



Clinical trial results:

Phase 2 Study Investigating Efficacy and Safety of Anti-PD-1 Monoclonal Antibody Tislelizumab (BGB-A317) Combined With or Without Anti-TIGIT Monoclonal Antibody BGB-A1217 in Patients With Previously Treated Recurrent or Metastatic Cervical Cancer

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2020-004657-77 |
| Trial protocol | BG PL |
| Global end of trial date | 31 August 2023 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 (current) |
| This version publication date | 07 September 2024 |
| First version publication date | 07 September 2024 |

Trial information

Trial identification

| | |
|-----------------------|--------------------|
| Sponsor protocol code | BGB-A317-A1217-202 |
|-----------------------|--------------------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04693234 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | CTR20212809: ChinaDrugTrials, CTR20210588: ChinaDrugTrials, AdvanTIG-202: BeiGene |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | BeiGene |
| Sponsor organisation address | 1840 Gateway Drive, San Mateo, CA , United States, 94404 |
| Public contact | BeiGene Clinical Support, BeiGene USA, Inc., 1 877-828-5568, clinicaltrials@beigene.com |
| Scientific contact | BeiGene Clinical Support, BeiGene USA, Inc., 1 877-828-5568, clinicaltrials@beigene.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 | 27 September 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 16 June 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 31 August 2023 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of BGB-A1217 combined with tislelizumab as measured by ORR according to RECIST v1.1, by Independent Review Committee (IRC) in patients who had previously treated recurrent or metastatic cervical cancer.

Protection of trial subjects:

This trial was designed and monitored in accordance with Sponsor procedures, which comply with the ethical principles of GCP as required by the major regulatory authorities, and in accordance with the Declaration of Helsinki. The IEC/IRB-approved ICF was signed and dated by the subject or the subject's legally authorized representative before his or her participation in the study. A copy of each signed ICF was provided to the subject or the subject's legally authorized representative. All signed and dated ICFs were retained in each patient's study file or in the site file. For any updated or revised ICFs, written informed consent was obtained using the IEC/IRB-approved updated/revised ICFs for continued participation in the study.

Background therapy: -

Evidence for comparator: -

| | |
|---|----------------------------------|
| Actual start date of recruitment | 15 February 2021 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety, Efficacy, Ethical reason |
| Long term follow-up duration | 2 Years |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--|
| Country: Number of subjects enrolled | China: 88 |
| Country: Number of subjects enrolled | Korea, Democratic People's Republic of: 38 |
| Country: Number of subjects enrolled | Taiwan: 16 |
| Country: Number of subjects enrolled | Ukraine: 10 |
| Country: Number of subjects enrolled | Russian Federation: 11 |
| Country: Number of subjects enrolled | Thailand: 12 |
| Country: Number of subjects enrolled | Bulgaria: 2 |
| Country: Number of subjects enrolled | Poland: 1 |
| Worldwide total number of subjects | 178 |
| EEA total number of subjects | 3 |

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) | 160 |
| From 65 to 84 years | 18 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled in multiple study centers in China, South Korea, and Europe. The first patient dosed was on March 3rd, 2021 and the last participant completed on August 31st, 2023.

Pre-assignment

Screening details:

The study was composed of an initial screening phase (up to 28 days), a treatment phase, an end of treatment visit, an on-site Safety Follow-up Visit, and 2 Safety Follow-up Visits by telephone after the last dose of study treatment.

Period 1

| | |
|----------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |
| Blinding implementation details: | |
| None (Open Label) | |

Arms

| | |
|------------------------------|--------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Cohort 1: Ociperlimab + Tislelizumab |

Arm description:

Tislelizumab 200 milligrams (mg) intravenously (IV) once every 3 weeks (Q3W) combined with ociperlimab (BGB-A1217) 900 mg IV Q3W

| | |
|--|--------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Tislelizumab |
| Investigational medicinal product code | |
| Other name | Tevimbra |
| Pharmaceutical forms | Injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

200 mg administered intravenously once every 3 weeks on day 1 of each cycle

| | |
|--|--------------------|
| Investigational medicinal product name | Ociperlimab |
| Investigational medicinal product code | |
| Other name | BGB-A1217 |
| Pharmaceutical forms | Injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

900 mg administered intravenously once every 3 weeks on day 1 of each cycle

| | |
|------------------|------------------------|
| Arm title | Cohort 2: Tislelizumab |
|------------------|------------------------|

Arm description:

Tislelizumab 200 mg IV Q3W monotherapy

| | |
|--|--------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Tislelizumab |
| Investigational medicinal product code | |
| Other name | Tevimbra |
| Pharmaceutical forms | Injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

200 mg administered intravenously once every 3 weeks on day 1 of each cycle

| Number of subjects in period 1 | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab |
|--------------------------------|--|---------------------------|
| | | |
| Started | 138 | 40 |
| Completed | 0 | 0 |
| Not completed | 138 | 40 |
| Consent withdrawn by subject | 10 | 2 |
| Death | 79 | 19 |
| Study Terminated by Sponsor | 47 | 18 |
| Lost to follow-up | 2 | 1 |

Baseline characteristics

Reporting groups

| | |
|--|--------------------------------------|
| Reporting group title | Cohort 1: Ociperlimab + Tislelizumab |
| Reporting group description: Tislelizumab 200 milligrams (mg) intravenously (IV) once every 3 weeks (Q3W) combined with ociperlimab (BGB-A1217) 900 mg IV Q3W | |
| Reporting group title | Cohort 2: Tislelizumab |
| Reporting group description: Tislelizumab 200 mg IV Q3W monotherapy | |

| Reporting group values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | Total |
|---|--|---------------------------|-------|
| Number of subjects | 138 | 40 | 178 |
| Age categorical Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 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) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | 52.7 | 51.2 | |
| standard deviation | ± 10.28 | ± 9.74 | - |
| Gender categorical Units: Subjects | | | |
| Female | 138 | 40 | 178 |
| Race/Ethnicity Units: Subjects | | | |
| Asian | 117 | 37 | 154 |
| White | 21 | 3 | 24 |
| ECOG Performance Status Units: Subjects | | | |
| ECOG Performance = 0 | 53 | 16 | 69 |
| ECOG Performance = 1 | 85 | 24 | 109 |
| PD-L1 Expression Units: Subjects | | | |
| PD-L1 Score ≥ 5% | 84 | 20 | 104 |
| PD-L1 Score < 5% | 53 | 20 | 73 |
| Not Evaluable | 1 | 0 | 1 |

End points

End points reporting groups

| | |
|--|--------------------------------------|
| Reporting group title | Cohort 1: Ociperlimab + Tislelizumab |
| Reporting group description: Tislelizumab 200 milligrams (mg) intravenously (IV) once every 3 weeks (Q3W) combined with ociperlimab (BGB-A1217) 900 mg IV Q3W | |
| Reporting group title | Cohort 2: Tislelizumab |
| Reporting group description: Tislelizumab 200 mg IV Q3W monotherapy | |
| Subject analysis set title | Cohort 1 (Predose) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: The Pharmacokinetic Analysis Set includes all participants who received ≥ 1 dose of any component of study drug per the protocol, for whom any post-dose PK data are available. Ociperlimab: 900 mg administered intravenously once every 3 weeks on day 1 of each cycle. Predose was collected within 60 minutes before starting infusion. Tislelizumab: 200 mg administered intravenously once every 3 weeks on day 1 of each cycle. Predose was collected within 60 minutes before starting infusion | |
| Subject analysis set title | Cohort 1 (Postdose) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: The Pharmacokinetic Analysis Set includes all participants who received ≥ 1 dose of any component of study drug per the protocol, for whom any post-dose PK data are available. Ociperlimab: 900 mg administered intravenously once every 3 weeks on day 1 of each cycle. Postdose was collected within 30 minutes after the end of infusion. Tislelizumab: 200 mg administered intravenously once every 3 weeks on day 1 of each cycle. Postdose was collected within 30 minutes after the end of infusion. | |
| Subject analysis set title | Cohort 2 (Predose) |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: The Pharmacokinetic Analysis Set includes all participants who received ≥ 1 dose of any component of study drug per the protocol, for whom any post-dose PK data are available. Tislelizumab: 200 mg administered intravenously once every 3 weeks on day 1 of each cycle. Predose was collected within 60 minutes before starting infusion | |
| Subject analysis set title | Cohort 2 (Postdose) |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: The Pharmacokinetic Analysis Set includes all participants who received ≥ 1 dose of any component of study drug per the protocol, for whom any post-dose PK data are available. Tislelizumab: 200 mg administered intravenously once every 3 weeks on day 1 of each cycle. Postdose was collected within 30 minutes after the end of infusion. | |

Primary: Cohort 1: Objective Response Rate (ORR) as Assessed by an Independent Review Committee (IRC) (PD-L1 Score \geq 5% Safety Analysis Set)

| | |
|---|--|
| End point title | Cohort 1: Objective Response Rate (ORR) as Assessed by an Independent Review Committee (IRC) (PD-L1 Score \geq 5% Safety Analysis Set) ^{[1][2]} |
| End point description: Defined as the percentage of participants who had confirmed complete response (CR) or partial response (PR) as assessed by the IRC per RECIST v1.1 in the PD-L1 Score \geq 5% Safety Analysis Set. The PD-L1 Score \geq 5% Safety Analysis Set includes all treated participants whose tumors have PD-L1 Score \geq 5%. | |
| End point type | Primary |
| End point timeframe: Up to approximately 2 years and 6 months | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Not estimable due to insufficient number of participants with events

[2] - 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: Not estimable due to insufficient number of participants with events

| | | | | |
|-----------------------------------|--|--|--|--|
| End point values | Cohort 1: Ociperlimab + Tislelizumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 84 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 27.4 (18.2 to 38.2) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: ORR as Assessed by an IRC (Safety Analysis Set)

| | |
|-----------------|---|
| End point title | Cohort 1: ORR as Assessed by an IRC (Safety Analysis Set) ^{[3][4]} |
|-----------------|---|

End point description:

Defined as the percentage of participants who had CR or PR as assessed by the IRC per RECIST v1.1 in the safety analysis set. The Safety Analysis Set is defined as all participants who received ≥ 1 dose of any study drug for each cohort.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to approximately 2 years and 6 months

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Not estimable due to insufficient number of participants with events

[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: Not estimable due to insufficient number of participants with events

| | | | | |
|-----------------------------------|--|--|--|--|
| End point values | Cohort 1: Ociperlimab + Tislelizumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 138 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 23.2 (16.4 to 31.1) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: ORR as Assessed by an Investigator's Review (PD-L1 Score \geq 5% Safety Analysis Set)

| | |
|-----------------|--|
| End point title | Cohort 1: ORR as Assessed by an Investigator's Review (PD-L1 Score \geq 5% Safety Analysis Set) ^[5] |
|-----------------|--|

End point description:

Defined as the percentage of participants who had CR or PR as assessed by the investigator per RECIST v1.1 in the PD-L1 Score \geq 5% Safety Analysis Set.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 2 years and 6 months

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: Not estimable due to insufficient number of participants with events

| | | | | |
|-----------------------------------|--|--|--|--|
| End point values | Cohort 1: Ociperlimab + Tislelizumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 84 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 26.2 (17.2 to 36.9) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: ORR as Assessed by an Investigator's Review (Safety Analysis Set)

| | |
|-----------------|--|
| End point title | Cohort 1: ORR as Assessed by an Investigator's Review (Safety Analysis Set) ^[6] |
|-----------------|--|

End point description:

Defined as the percentage of participants who had CR or PR as assessed by the investigator per RECIST v1.1 in the Safety Analysis Set.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 2 years and 6 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: Not estimable due to insufficient number of participants with events

| | | | | |
|-----------------------------------|--|--|--|--|
| End point values | Cohort 1: Ociperlimab + Tislelizumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 138 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 21.7 (15.2 to 29.6) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2: ORR (PD-L1 Score \geq 5% Safety Analysis Set)

| | |
|-----------------|--|
| End point title | Cohort 2: ORR (PD-L1 Score \geq 5% Safety Analysis Set) ^[7] |
|-----------------|--|

End point description:

Defined as the percentage of participants who had CR or PR as assessed by the IRC per RECIST v1.1 as assessed by an IRC and investigator's review in the PD-L1 Score \geq 5% Safety Analysis Set.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 2 years and 6 months

Notes:

[7] - 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: Not estimable due to insufficient number of participants with events

| | | | | |
|-----------------------------------|---------------------------|--|--|--|
| End point values | Cohort 2: Tislelizumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 20 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| IRC | 35.0 (15.4 to 59.2) | | | |
| Investigator | 30.0 (11.9 to 54.3) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2: ORR (Safety Analysis Set)

| | |
|-----------------|--|
| End point title | Cohort 2: ORR (Safety Analysis Set) ^[8] |
|-----------------|--|

End point description:

Defined as the percentage of participants who had CR or PR as assessed by the IRC per RECIST v1.1 as assessed by an IRC and investigator's review in the Safety Analysis Set.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 2 years and 6 months

Notes:

[8] - 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: Not estimable due to insufficient number of participants with events

| End point values | Cohort 2: Tislelizumab | | | |
|-----------------------------------|---------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 40 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| IRC | 35.0 (20.6 to 51.7) | | | |
| Investigator | 25.0 (12.7 to 41.2) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

| | |
|-----------------|----------------------------|
| End point title | Duration of Response (DOR) |
|-----------------|----------------------------|

End point description:

Defined as the time from the first confirmed objective response until the first documentation of progression or death, whichever comes first, assessed by both IRC and investigator's review according to RECIST v1.1 in the Safety Analysis Set. Data are based on number of responders. Due to EudraCT system limitations, the IRC category includes 32 respondents in Cohort 1 (C1) and 14 in Cohort 2 (C2). In the investigator category, there are 30 respondents in C1 and 10 in C2.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 2 years and 6 months

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|----------------------------------|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | | | | |

| | | | | |
|-----------------------------------|---------------------|--------------------|--|--|
| IRC (32 in C1, 14 in C2) | 17.3 (16.9 to 9999) | 9999 (4.6 to 9999) | | |
| Investigator (30 in C1, 10 in C2) | 15.5 (6.9 to 9999) | 9999 (5.5 to 9999) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

| | |
|--|---------------------------------|
| End point title | Progression Free Survival (PFS) |
| End point description: defined as the time from the date of first dose of study drug to the date of first documentation of disease progression or death, whichever occurs first as assessed by both IRC and investigator's review per RECIST v1.1 in the Safety Analysis Set. | |
| End point type | Secondary |
| End point timeframe: Up to approximately 2 years and 6 months | |

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|----------------------------------|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | | | | |
| IRC | 3.0 (2.6 to 4.9) | 5.7 (2.3 to 8.1) | | |
| Investigator | 3.9 (2.6 to 4.4) | 5.7 (2.6 to 9.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response (TTR)

| | |
|--|------------------------|
| End point title | Time to Response (TTR) |
| End point description: defined as the time from the date of first dose of study drug to first documentation of response as assessed by both IRC and investigator's review per RECIST v1.1 in the Safety Analysis Set. | |
| End point type | Secondary |
| End point timeframe: Up to the primary analysis data cut off point (approximately 16 months) | |

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|--------------------------------------|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: Weeks | | | | |
| arithmetic mean (standard deviation) | | | | |
| IRC | 9.02 (± 4.704) | 11.78 (± 4.709) | | |
| Investigator | 10.66 (± 5.010) | 8.92 (± 3.174) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR)

| | |
|--|----------------------------|
| End point title | Disease Control Rate (DCR) |
| End point description: defined as the proportion of participants who achieve CR, PR, or stable disease (SD) as assessed by both IRC and investigator's review per RECIST v1.1 in the Safety Analysis Set. | |
| End point type | Secondary |
| End point timeframe: Up to approximately 2 years and 6 months | |

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|-----------------------------------|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| IRC | 63.0 (54.4 to 71.1) | 67.5 (50.9 to 81.4) | | |
| Investigator | 62.3 (53.7 to 70.4) | 75.0 (58.8 to 87.3) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Benefit Rate (CBR)

| | |
|-----------------|-----------------------------|
| End point title | Clinical Benefit Rate (CBR) |
|-----------------|-----------------------------|

End point description:

defined as the percentage of participants who achieve CR, PR, or durable SD (SD \geq 24 weeks) as assessed by both IRC and investigator's review per RECIST v1.1 in the Safety Analysis Set.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 2 years and 6 months

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|-----------------------------------|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| IRC | 29.0 (21.6 to 37.3) | 50.0 (33.8 to 66.2) | | |
| Investigator | 31.2 (23.6 to 39.6) | 50.0 (33.8 to 66.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

| | |
|-----------------|-----------------------|
| End point title | Overall Survival (OS) |
|-----------------|-----------------------|

End point description:

defined as the time from the date of first dose of study drug until the date of death from any cause in the Safety Analysis Set.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 2 years and 6 months

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|----------------------------------|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 12.2 (9.9 to 16.6) | 23.5 (13.6 to 9999) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) Physical Functioning Score

| | |
|-----------------|--|
| End point title | Mean Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) Physical Functioning Score |
|-----------------|--|

End point description:

The EORTC QLQ-30 contains 30 questions that incorporate 5 functional scales (physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning), 1 global health status scale, 3 symptom scales (fatigue, nausea and vomiting, and pain), and 6 single items (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). The participant answers questions about their health during the past week. There are 28 questions answered on a 4-point scale where 1 =Not at all (best) to 4 =Very Much (worst) and 2 questions answered on a 7-point scale where 1 =Very poor (worst) to 7 =Excellent (best).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline to Cycle 15 (21 days per cycle)

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|--------------------------------------|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 78.91 (± 19.211) | 76.67 (± 22.501) | | |
| Change at Cycle 15 | 23.33 (± 4.714) | 7.33 (± 18.974) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Symptom Specific Scale for Cervical Cancer (EORTC QLQ-CX24) Index Score.

| | |
|-----------------|--|
| End point title | Change From Baseline in European Organization for Research |
|-----------------|--|

End point description:

The EORTC QLQ-CX24 is a questionnaire that rates the symptoms common to women with cervical cancer and evaluates the impact of disease and/or treatments. The 24 items use a 4-point scale (1=not at all to 4=very much) and are classified into 3 multi-item scales, 11 items with symptom experience, 3 items with body image, and 4 items with sexual/ vaginal functioning. The other items of the questionnaire are lymphedema, peripheral neuropathy, menopausal symptom, sexual worry, sexual activity, and sexual enjoyment. The change from baseline in EORTC QLQ-CX24 score will be presented.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline to Cycle 15 (21 days per cycle)

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|--------------------------------------|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 30.86 (± 6.942) | 31.43 (± 4.497) | | |
| Change at Cycle 15 | -2.59 (± 11.313) | 0.84 (± 4.196) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Adverse Events (AEs)

| | |
|-----------------|--|
| End point title | Number of Participants Experiencing Adverse Events (AEs) |
|-----------------|--|

End point description:

Number of participants with treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) characterized by type, frequency, severity (as graded by National Cancer Institute-Common Terminology Criteria for Adverse Events version 5.0 [NCICTCAE v5.0]), timing, seriousness, and relationship to study drugs, physical examinations, electrocardiograms (ECGs), and laboratory assessments

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From the date of the first dose of study drug(s) through 30 days after the last dose or the initiation of new anti-cancer therapy, whichever is earlier; up to approximately 2 years and 6 months

| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
|---|--|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 138 | 40 | | |
| Units: Participants | | | | |
| Number of Participants with at least one TEAE | 135 | 39 | | |
| Number of participants with at least one SAE | 61 | 17 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Ociperlimab (BGB-A1217) Concentrations at Specified Timepoints

| | |
|-----------------|--|
| End point title | Serum Ociperlimab (BGB-A1217) Concentrations at Specified Timepoints |
|-----------------|--|

End point description:

The timepoints are defined as predose (within 60 minutes before starting infusion) and postdose (within 30 minutes after the end of infusion).

The Pharmacokinetic Analysis Set includes all participants who received ≥ 1 dose of any component of study drug per the protocol, for whom any post-dose PK data are available.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 1 of Cycles 1, 2, 5, 9, and 17 (each cycle is 21 days)

| End point values | Cohort 1 (Predose) | Cohort 1 (Postdose) | | |
|---|-----------------------|------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 138 | | | |
| Units: Concentrations (µg/mL) | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cycle 1 Day 1 | 0000 (± 0000) | 363.19 (± 24.21) | | |
| Cycle 2 Day 1 | 46.60 (± 46.98) | 0000 (± 0000) | | |
| Cycle 5 Day 1 | 82.57 (± 55.30) | 440.70 (± 25.35) | | |
| Cycle 9 Day 1 | 89.13 (± 56.58) | 0000 (± 0000) | | |
| Cycle 17 Day 1 | 88.84 (± 63.62) | 0000 (± 0000) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Tislelizumab Concentrations at Specified Timepoints

| | |
|-----------------|---|
| End point title | Serum Tislelizumab Concentrations at Specified Timepoints |
|-----------------|---|

End point description:

The timepoints are defined as predose (within 60 minutes before starting infusion) and postdose (within 30 minutes after the end of infusion). The Pharmacokinetic Analysis Set includes all participants who received ≥ 1 dose of any component of study drug per the protocol, for whom any post-dose PK data are available.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 1 of Cycles 1, 2, 5, 9, and 17 (each cycle is 21 days)

| End point values | Cohort 1 (Predose) | Cohort 1 (Postdose) | Cohort 2 (Predose) | Cohort 2 (Postdose) |
|---|-----------------------|------------------------|-----------------------|------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | | | | |
| Units: Concentrations ($\mu\text{g/mL}$) | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cycle 1 Day 1 | 0000 (\pm 0000) | 77.38 (\pm 21.78) | 0000 (\pm 0000) | 84.24 (\pm 18.19) |
| Cycle 2 Day 1 | 17.86 (\pm 35.69) | 0000 (\pm 0000) | 20.03 (\pm 36.62) | 0000 (\pm 0000) |
| Cycle 5 Day 1 | 36.66 (\pm 44.97) | 113.80 (\pm 24.68) | 41.51 (\pm 42.89) | 128.48 (\pm 24.06) |
| Cycle 9 Day 1 | 42.84 (\pm 46.50) | 0000 (\pm 0000) | 56.78 (\pm 28.55) | 0000 (\pm 0000) |
| Cycle 17 Day 1 | 45.16 (\pm 55.71) | 0000 (\pm 0000) | 56.25 (\pm 21.56) | 0000 (\pm 0000) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Postive Anti-drug Antibodies (ADAs) to Ociperlimab

| | |
|-----------------|---|
| End point title | Number of Participants With Postive Anti-drug Antibodies (ADAs) to Ociperlimab ^[9] |
|-----------------|---|

End point description:

Number and percentage of participants who develop detectable ADAs. The ADA Analysis Set includes all participants who received at least 1 dose of any component of study drug for whom both baseline antidrug antibody result and at least 1 post-baseline antidrug antibody result are available.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline and up to approximately 2 years and 6 months

Notes:

[9] - 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: Not estimable due to insufficient number of participants with events

| | | | | |
|-----------------------------|--|--|--|--|
| End point values | Cohort 1: Ociperlimab + Tislelizumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 127 | | | |
| Units: participants | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive Anti-drug Antibodies (ADAs) to Tislelizumab

| | |
|-----------------|--|
| End point title | Number of Participants With Positive Anti-drug Antibodies (ADAs) to Tislelizumab |
|-----------------|--|

End point description:

Number and percentage of participants who develop detectable ADAs. The ADA Analysis Set includes all participants who received at least 1 dose of any component of study drug for whom both baseline antidrug antibody result and at least 1 post-baseline antidrug antibody result are available.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline and up to approximately 2 years and 6 months

| | | | | |
|-----------------------------|--|---------------------------|--|--|
| End point values | Cohort 1: Ociperlimab + Tislelizumab | Cohort 2: Tislelizumab | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 127 | 39 | | |
| Units: participants | 19 | 7 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the date of the first dose of study drug(s) through 30 days after the last dose or the initiation of new anti-cancer therapy, whichever is earlier; up to approximately 2 years and 6 months

Adverse event reporting additional description:

Number of participants with treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) characterized by type, frequency, severity (as graded by NCICTCAE v5.0), timing, seriousness, and relationship to study drugs, physical examinations, ECGs, and laboratory assessments.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|----|
| Dictionary version | 24 |
|--------------------|----|

Reporting groups

| | |
|-----------------------|------------------------|
| Reporting group title | Cohort 2: Tislelizumab |
|-----------------------|------------------------|

Reporting group description:

Cohort 2: Tislelizumab

| | |
|-----------------------|--------------------------------------|
| Reporting group title | Cohort 1: Ociperlimab + Tislelizumab |
|-----------------------|--------------------------------------|

Reporting group description:

Cohort 1: Ociperlimab + Tislelizumab

| Serious adverse events | Cohort 2: Tislelizumab | Cohort 1: Ociperlimab + Tislelizumab | |
|---|---------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 17 / 40 (42.50%) | 61 / 138 (44.20%) | |
| number of deaths (all causes) | 19 | 79 | |
| number of deaths resulting from adverse events | 4 | 13 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Tumour thrombosis | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |

| | | | |
|--|----------------|-----------------|--|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vena cava thrombosis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| 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 | | | |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 5 / 138 (3.62%) | |
| occurrences causally related to treatment / all | 2 / 2 | 3 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 4 / 138 (2.90%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 4 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Death | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Female genital tract fistula | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|----------------|-----------------|--|
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genital swelling | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 4 / 138 (2.90%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune-mediated lung disease | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|----------------|-----------------|--|
| Psychiatric disorders | | | |
| Completed suicide | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Procedural pain | | | |

| | | | |
|---|----------------|-----------------|--|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Angina unstable | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocarditis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiopulmonary failure | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Atrial thrombosis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 4 / 138 (2.90%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Intestinal obstruction | | | |

| | | | |
|---|----------------|-----------------|--|
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus paralytic | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 3 / 138 (2.17%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (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 | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal adhesions | | | |

| | | | |
|---|----------------|-----------------|--|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Small intestinal perforation | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mechanical ileus | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Vomiting | | | |

| | | | |
|---|----------------|-----------------|--|
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| 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 | | | |
| Drug eruption | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Urogenital fistula | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric obstruction | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|----------------|-----------------|--|
| Hypertonic bladder | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 4 / 138 (2.90%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus bladder | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| 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 | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyarthrititis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|----------------|-----------------|--|
| Infections and infestations | | | |
| Acute hepatitis C | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COVID-19 | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 138 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic abscess | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal abscess | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Upper respiratory tract infection | | | |

| | | | |
|---|----------------|------------------|--|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 11 / 138 (7.97%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 138 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 138 (0.72%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 3 %

| Non-serious adverse events | Cohort 2: Tislelizumab | Cohort 1: Ociperlimab + Tislelizumab | |
|---|-----------------------------------|---|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 37 / 40 (92.50%) | 128 / 138 (92.75%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Tumour pain | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 138 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Vascular disorders | | | |
| Lymphoedema | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 5 / 138 (3.62%) | |
| occurrences (all) | 1 | 5 | |
| Hypertension | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 5 / 138 (3.62%) | |
| occurrences (all) | 2 | 7 | |
| General disorders and administration site conditions | | | |
| Influenza like illness | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 2 / 138 (1.45%) | |
| occurrences (all) | 3 | 2 | |
| Malaise | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 6 / 138 (4.35%) | |
| occurrences (all) | 2 | 6 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 6 / 138 (4.35%) | |
| occurrences (all) | 1 | 7 | |
| Pyrexia | | | |
| subjects affected / exposed | 7 / 40 (17.50%) | 27 / 138 (19.57%) | |
| occurrences (all) | 7 | 38 | |
| Fatigue | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 8 / 138 (5.80%) | |
| occurrences (all) | 2 | 10 | |
| Asthenia | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 8 / 138 (5.80%) | |
| occurrences (all) | 6 | 12 | |

| | | | |
|---|--|---|--|
| Chills subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 11 / 138 (7.97%) 11 | |
| Reproductive system and breast disorders Vaginal haemorrhage subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 3 | 8 / 138 (5.80%) 9 | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 0 / 40 (0.00%) 0 | 13 / 138 (9.42%) 15 6 / 138 (4.35%) 6 | |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 5 / 138 (3.62%) 5 | |
| Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all) Aspartate aminotransferase increased subjects affected / exposed occurrences (all) Blood alkaline phosphatase increased subjects affected / exposed occurrences (all) Blood creatine phosphokinase increased subjects affected / exposed occurrences (all) Blood creatinine increased subjects affected / exposed occurrences (all) Blood lactate dehydrogenase increased | 4 / 40 (10.00%) 5 5 / 40 (12.50%) 6 3 / 40 (7.50%) 3 3 / 40 (7.50%) 3 6 / 40 (15.00%) 6 | 16 / 138 (11.59%) 24 24 / 138 (17.39%) 35 12 / 138 (8.70%) 14 4 / 138 (2.90%) 4 16 / 138 (11.59%) 25 | |

| | | |
|---|-----------------|-------------------|
| subjects affected / exposed | 4 / 40 (10.00%) | 2 / 138 (1.45%) |
| occurrences (all) | 4 | 4 |
| Blood thyroid stimulating hormone decreased | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 0 / 138 (0.00%) |
| occurrences (all) | 5 | 0 |
| Blood thyroid stimulating hormone increased | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 4 / 138 (2.90%) |
| occurrences (all) | 2 | 4 |
| Blood urea increased | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 5 / 138 (3.62%) |
| occurrences (all) | 0 | 5 |
| Gamma-glutamyltransferase increased | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 3 / 138 (2.17%) |
| occurrences (all) | 2 | 3 |
| Lymphocyte count decreased | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 7 / 138 (5.07%) |
| occurrences (all) | 1 | 9 |
| Neutrophil count decreased | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 6 / 138 (4.35%) |
| occurrences (all) | 15 | 10 |
| Thyroxine free increased | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 138 (0.00%) |
| occurrences (all) | 2 | 0 |
| Weight decreased | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 18 / 138 (13.04%) |
| occurrences (all) | 5 | 22 |
| Weight increased | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 3 / 138 (2.17%) |
| occurrences (all) | 2 | 4 |
| White blood cell count decreased | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 13 / 138 (9.42%) |
| occurrences (all) | 15 | 26 |
| Nervous system disorders | | |

| | | | |
|--|------------------------|-------------------------|--|
| Headache subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 9 / 138 (6.52%) 10 | |
| Hypoaesthesia subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 3 / 138 (2.17%) 3 | |
| Blood and lymphatic system disorders | | | |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 138 (0.72%) 1 | |
| Anaemia subjects affected / exposed occurrences (all) | 15 / 40 (37.50%) 23 | 48 / 138 (34.78%) 66 | |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed occurrences (all) | 6 / 40 (15.00%) 7 | 9 / 138 (6.52%) 11 | |
| Abdominal pain lower subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 9 / 138 (6.52%) 15 | |
| Diarrhoea subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 4 | 15 / 138 (10.87%) 18 | |
| Constipation subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 18 / 138 (13.04%) 20 | |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 9 / 138 (6.52%) 9 | |
| Vomiting subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 17 / 138 (12.32%) 22 | |
| Toothache subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 3 | 0 / 138 (0.00%) 0 | |
| Stomatitis | | | |

| | | | |
|--|----------------------|-------------------------|--|
| subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 138 (0.72%) 1 | |
| Nausea subjects affected / exposed occurrences (all) | 6 / 40 (15.00%) 7 | 27 / 138 (19.57%) 34 | |
| Flatulence subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 3 | 0 / 138 (0.00%) 0 | |
| Dyspepsia subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 5 / 138 (3.62%) 6 | |
| Hepatobiliary disorders Hepatitis subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 3 | 1 / 138 (0.72%) 1 | |
| Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all) | 5 / 40 (12.50%) 7 | 15 / 138 (10.87%) 18 | |
| Rash subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 18 / 138 (13.04%) 18 | |
| Urticaria subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 5 / 138 (3.62%) 6 | |
| Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 4 | 4 / 138 (2.90%) 4 | |
| Proteinuria subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 6 / 138 (4.35%) 6 | |
| Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all) | 8 / 40 (20.00%) 9 | 27 / 138 (19.57%) 28 | |
| Hyperthyroidism | | | |

| | | | |
|--|---------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 4 / 138 (2.90%) 4 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 5 / 138 (3.62%) | |
| occurrences (all) | 1 | 5 | |
| Back pain | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 14 / 138 (10.14%) | |
| occurrences (all) | 1 | 15 | |
| Flank pain | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 2 / 138 (1.45%) | |
| occurrences (all) | 5 | 2 | |
| Muscular weakness | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 2 / 138 (1.45%) | |
| occurrences (all) | 3 | 2 | |
| Myalgia | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 5 / 138 (3.62%) | |
| occurrences (all) | 3 | 5 | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 7 / 138 (5.07%) | |
| occurrences (all) | 0 | 7 | |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 10 / 138 (7.25%) | |
| occurrences (all) | 3 | 11 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 10 / 40 (25.00%) | 16 / 138 (11.59%) | |
| occurrences (all) | 11 | 18 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 8 / 40 (20.00%) | 15 / 138 (10.87%) | |
| occurrences (all) | 12 | 20 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 5 / 138 (3.62%) | |
| occurrences (all) | 2 | 5 | |
| Hyperlipidaemia | | | |

| | | |
|-----------------------------|-----------------|-------------------|
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 138 (0.00%) |
| occurrences (all) | 2 | 0 |
| Hypertriglyceridaemia | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 2 / 138 (1.45%) |
| occurrences (all) | 9 | 2 |
| Hyperuricaemia | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 6 / 138 (4.35%) |
| occurrences (all) | 0 | 6 |
| Hypoalbuminaemia | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 25 / 138 (18.12%) |
| occurrences (all) | 5 | 33 |
| Hypocalcaemia | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 12 / 138 (8.70%) |
| occurrences (all) | 1 | 15 |
| Hypokalaemia | | |
| subjects affected / exposed | 8 / 40 (20.00%) | 20 / 138 (14.49%) |
| occurrences (all) | 10 | 40 |
| Hypomagnesaemia | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 12 / 138 (8.70%) |
| occurrences (all) | 2 | 18 |
| Hyponatraemia | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 8 / 138 (5.80%) |
| occurrences (all) | 2 | 8 |
| Hypophosphataemia | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 5 / 138 (3.62%) |
| occurrences (all) | 0 | 5 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---------------------------------|
| 04 September 2020 | Original Protocol |
| 04 May 2023 | Protocol Amendment 0.1 (Russia) |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported