



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 surgery had 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/m²) 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/QoL scales 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 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 | 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 Func., CoT/ETV (n=144,n=131) | 38.9 | 34.4 | | |
| Physical Func., 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 Funct., PT FU 12 months (n=17,n=24) | 29.4 | 29.2 | | |
| Emotional Funct., PT FU 18 months (n=6,n=4) | 16.7 | 50.0 | | |
| Emotional Funct., 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 Respn ders |
| 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 - |
|-----------------|---|

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 |

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|-----------------------------------|-----------------------------------|
| 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 |

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|-----------------------------------|-----------------------------------|
| 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 Func., 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 FU 18 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

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 | |
| BACTERAEemia | | | |
| 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 | |
| HYPOMAGNEAEMIA | | | |
| 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 on the 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 on the 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