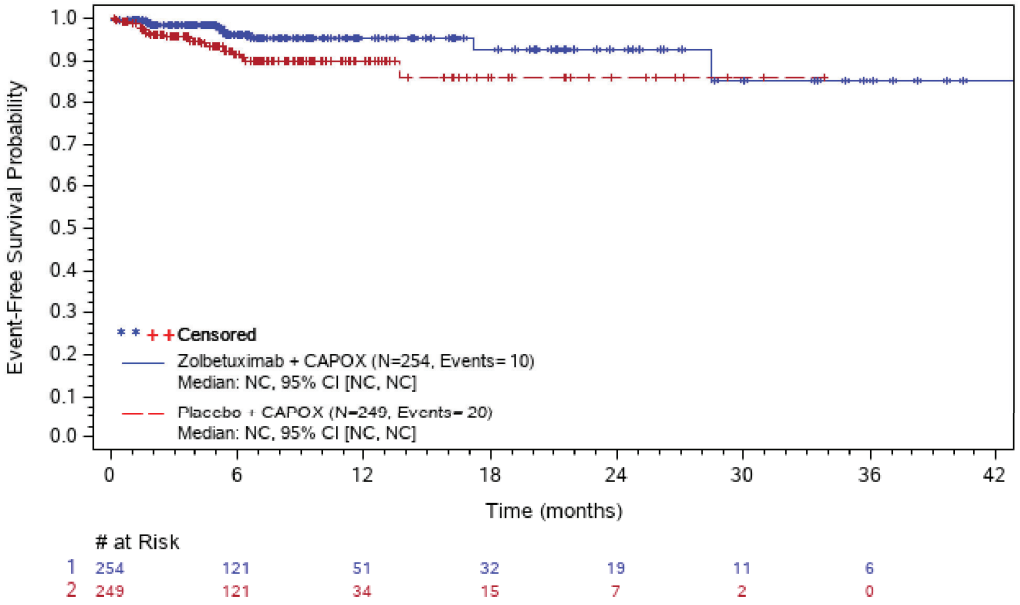
Figure 302.3.2001.71: Kaplan-Meier Plot of Time to first TEAE - Arthralgia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

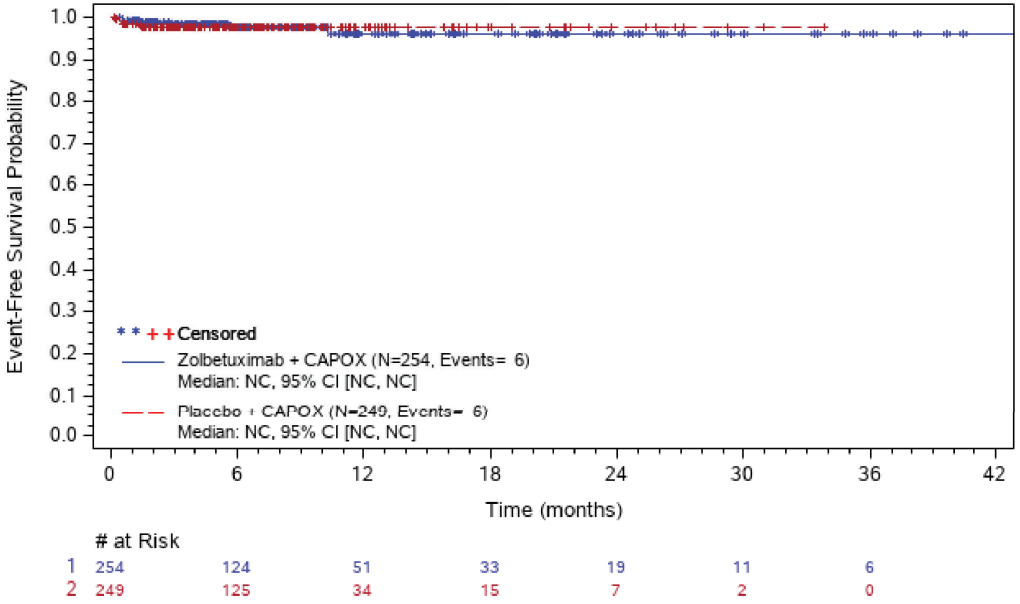
Figure 302.3.2001.72: Kaplan-Meier Plot of Time to first TEAE - Back Pain (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

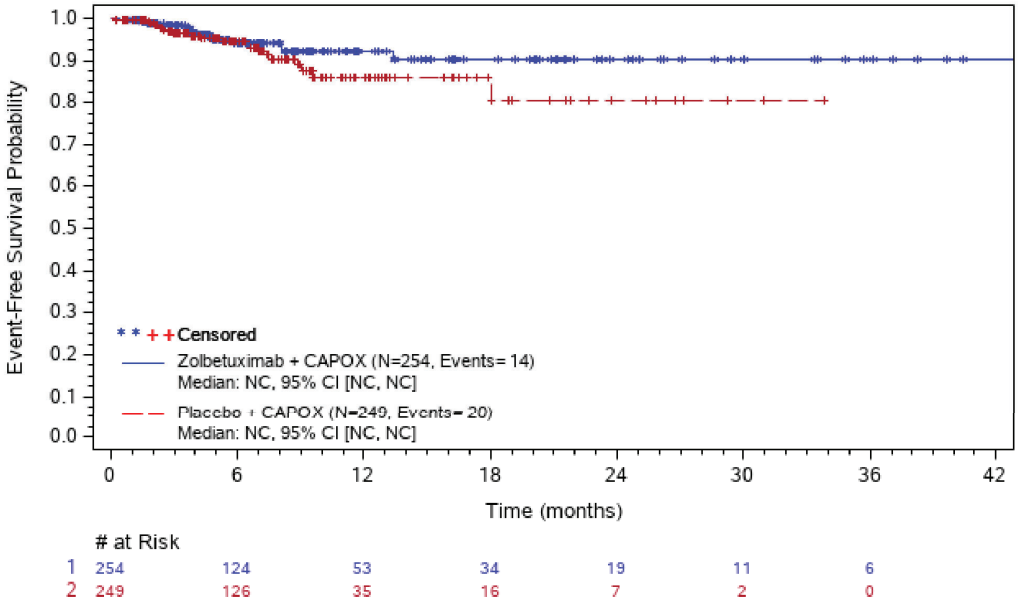
Figure 302.3.2001.73: Kaplan-Meier Plot of Time to first TEAE - Pain In Extremity (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

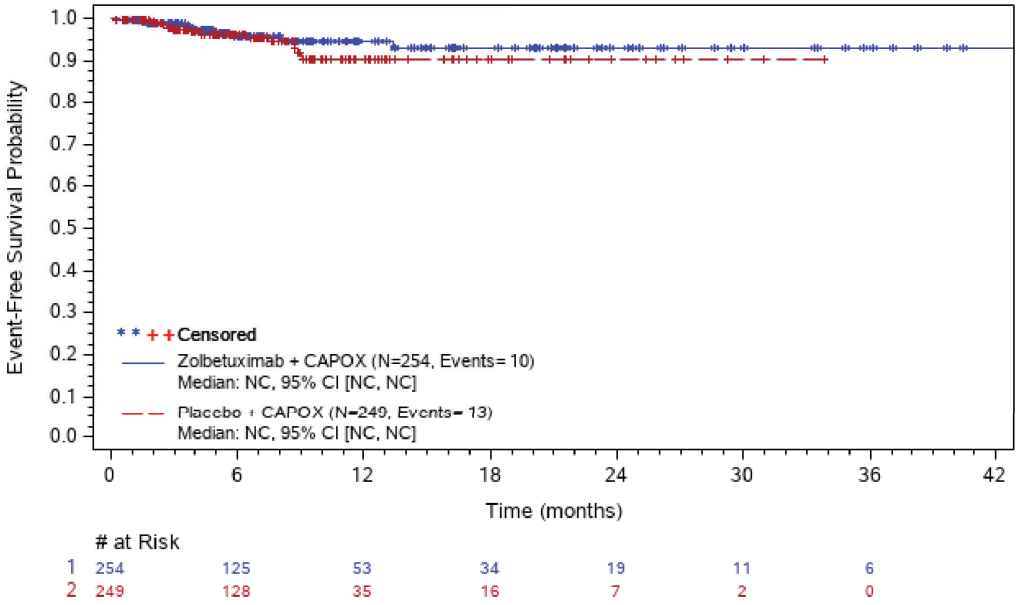
Figure 302.3.2001.74: Kaplan-Meier Plot of Time to first TEAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

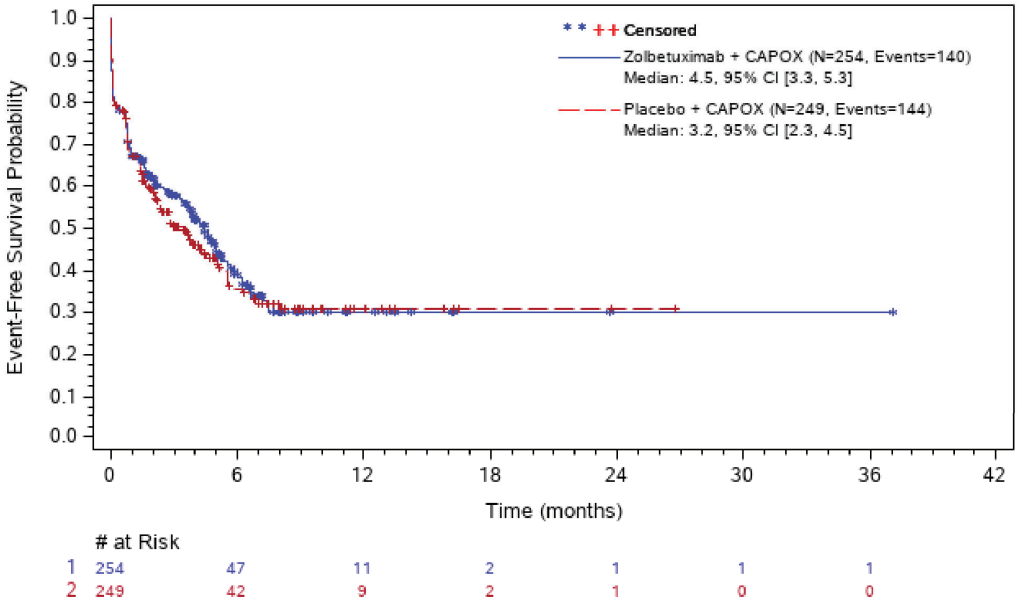
Figure 302.3.2001.75: Kaplan-Meier Plot of Time to first TEAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.76: Kaplan-Meier Plot of Time to first TEAE - Nervous System Disorders (SOC) - Safety Analysis Set

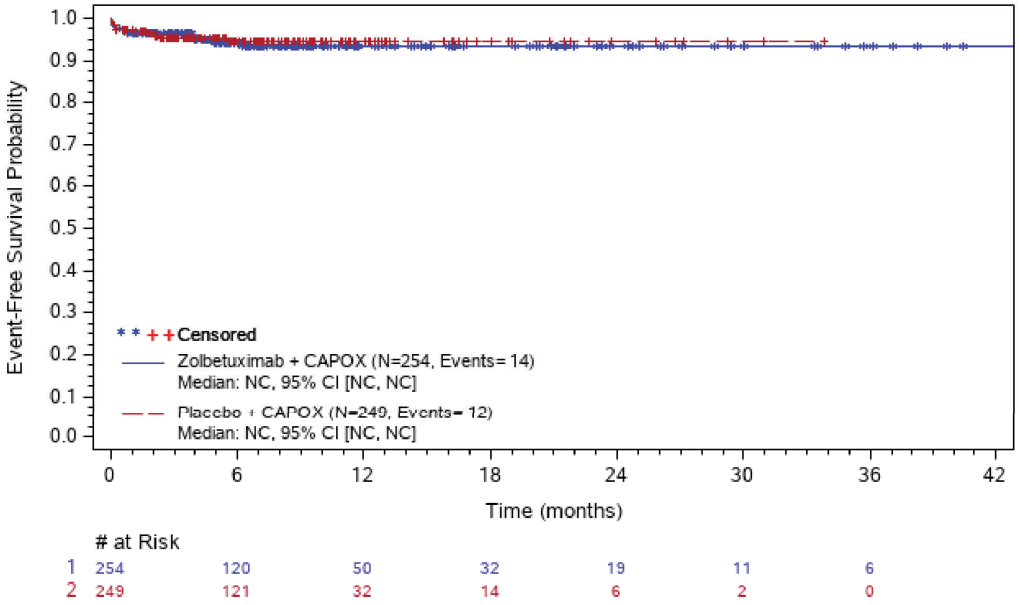


# at Risk							
1	254	47	11	2	1	1	1
2	249	42	9	2	1	0	0

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: 12JAN24

The SAS System

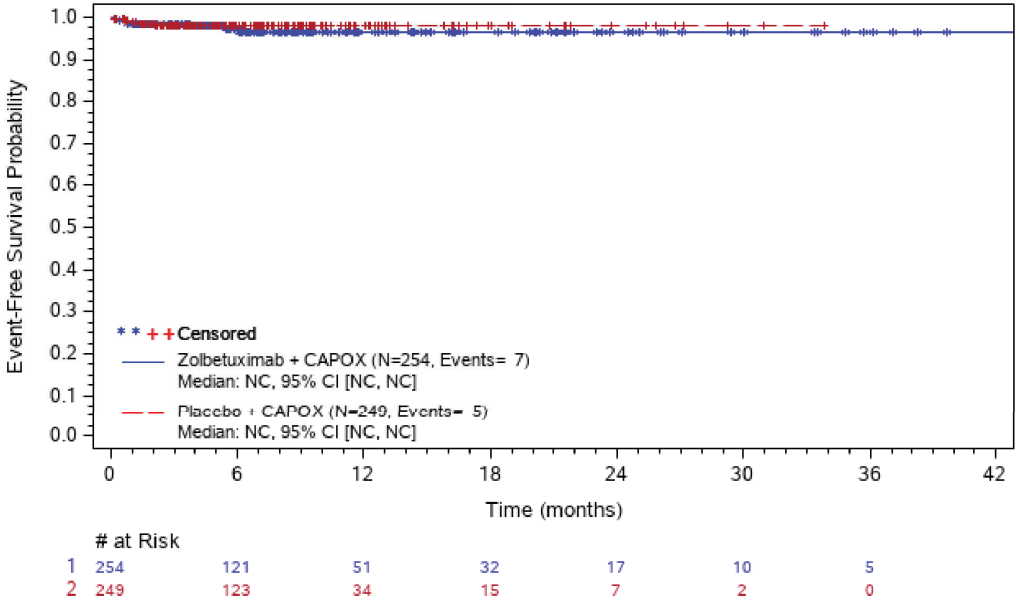
Figure 302.3.2001.77: Kaplan-Meier Plot of Time to first TEAE - Dizziness (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

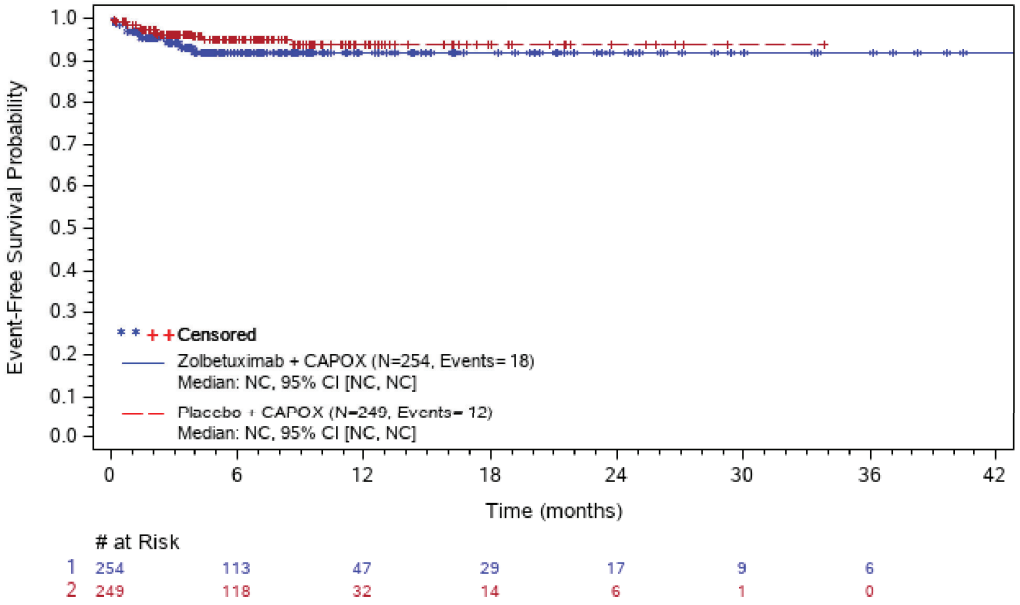
Figure 302.3.2001.78: Kaplan-Meier Plot of Time to first TEAE - Dysaesthesia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

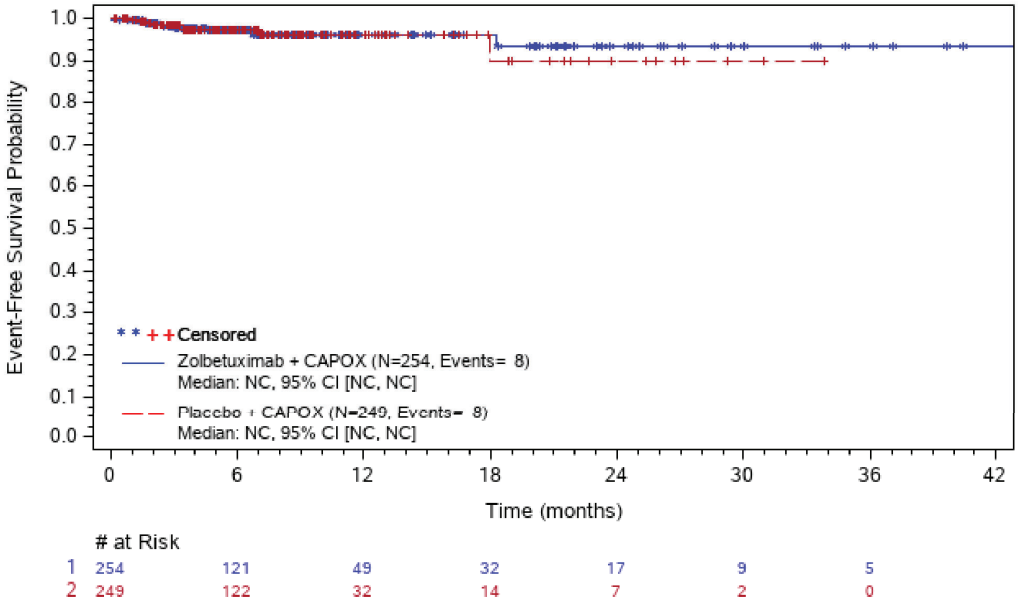
Figure 302.3.2001.79: Kaplan-Meier Plot of Time to first TEAE - Dysgeusia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

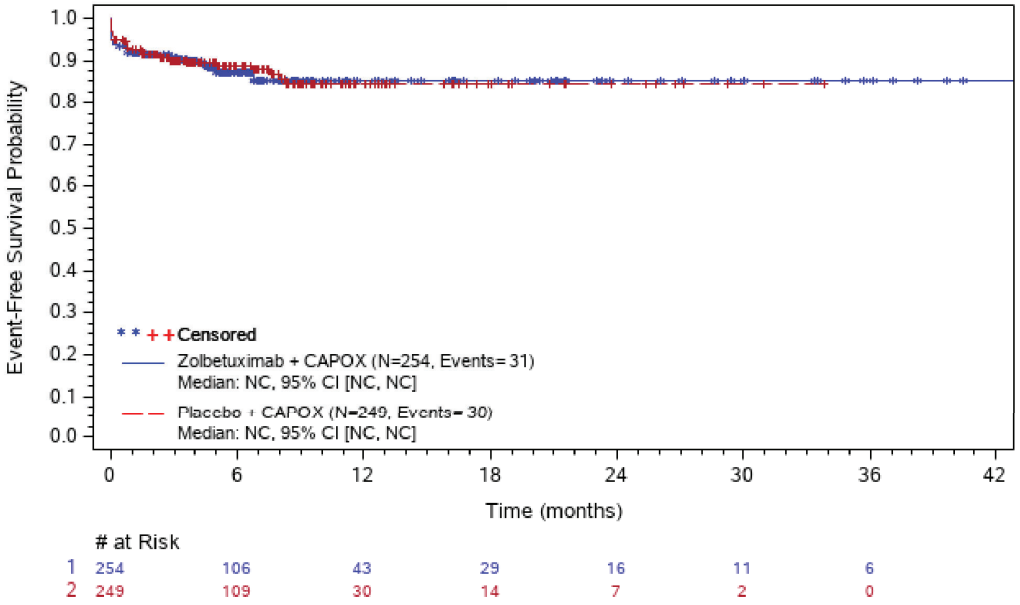
Figure 302.3.2001.80: Kaplan-Meier Plot of Time to first TEAE - Headache (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

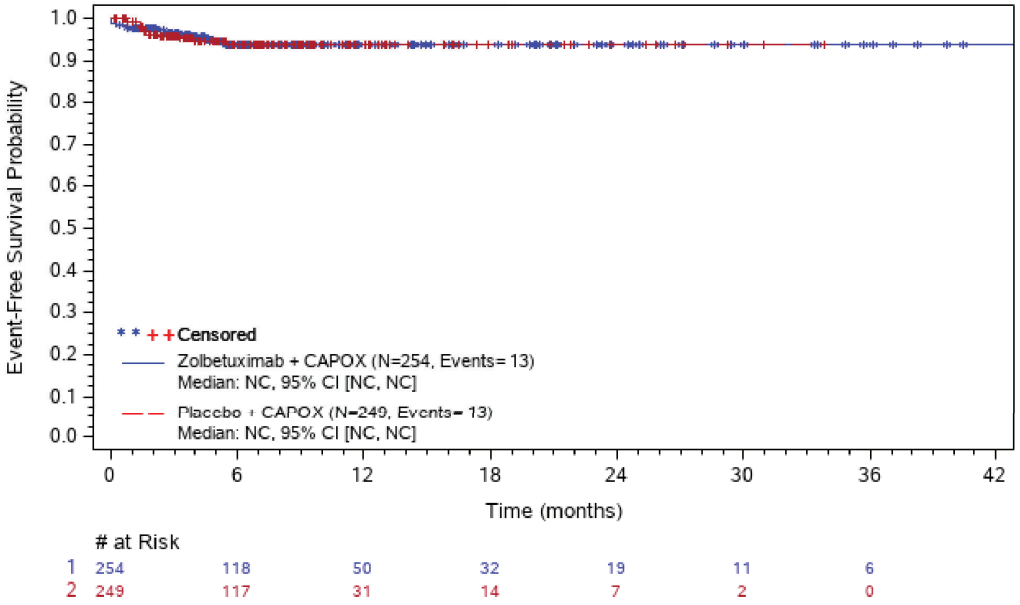
Figure 302.3.2001.81: Kaplan-Meier Plot of Time to first TEAE - Hypoaesthesia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.82: Kaplan-Meier Plot of Time to first TEAE - Neuropathy Peripheral (PT) - Safety Analysis Set

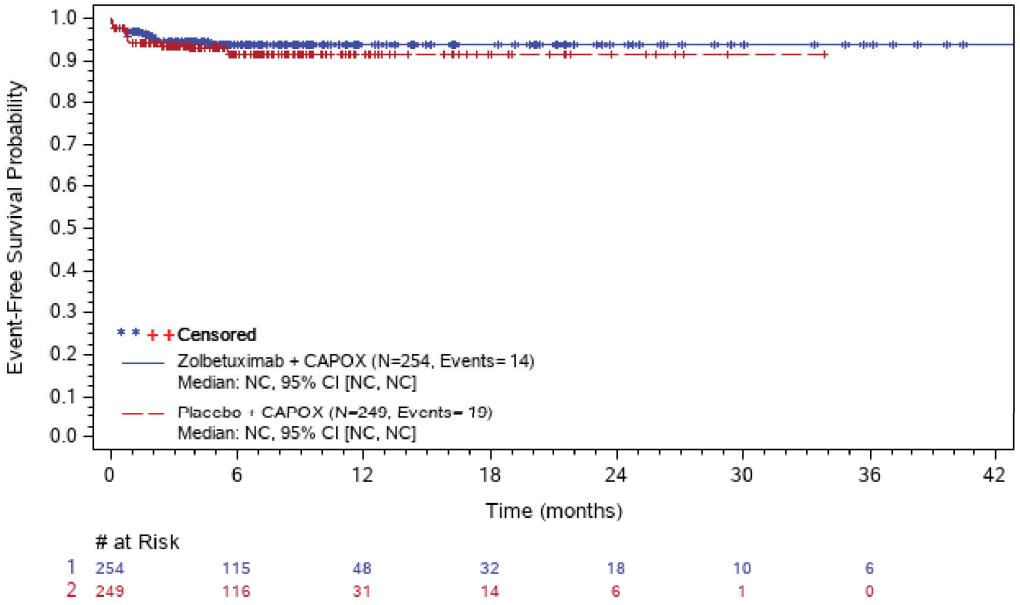


# at Risk							
1	254	118	50	32	19	11	6
2	249	117	31	14	7	2	0

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: 12JAN24

The SAS System

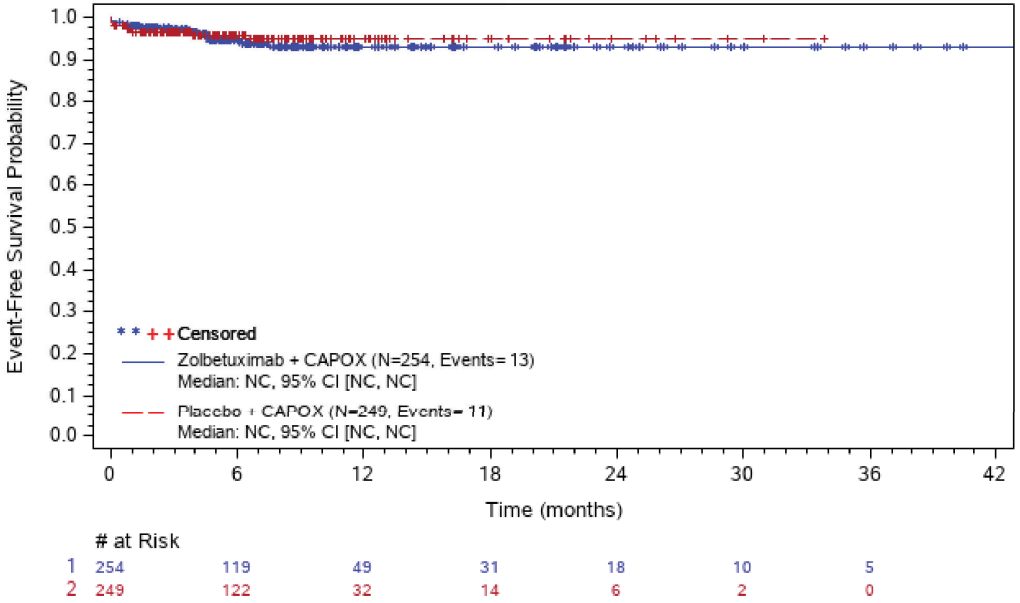
Figure 302.3.2001.83: Kaplan-Meier Plot of Time to first TEAE - Neurotoxicity (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

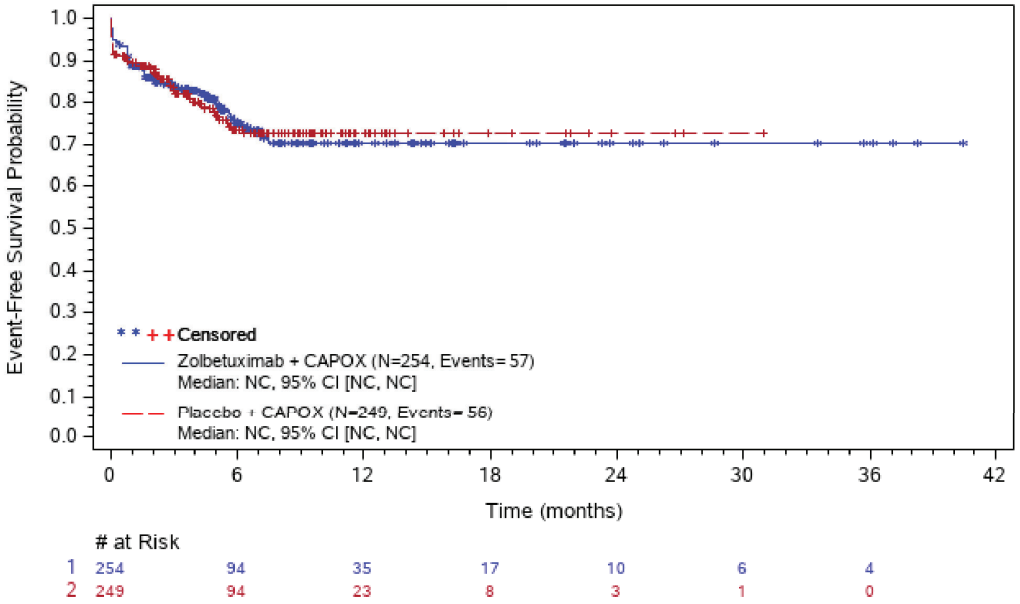
Figure 302.3.2001.84: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.85: Kaplan-Meier Plot of Time to first TEAE - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

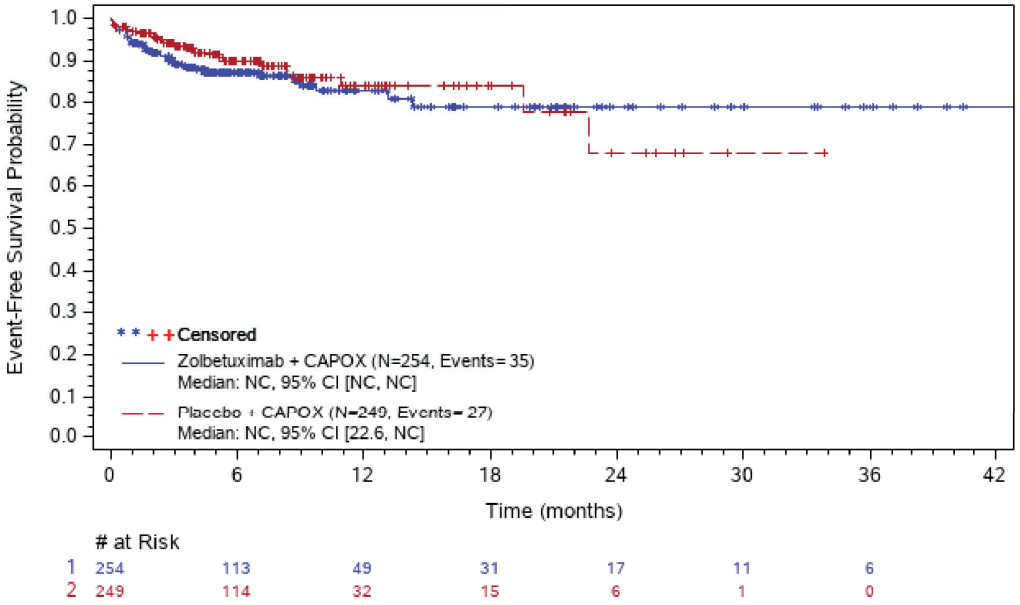


# at Risk							
1	254	94	35	17	10	6	4
2	249	94	23	8	3	1	0

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: 12JAN24

The SAS System

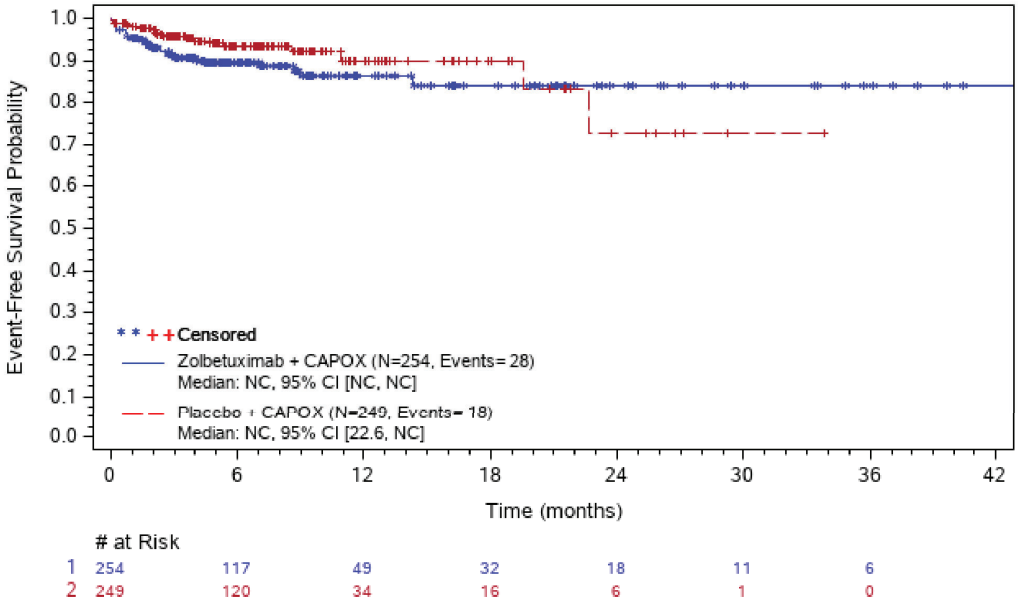
Figure 302.3.2001.86: Kaplan-Meier Plot of Time to first TEAE - Psychiatric Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

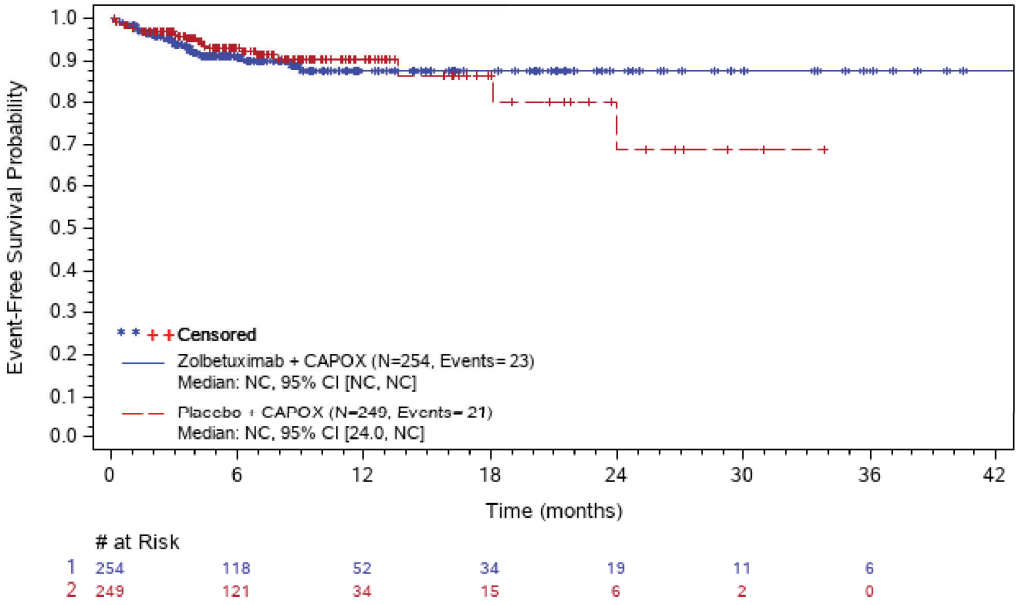
Figure 302.3.2001.87: Kaplan-Meier Plot of Time to first TEAE - Insomnia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

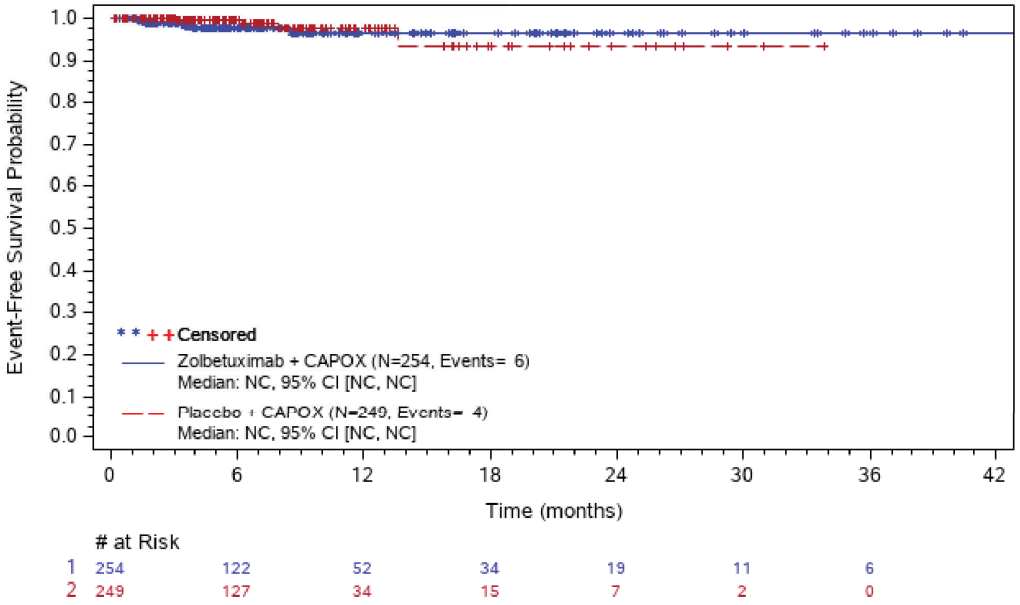
Figure 302.3.2001.88: Kaplan-Meier Plot of Time to first TEAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

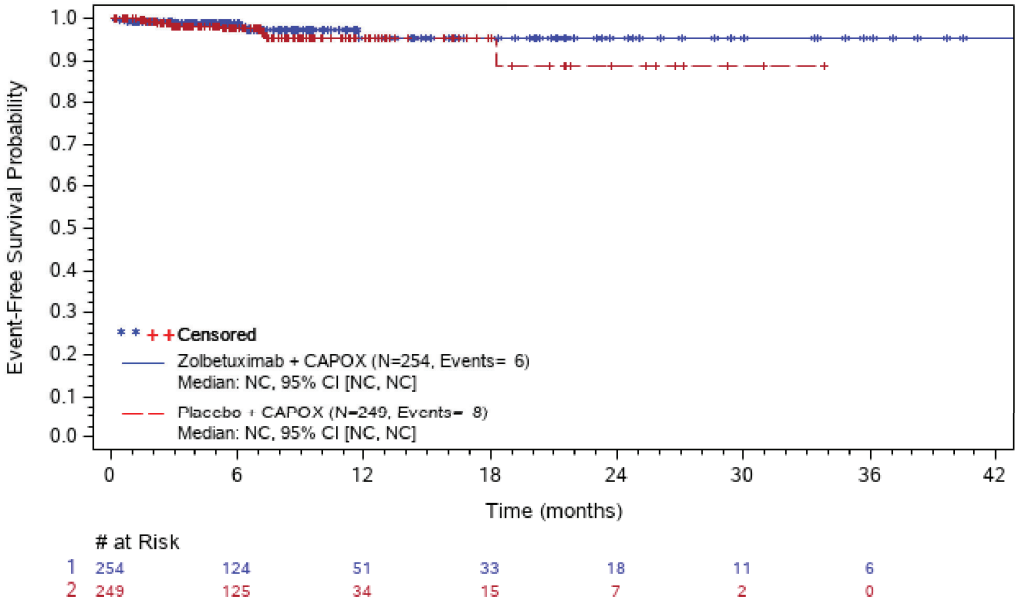
Figure 302.3.2001.89: Kaplan-Meier Plot of Time to first TEAE - Proteinuria (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

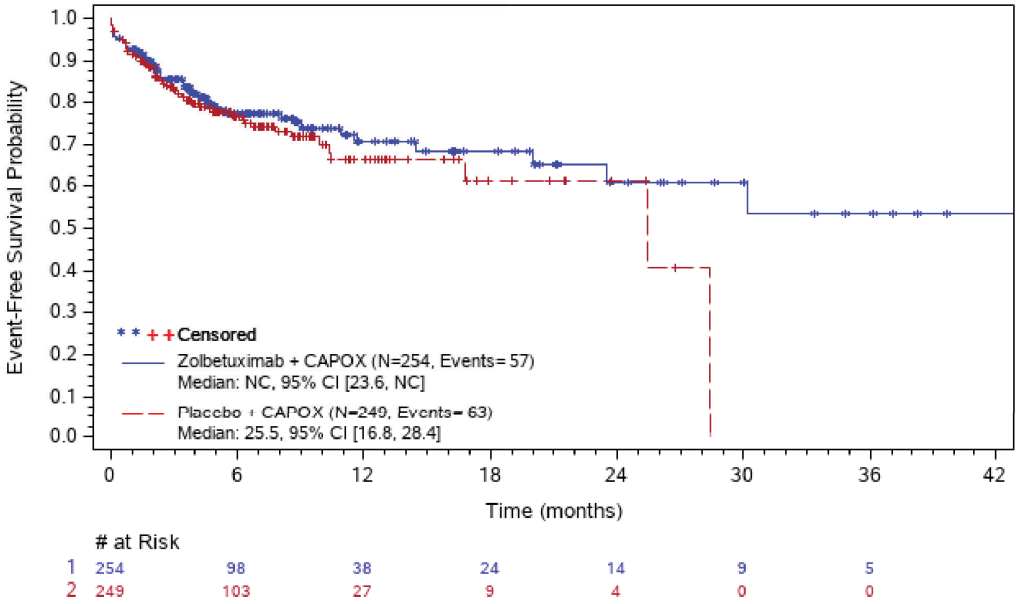
Figure 302.3.2001.90: Kaplan-Meier Plot of Time to first TEAE - Reproductive System And Breast Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

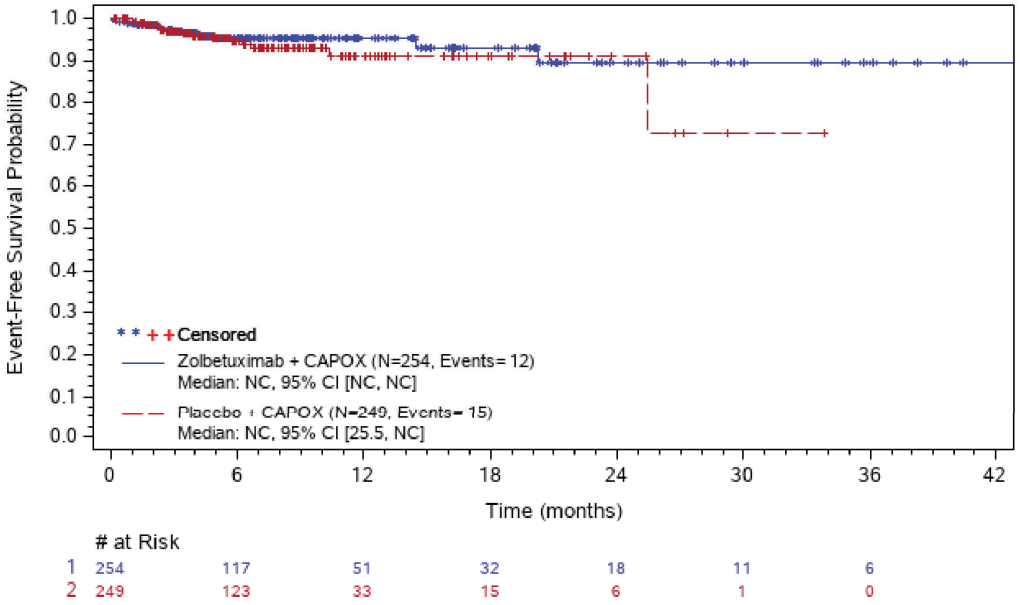
Figure 302.3.2001.91: Kaplan-Meier Plot of Time to first TEAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

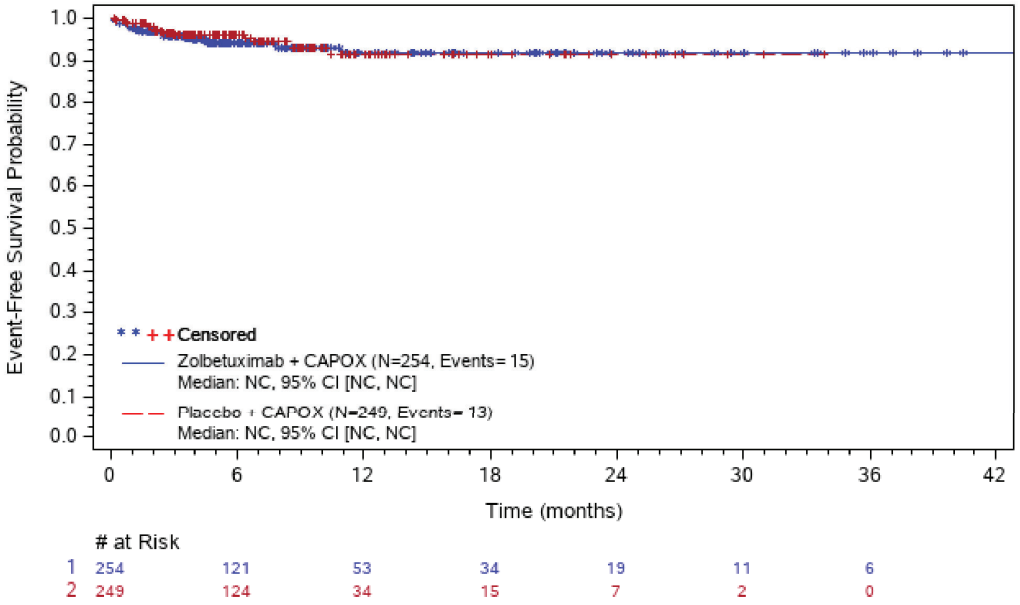
Figure 302.3.2001.92: Kaplan-Meier Plot of Time to first TEAE - Cough (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

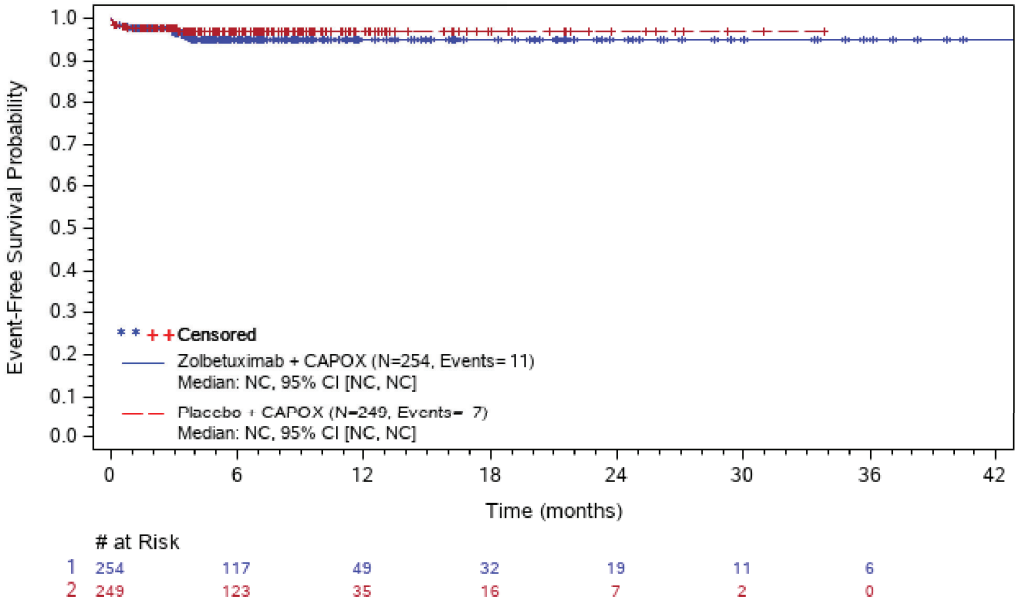
Figure 302.3.2001.93: Kaplan-Meier Plot of Time to first TEAE - Dyspnoea (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

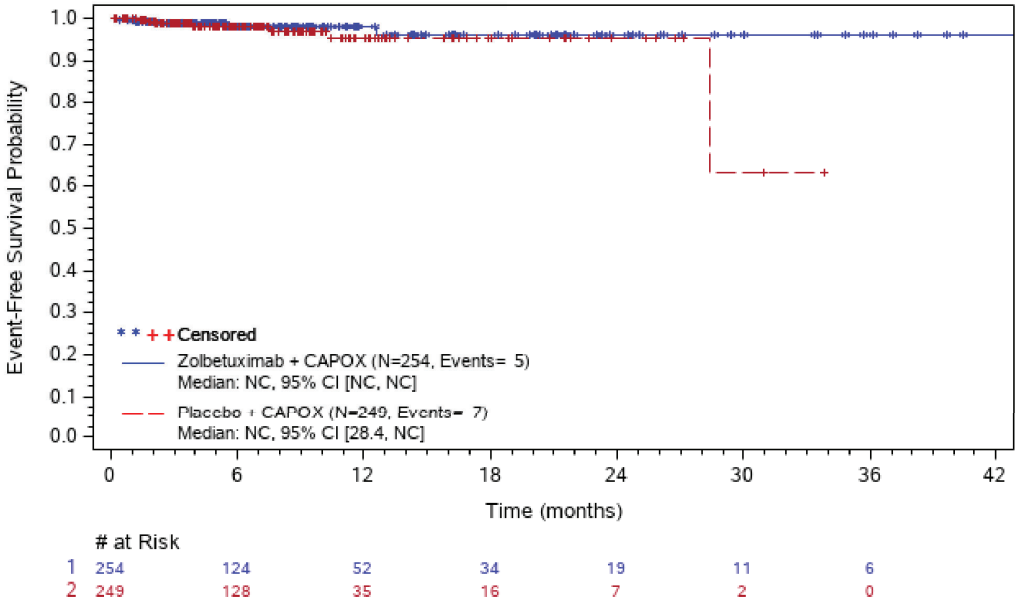
Figure 302.3.2001.94: Kaplan-Meier Plot of Time to first TEAE - Hiccups (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

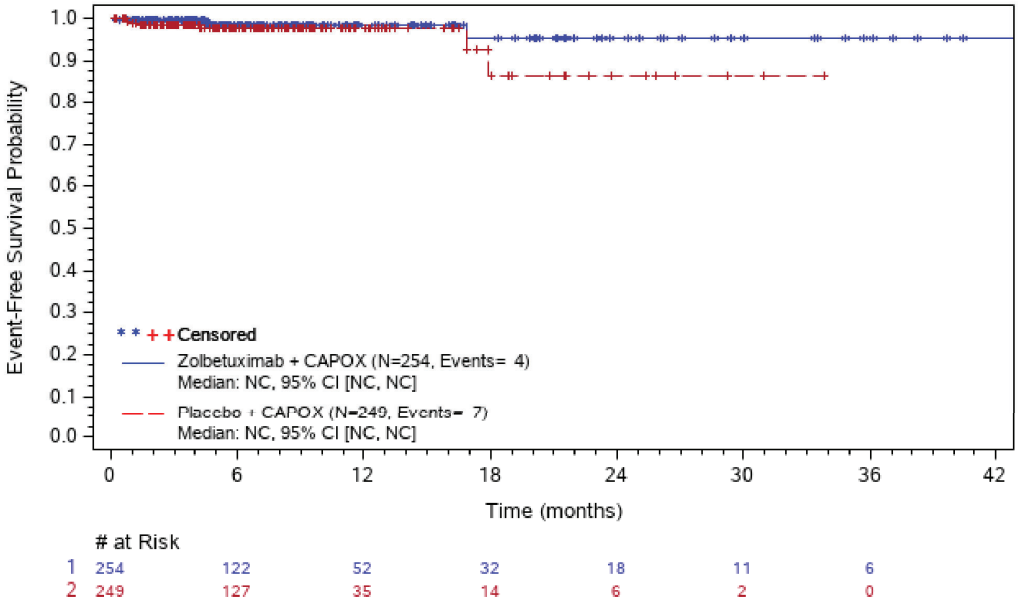
Figure 302.3.2001.95: Kaplan-Meier Plot of Time to first TEAE - Pleural Effusion (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

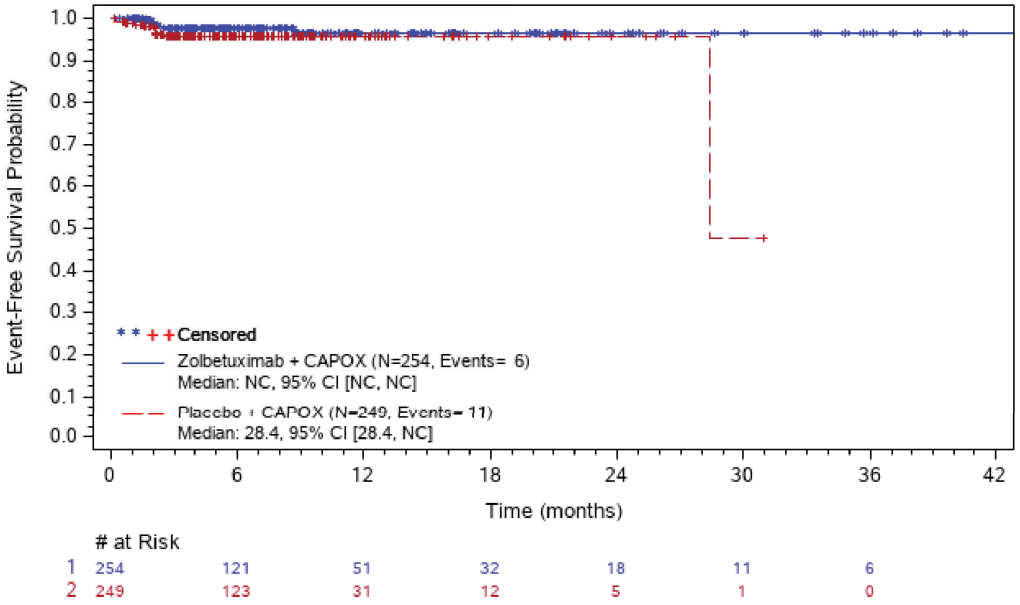
Figure 302.3.2001.96: Kaplan-Meier Plot of Time to first TEAE - Productive Cough (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

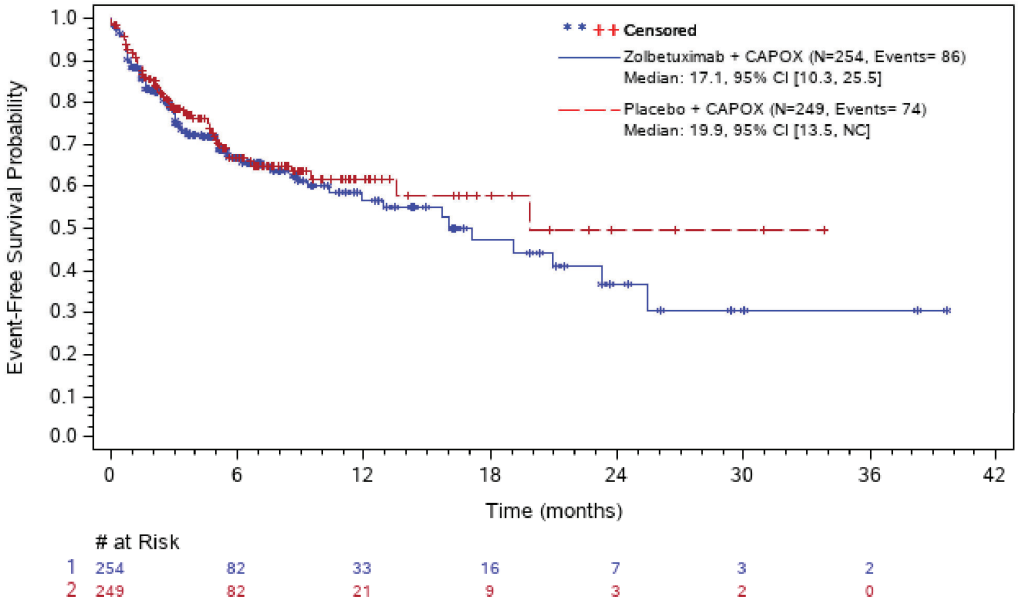
Figure 302.3.2001.97: Kaplan-Meier Plot of Time to first TEAE - Pulmonary Embolism (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

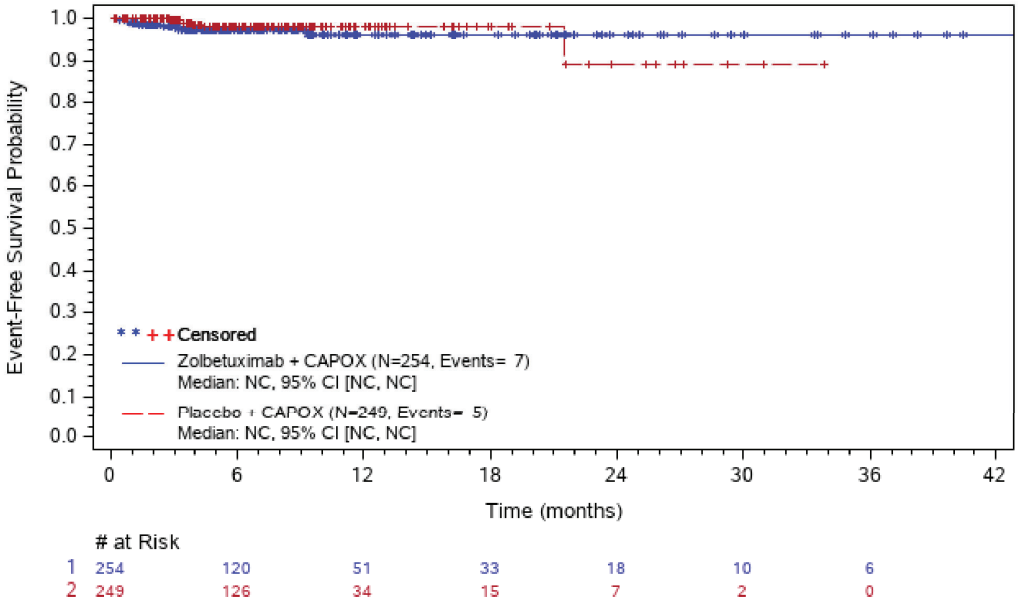
Figure 302.3.2001.98: Kaplan-Meier Plot of Time to first TEAE - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

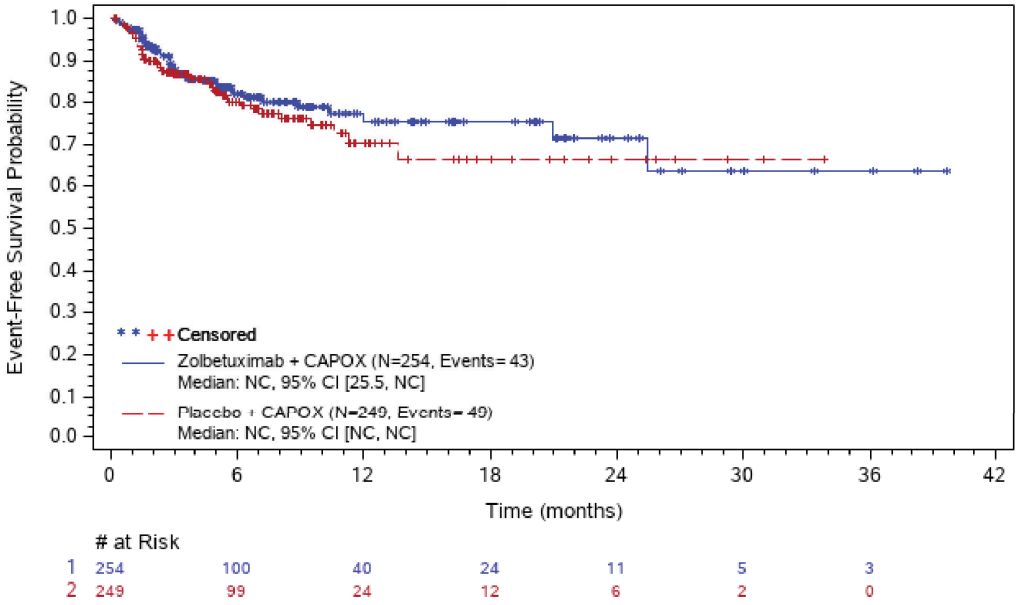
Figure 302.3.2001.99: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.100: Kaplan-Meier Plot of Time to first TEAE - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

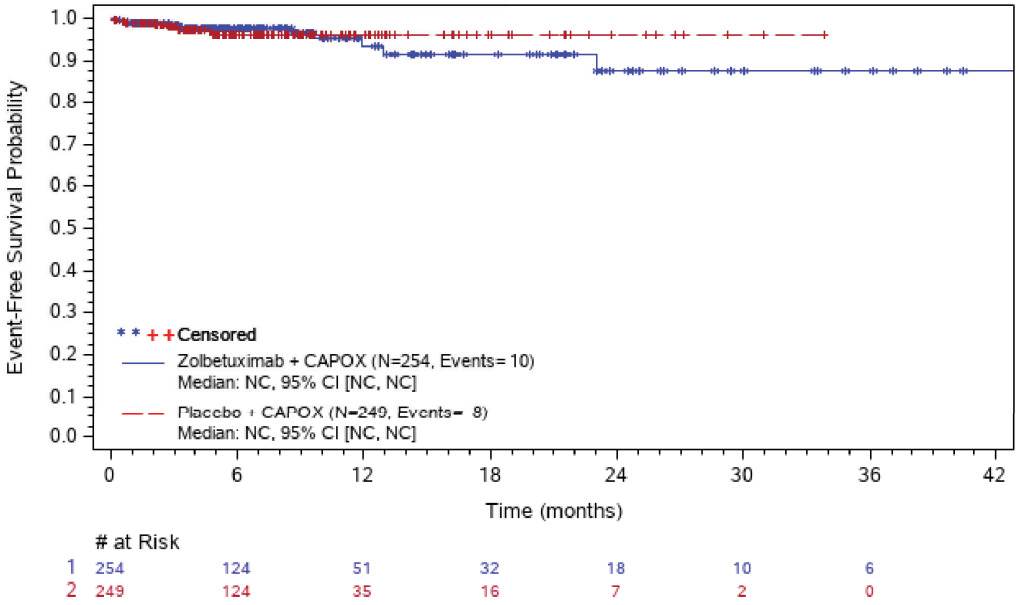


# at Risk							
1	254	100	40	24	11	5	3
2	249	99	24	12	6	2	0

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: 12JAN24

The SAS System

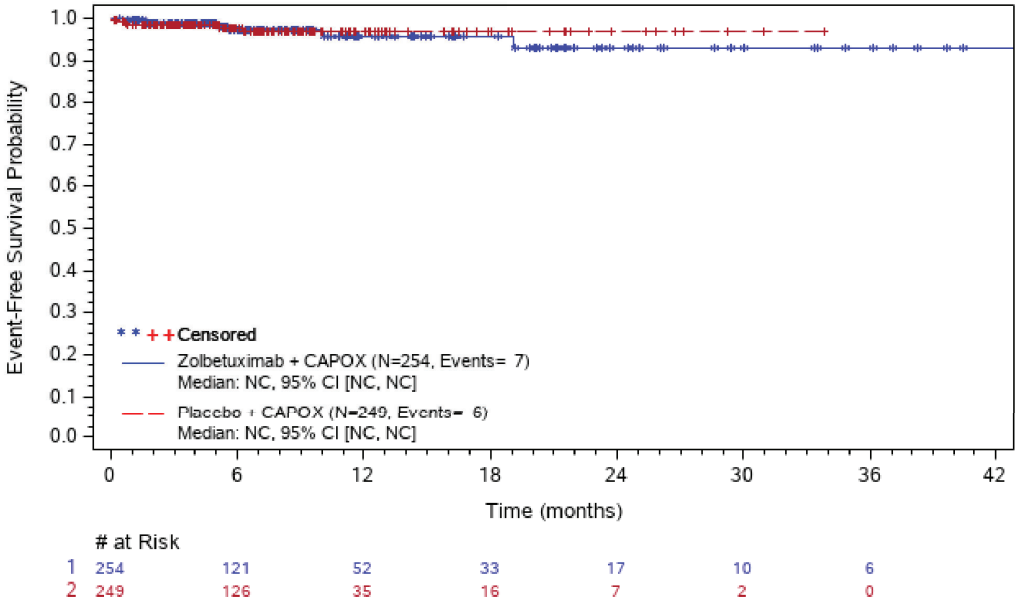
Figure 302.3.2001.101: Kaplan-Meier Plot of Time to first TEAE - Pruritus (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

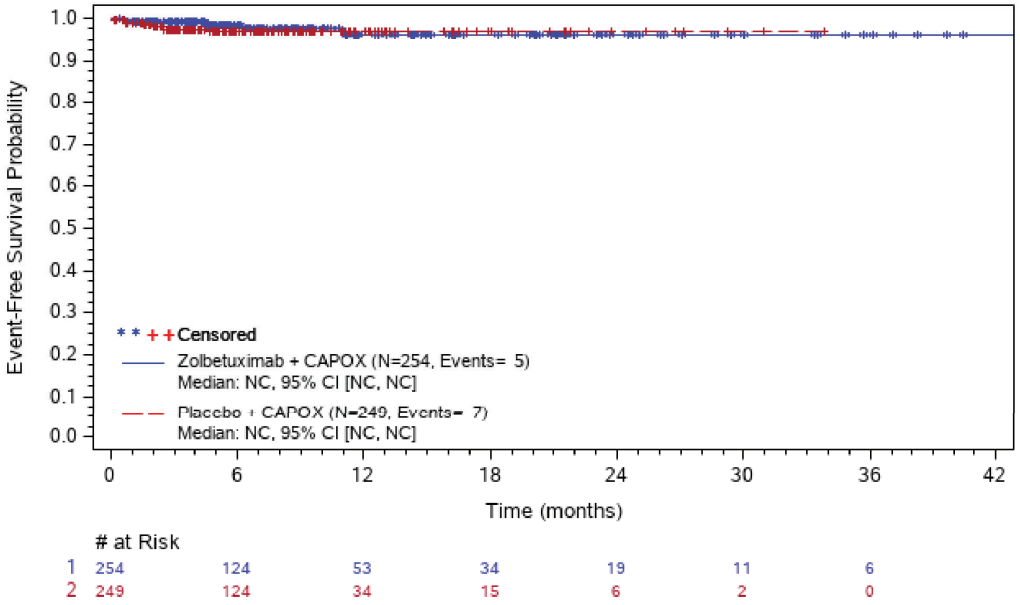
Figure 302.3.2001.102: Kaplan-Meier Plot of Time to first TEAE - Rash (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

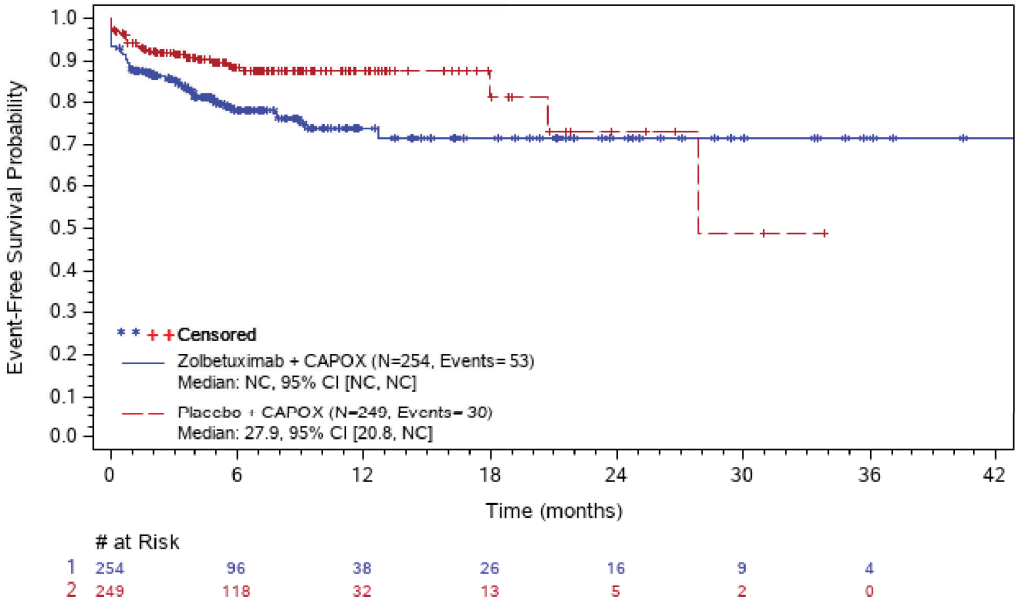
Figure 302.3.2001.103: Kaplan-Meier Plot of Time to first TEAE - Rash Maculo-Papular (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.104: Kaplan-Meier Plot of Time to first TEAE - Vascular Disorders (SOC) - Safety Analysis Set

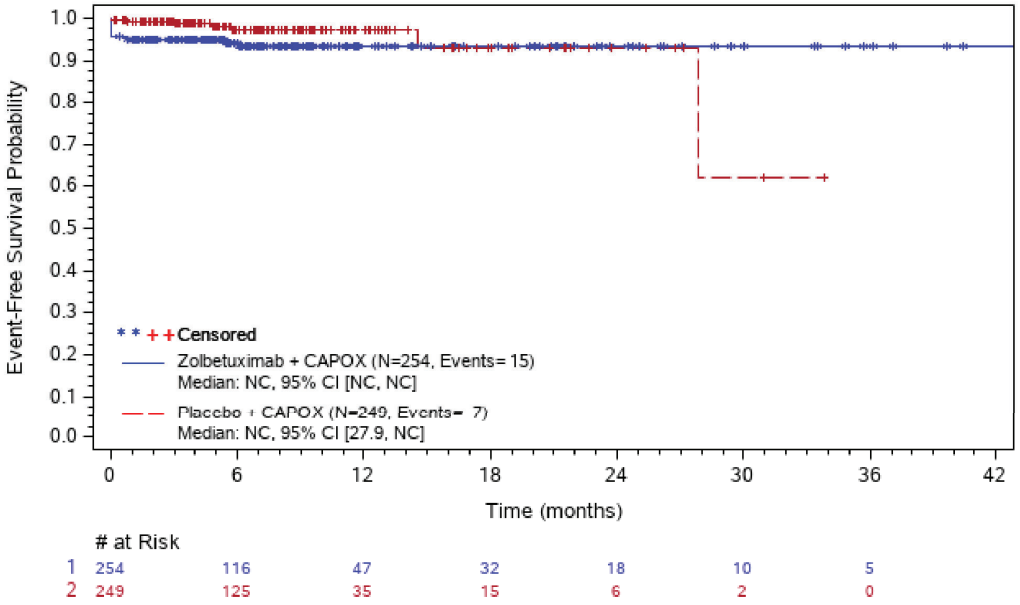


# at Risk							
1	254	96	38	26	16	9	4
2	249	118	32	13	5	2	0

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: 12JAN24

The SAS System

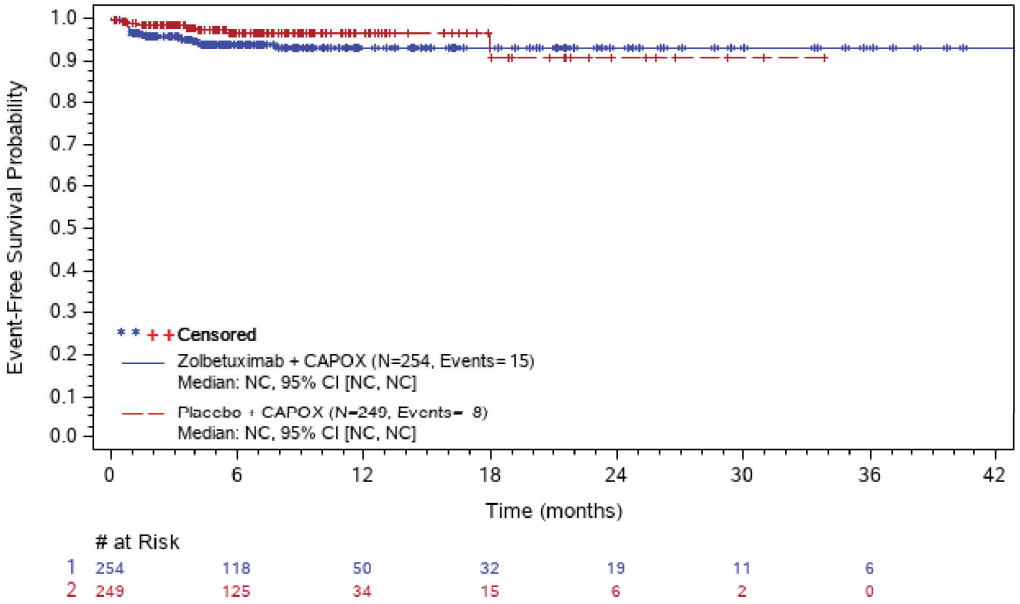
Figure 302.3.2001.105: Kaplan-Meier Plot of Time to first TEAE - Hypertension (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.106: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwere unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 302.3.2001.131.1: Summary and Results of Severe TEAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	51 (20.1%)	44 (17.7%)	
Number of patients censored	203 (79.9%)	205 (82.3%)	
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			1.073 [0.714, 1.612]
Log-rank test			
Two-sided stratified log-rank p-value			0.7333

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.132.1: Summary and Results of Severe TEAEs - Anaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	29 (11.4%)	28 (11.2%)	
Number of patients censored	225 (88.6%)	221 (88.8%)	
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			0.920 [0.543, 1.557]
Log-rank test			
Two-sided stratified log-rank p-value			0.7573

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.133.1: Summary and Results of Severe TEAEs - Neutropenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	18 (7.1%)	7 (2.8%)	
Number of patients censored	236 (92.9%)	242 (97.2%)	
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			2.549 [1.062, 6.117]
Log-rank test			
Two-sided stratified log-rank p-value			0.0300

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.133.2: Summary and Results of Severe TEAEs by Subgroups - Neutropenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	11 (6.3)	NC [NC, NC]	177	4 (2.3)	NC [NC, NC]	2.765 [0.880, 8.686]	0.0691	0.9255
>65 years	78	7 (9.0)	NC [NC, NC]	72	3 (4.2)	NC [NC, NC]	2.525 [0.652, 9.779]	0.1651	
Sex									
Male	160	8 (5.0)	NC [NC, NC]	152	4 (2.6)	NC [NC, NC]	1.774 [0.533, 5.903]	0.3438	0.4189
Female	94	10 (10.6)	NC [NC, NC]	97	3 (3.1)	NC [NC, NC]	3.864 [1.063, 14.052]	0.0270	
Region									
Asia	157	8 (5.1)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	2.484 [0.657, 9.398]	0.1658	0.9652
Non-Asia	97	10 (10.3)	NC [NC, NC]	93	4 (4.3)	NC [NC, NC]	2.679 [0.840, 8.547]	0.0832	
Number of Organs with Metastatic Sites									
0-2	190	13 (6.8)	NC [NC, NC]	186	6 (3.2)	NC [NC, NC]	2.202 [0.836, 5.798]	0.1012	0.5254
>=3	64	5 (7.8)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	4.707 [0.549, 40.335]	0.1192	

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: 12JAN24

Table 302.3.2001.134.1: Summary and Results of Severe TEAEs - Thrombocytopenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	7 (2.8%)	
Number of patients censored	247 (97.2%)	242 (97.2%)	
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			1.028 [0.359, 2.938]
Log-rank test			
Two-sided stratified log-rank p-value			0.9596

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.135.1: Summary and Results of Severe TEAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	75 (29.5%)	62 (24.9%)	
Number of patients censored	179 (70.5%)	187 (75.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [16.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.269 [0.905, 1.778]
Log-rank test			
Two-sided stratified log-rank p-value			0.1765

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.136.1: Summary and Results of Severe TEAEs - Ascites (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	8 (3.2%)	
Number of patients censored	249 (98.0%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.465 [0.140, 1.549]
Log-rank test			
Two-sided stratified log-rank p-value			0.2012

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.137.1: Summary and Results of Severe TEAEs - Diarrhoea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	18 (7.2%)	
Number of patients censored	239 (94.1%)	231 (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			0.813 [0.409, 1.615]
Log-rank test			
Two-sided stratified log-rank p-value			0.5534

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.138.1: Summary and Results of Severe TEAEs - Nausea (PT) - Safety Analysis Set

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

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.138.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	15 (8.5)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	3.117 [1.133, 8.577]	0.0204	0.5092
>65 years	78	7 (9.0)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	6.790 [0.835, 55.195]	0.0378	
Sex									
Male	160	14 (8.8)	NC [NC, NC]	152	3 (2.0)	NC [NC, NC]	4.600 [1.322, 16.007]	0.0084	0.6162
Female	94	8 (8.5)	NC [NC, NC]	97	3 (3.1)	NC [NC, NC]	2.870 [0.761, 10.821]	0.1037	
Region									
Asia	157	15 (9.6)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	5.221 [1.512, 18.035]	0.0035	0.3816
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	3 (3.2)	NC [NC, NC]	2.298 [0.594, 8.888]	0.2142	
Number of Organs with Metastatic Sites									
0-2	190	14 (7.4)	NC [NC, NC]	186	6 (3.2)	NC [NC, NC]	2.365 [0.909, 6.154]	0.0691	0.9890
>=3	64	8 (12.5)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	3.07E7 [0.000, NC]	0.0040	

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: 12JAN24

Table 302.3.2001.139.1: Summary and Results of Severe TEAEs - Vomiting (PT) - Safety Analysis Set

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

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.139.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	21 (11.9)	NC [NC, NC]	177	7 (4.0)	NC [NC, NC]	3.200 [1.360, 7.527]	0.0052	0.6169
>65 years	78	10 (12.8)	NC [NC, NC]	72	2 (2.8)	NC [NC, NC]	5.021 [1.100, 22.927]	0.0208	
Sex									
Male	160	17 (10.6)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	2.440 [1.012, 5.885]	0.0415	0.1815
Female	94	14 (14.9)	NC [NC, NC]	97	2 (2.1)	NC [NC, NC]	7.882 [1.791, 34.695]	0.0012	
Region									
Asia	157	18 (11.5)	NC [NC, NC]	156	4 (2.6)	NC [NC, NC]	4.782 [1.618, 14.131]	0.0019	0.4411
Non-Asia	97	13 (13.4)	NC [NC, NC]	93	5 (5.4)	NC [NC, NC]	2.661 [0.948, 7.465]	0.0543	
Number of Organs with Metastatic Sites									
0-2	190	22 (11.6)	NC [NC, NC]	186	8 (4.3)	NC [NC, NC]	2.871 [1.278, 6.449]	0.0080	0.2899
>=3	64	9 (14.1)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	9.621 [1.218, 75.962]	0.0085	

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: 12JAN24

Table 302.3.2001.140.1: Summary and Results of Severe TEAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	25 (9.8%)	19 (7.6%)	
Number of patients censored	229 (90.2%)	230 (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			1.293 [0.711, 2.350]
Log-rank test			
Two-sided stratified log-rank p-value			0.3987

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.141.1: Summary and Results of Severe TEAEs - Asthenia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	3 (1.2%)	
Number of patients censored	247 (97.2%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.330 [0.602, 9.015]
Log-rank test			
Two-sided stratified log-rank p-value			0.2084

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.142.1: Summary and Results of Severe TEAEs - Fatigue (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	9 (3.6%)	
Number of patients censored	247 (97.2%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.753 [0.280, 2.024]
Log-rank test			
Two-sided stratified log-rank p-value			0.5723

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.143.1: Summary and Results of Severe TEAEs - Hepatobiliary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	9 (3.6%)	
Number of patients censored	245 (96.5%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.967 [0.378, 2.472]
Log-rank test			
Two-sided stratified log-rank p-value			0.9438

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.144.1: Summary and Results of Severe TEAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	27 (10.6%)	32 (12.9%)	
Number of patients censored	227 (89.4%)	217 (87.1%)	
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			0.721 [0.423, 1.230]
Log-rank test			
Two-sided stratified log-rank p-value			0.2285

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.145.1: Summary and Results of Severe TEAEs - Pneumonia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	6 (2.4%)	
Number of patients censored	247 (97.2%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.250 [0.419, 3.730]
Log-rank test			
Two-sided stratified log-rank p-value			0.6884

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.146.1: Summary and Results of Severe TEAEs - Investigations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	57 (22.4%)	55 (22.1%)	
Number of patients censored	197 (77.6%)	194 (77.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [26.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.001 [0.687, 1.458]
Log-rank test			
Two-sided stratified log-rank p-value			0.9981

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.147.1: Summary and Results of Severe TEAEs - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	7 (2.8%)	
Number of patients censored	248 (97.6%)	242 (97.2%)	
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			0.783 [0.248, 2.475]
Log-rank test			
Two-sided stratified log-rank p-value			0.6764

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.148.1: Summary and Results of Severe TEAEs - Neutrophil Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	26 (10.2%)	24 (9.6%)	
Number of patients censored	228 (89.8%)	225 (90.4%)	
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			1.066 [0.608, 1.870]
Log-rank test			
Two-sided stratified log-rank p-value			0.8236

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.149.1: Summary and Results of Severe TEAEs - Platelet Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	19 (7.5%)	21 (8.4%)	
Number of patients censored	235 (92.5%)	228 (91.6%)	
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			0.902 [0.484, 1.681]
Log-rank test			
Two-sided stratified log-rank p-value			0.7435

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.150.1: Summary and Results of Severe TEAEs - White Blood Cell Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	10 (4.0%)	
Number of patients censored	249 (98.0%)	239 (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			0.518 [0.177, 1.521]
Log-rank test			
Two-sided stratified log-rank p-value			0.2231

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.151.1: Summary and Results of Severe TEAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	41 (16.1%)	33 (13.3%)	
Number of patients censored	213 (83.9%)	216 (86.7%)	
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			1.285 [0.811, 2.037]
Log-rank test			
Two-sided stratified log-rank p-value			0.2851

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.152.1: Summary and Results of Severe TEAEs - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	17 (6.7%)	4 (1.6%)	
Number of patients censored	237 (93.3%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			4.606 [1.548, 13.709]
Log-rank test			
Two-sided stratified log-rank p-value			0.0026

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.152.2: Summary and Results of Severe TEAEs by Subgroups - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	11 (6.3)	NC [NC, NC]	177	4 (2.3)	NC [NC, NC]	2.856 [0.910, 8.971]	0.0601	0.9898
>65 years	78	6 (7.7)	NC [NC, NC]	72	0 (0.0)	NC [NC, NC]	3.09E7 [0.000, NC]	0.0126	
Sex									
Male	160	15 (9.4)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	7.487 [1.712, 32.742]	0.0016	0.1191
Female	94	2 (2.1)	NC [NC, NC]	97	2 (2.1)	NC [NC, NC]	1.061 [0.149, 7.535]	0.9527	
Region									
Asia	157	10 (6.4)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	3.438 [0.946, 12.493]	0.0460	0.5636
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	1 (1.1)	NC [NC, NC]	7.310 [0.899, 59.441]	0.0291	
Number of Organs with Metastatic Sites									
0-2	190	11 (5.8)	NC [NC, NC]	186	3 (1.6)	NC [NC, NC]	3.755 [1.047, 13.459]	0.0291	0.6910
>=3	64	6 (9.4)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	6.093 [0.734, 50.592]	0.0560	

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: 12JAN24

Table 302.3.2001.153.1: Summary and Results of Severe TEAEs - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	4 (1.6%)	
Number of patients censored	246 (96.9%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.039 [0.613, 6.784]
Log-rank test			
Two-sided stratified log-rank p-value			0.2355

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.154.1: Summary and Results of Severe TEAEs - Hypokalaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	14 (5.5%)	17 (6.8%)	
Number of patients censored	240 (94.5%)	232 (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			0.776 [0.380, 1.587]
Log-rank test			
Two-sided stratified log-rank p-value			0.4866

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.155.1: Summary and Results of Severe TEAEs - Hyponatraemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	9 (3.6%)	
Number of patients censored	250 (98.4%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.469 [0.144, 1.524]
Log-rank test			
Two-sided stratified log-rank p-value			0.1971

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.156.1: Summary and Results of Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	16 (6.4%)	
Number of patients censored	243 (95.7%)	233 (93.6%)	
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			0.665 [0.297, 1.485]
Log-rank test			
Two-sided stratified log-rank p-value			0.3161

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.157.1: Summary and Results of Severe TEAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	13 (5.2%)	
Number of patients censored	244 (96.1%)	236 (94.8%)	
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			0.728 [0.306, 1.736]
Log-rank test			
Two-sided stratified log-rank p-value			0.4725

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.158.1: Summary and Results of Severe TEAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	14 (5.6%)	
Number of patients censored	243 (95.7%)	235 (94.4%)	
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			0.785 [0.356, 1.731]
Log-rank test			
Two-sided stratified log-rank p-value			0.5475

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.159.1: Summary and Results of Severe TEAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	6 (2.4%)	
Number of patients censored	246 (96.9%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.372 [0.475, 3.965]
Log-rank test			
Two-sided stratified log-rank p-value			0.5575

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.160.1: Summary and Results of Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	22 (8.8%)	
Number of patients censored	243 (95.7%)	227 (91.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [28.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.491 [0.236, 1.023]
Log-rank test			
Two-sided stratified log-rank p-value			0.0525

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.161.1: Summary and Results of Severe TEAEs - Pulmonary Embolism (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	9 (3.6%)	
Number of patients censored	250 (98.4%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [28.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.421 [0.129, 1.373]
Log-rank test			
Two-sided stratified log-rank p-value			0.1387

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.162.1: Summary and Results of Severe TEAEs - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	10 (4.0%)	
Number of patients censored	245 (96.5%)	239 (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			0.842 [0.338, 2.093]
Log-rank test			
Two-sided stratified log-rank p-value			0.7102

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.163.1: Summary and Results of Severe TEAEs - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	9 (3.6%)	
Number of patients censored	250 (98.4%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.429 [0.131, 1.400]
Log-rank test			
Two-sided stratified log-rank p-value			0.1487

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.164.1: Summary and Results of Severe TEAEs - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	5 (2.0%)	
Number of patients censored	242 (95.3%)	244 (98.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [27.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.290 [0.804, 6.528]
Log-rank test			
Two-sided stratified log-rank p-value			0.1115

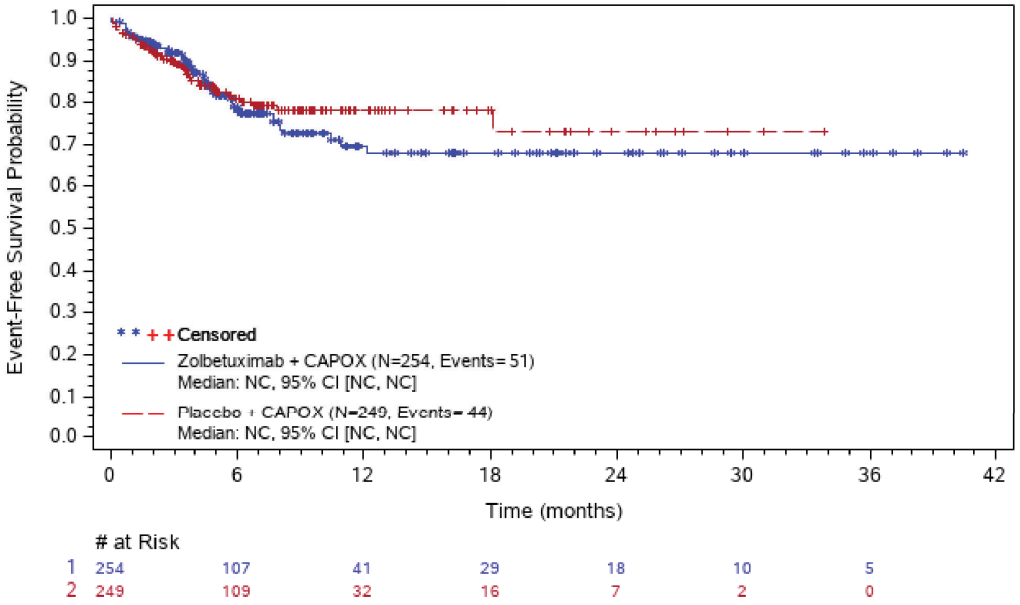
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwere unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

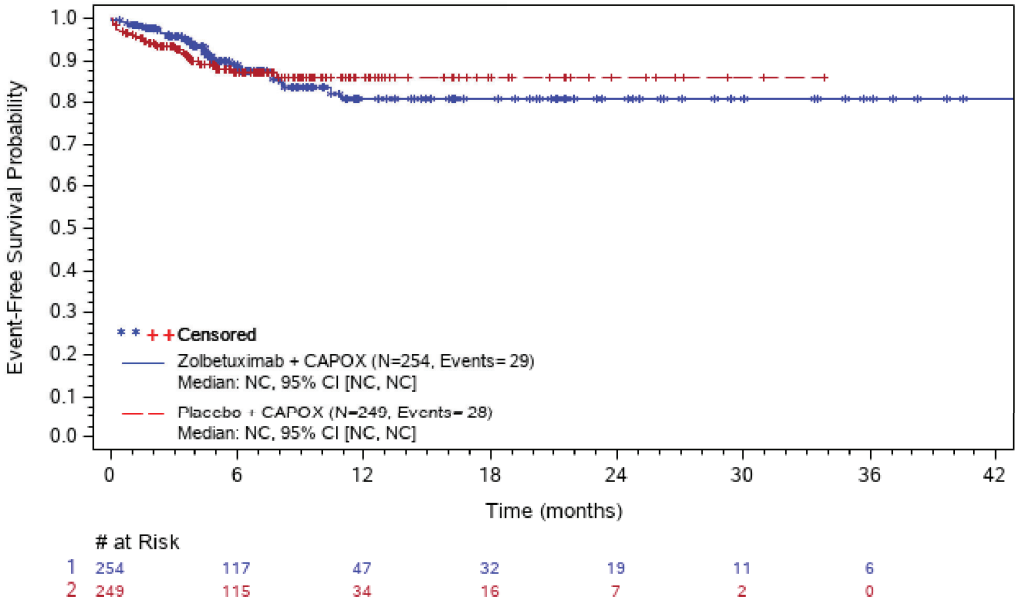
Figure 302.3.2001.131: Kaplan-Meier Plot of Time to first Severe TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

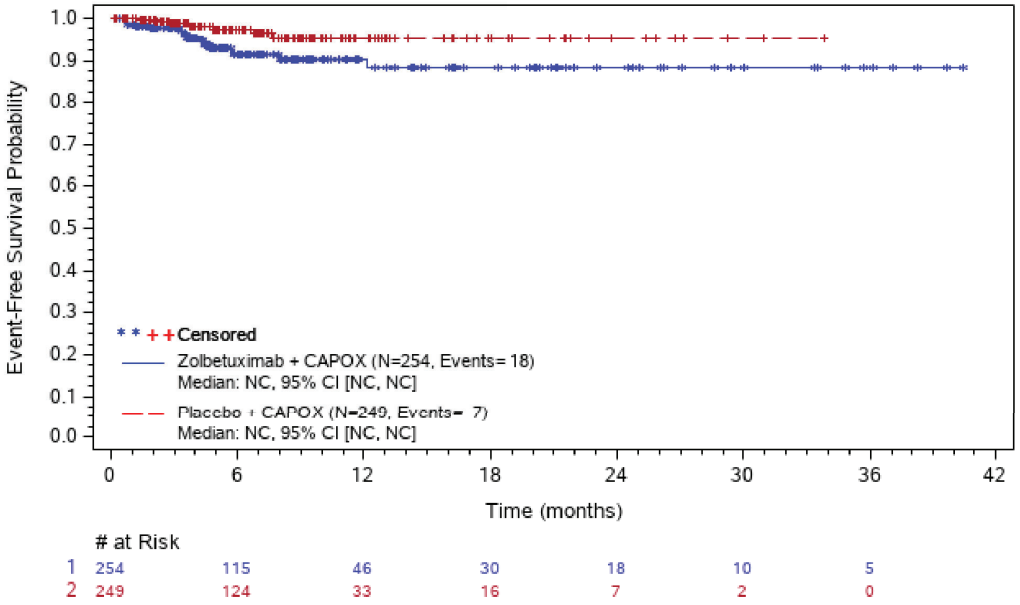
Figure 302.3.2001.132: Kaplan-Meier Plot of Time to first Severe TEAE - Anaemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

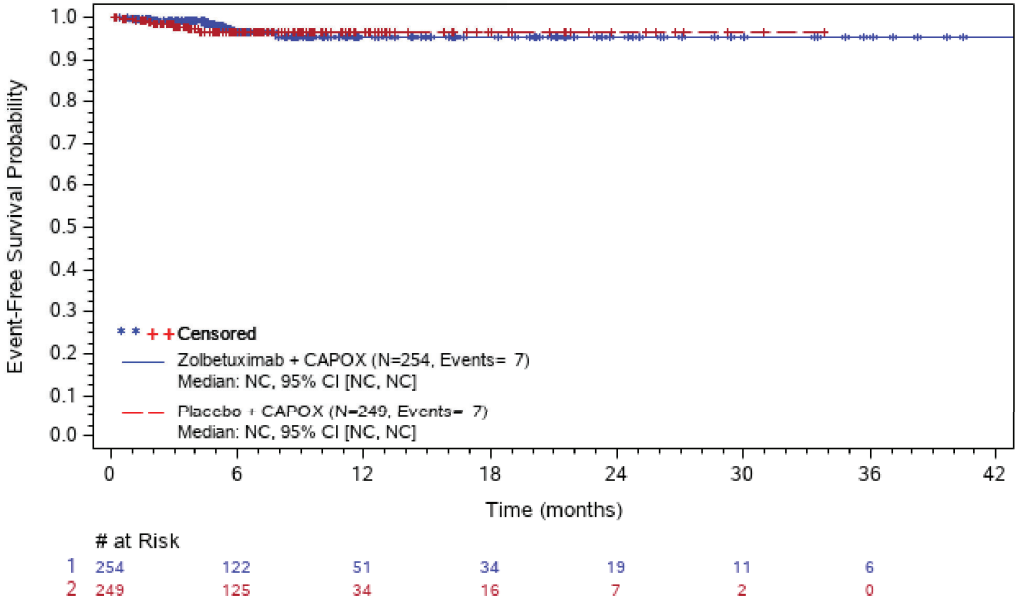
Figure 302.3.2001.133: Kaplan-Meier Plot of Time to first Severe TEAE - Neutropenia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

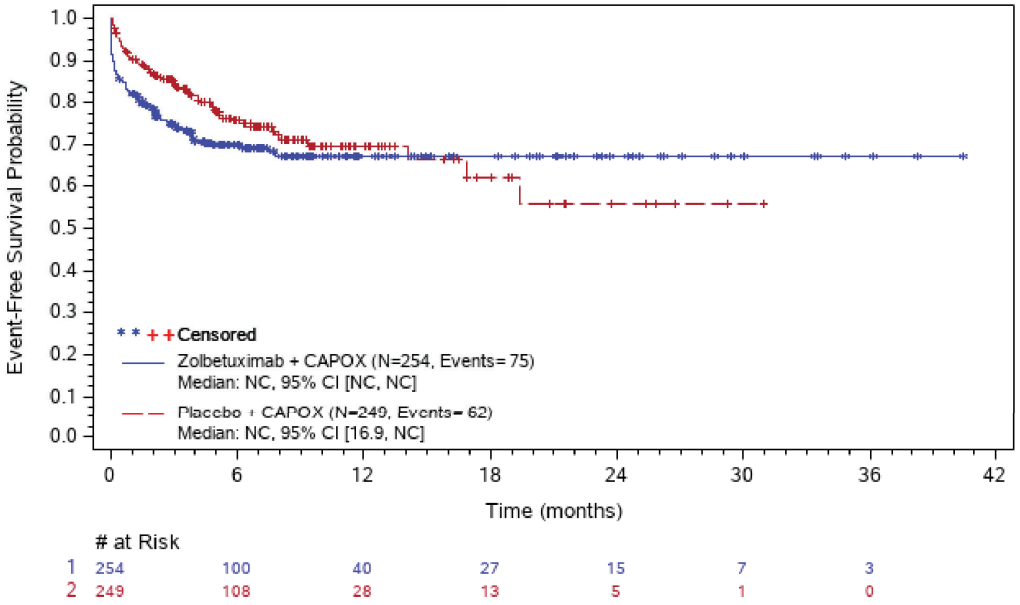
Figure 302.3.2001.134: Kaplan-Meier Plot of Time to first Severe TEAE - Thrombocytopenia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

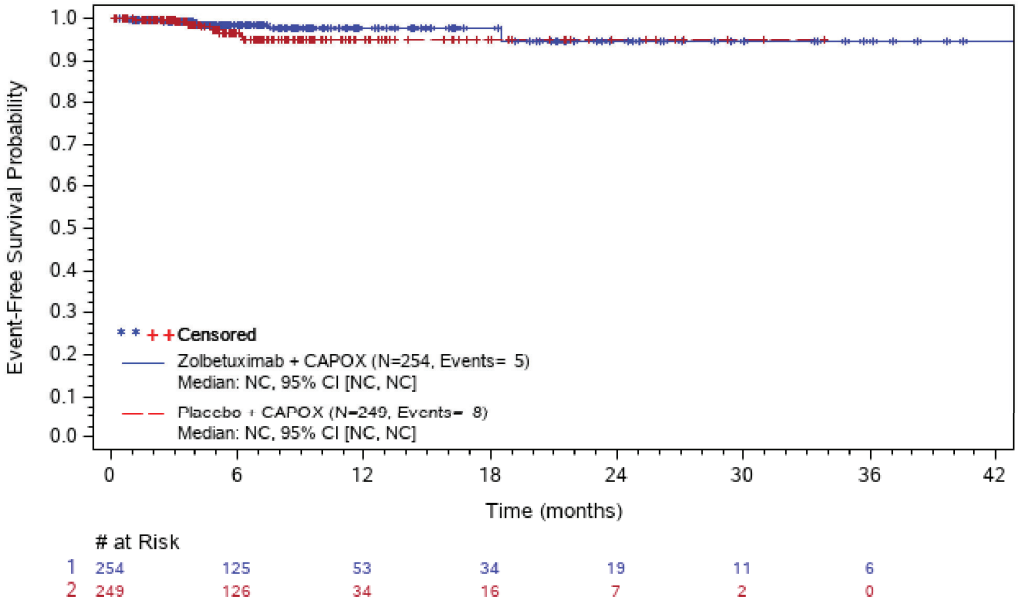
Figure 302.3.2001.135: Kaplan-Meier Plot of Time to first Severe TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

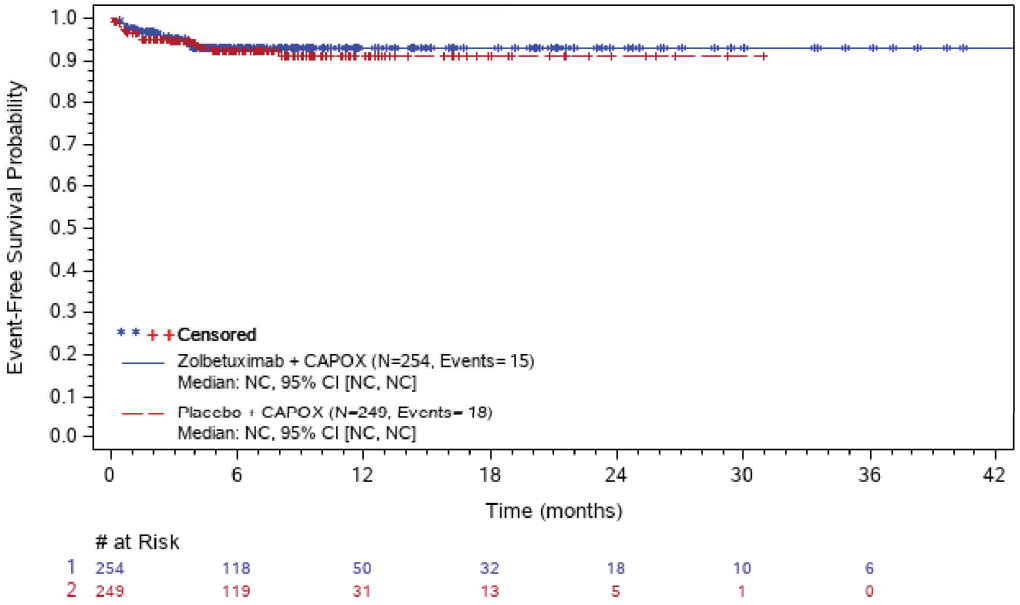
Figure 302.3.2001.136: Kaplan-Meier Plot of Time to first Severe TEAE - Ascites (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

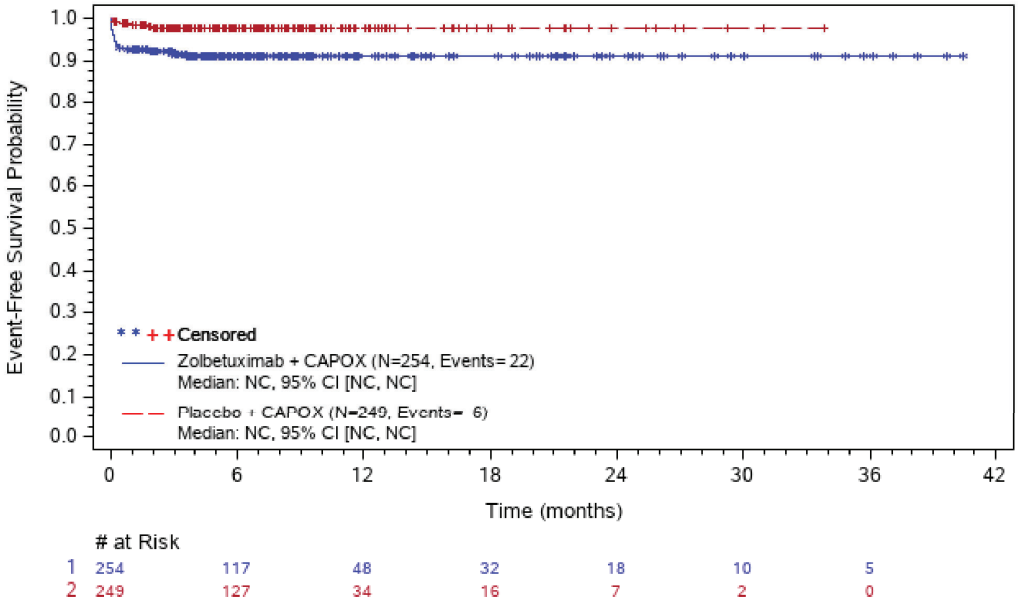
Figure 302.3.2001.137: Kaplan-Meier Plot of Time to first Severe TEAE - Diarrhoea (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

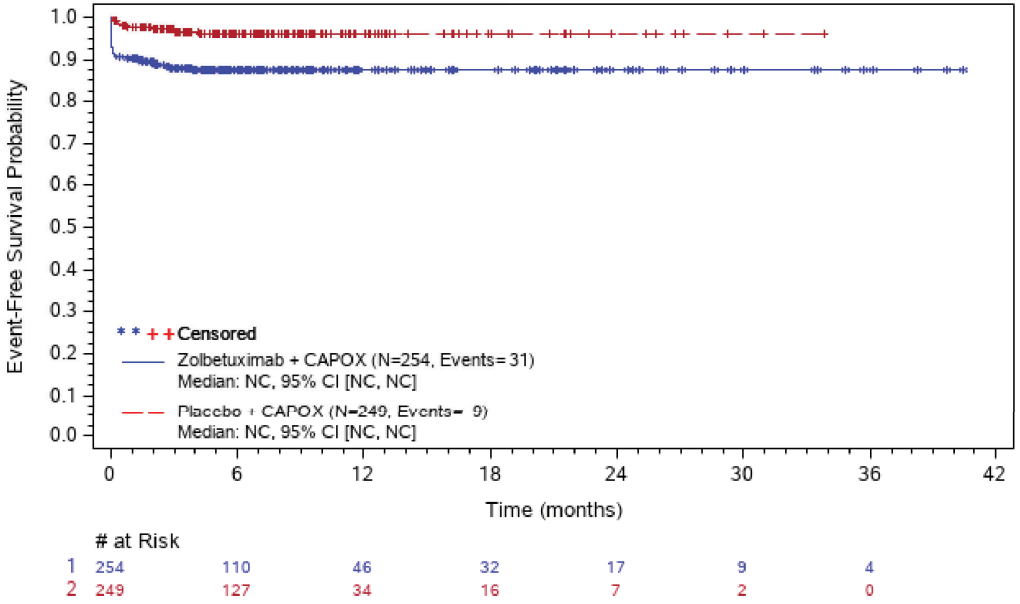
Figure 302.3.2001.138: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

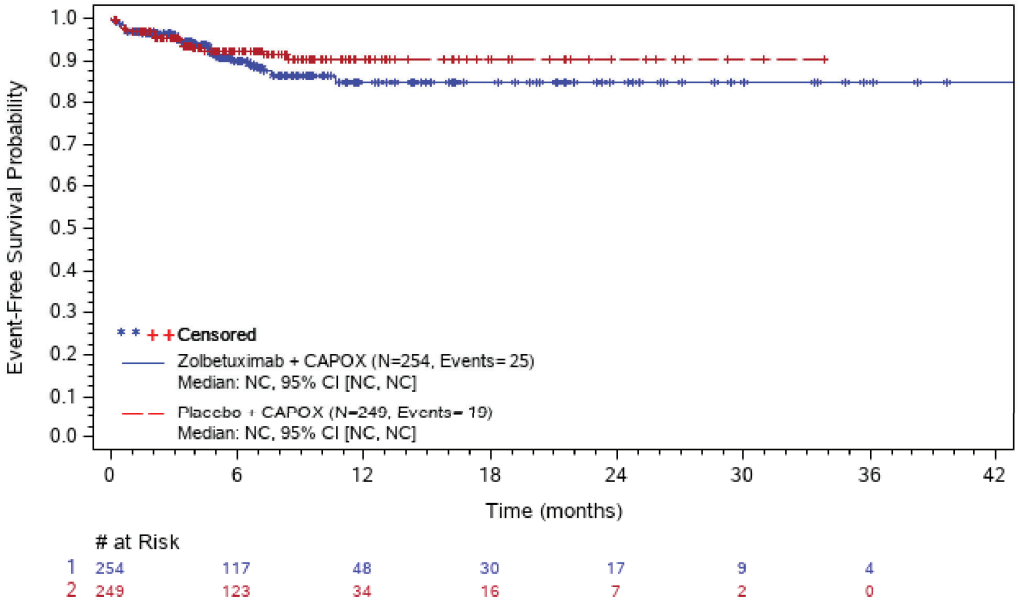
Figure 302.3.2001.139: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

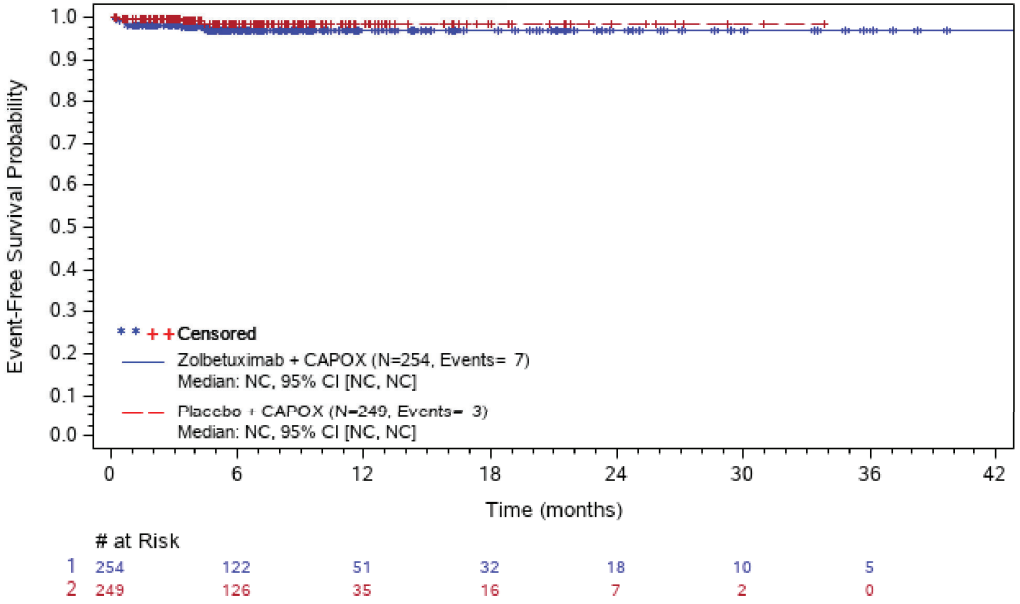
Figure 302.3.2001.140: Kaplan-Meier Plot of Time to first Severe TEAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

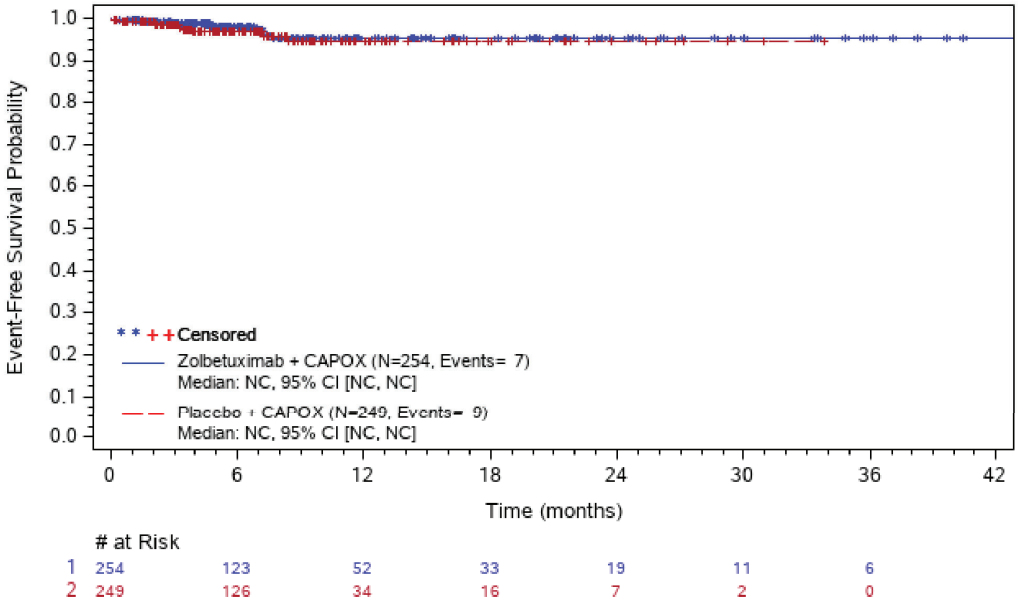
Figure 302.3.2001.141: Kaplan-Meier Plot of Time to first Severe TEAE - Asthenia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

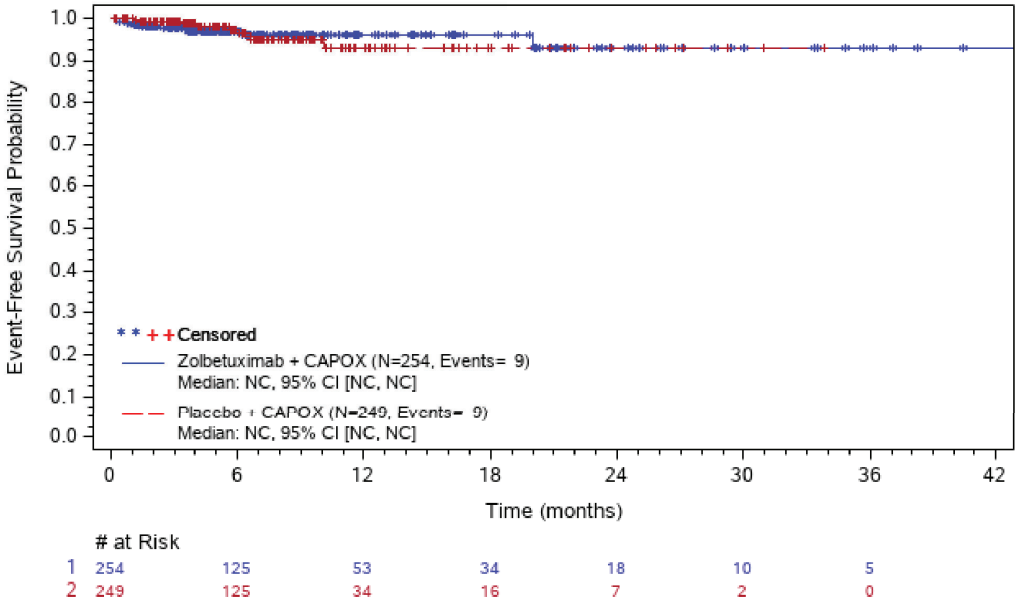
Figure 302.3.2001.142: Kaplan-Meier Plot of Time to first Severe TEAE - Fatigue (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

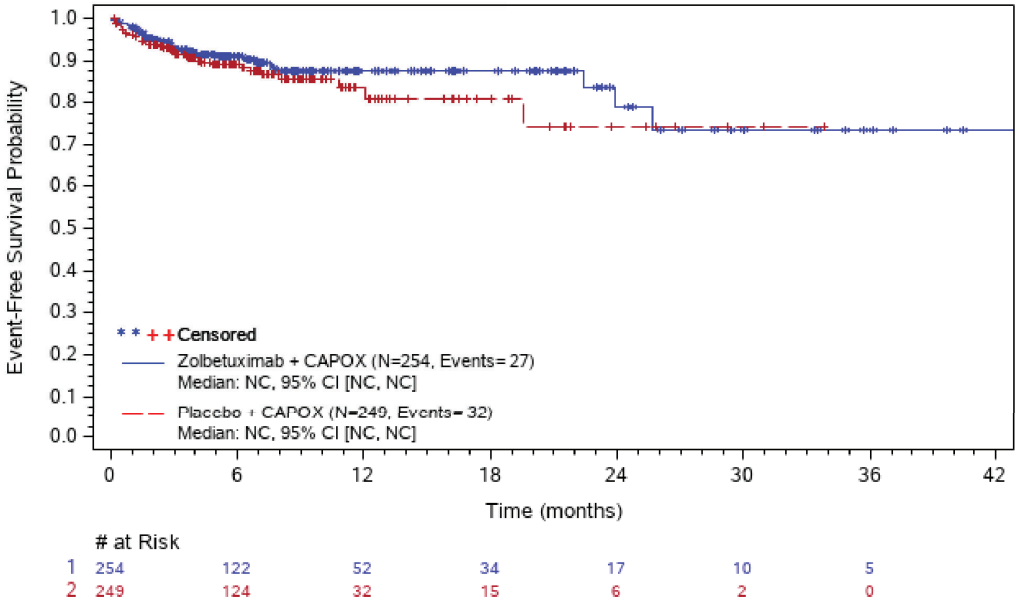
Figure 302.3.2001.143: Kaplan-Meier Plot of Time to first Severe TEAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

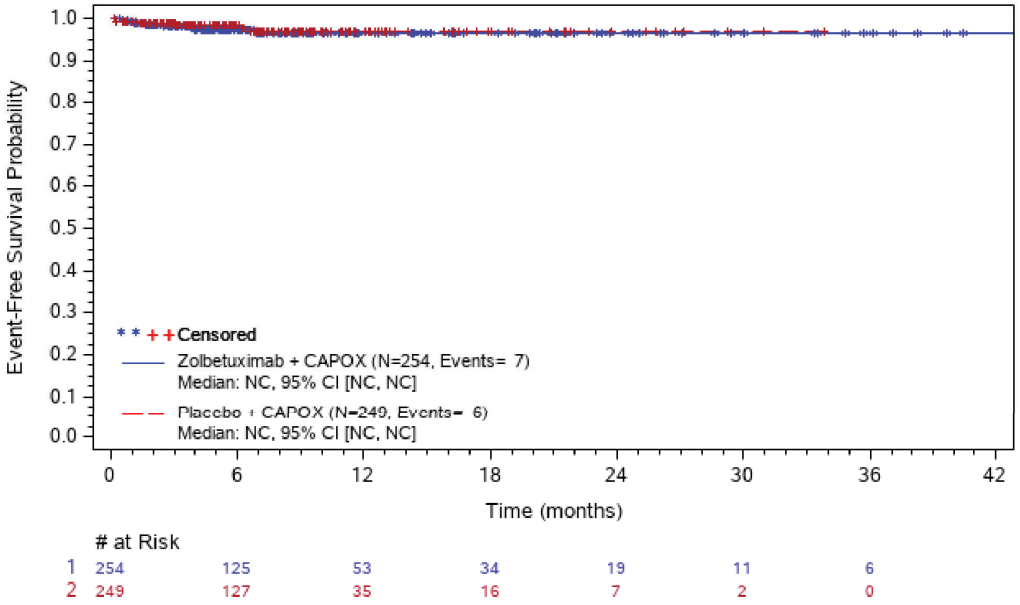
Figure 302.3.2001.144: Kaplan-Meier Plot of Time to first Severe TEAE - Infections And Infestations (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

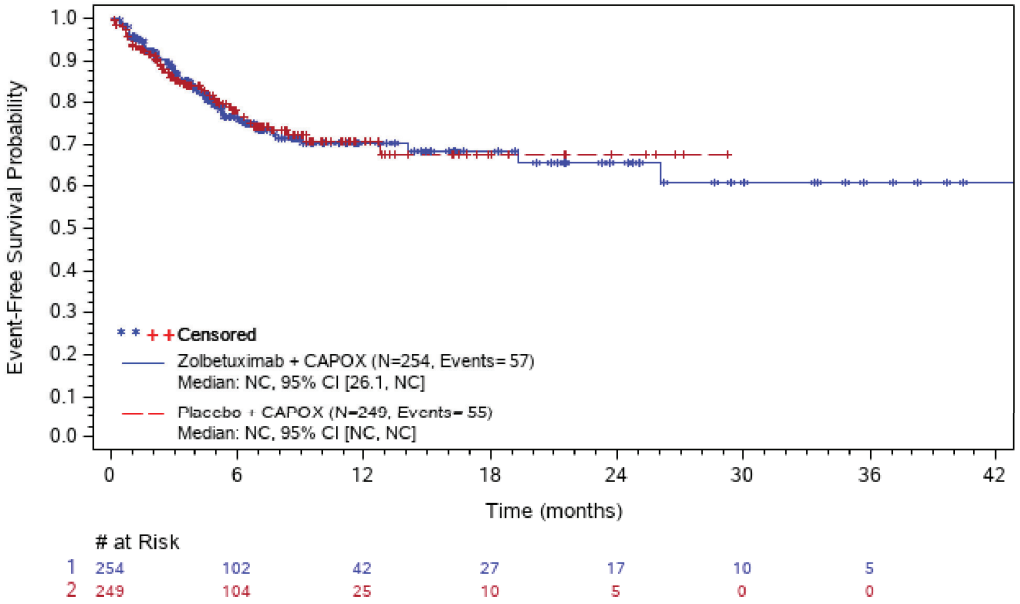
Figure 302.3.2001.145: Kaplan-Meier Plot of Time to first Severe TEAE - Pneumonia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.146: Kaplan-Meier Plot of Time to first Severe TEAE - Investigations (SOC) - Safety Analysis Set

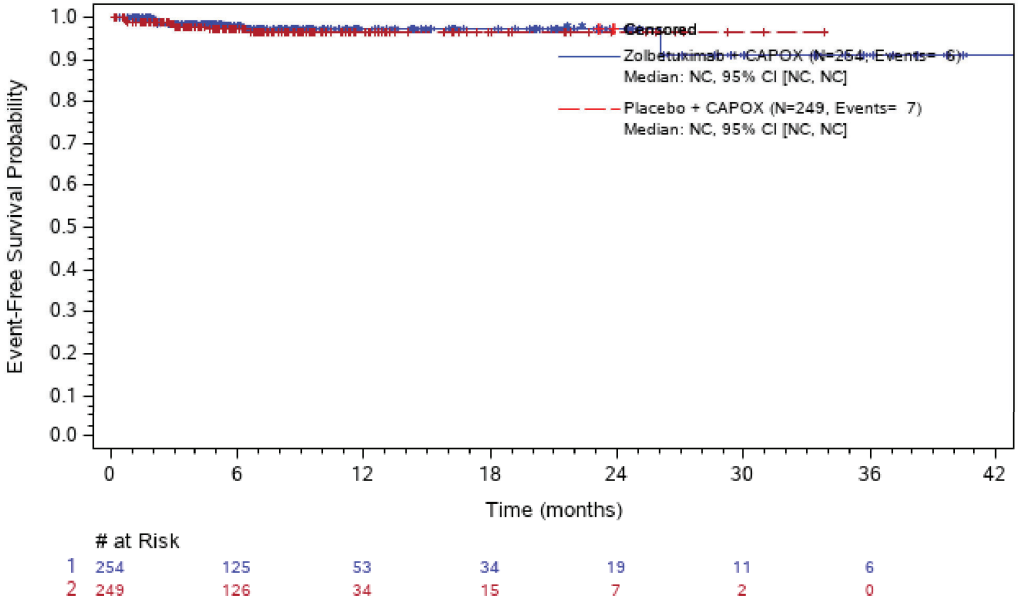


# at Risk							
1	254	102	42	27	17	10	5
2	249	104	25	10	5	0	0

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: 12JAN24

The SAS System

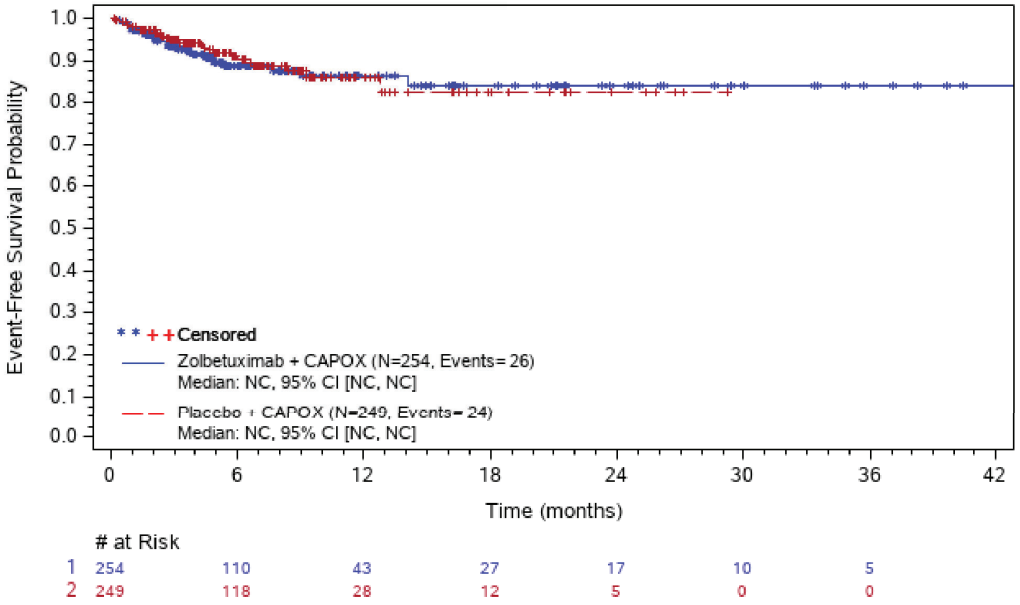
Figure 302.3.2001.147: Kaplan-Meier Plot of Time to first Severe TEAE - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

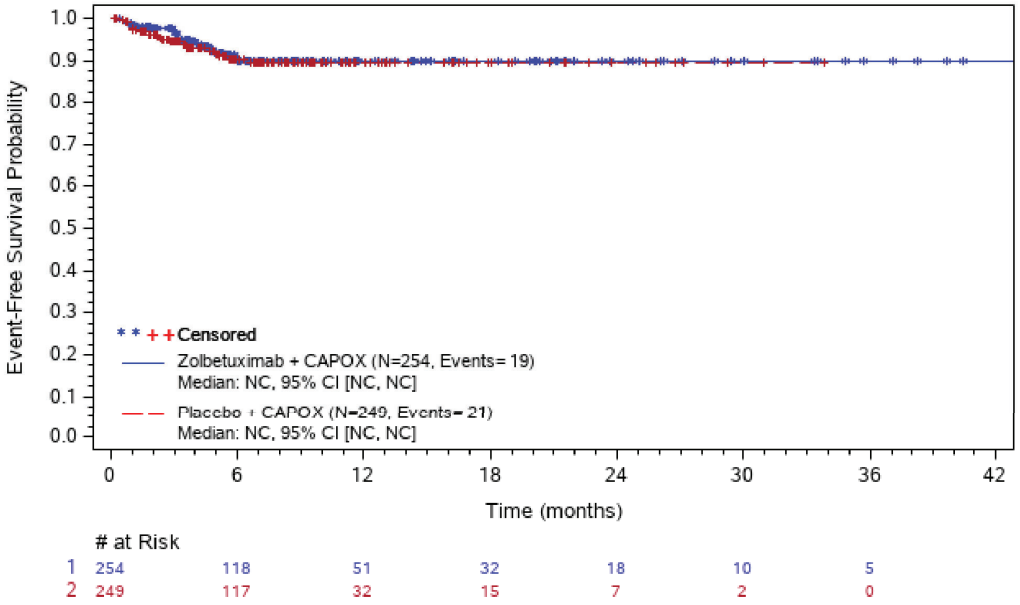
Figure 302.3.2001.148: Kaplan-Meier Plot of Time to first Severe TEAE - Neutrophil Count Decreased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

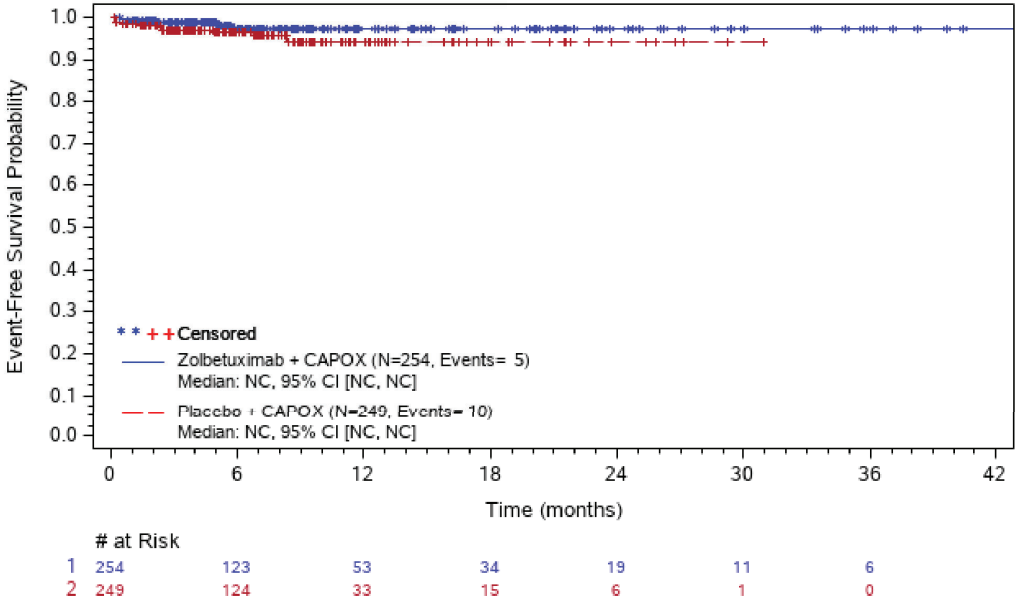
Figure 302.3.2001.149: Kaplan-Meier Plot of Time to first Severe TEAE - Platelet Count Decreased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

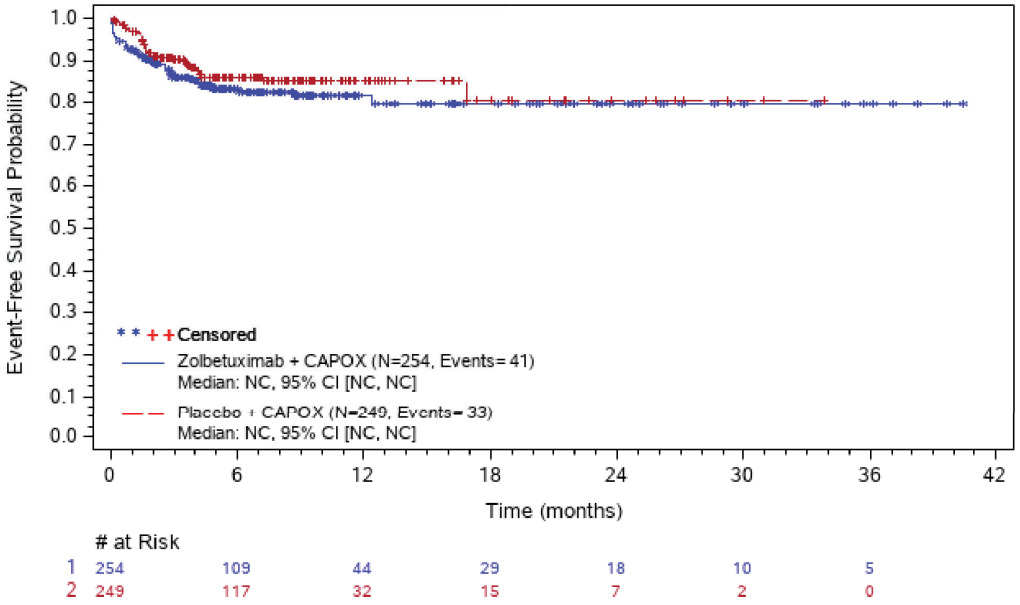
Figure 302.3.2001.150: Kaplan-Meier Plot of Time to first Severe TEAE - White Blood Cell Count Decreased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

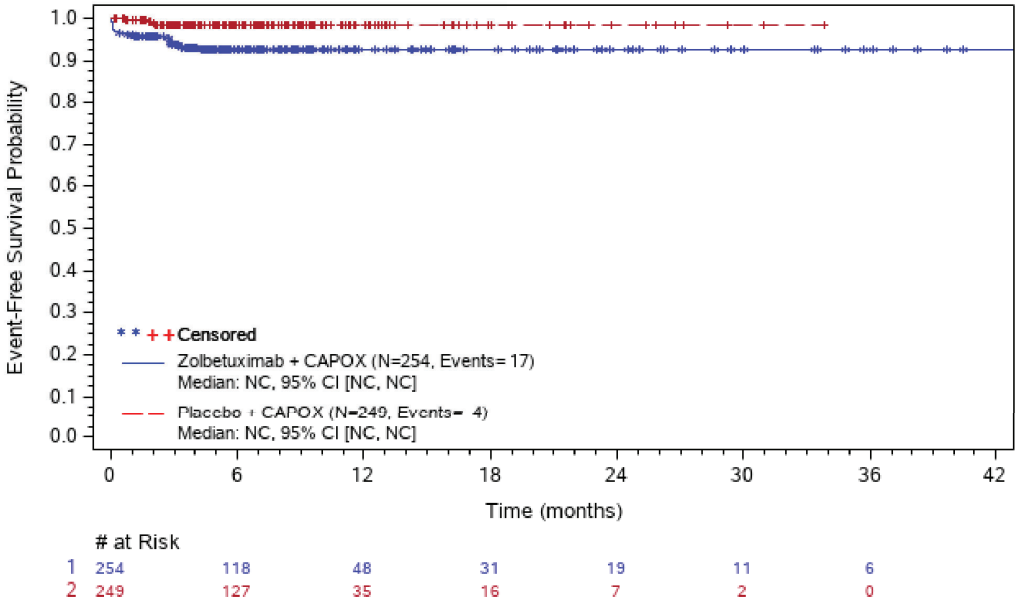
Figure 302.3.2001.151: Kaplan-Meier Plot of Time to first Severe TEAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

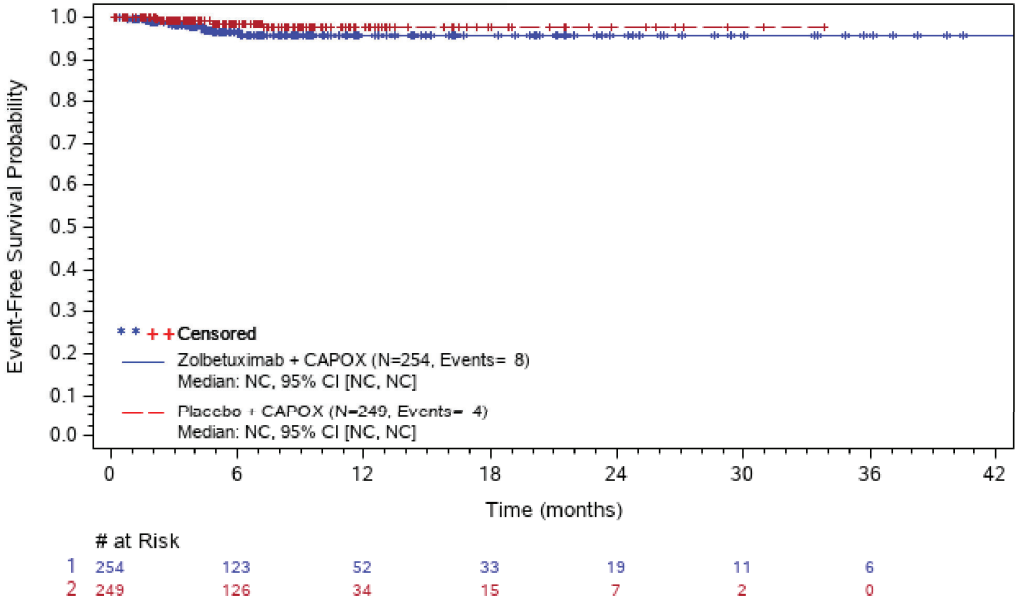
Figure 302.3.2001.152: Kaplan-Meier Plot of Time to first Severe TEAE - Decreased Appetite (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

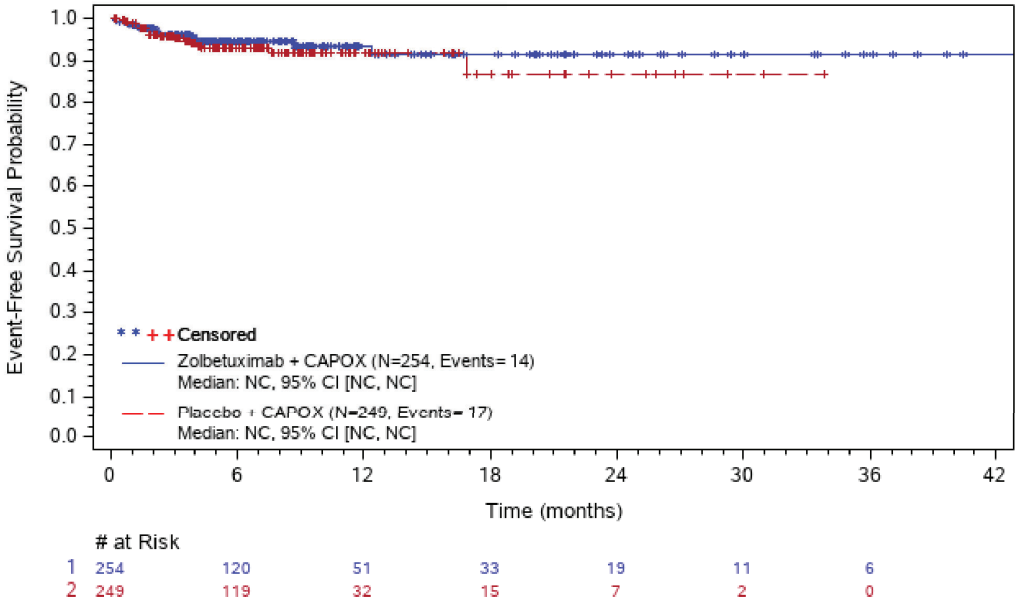
Figure 302.3.2001.153: Kaplan-Meier Plot of Time to first Severe TEAE - Hypoalbuminaemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

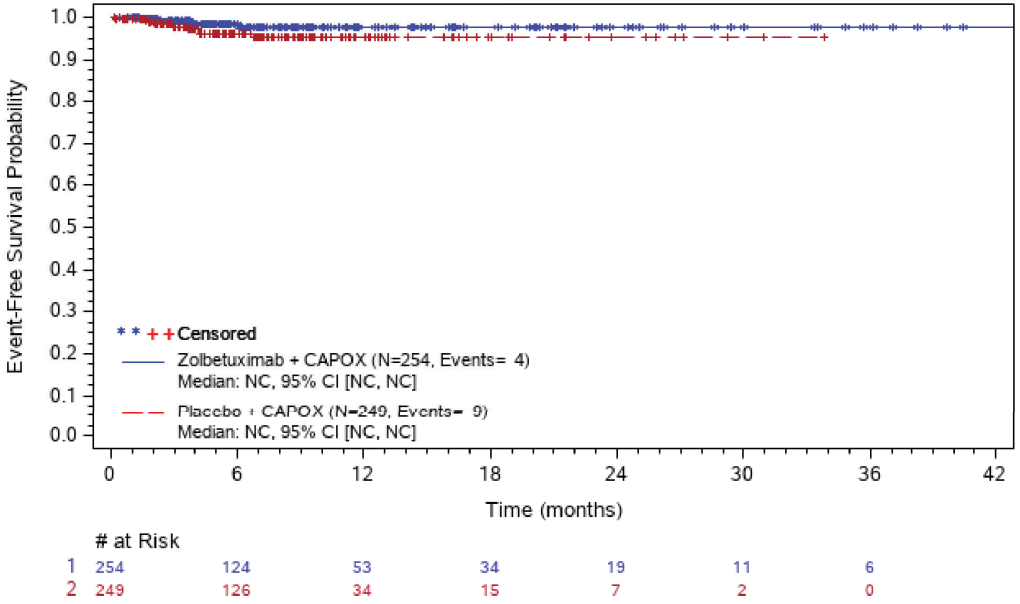
Figure 302.3.2001.154: Kaplan-Meier Plot of Time to first Severe TEAE - Hypokalaemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

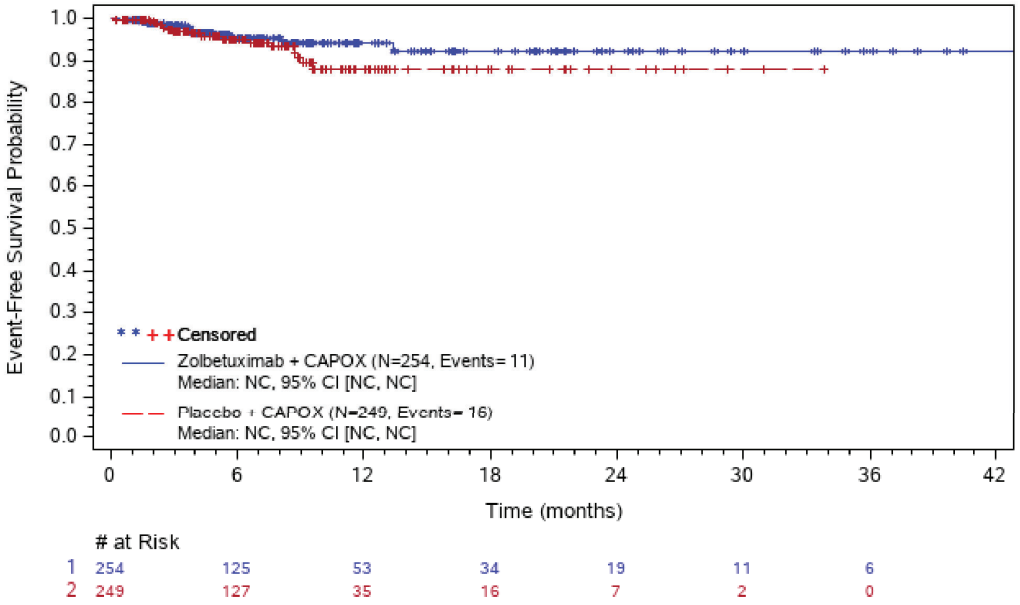
Figure 302.3.2001.155: Kaplan-Meier Plot of Time to first Severe TEAE - Hyponatraemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

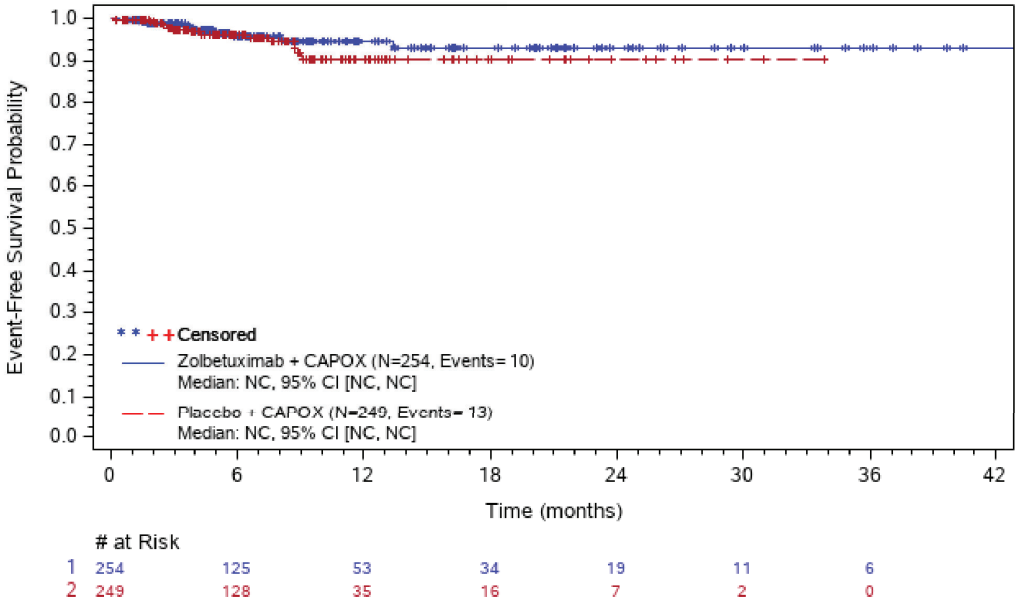
Figure 302.3.2001.156: Kaplan-Meier Plot of Time to first Severe TEAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

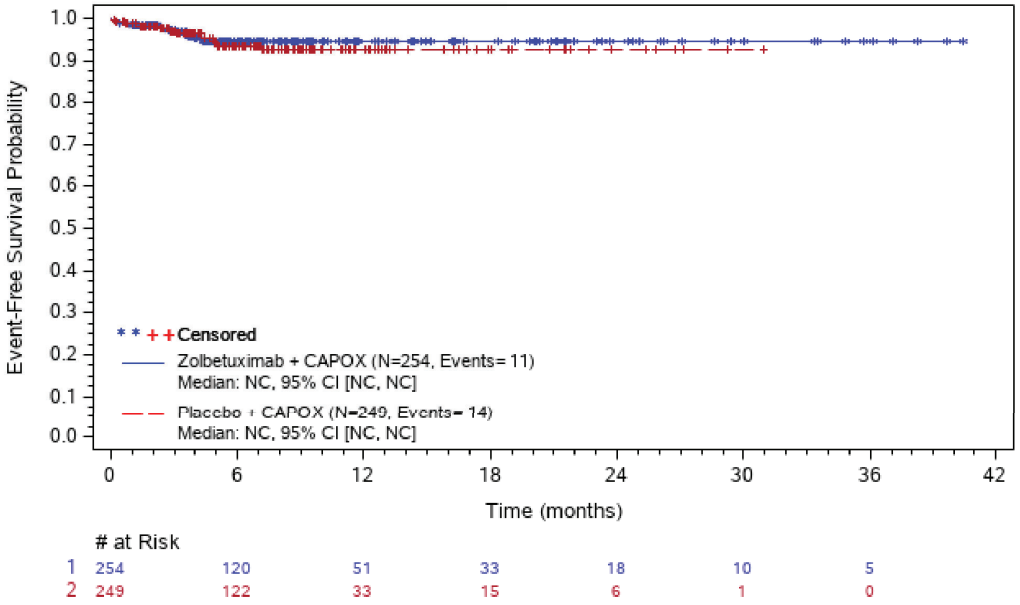
Figure 302.3.2001.157: Kaplan-Meier Plot of Time to first Severe TEAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

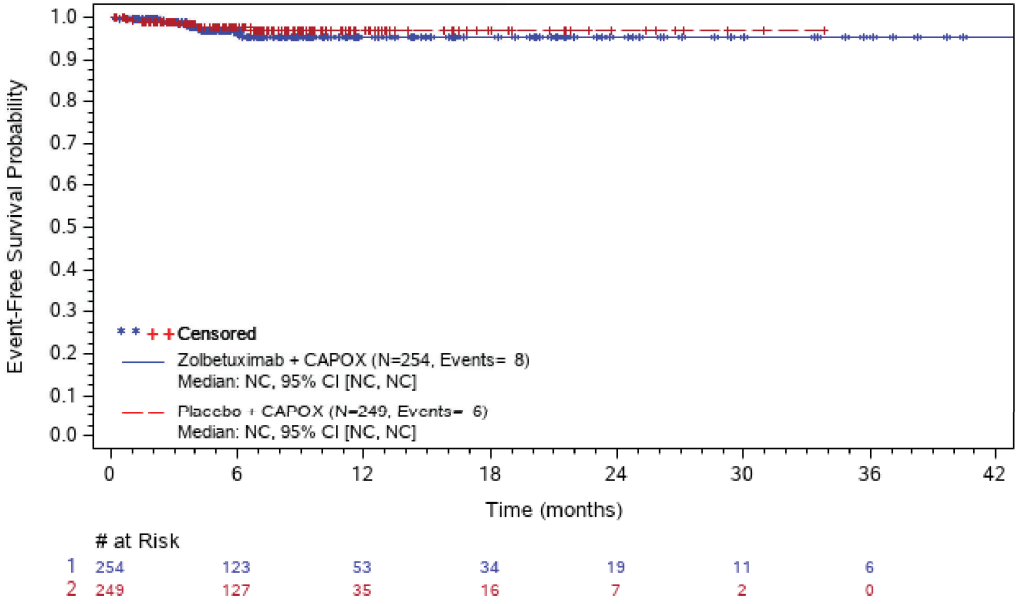
Figure 302.3.2001.158: Kaplan-Meier Plot of Time to first Severe TEAE - Nervous System Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

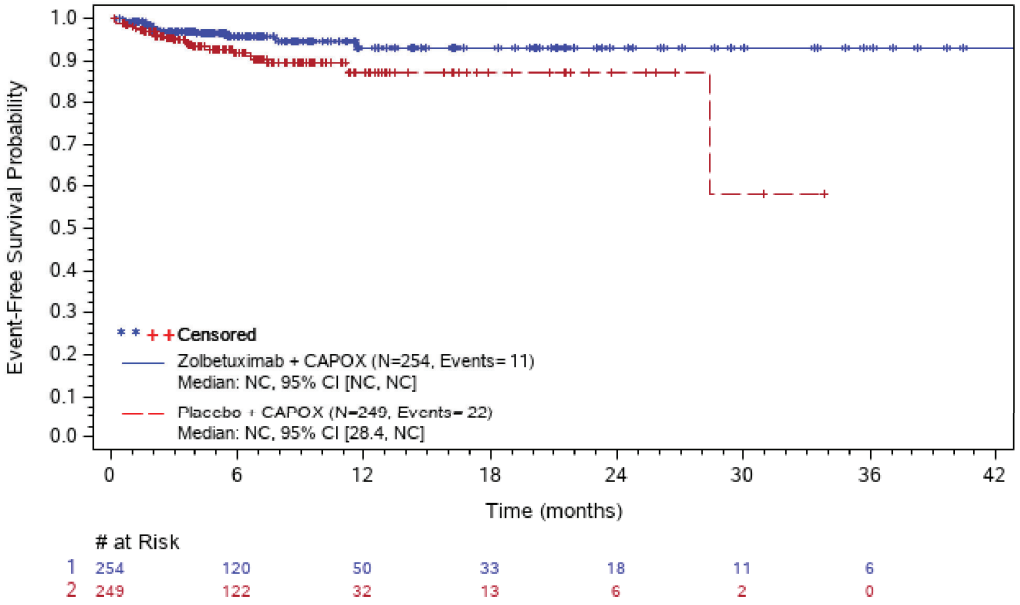
Figure 302.3.2001.159: Kaplan-Meier Plot of Time to first Severe TEAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

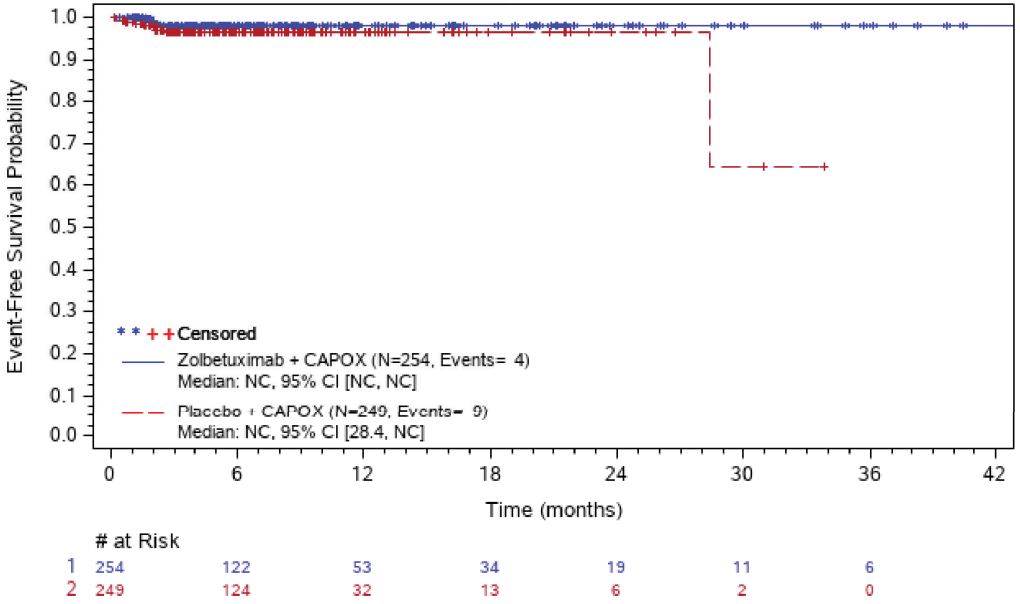
Figure 302.3.2001.160: Kaplan-Meier Plot of Time to first Severe TEAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

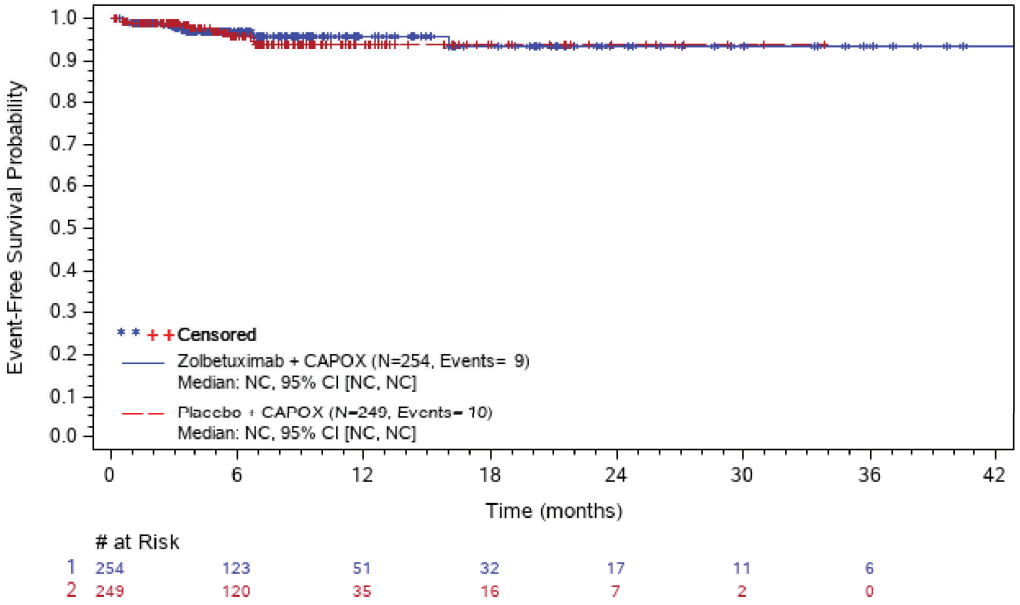
Figure 302.3.2001.161: Kaplan-Meier Plot of Time to first Severe TEAE - Pulmonary Embolism (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

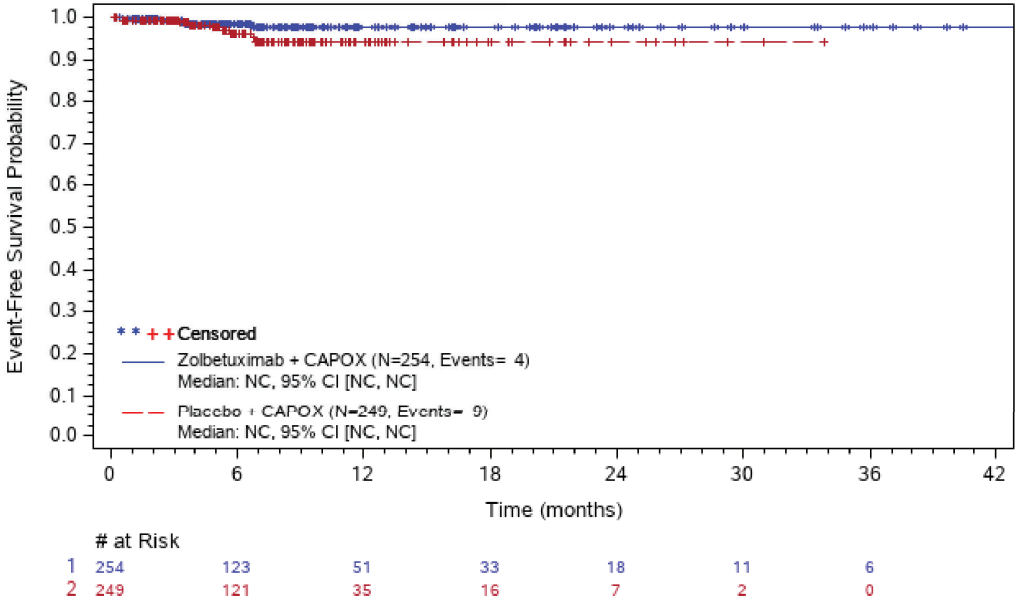
Figure 302.3.2001.162: Kaplan-Meier Plot of Time to first Severe TEAE - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

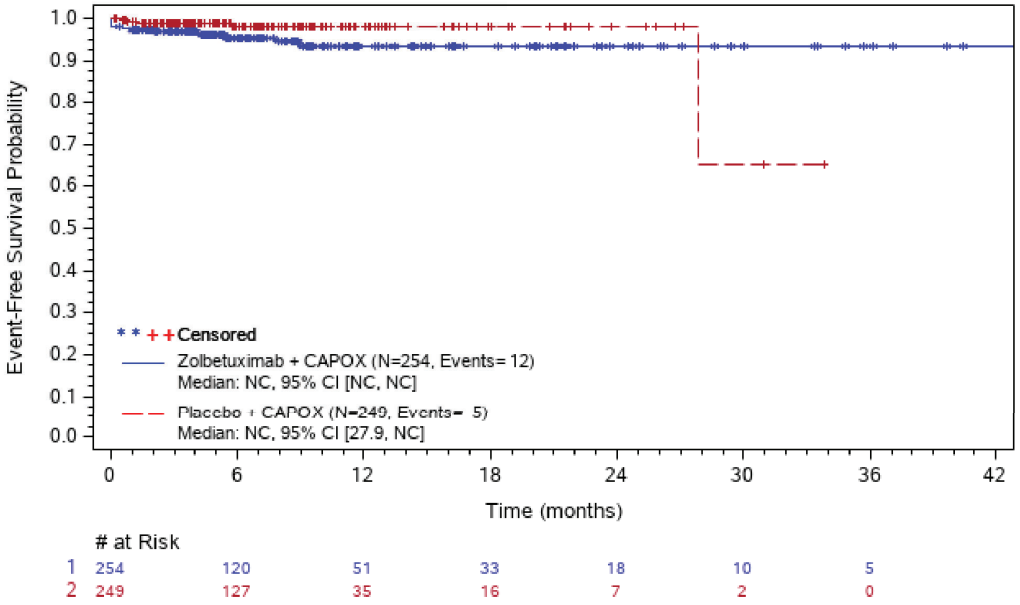
Figure 302.3.2001.163: Kaplan-Meier Plot of Time to first Severe TEAE - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.164: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwerwiegende unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 302.3.2001.107.1: Summary and Results of TESAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	12 (4.7%)	15 (6.0%)	
Number of patients censored	242 (95.3%)	234 (94.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.777 [0.362, 1.668]
Log-rank test			
Two-sided stratified log-rank p-value			0.5167

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.108.1: Summary and Results of TESAEs - Anaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	6 (2.4%)	
Number of patients censored	249 (98.0%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.821 [0.250, 2.696]
Log-rank test			
Two-sided stratified log-rank p-value			0.7453

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.109.1: Summary and Results of TESAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	57 (22.4%)	53 (21.3%)	
Number of patients censored	197 (77.6%)	196 (78.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [19.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.074 [0.737, 1.565]
Log-rank test			
Two-sided stratified log-rank p-value			0.7131

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.110.1: Summary and Results of TEAEs - Abdominal Pain (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	3 (1.2%)	7 (2.8%)	
Number of patients censored	251 (98.8%)	242 (97.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [22.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.339 [0.086, 1.345]
Log-rank test			
Two-sided stratified log-rank p-value			0.1082

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.111.1: Summary and Results of TESAEs - Diarrhoea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	10 (4.0%)	
Number of patients censored	247 (97.2%)	239 (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			0.682 [0.259, 1.795]
Log-rank test			
Two-sided stratified log-rank p-value			0.4352

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.112.1: Summary and Results of TESAEs - Nausea (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	6 (2.4%)	
Number of patients censored	243 (95.7%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.833 [0.677, 4.963]
Log-rank test			
Two-sided stratified log-rank p-value			0.2263

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.113.1: Summary and Results of TESAEs - Upper Gastrointestinal Haemorrhage (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	4 (1.6%)	
Number of patients censored	247 (97.2%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.885 [0.551, 6.449]
Log-rank test			
Two-sided stratified log-rank p-value			0.3048

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.114.1: Summary and Results of TESAEs - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	11 (4.4%)	
Number of patients censored	239 (94.1%)	238 (95.6%)	
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			1.359 [0.624, 2.961]
Log-rank test			
Two-sided stratified log-rank p-value			0.4382

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.115.1: Summary and Results of TESAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	18 (7.1%)	14 (5.6%)	
Number of patients censored	236 (92.9%)	235 (94.4%)	
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			1.333 [0.652, 2.723]
Log-rank test			
Two-sided stratified log-rank p-value			0.4277

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.116.1: Summary and Results of TESAEs - Hepatobiliary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	7 (2.8%)	
Number of patients censored	245 (96.5%)	242 (97.2%)	
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			1.268 [0.465, 3.455]
Log-rank test			
Two-sided stratified log-rank p-value			0.6416

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.117.1: Summary and Results of TESAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	26 (10.2%)	23 (9.2%)	
Number of patients censored	228 (89.8%)	226 (90.8%)	
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			1.108 [0.622, 1.974]
Log-rank test			
Two-sided stratified log-rank p-value			0.7276

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.118.1: Summary and Results of TESAEs - Pneumonia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	6 (2.4%)	
Number of patients censored	248 (97.6%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.311 [0.399, 4.308]
Log-rank test			
Two-sided stratified log-rank p-value			0.6549

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.119.1: Summary and Results of TESAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	1 (0.4%)	
Number of patients censored	245 (96.5%)	248 (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			8.914 [1.124, 70.701]
Log-rank test			
Two-sided stratified log-rank p-value			0.0124

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.119.2: Summary and Results of TESAEs by Subgroups - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	0 (0.0)				
>65 years	78	5 (6.4)		72	1 (1.4)				
Sex									
Male	160	8 (5.0)		152	1 (0.7)				
Female	94	1 (1.1)		97	0 (0.0)				
Region									
Asia	157	4 (2.5)		156	1 (0.6)				
Non-Asia	97	5 (5.2)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)		186	1 (0.5)				
>=3	64	3 (4.7)		63	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 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: 12JAN24

Table 302.3.2001.120.1: Summary and Results of TESAEs - Investigations (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	13 (5.1%)	10 (4.0%)	
Number of patients censored	241 (94.9%)	239 (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			1.268 [0.554, 2.902]
Log-rank test			
Two-sided stratified log-rank p-value			0.5733

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.121.1: Summary and Results of TESAEs - Platelet Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	6 (2.4%)	
Number of patients censored	246 (96.9%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.335 [0.463, 3.853]
Log-rank test			
Two-sided stratified log-rank p-value			0.5918

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.122.1: Summary and Results of TESAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	18 (7.1%)	15 (6.0%)	
Number of patients censored	236 (92.9%)	234 (94.0%)	
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			1.262 [0.633, 2.516]
Log-rank test			
Two-sided stratified log-rank p-value			0.5068

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.123.1: Summary and Results of TESAEs - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	3 (1.2%)	
Number of patients censored	244 (96.1%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.510 [0.963, 12.792]
Log-rank test			
Two-sided stratified log-rank p-value			0.0425

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.123.2: Summary and Results of TESAEs by Subgroups - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	6 (3.4)		177	1 (0.6)				
>65 years	78	4 (5.1)		72	2 (2.8)				
Sex									
Male	160	9 (5.6)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	4.381 [0.947, 20.277]	0.0387	0.3811
Female	94	1 (1.1)	NC [NC, NC]	97	1 (1.0)	NC [NC, NC]	1.021 [0.064, 16.330]	0.9881	
Region									
Asia	157	7 (4.5)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	2.367 [0.612, 9.151]	0.1977	0.9910
Non-Asia	97	3 (3.1)	NC [NC, NC]	93	0 (0.0)	NC [NC, NC]	3.04E7 [0.000, NC]	0.0793	
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)		186	2 (1.1)				
>=3	64	4 (6.3)		63	1 (1.6)				

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: 12JAN24

Table 302.3.2001.124.1: Summary and Results of TESAEs - Hypokalaemia (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	6 (2.4%)	
Number of patients censored	248 (97.6%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.036 [0.331, 3.244]
Log-rank test			
Two-sided stratified log-rank p-value			0.9510

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.125.1: Summary and Results of TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	17 (6.8%)	
Number of patients censored	243 (95.7%)	232 (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			0.581 [0.260, 1.296]
Log-rank test			
Two-sided stratified log-rank p-value			0.1794

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.126.1: Summary and Results of TESAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	13 (5.2%)	
Number of patients censored	244 (96.1%)	236 (94.8%)	
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			0.728 [0.306, 1.736]
Log-rank test			
Two-sided stratified log-rank p-value			0.4725

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.127.1: Summary and Results of TESAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	3 (1.2%)	
Number of patients censored	247 (97.2%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.390 [0.618, 9.243]
Log-rank test			
Two-sided stratified log-rank p-value			0.1926

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.128.1: Summary and Results of TESAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	8 (3.2%)	
Number of patients censored	247 (97.2%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.883 [0.319, 2.443]
Log-rank test			
Two-sided stratified log-rank p-value			0.8100

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.129.1: Summary and Results of TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	23 (9.2%)	
Number of patients censored	244 (96.1%)	226 (90.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [28.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.431 [0.203, 0.916]
Log-rank test			
Two-sided stratified log-rank p-value			0.0244

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.129.2: Summary and Results of TESAEs by Subgroups - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	8 (4.5)	NC [NC, NC]	177	17 (9.6)	28.4 [28.4, NC]	0.396 [0.168, 0.932]	0.0284	0.8170
>65 years	78	2 (2.6)	NC [NC, NC]	72	6 (8.3)	NC [17.9, NC]	0.301 [0.060, 1.503]	0.1211	
Sex									
Male	160	9 (5.6)	NC [NC, NC]	152	17 (11.2)	28.4 [NC, NC]	0.425 [0.187, 0.971]	0.0368	0.3905
Female	94	1 (1.1)	NC [NC, NC]	97	6 (6.2)	NC [17.9, NC]	0.155 [0.018, 1.302]	0.0495	
Region									
Asia	157	5 (3.2)	NC [NC, NC]	156	5 (3.2)	NC [NC, NC]	0.837 [0.237, 2.954]	0.7824	0.1450
Non-Asia	97	5 (5.2)	NC [NC, NC]	93	18 (19.4)	28.4 [17.9, 28.4]	0.253 [0.093, 0.686]	0.0036	
Number of Organs with Metastatic Sites									
0-2	190	3 (1.6)	NC [NC, NC]	186	14 (7.5)	NC [28.4, NC]	0.179 [0.050, 0.636]	0.0030	0.1018
>=3	64	7 (10.9)	NC [NC, NC]	63	9 (14.3)	17.9 [17.9, NC]	0.691 [0.257, 1.860]	0.4618	

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: 12JAN24

Table 302.3.2001.130.1: Summary and Results of TESAEs - Pulmonary Embolism (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	2 (0.8%)	8 (3.2%)	
Number of patients censored	252 (99.2%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [28.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.233 [0.049, 1.106]
Log-rank test			
Two-sided stratified log-rank p-value			0.0460

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, 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: 12JAN24

Table 302.3.2001.130.2: Summary and Results of TESAEs by Subgroups - Pulmonary Embolism (PT) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	1 (0.6)		177	6 (3.4)				
>65 years	78	1 (1.3)		72	2 (2.8)				
Sex									
Male	160	1 (0.6)		152	7 (4.6)				
Female	94	1 (1.1)		97	1 (1.0)				
Region									
Asia	157	1 (0.6)		156	0 (0.0)				
Non-Asia	97	1 (1.0)		93	8 (8.6)				
Number of Organs with Metastatic Sites									
0-2	190	2 (1.1)		186	7 (3.8)				
>=3	64	0 (0.0)		63	1 (1.6)				

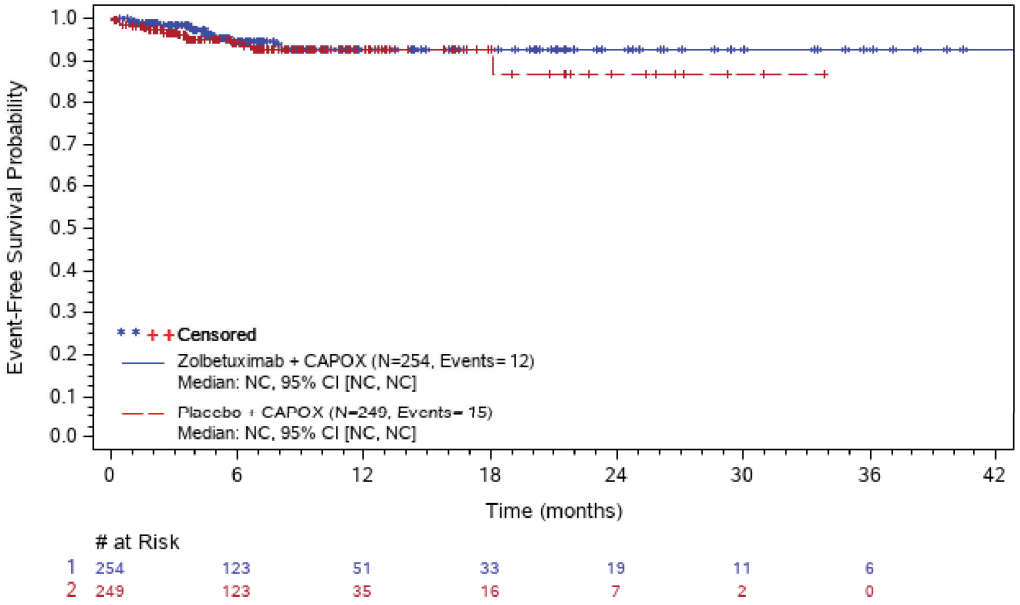
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Schwerwiegende unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

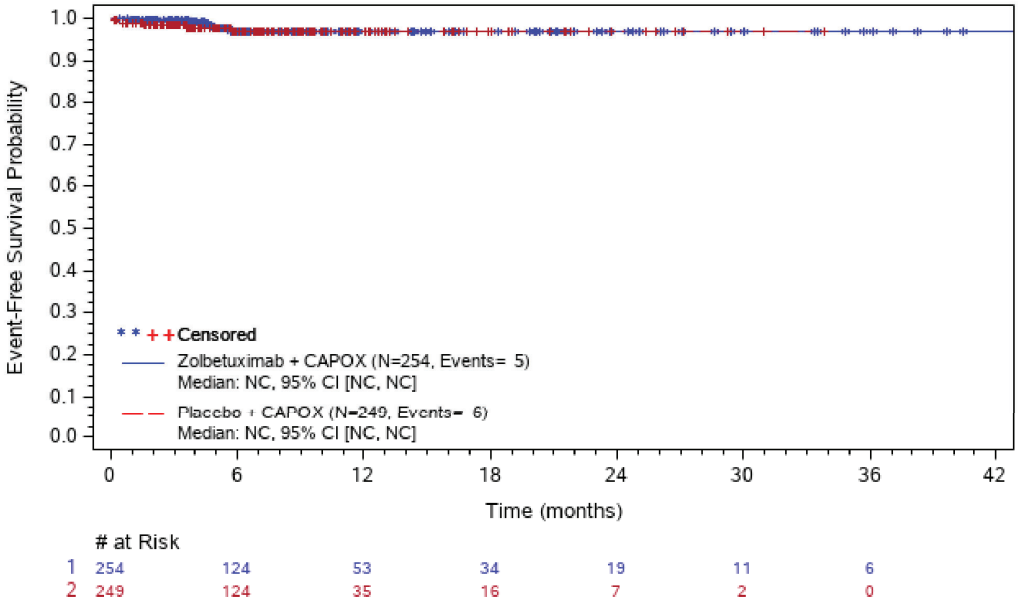
Figure 302.3.2001.107: Kaplan-Meier Plot of Time to first TESAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.108: Kaplan-Meier Plot of Time to first TESAE - Anaemia (PT) - Safety Analysis Set

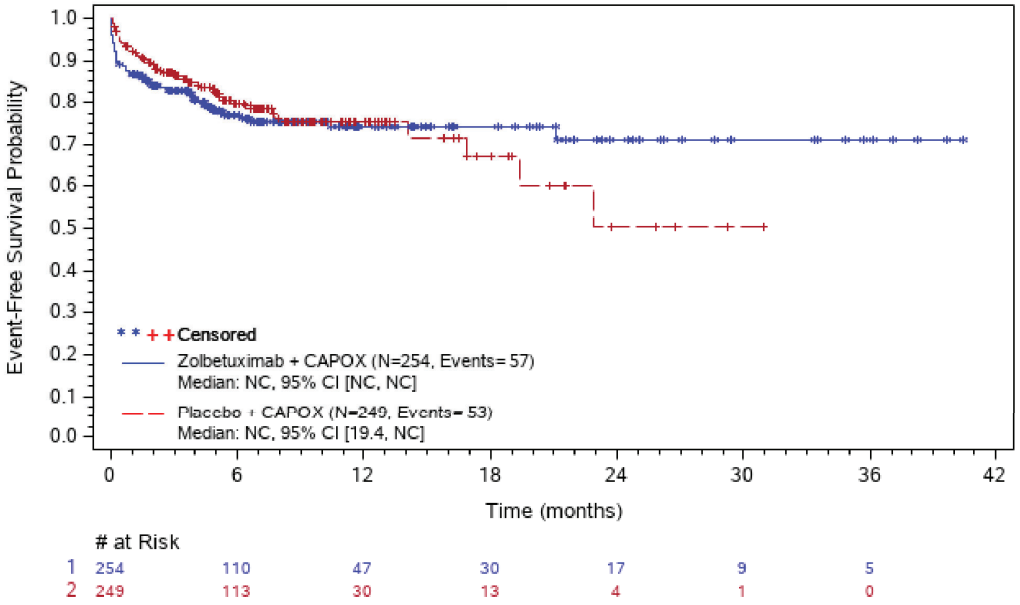


# at Risk							
1	254	124	53	34	19	11	6
2	249	124	35	16	7	2	0

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: 12JAN24

The SAS System

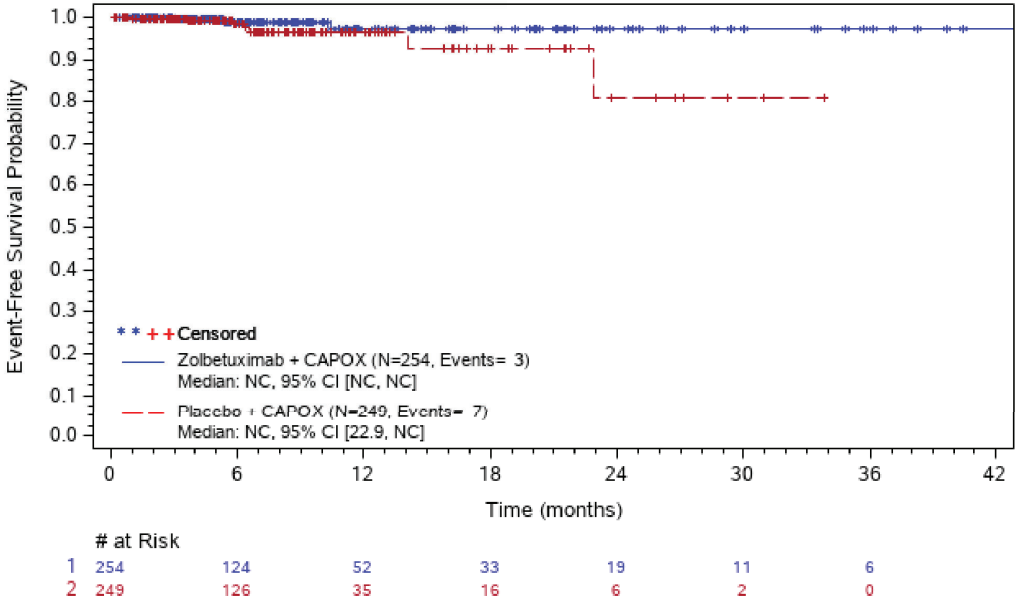
Figure 302.3.2001.109: Kaplan-Meier Plot of Time to first TESAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

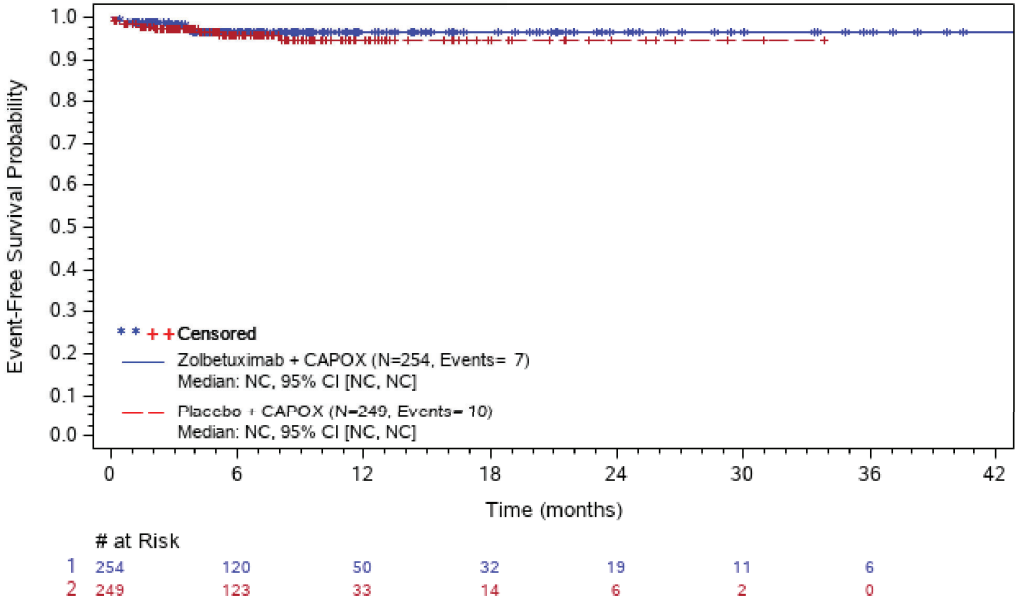
Figure 302.3.2001.110: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

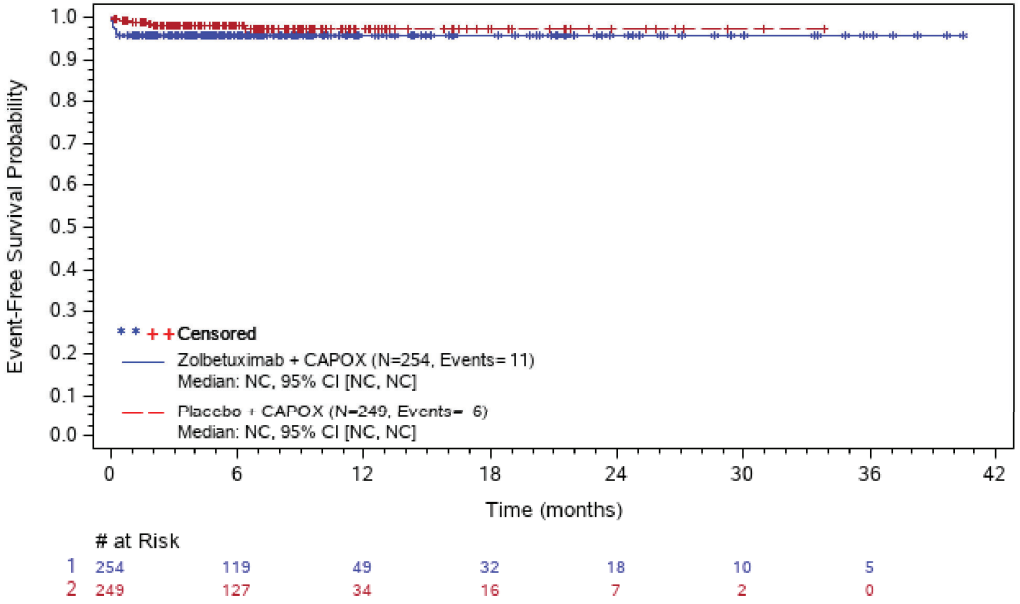
Figure 302.3.2001.111: Kaplan-Meier Plot of Time to first TESAE - Diarrhoea (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

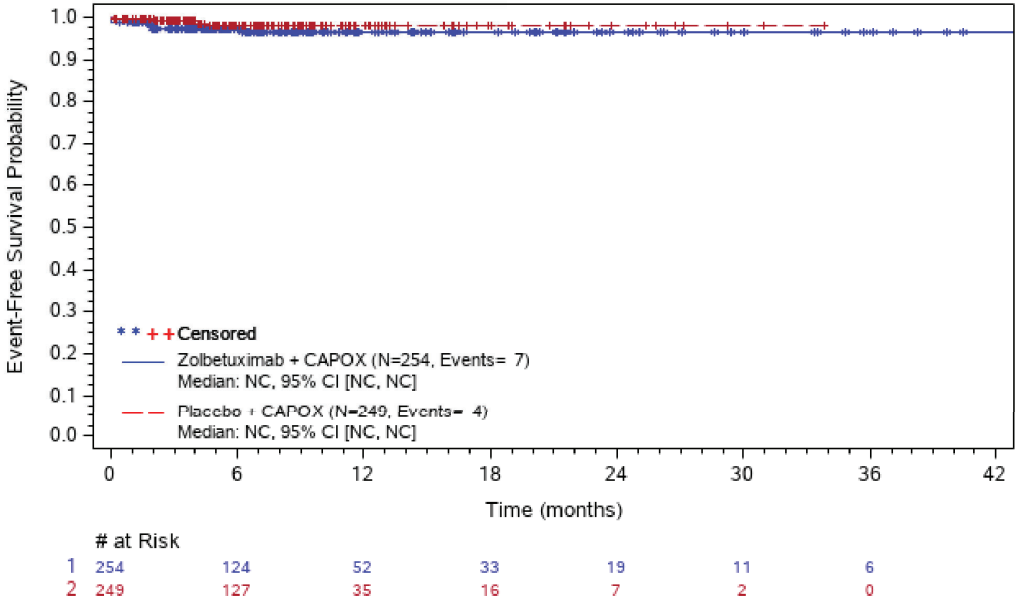
Figure 302.3.2001.112: Kaplan-Meier Plot of Time to first TESAE - Nausea (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

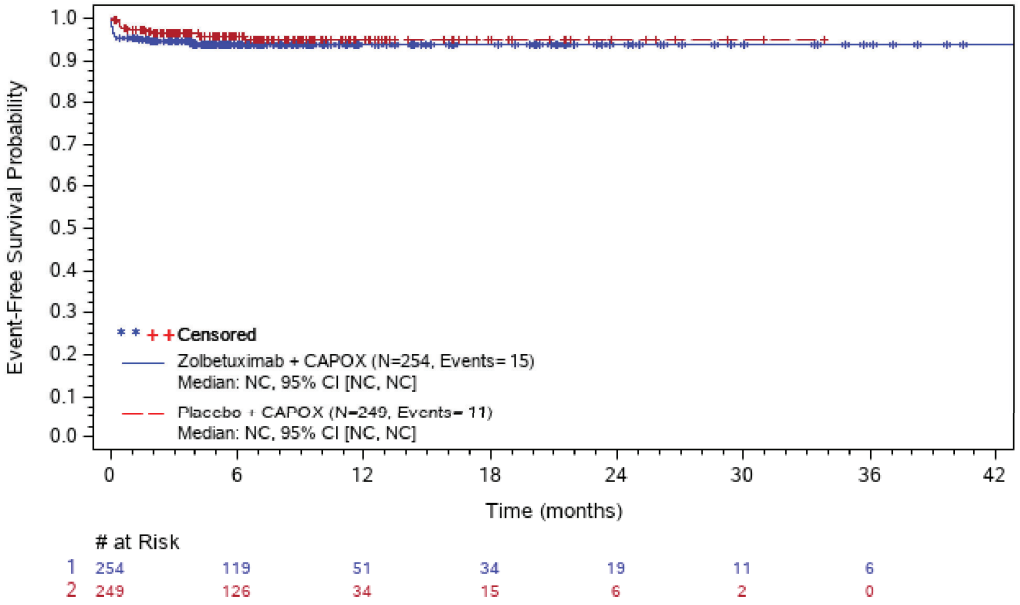
Figure 302.3.2001.113: Kaplan-Meier Plot of Time to first TESAE - Upper Gastrointestinal Haemorrhage (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

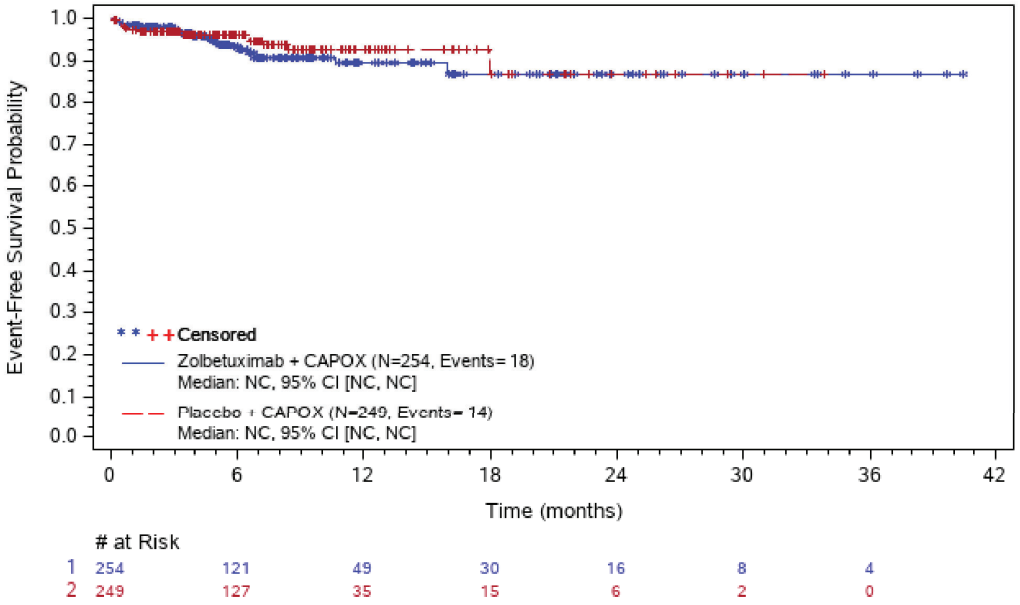
Figure 302.3.2001.114: Kaplan-Meier Plot of Time to first TESAE - Vomiting (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.115: Kaplan-Meier Plot of Time to first TESAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

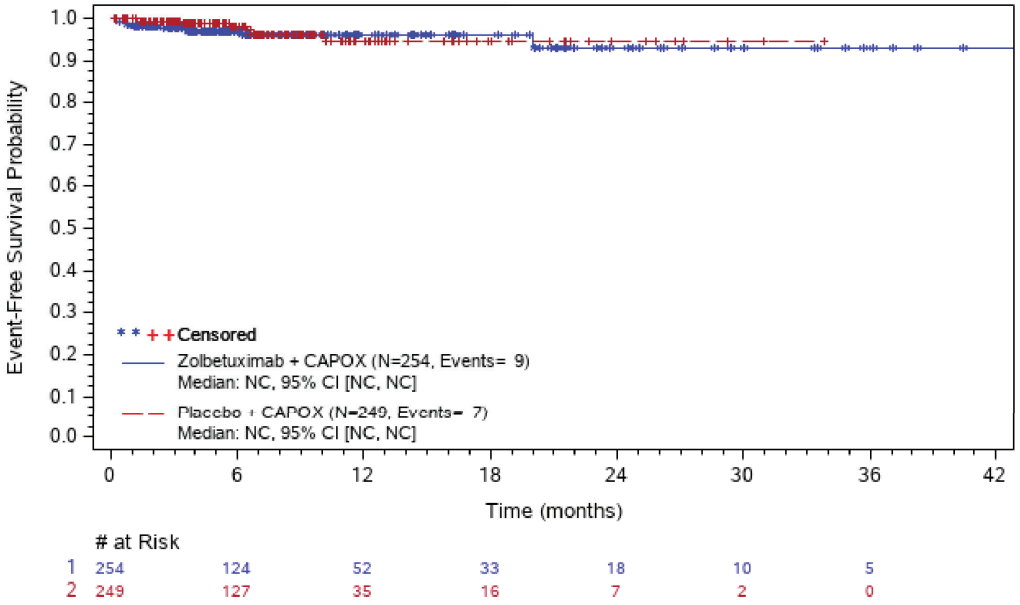


# at Risk							
1	254	121	49	30	16	8	4
2	249	127	35	15	6	2	0

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: 12JAN24

The SAS System

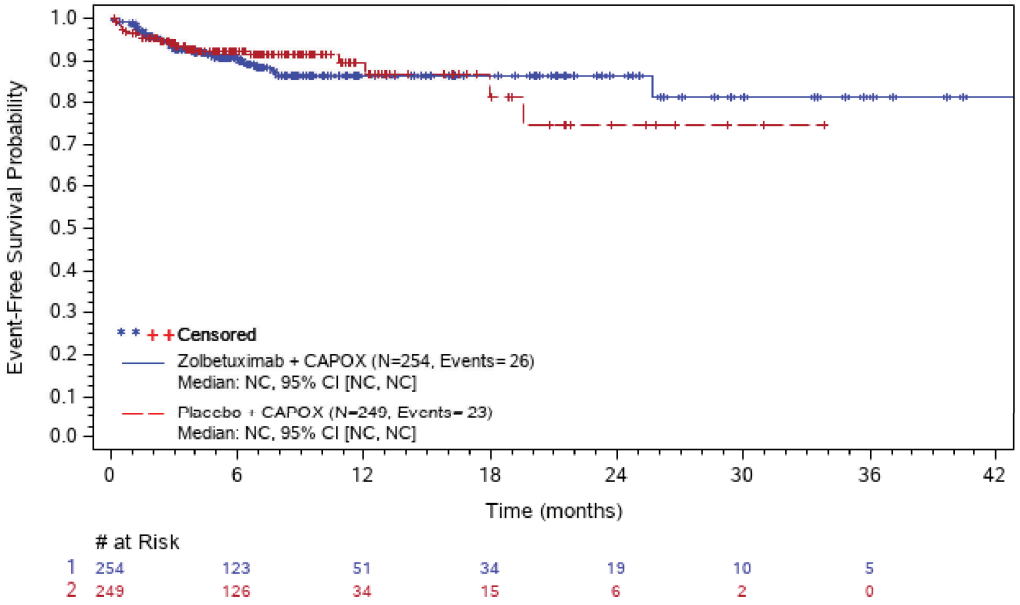
Figure 302.3.2001.116: Kaplan-Meier Plot of Time to first TESAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.117: Kaplan-Meier Plot of Time to first TESAE - Infections And Infestations (SOC) - Safety Analysis Set

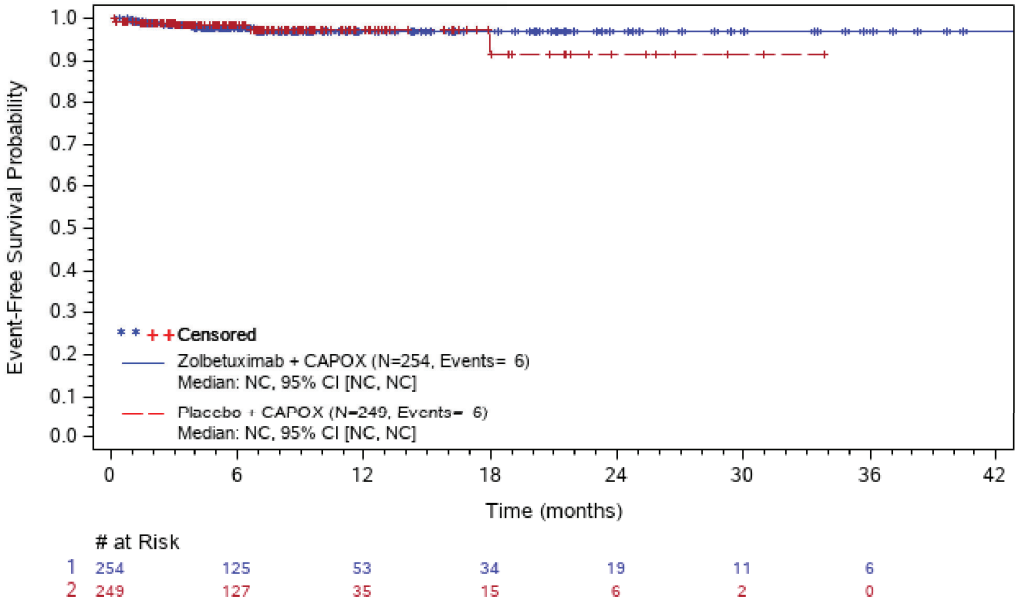


# at Risk							
1	254	123	51	34	19	10	5
2	249	126	34	15	6	2	0

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: 12JAN24

The SAS System

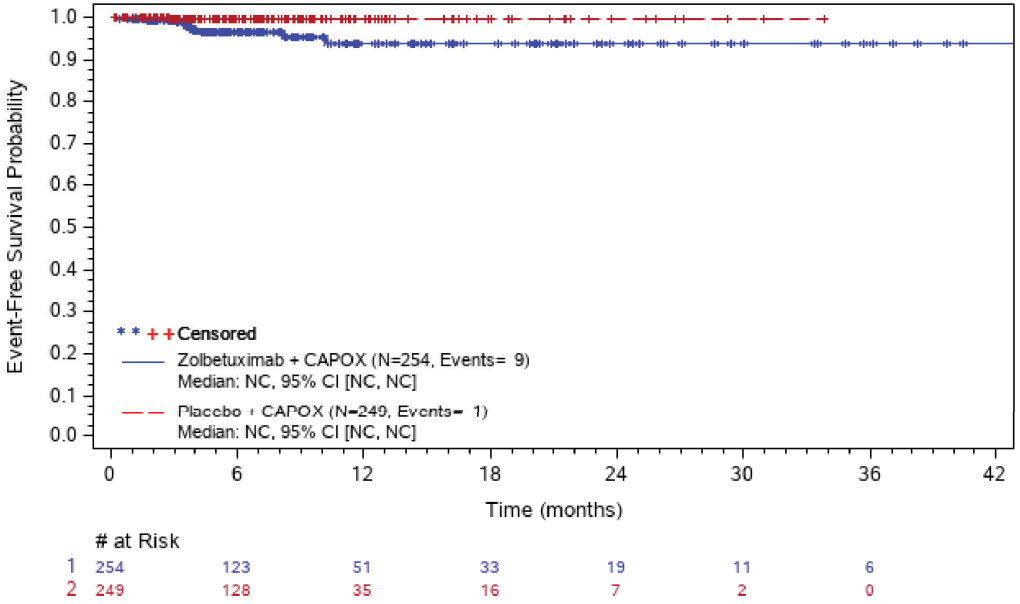
Figure 302.3.2001.118: Kaplan-Meier Plot of Time to first TESAE - Pneumonia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

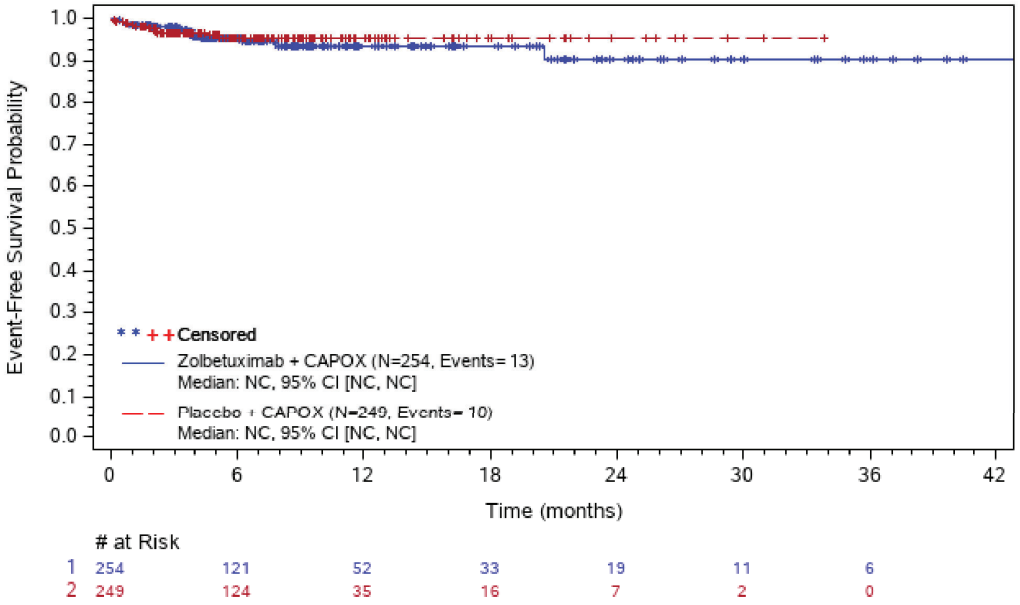
Figure 302.3.2001.119: Kaplan-Meier Plot of Time to first TESAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

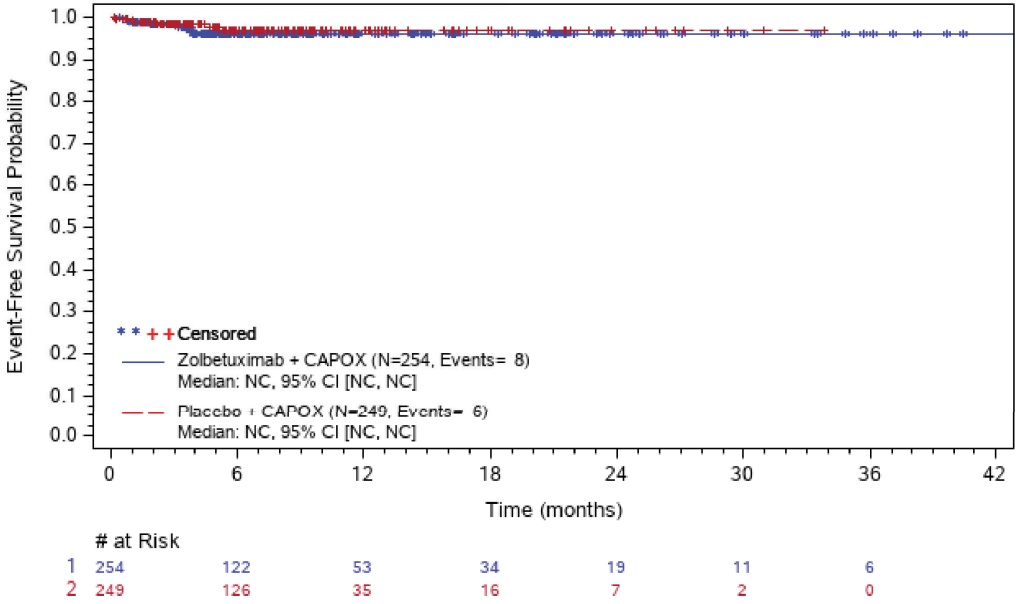
Figure 302.3.2001.120: Kaplan-Meier Plot of Time to first TESAE - Investigations (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

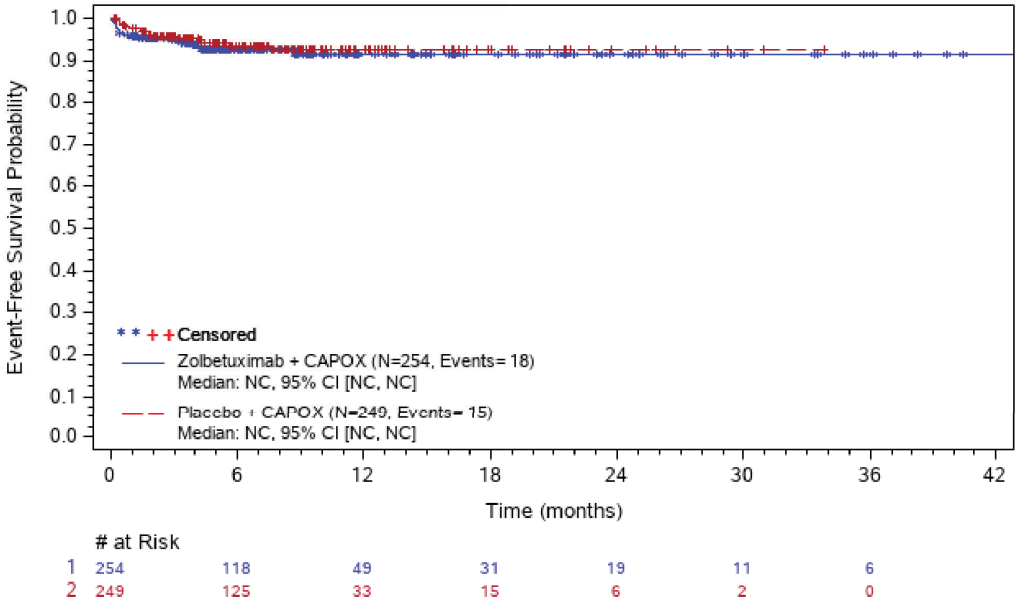
Figure 302.3.2001.121: Kaplan-Meier Plot of Time to first TESAE - Platelet Count Decreased (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.122: Kaplan-Meier Plot of Time to first TESAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

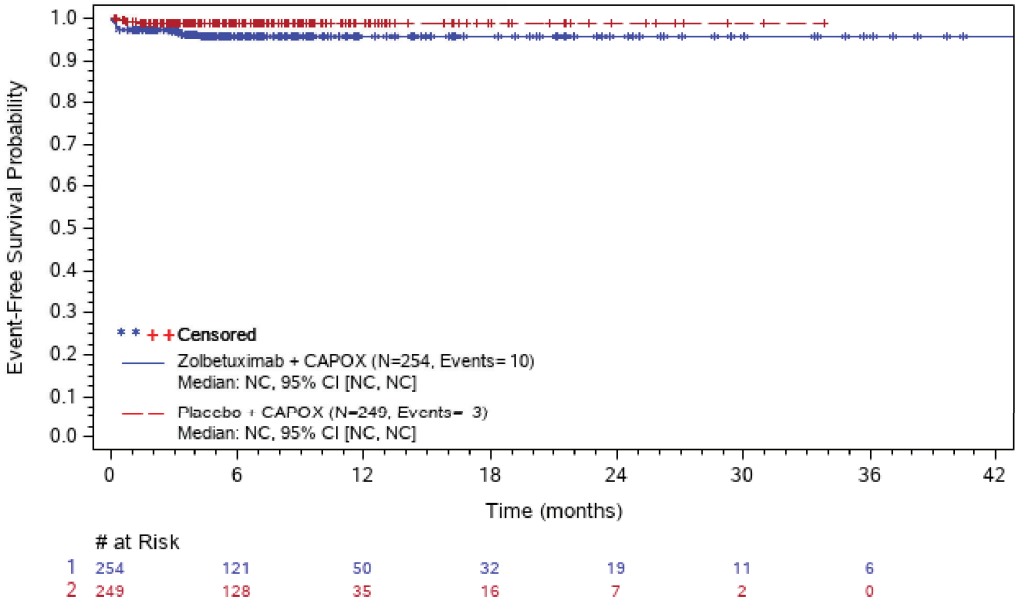


# at Risk							
1	254	118	49	31	19	11	6
2	249	125	33	15	6	2	0

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: 12JAN24

The SAS System

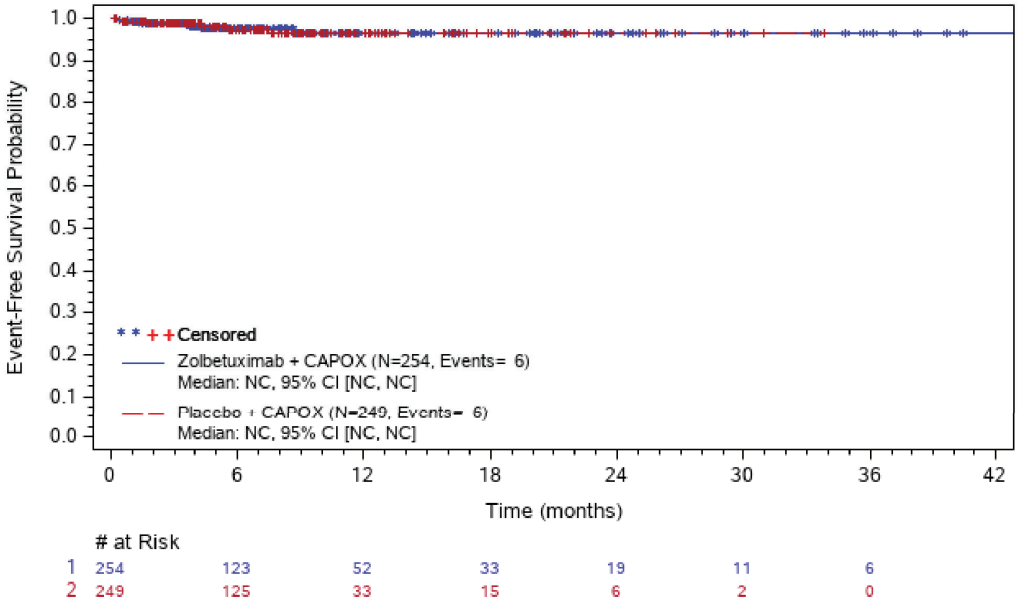
Figure 302.3.2001.123: Kaplan-Meier Plot of Time to first TESAE - Decreased Appetite (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

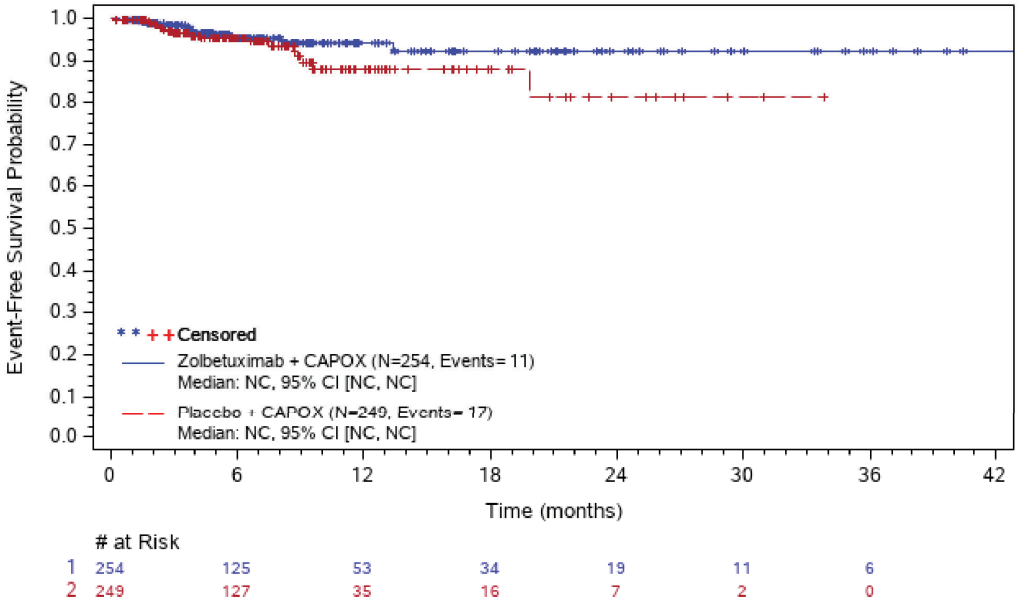
Figure 302.3.2001.124: Kaplan-Meier Plot of Time to first TESAE - Hypokalaemia (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.125: Kaplan-Meier Plot of Time to first TESAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

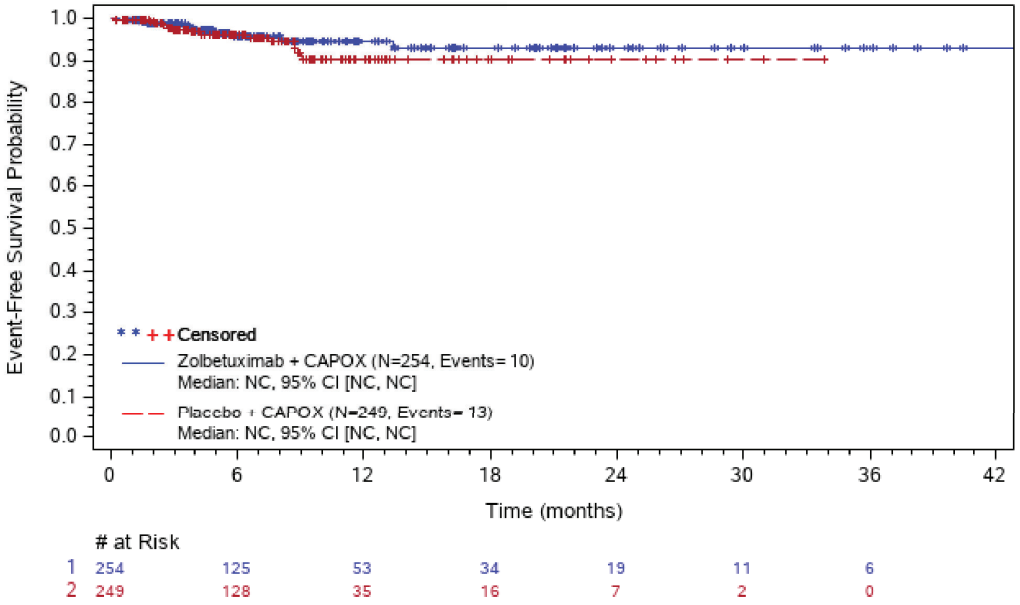


# at Risk							
1	254	125	53	34	19	11	6
2	249	127	35	16	7	2	0

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: 12JAN24

The SAS System

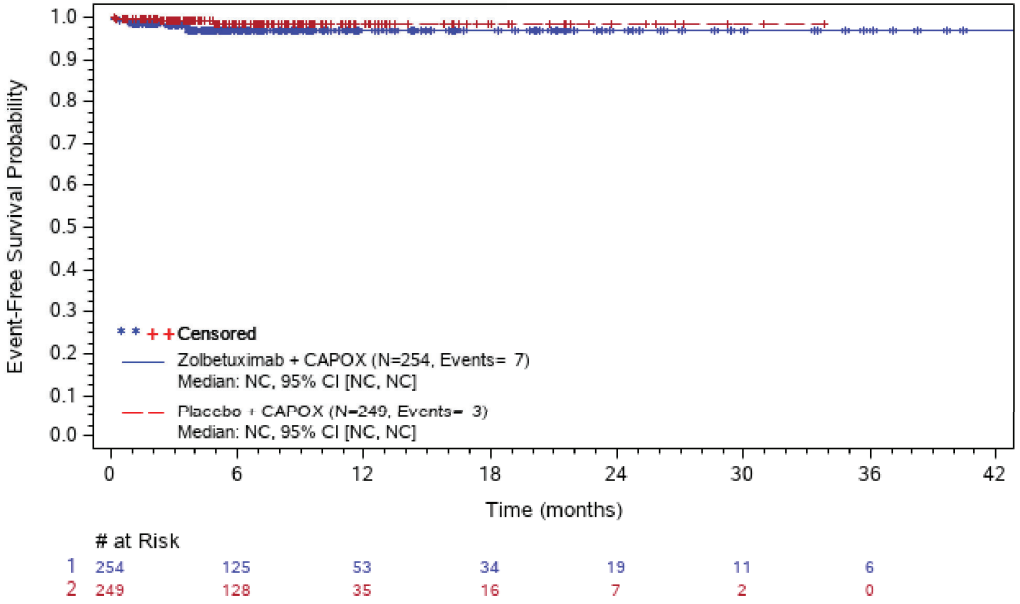
Figure 302.3.2001.126: Kaplan-Meier Plot of Time to first TESAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



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: 12JAN24

The SAS System

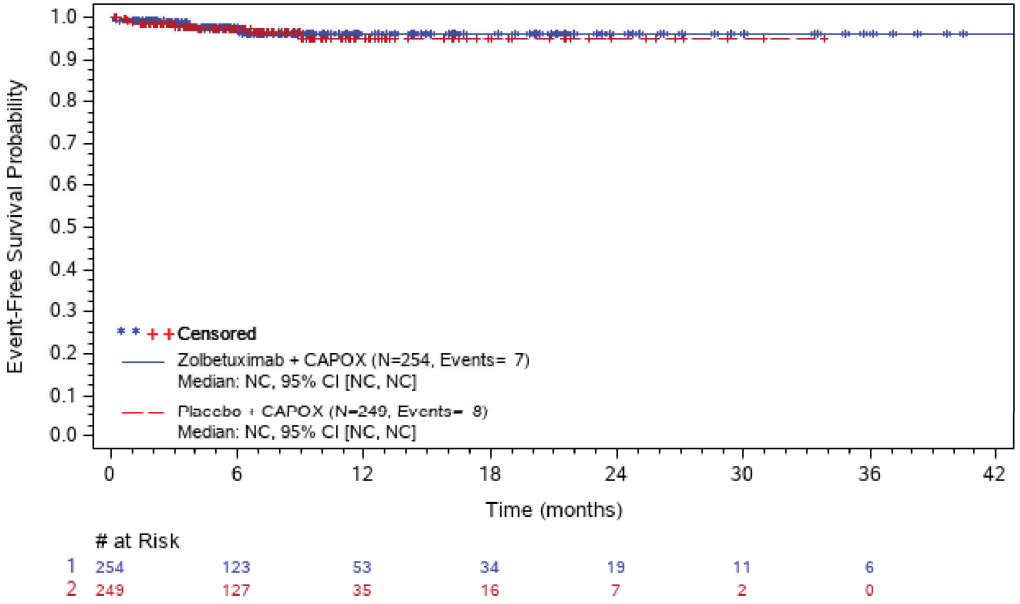
Figure 302.3.2001.127: Kaplan-Meier Plot of Time to first TESAE - Nervous System Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

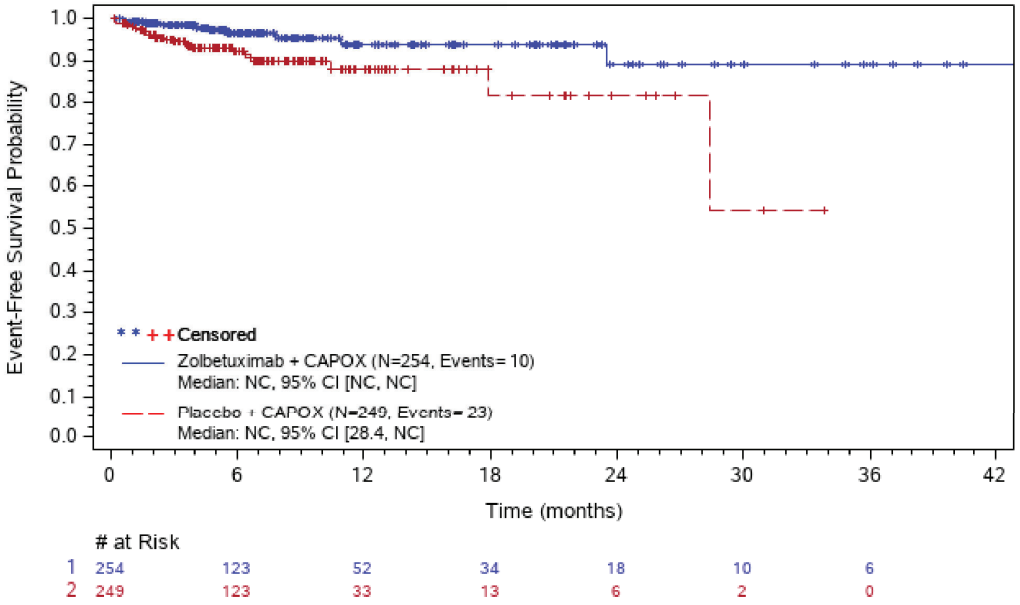
Figure 302.3.2001.128: Kaplan-Meier Plot of Time to first TESAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set



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: 12JAN24

The SAS System

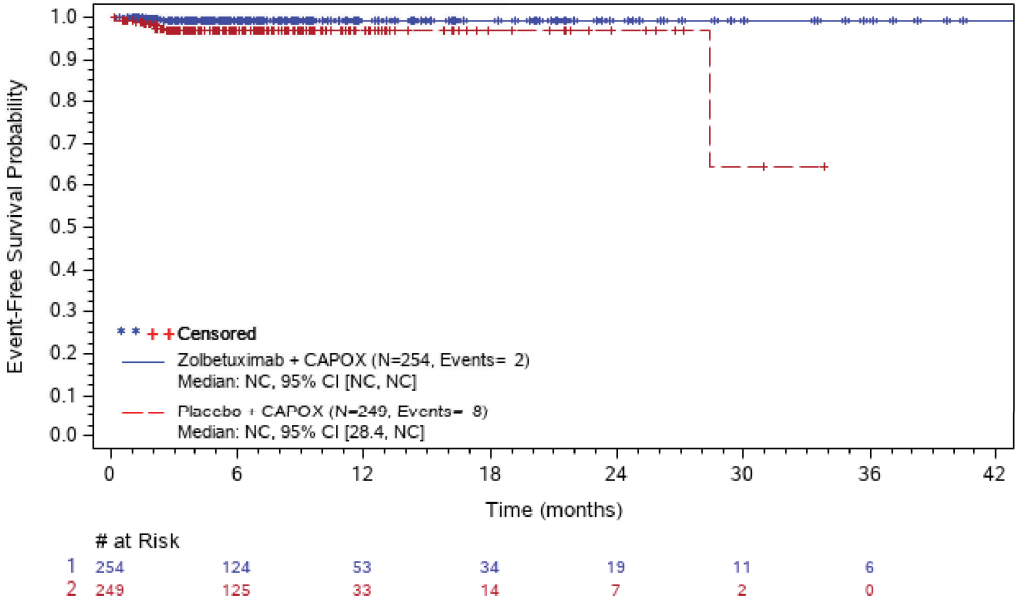
Figure 302.3.2001.129: Kaplan-Meier Plot of Time to first TESAE - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

Figure 302.3.2001.130: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Abbruchgründe – SOC und PT

Table 302.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Overall	81 (31.9%)	64 (25.7%)	145 (28.8%)
Gastrointestinal Disorders	27 (10.6%)	13 (5.2%)	40 (8.0%)
Vomiting	9 (3.5%)	4 (1.6%)	13 (2.6%)
Nausea	6 (2.4%)	3 (1.2%)	9 (1.8%)
Diarrhoea	5 (2.0%)	2 (0.8%)	7 (1.4%)
Upper Gastrointestinal Haemorrhage	3 (1.2%)	1 (0.4%)	4 (0.8%)
Abdominal Pain	3 (1.2%)	0	3 (0.6%)
Abdominal Pain Upper	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dysphagia	2 (0.8%)	0	2 (0.4%)
Obstruction Gastric	2 (0.8%)	0	2 (0.4%)
Enterocolitis	0	1 (0.4%)	1 (0.2%)
Gastric Haemorrhage	0	1 (0.4%)	1 (0.2%)
Gastric Stenosis	1 (0.4%)	0	1 (0.2%)
Gastrooesophageal Reflux Disease	0	1 (0.4%)	1 (0.2%)
Haematemesis	0	1 (0.4%)	1 (0.2%)
Haemorrhagic Ascites	1 (0.4%)	0	1 (0.2%)
Ileus	1 (0.4%)	0	1 (0.2%)
Intestinal Obstruction	1 (0.4%)	0	1 (0.2%)
Intra-Abdominal Haemorrhage	0	1 (0.4%)	1 (0.2%)
Swollen Tongue	1 (0.4%)	0	1 (0.2%)
Nervous System Disorders	15 (5.9%)	10 (4.0%)	25 (5.0%)
Peripheral Sensory Neuropathy	5 (2.0%)	5 (2.0%)	10 (2.0%)
Neuropathy Peripheral	1 (0.4%)	2 (0.8%)	3 (0.6%)
Dizziness	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypoaesthesia	2 (0.8%)	0	2 (0.4%)
Paraesthesia	2 (0.8%)	0	2 (0.4%)
Cerebral Haemorrhage	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: 12JAN24

Table 302.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Cerebrovascular Accident	1 (0.4%)	0	1 (0.2%)
Dysaesthesia	1 (0.4%)	0	1 (0.2%)
Dysarthria	0	1 (0.4%)	1 (0.2%)
Epilepsy	0	1 (0.4%)	1 (0.2%)
Intracranial Pressure Increased	1 (0.4%)	0	1 (0.2%)
Neurotoxicity	0	1 (0.4%)	1 (0.2%)
Investigations	14 (5.5%)	8 (3.2%)	22 (4.4%)
Platelet Count Decreased	5 (2.0%)	3 (1.2%)	8 (1.6%)
Neutrophil Count Decreased	3 (1.2%)	2 (0.8%)	5 (1.0%)
Alanine Aminotransferase Increased	3 (1.2%)	1 (0.4%)	4 (0.8%)
Aspartate Aminotransferase Increased	2 (0.8%)	2 (0.8%)	4 (0.8%)
Blood Bilirubin Increased	4 (1.6%)	0	4 (0.8%)
Blood Pressure Decreased	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%)
Weight Decreased	1 (0.4%)	0	1 (0.2%)
White Blood Cell Count Decreased	0	1 (0.4%)	1 (0.2%)
Blood And Lymphatic System Disorders	7 (2.8%)	9 (3.6%)	16 (3.2%)
Neutropenia	4 (1.6%)	5 (2.0%)	9 (1.8%)
Anaemia	0	3 (1.2%)	3 (0.6%)
Thrombocytopenia	2 (0.8%)	0	2 (0.4%)
Coagulopathy	0	1 (0.4%)	1 (0.2%)
Disseminated Intravascular Coagulation	1 (0.4%)	0	1 (0.2%)
Leukopenia	0	1 (0.4%)	1 (0.2%)
General Disorders And Administration Site Conditions	9 (3.5%)	6 (2.4%)	15 (3.0%)
Asthenia	1 (0.4%)	2 (0.8%)	3 (0.6%)
Chest Discomfort	2 (0.8%)	1 (0.4%)	3 (0.6%)

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: 12JAN24

Table 302.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Death	2 (0.8%)	1 (0.4%)	3 (0.6%)
Malaise	2 (0.8%)	0	2 (0.4%)
Fatigue	1 (0.4%)	0	1 (0.2%)
Mucosal Inflammation	0	1 (0.4%)	1 (0.2%)
Performance Status Decreased	0	1 (0.4%)	1 (0.2%)
Sudden Death	1 (0.4%)	0	1 (0.2%)
Infections And Infestations	6 (2.4%)	7 (2.8%)	13 (2.6%)
Pneumonia	3 (1.2%)	2 (0.8%)	5 (1.0%)
Septic Shock	1 (0.4%)	2 (0.8%)	3 (0.6%)
Abdominal Infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Escherichia Infection	0	1 (0.4%)	1 (0.2%)
Infection	0	1 (0.4%)	1 (0.2%)
Lower Respiratory Tract Infection	1 (0.4%)	0	1 (0.2%)
Mucosal Infection	0	1 (0.4%)	1 (0.2%)
Metabolism And Nutrition Disorders	5 (2.0%)	6 (2.4%)	11 (2.2%)
Decreased Appetite	2 (0.8%)	3 (1.2%)	5 (1.0%)
Acidosis	0	1 (0.4%)	1 (0.2%)
Dehydration	1 (0.4%)	0	1 (0.2%)
Electrolyte Imbalance	0	1 (0.4%)	1 (0.2%)
Hypoalbuminaemia	0	1 (0.4%)	1 (0.2%)
Hypokalaemia	1 (0.4%)	0	1 (0.2%)
Hypophosphataemia	1 (0.4%)	0	1 (0.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	4 (1.6%)	7 (2.8%)	11 (2.2%)
Malignant Neoplasm Progression	4 (1.6%)	4 (1.6%)	8 (1.6%)
Metastases To Meninges	0	1 (0.4%)	1 (0.2%)
Metastases To Peritoneum	0	1 (0.4%)	1 (0.2%)
Tumour Haemorrhage	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: 12JAN24

Table 302.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Respiratory, Thoracic And Mediastinal Disorders	1 (0.4%)	9 (3.6%)	10 (2.0%)
Dyspnoea	1 (0.4%)	3 (1.2%)	4 (0.8%)
Pleural Effusion	0	4 (1.6%)	4 (0.8%)
Acute Respiratory Distress Syndrome	0	1 (0.4%)	1 (0.2%)
Epistaxis	0	1 (0.4%)	1 (0.2%)
Pulmonary Oedema	0	1 (0.4%)	1 (0.2%)
Respiratory Failure	0	1 (0.4%)	1 (0.2%)
Skin And Subcutaneous Tissue Disorders	5 (2.0%)	2 (0.8%)	7 (1.4%)
Palmar-Plantar Erythrodysaesthesia Syndrome	2 (0.8%)	1 (0.4%)	3 (0.6%)
Cold Sweat	0	1 (0.4%)	1 (0.2%)
Pruritus	1 (0.4%)	0	1 (0.2%)
Rash Erythematous	1 (0.4%)	0	1 (0.2%)
Skin Necrosis	1 (0.4%)	0	1 (0.2%)
Hepatobiliary Disorders	3 (1.2%)	3 (1.2%)	6 (1.2%)
Deficiency Of Bile Secretion	1 (0.4%)	0	1 (0.2%)
Hepatic Failure	1 (0.4%)	0	1 (0.2%)
Hepatic Function Abnormal	1 (0.4%)	0	1 (0.2%)
Hepatitis Acute	0	1 (0.4%)	1 (0.2%)
Hepatotoxicity	0	1 (0.4%)	1 (0.2%)
Hyperbilirubinaemia	0	1 (0.4%)	1 (0.2%)
Jaundice	1 (0.4%)	0	1 (0.2%)
Renal And Urinary Disorders	2 (0.8%)	3 (1.2%)	5 (1.0%)
Acute Kidney Injury	1 (0.4%)	2 (0.8%)	3 (0.6%)
Choluria	1 (0.4%)	0	1 (0.2%)
Chronic Kidney Disease	0	1 (0.4%)	1 (0.2%)
Cardiac Disorders	2 (0.8%)	2 (0.8%)	4 (0.8%)
Cardio-Respiratory Arrest	1 (0.4%)	1 (0.4%)	2 (0.4%)

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: 12JAN24

Table 302.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)	Total (N=503)
Atrial Fibrillation	1 (0.4%)	0	1 (0.2%)
Cardiac Arrest	0	1 (0.4%)	1 (0.2%)
Immune System Disorders	3 (1.2%)	1 (0.4%)	4 (0.8%)
Anaphylactic Reaction	3 (1.2%)	1 (0.4%)	4 (0.8%)
Injury, Poisoning And Procedural Complications	3 (1.2%)	0	3 (0.6%)
Fall	1 (0.4%)	0	1 (0.2%)
Head Injury	1 (0.4%)	0	1 (0.2%)
Infusion Related Reaction	1 (0.4%)	0	1 (0.2%)
Procedural Complication	1 (0.4%)	0	1 (0.2%)
Vascular Disorders	2 (0.8%)	0	2 (0.4%)
Embolism Venous	1 (0.4%)	0	1 (0.2%)
Flushing	1 (0.4%)	0	1 (0.2%)
Hypotension	1 (0.4%)	0	1 (0.2%)
Congenital, Familial And Genetic Disorders	1 (0.4%)	0	1 (0.2%)
Gene Mutation	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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse von besonderem Interesse

1. Time-to-Event-Analysen

Table 302.3.2001.165.1: Summary and Results of TEAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	61 (24.0%)	65 (26.1%)	
Number of patients censored	193 (76.0%)	184 (73.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	22.9 [14.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.921 [0.649, 1.309]
Log-rank test			
Two-sided stratified log-rank p-value			0.6427

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.165.2: Summary and Results of TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	41 (23.3)	NC [18.5, NC]	177	50 (28.2)	22.9 [14.1, NC]	0.773 [0.510, 1.171]	0.2216	0.1752
>65 years	78	20 (25.6)	NC [NC, NC]	72	15 (20.8)	NC [NC, NC]	1.382 [0.707, 2.701]	0.3438	
Sex									
Male	160	37 (23.1)	NC [NC, NC]	152	37 (24.3)	NC [14.1, NC]	0.966 [0.612, 1.524]	0.8777	0.8891
Female	94	24 (25.5)	NC [14.7, NC]	97	28 (28.9)	22.9 [14.9, NC]	0.858 [0.496, 1.486]	0.5802	
Region									
Asia	157	37 (23.6)	NC [NC, NC]	156	39 (25.0)	22.9 [14.1, NC]	0.939 [0.597, 1.476]	0.7817	0.9115
Non-Asia	97	24 (24.7)	NC [14.7, NC]	93	26 (28.0)	NC [NC, NC]	0.885 [0.507, 1.543]	0.6635	
Number of Organs with Metastatic Sites									
0-2	190	45 (23.7)	NC [NC, NC]	186	51 (27.4)	22.9 [14.9, NC]	0.860 [0.575, 1.286]	0.4576	0.5761
>=3	64	16 (25.0)	NC [7.5, NC]	63	14 (22.2)	NC [8.5, NC]	1.120 [0.546, 2.294]	0.7591	

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; 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: 12JAN24

Table 302.3.2001.166.1: Summary and Results of TEAEs - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	93 (36.6%)	93 (37.3%)	
Number of patients censored	161 (63.4%)	156 (62.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	13.4 [7.4, NC]	18.1 [8.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.965 [0.723, 1.288]
Log-rank test			
Two-sided stratified log-rank p-value			0.8058

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.166.2: Summary and Results of TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	67 (38.1)	13.4 [6.7, NC]	177	63 (35.6)	18.1 [8.4, NC]	1.056 [0.749, 1.491]	0.7556	0.4939
>65 years	78	26 (33.3)	NC [4.1, NC]	72	30 (41.7)	22.0 [3.7, NC]	0.843 [0.499, 1.426]	0.5200	
Sex									
Male	160	50 (31.3)	NC [9.4, NC]	152	56 (36.8)	18.1 [6.4, NC]	0.809 [0.552, 1.185]	0.2750	0.0765
Female	94	43 (45.7)	5.1 [3.9, 11.5]	97	37 (38.1)	22.0 [5.5, NC]	1.383 [0.890, 2.149]	0.1469	
Region									
Asia	157	61 (38.9)	13.4 [5.6, NC]	156	68 (43.6)	8.4 [4.2, NC]	0.836 [0.591, 1.182]	0.3085	0.1095
Non-Asia	97	32 (33.0)	11.5 [8.0, NC]	93	25 (26.9)	NC [18.1, NC]	1.409 [0.834, 2.379]	0.1986	
Number of Organs with Metastatic Sites									
0-2	190	67 (35.3)	NC [8.0, NC]	186	64 (34.4)	22.0 [12.9, NC]	1.036 [0.735, 1.460]	0.8394	0.6034
>=3	64	26 (40.6)	7.7 [3.6, NC]	63	29 (46.0)	6.0 [3.2, NC]	0.867 [0.511, 1.473]	0.5947	

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; 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: 12JAN24

Table 302.3.2001.167.1: Summary and Results of TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	39 (15.4%)	27 (10.8%)	
Number of patients censored	215 (84.6%)	222 (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			1.422 [0.868, 2.330]
Log-rank test			
Two-sided stratified log-rank p-value			0.1618

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.167.2: Summary and Results of TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	27 (15.3)	NC [NC, NC]	177	18 (10.2)	NC [NC, NC]	1.468 [0.807, 2.671]	0.2071	0.7861
>65 years	78	12 (15.4)	NC [16.0, NC]	72	9 (12.5)	NC [NC, NC]	1.247 [0.525, 2.966]	0.6175	
Sex									
Male	160	24 (15.0)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	1.801 [0.898, 3.612]	0.0923	0.2489
Female	94	15 (16.0)	NC [NC, NC]	97	15 (15.5)	NC [NC, NC]	1.070 [0.523, 2.191]	0.8674	
Region									
Asia	157	23 (14.6)	NC [NC, NC]	156	14 (9.0)	NC [NC, NC]	1.543 [0.791, 3.006]	0.1999	0.6010
Non-Asia	97	16 (16.5)	NC [NC, NC]	93	13 (14.0)	NC [NC, NC]	1.212 [0.582, 2.525]	0.6120	
Number of Organs with Metastatic Sites									
0-2	190	29 (15.3)	NC [NC, NC]	186	20 (10.8)	NC [NC, NC]	1.380 [0.779, 2.444]	0.2682	0.9527
>=3	64	10 (15.6)	NC [NC, NC]	63	7 (11.1)	NC [NC, NC]	1.446 [0.550, 3.801]	0.4552	

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; 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: 12JAN24

Table 302.3.2001.168.1: Summary and Results of TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	91 (35.8%)	25 (10.0%)	
Number of patients censored	163 (64.2%)	224 (90.0%)	
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			4.541 [2.908, 7.092]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.168.2: Summary and Results of TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	65 (36.9)	NC [NC, NC]	177	21 (11.9)	NC [NC, NC]	3.783 [2.312, 6.190]	<.0001	0.2585
>65 years	78	26 (33.3)	NC [NC, NC]	72	4 (5.6)	NC [NC, NC]	7.217 [2.515, 20.709]	<.0001	
Sex									
Male	160	55 (34.4)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	5.242 [2.806, 9.793]	<.0001	0.3724
Female	94	36 (38.3)	NC [10.7, NC]	97	13 (13.4)	NC [NC, NC]	3.545 [1.878, 6.691]	<.0001	
Region									
Asia	157	44 (28.0)	NC [NC, NC]	156	12 (7.7)	NC [NC, NC]	4.083 [2.155, 7.733]	<.0001	0.8255
Non-Asia	97	47 (48.5)	6.3 [0.7, NC]	93	13 (14.0)	NC [NC, NC]	4.879 [2.633, 9.039]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	71 (37.4)	NC [NC, NC]	186	20 (10.8)	NC [NC, NC]	4.279 [2.604, 7.033]	<.0001	0.8699
>=3	64	20 (31.3)	NC [NC, NC]	63	5 (7.9)	NC [NC, NC]	4.649 [1.743, 12.397]	0.0008	

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; 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: 12JAN24

Table 302.3.2001.169.1: Summary and Results of TEAEs - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	175 (68.9%)	125 (50.2%)	
Number of patients censored	79 (31.1%)	124 (49.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.1, 0.4]	5.5 [2.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.961 [1.554, 2.477]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.169.2: Summary and Results of TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	125 (71.0)	0.1 [0.0, 0.1]	177	95 (53.7)	2.9 [0.9, NC]	1.914 [1.463, 2.502]	<.0001	0.7043
>65 years	78	50 (64.1)	0.5 [0.1, 3.8]	72	30 (41.7)	12.8 [2.9, NC]	2.033 [1.289, 3.209]	0.0021	
Sex									
Male	160	108 (67.5)	0.1 [0.0, 0.7]	152	72 (47.4)	7.6 [2.3, NC]	1.946 [1.442, 2.625]	<.0001	0.8054
Female	94	67 (71.3)	0.1 [0.0, 0.7]	97	53 (54.6)	2.9 [0.8, NC]	1.891 [1.316, 2.717]	0.0011	
Region									
Asia	157	114 (72.6)	0.1 [0.0, 0.4]	156	77 (49.4)	6.3 [0.8, NC]	2.046 [1.530, 2.736]	<.0001	0.4862
Non-Asia	97	61 (62.9)	0.1 [0.1, 0.9]	93	48 (51.6)	5.5 [2.0, NC]	1.721 [1.176, 2.517]	0.0094	
Number of Organs with Metastatic Sites									
0-2	190	133 (70.0)	0.1 [0.0, 0.1]	186	101 (54.3)	2.9 [1.0, 8.3]	1.816 [1.400, 2.355]	<.0001	0.3368
>=3	64	42 (65.6)	0.7 [0.0, 2.9]	63	24 (38.1)	12.8 [2.9, 12.8]	2.281 [1.378, 3.777]	0.0014	

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; 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: 12JAN24

Table 302.3.2001.170.1: Summary and Results of TEAEs - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	119 (46.9%)	95 (38.2%)	
Number of patients censored	135 (53.1%)	154 (61.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.1 [3.8, 5.9]	9.8 [5.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.311 [0.998, 1.721]
Log-rank test			
Two-sided stratified log-rank p-value			0.0521

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.170.2: Summary and Results of TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	83 (47.2)	5.3 [3.8, 7.9]	177	62 (35.0)	NC [6.7, NC]	1.427 [1.027, 1.984]	0.0331	0.5198
>65 years	78	36 (46.2)	4.1 [2.3, NC]	72	33 (45.8)	5.7 [3.1, 8.3]	1.206 [0.750, 1.937]	0.4490	
Sex									
Male	160	69 (43.1)	5.3 [3.8, NC]	152	52 (34.2)	NC [6.1, NC]	1.345 [0.938, 1.928]	0.1053	0.8812
Female	94	50 (53.2)	4.1 [3.1, 5.4]	97	43 (44.3)	8.3 [4.4, NC]	1.405 [0.933, 2.116]	0.1022	
Region									
Asia	157	80 (51.0)	4.2 [3.4, 5.9]	156	63 (40.4)	9.8 [4.4, NC]	1.315 [0.945, 1.831]	0.1023	0.9007
Non-Asia	97	39 (40.2)	5.7 [4.1, NC]	93	32 (34.4)	NC [5.8, NC]	1.398 [0.875, 2.233]	0.1610	
Number of Organs with Metastatic Sites									
0-2	190	92 (48.4)	5.1 [3.6, 5.8]	186	75 (40.3)	NC [4.7, NC]	1.307 [0.963, 1.773]	0.0858	0.6585
>=3	64	27 (42.2)	4.2 [3.5, NC]	63	20 (31.7)	9.8 [5.7, NC]	1.470 [0.819, 2.637]	0.1930	

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; 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: 12JAN24

Table 302.3.2001.171.1: Summary and Results of TEAEs - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	169 (66.5%)	79 (31.7%)	
Number of patients censored	85 (33.5%)	170 (68.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.0, 0.7]	NC [17.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.345 [2.552, 4.383]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.171.2: Summary and Results of TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	122 (69.3)	0.0 [0.0, 0.2]	177	60 (33.9)	NC [17.3, NC]	3.417 [2.502, 4.666]	<.0001	0.9853
>65 years	78	47 (60.3)	0.9 [0.2, 6.8]	72	19 (26.4)	NC [NC, NC]	3.174 [1.858, 5.423]	<.0001	
Sex									
Male	160	101 (63.1)	0.3 [0.1, 1.4]	152	42 (27.6)	NC [17.3, NC]	3.418 [2.380, 4.907]	<.0001	0.7195
Female	94	68 (72.3)	0.0 [0.0, 0.2]	97	37 (38.1)	NC [5.5, NC]	3.313 [2.210, 4.965]	<.0001	
Region									
Asia	157	109 (69.4)	0.0 [0.0, 0.2]	156	46 (29.5)	NC [NC, NC]	3.828 [2.705, 5.416]	<.0001	0.1991
Non-Asia	97	60 (61.9)	0.7 [0.1, 1.9]	93	33 (35.5)	NC [17.3, NC]	2.634 [1.718, 4.039]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	125 (65.8)	0.1 [0.0, 0.9]	186	59 (31.7)	NC [17.3, NC]	3.182 [2.331, 4.344]	<.0001	0.6995
>=3	64	44 (68.8)	0.1 [0.0, 0.7]	63	20 (31.7)	NC [5.8, NC]	3.697 [2.166, 6.310]	<.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; 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: 12JAN24

Table 302.3.2001.172.1: Summary and Results of Non-Severe TEAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	61 (24.0%)	63 (25.3%)	
Number of patients censored	193 (76.0%)	186 (74.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [22.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.958 [0.673, 1.365]
Log-rank test			
Two-sided stratified log-rank p-value			0.8094

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.172.2: Summary and Results of Non-Severe TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	41 (23.3)	NC [18.5, NC]	177	48 (27.1)	22.9 [14.9, NC]	0.816 [0.537, 1.242]	0.3395	0.2210
>65 years	78	20 (25.6)	NC [NC, NC]	72	15 (20.8)	NC [NC, NC]	1.382 [0.707, 2.701]	0.3438	
Sex									
Male	160	37 (23.1)	NC [NC, NC]	152	35 (23.0)	NC [NC, NC]	1.031 [0.649, 1.638]	0.8982	0.7936
Female	94	24 (25.5)	NC [14.7, NC]	97	28 (28.9)	22.9 [14.9, NC]	0.868 [0.501, 1.502]	0.6070	
Region									
Asia	157	37 (23.6)	NC [NC, NC]	156	37 (23.7)	22.9 [14.9, NC]	1.006 [0.637, 1.591]	0.9805	0.7816
Non-Asia	97	24 (24.7)	NC [14.7, NC]	93	26 (28.0)	NC [NC, NC]	0.885 [0.507, 1.543]	0.6635	
Number of Organs with Metastatic Sites									
0-2	190	45 (23.7)	NC [NC, NC]	186	50 (26.9)	22.9 [14.9, NC]	0.886 [0.591, 1.328]	0.5527	0.5008
>=3	64	16 (25.0)	NC [7.5, NC]	63	13 (20.6)	NC [NC, NC]	1.207 [0.580, 2.510]	0.6159	

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; 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: 12JAN24

Table 302.3.2001.173.1: Summary and Results of Non-Severe TEAEs - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	82 (32.3%)	88 (35.3%)	
Number of patients censored	172 (67.7%)	161 (64.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [10.4, NC]	22.0 [12.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.898 [0.664, 1.215]
Log-rank test			
Two-sided stratified log-rank p-value			0.4848

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.173.2: Summary and Results of Non-Severe TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	59 (33.5)	NC [8.5, NC]	177	59 (33.3)	18.1 [12.9, NC]	0.983 [0.685, 1.411]	0.9250	0.4632
>65 years	78	23 (29.5)	NC [9.4, NC]	72	29 (40.3)	22.0 [3.9, NC]	0.767 [0.443, 1.326]	0.3370	
Sex									
Male	160	45 (28.1)	NC [NC, NC]	152	54 (35.5)	18.1 [6.4, NC]	0.747 [0.502, 1.110]	0.1470	0.0956
Female	94	37 (39.4)	10.4 [4.4, NC]	97	34 (35.1)	22.0 [8.4, NC]	1.261 [0.791, 2.011]	0.3272	
Region									
Asia	157	55 (35.0)	NC [7.4, NC]	156	65 (41.7)	12.9 [4.5, NC]	0.780 [0.544, 1.118]	0.1750	0.1476
Non-Asia	97	27 (27.8)	NC [9.4, NC]	93	23 (24.7)	NC [18.1, NC]	1.282 [0.735, 2.238]	0.3827	
Number of Organs with Metastatic Sites									
0-2	190	60 (31.6)	NC [10.4, NC]	186	61 (32.8)	22.0 [12.9, NC]	0.968 [0.677, 1.383]	0.8570	0.5267
>=3	64	22 (34.4)	NC [4.2, NC]	63	27 (42.9)	6.0 [3.6, NC]	0.780 [0.444, 1.371]	0.3851	

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; 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: 12JAN24

Table 302.3.2001.174.1: Summary and Results of Non-Severe TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	34 (13.4%)	25 (10.0%)	
Number of patients censored	220 (86.6%)	224 (90.0%)	
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			1.354 [0.806, 2.275]
Log-rank test			
Two-sided stratified log-rank p-value			0.2524

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.174.2: Summary and Results of Non-Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	24 (13.6)	NC [NC, NC]	177	17 (9.6)	NC [NC, NC]	1.363 [0.730, 2.544]	0.3302	0.8107
>65 years	78	10 (12.8)	NC [NC, NC]	72	8 (11.1)	NC [NC, NC]	1.212 [0.478, 3.073]	0.6866	
Sex									
Male	160	20 (12.5)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	1.494 [0.728, 3.067]	0.2698	0.5619
Female	94	14 (14.9)	NC [NC, NC]	97	13 (13.4)	NC [NC, NC]	1.162 [0.546, 2.475]	0.7068	
Region									
Asia	157	21 (13.4)	NC [NC, NC]	156	12 (7.7)	NC [NC, NC]	1.661 [0.815, 3.384]	0.1587	0.3140
Non-Asia	97	13 (13.4)	NC [NC, NC]	93	13 (14.0)	NC [NC, NC]	0.975 [0.451, 2.108]	0.9448	
Number of Organs with Metastatic Sites									
0-2	190	24 (12.6)	NC [NC, NC]	186	18 (9.7)	NC [NC, NC]	1.268 [0.687, 2.342]	0.4472	0.8378
>=3	64	10 (15.6)	NC [NC, NC]	63	7 (11.1)	NC [NC, NC]	1.448 [0.551, 3.806]	0.4524	

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; 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: 12JAN24

Table 302.3.2001.175.1: Summary and Results of Non-Severe TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	84 (33.1%)	24 (9.6%)	
Number of patients censored	170 (66.9%)	225 (90.4%)	
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			4.269 [2.704, 6.738]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.175.2: Summary and Results of Non-Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	62 (35.2)	NC [NC, NC]	177	21 (11.9)	NC [NC, NC]	3.564 [2.172, 5.850]	<.0001	0.2090
>65 years	78	22 (28.2)	NC [NC, NC]	72	3 (4.2)	NC [NC, NC]	7.972 [2.383, 26.675]	<.0001	
Sex									
Male	160	53 (33.1)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	4.996 [2.669, 9.354]	<.0001	0.3444
Female	94	31 (33.0)	NC [10.7, NC]	97	12 (12.4)	NC [NC, NC]	3.224 [1.654, 6.284]	0.0004	
Region									
Asia	157	41 (26.1)	NC [NC, NC]	156	11 (7.1)	NC [NC, NC]	4.114 [2.113, 8.007]	<.0001	0.9675
Non-Asia	97	43 (44.3)	NC [0.7, NC]	93	13 (14.0)	NC [NC, NC]	4.323 [2.320, 8.058]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	64 (33.7)	NC [NC, NC]	186	19 (10.2)	NC [NC, NC]	3.976 [2.381, 6.639]	<.0001	0.7863
>=3	64	20 (31.3)	NC [NC, NC]	63	5 (7.9)	NC [NC, NC]	4.637 [1.739, 12.364]	0.0008	

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; 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: 12JAN24

Table 302.3.2001.176.1: Summary and Results of Non-Severe TEAEs - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	168 (66.1%)	123 (49.4%)	
Number of patients censored	86 (33.9%)	126 (50.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.1, 0.7]	6.3 [2.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.861 [1.470, 2.357]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.176.2: Summary and Results of Non-Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	119 (67.6)	0.1 [0.0, 0.7]	177	93 (52.5)	3.1 [1.1, NC]	1.806 [1.375, 2.372]	<.0001	0.6898
>65 years	78	49 (62.8)	0.7 [0.1, 3.8]	72	30 (41.7)	12.8 [2.9, NC]	1.943 [1.229, 3.072]	0.0041	
Sex									
Male	160	103 (64.4)	0.1 [0.1, 0.9]	152	71 (46.7)	8.3 [2.3, NC]	1.833 [1.353, 2.484]	0.0002	0.8736
Female	94	65 (69.1)	0.1 [0.0, 0.7]	97	52 (53.6)	2.9 [0.8, NC]	1.812 [1.256, 2.615]	0.0026	
Region									
Asia	157	109 (69.4)	0.1 [0.0, 0.7]	156	77 (49.4)	6.3 [0.8, NC]	1.885 [1.406, 2.527]	<.0001	0.6903
Non-Asia	97	59 (60.8)	0.2 [0.1, 1.4]	93	46 (49.5)	7.4 [2.3, NC]	1.714 [1.163, 2.525]	0.0112	
Number of Organs with Metastatic Sites									
0-2	190	127 (66.8)	0.1 [0.1, 0.7]	186	99 (53.2)	3.7 [1.2, NC]	1.720 [1.321, 2.239]	0.0002	0.3419
>=3	64	41 (64.1)	0.7 [0.0, 2.9]	63	24 (38.1)	12.8 [2.9, 12.8]	2.169 [1.307, 3.598]	0.0029	

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; 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: 12JAN24

Table 302.3.2001.177.1: Summary and Results of Non-Severe TEAEs - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	111 (43.7%)	82 (32.9%)	
Number of patients censored	143 (56.3%)	167 (67.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.3 [4.2, 20.7]	NC [9.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.405 [1.054, 1.873]
Log-rank test			
Two-sided stratified log-rank p-value			0.0200

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.177.2: Summary and Results of Non-Severe TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	76 (43.2)	5.8 [4.6, NC]	177	55 (31.1)	NC [NC, NC]	1.440 [1.017, 2.037]	0.0381	0.9343
>65 years	78	35 (44.9)	4.1 [2.8, NC]	72	27 (37.5)	7.9 [5.3, NC]	1.482 [0.895, 2.455]	0.1253	
Sex									
Male	160	65 (40.6)	5.9 [4.2, NC]	152	46 (30.3)	NC [NC, NC]	1.423 [0.975, 2.076]	0.0652	0.7753
Female	94	46 (48.9)	5.1 [3.5, 7.9]	97	36 (37.1)	14.7 [5.3, NC]	1.516 [0.979, 2.348]	0.0606	
Region									
Asia	157	75 (47.8)	4.8 [3.7, 7.9]	156	55 (35.3)	14.7 [7.9, NC]	1.404 [0.990, 1.989]	0.0548	0.8904
Non-Asia	97	36 (37.1)	6.0 [4.1, NC]	93	27 (29.0)	NC [NC, NC]	1.502 [0.911, 2.475]	0.1082	
Number of Organs with Metastatic Sites									
0-2	190	88 (46.3)	5.2 [4.1, 7.9]	186	63 (33.9)	NC [7.9, NC]	1.485 [1.074, 2.053]	0.0160	0.7057
>=3	64	23 (35.9)	NC [3.8, NC]	63	19 (30.2)	NC [5.7, NC]	1.299 [0.707, 2.385]	0.3971	

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; 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: 12JAN24

Table 302.3.2001.178.1: Summary and Results of Non-Severe TEAEs - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	161 (63.4%)	75 (30.1%)	
Number of patients censored	93 (36.6%)	174 (69.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.5 [0.1, 1.1]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.204 [2.429, 4.226]
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; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2001.178.2: Summary and Results of Non-Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	117 (66.5)	0.1 [0.0, 0.8]	177	58 (32.8)	NC [17.3, NC]	3.219 [2.345, 4.419]	<.0001	0.8839
>65 years	78	44 (56.4)	1.1 [0.3, NC]	72	17 (23.6)	NC [NC, NC]	3.157 [1.800, 5.540]	<.0001	
Sex									
Male	160	97 (60.6)	0.9 [0.2, 2.4]	152	39 (25.7)	NC [17.3, NC]	3.406 [2.345, 4.947]	<.0001	0.5312
Female	94	64 (68.1)	0.1 [0.0, 0.8]	97	36 (37.1)	NC [5.5, NC]	2.986 [1.978, 4.507]	<.0001	
Region									
Asia	157	105 (66.9)	0.1 [0.0, 0.9]	156	44 (28.2)	NC [NC, NC]	3.677 [2.581, 5.240]	<.0001	0.1890
Non-Asia	97	56 (57.7)	1.1 [0.2, NC]	93	31 (33.3)	NC [17.3, NC]	2.497 [1.606, 3.881]	<.0001	
Number of Organs with Metastatic Sites									
0-2	190	118 (62.1)	0.7 [0.1, 1.6]	186	55 (29.6)	NC [17.3, NC]	3.065 [2.222, 4.227]	<.0001	0.7709
>=3	64	43 (67.2)	0.2 [0.0, 1.2]	63	20 (31.7)	NC [5.8, NC]	3.483 [2.037, 5.954]	<.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; 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: 12JAN24

Table 302.3.2001.179.1: Summary and Results of Severe TEAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	1 (0.4%)	5 (2.0%)	
Number of patients censored	253 (99.6%)	244 (98.0%)	
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			0.160 [0.018, 1.403]
Log-rank test			
Two-sided stratified log-rank p-value			0.0608

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.179.2: Summary and Results of Severe TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	1 (0.6)		177	5 (2.8)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	1 (0.6)		152	4 (2.6)				
Female	94	0 (0.0)		97	1 (1.0)				
Region									
Asia	157	0 (0.0)		156	4 (2.6)				
Non-Asia	97	1 (1.0)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	1 (0.5)		186	3 (1.6)				
>=3	64	0 (0.0)		63	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; 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: 12JAN24

Table 302.3.2001.180.1: Summary and Results of Severe TEAEs - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	29 (11.4%)	28 (11.2%)	
Number of patients censored	225 (88.6%)	221 (88.8%)	
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			0.920 [0.543, 1.557]
Log-rank test			
Two-sided stratified log-rank p-value			0.7573

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.180.2: Summary and Results of Severe TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	22 (12.5)	NC [NC, NC]	177	18 (10.2)	NC [NC, NC]	1.173 [0.629, 2.187]	0.6152	0.3687
>65 years	78	7 (9.0)	NC [NC, NC]	72	10 (13.9)	NC [NC, NC]	0.698 [0.265, 1.835]	0.4636	
Sex									
Male	160	16 (10.0)	NC [NC, NC]	152	19 (12.5)	NC [NC, NC]	0.754 [0.387, 1.467]	0.4035	0.1687
Female	94	13 (13.8)	NC [NC, NC]	97	9 (9.3)	NC [NC, NC]	1.623 [0.693, 3.800]	0.2601	
Region									
Asia	157	20 (12.7)	NC [NC, NC]	156	20 (12.8)	NC [NC, NC]	0.930 [0.500, 1.731]	0.8208	0.6993
Non-Asia	97	9 (9.3)	NC [NC, NC]	93	8 (8.6)	NC [NC, NC]	1.171 [0.451, 3.035]	0.7453	
Number of Organs with Metastatic Sites									
0-2	190	18 (9.5)	NC [NC, NC]	186	16 (8.6)	NC [NC, NC]	1.122 [0.572, 2.201]	0.7380	0.5983
>=3	64	11 (17.2)	NC [10.4, NC]	63	12 (19.0)	NC [NC, NC]	0.829 [0.365, 1.881]	0.6557	

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; 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: 12JAN24

Table 302.3.2001.181.1: Summary and Results of Severe TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	4 (1.6%)	
Number of patients censored	247 (97.2%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.580 [0.456, 5.472]
Log-rank test			
Two-sided stratified log-rank p-value			0.4664

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.181.2: Summary and Results of Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	5 (2.8)		177	2 (1.1)				
>65 years	78	2 (2.6)		72	2 (2.8)				
Sex									
Male	160	5 (3.1)		152	1 (0.7)				
Female	94	2 (2.1)		97	3 (3.1)				
Region									
Asia	157	3 (1.9)		156	3 (1.9)				
Non-Asia	97	4 (4.1)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)	NC [NC, NC]	186	4 (2.2)	NC [NC, NC]	1.417 [0.398, 5.039]	0.5883	0.9932
>=3	64	1 (1.6)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	2.82E7 [0.000, NC]	0.3293	

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; 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: 12JAN24

Table 302.3.2001.182.1: Summary and Results of Severe TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	17 (6.7%)	1 (0.4%)	
Number of patients censored	237 (93.3%)	248 (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			16.899 [2.248, 127.02]
Log-rank test			
Two-sided stratified log-rank p-value			0.0002

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.182.2: Summary and Results of Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	10 (5.7)	NC [NC, NC]	177	0 (0.0)	NC [NC, NC]	3.06E7 [0.000, NC]	0.0013	0.9922
>65 years	78	7 (9.0)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	6.680 [0.821, 54.323]	0.0398	
Sex									
Male	160	9 (5.6)		152	0 (0.0)				
Female	94	8 (8.5)		97	1 (1.0)				
Region									
Asia	157	8 (5.1)		156	1 (0.6)				
Non-Asia	97	9 (9.3)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	13 (6.8)	NC [NC, NC]	186	1 (0.5)	NC [NC, NC]	13.164 [1.722, 100.62]	0.0012	0.9927
>=3	64	4 (6.3)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	3.04E7 [0.000, NC]	0.0426	

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; 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: 12JAN24

Table 302.3.2001.183.1: Summary and Results of Severe TEAEs - Nausea (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.183.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	15 (8.5)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	3.117 [1.133, 8.577]	0.0204	0.5092
>65 years	78	7 (9.0)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	6.790 [0.835, 55.195]	0.0378	
Sex									
Male	160	14 (8.8)	NC [NC, NC]	152	3 (2.0)	NC [NC, NC]	4.600 [1.322, 16.007]	0.0084	0.6162
Female	94	8 (8.5)	NC [NC, NC]	97	3 (3.1)	NC [NC, NC]	2.870 [0.761, 10.821]	0.1037	
Region									
Asia	157	15 (9.6)	NC [NC, NC]	156	3 (1.9)	NC [NC, NC]	5.221 [1.512, 18.035]	0.0035	0.3816
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	3 (3.2)	NC [NC, NC]	2.298 [0.594, 8.888]	0.2142	
Number of Organs with Metastatic Sites									
0-2	190	14 (7.4)	NC [NC, NC]	186	6 (3.2)	NC [NC, NC]	2.365 [0.909, 6.154]	0.0691	0.9890
>=3	64	8 (12.5)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	3.07E7 [0.000, NC]	0.0040	

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; 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: 12JAN24

Table 302.3.2001.184.1: Summary and Results of Severe TEAEs - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	44 (17.3%)	35 (14.1%)	
Number of patients censored	210 (82.7%)	214 (85.9%)	
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			1.284 [0.820, 2.009]
Log-rank test			
Two-sided stratified log-rank p-value			0.2731

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.184.2: Summary and Results of Severe TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	32 (18.2)	NC [NC, NC]	177	16 (9.0)	NC [NC, NC]	2.099 [1.151, 3.827]	0.0133	0.0117
>65 years	78	12 (15.4)	NC [12.1, NC]	72	19 (26.4)	12.7 [7.6, NC]	0.625 [0.303, 1.289]	0.1982	
Sex									
Male	160	23 (14.4)	NC [NC, NC]	152	17 (11.2)	NC [NC, NC]	1.260 [0.672, 2.364]	0.4698	0.9364
Female	94	21 (22.3)	NC [NC, NC]	97	18 (18.6)	NC [NC, NC]	1.352 [0.720, 2.540]	0.3451	
Region									
Asia	157	31 (19.7)	NC [NC, NC]	156	25 (16.0)	NC [12.7, NC]	1.210 [0.713, 2.054]	0.4800	0.7747
Non-Asia	97	13 (13.4)	NC [NC, NC]	93	10 (10.8)	NC [NC, NC]	1.421 [0.623, 3.244]	0.4014	
Number of Organs with Metastatic Sites									
0-2	190	34 (17.9)	NC [NC, NC]	186	31 (16.7)	NC [NC, NC]	1.135 [0.697, 1.847]	0.6120	0.1959
>=3	64	10 (15.6)	NC [14.0, NC]	63	4 (6.3)	NC [NC, NC]	2.462 [0.768, 7.890]	0.1172	

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; 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: 12JAN24

Table 302.3.2001.185.1: Summary and Results of Severe TEAEs - Vomiting (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.185.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	21 (11.9)	NC [NC, NC]	177	7 (4.0)	NC [NC, NC]	3.200 [1.360, 7.527]	0.0052	0.6169
>65 years	78	10 (12.8)	NC [NC, NC]	72	2 (2.8)	NC [NC, NC]	5.021 [1.100, 22.927]	0.0208	
Sex									
Male	160	17 (10.6)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	2.440 [1.012, 5.885]	0.0415	0.1815
Female	94	14 (14.9)	NC [NC, NC]	97	2 (2.1)	NC [NC, NC]	7.882 [1.791, 34.695]	0.0012	
Region									
Asia	157	18 (11.5)	NC [NC, NC]	156	4 (2.6)	NC [NC, NC]	4.782 [1.618, 14.131]	0.0019	0.4411
Non-Asia	97	13 (13.4)	NC [NC, NC]	93	5 (5.4)	NC [NC, NC]	2.661 [0.948, 7.465]	0.0543	
Number of Organs with Metastatic Sites									
0-2	190	22 (11.6)	NC [NC, NC]	186	8 (4.3)	NC [NC, NC]	2.871 [1.278, 6.449]	0.0080	0.2899
>=3	64	9 (14.1)	NC [NC, NC]	63	1 (1.6)	NC [NC, NC]	9.621 [1.218, 75.962]	0.0085	

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; 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: 12JAN24

Table 302.3.2001.186.1: Summary and Results of TESAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	3 (1.2%)	7 (2.8%)	
Number of patients censored	251 (98.8%)	242 (97.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [22.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.339 [0.086, 1.345]
Log-rank test			
Two-sided stratified log-rank p-value			0.1082

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.186.2: Summary and Results of TESAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	2 (1.1)		177	7 (4.0)				
>65 years	78	1 (1.3)		72	0 (0.0)				
Sex									
Male	160	3 (1.9)		152	5 (3.3)				
Female	94	0 (0.0)		97	2 (2.1)				
Region									
Asia	157	2 (1.3)		156	5 (3.2)				
Non-Asia	97	1 (1.0)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	1 (0.5)		186	5 (2.7)				
>=3	64	2 (3.1)		63	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; 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: 12JAN24

Table 302.3.2001.187.1: Summary and Results of TESAEs - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	6 (2.4%)	
Number of patients censored	249 (98.0%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.821 [0.250, 2.696]
Log-rank test			
Two-sided stratified log-rank p-value			0.7453

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.187.2: Summary and Results of TESAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	4 (2.3)				
>65 years	78	1 (1.3)		72	2 (2.8)				
Sex									
Male	160	3 (1.9)		152	3 (2.0)				
Female	94	2 (2.1)		97	3 (3.1)				
Region									
Asia	157	2 (1.3)		156	5 (3.2)				
Non-Asia	97	3 (3.1)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	1 (0.5)				
>=3	64	0 (0.0)		63	5 (7.9)				

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; 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: 12JAN24

Table 302.3.2001.188.1: Summary and Results of TESAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	3 (1.2%)	
Number of patients censored	247 (97.2%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.394 [0.618, 9.266]
Log-rank test			
Two-sided stratified log-rank p-value			0.1921

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.188.2: Summary and Results of TESAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	5 (2.8)		177	3 (1.7)				
>65 years	78	2 (2.6)		72	0 (0.0)				
Sex									
Male	160	5 (3.1)		152	1 (0.7)				
Female	94	2 (2.1)		97	2 (2.1)				
Region									
Asia	157	3 (1.9)		156	1 (0.6)				
Non-Asia	97	4 (4.1)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	4 (2.1)		186	3 (1.6)				
>=3	64	3 (4.7)		63	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; 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: 12JAN24

Table 302.3.2001.189.1: Summary and Results of TESAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	0 (0.0%)	
Number of patients censored	245 (96.5%)	249 (100.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.0028

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.189.2: Summary and Results of TESAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	6 (3.4)		177	0 (0.0)				
>65 years	78	3 (3.8)		72	0 (0.0)				
Sex									
Male	160	6 (3.8)		152	0 (0.0)				
Female	94	3 (3.2)		97	0 (0.0)				
Region									
Asia	157	4 (2.5)		156	0 (0.0)				
Non-Asia	97	5 (5.2)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	0 (0.0)				
>=3	64	4 (6.3)		63	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; 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: 12JAN24

Table 302.3.2001.190.1: Summary and Results of TESAEs - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	11 (4.3%)	6 (2.4%)	
Number of patients censored	243 (95.7%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.833 [0.677, 4.963]
Log-rank test			
Two-sided stratified log-rank p-value			0.2263

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.190.2: Summary and Results of TESAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	6 (3.4)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	1.224 [0.374, 4.011]	0.7385	0.2713
>65 years	78	5 (6.4)	NC [NC, NC]	72	1 (1.4)	NC [NC, NC]	4.822 [0.563, 41.282]	0.1127	
Sex									
Male	160	6 (3.8)		152	3 (2.0)				
Female	94	5 (5.3)		97	3 (3.1)				
Region									
Asia	157	9 (5.7)	NC [NC, NC]	156	2 (1.3)	NC [NC, NC]	4.632 [1.001, 21.439]	0.0310	0.0547
Non-Asia	97	2 (2.1)	NC [NC, NC]	93	4 (4.3)	NC [NC, NC]	0.491 [0.090, 2.682]	0.4012	
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)	NC [NC, NC]	186	6 (3.2)	NC [NC, NC]	0.999 [0.322, 3.099]	0.9974	0.9910
>=3	64	5 (7.8)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	2.99E7 [0.000, NC]	0.0246	

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; 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: 12JAN24

Table 302.3.2001.191.1: Summary and Results of TESAEs - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	5 (2.0%)	7 (2.8%)	
Number of patients censored	249 (98.0%)	242 (97.2%)	
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			0.709 [0.224, 2.241]
Log-rank test			
Two-sided stratified log-rank p-value			0.5558

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.191.2: Summary and Results of TESAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	5 (2.8)		177	4 (2.3)				
>65 years	78	0 (0.0)		72	3 (4.2)				
Sex									
Male	160	3 (1.9)		152	4 (2.6)				
Female	94	2 (2.1)		97	3 (3.1)				
Region									
Asia	157	2 (1.3)		156	2 (1.3)				
Non-Asia	97	3 (3.1)		93	5 (5.4)				
Number of Organs with Metastatic Sites									
0-2	190	2 (1.1)		186	6 (3.2)				
>=3	64	3 (4.7)		63	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; 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: 12JAN24

Table 302.3.2001.192.1: Summary and Results of TESAEs - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	11 (4.4%)	
Number of patients censored	239 (94.1%)	238 (95.6%)	
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			1.359 [0.624, 2.961]
Log-rank test			
Two-sided stratified log-rank p-value			0.4382

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.192.2: Summary and Results of TESAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	8 (4.5)	NC [NC, NC]	177	7 (4.0)	NC [NC, NC]	1.173 [0.425, 3.236]	0.7600	0.6494
>65 years	78	7 (9.0)	NC [NC, NC]	72	4 (5.6)	NC [NC, NC]	1.706 [0.499, 5.832]	0.3892	
Sex									
Male	160	10 (6.3)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	1.407 [0.535, 3.696]	0.4888	0.9495
Female	94	5 (5.3)	NC [NC, NC]	97	4 (4.1)	NC [NC, NC]	1.335 [0.358, 4.972]	0.6652	
Region									
Asia	157	8 (5.1)	NC [NC, NC]	156	4 (2.6)	NC [NC, NC]	2.052 [0.618, 6.815]	0.2313	0.3735
Non-Asia	97	7 (7.2)	NC [NC, NC]	93	7 (7.5)	NC [NC, NC]	0.997 [0.350, 2.843]	0.9942	
Number of Organs with Metastatic Sites									
0-2	190	10 (5.3)	NC [NC, NC]	186	9 (4.8)	NC [NC, NC]	1.125 [0.457, 2.769]	0.7997	0.3925
>=3	64	5 (7.8)	NC [NC, NC]	63	2 (3.2)	NC [NC, NC]	2.530 [0.491, 13.040]	0.2510	

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; 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: 12JAN24

Table 302.3.2001.193.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	4 (1.6%)	1 (0.4%)	
Number of patients censored	250 (98.4%)	248 (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			3.649 [0.408, 32.666]
Log-rank test			
Two-sided stratified log-rank p-value			0.2150

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.193.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	1 (1.4)				
Sex									
Male	160	3 (1.9)		152	0 (0.0)				
Female	94	1 (1.1)		97	1 (1.0)				
Region									
Asia	157	3 (1.9)		156	1 (0.6)				
Non-Asia	97	1 (1.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	3 (1.6)		186	0 (0.0)				
>=3	64	1 (1.6)		63	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; 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: 12JAN24

Table 302.3.2001.194.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	0 (0.0%)	3 (1.2%)	
Number of patients censored	254 (100.0%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.0988

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.194.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	2 (1.1)				
>65 years	78	0 (0.0)		72	1 (1.4)				
Sex									
Male	160	0 (0.0)		152	2 (1.3)				
Female	94	0 (0.0)		97	1 (1.0)				
Region									
Asia	157	0 (0.0)		156	2 (1.3)				
Non-Asia	97	0 (0.0)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	2 (1.1)				
>=3	64	0 (0.0)		63	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; 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: 12JAN24

Table 302.3.2001.195.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	1 (0.4%)	
Number of patients censored	247 (97.2%)	248 (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			6.978 [0.858, 56.754]
Log-rank test			
Two-sided stratified log-rank p-value			0.0344

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.195.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	6 (3.4)		177	1 (0.6)				
>65 years	78	1 (1.3)		72	0 (0.0)				
Sex									
Male	160	4 (2.5)		152	0 (0.0)				
Female	94	3 (3.2)		97	1 (1.0)				
Region									
Asia	157	1 (0.6)		156	1 (0.6)				
Non-Asia	97	6 (6.2)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	1 (0.5)				
>=3	64	2 (3.1)		63	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; 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: 12JAN24

Table 302.3.2001.196.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	10 (3.9%)	1 (0.4%)	
Number of patients censored	244 (96.1%)	248 (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			9.604 [1.229, 75.046]
Log-rank test			
Two-sided stratified log-rank p-value			0.0082

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.196.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	7 (4.0)		177	1 (0.6)				
>65 years	78	3 (3.8)		72	0 (0.0)				
Sex									
Male	160	5 (3.1)		152	0 (0.0)				
Female	94	5 (5.3)		97	1 (1.0)				
Region									
Asia	157	4 (2.5)		156	1 (0.6)				
Non-Asia	97	6 (6.2)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	8 (4.2)		186	1 (0.5)				
>=3	64	2 (3.1)		63	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; 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: 12JAN24

Table 302.3.2001.197.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.197.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	5 (2.8)		177	3 (1.7)				
>65 years	78	1 (1.3)		72	0 (0.0)				
Sex									
Male	160	4 (2.5)		152	1 (0.7)				
Female	94	2 (2.1)		97	2 (2.1)				
Region									
Asia	157	2 (1.3)		156	2 (1.3)				
Non-Asia	97	4 (4.1)		93	1 (1.1)				
Number of Organs with Metastatic Sites									
0-2	190	5 (2.6)		186	3 (1.6)				
>=3	64	1 (1.6)		63	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; 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: 12JAN24

Table 302.3.2001.198.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	7 (2.8%)	7 (2.8%)	
Number of patients censored	247 (97.2%)	242 (97.2%)	
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			0.854 [0.293, 2.490]
Log-rank test			
Two-sided stratified log-rank p-value			0.7723

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.198.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	3 (1.7)				
>65 years	78	3 (3.8)		72	4 (5.6)				
Sex									
Male	160	4 (2.5)		152	3 (2.0)				
Female	94	3 (3.2)		97	4 (4.1)				
Region									
Asia	157	6 (3.8)	NC [NC, NC]	156	4 (2.6)	NC [NC, NC]	1.226 [0.341, 4.403]	0.7541	0.3165
Non-Asia	97	1 (1.0)	NC [NC, NC]	93	3 (3.2)	NC [NC, NC]	0.357 [0.037, 3.433]	0.3514	
Number of Organs with Metastatic Sites									
0-2	190	6 (3.2)	NC [NC, NC]	186	5 (2.7)	NC [NC, NC]	1.086 [0.328, 3.595]	0.8912	0.4789
>=3	64	1 (1.6)	NC [NC, NC]	63	2 (3.2)	NC [NC, NC]	0.395 [0.036, 4.370]	0.4326	

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; 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: 12JAN24

Table 302.3.2001.199.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.199.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	4 (2.3)		177	2 (1.1)				
>65 years	78	5 (6.4)		72	2 (2.8)				
Sex									
Male	160	4 (2.5)		152	2 (1.3)				
Female	94	5 (5.3)		97	2 (2.1)				
Region									
Asia	157	5 (3.2)		156	2 (1.3)				
Non-Asia	97	4 (4.1)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	8 (4.2)	NC [NC, NC]	186	4 (2.2)	NC [NC, NC]	1.969 [0.593, 6.539]	0.2598	0.9929
>=3	64	1 (1.6)	NC [NC, NC]	63	0 (0.0)	NC [NC, NC]	2.82E7 [0.000, NC]	0.3293	

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; 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: 12JAN24

Table 302.3.2001.221.1: Summary and Results of TEAEs leading to Death - Abdominal Pain (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.221.2: Summary and Results of TEAEs leading to Death by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 12JAN24

Table 302.3.2001.222.1: Summary and Results of TEAEs leading to Death - Anemia (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.222.2: Summary and Results of TEAEs leading to Death by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 12JAN24

Table 302.3.2001.223.1: Summary and Results of TEAEs leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.223.2: Summary and Results of TEAEs leading to Death by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 12JAN24

Table 302.3.2001.224.1: Summary and Results of TEAEs leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.224.2: Summary and Results of TEAEs leading to Death by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 12JAN24

Table 302.3.2001.225.1: Summary and Results of TEAEs leading to Death - Nausea (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.225.2: Summary and Results of TEAEs leading to Death by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	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; 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: 12JAN24

Table 302.3.2001.226.1: Summary and Results of TEAEs leading to Death - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	0 (0.0%)	2 (0.8%)	
Number of patients censored	254 (100.0%)	247 (99.2%)	
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			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.1546

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.226.2: Summary and Results of TEAEs leading to Death by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	176	0 (0.0)		177	1 (0.6)				
>65 years	78	0 (0.0)		72	1 (1.4)				
Sex									
Male	160	0 (0.0)		152	1 (0.7)				
Female	94	0 (0.0)		97	1 (1.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	2 (2.2)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	2 (1.1)				
>=3	64	0 (0.0)		63	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; 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: 12JAN24

Table 302.3.2001.227.1: Summary and Results of TEAEs leading to Death - Vomiting (AESI) - Safety Analysis Set

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

Abbreviations: AESI=adverse event of special interest; 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: 12JAN24

Table 302.3.2001.227.2: Summary and Results of TEAEs leading to Death by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX			Placebo + CAPOX			Zolbetuximab + CAPOX vs. Placebo + CAPOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	176	0 (0.0)		177	0 (0.0)				
>65 years	78	0 (0.0)		72	0 (0.0)				
Sex									
Male	160	0 (0.0)		152	0 (0.0)				
Female	94	0 (0.0)		97	0 (0.0)				
Region									
Asia	157	0 (0.0)		156	0 (0.0)				
Non-Asia	97	0 (0.0)		93	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	190	0 (0.0)		186	0 (0.0)				
>=3	64	0 (0.0)		63	0 (0.0)				

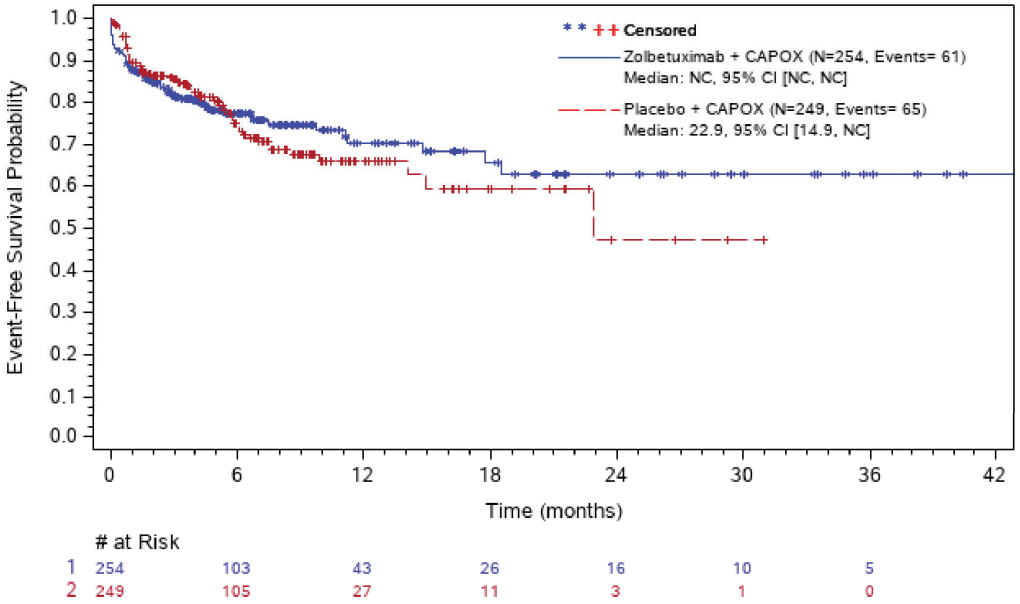
Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Sicherheit
Anhang 4-G1 Unerwünschte Ereignisse von besonderem Interesse

2. Kaplan-Meier-Plots

The SAS System

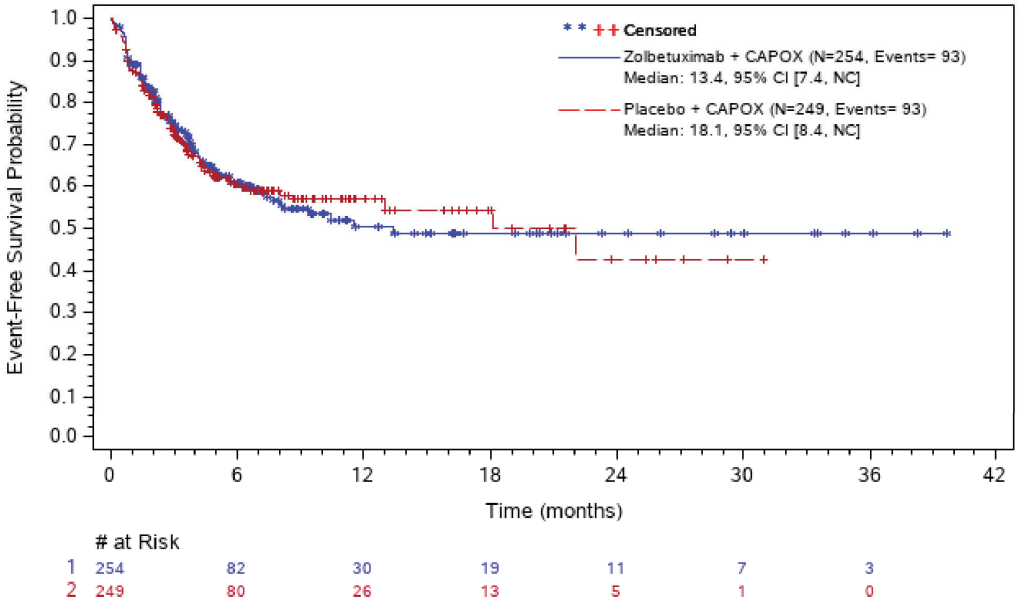
Figure 302.3.2001.165: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

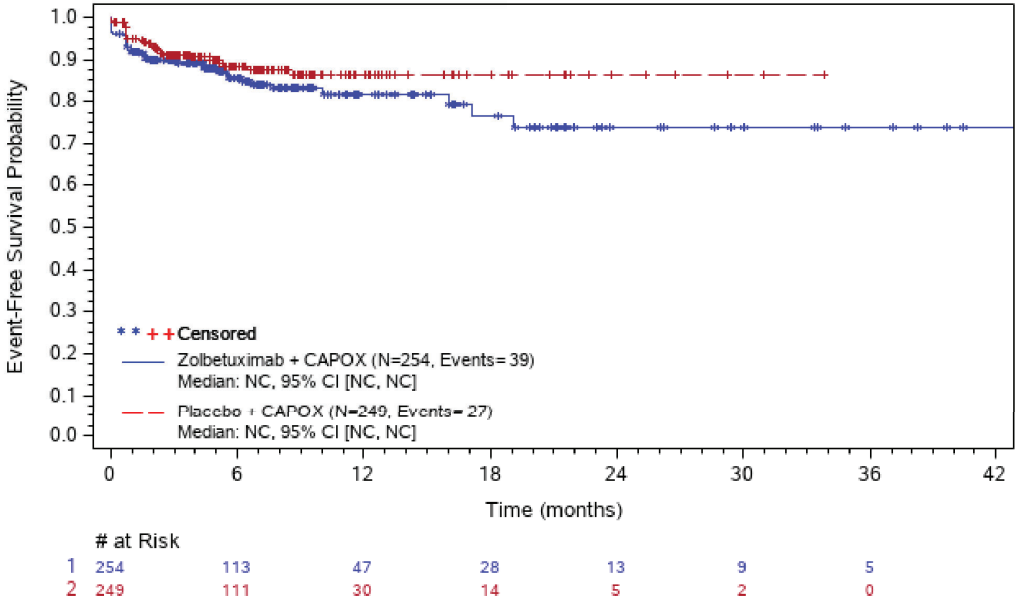
Figure 302.3.2001.166: Kaplan-Meier Plot of Time to first TEAE - Anemia (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

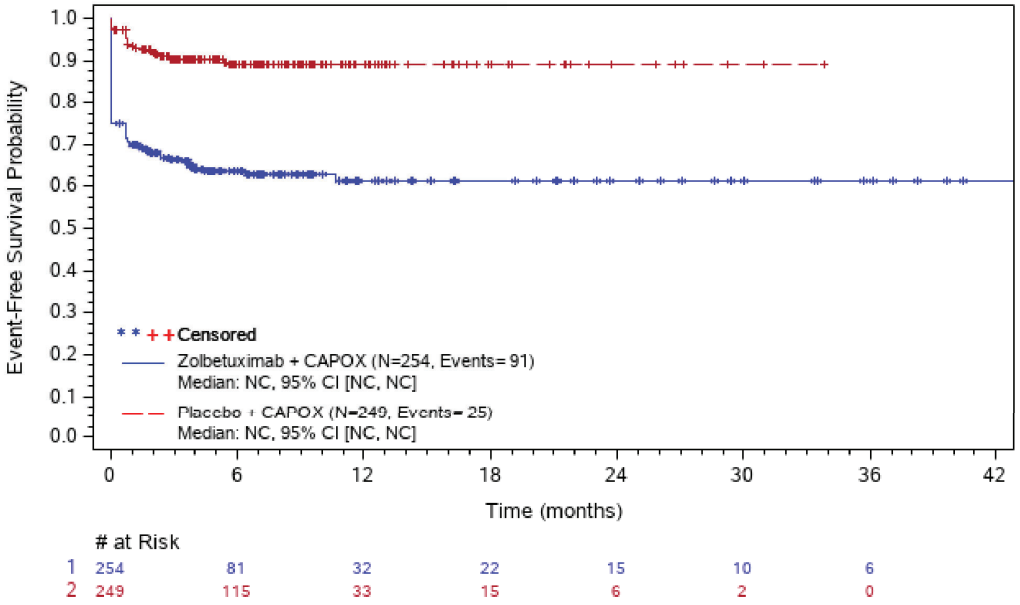
Figure 302.3.2001.167: Kaplan-Meier Plot of Time to first TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

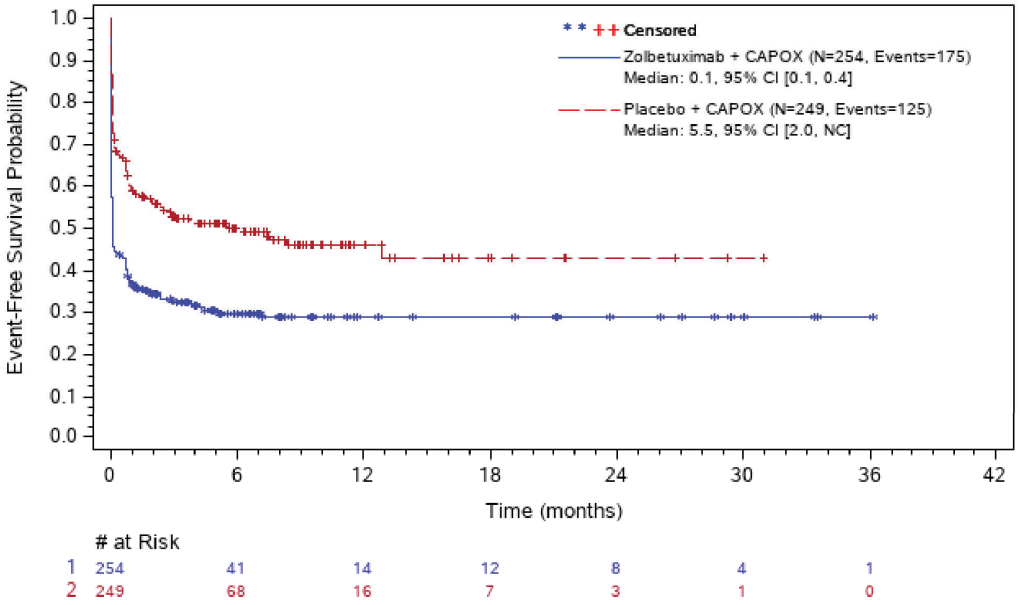
Figure 302.3.2001.168: Kaplan-Meier Plot of Time to first TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

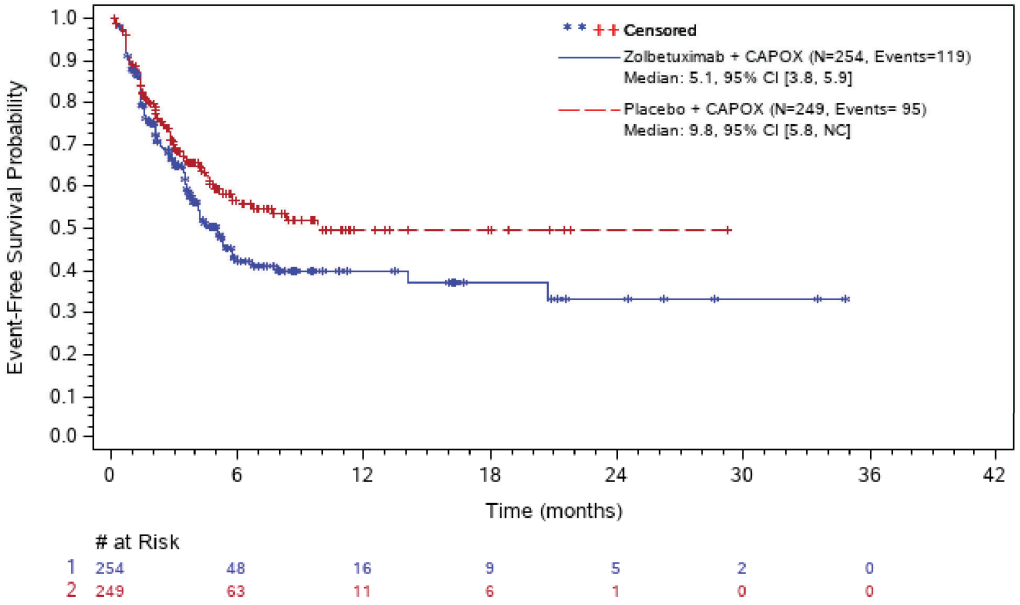
Figure 302.3.2001.169: Kaplan-Meier Plot of Time to first TEAE - Nausea (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

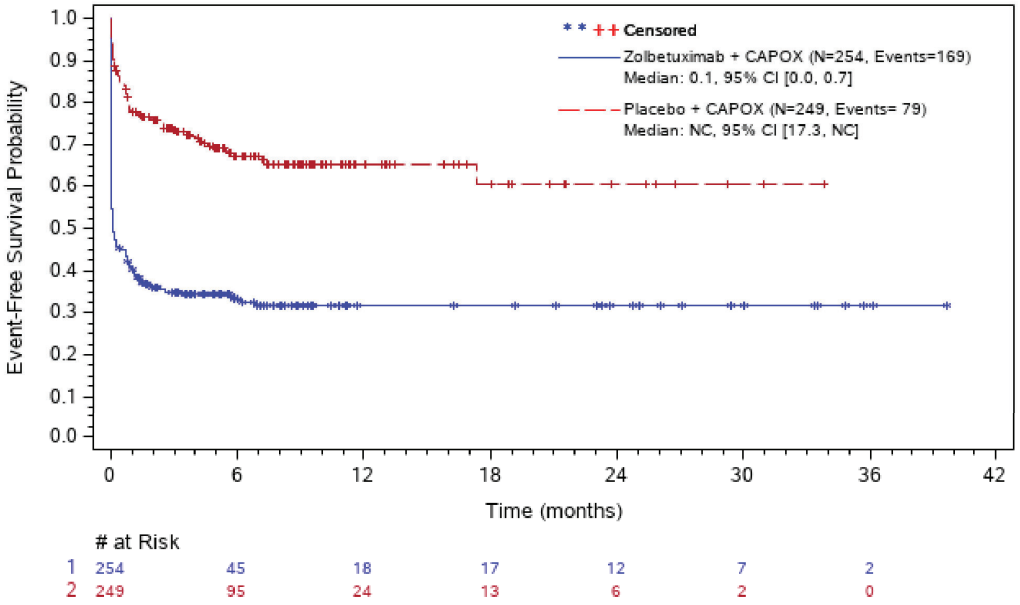
Figure 302.3.2001.170: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

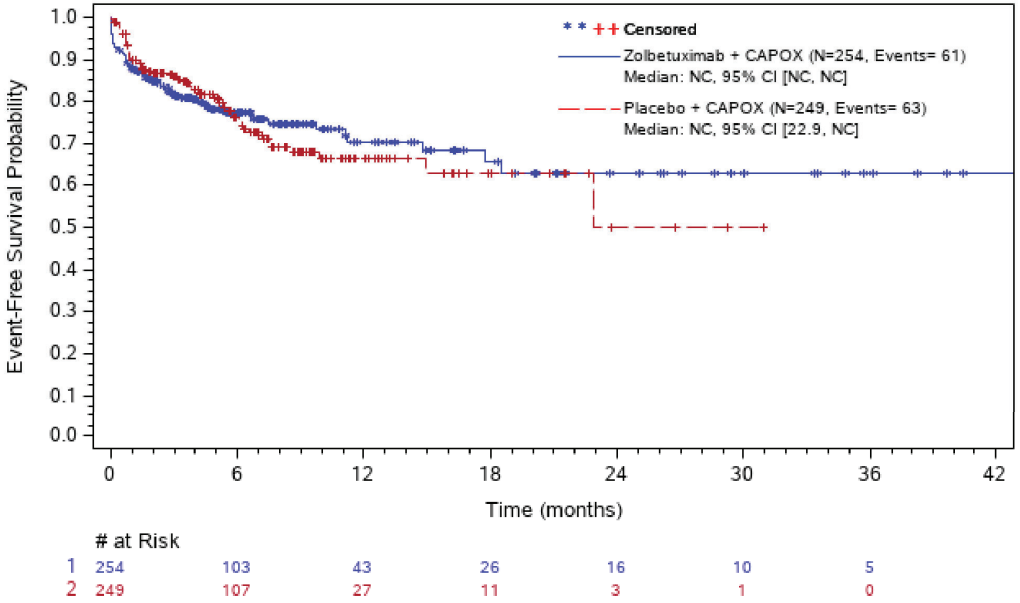
Figure 302.3.2001.171: Kaplan-Meier Plot of Time to first TEAE - Vomiting (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.172: 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: 12JAN24

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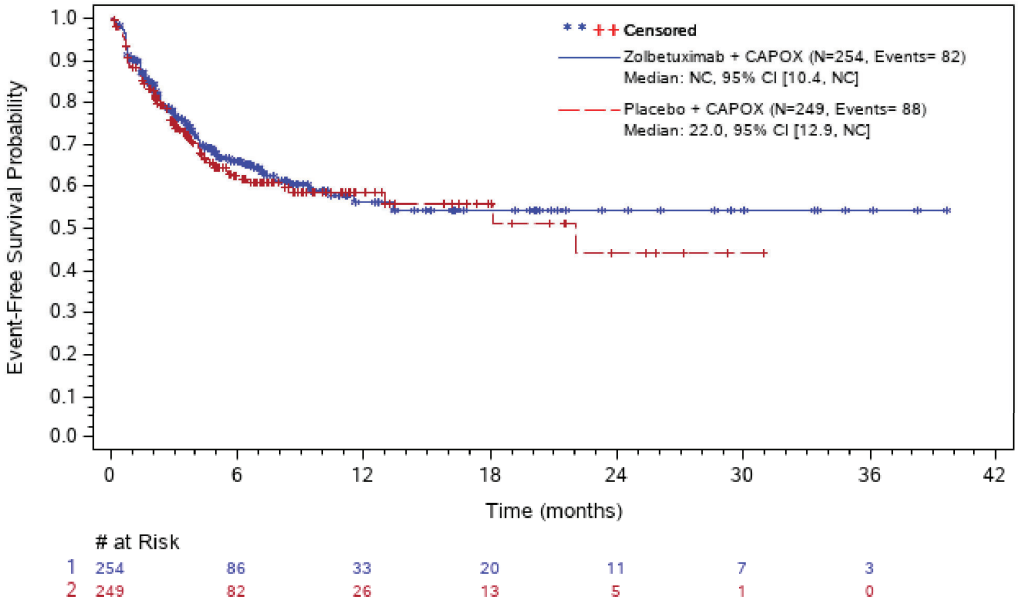
Figure 302.3.2001.173: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Anemia (AESI) - Safety Analysis Set



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: 12JAN24

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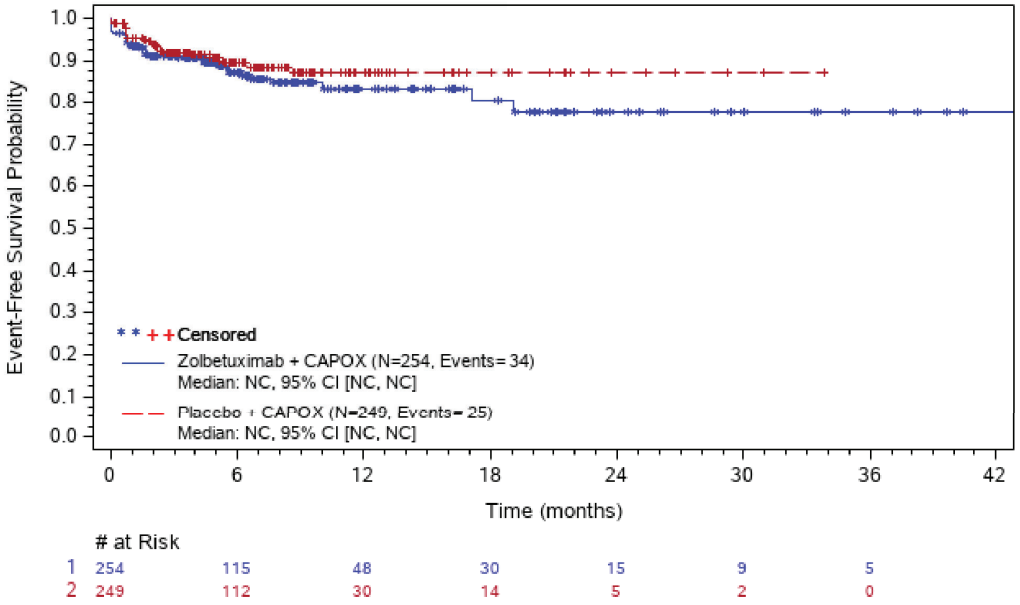
Figure 302.3.2001.174: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 12JAN24

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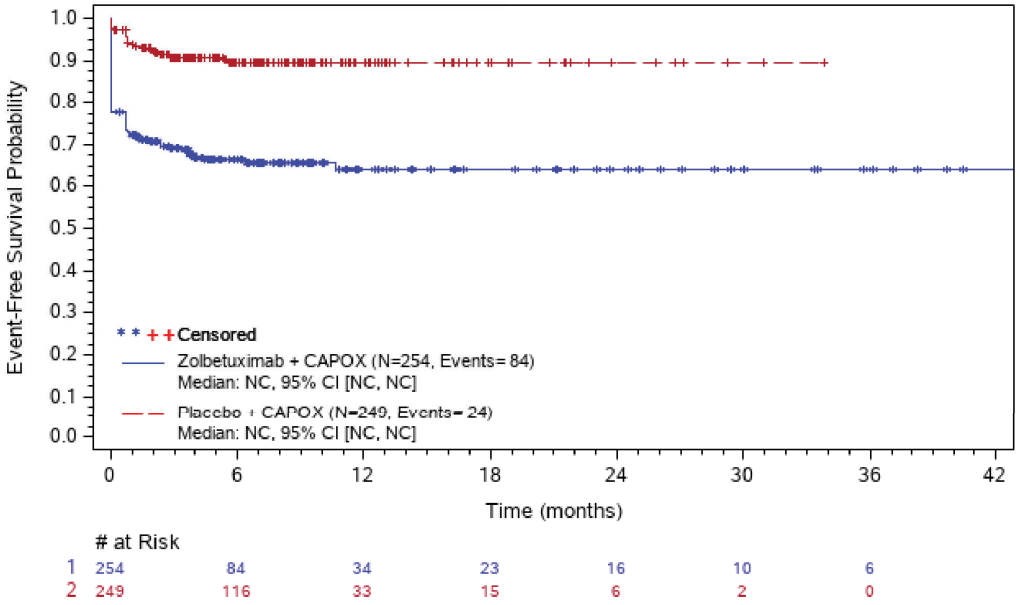
Figure 302.3.2001.175: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 12JAN24

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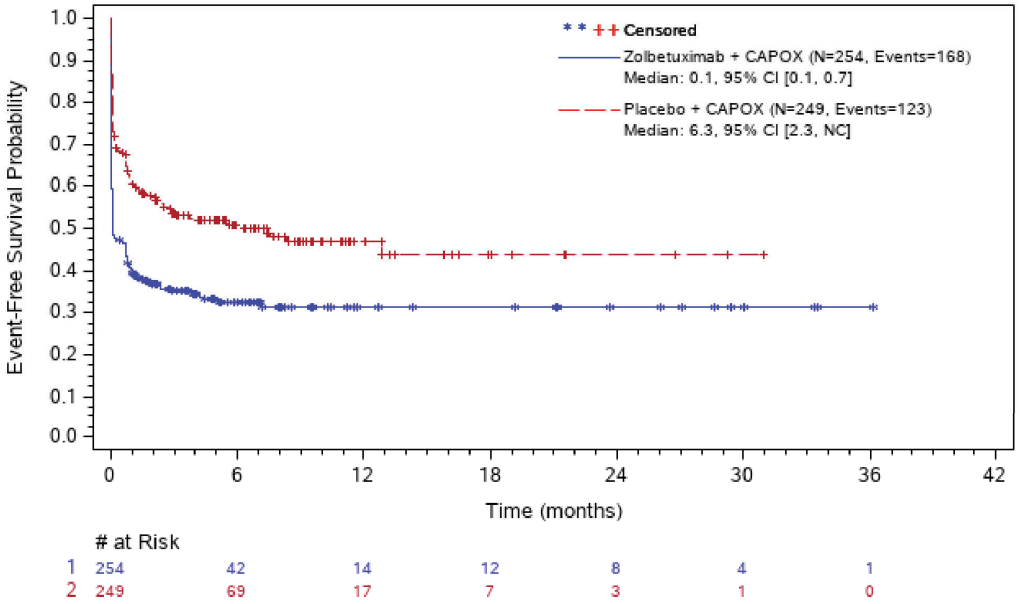
Figure 302.3.2001.176: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Nausea (AESI) - Safety Analysis Set



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: 12JAN24

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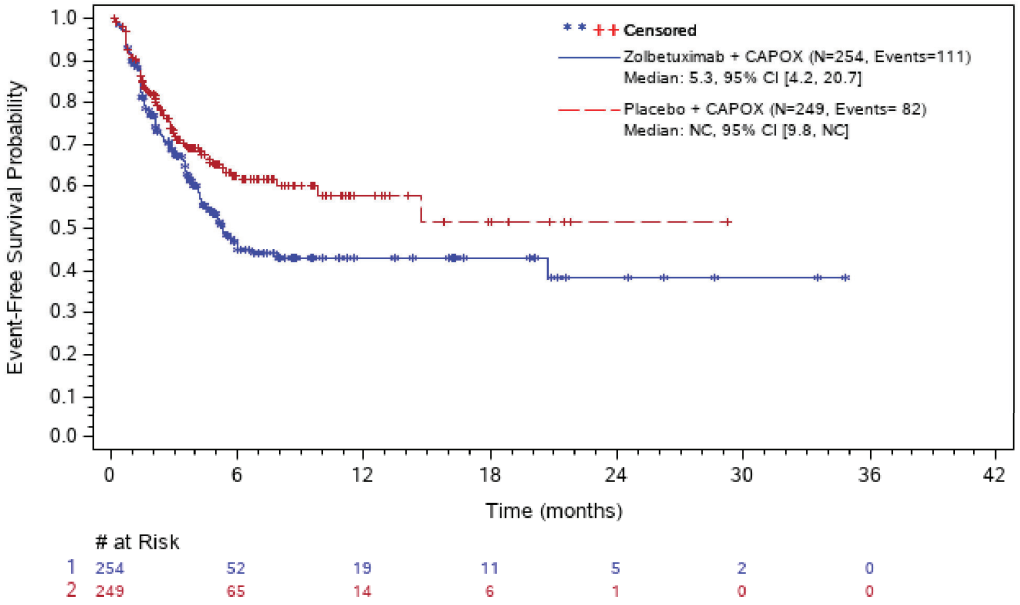
Figure 302.3.2001.177: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Neutropenia (AESI) - Safety Analysis Set



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: 12JAN24

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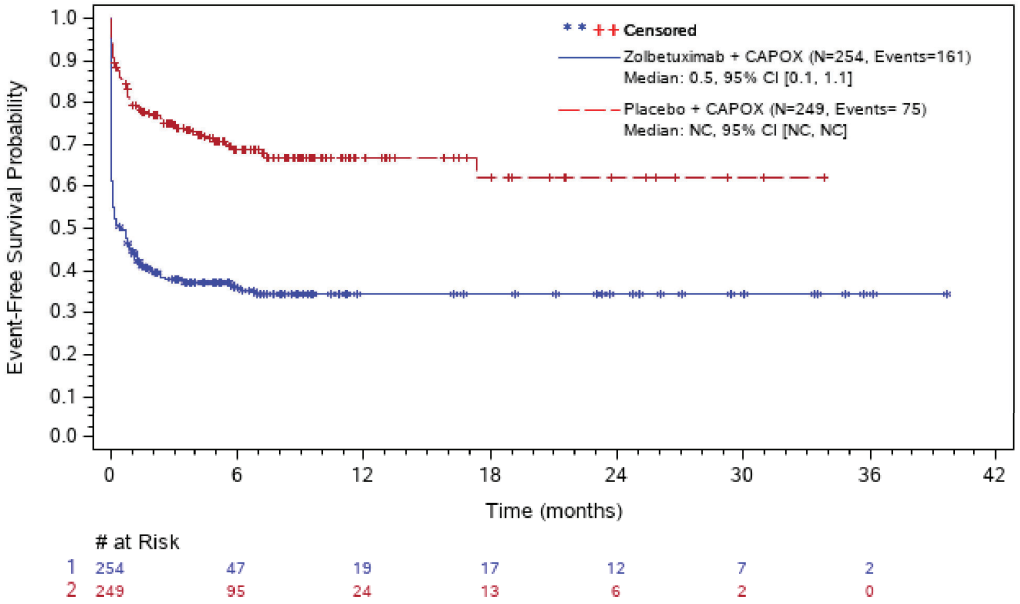
Figure 302.3.2001.178: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Vomiting (AESI) - Safety Analysis Set



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: 12JAN24

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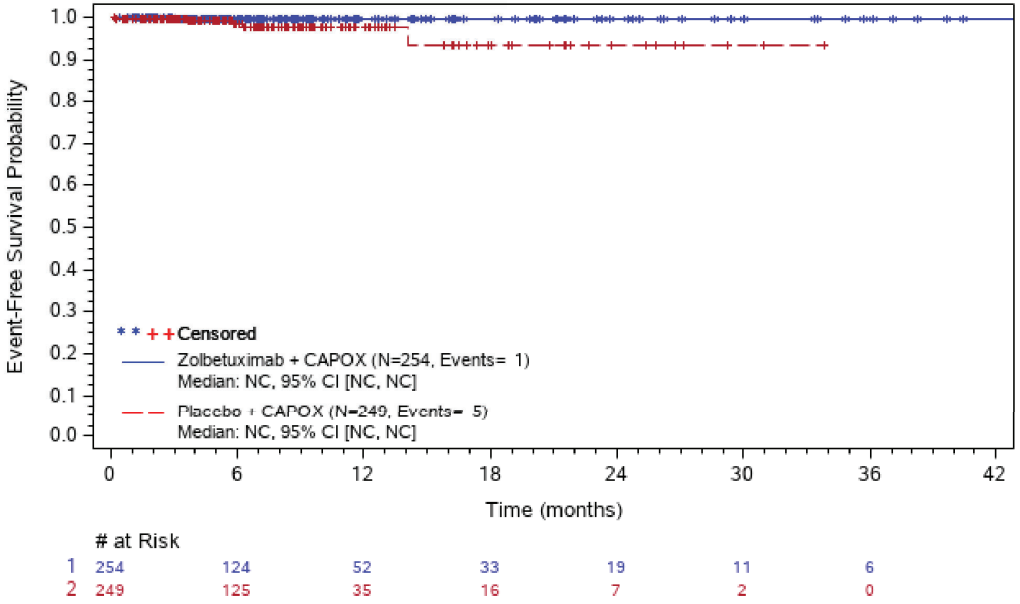
Figure 302.3.2001.179: Kaplan-Meier Plot of Time to first Severe TEAE - Abdominal Pain (AESI) - Safety Analysis Set



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: 12JAN24

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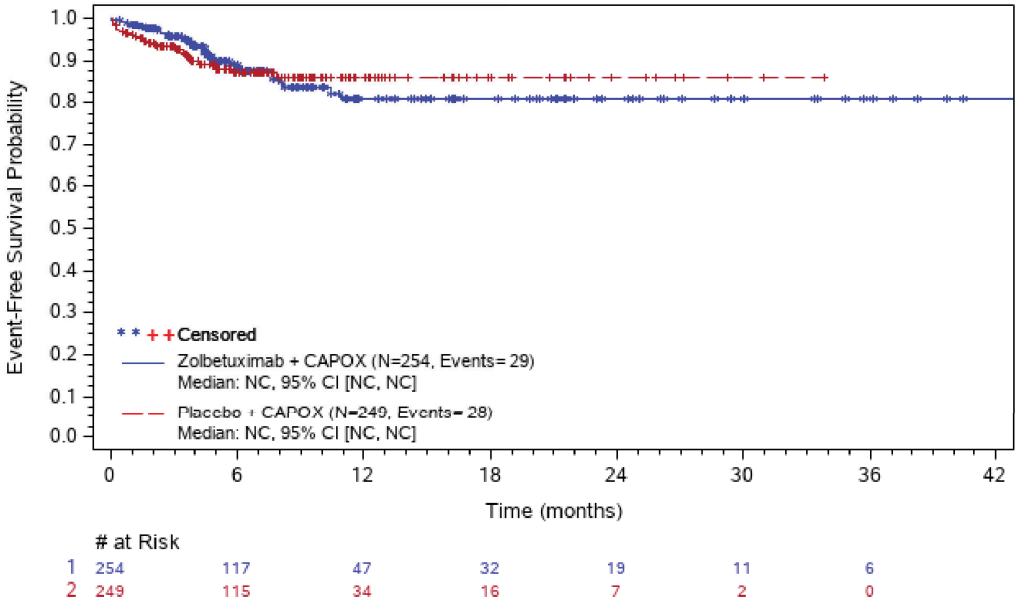
Figure 302.3.2001.180: Kaplan-Meier Plot of Time to first TEAE - Severe Anemia (AESI) - Safety Analysis Set



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: 12JAN24

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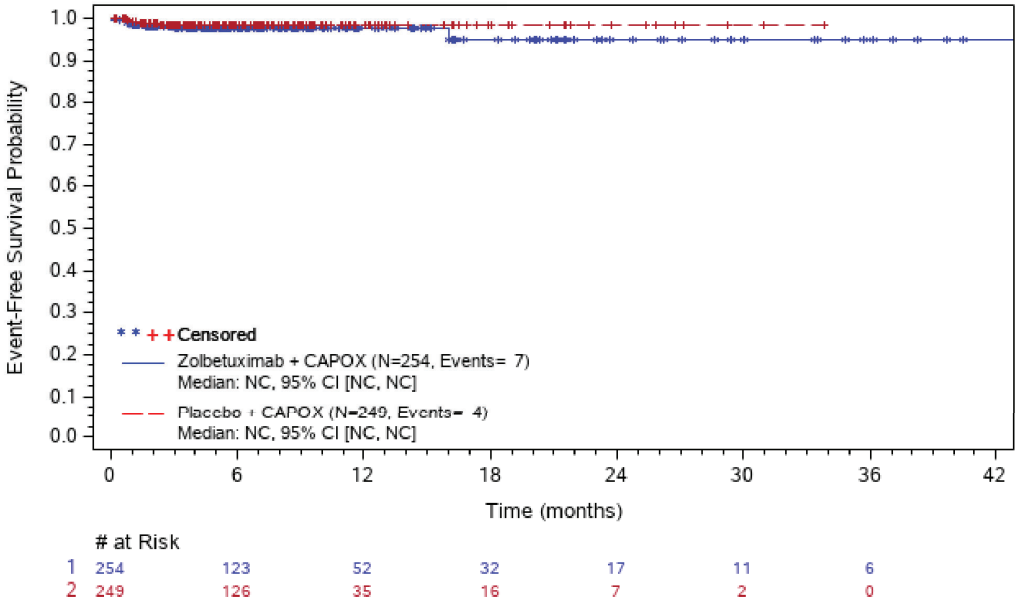
Figure 302.3.2001.181: Kaplan-Meier Plot of Time to first Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set

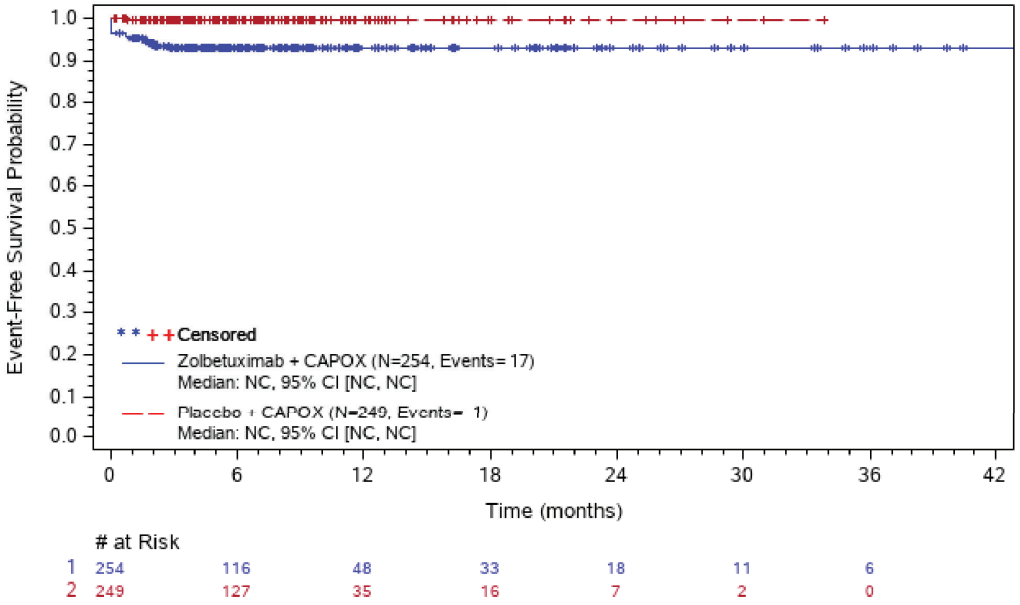


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

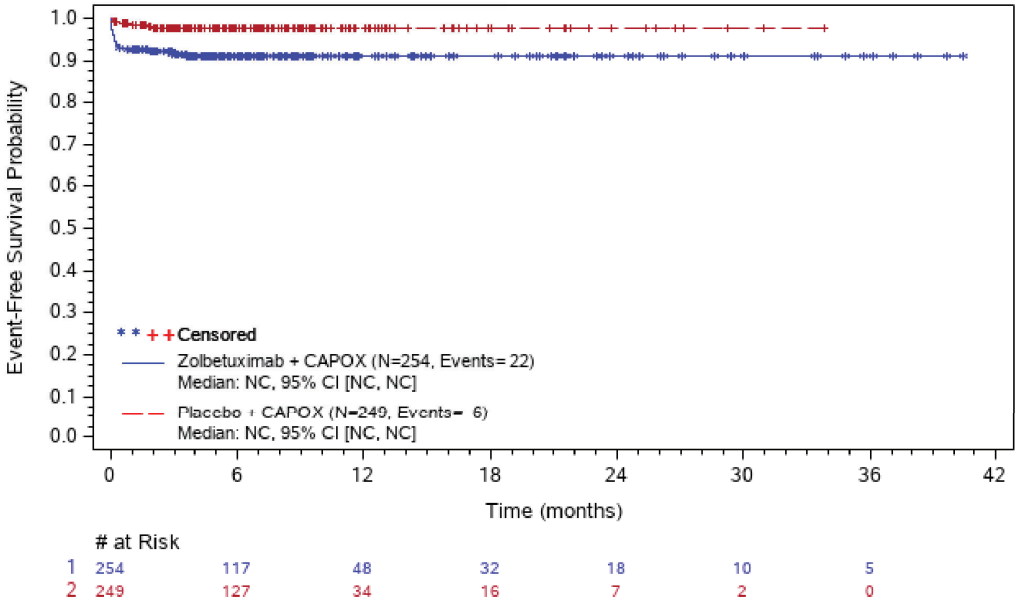
Figure 302.3.2001.182: Kaplan-Meier Plot of Time to first Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

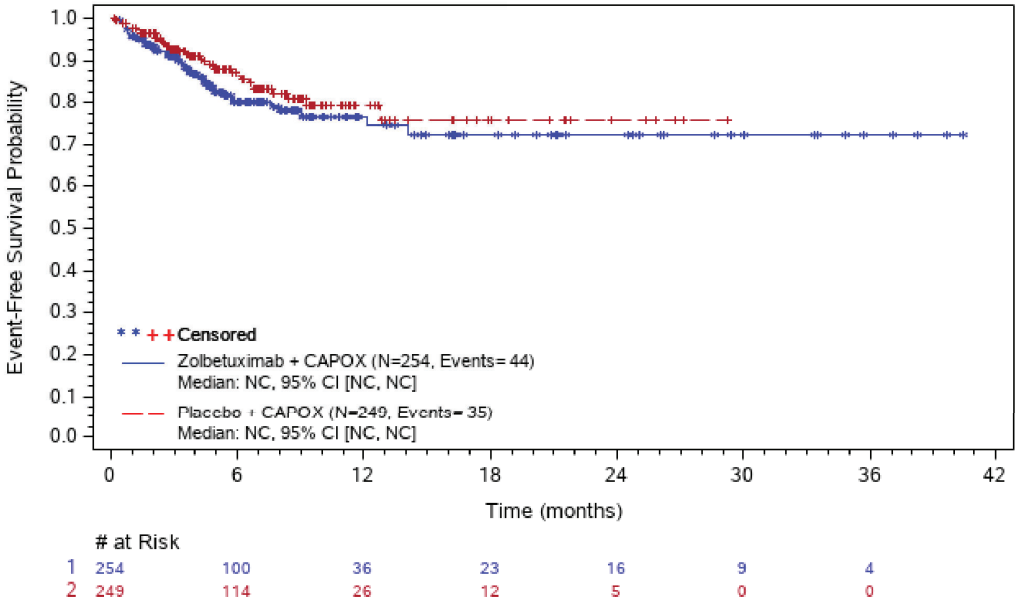
Figure 302.3.2001.183: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

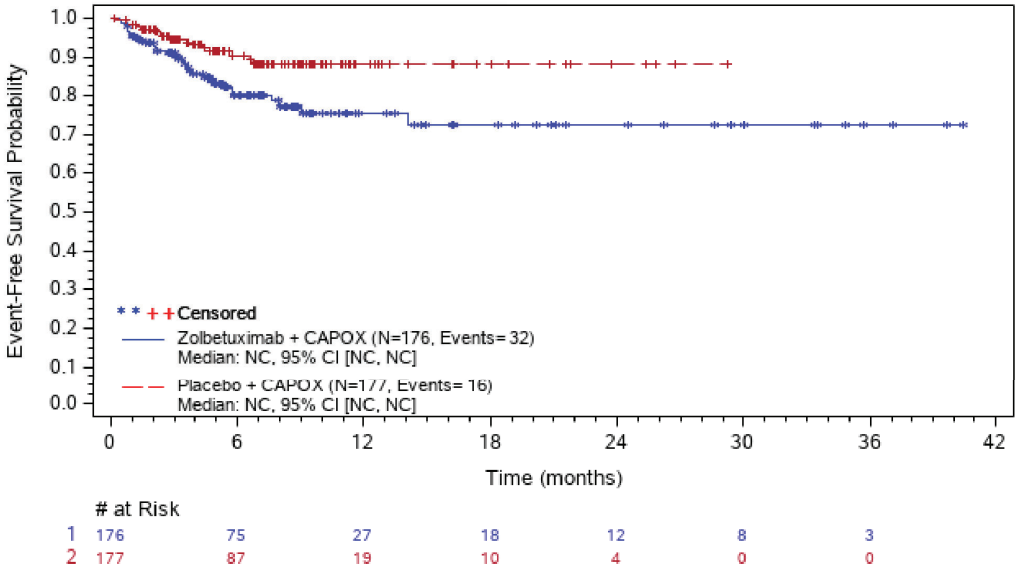
Figure 302.3.2001.184: Kaplan-Meier Plot of Time to first TEAE - Severe Neutropenia (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.184.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Severe Neutropenia (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: 12JAN24

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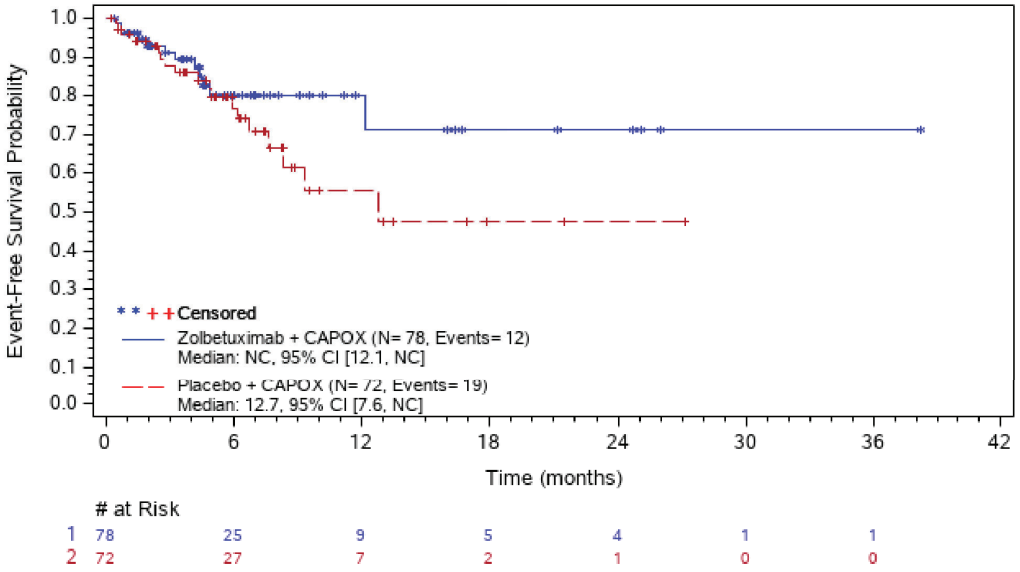
Figure 302.3.2001.184.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Severe Neutropenia (AESI) - Safety Analysis Set
Pooled Age Group 1: >65 years



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: 12JAN24

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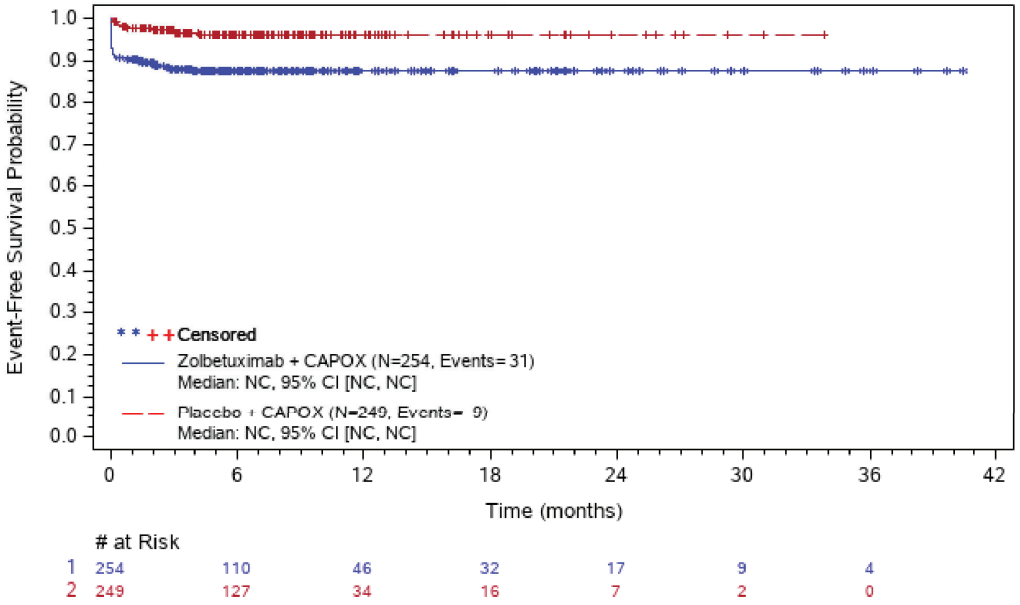
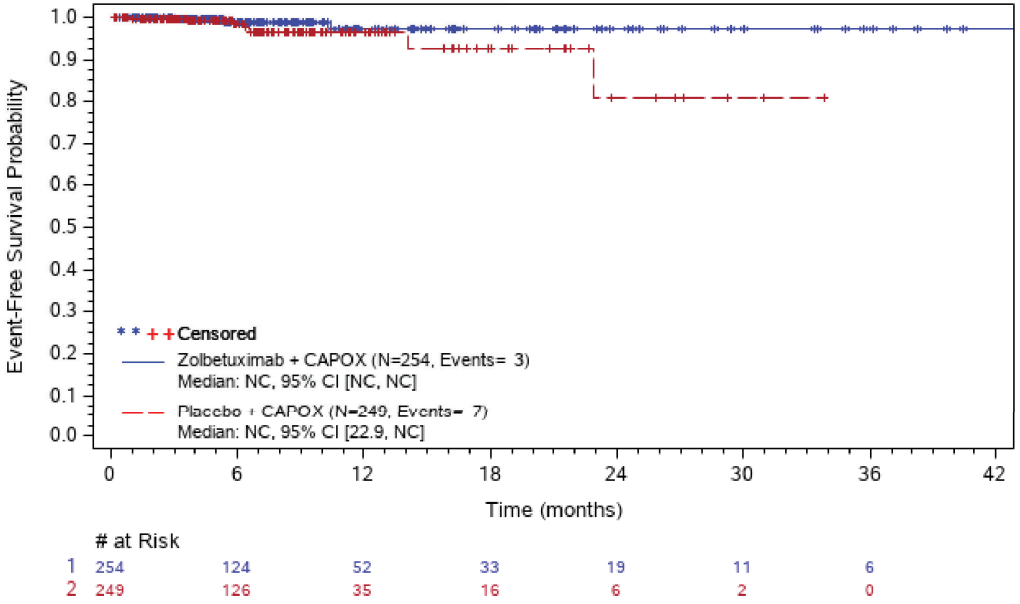
Figure 302.3.2001.185: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

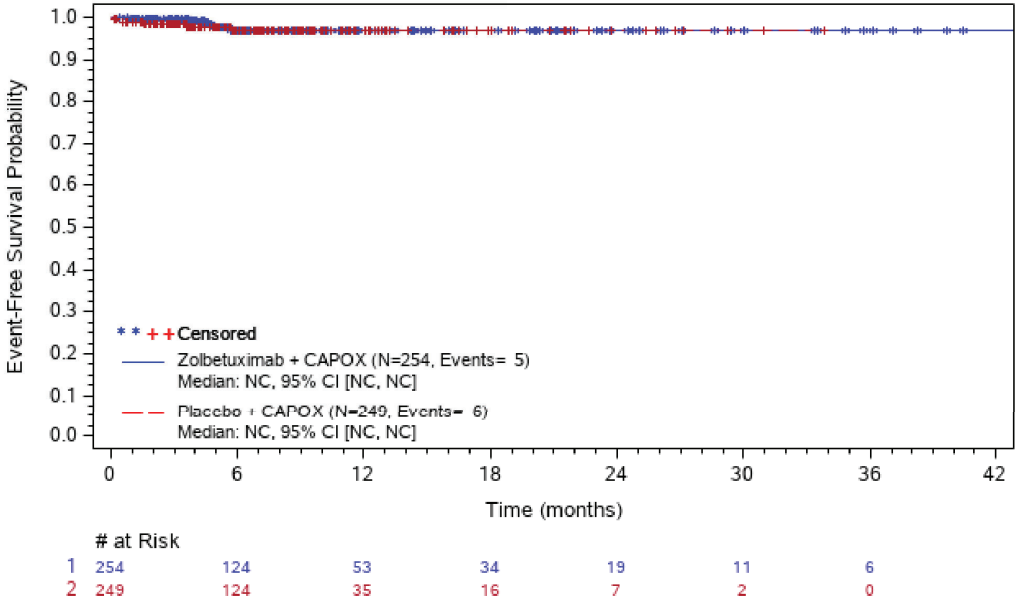
Figure 302.3.2001.186: Kaplan-Meier Plot of Time to first TESAE - Abdominal Pain (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.187: Kaplan-Meier Plot of Time to first TESAE - Anemia (AESI) - Safety Analysis Set

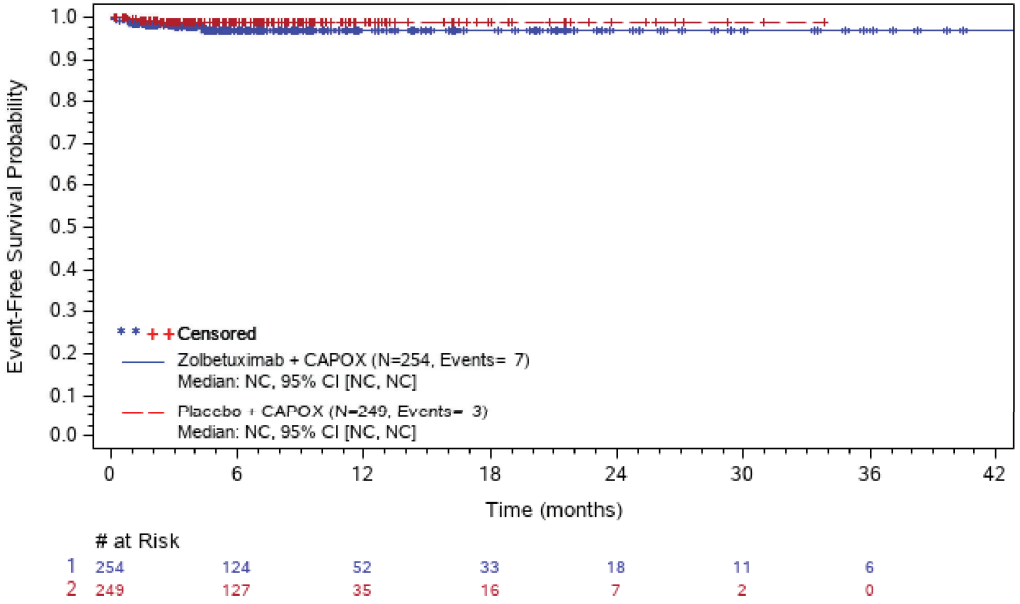


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

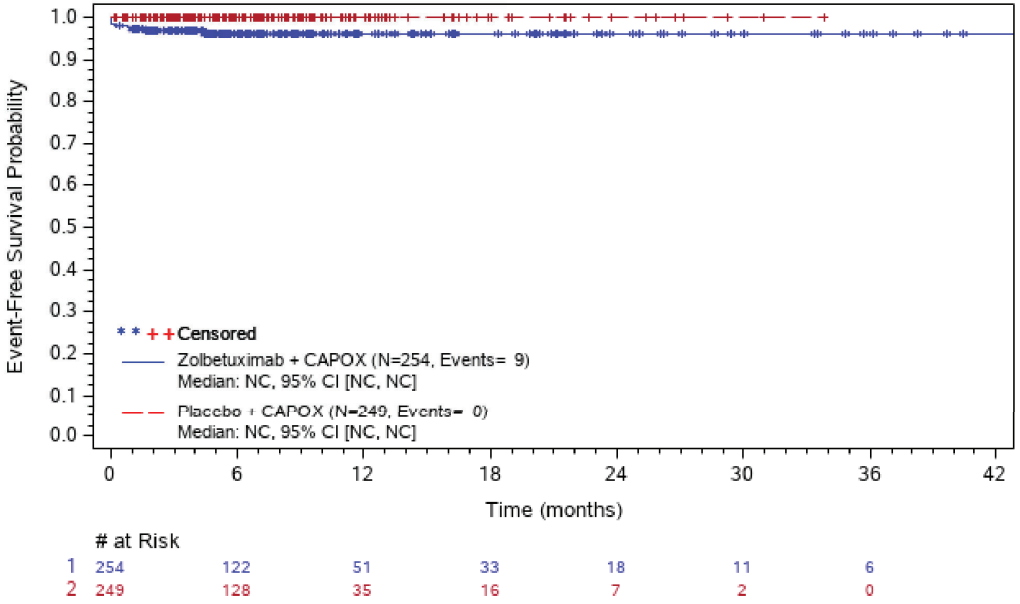
Figure 302.3.2001.188: Kaplan-Meier Plot of Time to first TESAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

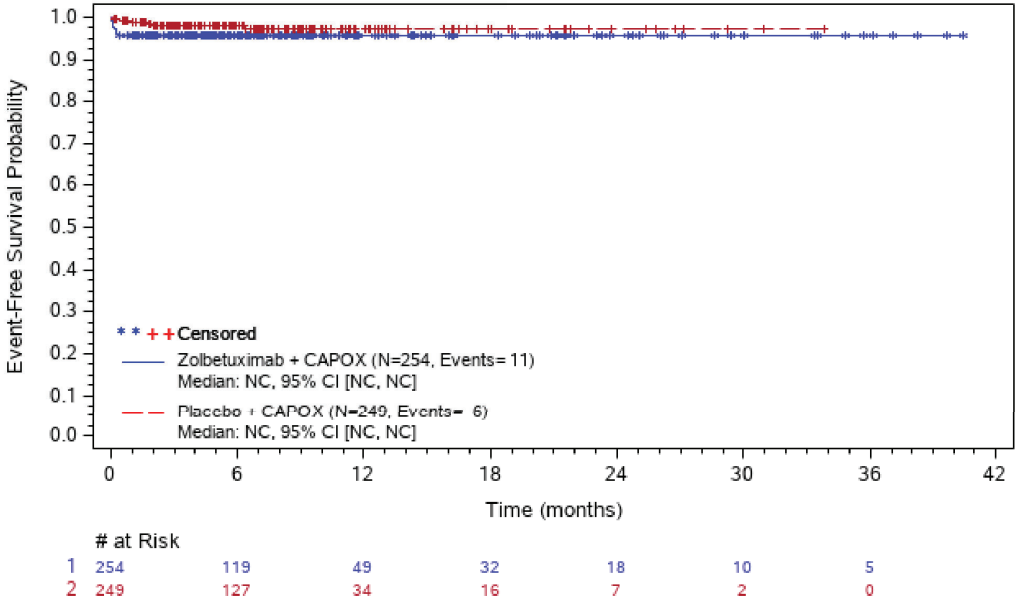
Figure 302.3.2001.189: Kaplan-Meier Plot of Time to first TESAE - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.190: Kaplan-Meier Plot of Time to first TESAE - Nausea (AESI) - Safety Analysis Set

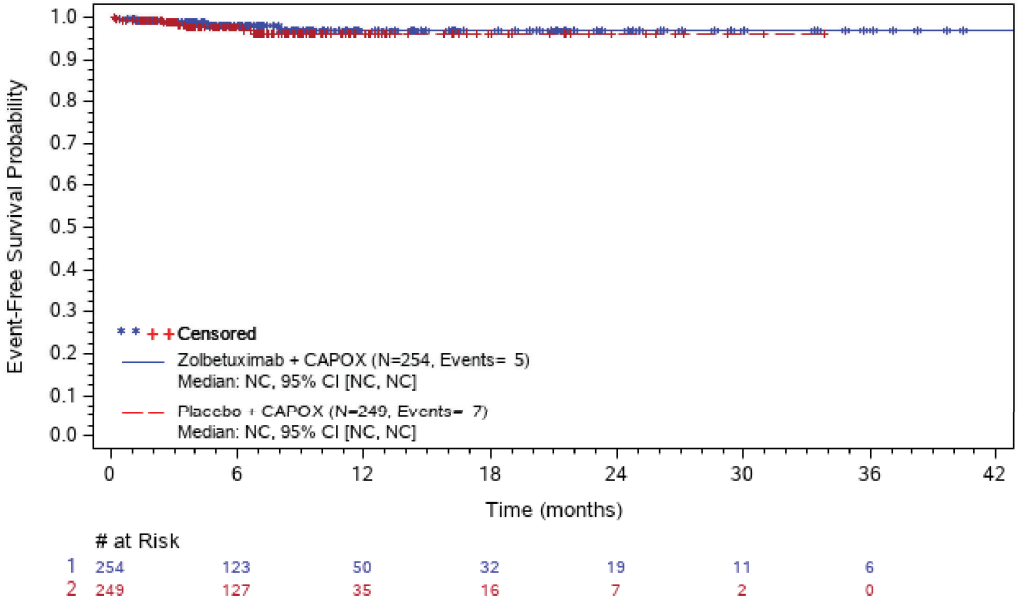


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

Figure 302.3.2001.191: 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: 12JAN24

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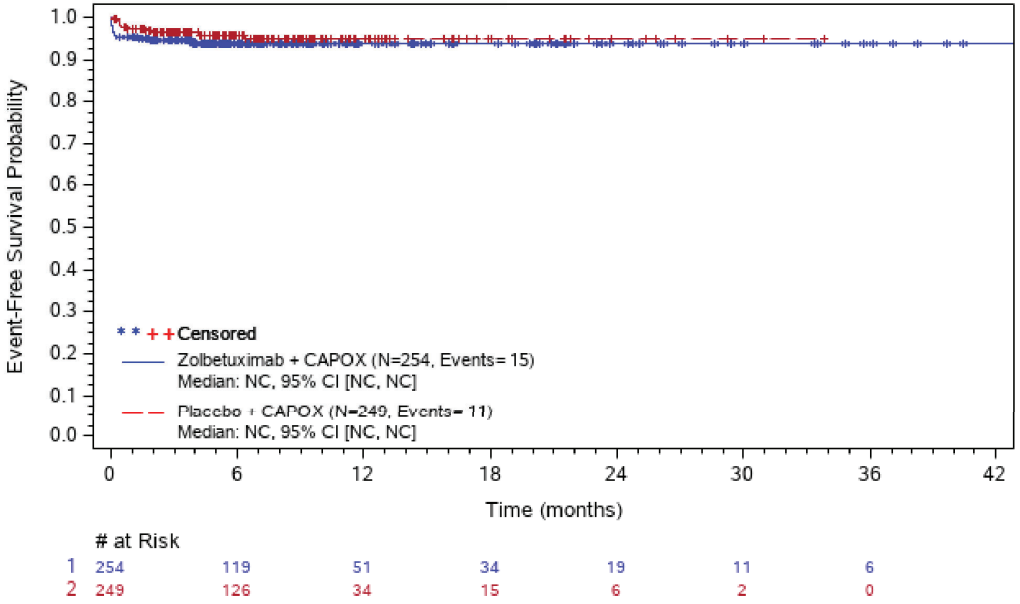
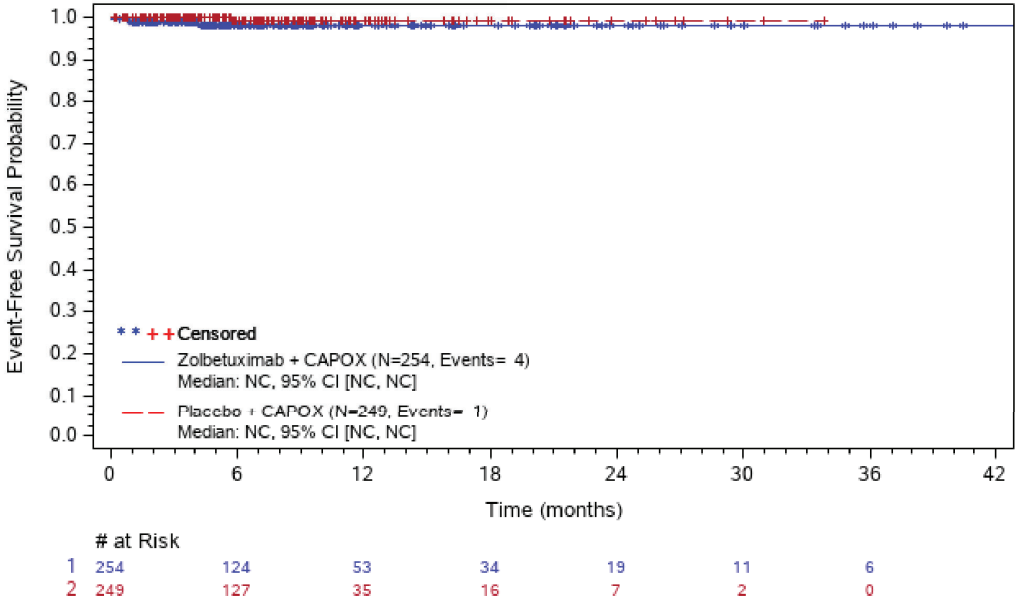
Figure 302.3.2001.192: Kaplan-Meier Plot of Time to first TESAE - Vomiting (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

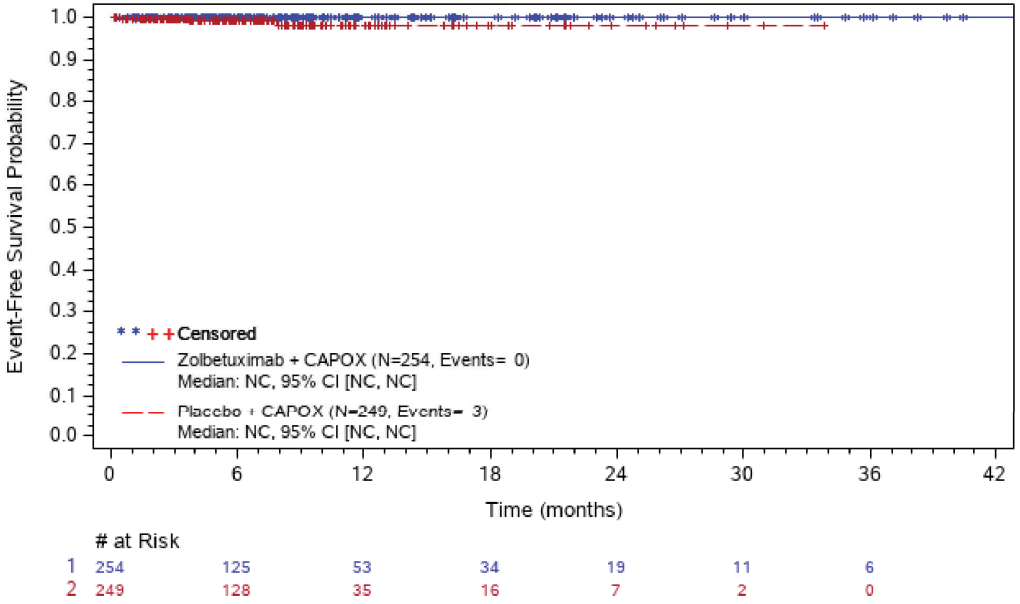
Figure 302.3.2001.193: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Abdominal Pain (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

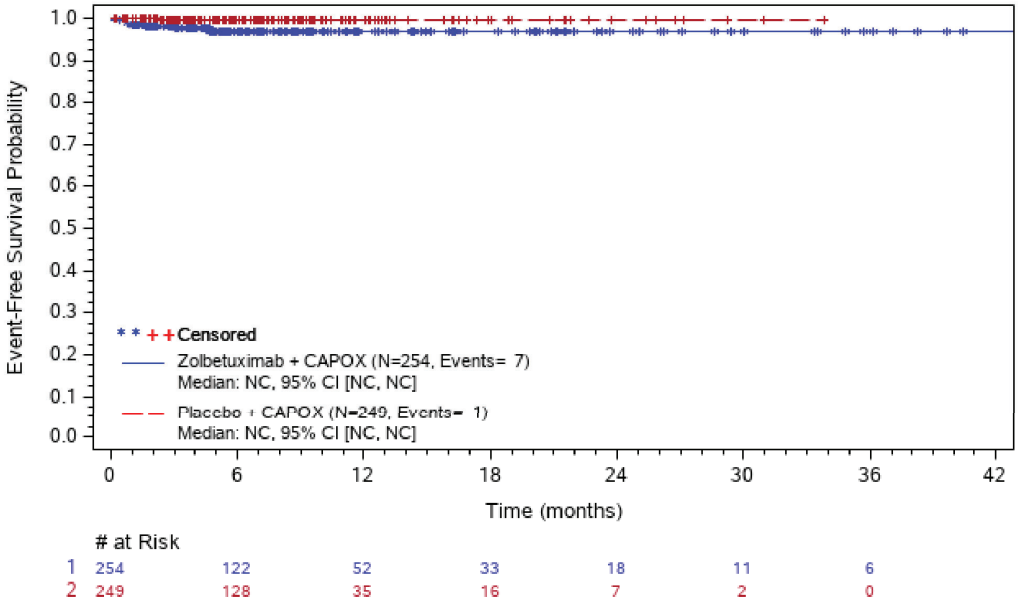
Figure 302.3.2001.194: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Anemia (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

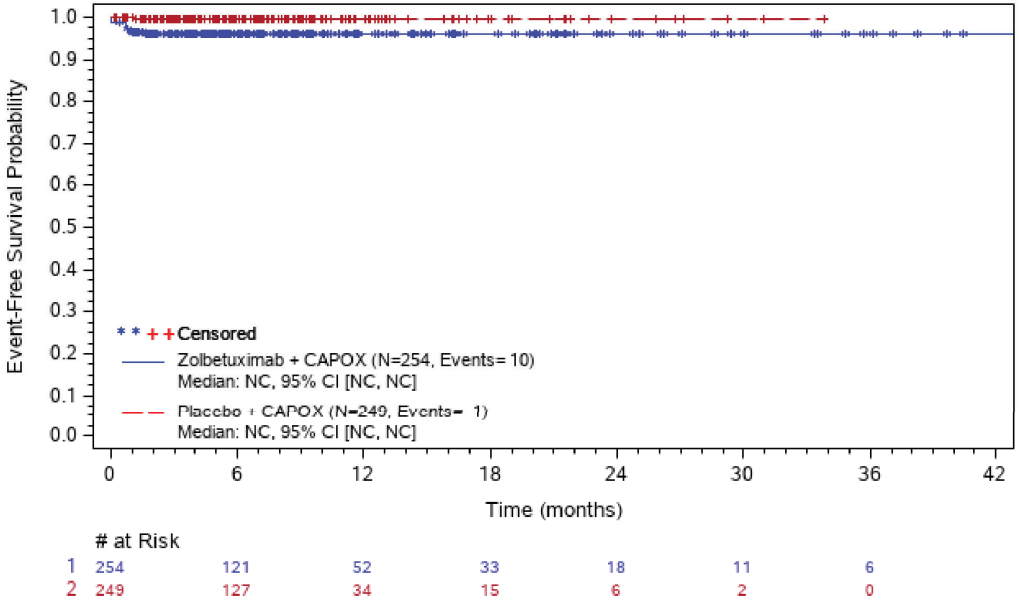
Figure 302.3.2001.195: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

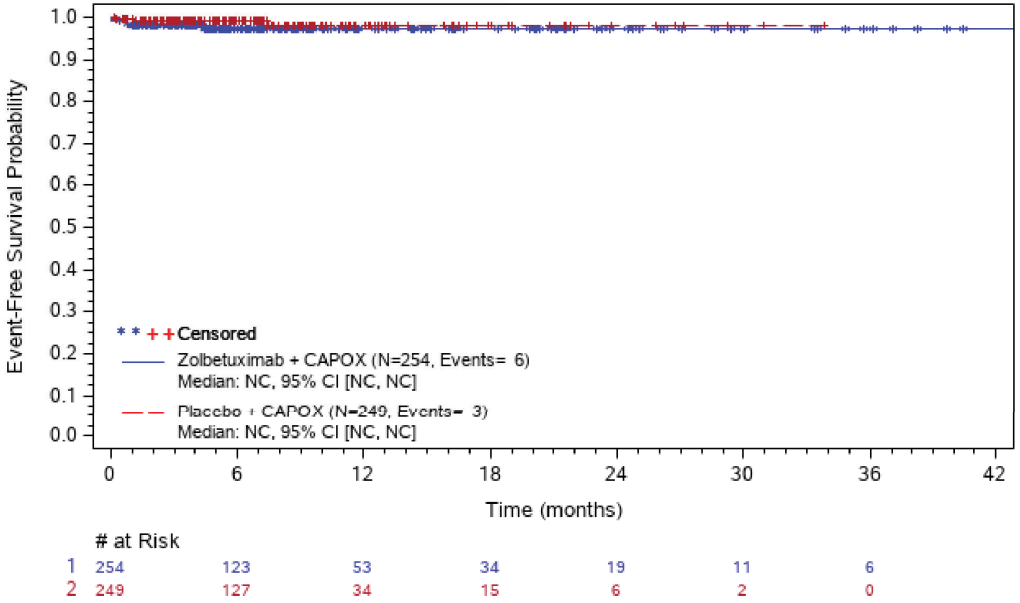
Figure 302.3.2001.196: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

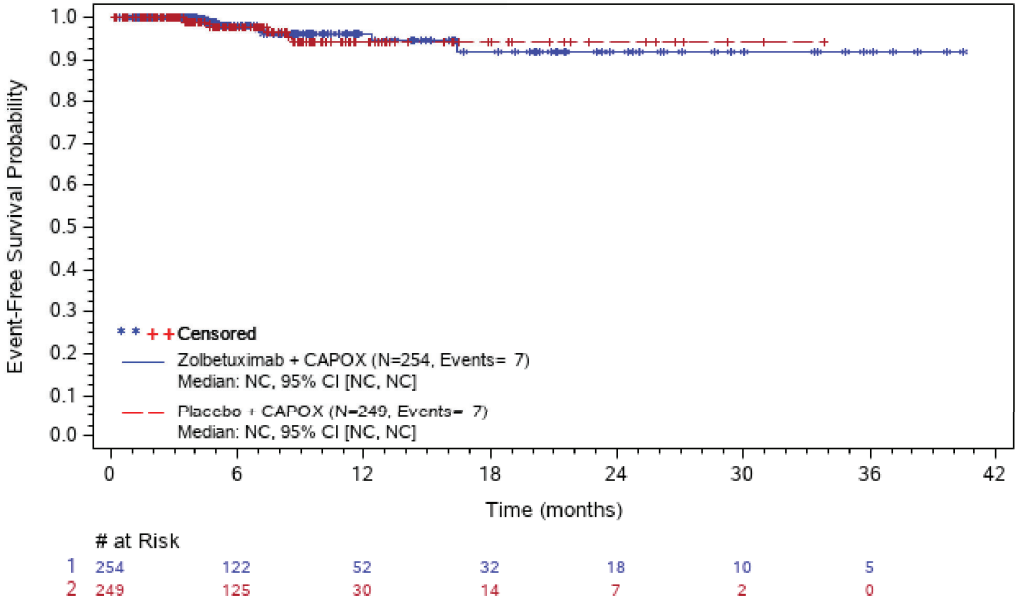
Figure 302.3.2001.197: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.198: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Neutropenia (AESI) - Safety Analysis Set

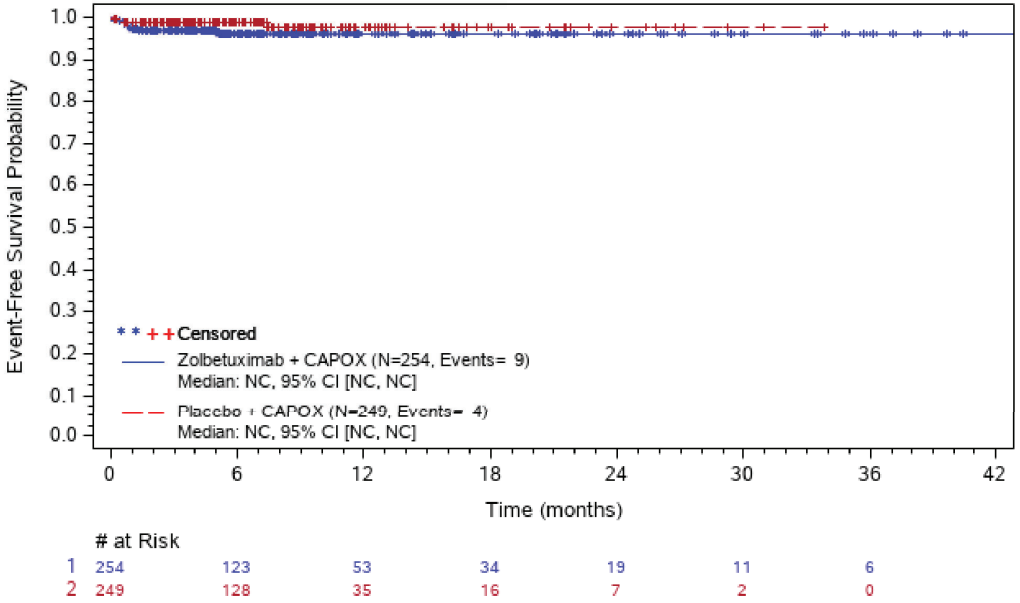


# at Risk							
1	254	122	52	32	18	10	5
2	249	125	30	14	7	2	0

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: 12JAN24

The SAS System

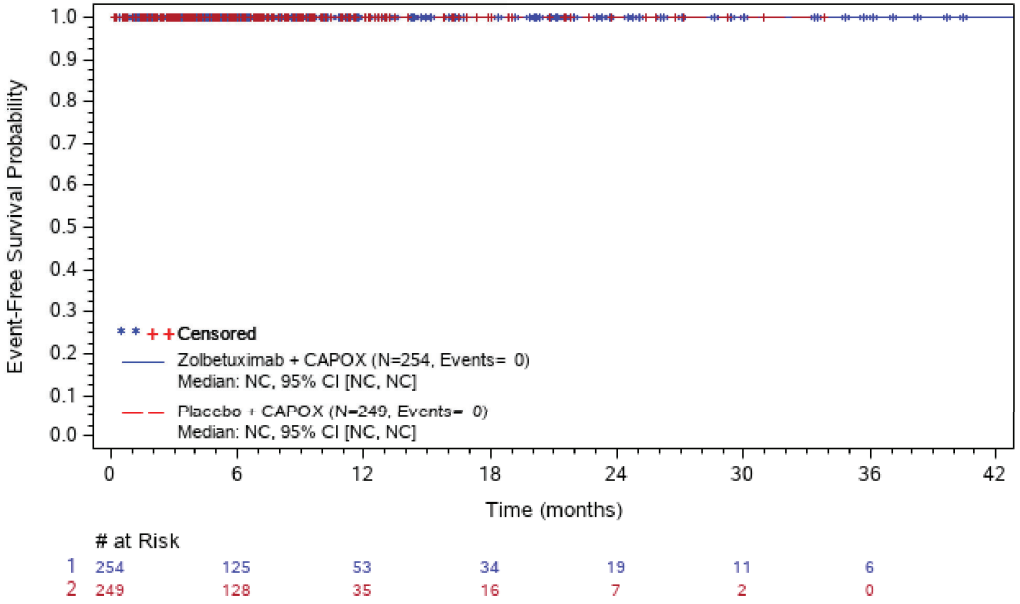
Figure 302.3.2001.199: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

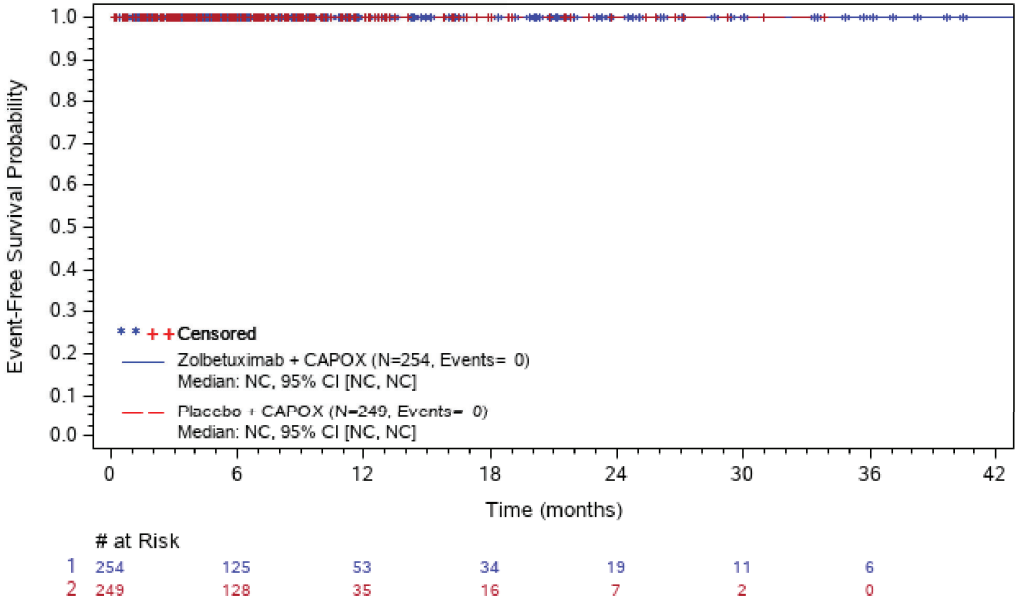
Figure 302.3.2001.221: Kaplan-Meier Plot of Time to first TEAE leading to Death - Abdominal Pain (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.222: Kaplan-Meier Plot of Time to first TEAE leading to Death - Anemia (AESI) - Safety Analysis Set

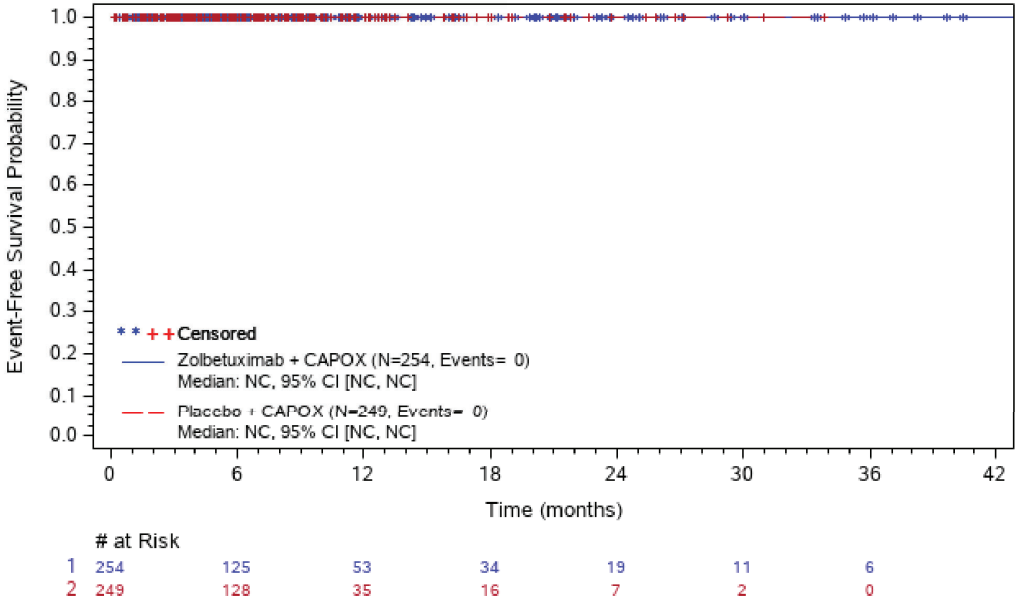


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

Figure 302.3.2001.223: Kaplan-Meier Plot of Time to first TEAE leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set

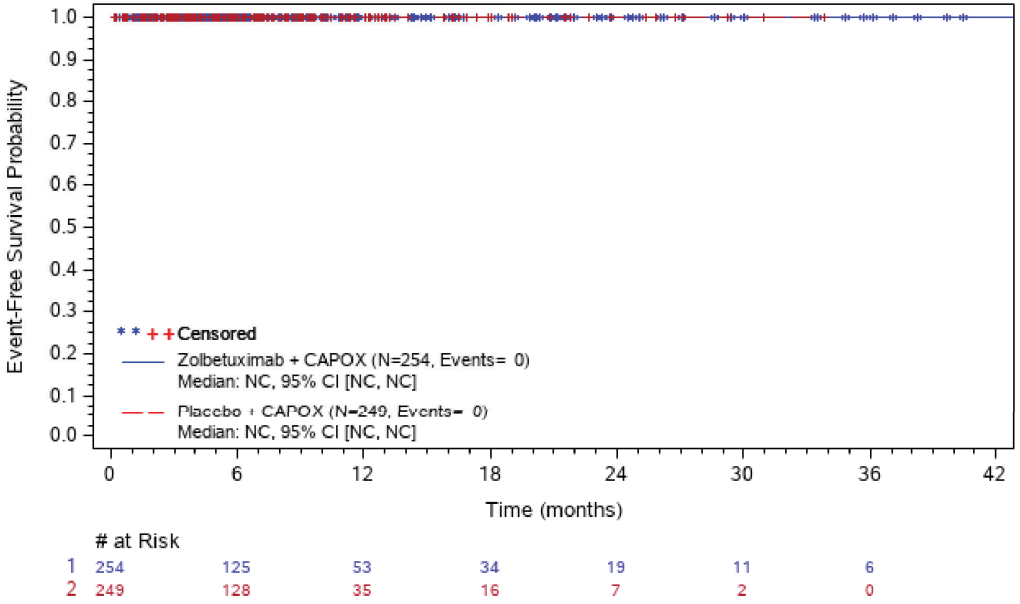


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

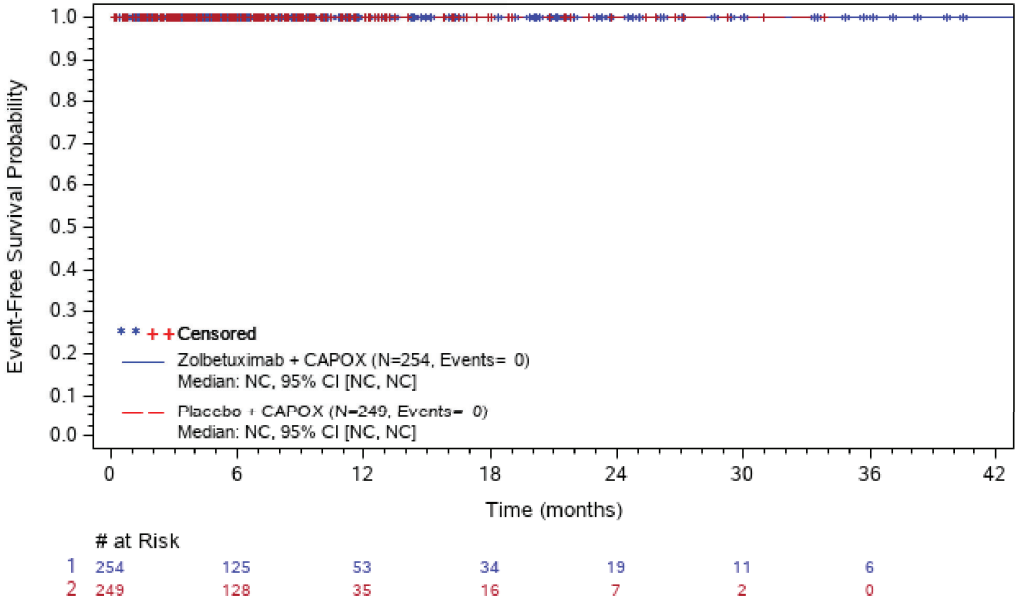
Figure 302.3.2001.224: Kaplan-Meier Plot of Time to first TEAE leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 12JAN24

The SAS System

Figure 302.3.2001.225: Kaplan-Meier Plot of Time to first TEAE leading to Death - Nausea (AESI) - Safety Analysis Set

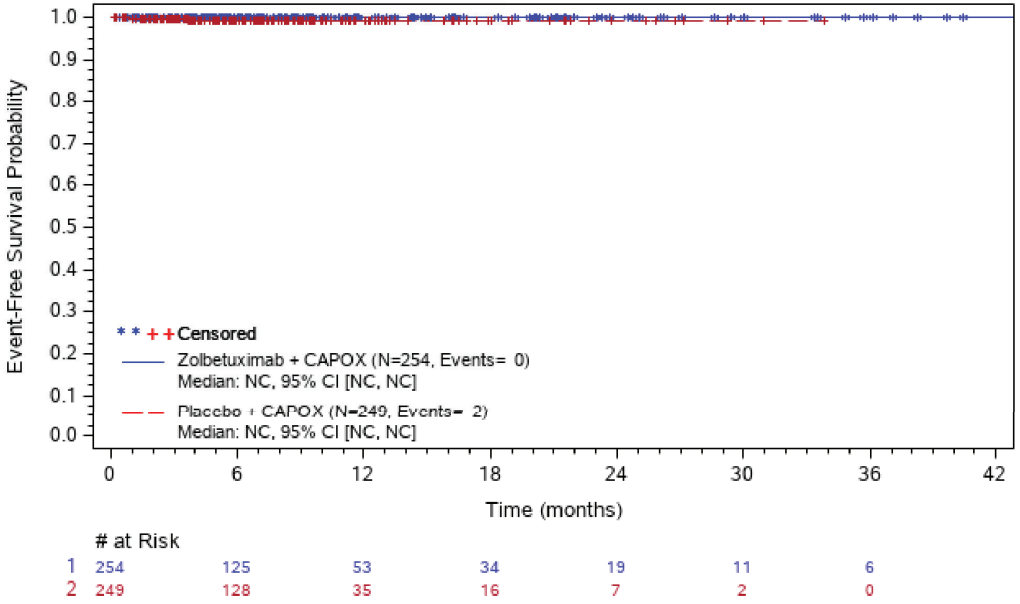


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

Figure 302.3.2001.226: Kaplan-Meier Plot of Time to first TEAE leading to Death - Neutropenia (AESI) - Safety Analysis Set

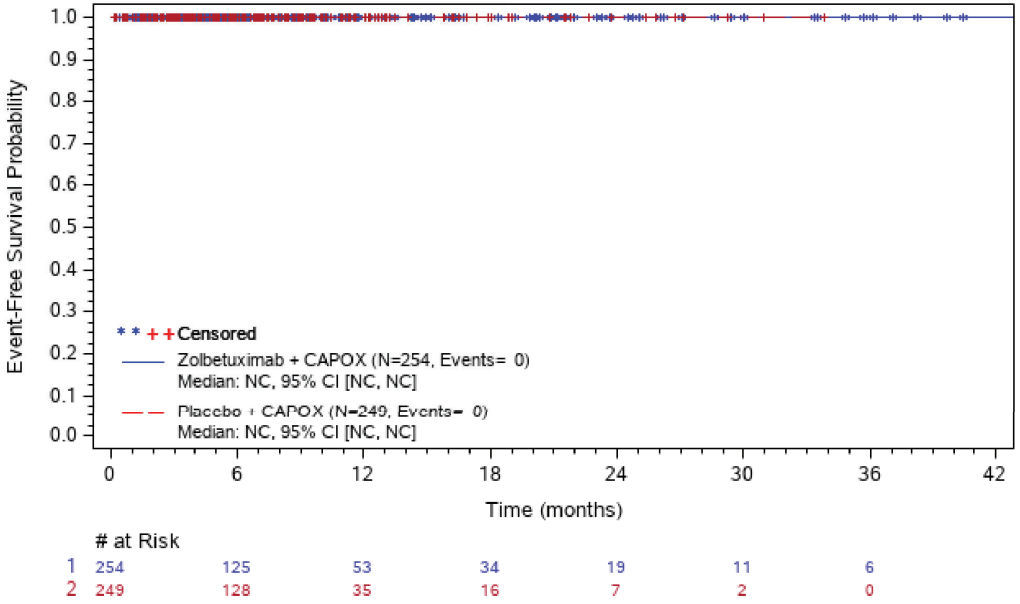


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 12JAN24

The SAS System

Figure 302.3.2001.227: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024

Anhang 4-G1 Weitere Analysen

Anhang 4-G1 Beobachtungsdauern

Table 302.3.1001.2.1: Summary of Duration of Observation Time of Overall Survival - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	254	253
Mean (SD)	15.1 (11.03)	13.2 (9.92)
Median	12.3	10.9
Q1-Q3	6.4 - 22.6	5.5 - 18.6
Range	0 - 50	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: 12JAN24

Table 302.3.1001.2.2: Summary of Duration of Observation Time of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	254	253
Mean (SD)	8.4 (8.64)	6.9 (6.14)
Median	6.1	6.0
Q1-Q3	2.7 - 10.3	2.7 - 8.3
Range	0 - 46	0 - 38

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: 12JAN24

Table 302.3.1001.2.3: Summary of Duration of Observation Time of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	254	253
Mean (SD)	8.2 (8.45)	6.7 (5.88)
Median	5.9	5.3
Q1-Q3	2.3 - 10.2	3.0 - 8.3
Range	0 - 43	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: 12JAN24

Table 302.3.3000.1: EORTC QLQ-C30 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	252	249
Mean (SD)	8.6 (8.88)	7.6 (6.09)
Median	6.2	6.5
Q1-Q3	2.8 - 10.8	3.4 - 10.2
Range	0 - 46	0 - 32

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: 12JAN24

Table 302.3.3000.2: EORTC QLQ-OG25 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	252	249
Mean (SD)	8.6 (8.89)	7.6 (6.09)
Median	6.2	6.5
Q1-Q3	2.8 - 10.8	3.4 - 10.2
Range	0 - 46	0 - 32

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: 12JAN24

Table 302.3.3000.3: EQ-5D Visual Analog Scale - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	252	249
Mean (SD)	8.7 (8.88)	7.6 (6.09)
Median	6.2	6.5
Q1-Q3	2.8 - 10.8	3.4 - 10.2
Range	0 - 46	0 - 32

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: 12JAN24

Table 302.3.3000.4: Global Pain - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	252	249
Mean (SD)	8.6 (8.89)	7.6 (6.09)
Median	6.2	6.5
Q1-Q3	2.8 - 10.8	3.4 - 10.2
Range	0 - 46	0 - 32

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: 12JAN24

Table 302.3.3000.5: EORTC QLQ-STO22 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=253)**
Duration of observation period (months)		
n	252	249
Mean (SD)	8.6 (8.89)	7.6 (6.09)
Median	6.2	6.5
Q1-Q3	2.8 - 10.8	3.4 - 10.2
Range	0 - 46	0 - 32

Abbreviations: EORTC QLQ-STO22=european organisation for research and treatment of cancer gastric cancer module; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for EORTC QLQ-STO22 questionnaire includes the time from randomisation until the last date data were collected for EORTC QLQ-STO22 questionnaire.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.6.1: Summary of Duration of Observation Time for Safety Endpoints - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Duration of observation period (months)		
n	254	249
Mean (SD)	10.4 (8.35)	9.3 (6.09)
Median	8.0	8.0
Q1-Q3	4.4 - 12.5	5.2 - 11.5
Range	0 - 46	0 - 33

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: 12JAN24

Table 302.3.2000.6.2: Summary of Duration of Observation Time for any TEAE - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Duration of observation period (months)		
n	254	249
Mean (SD)	8.9 (8.37)	7.9 (5.85)
Median	6.2	6.6
Q1-Q3	3.2 - 10.6	3.7 - 9.6
Range	0 - 46	0 - 33

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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Weitere Analysen
Anhang 4-G1 Begleitmedikationen

Table 302.3.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Overall	247 (97.2%)	246 (97.2%)
Agents Acting On The Renin-Angiotensin System	40 (15.7%)	28 (11.1%)
All Other Therapeutic Products	5 (2.0%)	6 (2.4%)
Analgesics	115 (45.3%)	123 (48.6%)
Anesthetics	18 (7.1%)	7 (2.8%)
Anti-Acne Preparations	0	2 (0.8%)
Anti-Parkinson Drugs	0	1 (0.4%)
Antianemic Preparations	55 (21.7%)	66 (26.1%)
Antibacterials For Systemic Use	66 (26.0%)	53 (20.9%)
Antibiotics And Chemotherapeutics For Dermatological Use	13 (5.1%)	11 (4.3%)
Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents	70 (27.6%)	72 (28.5%)
Antiemetics And Antinauseants	207 (81.5%)	187 (73.9%)
Antiepileptics	1 (0.4%)	0
Antifungals For Dermatological Use	5 (2.0%)	5 (2.0%)
Antigout Preparations	4 (1.6%)	12 (4.7%)
Antihemorrhagics	33 (13.0%)	24 (9.5%)
Antihistamines For Systemic Use	86 (33.9%)	56 (22.1%)
Antihypertensives	1 (0.4%)	3 (1.2%)
Antiinflammatory And Antirheumatic Products	41 (16.1%)	46 (18.2%)
Antimycobacterials	1 (0.4%)	1 (0.4%)
Antimycotics For Systemic Use	1 (0.4%)	4 (1.6%)
Antineoplastic Agents	2 (0.8%)	0
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	16 (6.3%)	10 (4.0%)
Antiseptics And Disinfectants	2 (0.8%)	1 (0.4%)
Antithrombotic Agents	44 (17.3%)	34 (13.4%)
Antivirals For Systemic Use	10 (3.9%)	5 (2.0%)
Appetite Stimulants	27 (10.6%)	28 (11.1%)
Beta Blocking Agents	12 (4.7%)	14 (5.5%)
Bile And Liver Therapy	53 (20.9%)	40 (15.8%)
Blood Substitutes And Perfusion Solutions	86 (33.9%)	72 (28.5%)
Calcium Channel Blockers	33 (13.0%)	27 (10.7%)
Cardiac Therapy	12 (4.7%)	15 (5.9%)
Contrast Media	2 (0.8%)	3 (1.2%)
Corticosteroids For Systemic Use	101 (39.8%)	73 (28.9%)
Corticosteroids, Dermatological Preparations	24 (9.4%)	14 (5.5%)
Cough And Cold Preparations	11 (4.3%)	20 (7.9%)
Diagnostic Agents	0	1 (0.4%)

Therapeutic Subgroup	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)
Digestives, Incl. Enzymes	7 (2.8%)	14 (5.5%)
Diuretics	40 (15.7%)	34 (13.4%)
Drugs For Acid Related Disorders	196 (77.2%)	172 (68.0%)
Drugs For Constipation	64 (25.2%)	92 (36.4%)
Drugs For Functional Gastrointestinal Disorders	78 (30.7%)	67 (26.5%)
Drugs For Obstructive Airway Diseases	16 (6.3%)	12 (4.7%)
Drugs For Treatment Of Bone Diseases	11 (4.3%)	7 (2.8%)
Drugs Used In Diabetes	31 (12.2%)	28 (11.1%)
Emollients And Protectives	30 (11.8%)	38 (15.0%)
General Nutrients	37 (14.6%)	37 (14.6%)
Gynecological Antiinfectives And Antiseptics	1 (0.4%)	1 (0.4%)
Immune Sera And Immunoglobulins	0	1 (0.4%)
Immunostimulants	66 (26.0%)	45 (17.8%)
Immunosuppressants	0	1 (0.4%)
Lipid Modifying Agents	28 (11.0%)	23 (9.1%)
Medicated Dressings	0	1 (0.4%)
Mineral Supplements	49 (19.3%)	31 (12.3%)
Muscle Relaxants	5 (2.0%)	13 (5.1%)
Nasal Preparations	2 (0.8%)	2 (0.8%)
Ophthalmologicals	7 (2.8%)	6 (2.4%)
Other Alimentary Tract And Metabolism Products	11 (4.3%)	13 (5.1%)
Other Dermatological Preparations	8 (3.1%)	6 (2.4%)
Other Drugs For Disorders Of The Musculo-Skeletal System	1 (0.4%)	0
Other Gynecologicals	0	1 (0.4%)
Other Hematological Agents	1 (0.4%)	5 (2.0%)
Other Nervous System Drugs	24 (9.4%)	12 (4.7%)
Pituitary And Hypothalamic Hormones And Analogues	4 (1.6%)	3 (1.2%)
Preparations For Treatment Of Wounds And Ulcers	4 (1.6%)	2 (0.8%)
Psychoanaleptics	17 (6.7%)	16 (6.3%)
Psycholeptics	89 (35.0%)	83 (32.8%)
Sex Hormones And Modulators Of The Genital System	2 (0.8%)	3 (1.2%)
Stomatological Preparations	18 (7.1%)	12 (4.7%)
Throat Preparations	7 (2.8%)	9 (3.6%)
Thyroid Therapy	10 (3.9%)	6 (2.4%)
Tonics	0	1 (0.4%)
Topical Products For Joint And Muscular Pain	7 (2.8%)	3 (1.2%)
Unspecified Herbal And Traditional Medicine	9 (3.5%)	12 (4.7%)
Urologicals	15 (5.9%)	15 (5.9%)
Vaccines	17 (6.7%)	20 (7.9%)
Vasoprotectives	20 (7.9%)	10 (4.0%)
Vitamins	59 (23.2%)	40 (15.8%)

Therapeutic Subgroup	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Weitere Analysen
Anhang 4-G1 Studienmedikation - Exposition

Table 302.3.1001.6: Summary of Study Drug Exposure - Safety Analysis Set

	Zolbetuximab + CAPOX (N=253)	**Placebo + CAPOX (N=250)**
Duration of Zolbetuximab/Placebo (days)		
n	252	250
Mean (SD)	223.7 (258.6)	187.7 (176.4)
Median	134.0	148.5
Range	1 - 1395	1 - 987
Duration of Oxaliplatin (days)		
n	249	250
Mean (SD)	110.1 (62.02)	110.5 (58.85)
Median	123.0	119.5
Range	1 - 240	1 - 223
Duration of Capecitabine (days)		
n	247	250
Mean (SD)	212.7 (230.4)	179.6 (159.9)
Median	141.0	143.5
Range	1 - 1177	1 - 1001

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 + CAPOX components: Zolbetuximab, Oxaliplatin and Capecitabine.
Placebo + CAPOX components: Placebo, Oxaliplatin and Capecitabine.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Weitere Analysen
Anhang 4-G1 Patientenfluss

Table 302.3.1001.7: Summary of Disposition of Subjects

	Zolbetuximab + CAPOX	Placebo + CAPOX	Total
Number of Subjects with Informed Consent			2333
Discontinued Before Randomization to Treatment			1826 (78.3%)
Randomized to Treatment			507 (21.7%)
Number of Randomized Patients	254	253	507
Safety Analysis Set [1]	254 (100.0%)	249 (98.4%)	503 (99.2%)
Full Analysis Set	254 (100.0%)	253 (100.0%)	507 (100.0%)
Pharmacokinetics Analysis Set	245 (96.5%)	0	245 (48.3%)
Overall Treatment Discontinuation [2]			
Yes	230 (90.6%)	231 (91.3%)	461 (90.9%)
No	24 (9.4%)	22 (8.7%)	46 (9.1%)
Reason for Overall Treatment Discontinuation [3]			
Adverse Event	30 (11.8%)	16 (6.3%)	46 (9.1%)
Death	24 (9.4%)	20 (7.9%)	44 (8.7%)
Lost to Follow-Up	1 (0.4%)	1 (0.4%)	2 (0.4%)
Other	32 (12.6%)	23 (9.1%)	55 (10.8%)
Pregnancy	0	0	0
Progressive Disease	111 (43.7%)	154 (60.9%)	265 (52.3%)
Protocol Deviation	2 (0.8%)	1 (0.4%)	3 (0.6%)
Withdrawal by Subject	39 (15.4%)	23 (9.1%)	62 (12.2%)
Post-Treatment Follow-Up Discontinuation			
Yes	234 (92.1%)	243 (96.0%)	477 (94.1%)
No	20 (7.9%)	10 (4.0%)	30 (5.9%)
Primary Post-Treatment Follow-Up Status			
Adverse Event	1 (0.4%)	2 (0.8%)	3 (0.6%)
Death	99 (39.0%)	111 (43.9%)	210 (41.4%)
Lost to Follow-Up	4 (1.6%)	2 (0.8%)	6 (1.2%)
Other	34 (13.4%)	37 (14.6%)	71 (14.0%)
Pregnancy	0	0	0
Progressive Disease	55 (21.7%)	67 (26.5%)	122 (24.1%)
Protocol Deviation	2 (0.8%)	0	2 (0.4%)
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	39 (15.4%)	24 (9.5%)	63 (12.4%)
Survival Follow-Up Discontinuation			
Yes	214 (84.3%)	229 (90.5%)	443 (87.4%)
No	40 (15.7%)	24 (9.5%)	64 (12.6%)

	Zolbetuximab + CAPOX	Placebo + CAPOX	Total
Primary Survival Follow-Up Status			
Death	178 (70.1%)	201 (79.4%)	379 (74.8%)
Lost to Follow-Up	4 (1.6%)	2 (0.8%)	6 (1.2%)
Other	2 (0.8%)	1 (0.4%)	3 (0.6%)
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	30 (11.8%)	25 (9.9%)	55 (10.8%)

[1]: All subjects who received at least one dose of any study drug (Zolbetuximab/Placebo/CAPOX). If a subject received at least one dose of zolbetuximab, the subject is counted under the zolbetuximab arm.
[2]: Of both treatments.
[3]: 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: 12JAN24

Anhang 4-G1 *Post hoc* Analysen für die Studie GLOW, finaler Datenschnitt 12.01.2024
Anhang 4-G1 Weitere Analysen
Anhang 4-G1 Folgetherapien

Table 302.3.1001.8: Summary of Subsequent Therapies - Full Analysis Set

Subsequent Therapies	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Overall	118 (46.5%)	140 (55.3%)	258 (50.9%)
All Other Therapeutic Products	12 (4.7%)	12 (4.7%)	24 (4.7%)
All Other Therapeutic Products	5 (2.0%)	4 (1.6%)	9 (1.8%)
All Other Therapeutic Products	5 (2.0%)	4 (1.6%)	9 (1.8%)
Detoxifying Agents For Antineoplastic Treatment	7 (2.8%)	8 (3.2%)	15 (3.0%)
Calcium Folinate	4 (1.6%)	6 (2.4%)	10 (2.0%)
Calcium Levofolinate Pentahydrate	1 (0.4%)	0	1 (0.2%)
Folinic Acid	1 (0.4%)	2 (0.8%)	3 (0.6%)
Levofolinic Acid	0	1 (0.4%)	1 (0.2%)
Sodium Folinate	1 (0.4%)	0	1 (0.2%)
Antineoplastic Agents	115 (45.3%)	135 (53.4%)	250 (49.3%)
Anthracyclines And Related Substances	1 (0.4%)	0	1 (0.2%)
Epirubicin Hydrochloride	1 (0.4%)	0	1 (0.2%)
Antineoplastic Agents	3 (1.2%)	2 (0.8%)	5 (1.0%)
Antineoplastic Agents	2 (0.8%)	1 (0.4%)	3 (0.6%)
Investigational Antineoplastic Drugs	1 (0.4%)	1 (0.4%)	2 (0.4%)
Combinations Of Antineoplastic Agents	21 (8.3%)	22 (8.7%)	43 (8.5%)
Calcium Folinate;fluorouracil;irinotecan Hydrochloride	3 (1.2%)	8 (3.2%)	11 (2.2%)
Capecitabine;oxaliplatin	4 (1.6%)	3 (1.2%)	7 (1.4%)
Capecitabine;oxaliplatin;trastuzumab	1 (0.4%)	0	1 (0.2%)
Cisplatin;fluorouracil	0	1 (0.4%)	1 (0.2%)
Combinations Of Antineoplastic Agents	1 (0.4%)	2 (0.8%)	3 (0.6%)
Fluorouracil;folinic Acid;irinotecan	0	1 (0.4%)	1 (0.2%)
Fluorouracil;folinic Acid;oxaliplatin	4 (1.6%)	2 (0.8%)	6 (1.2%)
Paclitaxel;pembrolizumab	1 (0.4%)	0	1 (0.2%)
Paclitaxel;ramucirumab	8 (3.1%)	10 (4.0%)	18 (3.6%)
Egfr (Epidermal Growth Factor Receptor) Inhibitors	1 (0.4%)	0	1 (0.2%)
Nimotuzumab	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup, Chemical Subgroup and Preferred WHO Name. Ingredients are the list of active ingredients for combination drugs.
ASTELLAS Data Cutoff Date: 07OCT2022

Table 302.3.1001.8: Summary of Subsequent Therapies - Full Analysis Set

Subsequent Therapies	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Folic Acid Analogues	1 (0.4%)	3 (1.2%)	4 (0.8%)
Methotrexate	0	2 (0.8%)	2 (0.4%)
Raltitrexed	1 (0.4%)	1 (0.4%)	2 (0.4%)
Herbal Anticancer Remedies	2 (0.8%)	3 (1.2%)	5 (1.0%)
Coix Lacryma-Jobi Subsp. Ma-Yuen Seed	0	1 (0.4%)	1 (0.2%)
Herbal Anticancer Remedies	2 (0.8%)	2 (0.8%)	4 (0.8%)
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%)	1 (0.4%)	2 (0.4%)
Endostatin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Other Cytotoxic Antibiotics	1 (0.4%)	0	1 (0.2%)
Mitomycin	1 (0.4%)	0	1 (0.2%)
Other Monoclonal Antibodies And Antibody Drug Conjugates	3 (1.2%)	4 (1.6%)	7 (1.4%)
Catumaxomab	1 (0.4%)	0	1 (0.2%)
Cmg 901	1 (0.4%)	3 (1.2%)	4 (0.8%)
Dkn 01	1 (0.4%)	0	1 (0.2%)
Tusamitamab Ravtansine	0	1 (0.4%)	1 (0.2%)
Other Plant Alkaloids And Natural Products	0	1 (0.4%)	1 (0.2%)
Cinobufagin	0	1 (0.4%)	1 (0.2%)
Other Protein Kinase Inhibitors	1 (0.4%)	6 (2.4%)	7 (1.4%)
Al 2846	0	1 (0.4%)	1 (0.2%)
Catequentinib Hydrochloride	0	4 (1.6%)	4 (0.8%)
Lenvatinib	1 (0.4%)	0	1 (0.2%)
Regorafenib	0	1 (0.4%)	1 (0.2%)
Pd-1/Pdl-1 (Programmed Cell Death Protein 1/Death Ligand 1) Inhibitors	32 (12.6%)	34 (13.4%)	66 (13.0%)
Camrelizumab	3 (1.2%)	1 (0.4%)	4 (0.8%)
Nivolumab	17 (6.7%)	12 (4.7%)	29 (5.7%)
Pembrolizumab	5 (2.0%)	4 (1.6%)	9 (1.8%)

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ASTELLAS Data Cutoff Date: 07OCT2022

Table 302.3.1001.8: Summary of Subsequent Therapies - Full Analysis Set

Subsequent Therapies	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Penpulimab	0	4 (1.6%)	4 (0.8%)
Sintilimab	6 (2.4%)	11 (4.3%)	17 (3.4%)
Tislelizumab	1 (0.4%)	2 (0.8%)	3 (0.6%)
Toripalimab	2 (0.8%)	1 (0.4%)	3 (0.6%)
Tq B2450	0	1 (0.4%)	1 (0.2%)
Zimberelimab	0	1 (0.4%)	1 (0.2%)
Plant Alkaloids And Other Natural Products	1 (0.4%)	0	1 (0.2%)
Brucea Javanica Oil;glycerol;lecithin	1 (0.4%)	0	1 (0.2%)
Platinum Compounds	27 (10.6%)	19 (7.5%)	46 (9.1%)
Carboplatin	3 (1.2%)	0	3 (0.6%)
Cisplatin	9 (3.5%)	8 (3.2%)	17 (3.4%)
Oxaliplatin	15 (5.9%)	13 (5.1%)	28 (5.5%)
Podophyllotoxin Derivatives	0	1 (0.4%)	1 (0.2%)
Etoposide	0	1 (0.4%)	1 (0.2%)
Pyrimidine Analogues	33 (13.0%)	44 (17.4%)	77 (15.2%)
Capecitabine	12 (4.7%)	17 (6.7%)	29 (5.7%)
Fluorouracil	15 (5.9%)	18 (7.1%)	33 (6.5%)
Gemcitabine	1 (0.4%)	0	1 (0.2%)
Gimeracil;oteracil Potassium;tegafur	7 (2.8%)	9 (3.6%)	16 (3.2%)
Tegafur	1 (0.4%)	1 (0.4%)	2 (0.4%)
Tipiracil Hydrochloride;trifluridine	1 (0.4%)	4 (1.6%)	5 (1.0%)
Taxanes	69 (27.2%)	79 (31.2%)	148 (29.2%)
Docetaxel	10 (3.9%)	14 (5.5%)	24 (4.7%)
Paclitaxel	46 (18.1%)	51 (20.2%)	97 (19.1%)
Paclitaxel Nanoparticle Albumin-Bound	14 (5.5%)	17 (6.7%)	31 (6.1%)
Topoisomerase 1 (Top1) Inhibitors	20 (7.9%)	24 (9.5%)	44 (8.7%)
Irinotecan	16 (6.3%)	19 (7.5%)	35 (6.9%)
Irinotecan Hydrochloride	3 (1.2%)	4 (1.6%)	7 (1.4%)

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Sorting order: alphabetical order by Therapeutic Subgroup, Chemical Subgroup and Preferred WHO Name. Ingredients are the list of active ingredients for combination drugs.
ASTELLAS Data Cutoff Date: 07OCT2022

Table 302.3.1001.8: Summary of Subsequent Therapies - Full Analysis Set

Subsequent Therapies	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=253)	Total (N=507)
Irinotecan Hydrochloride Trihydrate	0	1 (0.4%)	1 (0.2%)
Irinotecan Hydrochloride Trihydrate Liposomal	1 (0.4%)	0	1 (0.2%)
Vascular Endothelial Growth Factor Receptor (Vegfr) Tyrosine Kinase Inhibitors	9 (3.5%)	7 (2.8%)	16 (3.2%)
Fruquintinib	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rivoceranib	3 (1.2%)	3 (1.2%)	6 (1.2%)
Rivoceranib Mesylate	5 (2.0%)	3 (1.2%)	8 (1.6%)
Vegf/Vegfr (Vascular Endothelial Growth Factor) Inhibitors	21 (8.3%)	28 (11.1%)	49 (9.7%)
Ramucirumab	21 (8.3%)	28 (11.1%)	49 (9.7%)
Corticosteroids For Systemic Use	0	1 (0.4%)	1 (0.2%)
Glucocorticoids	0	1 (0.4%)	1 (0.2%)
Prednisolone Sodium Succinate	0	1 (0.4%)	1 (0.2%)
Immunostimulants	1 (0.4%)	1 (0.4%)	2 (0.4%)
Immunostimulants	1 (0.4%)	0	1 (0.2%)
Immunotherapy	1 (0.4%)	0	1 (0.2%)
Interleukins	0	1 (0.4%)	1 (0.2%)
Thor 707	0	1 (0.4%)	1 (0.2%)
Various	10 (3.9%)	14 (5.5%)	24 (4.7%)
Various	10 (3.9%)	14 (5.5%)	24 (4.7%)
Blinded Therapy	3 (1.2%)	1 (0.4%)	4 (0.8%)
Radiotherapy	7 (2.8%)	13 (5.1%)	20 (3.9%)

Abbreviations: N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup, Chemical Subgroup and Preferred WHO Name. Ingredients are the list of active ingredients for combination drugs.
ASTELLAS Data Cutoff Date: 07OCT2022