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 ≥ 5% Safety Analysis Set)

End point title	Cohort 1: Objective Response Rate (ORR) as Assessed by an Independent Review Committee (IRC) (PD-L1 Score ≥ 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 ≥ 5% Safety Analysis Set. The PD-L1 Score >= 5% Safety Analysis Set includes all treated participants whose tumors have PD-L1 Score >= 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 ≥ 5% Safety Analysis Set)

End point title	Cohort 1: ORR as Assessed by an Investigator's Review (PD-L1 Score ≥ 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 >= 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 >= 5% Safety Analysis Set)

End point title	Cohort 2: ORR (PD-L1 Score >= 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 >= 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 Investigator	35.0 (15.4 to 59.2) 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 ≥ 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

	and Treatment of Cancer Quality of Life Questionnaire Symptom Specific Scale for Cervical Cancer (EORTC QLQ-CX24) Index Score.

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 (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1	0000 (± 0000)	77.38 (± 21.78)	0000 (± 0000)	84.24 (± 18.19)
Cycle 2 Day 1	17.86 (± 35.69)	0000 (± 0000)	20.03 (± 36.62)	0000 (± 0000)
Cycle 5 Day 1	36.66 (± 44.97)	113.80 (± 24.68)	41.51 (± 42.89)	128.48 (± 24.06)
Cycle 9 Day 1	42.84 (± 46.50)	0000 (± 0000)	56.78 (± 28.55)	0000 (± 0000)
Cycle 17 Day 1	45.16 (± 55.71)	0000 (± 0000)	56.25 (± 21.56)	0000 (± 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	
Polyarthritis			
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	1 / 40 (2.50%)	11 / 138 (7.97%)	
occurrences (all)	1	11	
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	1 / 40 (2.50%)	8 / 138 (5.80%)	
occurrences (all)	3	9	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 40 (5.00%)	13 / 138 (9.42%)	
occurrences (all)	2	15	
Dyspnoea			
subjects affected / exposed	0 / 40 (0.00%)	6 / 138 (4.35%)	
occurrences (all)	0	6	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	3 / 40 (7.50%)	5 / 138 (3.62%)	
occurrences (all)	3	5	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 40 (10.00%)	16 / 138 (11.59%)	
occurrences (all)	5	24	
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 40 (12.50%)	24 / 138 (17.39%)	
occurrences (all)	6	35	
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 40 (7.50%)	12 / 138 (8.70%)	
occurrences (all)	3	14	
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 40 (7.50%)	4 / 138 (2.90%)	
occurrences (all)	3	4	
Blood creatinine increased			
subjects affected / exposed	6 / 40 (15.00%)	16 / 138 (11.59%)	
occurrences (all)	6	25	
Blood lactate dehydrogenase increased			

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

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

subjects affected / exposed	3 / 40 (7.50%)	4 / 138 (2.90%)	
occurrences (all)	3	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