EU Clinical Trials Register

Clinical trial results:
A Phase III, Multicenter, Randomized, Study of Atezolizumab Versus Placebo Administered in Combination With Paclitaxel, Carboplatin, and Bevacizumab to Patients With Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Summary

EudraCT number	2016-003472-52
Trial protocol	ES SE NO CZ DE AT PL FI GR DK FR BE IT
Global end of trial date	12 August 2022

Results information

Result version number	v1 (current)
This version publication date	26 January 2023
First version publication date	26 January 2023

Trial information

Trial identification

Sponsor protocol code	YO39523

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03038100
WHO universal trial number (UTN)	-
Other trial identifiers	Other Sponsor ID: IMagyn050

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 August 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 August 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was designed to evaluate the efficacy and safety of atezolizumab administered with paclitaxel+carboplatin+bevacizumab (Atezo+CP+Bev) compared with placebo+paclitaxel+carboplatin+bevacizumab (Placebo+CP+Bev) in participants with newly diagnosed, untreated ovarian, fallopian tube, and/or primary peritoneal cancer.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 March 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	50 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 28
Country: Number of subjects enrolled	Austria: 11
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Brazil: 19
Country: Number of subjects enrolled	China: 135
Country: Number of subjects enrolled	Czechia: 18
Country: Number of subjects enrolled	Germany: 65
Country: Number of subjects enrolled	Denmark: 1
Country: Number of subjects enrolled	Spain: 25
Country: Number of subjects enrolled	Finland: 19
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Greece: 26
Country: Number of subjects enrolled	Israel: 11
Country: Number of subjects enrolled	Italy: 83
Country: Number of subjects enrolled	Japan: 110
Country: Number of subjects enrolled	Korea, Republic of: 38
Country: Number of subjects enrolled	Norway: 9
Country: Number of subjects enrolled	Poland: 23

Country: Number of subjects enrolled	Russian Federation: 91
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	Turkey: 51
Country: Number of subjects enrolled	United States: 507
Worldwide total number of subjects	1301
EEA total number of subjects	311

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	879
From 65 to 84 years	422
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment included: United States (113 centers), Japan (22), Italy (18), Germany (16), China (13), Spain (9), France (7), Turkey (6), Austria (4), Belgium (4), Czech Republic (4), Greece (4), Israel (4), Poland (4), Republic of Korea (4), Russia (4), Australia (3), Finland (3), Norway (2), Sweden (2), Brazil (2), Denmark (1)

Pre-assignment

Screening details:

Participants in this study included: a histologic diagnosis of epithelial ovarian cancer, peritoneal primary carcinoma, or fallopian tube cancer. Patients who were to undergo primary tumor reductive surgeryhad to have International Federation of Gynecological Oncologists Stage III with gross residual disease or Stage IV.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo With Paclitaxel, Carboplatin and Bevacizumab

Arm description:

Participants in the primary tumor-reductive surgery group received paclitaxel, carboplatin, atezolizumab placebo IV infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab placebo for a total of 22 cycles of atezolizumab placebo and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group received paclitaxel, carboplatin and placebo for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants started maintenance therapy of bevacizumab and placebo for additional 16 cycles.

Arm type	Active comparator
Investigational medicinal product name	Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Paclitaxel 175 milligrams per square meter (mg/m^2) IV infusion was administered on Day 1 of each 21-day cycle.

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Carboplatin was administered at a dose to achieve a target area under the curve (AUC) of 6 milligrams per milliliter*minute (mg/mL*min) on Day 1 of each 21-day cycle for a total of 6 cycles.

Investigational medicinal product name	Bevacizumab
Investigational medicinal product code	
Other name	Avastin
Pharmaceutical forms	Infusion

Routes of administration	Intravenous use

Dosage and administration details:

Bevacizumab was administered at a dose of 15 milligrams per kilogram (mg/kg) IV infusion as per the schedule.

Investigational medicinal product name	Atezolizumab placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab placebo was administered by IV infusion at a fixed dose of 1200mg on Day 1 of each 21-day cycle for 22cycles total or until disease progression, unacceptable toxicity, patient or physician's decision to discontinue, patient death, or study termination by the Sponsor

Arm title	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Arm description:

Participants in the primary tumor-reductive surgery group received paclitaxel, carboplatin, atezolizumab intravenous (IV) infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab for a total of 22 cycles of atezolizumab and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group received paclitaxel, carboplatin and atezolizumab for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants started maintenance therapy of bevacizumab and atezolizumab for additional 16 cycles.

Arm type	Experimental
Investigational medicinal product name	Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Paclitaxel 175 milligrams per square meter (mg/m^2) IV infusion was administered on Day 1 of each 21-day cycle.

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	Tecentriq
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab was administered by IV infusion at a fixed dose of 1200mg on Day 1 of each 21-day cycle for 22 cycles total or until disease progression, unacceptable toxicity, patient or physician's decision to discontinue, patient death, or study termination by the Sponsor.

Investigational medicinal product name	Bevacizumab
Investigational medicinal product code	
Other name	Avastin
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bevacizumab was administered at a dose of 15 milligrams per kilogram (mg/kg) IV infusion as per the schedule.

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Carboplatin was administered at a dose to achieve a target area under the curve (AUC) of 6 milligrams per milliliter*minute (mg/mL*min) on Day 1 of each 21-day cycle for a total of 6 cycles.

Number of subjects in period 1	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Started	650	651
Completed	0	0
Not completed	650	651
Consent withdrawn by subject	45	51
Physician decision	1	3
Protocol Deviation	1	4
Study Terminated By Sponsor	305	311
Death	289	272
Lost to follow-up	9	10

Baseline characteristics

Reporting groups

Reporting group title	Placebo With Paclitaxel, Carboplatin and Bevacizumab

Reporting group description:

Participants in the primary tumor-reductive surgery group received paclitaxel, carboplatin, atezolizumab placebo IV infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab placebo for a total of 22 cycles of atezolizumab placebo and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group received paclitaxel, carboplatin and placebo for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants started maintenance therapy of bevacizumab and placebo for additional 16 cycles.

Reporting group title	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Reporting group description:

Participants in the primary tumor-reductive surgery group received paclitaxel, carboplatin, atezolizumab intravenous (IV) infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab for a total of 22 cycles of atezolizumab and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group received paclitaxel, carboplatin and atezolizumab for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants started maintenance therapy of bevacizumab and atezolizumab for additional 16 cycles.

Reporting group values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab	Total
Number of subjects	650	651	1301
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	429	450	879
From 65-84 years	221	201	422
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	59.3	58.9	
standard deviation	± 10.7	± 10.5	-
Sex: Female, Male			
Units: Participants			
Female	650	651	1301
Male	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	6	5	11
Asian	155	150	305

Native Hawaiian or Other Pacific Islander	0	2	2
Black or African American	13	8	21
White	461	464	925
More than one race	0	0	0
Unknown or Not Reported	15	22	37
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	38	39	77
Not Hispanic or Latino	598	589	1187
Unknown or Not Reported	14	23	37

End points

End points reporting groups

Reporting group title	Placebo With Paclitaxel, Carboplatin and Bevacizumab

Reporting group description:

Participants in the primary tumor-reductive surgery group received paclitaxel, carboplatin, atezolizumab placebo IV infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab placebo for a total of 22 cycles of atezolizumab placebo and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group received paclitaxel, carboplatin and placebo for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants started maintenance therapy of bevacizumab and placebo for additional 16 cycles.

Reporting group title	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Reporting group description:

Participants in the primary tumor-reductive surgery group received paclitaxel, carboplatin, atezolizumab intravenous (IV) infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab for a total of 22 cycles of atezolizumab and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group received paclitaxel, carboplatin and atezolizumab for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants started maintenance therapy of bevacizumab and atezolizumab for additional 16 cycles.

Primary: Progression-Free Survival (PFS) Assessed by Investigator as Per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) - Intent-to-Treat (ITT) Population

End point title	Progression-Free Survival (PFS) Assessed by Investigator as Per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) - Intent-to-Treat (ITT) Population

End point description:

Investigator-assessed PFS is defined as the time from randomization to the occurrence of disease progression, as determined by the investigator from tumor assessments per RECIST v1.1, or death from any cause during the study, whichever occurs first.

End point type	Primary

End point timeframe:

From randomization until disease progression or death from any cause (up to approximately 55 months)

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	650	651		
Units: Months				
median (confidence interval 95%)	18.37 (17.22 to 19.75)	19.48 (18.14 to 20.76)		

Statistical analyses

Statistical analysis title	PFS in ITT Population
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	1301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2785
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.07

Primary: PFS Assessed by Investigator as Per RECIST v1.1 - Programmed Death−Ligand 1 (PD-L1)−Positive Subpopulation

End point title	PFS Assessed by Investigator as Per RECIST v1.1 - Programmed Death−Ligand 1 (PD-L1)−Positive Subpopulation

End point description:

Investigator-assessed PFS is defined as the time from randomization to the occurrence of disease progression, as determined by the investigator from tumor assessments per RECIST v1.1, or death from any cause during the study, whichever occurs first.

End point type	Primary

End point timeframe:

From randomization until disease progression or death from any cause (up to approximately 55 months)

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	393	391		
Units: Months				
median (confidence interval 95%)	18.50 (16.62 to 21.36)	20.83 (19.06 to 24.21)		

Statistical analyses

Statistical analysis title	PFS in PD-L1-Positive Subpopulation
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	784
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.0376
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.99

Notes:

[1] - Stratified Analysis

Primary: Overall Survival - ITT Population

End point title	Overall Survival - ITT Population

End point description:

Overall Survival (OS) is defined as the time from randomization to death from any cause. Note: 999999=not estimable.

End point type	Primary

End point timeframe:

From randomization up to death from any cause (up to approximately 59 months)

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	650	651		
Units: Months				
median (confidence interval 95%)	46.59 (45.31 to 49.74)	50.53 (46.26 to 999999)		

Statistical analyses

Statistical analysis title	OS in ITT Population

Statistical analysis description:

Stratified by: stage and/or surgical status (Stage III vs. Stage IV), ECOG performance status (0 vs. 1 or 2), tumor PD-L1 status (IC0 vs. IC1/2/3), and treatment strategy (adjuvant vs. neoadjuvant).

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	1301
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.3432
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.09

Notes:

[2] - Stratified Analysis

Primary: Overall Survival - PD-L1−Positive Subpopulation

End point title	Overall Survival - PD-L1−Positive Subpopulation

End point description:

Overall Survival (OS) is defined as the time from randomization to death from any cause. Note: 999999=not estimable.

End point type	Primary

End point timeframe:

From randomization up to death from any cause (up to approximately 59 months)

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	393	391		
Units: Months				
median (confidence interval 95%)	49.15 (45.54 to 999999)	999999 (999999 to 999999)		

Statistical analyses

Statistical analysis title	OS in PD-L1-Positive Subpopulation

Statistical analysis description:

Stratified by: stage and/or surgical status (Stage III vs. Stage IV), ECOG performance status (0 vs. 1 or 2) and treatment strategy (adjuvant vs. neoadjuvant).

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	784
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1316
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.06

Secondary: Percentage of Participants With Objective Response (OR) Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery Group in ITT Population

End point title	Percentage of Participants With Objective Response (OR) Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery Group in ITT Population

End point description:

OR is defined as either a CR or PR as determined by the investigator with the use of RECIST v1.1 for patients with measurable residual disease after primary surgery.

End point type	Secondary

End point timeframe:

From randomization until disease progression or death from any cause (up to approximately 55 months)

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	650	651		
Units: Percentage of participants				
number (not applicable)	88.7	92.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Objective Response (OR) Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery Group in PD-L1-Positive Population

End point title	Percentage of Participants With Objective Response (OR) Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery Group in PD-L1-Positive Population

End point description:

OR is defined as either a CR or PR as determined by the investigator with the use of RECIST v1.1 for patients with measurable residual disease after primary surgery.

End point type	Secondary

End point timeframe:

From randomization until disease progression or death from any cause (up to approximately 55 months)

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	393	391		
Units: Percentage of participants				
number (not applicable)	89.9	92.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery (Having Residual Measurable Disease) Group in ITT Population

End point title	Duration of Response Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery (Having Residual Measurable Disease) Group in ITT Population

End point description:

DOR is defined as the time interval from first occurrence of a CR or PR to the time of disease progression, as determined by the investigator with the use of RECIST v1.1, or death from any cause, whichever comes first for patients with measurable residual disease after primary surgery.

End point type	Secondary

End point timeframe:

From the date of first occurrence of a confirmed complete or partial response until disease progression or death from any cause (up to approximately 55 months)

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	650	651		
Units: Months				
median (confidence interval 95%)	14.06 (13.01 to 16.62)	16.59 (14.52 to 19.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery (Having Residual Measurable Disease) Group in PD-L1-Positive Population

End point title	Duration of Response Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery (Having Residual Measurable Disease) Group in PD-L1-Positive Population

End point description:

DOR is defined as the time interval from first occurrence of a CR or PR to the time of disease progression, as determined by the investigator with the use of RECIST v1.1, or death from any cause, whichever comes first for patients with measurable residual disease after primary surgery.

End point type	Secondary

End point timeframe:

From the date of first occurrence of a confirmed complete or partial response until disease progression or death from any cause (up to approximately 55 months)

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	650	651		
Units: Months				
median (confidence interval 95%)	13.44 (12.71 to 19.29)	17.71 (15.01 to 19.61)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieve a Clinically-Meaningful Improvement in Patient-Reported Abdominal Pain and Bloating - Neoadjuvant Group

End point title	Percentage of Participants who Achieve a Clinically-Meaningful Improvement in Patient-Reported Abdominal Pain and Bloating - Neoadjuvant Group

End point description:

Clinically-meaningful improvement defined as a >=10-point decrease from the baseline score in patient-reported abdominal pain or bloating will be assessed using European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaires Ovarian Cancer Module 28 (EORTC QLQ-OV28) Abdominal/Gastrointestinal Symptom Scale (Items 31 and 31). Note: n=participants with data at given

timepoint. C=Cycle, D=Day, CoT=Completion of Treatment, FU=Follow Up, ETV=Early Termination Visit.

End point type	Secondary
End point timeframe:	

From randomization to the end of treatment/discontinuation (up to approximately 66 weeks), and during follow-up period (up to approximately 55 months). Cycle length=21 days.

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	152		
Units: Percentage of participants				
number (not applicable)				
Abdominal Pain, Presurgical/Surgery (n=142,n=136)	54.2	50.7		
Abdominal Pain, C4D1 (n=140,n=133)	36.4	32.3		
Abdominal Pain, C6D1 (n=131,n=133)	55.0	48.1		
Abdominal Pain, C8D1 (n=129,n=122)	64.3	54.1		
Abdominal Pain, C12D1 (n=111,n=101)	63.1	57.4		
Abdominal Pain, C16D1 (n=96,n=88)	63.5	58.0		
Abdominal Pain, C20D1(n=83,n=62)	68.7	48.4		
Abd. Pain, CoT/ETV (n=143,n=130)	51.0	51.5		
Abdominal Pain, PT FU 3 Months (n=96,n=96)	58.3	51.0		
Abdominal Pain, PT FU 6 Months (n=75,n=74)	61.3	51.4		
Abdominal Pain, PT FU 9 Months (n=73,n=38)	60.5	50.0		
Abdominal Pain, PT FU 12 Months (n=17,n=24)	70.6	58.3		
Abdominal Pain, PT FU 18 Months	100	50.0		
Abdominal Pain, PT FU 24 Months (n=1,n=2)	100	100		
Bloating, Presurgical/Surgery (n=142,n=137)	62.7	54.0		
Bloating, C4D1 (n=140,n=132)	65.0	59.8		
Bloating, C6D1 (n=131,n=133)	71.0	66.9		
Bloating, C8D1 (n=128,n=123)	71.9	63.4		
Bloating, C12D1 (n=111,n=101)	68.5	63.4		
Bloating, C16D1 (n=96,n=88)	66.7	64.8		
Bloating, C20D1 (n=83,n=62)	66.3	56.5		
Bloating, CoT/ETV (n=145,n=130)	62.1	58.5		
Bloating, PT FU 3 Months (n=96,n=96)	57.3	53.1		
Bloating, PT FU 6 Months (n=76,n=74)	59.2	62.2		
Bloating, PT FU 9 Months (n=43,n=38)	67.4	63.2		
Bloating, PT FU 12 Months (n=17,n=24)	47.1	62.5		
Bloating, PT FU 18 Months (n=6,n=4)	66.7	50.0		
Bloating, PT FU 24 Months (n=1,n=2)	0	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieve a Clinically-Meaningful Improvement in Patient-Reported Function and Health Related Quality of Life (HRQoL) - Neoadjuvant Group

End point title	Percentage of Participants who Achieve a Clinically-Meaningful Improvement in Patient-Reported Function and Health Related Quality of Life (HRQoL) - Neoadjuvant Group

End point description:

Clinically-meaningful improvement in patient-reported function and HRQoL during the treatment period, defined as a >=10-point increase from the baseline score on each of the functional (social, emotional, physical, role) and GHS/QoLscales of the European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaires Core 30 (EORTC QLQ-C30). Note: n=participants with data at given timepoint. C=Cycle, D=Day, ETV= Early Termination Vist, FU=Follow Up, CoT=Completion of Treatment, PT=Post Treatment.

End point type	Secondary

End point timeframe:

From randomization to the end of treatment/discontinuation (up to approximately 66 weeks), and during follow-up period (up to approximately 55 months). Cycle length=21 days.

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	152		
Units: Percentage of participants				
number (not applicable)				
Physical Func., Presurgical/Surgery (n=142,n=137)	35.9	33.6		
Physical Functioning, C4D1 (n=141,n=133)	28.4	18.0		
Physical Functioning, C6D1 (n=132,n=133)	35.6	25.6		
Physical Functioning, C8D1 (n=129, n=123)	37.2	36.6		
Physical Functioning, C12D1 (n=111,n=102)	45.9	43.1		
Physical Functioning, C16D1 (n=96, n=88)	42.7	42.0		
Physical Functioning, C20D1 (n=83,n=63)	41.0	31.7		
Physical Funct., CoT/ETV (n=144,n=131)	38.9	34.4		
Physical Funct., PT FU 3 Months (n=97,n=97)	37.1	39.2		

Physical Funct., PT FU 6 Months (n=76,n=74)	40.8	39.2
Physical Funct., PT FU 9 Months (n=43,n=38)	32.6	50.0
Physical Funct., PT FU 12 Months (n=17,n=24)	23.5	37.5
Physical Funct., PT FU 18 Months (n=6,n=4)	33.3	50.0
Physical Funct., PT FU 24 Months (n=1,n=2)	100	50.0
Role Func., Presurgical/Surgery (n=142,n=137)	48.6	40.9
Role Functioning, C4D1 (n=141,n=133)	38.3	22.6
Role Functioning, C6D1 (n=133,n=134)	45.9	33.6
Role Functioning, C8D1 (n=129,n=123)	50.4	39.8
Role Functioning, C12D1 (n=111,n=102)	55.9	47.1
Role Functioning, C16D1 (n=96,n=88)	53.1	46.6
Role Functioning, C20D1 (n=83,n=63)	56.6	52.4
Role Funct., CoT/ETV (n=145,n=131)	46.9	39.7
Role Funct., PT FU 3 Months (n=97,n=97)	49.5	40.2
Role Funct., PT FU 6 Months (n=76,n=74)	51.3	48.6
Role Funct., PT FU 9 Months (n=43,n=38)	53.5	52.6
Role Funct., PT FU 12 Months (n=17,n=24)	23.5	54.2
Role Funct., PT FU 18 Months (n=6,n=4)	50.0	50.0
Role Funct., PT FU 24 Months (n=1,n=2)	0	50.0
Social Func., Presurgical/Surgery (n=142,n=137)	32.4	33.6
Social Functioning, C4D1 (n=141,n=133)	31.2	25.6
Social Functioning, C6D1 (n=133,n=132)	36.8	33.3
Social Functioning, C8D1 (n=129,n=122)	40.3	39.3
Social Functioning, C12D1 (n=111,n=101)	39.6	44.6
Social Functioning, C16D1 (n=95,n=88)	40.0	44.3
Social Functioning, C20D1 (n=83,n=62)	45.8	43.5
Social Funct., CoT/ETV (n=144,n=130)	40.3	41.5
Social Funct., PT FU 3 Months (n=96,n=96)	42.7	44.8
Social Funct., PT FU 6 Months (n=76,n=74)	46.1	35.1
Social Funct., PT FU 9 Months (n=43,n=38)	46.5	47.4
Social Funct., PT FU 12 Months (n=17,n=24)	29.4	54.2
Social Funct., PT FU 18 Months (n=6,n=4)	66.7	75.0
Social Funct., PT FU 24 Months (n=1,n=2)	0	50.0
Emotional Func., Presurgical/Surgery (n=142,n=137)	31.7	30.7

Emotional Functioning, C4D1 (n=141,n=132)	31.2	35.6
Emotional Functioning, C6D1 (n=133,n=131)	42.1	38.2
Emotional Functioning, C8D1 (n=129,n=123)	39.5	44.7
Emotional Functioning, C12D1 (n=111,n=101)	41.4	41.6
Emotional Functioning, C16D1 (n=96,n=88)	44.8	42.0
Emotional Functioning, C20D1 (n=83,n=62)	44.6	32.3
Emotional Funct.,CoT/ETV (n=145,n=130)	33.8	33.8
Emotional Funct., PT FU 3 months (n=96,n=96)	35.4	33.3
Emotional Funct., PT FU 6 months (n=76,n=74)	30.3	33.8
Emotional Funct., PT FU 9 months (n=43,n=38)	39.5	34.2
Emotional Func., PT FU 12 months (n=17,n=24)	29.4	29.2
Emotional Func., PT FU 18 months (n=6,n=4)	16.7	50.0
Emotional Func., PT FU 24 months (n=1,n=2)	0	50.0
GHS/HRQoL, PresurgicalSurgery (n=142,n=137)	44.4	46.7
GHS/HRQoL, C4D1 (n=141,n=132)	43.3	37.1
GHS/HRQoL, C6D1 (n=133,n=132)	51.1	47.7
GHS/HRQoL, C8D1 (n=129,n=122)	55.0	59.0
GHS/HRQoL, C12D1 (n=111,n=101)	60.4	61.4
GHS/HRQoL, C16D1 (n=96,n=88)	53.1	58.0
GHS/HRQoL, C20D1 (n=83,n=62)	59.0	61.3
GHS/HRQoL, CoT/ ETV (n=145,n=130)	46.9	53.1
GHS/HRQoL, PT FU 3 Months (n=95,n=96)	53.7	53.1
GHS/HRQoL, PT FU 6 Months (n=76,n=74)	48.7	41.9
GHS/HRQoL, PT FU 9 Months (n=43,n=38)	39.5	50.0
GHS/HRQoL, PT FU 12 Months (n=17,n=24)	17.6	41.7
GHS/HRQoL, PT FU 18 Months (n=6,n=4)	16.7	50.0
GHS/HRQoL, PT FU 24 Months (n=1,n=2)	0	50.0

Statistical analyses

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Presurgical/Surgery	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.9096
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.62

Notes:

[3] - Stratified Analysis

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 4 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4662
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	2.01

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 6 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5237
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.85

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.4

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3826
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	2.07

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9893
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.76

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Emotional Functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6892
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.61

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1324
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	1.17

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Completion of Treatment/Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9176
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.7

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7861
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.68

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4539
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	2.65

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4849
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	1.86

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.747
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.19
upper limit	3.34

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0896
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	33.33

Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.86
upper limit	100

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	-94.3
upper limit	100

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Presurgical/Surgery	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7347
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.5

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Cycle 4 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0479
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Cycle 6 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0712
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	1.05

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8168
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.58

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6417
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.52

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8821
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.72

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:

Physical Functioning, Cycle 20 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2158
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1.3

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:

Physical Functioning, Completion of Treatment/Early Termination Visit

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4762
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.37

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:

Physical Functioning, Post-Treatment Follow Up 3 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7585
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.96

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9985
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.93

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1067
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	5.06

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Physical Functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6171
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	5.61

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8084
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	23.57

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical Functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3173
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	-50

Confidence interval	
level	95 %
sides	2-sided
lower limit	-100
upper limit	94.3

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:

Global health status/QoL, Presurgical/Surgery

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6802
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.77

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:

Global health status/QoL, Cycle 4 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.347
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.29

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Global health status/QoL, Cycle 6 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5564
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.41

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.99

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9778
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	1.78

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6005
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	2.12

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.99
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	2

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Global health status/QoL, Completion of Treatment/Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2634
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	2.15

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.964
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.74

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4117
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.76

Confidence interval

level	95 %
sides	2-sided
lower limit	0.4
upper limit	1.46

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3505
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	3.62

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2439
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	9.45

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1573
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	33.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.86
upper limit	100

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	-94.3
upper limit	100

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role Functioning, Presurgical/Surgery	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.182
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.16

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 4 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0046
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	0.8

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 6 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0361
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	0.97

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Role functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0848
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	1.06

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1224
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	1.13

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3127
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.74

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	1.33

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6065
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	1.65

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2173
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.2

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1316
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	1.15

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7678
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.76

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7331
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.85

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	2.14

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1235
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	10.92

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-84.09
upper limit	84.09

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	-94.3
upper limit	100

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Presurgical/Surgery	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7869
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.78

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 4 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2502
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.25

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 6 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5066
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.41

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8124
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.59

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4656
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.17

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6725
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	2.12

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.578
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.82

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	1.64

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Completion of Treatment/Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7611
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.76

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7588
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.94

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1428
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	1.19

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9802
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	2.39

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1967
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.34

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	8.7

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4795
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Respnders
Point estimate	8.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-69.28
upper limit	85.94

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	-94.3
upper limit	100

Secondary: Percentage of Participants Who Achieve a Clinically-Meaningful Improvement in Patient-Reported Function and HRQoL - Primary Tumor-Reductive Surgery Group

End point title	Percentage of Participants Who Achieve a Clinically-Meaningful Improvement in Patient-Reported Function and HRQoL -

	Primary Tumor-Reductive Surgery Group

End point description:

Percentage of participants with clinical improvement, defined as >= 10-point increase from the baseline score on each of the functional (physical, role, emotional, and social) and GHS/QoL scales of the EORTC QLQ-C30. Note: n=participants with data at given timepoint. C=Cycle, D=Day, ETV= Early Termination Visit, FU=Follow Up, CoT=Completion of Treatment, PT=Post Treatment.

End point type	Secondary

End point timeframe:

From randomization to the end of treatment/discontinuation (up to approximately 66 weeks), and during follow-up period (up to approximately 55 months). Cycle length=21 days.

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	473	473		
Units: Percentage of participants				
number (not applicable)				
Physical Functioning, C3D1 (n=456, n=444)	22.6	19.8		
Physical Functioning, C5D1 (n=439,n=423)	23.7	21.3		
Physical Functioning, C8D1 (n=414,n=403)	28.7	27.0		
Physical Functioning, C12D1 (n=378,n=358)	35.4	32.4		
Physical Functioning, C16D1 (n=333,n=312)	32.1	34.3		
Physical Functioning, C20D1 (n=253,n=234)	34.8	32.5		
Physical Func., CoT/ETV (n=370,n=366)	32.4	30.3		
Physical Func., PT FU 3 Months (n=235,n=236)	35.7	28.4		
Physical Func., PT FU 6 Months (n=147,n=164)	32.7	31.1		
Physical Func., PT FU 9 Months (n=84,n=98)	34.5	27.6		
Physical Func., PT FU 12 Months (n=45,n=58)	37.8	24.1		
Physical Func., PT FU 18 Months (n=14,n=16)	42.9	18.8		
Physical Func., PT FU 24 Months (n=2,n=6)	0	16.7		
Role Functioning, C3D1 (n=455,n=443)	42.6	40.9		
Role Functioning, C5D1 (n=438,n=422)	42.9	38.9		
Role Functioning, C8D1 (n=413,n=401)	47.5	45.9		
Role Functioning, C12D1 (n=377,n=358)	50.1	50.6		
Role Functioning, C16Day1 (n=333,n=311)	52.0	50.8		
Role Functioning, C20D1 (n=253,n=233)	53.8	51.5		
Role Func.,CoT/ETV (n=370,n=367)	48.4	46.6		

Role Func., PT FU 3 Months (n=235,n=236)	54.0	45.3
Role Func., PT FU 6 Months (n=147,n=164)	55.1	43.9
Role Func., PT FU 9 Months (n=84,n=98)	57.1	38.8
Role Func., PT FU 12 Months (n=45,n=58)	60	27.6
Role Func., PT FU 18 Months (n=14,n=16)	50	43.8
Role Func., PT FU 24 Months (n=2,n=6)	50	16.7
Social Functioning, C3D1 (n=455,n=442)	30.1	31.4
Social Functioning, C5D1 (n=439,n=422)	32.6	32.0
Social Functioning, C8D1 (n=413,n=403)	37.8	38.7
Social Functioning, C12D1 (n=376,n=357)	42.6	41.2
Social Functioning, C16D1 (n=333,n=312)	43.5	48.7
Social Functioning, C20D1 (n=252,n=234)	45.6	50.0
Social Func, CoT/ETV	40.6	40.1
Social Func, PT FU 3 Months (n=367,n=367)	42.7	41.1
Social Func., PT FU 6 Months (n=234,n=236)	43.2	34.1
Social Func., PT FU 9 Months (n=148,n=164)	50.0	36.7
Social Func, PT FU 12 Months (n=84,n=98)	62.2	36.2
Social Func., PT FU 18 Months (n=14,n=16)	57.1	43.8
Social Func., PT FU 24 Months (n=2,n=6)	100	50.0
Emotional Functioning, C3D1 (n=454,n=443)	29.7	28.4
Emotional Functioning, C5D1 (n=439,n=422)	30.3	30.3
Emotional Functioning, C8D1 (n=412,n=403)	32.3	33.0
Emotional Functioning, C12D1 (n=376,n=357)	34.6	36.1
Emotional Functioning, C16D1 (n=333,n=312)	31.8	35.9
Emotional Functioning, C20D1 (n=252,n=234)	35.3	36.8
Emotional Func., CoT/ETV (n=368,n=367)	27.7	28.6
Emotional Func., PT FU 3 Months (n=234,n=236)	29.1	27.5
Emotional Func., PT FU 6 Months (n=148,n=164)	30.4	37.8
Emotional Func., PT FU 9 Months (n=84,n=98)	38.1	33.7
Emotional Func., PT FU 12 Months (n=45,n=58)	44.4	34.5
Emotional Func., PT FU 18 Months (n=14,n=16)	42.9	31.3
Emotional Func., PT FU 24 Months (n=2,n=6)	50.0	16.7

GHS/OoL, C3D1 (n=455,n=443)	32.3	34.5		
GHS/OoL, C5D1 (n=439,n=422)	33.0	31.0		
GHS/OoL, C8D1 (n=413,n=403)	39.5	38.7		
GHS/OoL, C12D1 (n=376,n=357)	41.5	43.4		
GHS/OoL, C16D1 (n=333,n=312)	42.9	42.9		
GHS/OoL, C20D1 (n=252,n=234)	42.5	46.2		
GHS/OoL,CoT/ETV (n=368,n=367)	38.0	34.9		
GHS/OoL, PT FU 3 Months (n=234,n=236)	40.6	38.6		
GHS/OoL, PT FU 6 Months (n=148,n=164)	39.2	34.1		
GHS/OoL, PT FU 9 Months (n=84,n=98)	39.3	35.7		
GHS/OoL, PT FU 12 Months (n=45,n=58)	40.0	32.8		
GHS/OoL, PT FU 18 Months (n=14,n=16)	42.9	18.8		
GHS/OoL, PT FU 24 Months (n=2,n=6)	100	33.3		

Statistical analyses

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6651
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.25

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9927
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.34

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8209
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.39

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6507
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.45

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2596
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.67

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6532
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.58

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Emotional functioning, Completion Of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7592
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.45

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7424
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.4

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1912
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.37

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	2.19

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5526
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.53

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3609
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1.52

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7527
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	3.23

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	-33.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-100
upper limit	75.44

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3177
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.85

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.17

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4184
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.21

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3973
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.19

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description: Physical functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.571
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.24

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description: Physical functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5163
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.55

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description: Physical functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6897
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.35

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Completion Of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5735
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.25

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8655
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.55

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1414
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.1

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3017
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.35

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2325
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	1.39

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1717
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	1.69

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	16.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.49
upper limit	79.82

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4745
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.46

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5499
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.22

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8436
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.29

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5798
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.46

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9094
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.39

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Global health status/QoL, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.67

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4024
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.19

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8796
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.41

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.435
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.32

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6225
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	1.56

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5775
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	1.77

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2343
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.07
upper limit	1.94

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0833
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	-66.67

Confidence interval	
level	95 %
sides	2-sided
lower limit	-100
upper limit	4.39

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6012
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.21

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2291
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.11

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Role functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6574
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.24

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9217
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.35

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7693
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.95

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.3

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.647
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.31

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Completion Of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6391
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.25

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0892
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.05

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.055
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	1.01

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0168
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.49

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	0.88

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7817
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	3.8

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0021
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	0.65

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Odds ratio (OR)
Point estimate	-33.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-100
upper limit	75.44

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6646
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.41

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8677
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.3

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.767
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.38

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7487
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.28

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Social functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1882
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.68

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3015
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.72

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9059
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.32

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7125
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.35

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0947
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.07

Statistical analysis title	Clinically-Meaningful Improvement

Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0686
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1.05

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3376
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	2.3

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0175
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.39

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	0.86

Statistical analysis title	Clinically-Meaningful Improvement
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5637
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	-50
Confidence interval	
level	95 %
sides	2-sided
lower limit	-100
upper limit	23.34

Secondary: Percentage of Participants Who Remain Stable in Patient-Reported Function and HRQoL - Primary Tumor-Reductive Surgery Group

End point title	Percentage of Participants Who Remain Stable in Patient-Reported Function and HRQoL - Primary Tumor-Reductive Surgery Group
End point description:	

Percentage of participants who remain stable defined as changes within 10 points from the baseline score on each of the functional (physical, role, emotional, and social) and GHS/QoL scales of the EORTC QLQ-C30. Note: n=participants with data at given timepoint. C=Cycle, D=Day, ETV= Early Termination Visit, FU=Follow Up, CoT=Completion of Treatment, PT=Post Treatment.

End point type	Secondary
End point timeframe:	

From randomization to the end of treatment/discontinuation (up to approximately 66 weeks), and during follow-up period (up to approximately 55 months). Cycle length=21 days.

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	473	473		
Units: Percentage of participants				

number (not applicable)				
Physical Functioning, C3D1 (n=456, n=444)	53.1	56.1		
Physical Functioning, C5D1 (n=439, n=423)	49.0	50.1		
Physical Functioning, C8D1 (n=414, n=403)	47.8	49.4		
Physical Functioning, C12D1 (n=378, n=358)	47.1	51.1		
Physical Functioning, C16D1 (n=333, n=312)	50.5	48.7		
Physical Functioning, C20D1 (n=253, n=234)	46.6	50.9		
Physical Func., CoT/ETV (n=370, n=366)	46.8	44.5		
Physical Func., PT FU 3 Months (n=235, n=236)	41.3	47.9		
Physical Func., PT FU 6 Months (n=147, n=164)	42.2	43.9		
Physical Funct., PT FU 9 Months (n=84, n=98)	46.4	46.9		
Physical Func., PT FU 12 Months (n=45, n=58)	44.4	50.0		
Physical Func., PT FU 18 Months (n=14, n=16)	35.7	56.3		
Physical Func., PT FU 24 Months (n=2, n=6)	100	33.3		
Role Functioning, C3D1 (n=455, n=443)	35.8	30.9		
Role Functioning, C5D1 (n=438, n=422)	30.1	33.6		
Role Functioning, C8D1 (n=413, n=401)	31.2	30.9		
Role Functioning, C12D1 (n=377, n=358)	32.9	32.1		
Role Functioning, C16D1 (n=333, n=311)	27.6	33.4		
Role Functioning, C20D1 (n=253, n=233)	27.3	34.8		
Role Func., CoT/ETV (n=370, n=367)	28.6	28.6		
Role Func., PT FU 3 Months (n=235, n=236)	25.1	27.1		
Role Func., PT FU 6 Months (n=147, n=164)	24.5	29.9		
Role Func., PT FU 9 Months (n=84, n=98)	23.8	34.7		
Role Func., PT FU 12 Months (n=45, n=58)	33.3	34.5		
Role Func., PT FU 18 Months (n=14, n=16)	42.9	25.0		
Role Func., PT FU 24 Months (n=2, n=6)	50	66.7		
Social Functioning, C3D1 (n=455, n=442)	40.7	36.7		
Social Functioning, C5D1 (n=439, n=422)	37.6	36.7		
Social Functioning, C8D1 (n=413, n=403)	40.2	35.2		
Social Functioning, C12D1 (n=376, n=357)	38.3	39.2		
Social Functioning, C16D1 (n=333, n=312)	36.6	33.3		
Social Functioning, C20D1 (n=252, n=234)	34.1	33.8		

Social Func.,CoT/ETV (n=367, n=367)	31.9	31.1		
Social Func., PT FU 3 Months (n=234, n=236)	30.3	32.6		
Social Func., PT FU 6 Months (n=148, n=164)	33.8	34.8		
Social Func., PT FU 9 Months (n=84, n=98)	27.4	30.6		
Social Func., PT FU 12 Months (n=45, n=58)	28.9	25.9		
Social Func., PT FU 18 Months (n=14, n=16)	28.6	18.8		
Social Func., PT FU 24 Months (n=2, n=6)	0	16.7		
Emotional Functioning, C3D1 (n=454, n=443)	57.5	57.3		
Emotional Functioning, C5D1 (n=439, n=422)	52.4	53.6		
Emotional Functioning, C8D1 (n=412, n=403)	53.2	54.6		
Emotional Functioning, C12D1 (n=376, n=357)	53.2	50.1		
Emotional Functioning, C16D1 (n=333, n=312)	55.0	51.3		
Emotional Functioning, C20D1 (n=252, n=234)	49.2	52.1		
Emotional Func., CoT/ETV (n=368, n=367)	53.0	51.8		
Emotional Func., PT FU 3 Months (n=234, n=236)	51.3	55.5		
Emotional Func., PT FU 6 Months (n=148, n=164)	48.6	47.6		
Emotional Func., PT FU 9 Months (n=84, n=98)	53.6	48.0		
Emotional Func., PT FU 12 Months (n=45, n=58)	46.7	43.1		
Emotional Func., PT FU18 Months (n=14, n=16)	50.0	37.5		
Emotional Func., PT FU 24 Months (n=2, n=6)	50.0	16.7		
GHS/OoL, C3D1 (n=455, n=443)	43.3	42.2		
GHS/OoL, C5D1 (n=439, n=422)	42.6	44.8		
GHS/OoL, C8D1 (n=413, n=403)	39.0	42.9		
GHS/OoL, C12D1 (n=376, n=357)	40.7	42.9		
GHS/OoL, C16D1 (n=333, n=312)	38.4	43.3		
GHS/OoL, C20D1 (n=252, n=234)	36.9	42.3		
GHS/OoL, CoT/ETV (n=368, n=367)	37.2	40.3		
GHS/OoL, PT FU 3 Months (n=234, n=236)	38.9	38.6		
GHS/OoL, PT FU 6 Months (n=148, n=164)	39.9	42.1		
GHS/OoL, PT FU 9 Months (n=84, n=98)	39.3	38.8		
GHS/OoL, PT FU 12 Months (n=45, n=58)	42.2	32.8		
GHS/OoL, PT FU 18 Months (n=14, n=16)	35.7	37.5		
GHS/OoL, PT FU Up 24 Months (n=2, n=6)	0	16.7		

Statistical analyses

Statistical analysis title	Remain Stable
Statistical analysis description: Emotional Functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.977
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.3

Statistical analysis title	Remain Stable
Statistical analysis description: Emotional Functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7317
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.37

Statistical analysis title	Remain Stable
Statistical analysis description: Emotional Functioning, Cycle 8 Day 1	

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6937
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.39

Statistical analysis title	Remain Stable

Statistical analysis description:

Emotional Functioning, Cycle 12 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3916
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.18

Statistical analysis title	Remain Stable

Statistical analysis description:

Emotional Functioning, Cycle 16 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3363
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.86

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.17

Statistical analysis title	Remain Stable
Statistical analysis description:	
Emotional Functioning, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6997
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.26

Statistical analysis title	Remain Stable
Statistical analysis description:	
Emotional Functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6761
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.55

Statistical analysis title	Remain Stable

Statistical analysis description:

Emotional Functioning, Post-Treatment Follow Up 3 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3592
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.72

Statistical analysis title	Remain Stable

Statistical analysis description:

Emotional Functioning, Post-Treatment Follow Up 6 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8798
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.51

Statistical analysis title	Remain Stable

Statistical analysis description:

Emotional Functioning, Post-Treatment Follow Up 9 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3857
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.77

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.39

Statistical analysis title	Remain Stable
Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6854
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	1.85

Statistical analysis title	Remain Stable
Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4533
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	2.7

Statistical analysis title	Remain Stable

Statistical analysis description:	
Emotional Functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3173
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	-33.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-100
upper limit	75.44

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3658
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.47

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7619
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.04

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.36

Statistical analysis title	Remain Stable

Statistical analysis description:

Physical functioning, Cycle 8 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.658
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.4

Statistical analysis title	Remain Stable

Statistical analysis description:

Physical functioning, Cycle 12 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2726
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.57

Statistical analysis title	Remain Stable

Statistical analysis description:	
Physical functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6973
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.29

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.447
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.64

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.515
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.91

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.21

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2103
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.82

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7969
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.66

Statistical analysis title	Remain Stable

Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.83
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.91

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6987
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	2.55

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1441
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.32

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	17.77

Statistical analysis title	Remain Stable
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3173
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion of Responders
Point estimate	-66.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-100
upper limit	4.39

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7591
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.25

Statistical analysis title	Remain Stable

Statistical analysis description:	
Global health status/ QoL, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5403
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.42

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2654
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.55

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5138
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.48

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2138
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.67

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2114
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.82

Statistical analysis title	Remain Stable

Statistical analysis description:	
Global health status/ QoL, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3938
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.53

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7793
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.38

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.737
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.08

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.39

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9658
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	1.79

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3015
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	1.46

Statistical analysis title	Remain Stable

Statistical analysis description:	
Global health status/ QoL, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7534
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	3.94

Statistical analysis title	Remain Stable
Statistical analysis description:	
Global health status/ QoL, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5637
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	16.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.49
upper limit	79.82

Statistical analysis title	Remain Stable
Statistical analysis description:	
Role functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1177
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.06

Statistical analysis title	Remain Stable
Statistical analysis description:	
Role functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.273
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.56

Statistical analysis title	Remain Stable
Statistical analysis description:	
Role functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9306
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.33

Statistical analysis title	Remain Stable

Statistical analysis description:	
Role functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8631
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.32

Statistical analysis title	Remain Stable
Statistical analysis description:	
Role functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0977
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.86

Statistical analysis title	Remain Stable
Statistical analysis description:	
Role functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0726
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.43

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	2.1

Statistical analysis title	Remain Stable

Statistical analysis description:

Role functioning, Completion of Treatment/ Early Termination Visit

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9974
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.38

Statistical analysis title	Remain Stable

Statistical analysis description:

Role functioning, Post-Treatment Follow Up 3 Months

Comparison groups	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab v Placebo With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7069
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.63

Statistical analysis title	Remain Stable

Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3068
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	2.16

Statistical analysis title	Remain Stable
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1375
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	3.16

Statistical analysis title	Remain Stable
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.954
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	2.29

Statistical analysis title	Remain Stable

Statistical analysis description:

Role functioning, Post-Treatment Follow Up 18 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4283
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	2.64

Statistical analysis title	Remain Stable

Statistical analysis description:

Role functioning, Post-Treatment Follow Up 24 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	16.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-95.56
upper limit	100

Statistical analysis title	Remain Stable

Statistical analysis description:

Social Functioning, Cycle 3 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2153
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.1

Statistical analysis title	Remain Stable
Statistical analysis description: Social Functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7878
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.27

Statistical analysis title	Remain Stable
Statistical analysis description: Social Functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1544
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.08

Statistical analysis title	Remain Stable
Statistical analysis description:	
Social Functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8017
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.4

Statistical analysis title	Remain Stable
Statistical analysis description:	
Social Functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4295
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.21

Statistical analysis title	Remain Stable

Statistical analysis description:	
Social Functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.954
Method	Cochran-Mantel-Haenszel
Parameter estimate	Log odds ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.44

Statistical analysis title	Remain Stable
Statistical analysis description:	
Social Functioning, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7494
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.3

Statistical analysis title	Remain Stable
Statistical analysis description:	
Social Functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6412
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.62

Statistical analysis title	Remain Stable
Statistical analysis description:	
Social Functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8652
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.67

Statistical analysis title	Remain Stable
Statistical analysis description:	
Social Functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6912
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	2.18

Statistical analysis title	Remain Stable

Statistical analysis description:	
Social Functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5834
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	1.86

Statistical analysis title	Remain Stable
Statistical analysis description:	
Social Functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9578
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	16.05

Statistical analysis title	Remain Stable
Statistical analysis description:	
Social Functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5637
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	16.67

Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.49
upper limit	79.82

Secondary: Percentage of Participants With Deterioration in Patient-Reported Function and HRQoL - Primary Tumor-Reductive Surgery Group

End point title	Percentage of Participants With Deterioration in Patient-Reported Function and HRQoL - Primary Tumor-Reductive Surgery Group

End point description:

Percentage of participants with deterioration in patient-reported function and HRQoL, defined as >= 10 points decrease from the baseline score on each of the functional (physical, role, emotional, and social) and GHS/QoL scales of the EORTC QLQ-C30. Note: n=participants with data at given timepoint. C=Cycle, D=Day, ETV= Early Termination Visit, FU=Follow Up, CoT=Completion of Treatment, PT=Post Treatment.

End point type	Secondary

End point timeframe:

From randomization to the end of treatment/discontinuation (up to approximately 66 weeks), and during follow-up period (up to approximately 60 months). Cycle length=21 days.

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	473	473		
Units: Percentage of participants				
number (not applicable)				
Physical Functioning, C3D1 (n=456, n=444)	24.1	24.1		
Physical Functioning, C5D1 (n=439, n=423)	27.1	28.6		
Physical Functioning, C8D1 (n=414, n=403)	23.4	23.6		
Physical Functioning, C12D1 (n=378, n=358)	17.2	16.5		
Physical Functioning, C16D1 (n=333, n=312)	17.1	17.0		
Physical Functioning, C20D1 (n=253, n=234)	18.2	16.7		
Physical Func.,CoT/ETV (n=370, n=366)	20.5	25.1		
Physical Func., PT FU 3 Months (n=235, n=236)	22.6	23.7		
Physical Func., PT FU 6 Months (n=147, n=164)	24.5	25.0		
Physical Func., PT FU 9 Months (n=84, n=98)	19.0	25.5		
Physical Func., PT FU 12 Months (n=45, n=58)	17.8	25.9		

Physical Func., PT FU 18 Months (n=14, n=16)	21.4	25.0
Physical Func., PT FU 24 Months (n=2, n=6)	0	50
Role Functioning, C3D1 (n=455, n=443)	21.3	27.8
Role Functioning, C5D1 (n=438, n=422)	26.7	27.0
Role Functioning, C8D1 (n=413, n=401)	21.1	22.7
Role Functioning, C12D1 (n=377, n=358)	16.7	16.8
Role Functioning, C16D1 (n=333, n=311)	20.1	15.8
Role Functioning, C20D1 (n=253, n=233)	18.6	13.3
Role Func., CoT/ETV (n=370, n=367)	23.0	24.3
Role Func., PT FU 3 Months (n=235, n=236)	20.9	27.1
Role Func., PT FU 6 Months (n=147, n=164)	20.4	25.6
Role Func., PT FU 9 Months (n=84, n=98)	19.0	26.5
Role Func., PT FU 12 Months (n=45, n=58)	6.7	37.9
Role Func., PT FU 18 Months (n=14, n=16)	7.1	31.3
Role Func., PT FU 24 Months (n=2, n=6)	0	16.7
Social Functioning, C3D1 (n=455, n=442)	29.0	31.2
Social Functioning, C5D1 (n=439, n=422)	29.6	30.6
Social Functioning, C8D1 (n=413, n=403)	21.8	25.8
Social Functioning, C12D1 (n=376, n=357)	18.9	19.0
Social Functioning, C16D1 (n=333, n=312)	19.5	17.6
Social Functioning, C20D1 (n=252, n=234)	20.2	16.2
Social Func., CoT/ETV (n=367, n=367)	27.2	28.1
Social Func., PT FU 3 Months (n=234, n=236)	26.5	25.4
Social Func., PT FU 6 Months (n=148, n=164)	23.0	30.5
Social Func., PT FU 9 Months (n=84, n=98)	22.6	32.7
Social Func., PT FU 12 Months (n=45, n=58)	8.9	37.9
Social Func., PT FU 18 Months (n=14, n=16)	14.3	37.5
Social Func., PT FU 24 Months (n=2, n=6)	0	33.3
Emotional Functioning, C3D1 (n=454, n=443)	12.8	14.0
Emotional Functioning, C5D1 (n=439, n=422)	17.3	15.9
Emotional Functioning, C8D1 (n=412, n=403)	14.6	12.4
Emotional Functioning, C12D1 (n=376, n=357)	12.2	13.4
Emotional Functioning, C16D1 (n=333, n=312)	13.2	12.5

Emotional Functioning, C20D1 (n=252, n=234)	15.5	11.1		
Emotional Func., CoT/ETV (n=368, n=367)	19.3	19.3		
Emotional Func., PT FU 3 Months (n=234, n=236)	19.7	16.9		
Emotional Func., PT FU 6 Months (n=148, n=164)	20.9	14.6		
Emotional Func., PT FU 9 Months (n=84, n=98)	8.3	18.4		
Emotional Func., PT FU 12 Months (n=45, n=58)	8.9	22.4		
Emotional Func., PT FU 18 Months (n=14, n=16)	7.1	31.3		
Emotional Func., PT FU 24 Months (n=2, n=6)	0	66.7		
GHS/OoL Function, C3D1 (n=455, n=443)	24.2	22.8		
GHS/OoL Function, C5D1 (n=439, n=422)	24.1	23.7		
GHS/OoL Function, C8D1 (n=413, n=403)	21.3	18.1		
GHS/OoL Function, C12D1 (n=376, n=357)	17.6	13.2		
GHS/OoL Function, C16D1 (n=333, n=312)	18.3	13.5		
GHS/OoL Function, C20D1 (n=252, n=234)	20.2	11.1		
GHS/OoL Func., CoT/ETV (n=368, n=367)	24.5	24.3		
GHS/OoL Func., PT FU 3 Months (n=234, n=236)	20.5	22.9		
GHS/OoL Func., PT FU 6 Months (n=148, n=164)	20.9	23.8		
GHS/OoL Func., PT FU 9 Months (n=84, n=98)	21.4	25.5		
GHS/OoL Func., PT FU 12 Months (n=45, n=58)	17.8	34.5		
GHS/OoL Func., PT FU 18 Months (n=14, n=16)	21.4	43.8		
GHS/OoL Func., PT FU 24 Months (n=2, n=6)	0	50.0		

Statistical analyses

Statistical analysis title	Deterioration
Statistical analysis description: Emotional functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6063
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.63

Statistical analysis title	Deterioration
Statistical analysis description:	
Emotional functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5739
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.29

Statistical analysis title	Deterioration
Statistical analysis description:	
Emotional functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3792
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.25

Statistical analysis title	Deterioration

Statistical analysis description:	
Emotional functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6022
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.73

Statistical analysis title	Deterioration
Statistical analysis description:	
Emotional functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7893
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.49

Statistical analysis title	Deterioration
Statistical analysis description:	
Emotional functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2125
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.71

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	1.22

Statistical analysis title	Deterioration

Statistical analysis description:

Emotional functioning, Completion of Treatment/ Early Termination Visit

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9661
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.46

Statistical analysis title	Deterioration

Statistical analysis description:

Emotional functioning, Post-Treatment Follow Up 3 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4299
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.32

Statistical analysis title	Deterioration

Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0363
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	6.76

Statistical analysis title	Deterioration
Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1542
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	1.18

Statistical analysis title	Deterioration
Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0814
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.75

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	8.93

Statistical analysis title	Deterioration
Statistical analysis description:	
Emotional functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1915
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	4.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	38

Statistical analysis title	Deterioration
Statistical analysis description:	
Physical functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9818
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.35

Statistical analysis title	Deterioration

Statistical analysis description:

Emotional functioning, Post-Treatment Follow Up 24 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3173
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	66.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.39
upper limit	100

Statistical analysis title	Deterioration

Statistical analysis description:

Physical functioning, Cycle 5 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6263
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.45

Statistical analysis title	Deterioration

Statistical analysis description:

Physical functioning, Cycle 8 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9407
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.4

Statistical analysis title	Deterioration

Statistical analysis description:

Physical functioning, Cycle 12 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.77
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.39

Statistical analysis title	Deterioration

Statistical analysis description:

Physical functioning, Cycle 16 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8458
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.45

Statistical analysis title	Deterioration

Statistical analysis description:

Physical functioning, Cycle 20 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7028
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	1.46

Statistical analysis title	Deterioration

Statistical analysis description:

Physical functioning, Completion of Treatment/ Early Termination Visit

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1391
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.83

Statistical analysis title	Deterioration

Statistical analysis description:

Physical functioning, Post-Treatment Follow Up 3 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.62

Statistical analysis title	Deterioration
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9751
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.68

Statistical analysis title	Deterioration
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3811
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	2.78

Statistical analysis title	Deterioration

Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.395
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	3.9

Statistical analysis title	Deterioration
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8993
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	5.12

Statistical analysis title	Deterioration
Statistical analysis description:	
Physical functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3173
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	50

Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.34
upper limit	100

Statistical analysis title	Deterioration
Statistical analysis description:	
Global health status/QoL, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5988
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.25

Statistical analysis title	Deterioration
Statistical analysis description:	
Global health status/QoL, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8859
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.34

Statistical analysis title	Deterioration

Statistical analysis description:	
Global health status/QoL, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2531
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.16

Statistical analysis title	Deterioration
Statistical analysis description:	
Global health status/QoL, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0785
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.04

Statistical analysis title	Deterioration
Statistical analysis description:	
Global health status/QoL, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0641
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.67

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.03

Statistical analysis title	Deterioration
Statistical analysis description:	
Global health status/QoL, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0046
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	0.8

Statistical analysis title	Deterioration
Statistical analysis description:	
Global health status/QoL, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8928
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.37

Statistical analysis title	Deterioration

Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6106
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.74

Statistical analysis title	Deterioration
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6159
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.95

Statistical analysis title	Deterioration
Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0845
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.22

Confidence interval

level	95 %
sides	2-sided
lower limit	0.89
upper limit	5.58

Statistical analysis title	Deterioration

Statistical analysis description:

Global health status/QoL, Post-Treatment Follow Up 9 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5372
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.24
Confidence interval	

level	95 %
sides	2-sided
lower limit	0.62
upper limit	2.49

Statistical analysis title	Deterioration

Statistical analysis description:

Global health status/QoL, Post-Treatment Follow Up 18 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1344
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.67
Confidence interval	

level	95 %
sides	2-sided
lower limit	0.62
upper limit	21.56

Statistical analysis title	Deterioration

Statistical analysis description:	
Global health status/QoL, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3173
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Proportion of Responders
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.34
upper limit	100

Statistical analysis title	Deterioration
Statistical analysis description:	
Role functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9179
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.37

Statistical analysis title	Deterioration
Statistical analysis description:	
Role functioning, Cycle 3 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.026
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.41

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	1.92

Statistical analysis title	Deterioration
Statistical analysis description:	
Role functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.582
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.53

Statistical analysis title	Deterioration
Statistical analysis description:	
Role functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9772
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.47

Statistical analysis title	Deterioration

Statistical analysis description:	
Role functioning, Cycle 16 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.13
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.1

Statistical analysis title	Deterioration
Statistical analysis description:	
Role functioning, Cycle 20 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.099
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	1.08

Statistical analysis title	Deterioration
Statistical analysis description:	
Role functioning, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7133
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.5

Statistical analysis title	Deterioration

Statistical analysis description:

Role functioning, Post-Treatment Follow Up 3 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1384
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	2.11

Statistical analysis title	Deterioration

Statistical analysis description:

Role functioning, Post-Treatment Follow Up 6 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2895
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	2.26

Statistical analysis title	Deterioration

Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2221
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	3.14

Statistical analysis title	Deterioration
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0005
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	7.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.08
upper limit	26.1

Statistical analysis title	Deterioration
Statistical analysis description:	
Role functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	16.67

Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.49
upper limit	79.82

Statistical analysis title	Deterioration

Statistical analysis description:

Role functioning, Post-Treatment Follow Up 18 Months

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2171
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	34.56

Statistical analysis title	Deterioration

Statistical analysis description:

Social functioning, Cycle 3 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4647
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.48

Statistical analysis title	Deterioration

Statistical analysis description:	
Social functioning, Cycle 5 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7676
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.4

Statistical analysis title	Deterioration
Statistical analysis description:	
Social functioning, Cycle 8 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1983
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.71

Statistical analysis title	Deterioration
Statistical analysis description:	
Social functioning, Cycle 12 Day 1	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9874
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.44

Statistical analysis title	Deterioration

Statistical analysis description:

Social functioning, Cycle 16 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4716
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.29

Statistical analysis title	Deterioration

Statistical analysis description:

Social functioning, Cycle 20 Day 1

Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2041
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.18

Statistical analysis title	Deterioration

Statistical analysis description:	
Social functioning, Completion of Treatment/ Early Termination Visit	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7771
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.45

Statistical analysis title	Deterioration
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 3 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8542
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.45

Statistical analysis title	Deterioration
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 6 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.123
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	2.5

Statistical analysis title	Deterioration
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 9 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1089
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	3.34

Statistical analysis title	Deterioration
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 12 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0011
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	5.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.85
upper limit	18.3

Statistical analysis title	Deterioration

Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 18 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.295
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	14.74

Statistical analysis title	Deterioration
Statistical analysis description:	
Social functioning, Post-Treatment Follow Up 24 Months	
Comparison groups	Placebo With Paclitaxel, Carboplatin and Bevacizumab v Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Proportion of Responders
Point estimate	33.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.72
upper limit	100

Secondary: Percentage of Participants With at Least One Adverse Event

End point title	Percentage of Participants With at Least One Adverse Event
End point description:	
Percentage of participants with at least one adverse event	
End point type	Secondary
End point timeframe:	
From randomization up to approximately 59 months	

End point values	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	644	642		
Units: Percentage				
number (not applicable)	99.8	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Serum Concentration (Cmax) of Atezolizumab

End point title	Maximum Serum Concentration (Cmax) of Atezolizumab[4]
End point description:	

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 post dose and Cycle 3 Day 1 post dose

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No statistical analysis for this endpoint.

End point values	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab			
Subject group type	Reporting group			
Number of subjects analysed	538			
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	487 (± 163)			
Cycle 3 Day 1	614 (± 209)			

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Serum Concentration (Cmin) of Atezolizumab

End point title	Minimum Serum Concentration (Cmin) of Atezolizumab[5]
End point description:	

End point type	Secondary

End point timeframe:

Cycle 2 Day 1 predose, Cycle 3 Day 1 Predose, Cycle 4 Day 1 predose, Cycle 8 Day 1 predose, Cycle 16

Day 1 predose

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No statistical analysis for this endpoint.

End point values	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab			
Subject group type	Reporting group			
Number of subjects analysed	532			
Units: μg/mL				
arithmetic mean (standard deviation)				
Cycle 2 Day 1	88.9 (± 35.8)			
Cycle 3 Day 1	146 (± 93.0)			
Cycle 4 Day 1	149 (± 88.1)			
Cycle 8 Day 1	242 (± 96.3)			
Cycle 16 Day 1	286 (± 111)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Anti-Drug Antibodies (ADAs) to Atezolizumab

End point title	Percentage of Participants With Anti-Drug Antibodies (ADAs) to Atezolizumab[6]

End point description:

End point type	Secondary

End point timeframe:

Baseline to approximately 55 months

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No statistical analysis for this endpoint.

End point values	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab			
Subject group type	Reporting group			
Number of subjects analysed	569			
Units: Percentage of participants				
number (not applicable)				
Baseline evaluable participants	0.7			
Post-baseline evaluable participants	22.7			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first study drug to the data cutoff date: 12 August 2022 (up to 65 months)

Adverse event reporting additional description:

Adverse events reported based on safety population, which included participants who received any amount of any study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Placebo With Paclitaxel, Carboplatin and Bevacizumab

Reporting group description:

Participants in the primary tumor-reductive surgery group received paclitaxel, carboplatin, atezolizumab placebo IV infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab placebo for a total of 22 cycles of atezolizumab placebo and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group received paclitaxel, carboplatin and placebo for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants started maintenance therapy of bevacizumab and placebo for additional 16 cycles.

Reporting group title	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab

Reporting group description:

Participants in the primary tumor-reductive surgery group received paclitaxel, carboplatin, atezolizumab placebo IV infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab placebo for a total of 22 cycles of atezolizumab placebo and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group received paclitaxel, carboplatin and placebo for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants started maintenance therapy of bevacizumab and placebo for additional 16 cycles.

Serious adverse events	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	215 / 644 (33.39%)	304 / 642 (47.35%)	
number of deaths (all causes)	301	280	
number of deaths resulting from adverse events	4	4	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
PAPILLARY THYROID CANCER			
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INVASIVE DUCTAL BREAST CARCINOMA			

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
GASTROINTESTINAL STROMAL TUMOUR		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ANAPLASTIC ASTROCYTOMA		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular disorders		
AORTIC DISSECTION		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
CIRCULATORY COLLAPSE		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
DEEP VEIN THROMBOSIS		
subjects affected / exposed	2 / 644 (0.31%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
EMBOLISM		
subjects affected / exposed	3 / 644 (0.47%)	3 / 642 (0.47%)
occurrences causally related to treatment / all	2 / 3	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
EMBOLISM VENOUS		
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
HAEMORRHAGE		

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HYPERTENSION		
subjects affected / exposed	4 / 644 (0.62%)	5 / 642 (0.78%)
occurrences causally related to treatment / all	2 / 4	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
HYPERTENSIVE URGENCY		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HYPOTENSION		
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
LYMPHOCELE		
subjects affected / exposed	2 / 644 (0.31%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
LYMPHORRHOEA		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ORTHOSTATIC HYPOTENSION		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SHOCK HAEMORRHAGIC		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
General disorders and administration site conditions		
ASTHENIA		

subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
CONDITION AGGRAVATED		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
DEATH		
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 2
DEVICE RELATED THROMBOSIS		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
EARLY SATIETY		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
FATIGUE		
subjects affected / exposed	2 / 644 (0.31%)	4 / 642 (0.62%)
occurrences causally related to treatment / all	2 / 2	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION		
subjects affected / exposed	0 / 644 (0.00%)	3 / 642 (0.47%)
occurrences causally related to treatment / all	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
MUCOSAL INFLAMMATION		
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME		

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
NON-CARDIAC CHEST PAIN		
subjects affected / exposed	2 / 644 (0.31%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
PYREXIA		
subjects affected / exposed	8 / 644 (1.24%)	26 / 642 (4.05%)
occurrences causally related to treatment / all	5 / 9	17 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
PAIN		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Immune system disorders		
ANAPHYLACTIC SHOCK		
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
ANAPHYLACTIC REACTION		
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
CONTRAST MEDIA ALLERGY		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
DRUG HYPERSENSITIVITY		

subjects affected / exposed	3 / 644 (0.47%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	2 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
CYTOKINE RELEASE SYNDROME		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HYPERSENSITIVITY		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
SYSTEMIC IMMUNE ACTIVATION		
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
IMMUNE-MEDIATED ADVERSE REACTION		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SARCOIDOSIS		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reproductive system and breast disorders		
FEMALE GENITAL TRACT FISTULA		
subjects affected / exposed	2 / 644 (0.31%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
VAGINAL FISTULA		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
HEAVY MENSTRUAL BLEEDING		

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory, thoracic and mediastinal disorders

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

ASPIRATION

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

ACUTE RESPIRATORY DISTRESS SYNDROME

subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	

DYSPNOEA

subjects affected / exposed	2 / 644 (0.31%)	3 / 642 (0.47%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

EPISTAXIS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

HYPERVENTILATION

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

HYPOXIA

subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

LOWER RESPIRATORY TRACT CONGESTION				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PLEURAL EFFUSION				
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
PNEUMONITIS				
subjects affected / exposed	2 / 644 (0.31%)	5 / 642 (0.78%)		
occurrences causally related to treatment / all	2 / 2	5 / 6		
deaths causally related to treatment / all	0 / 0	0 / 0		
PULMONARY EMBOLISM				
subjects affected / exposed	6 / 644 (0.93%)	10 / 642 (1.56%)		
occurrences causally related to treatment / all	3 / 6	7 / 10		
deaths causally related to treatment / all	0 / 0	0 / 1		
PULMONARY HAEMORRHAGE				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Psychiatric disorders				
DELIRIUM				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
SUICIDAL IDEATION				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
DEPRESSION				
subjects affected / exposed	2 / 644 (0.31%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 3	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		

Investigations				
BLOOD POTASSIUM DECREASED				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
BLOOD CREATININE INCREASED				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ASPARTATE AMINOTRANSFERASE INCREASED				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ALANINE AMINOTRANSFERASE INCREASED				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
LYMPHOCYTE COUNT DECREASED				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
LIPASE INCREASED				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
INTERNATIONAL NORMALISED RATIO INCREASED				
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	1 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
HEPATIC ENZYME INCREASED				

subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

C-REACTIVE PROTEIN INCREASED

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

NEUTROPHIL COUNT DECREASED

subjects affected / exposed	7 / 644 (1.09%)	3 / 642 (0.47%)
occurrences causally related to treatment / all	7 / 7	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

PLATELET COUNT DECREASED

subjects affected / exposed	10 / 644 (1.55%)	6 / 642 (0.93%)
occurrences causally related to treatment / all	10 / 13	9 / 9
deaths causally related to treatment / all	0 / 0	0 / 0

WHITE BLOOD CELL COUNT DECREASED

subjects affected / exposed	2 / 644 (0.31%)	3 / 642 (0.47%)
occurrences causally related to treatment / all	2 / 3	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

Injury, poisoning and procedural complications

FASCIAL RUPTURE

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

FALL

subjects affected / exposed	1 / 644 (0.16%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

CONCUSSION

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

ANKLE FRACTURE

subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOT FRACTURE			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FRACTURE			
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FRACTURED SACRUM			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL ANASTOMOTIC LEAK			
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL INJURY			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIP FRACTURE			
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCISION SITE IMPAIRED HEALING			
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCISIONAL HERNIA			

	subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)		
	occurrences causally related to treatment / all	0 / 2	0 / 0		
	deaths causally related to treatment / all	0 / 0	0 / 0		
INFUSION RELATED REACTION					
	subjects affected / exposed	2 / 644 (0.31%)	5 / 642 (0.78%)		
	occurrences causally related to treatment / all	2 / 2	5 / 5		
	deaths causally related to treatment / all	0 / 0	0 / 0		
PERIPROSTHETIC FRACTURE					
	subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
	occurrences causally related to treatment / all	0 / 0	1 / 1		
	deaths causally related to treatment / all	0 / 0	0 / 0		
POST PROCEDURAL HAEMORRHAGE					
	subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)		
	occurrences causally related to treatment / all	0 / 1	0 / 1		
	deaths causally related to treatment / all	0 / 0	0 / 0		
PROCEDURAL INTESTINAL PERFORATION					
	subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
	occurrences causally related to treatment / all	0 / 0	1 / 1		
	deaths causally related to treatment / all	0 / 0	0 / 0		
SPINAL COMPRESSION FRACTURE					
	subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)		
	occurrences causally related to treatment / all	0 / 1	0 / 1		
	deaths causally related to treatment / all	0 / 0	0 / 0		
WOUND COMPLICATION					
	subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)		
	occurrences causally related to treatment / all	0 / 3	0 / 0		
	deaths causally related to treatment / all	0 / 0	0 / 0		
VAGINAL CUFF DEHISCENCE					
	subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
	occurrences causally related to treatment / all	0 / 0	1 / 1		
	deaths causally related to treatment / all	0 / 0	0 / 0		
WOUND DEHISCENCE					

subjects affected / exposed	3 / 644 (0.47%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	1 / 5	2 / 2		
deaths causally related to treatment / all	0 / 1	0 / 0		
STOMA PROLAPSE				
subjects affected / exposed	2 / 644 (0.31%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		

Cardiac disorders

ACUTE MYOCARDIAL INFARCTION				
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	0 / 0	1 / 2		
deaths causally related to treatment / all	0 / 0	0 / 1		
ANGINA UNSTABLE				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ARRHYTHMIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ATRIAL FIBRILLATION				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ATRIAL TACHYCARDIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ATRIAL THROMBOSIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ATRIOVENTRICULAR BLOCK				

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
CARDIAC ARREST				
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
CARDIAC FAILURE CONGESTIVE				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
CARDIAC FAILURE				
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 1	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
CARDIOMYOPATHY				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
MYOCARDIAL INFARCTION				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
CARDIOVASCULAR DISORDER				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
MYOCARDIAL ISCHAEMIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PALPITATIONS				

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

MYOCARDITIS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Nervous system disorders

APHASIA

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

CEREBROVASCULAR ACCIDENT

subjects affected / exposed	3 / 644 (0.47%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	2 / 3	3 / 3
deaths causally related to treatment / all	1 / 2	0 / 0

CEREBRAL INFARCTION

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

CEREBELLAR INFARCTION

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

ATAXIA

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

COGNITIVE DISORDER

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

DIZZINESS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

DEPRESSED LEVEL OF CONSCIOUSNESS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

DEMENTIA

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

ENCEPHALOPATHY

subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

EPILEPSY

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

HEADACHE

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

HAEMORRHAGE INTRACRANIAL

subjects affected / exposed	1 / 644 (0.16%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	1 / 1	2 / 2
deaths causally related to treatment / all	1 / 1	0 / 0

ISCHAEMIC STROKE

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

MYASTHENIA GRAVIS

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1
NEUROPATHY PERIPHERAL		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
PERIPHERAL MOTOR NEUROPATHY		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
PRESYNCOPE		
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
SEIZURE		
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
SUBARACHNOID HAEMORRHAGE		
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK		
subjects affected / exposed	2 / 644 (0.31%)	4 / 642 (0.62%)
occurrences causally related to treatment / all	2 / 2	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
SYNCOPE		
subjects affected / exposed	2 / 644 (0.31%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Blood and lymphatic system disorders		
ANAEMIA		

subjects affected / exposed	10 / 644 (1.55%)	6 / 642 (0.93%)		
occurrences causally related to treatment / all	9 / 10	7 / 7		
deaths causally related to treatment / all	0 / 0	0 / 0		
AGRANULOCYTOSIS				
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	2 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
FEBRILE NEUTROPENIA				
subjects affected / exposed	24 / 644 (3.73%)	54 / 642 (8.41%)		
occurrences causally related to treatment / all	25 / 25	58 / 59		
deaths causally related to treatment / all	0 / 0	0 / 0		
GRANULOCYTOSIS				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
LEUKOPENIA				
subjects affected / exposed	2 / 644 (0.31%)	3 / 642 (0.47%)		
occurrences causally related to treatment / all	2 / 2	3 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
IMMUNE THROMBOCYTOPENIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
NEUTROPENIA				
subjects affected / exposed	5 / 644 (0.78%)	5 / 642 (0.78%)		
occurrences causally related to treatment / all	4 / 5	5 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
PANCYTOPENIA				
subjects affected / exposed	2 / 644 (0.31%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	2 / 2	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
THROMBOCYTOPENIA				

subjects affected / exposed	10 / 644 (1.55%)	8 / 642 (1.25%)		
occurrences causally related to treatment / all	11 / 12	11 / 11		
deaths causally related to treatment / all	0 / 0	0 / 0		
THROMBOTIC MICROANGIOPATHY				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
MYELOSUPPRESSION				
subjects affected / exposed	2 / 644 (0.31%)	3 / 642 (0.47%)		
occurrences causally related to treatment / all	2 / 2	5 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
Ear and labyrinth disorders				
OTOLITHIASIS				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
VERTIGO				
subjects affected / exposed	3 / 644 (0.47%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	2 / 3	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Eye disorders				
OCULAR MYASTHENIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
OPTIC NEUROPATHY				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
RETINAL VEIN OCCLUSION				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ULCERATIVE KERATITIS				

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		

Gastrointestinal disorders

ABDOMINAL ADHESIONS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		

ABDOMINAL PAIN

subjects affected / exposed	2 / 644 (0.31%)	9 / 642 (1.40%)		
occurrences causally related to treatment / all	0 / 2	3 / 9		
deaths causally related to treatment / all	0 / 0	0 / 0		

ABDOMINAL HERNIA

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		

ABDOMINAL DISTENSION

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		

ANAL HAEMORRHAGE

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		

ANAL FISTULA

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		

ABDOMINAL PAIN UPPER

subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		

ABDOMINAL PAIN LOWER

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

COLITIS

subjects affected / exposed	6 / 644 (0.93%)	11 / 642 (1.71%)
occurrences causally related to treatment / all	5 / 6	11 / 12
deaths causally related to treatment / all	0 / 0	0 / 0

CONSTIPATION

subjects affected / exposed	5 / 644 (0.78%)	4 / 642 (0.62%)
occurrences causally related to treatment / all	2 / 5	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0

DIARRHOEA

subjects affected / exposed	11 / 644 (1.71%)	9 / 642 (1.40%)
occurrences causally related to treatment / all	8 / 13	7 / 11
deaths causally related to treatment / all	0 / 0	0 / 0

DIARRHOEA HAEMORRHAGIC

subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

ASCITES

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

DIVERTICULUM

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

DIVERTICULAR PERFORATION

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

DUODENAL PERFORATION

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

DYSPEPSIA

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

DYSPHAGIA

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

ENTERITIS

subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

ENTEROCOLITIS

subjects affected / exposed	4 / 644 (0.62%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	3 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

GASTRIC STENOSIS

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0

ENTEROCUTANEOUS FISTULA

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

GASTRITIS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

GASTROINTESTINAL PERFORATION

subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

GASTROINTESTINAL HAEMORRHAGE

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

GINGIVAL PAIN

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

ILEAL PERFORATION

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

HAEMORRHOIDAL HAEMORRHAGE

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

ILEUS

subjects affected / exposed	8 / 644 (1.24%)	12 / 642 (1.87%)
occurrences causally related to treatment / all	3 / 10	3 / 14
deaths causally related to treatment / all	0 / 0	0 / 0

INCARCERATED INGUINAL HERNIA

subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

ILEUS PARALYTIC

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

INCARCERATED UMBILICAL HERNIA

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
INTESTINAL OBSTRUCTION				
subjects affected / exposed	7 / 644 (1.09%)	8 / 642 (1.25%)		
occurrences causally related to treatment / all	1 / 9	2 / 8		
deaths causally related to treatment / all	0 / 0	0 / 0		
INTESTINAL PERFORATION				
subjects affected / exposed	3 / 644 (0.47%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	3 / 3	2 / 2		
deaths causally related to treatment / all	0 / 0	1 / 1		
LARGE INTESTINAL HAEMORRHAGE				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
LARGE INTESTINAL OBSTRUCTION				
subjects affected / exposed	2 / 644 (0.31%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
LARGE INTESTINE PERFORATION				
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	0 / 0	2 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
LOWER GASTROINTESTINAL HAEMORRHAGE				
subjects affected / exposed	1 / 644 (0.16%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	1 / 1	2 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
MECHANICAL ILEUS				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
NAUSEA				

subjects affected / exposed	5 / 644 (0.78%)	5 / 642 (0.78%)		
occurrences causally related to treatment / all	5 / 5	4 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
OBSTRUCTION GASTRIC				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ORAL LICHEN PLANUS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
OESOPHAGITIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PANCREATIC FISTULA				
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
RECTAL HAEMORRHAGE				
subjects affected / exposed	1 / 644 (0.16%)	3 / 642 (0.47%)		
occurrences causally related to treatment / all	0 / 1	2 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
PNEUMATOSIS INTESTINALIS				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
PERITONEAL ADHESIONS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PANCREATITIS				

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
SMALL INTESTINAL OBSTRUCTION				
subjects affected / exposed	6 / 644 (0.93%)	10 / 642 (1.56%)		
occurrences causally related to treatment / all	1 / 6	3 / 11		
deaths causally related to treatment / all	0 / 0	0 / 0		
SMALL INTESTINAL PERFORATION				
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	0 / 0	1 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
SUBILEUS				
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
THROMBOSIS MESENTERIC VESSEL				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
UMBILICAL HERNIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
VOMITING				
subjects affected / exposed	7 / 644 (1.09%)	4 / 642 (0.62%)		
occurrences causally related to treatment / all	7 / 8	5 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
Hepatobiliary disorders				
CHOLESTASIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
DRUG-INDUCED LIVER INJURY				

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
JAUNDICE			
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMMUNE-MEDIATED HEPATITIS			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC FUNCTION ABNORMAL			
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATOTOXICITY			
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER INJURY			
subjects affected / exposed	1 / 644 (0.16%)	4 / 642 (0.62%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC FAILURE			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
ECZEMA			

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

DRUG ERUPTION

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

ERYTHEMA MULTIFORME

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

SKIN ULCER

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

RASH MACULO-PAPULAR

subjects affected / exposed	0 / 644 (0.00%)	3 / 642 (0.47%)
occurrences causally related to treatment / all	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

RASH

subjects affected / exposed	0 / 644 (0.00%)	7 / 642 (1.09%)
occurrences causally related to treatment / all	0 / 0	5 / 7
deaths causally related to treatment / all	0 / 0	0 / 0

LICHEN PLANUS

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

URTICARIA

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

TOXIC SKIN ERUPTION

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

STEVENS-JOHNSON SYNDROME

subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

Renal and urinary disorders

ACUTE KIDNEY INJURY

subjects affected / exposed	2 / 644 (0.31%)	3 / 642 (0.47%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

HAEMATURIA

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

HYDRONEPHROSIS

subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

IMMUNE-MEDIATED NEPHRITIS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

NEPHRITIS

subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

NEPHROPATHY

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROTEINURIA			
subjects affected / exposed	3 / 644 (0.47%)	3 / 642 (0.47%)	
occurrences causally related to treatment / all	3 / 3	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UROGENITAL FISTULA			
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GLOMERULONEPHRITIS CHRONIC			
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
ADDISON'S DISEASE			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERPARATHYROIDISM			

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
AUTOIMMUNE THYROIDITIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
HYPOTHYROIDISM				
subjects affected / exposed	1 / 644 (0.16%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	1 / 1	2 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
SECONDARY ADRENOCORTICAL INSUFFICIENCY				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Musculoskeletal and connective tissue disorders				
ARTHRALGIA				
subjects affected / exposed	2 / 644 (0.31%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	2 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
MYOSITIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
MYOPATHY				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
MYALGIA				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
FLANK PAIN				

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PAIN IN EXTREMITY				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
BACK PAIN				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
SPINAL PAIN				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Infections and infestations				
ABDOMINAL ABSCESS				
subjects affected / exposed	3 / 644 (0.47%)	5 / 642 (0.78%)		
occurrences causally related to treatment / all	0 / 3	4 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
ABDOMINAL INFECTION				
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	0 / 0	2 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
APPENDICITIS				
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
BACTERAEMIA				
subjects affected / exposed	2 / 644 (0.31%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 3	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
BRONCHITIS				

subjects affected / exposed	2 / 644 (0.31%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	2 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
BRONCHITIS VIRAL				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
CELLULITIS				
subjects affected / exposed	2 / 644 (0.31%)	3 / 642 (0.47%)		
occurrences causally related to treatment / all	1 / 2	1 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
CLOSTRIDIUM DIFFICILE INFECTION				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
CLOSTRIDIUM DIFFICILE COLITIS				
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	0 / 0	1 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
DEVICE RELATED INFECTION				
subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 1	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ENCEPHALITIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
EPSTEIN-BARR VIRUS INFECTION				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ESCHERICHIA BACTERAEMIA				

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
FOURNIER'S GANGRENE				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
GASTROENTERITIS CLOSTRIDIAL				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
GINGIVITIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
HERPES ZOSTER				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
INFECTED LYMPHOCELE				
subjects affected / exposed	1 / 644 (0.16%)	4 / 642 (0.62%)		
occurrences causally related to treatment / all	0 / 1	1 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
INFECTION				
subjects affected / exposed	1 / 644 (0.16%)	3 / 642 (0.47%)		
occurrences causally related to treatment / all	1 / 1	2 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
LYMPHANGITIS				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
KIDNEY INFECTION				

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

INFLUENZA

subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

INFECTIOUS MONONUCLEOSIS

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

PELVIC ABSCESS

subjects affected / exposed	1 / 644 (0.16%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

NASOPHARYNGITIS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

MENINGOENCEPHALITIS HERPETIC

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

PELVIC INFECTION

subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

MENINGITIS BACTERIAL

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

PERITONITIS

subjects affected / exposed	0 / 644 (0.00%)	4 / 642 (0.62%)
occurrences causally related to treatment / all	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	1 / 1
PERITONSILLITIS		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
PNEUMONIA		
subjects affected / exposed	7 / 644 (1.09%)	10 / 642 (1.56%)
occurrences causally related to treatment / all	4 / 7	3 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
PNEUMONIA BACTERIAL		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
PNEUMONIA VIRAL		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
POSTOPERATIVE ABSCESS		
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION		
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
PULPITIS DENTAL		
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
PYELONEPHRITIS		

subjects affected / exposed	3 / 644 (0.47%)	4 / 642 (0.62%)		
occurrences causally related to treatment / all	0 / 3	0 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
PYELONEPHRITIS ACUTE				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
SEPSIS				
subjects affected / exposed	9 / 644 (1.40%)	3 / 642 (0.47%)		
occurrences causally related to treatment / all	3 / 9	3 / 3		
deaths causally related to treatment / all	1 / 1	0 / 0		
SKIN INFECTION				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
STAPHYLOCOCCAL SEPSIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
TONSILLITIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
UPPER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	1 / 644 (0.16%)	4 / 642 (0.62%)		
occurrences causally related to treatment / all	0 / 1	3 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
VAGINAL CELLULITIS				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
VAGINAL ABSCESS				

subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

UROSEPSIS

subjects affected / exposed	2 / 644 (0.31%)	4 / 642 (0.62%)
occurrences causally related to treatment / all	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0

URINARY TRACT INFECTION

subjects affected / exposed	5 / 644 (0.78%)	9 / 642 (1.40%)
occurrences causally related to treatment / all	0 / 6	4 / 9
deaths causally related to treatment / all	0 / 0	0 / 0

VASCULAR DEVICE INFECTION

subjects affected / exposed	1 / 644 (0.16%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

WOUND INFECTION

subjects affected / exposed	3 / 644 (0.47%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

DIVERTICULITIS

subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

BACTERIAL SEPSIS

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

GASTROENTERITIS

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

Metabolism and nutrition disorders
DECREASED APPETITE

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
DEHYDRATION				
subjects affected / exposed	0 / 644 (0.00%)	6 / 642 (0.93%)		
occurrences causally related to treatment / all	0 / 0	5 / 6		
deaths causally related to treatment / all	0 / 0	0 / 0		
ELECTROLYTE IMBALANCE				
subjects affected / exposed	0 / 644 (0.00%)	2 / 642 (0.31%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
FOOD REFUSAL				
subjects affected / exposed	1 / 644 (0.16%)	0 / 642 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
HYPERCALCAEMIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
HYPERMAGNESAEMIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
HYPERGLYCAEMIA				
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
HYPOKALAEMIA				
subjects affected / exposed	3 / 644 (0.47%)	1 / 642 (0.16%)		
occurrences causally related to treatment / all	1 / 3	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
TYPE 1 DIABETES MELLITUS				

subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 644 (0.00%)	1 / 642 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIA			
subjects affected / exposed	4 / 644 (0.62%)	4 / 642 (0.62%)	
occurrences causally related to treatment / all	2 / 5	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo With Paclitaxel, Carboplatin and Bevacizumab	Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	637 / 644 (98.91%)	637 / 642 (99.22%)	
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	48 / 644 (7.45%)	35 / 642 (5.45%)	
occurrences (all)	57	37	
HYPERTENSION			
subjects affected / exposed	263 / 644 (40.84%)	225 / 642 (35.05%)	
occurrences (all)	392	354	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	79 / 644 (12.27%)	78 / 642 (12.15%)	
occurrences (all)	117	102	
MUCOSAL INFLAMMATION			
subjects affected / exposed	26 / 644 (4.04%)	45 / 642 (7.01%)	
occurrences (all)	36	49	
MALAISE			

subjects affected / exposed	33 / 644 (5.12%)	35 / 642 (5.45%)	
occurrences (all)	42	59	
FATIGUE			
subjects affected / exposed	251 / 644 (38.98%)	241 / 642 (37.54%)	
occurrences (all)	339	297	
OEDEMA PERIPHERAL			
subjects affected / exposed	40 / 644 (6.21%)	40 / 642 (6.23%)	
occurrences (all)	42	44	
PYREXIA			
subjects affected / exposed	54 / 644 (8.39%)	104 / 642 (16.20%)	
occurrences (all)	75	124	
PAIN			
subjects affected / exposed	32 / 644 (4.97%)	33 / 642 (5.14%)	
occurrences (all)	39	35	
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	80 / 644 (12.42%)	102 / 642 (15.89%)	
occurrences (all)	101	127	
DYSPHONIA			
subjects affected / exposed	44 / 644 (6.83%)	44 / 642 (6.85%)	
occurrences (all)	50	47	
DYSPNOEA			
subjects affected / exposed	86 / 644 (13.35%)	87 / 642 (13.55%)	
occurrences (all)	110	112	
EPISTAXIS			
subjects affected / exposed	139 / 644 (21.58%)	136 / 642 (21.18%)	
occurrences (all)	178	166	
NASAL CONGESTION			
subjects affected / exposed	36 / 644 (5.59%)	32 / 642 (4.98%)	
occurrences (all)	40	38	
OROPHARYNGEAL PAIN			
subjects affected / exposed	41 / 644 (6.37%)	47 / 642 (7.32%)	
occurrences (all)	50	58	
Psychiatric disorders			

ANXIETY		
subjects affected / exposed	49 / 644 (7.61%)	38 / 642 (5.92%)
occurrences (all)	58	43
DEPRESSION		
subjects affected / exposed	38 / 644 (5.90%)	35 / 642 (5.45%)
occurrences (all)	41	41
INSOMNIA		
subjects affected / exposed	97 / 644 (15.06%)	89 / 642 (13.86%)
occurrences (all)	119	100
Investigations		
ALANINE AMINOTRANSFERASE INCREASED		
subjects affected / exposed	59 / 644 (9.16%)	91 / 642 (14.17%)
occurrences (all)	100	142
ASPARTATE AMINOTRANSFERASE INCREASED		
subjects affected / exposed	56 / 644 (8.70%)	89 / 642 (13.86%)
occurrences (all)	93	149
BLOOD ALKALINE PHOSPHATASE INCREASED		
subjects affected / exposed	33 / 644 (5.12%)	40 / 642 (6.23%)
occurrences (all)	48	50
LYMPHOCYTE COUNT DECREASED		
subjects affected / exposed	24 / 644 (3.73%)	42 / 642 (6.54%)
occurrences (all)	44	55
NEUTROPHIL COUNT DECREASED		
subjects affected / exposed	168 / 644 (26.09%)	177 / 642 (27.57%)
occurrences (all)	610	567
WEIGHT INCREASED		
subjects affected / exposed	44 / 644 (6.83%)	50 / 642 (7.79%)
occurrences (all)	46	51
WEIGHT DECREASED		
subjects affected / exposed	68 / 644 (10.56%)	84 / 642 (13.08%)
occurrences (all)	72	91
PLATELET COUNT DECREASED		
subjects affected / exposed	142 / 644 (22.05%)	137 / 642 (21.34%)
occurrences (all)	329	267
WHITE BLOOD CELL COUNT		

DECREASED			
subjects affected / exposed	122 / 644 (18.94%)	143 / 642 (22.27%)	
occurrences (all)	535	455	
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			
subjects affected / exposed	50 / 644 (7.76%)	78 / 642 (12.15%)	
occurrences (all)	71	116	
Nervous system disorders			
DYSGEUSIA			
subjects affected / exposed	50 / 644 (7.76%)	56 / 642 (8.72%)	
occurrences (all)	52	66	
DIZZINESS			
subjects affected / exposed	80 / 644 (12.42%)	76 / 642 (11.84%)	
occurrences (all)	102	93	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	166 / 644 (25.78%)	152 / 642 (23.68%)	
occurrences (all)	196	175	
HYPOAESTHESIA			
subjects affected / exposed	59 / 644 (9.16%)	50 / 642 (7.79%)	
occurrences (all)	78	63	
HEADACHE			
subjects affected / exposed	179 / 644 (27.80%)	149 / 642 (23.21%)	
occurrences (all)	278	220	
PARAESTHESIA			
subjects affected / exposed	40 / 644 (6.21%)	47 / 642 (7.32%)	
occurrences (all)	65	57	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	163 / 644 (25.31%)	178 / 642 (27.73%)	
occurrences (all)	186	201	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	266 / 644 (41.30%)	284 / 642 (44.24%)	
occurrences (all)	440	468	
LEUKOPENIA			
subjects affected / exposed	76 / 644 (11.80%)	69 / 642 (10.75%)	
occurrences (all)	243	197	

NEUTROPENIA				
subjects affected / exposed	197 / 644 (30.59%)	195 / 642 (30.37%)		
occurrences (all)	507	477		
THROMBOCYTOPENIA				
subjects affected / exposed	134 / 644 (20.81%)	137 / 642 (21.34%)		
occurrences (all)	275	278		
Eye disorders				
VISION BLURRED				
subjects affected / exposed	45 / 644 (6.99%)	31 / 642 (4.83%)		
occurrences (all)	48	34		
Gastrointestinal disorders				
ABDOMINAL DISTENSION				
subjects affected / exposed	49 / 644 (7.61%)	39 / 642 (6.07%)		
occurrences (all)	60	51		
ABDOMINAL PAIN UPPER				
subjects affected / exposed	66 / 644 (10.25%)	49 / 642 (7.63%)		
occurrences (all)	98	56		
ABDOMINAL PAIN				
subjects affected / exposed	173 / 644 (26.86%)	182 / 642 (28.35%)		
occurrences (all)	241	253		
CONSTIPATION				
subjects affected / exposed	240 / 644 (37.27%)	226 / 642 (35.20%)		
occurrences (all)	334	297		
DIARRHOEA				
subjects affected / exposed	199 / 644 (30.90%)	223 / 642 (34.74%)		
occurrences (all)	328	336		
DRY MOUTH				
subjects affected / exposed	18 / 644 (2.80%)	34 / 642 (5.30%)		
occurrences (all)	22	39		
NAUSEA				
subjects affected / exposed	337 / 644 (52.33%)	325 / 642 (50.62%)		
occurrences (all)	628	565		
DYSPEPSIA				
subjects affected / exposed	53 / 644 (8.23%)	44 / 642 (6.85%)		
occurrences (all)	61	54		
STOMATITIS				

subjects affected / exposed	67 / 644 (10.40%)	98 / 642 (15.26%)
occurrences (all)	106	138
VOMITING		
subjects affected / exposed	156 / 644 (24.22%)	150 / 642 (23.36%)
occurrences (all)	230	209
GASTROOESOPHAGEAL REFLUX DISEASE		
subjects affected / exposed	33 / 644 (5.12%)	28 / 642 (4.36%)
occurrences (all)	39	29
Skin and subcutaneous tissue disorders		
ALOPECIA		
subjects affected / exposed	410 / 644 (63.66%)	386 / 642 (60.12%)
occurrences (all)	415	393
DRY SKIN		
subjects affected / exposed	33 / 644 (5.12%)	35 / 642 (5.45%)
occurrences (all)	39	37
URTICARIA		
subjects affected / exposed	10 / 644 (1.55%)	33 / 642 (5.14%)
occurrences (all)	12	49
RASH MACULO-PAPULAR		
subjects affected / exposed	17 / 644 (2.64%)	45 / 642 (7.01%)
occurrences (all)	19	67
RASH		
subjects affected / exposed	99 / 644 (15.37%)	152 / 642 (23.68%)
occurrences (all)	119	205
PRURITUS		
subjects affected / exposed	61 / 644 (9.47%)	87 / 642 (13.55%)
occurrences (all)	74	108
Renal and urinary disorders		
PROTEINURIA		
subjects affected / exposed	140 / 644 (21.74%)	137 / 642 (21.34%)
occurrences (all)	178	172
Endocrine disorders		
HYPERTHYROIDISM		
subjects affected / exposed	23 / 644 (3.57%)	51 / 642 (7.94%)
occurrences (all)	26	56
HYPOTHYROIDISM		

subjects affected / exposed	54 / 644 (8.39%)	118 / 642 (18.38%)	
occurrences (all)	57	131	

Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	285 / 644 (44.25%)	286 / 642 (44.55%)	
occurrences (all)	451	444	
BACK PAIN			
subjects affected / exposed	90 / 644 (13.98%)	88 / 642 (13.71%)	
occurrences (all)	115	97	
BONE PAIN			
subjects affected / exposed	51 / 644 (7.92%)	45 / 642 (7.01%)	
occurrences (all)	92	70	
MYALGIA			
subjects affected / exposed	163 / 644 (25.31%)	144 / 642 (22.43%)	
occurrences (all)	239	205	
MUSCULAR WEAKNESS			
subjects affected / exposed	44 / 644 (6.83%)	45 / 642 (7.01%)	
occurrences (all)	57	50	
NECK PAIN			
subjects affected / exposed	32 / 644 (4.97%)	34 / 642 (5.30%)	
occurrences (all)	35	34	
PAIN IN EXTREMITY			
subjects affected / exposed	89 / 644 (13.82%)	81 / 642 (12.62%)	
occurrences (all)	121	110	

Infections and infestations			
NASOPHARYNGITIS			
subjects affected / exposed	41 / 644 (6.37%)	41 / 642 (6.39%)	
occurrences (all)	59	60	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	55 / 644 (8.54%)	63 / 642 (9.81%)	
occurrences (all)	71	83	
URINARY TRACT INFECTION			
subjects affected / exposed	104 / 644 (16.15%)	109 / 642 (16.98%)	
occurrences (all)	140	169	

Metabolism and nutrition disorders			

DECREASED APPETITE		
subjects affected / exposed	120 / 644 (18.63%)	119 / 642 (18.54%)
occurrences (all)	154	160
HYPERGLYCAEMIA		
subjects affected / exposed	52 / 644 (8.07%)	46 / 642 (7.17%)
occurrences (all)	85	69
HYPOKALAEMIA		
subjects affected / exposed	60 / 644 (9.32%)	72 / 642 (11.21%)
occurrences (all)	94	97
HYPOMAGNESAEMIA		
subjects affected / exposed	83 / 644 (12.89%)	92 / 642 (14.33%)
occurrences (all)	112	134
HYPONATRAEMIA		
subjects affected / exposed	45 / 644 (6.99%)	48 / 642 (7.48%)
occurrences (all)	61	63

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2017	Protocol was amended to include clarification on the timing from randomization to primary surgery to allow a more feasible retrieval timeframe for the pathology tissue blocks. Following review of newly available PK and ADA data for bevacizumab when administered in combination with atezolizumab, it was decided that no additional assessments were required. Therefore, the bevacizumab PK and ADA assessments were removed.
06 October 2017	Protocol was amended to clarify that head and neck imaging was mandated only if clinically indicated. Clarification of the guidance surrounding bevacizumab and proteinuria to allow for urine protein/creatinine ratio and when bevacizumab may be started in relation to major surgery. Clarification that screening tumor assessment by CT scan was to be performed within 28 days prior to randomization for both primary surgery participants and neoadjuvant participants.
22 May 2018	Protocol was amended to include consistent windows around tumor response evaluations. Clarification of tumor tissue requirements for participants undergoing neoadjuvant treatment. Clarification of the PRO questionnaire distribution and completion. The reporting period for SAEs and AESIs were clarified. Instructions onthe reporting of accidental overdose or medication error administered by the site or not administered by the site were added to strengthen safety monitoring for special situations that may or may not result in an AE. Instructions onthe reporting of accidental overdose or medication error administered by the site or not administered by the site were added to strengthen safety monitoring for special situations that may or may not result in an AE.
03 November 2018	Protocol was amended to include risks for atezolizumab and guidelines for managing patients who experience atezolizumab-associated AEs were revised to include nephritis. Modification of exclusion criteria to include venous thromboembolism, to specify Grade >=2 hemoptysis, and to clarify current or recent usage of associated medications. Clarification of dosing for bevacizumab to allow sites to obtain and account for the participant's current weight according to their clinical practice. Clarifications for carboplatin and paclitaxel dose reductions to reinforce allowance of institutional practice. HIPEC was added as a prohibited therapy because it is an anti-cancer chemotherapy.
29 January 2020	Protocol was amended to include myositis as a risk for atezolizumab. Language was added to clarify that anti-cancer therapy was not permitted after Cycle 22.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

 None reported