



Clinical trial results:

A Phase 3, Randomized, Open-Label Study to Compare Ociperlimab (BGB-A1217) Plus Tislelizumab (BGB-A317) Versus Durvalumab in Patients With Locally Advanced, Unresectable, PD-L1-Selected Non-Small Cell Lung Cancer Whose Disease Has Not Progressed After Concurrent Chemoradiotherapy

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2020-004656-14 |
| Trial protocol | FR DE NL PL ES IT |
| Global end of trial date | 17 October 2023 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 25 October 2024 |
| First version publication date | 25 October 2024 |

Trial information

Trial identification

| | |
|-----------------------|--------------------|
| Sponsor protocol code | BGB-A317-A1217-301 |
|-----------------------|--------------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04866017 |
| WHO universal trial number (UTN) | - |

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 | 17 October 2023 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 17 October 2023 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the safety and efficacy of ociperlimab in combination with tislelizumab compared to durvalumab in adults with stage III unresectable PD-L1-selected non-small cell lung cancer whose disease has not progressed after cCRT.

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 | 17 June 2021 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------|
| Country: Number of subjects enrolled | China: 45 |
| Country: Number of subjects enrolled | Taiwan: 6 |
| Country: Number of subjects enrolled | United States: 4 |
| Country: Number of subjects enrolled | Australia: 3 |
| Country: Number of subjects enrolled | Spain: 5 |
| Worldwide total number of subjects | 63 |
| EEA total number of subjects | 5 |

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) | 33 |
| From 65 to 84 years | 30 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled in multiple study centers in Taiwan, China, Spain , United States, and Australia. The first participant was consented on June 17th, 2021, and the last participant completed on October 17th, 2023. The decision to terminate the study was made on July 11th, 2023.

Pre-assignment

Screening details:

This study began under Protocol Amendment (PA) 1. PA 2 was later introduced, but no participants enrolled under it before the study ended. PA 2 revised eligibility criteria, treatment, objectives, and endpoints, and excluded participants from PA 1 in the primary and secondary efficacy analyses.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|-----------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Ociperlimab + Tislelizumab + cCRT |

Arm description:

Participants enrolled in PA 1 received two cycles of ociperlimab (900 mg) and tislelizumab (200 mg) intravenously every three weeks, combined with concurrent chemoradiotherapy (cCRT). Chemotherapy regimens varied based on investigator discretion, including options such as cisplatin with etoposide, carboplatin with paclitaxel, or platinum-based regimens with pemetrexed for non-squamous histology; alongside radiotherapy. After the cCRT phase, participants continued ociperlimab and tislelizumab treatment for up to one year.

| | |
|--|-----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Tislelizumab |
| Investigational medicinal product code | |
| Other name | BGB-A317 |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

200 mg intravenously every three weeks

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

Dosage and administration details:

900 milligrams (mg) intravenously every three weeks

| | |
|------------------|---------------------|
| Arm title | Tislelizumab + cCRT |
|------------------|---------------------|

Arm description:

Participants in PA 1 received two cycles of tislelizumab (200 mg) intravenously every three weeks, combined with concurrent chemoradiotherapy (cCRT). The chemotherapy regimen was determined by the investigator and included options like cisplatin with etoposide, carboplatin with paclitaxel, or platinum-based regimens with pemetrexed for non-squamous histology; alongside radiotherapy. Following the cCRT phase, participants continued tislelizumab treatment for up to one year.

| | |
|--|-----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Tislelizumab |
| Investigational medicinal product code | |
| Other name | BGB-A317 |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

200 mg intravenously every three weeks

| | |
|------------------|-----------------------------|
| Arm title | cCRT Followed by Durvalumab |
|------------------|-----------------------------|

Arm description:

Participants in PA 1 received two cycles of concurrent chemoradiotherapy (cCRT), followed by durvalumab (10 mg/kg intravenously every 2 weeks, or 1500 mg every 4 weeks if locally approved). The chemotherapy regimen was chosen by the investigator and included options such as cisplatin with etoposide, carboplatin with paclitaxel, or pemetrexed with a platinum agent for non-squamous histology; alongside radiotherapy. After cCRT, participants continued durvalumab treatment for up to one year.

| | |
|--|-----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Durvalumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

10 milligrams per kilogram (mg/kg) intravenously once every 2 weeks (or 1500 mg intravenously once every 4 weeks where the dosage has been approved by a local health authority)

| Number of subjects in period 1 | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab |
|---------------------------------------|--------------------------------------|---------------------|--------------------------------|
| Started | 22 | 19 | 22 |
| Treated | 22 | 18 | 22 |
| Completed | 0 | 0 | 0 |
| Not completed | 22 | 19 | 22 |
| Consent withdrawn by subject | 1 | - | 1 |
| Physician decision | - | 1 | - |
| Death | 8 | 4 | 8 |
| Study Terminated by Sponsor | 13 | 14 | 13 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-----------------------------------|
| Reporting group title | Ociperlimab + Tislelizumab + cCRT |
|-----------------------|-----------------------------------|

Reporting group description:

Participants enrolled in PA 1 received two cycles of ociperlimab (900 mg) and tislelizumab (200 mg) intravenously every three weeks, combined with concurrent chemoradiotherapy (cCRT). Chemotherapy regimens varied based on investigator discretion, including options such as cisplatin with etoposide, carboplatin with paclitaxel, or platinum-based regimens with pemetrexed for non-squamous histology; alongside radiotherapy. After the cCRT phase, participants continued ociperlimab and tislelizumab treatment for up to one year.

| | |
|-----------------------|---------------------|
| Reporting group title | Tislelizumab + cCRT |
|-----------------------|---------------------|

Reporting group description:

Participants in PA 1 received two cycles of tislelizumab (200 mg) intravenously every three weeks, combined with concurrent chemoradiotherapy (cCRT). The chemotherapy regimen was determined by the investigator and included options like cisplatin with etoposide, carboplatin with paclitaxel, or platinum-based regimens with pemetrexed for non-squamous histology; alongside radiotherapy. Following the cCRT phase, participants continued tislelizumab treatment for up to one year.

| | |
|-----------------------|-----------------------------|
| Reporting group title | cCRT Followed by Durvalumab |
|-----------------------|-----------------------------|

Reporting group description:

Participants in PA 1 received two cycles of concurrent chemoradiotherapy (cCRT), followed by durvalumab (10 mg/kg intravenously every 2 weeks, or 1500 mg every 4 weeks if locally approved). The chemotherapy regimen was chosen by the investigator and included options such as cisplatin with etoposide, carboplatin with paclitaxel, or pemetrexed with a platinum agent for non-squamous histology; alongside radiotherapy. After cCRT, participants continued durvalumab treatment for up to one year.

| Reporting group values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab |
|---|--------------------------------------|---------------------|--------------------------------|
| Number of subjects | 22 | 19 | 22 |
| Age categorical Units: Subjects | | | |
| In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over | | | |
| Age continuous | | | |
| The Intent-to-Treat (ITT) Analysis Set is defined as all randomized participants. | | | |
| Units: years | | | |
| arithmetic mean | 63.4 | 62.4 | 64.1 |
| standard deviation | ± 7.51 | ± 9.27 | ± 7.36 |
| Gender categorical | | | |
| The Intent-to-Treat (ITT) Analysis Set is defined as all randomized participants. | | | |
| Units: Subjects | | | |

| | | | |
|--------|----|----|----|
| Female | 3 | 5 | 0 |
| Male | 19 | 14 | 22 |

| | | | |
|---|-------|--|--|
| Reporting group values | Total | | |
| Number of subjects | 63 | | |
| 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 | | | |
| The Intent-to-Treat (ITT) Analysis Set is defined as all randomized participants. | | | |
| Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Gender categorical | | | |
| The Intent-to-Treat (ITT) Analysis Set is defined as all randomized participants. | | | |
| Units: Subjects | | | |
| Female | 8 | | |
| Male | 55 | | |

End points

End points reporting groups

| | |
|-----------------------|-----------------------------------|
| Reporting group title | Ociperlimab + Tislelizumab + cCRT |
|-----------------------|-----------------------------------|

Reporting group description:

Participants enrolled in PA 1 received two cycles of ociperlimab (900 mg) and tislelizumab (200 mg) intravenously every three weeks, combined with concurrent chemoradiotherapy (cCRT). Chemotherapy regimens varied based on investigator discretion, including options such as cisplatin with etoposide, carboplatin with paclitaxel, or platinum-based regimens with pemetrexed for non-squamous histology; alongside radiotherapy. After the cCRT phase, participants continued ociperlimab and tislelizumab treatment for up to one year.

| | |
|-----------------------|---------------------|
| Reporting group title | Tislelizumab + cCRT |
|-----------------------|---------------------|

Reporting group description:

Participants in PA 1 received two cycles of tislelizumab (200 mg) intravenously every three weeks, combined with concurrent chemoradiotherapy (cCRT). The chemotherapy regimen was determined by the investigator and included options like cisplatin with etoposide, carboplatin with paclitaxel, or platinum-based regimens with pemetrexed for non-squamous histology; alongside radiotherapy. Following the cCRT phase, participants continued tislelizumab treatment for up to one year.

| | |
|-----------------------|-----------------------------|
| Reporting group title | cCRT Followed by Durvalumab |
|-----------------------|-----------------------------|

Reporting group description:

Participants in PA 1 received two cycles of concurrent chemoradiotherapy (cCRT), followed by durvalumab (10 mg/kg intravenously every 2 weeks, or 1500 mg every 4 weeks if locally approved). The chemotherapy regimen was chosen by the investigator and included options such as cisplatin with etoposide, carboplatin with paclitaxel, or pemetrexed with a platinum agent for non-squamous histology; alongside radiotherapy. After cCRT, participants continued durvalumab treatment for up to one year.

Primary: Progression-Free Survival (PFS) as Assessed by the Independent Review Committee (IRC)

| | |
|-----------------|--|
| End point title | Progression-Free Survival (PFS) as Assessed by the Independent Review Committee (IRC) ^[1] |
|-----------------|--|

End point description:

PFS is defined as the time from the date of randomization to the date of first documentation of disease progression as assessed by the IRC per Response Evaluation Criteria in Solid Tumors (RECIST) Version (v) 1.1 or death, whichever occurred first.

The primary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

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

End point timeframe:

From randomization through to the end of study, planned duration was 20 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: Since no participants were enrolled under PA 2, no analyses of the primary or secondary endpoints were conducted. Participants enrolled under PA 1 were excluded from the primary and secondary analyses outlined for PA 2.

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|----------------------------------|---|------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[2] | 0 ^[3] | 0 ^[4] | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | (to) | (to) | |

Notes:

[2] - No participants were enrolled under PA 2.

[3] - No participants were enrolled under PA 2.

[4] - No participants were enrolled under PA 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 randomization until the date of death due to any cause. This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

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

End point timeframe:

From randomization through to the end of study, planned duration was 20 months

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|----------------------------------|---|------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[5] | 0 ^[6] | 0 ^[7] | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | (to) | (to) | |

Notes:

[5] - No participants were enrolled under PA 2.

[6] - No participants were enrolled under PA 2.

[7] - No participants were enrolled under PA 2.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR)

| | |
|-----------------|-----------------------------|
| End point title | Overall Response Rate (ORR) |
|-----------------|-----------------------------|

End point description:

Defined as the percentage of participants who achieved a complete response (CR) or partial response (PR) assessed by both the IRC and investigators per RECIST v1.1. This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From randomization through to the end of study, planned duration was 20 months | |

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|-----------------------------------|-----------------------------------|---------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[8] | 0 ^[9] | 0 ^[10] | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | (to) | (to) | (to) | |

Notes:

[8] - No participants were enrolled under PA 2.

[9] - No participants were enrolled under PA 2.

[10] - No participants were enrolled under PA 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 determination of a confirmed objective response assessed by both the IRC and investigators per RECIST v1.1 until the first documentation of disease progression or death, whichever occurs first. This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2. | |
| End point type | Secondary |
| End point timeframe: | |
| From randomization through to the end of study, planned duration was 20 months | |

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|----------------------------------|-----------------------------------|---------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[11] | 0 ^[12] | 0 ^[13] | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | (to) | (to) | |

Notes:

[11] - No participants were enrolled under PA 2.

[12] - No participants were enrolled under PA 2.

[13] - No participants were enrolled under PA 2.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Death or Distant Metastasis (TTDM) as Assessed by the Investigator

| | |
|-----------------|--|
| End point title | Time to Death or Distant Metastasis (TTDM) as Assessed by the Investigator |
|-----------------|--|

End point description:

defined as the time from the date of randomization until the first date of distant metastasis assessed by both the IRC and investigators, or death. Distant metastasis is defined as any new lesion that is outside of the radiation field per RECIST v1.1 or proven by biopsy. This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

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

End point timeframe:

From randomization through to the end of study, planned duration was 20 months

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|----------------------------------|---|------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[14] | 0 ^[15] | 0 ^[16] | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | (to) | (to) | |

Notes:

[14] - No participants were enrolled under PA 2.

[15] - No participants were enrolled under PA 2.

[16] - No participants were enrolled under PA 2.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival 2 (PFS2)

| | |
|-----------------|------------------------------------|
| End point title | Progression-Free Survival 2 (PFS2) |
|-----------------|------------------------------------|

End point description:

Defined as the time from randomization to the disease progression after next line of treatment, or death from any cause, whichever occurs first. This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

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

End point timeframe:

From randomization through to the end of study, planned duration was 20 months

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|----------------------------------|-----------------------------------|---------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[17] | 0 ^[18] | 0 ^[19] | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | (to) | (to) | |

Notes:

[17] - No participants were enrolled under PA 2.

[18] - No participants were enrolled under PA 2.

[19] - No participants were enrolled under PA 2.

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) determined according to National Cancer Institute Common Terminology Criteria for Adverse Events Version 5.0 (NCI CTCAE v5.0). The Safety Analysis Set included all randomized patients who received any dose of study treatment.

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

End point timeframe:

From first dose to 30 days after the last dose or initiation of a new anticancer therapy, whichever occurred first; through study completion data cut-off date of October 17th, 2023 (maximum time on treatment was 16 months)

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|------------------------------|-----------------------------------|---------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 22 | 18 | 22 | |
| Units: Count of Participants | | | | |
| number (not applicable) | | | | |
| TEAEs | 22 | 18 | 22 | |
| SAEs | 11 | 8 | 8 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) Global Health Status

| | |
|-----------------|---|
| End point title | Change From Baseline in European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) Global Health Status |
|-----------------|---|

End point description:

Mean change from baseline in EORTC QLQ-C30 Global Health Status/Quality of Life score. The EORTC QLQ-C30 v3.0 is a questionnaire that assesses quality of life of participants with cancer. It includes global health status and quality of life questions related to overall health in which participants respond based on a 7-point scale, where 1 is very poor and 7 is excellent. Raw scores are transformed into a 0 to 100 scale via linear transformation. A higher score indicates better health outcomes.

This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Every 2 Cycles (6 weeks) until End of Treatment (each cycle is 21 days) | |

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|--------------------------------------|---|------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[20] | 0 ^[21] | 0 ^[22] | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | () | () | () | |

Notes:

[20] - No participants were enrolled under PA 2.

[21] - No participants were enrolled under PA 2.

[22] - No participants were enrolled under PA 2.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Related Quality of Life (HRQoL) as Assessed by Quality of Life QuestionnaireLung Cancer 13 (QLQ-LC13)

| | |
|-----------------|--|
| End point title | Change From Baseline in Health Related Quality of Life (HRQoL) as Assessed by Quality of Life QuestionnaireLung Cancer 13 (QLQ-LC13) |
|-----------------|--|

End point description:

Mean change from baseline in QLQ-CL13 scores for coughing, dyspnea, and chest pain. The QLQ-LC13 is a questionnaire that measures lung cancer-specific disease and treatment symptoms. It includes questions about specific symptoms in which participants respond based on a 4-point scale, where 1 is "not at all" and 4 is "very much". Raw scores are transformed into a 0 to 100 scale via linear transformation. A lower score indicates an improvement in symptoms.

This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Every 2 Cycles (6 weeks) until End of Treatment (each cycle is 21 days) | |

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|--------------------------------------|-----------------------------------|---------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[23] | 0 ^[24] | 0 ^[25] | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | () | () | () | |

Notes:

[23] - No participants were enrolled under PA 2.

[24] - No participants were enrolled under PA 2.

[25] - No participants were enrolled under PA 2.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Related Quality of Life (HRQoL) as Assessed by European Quality of Life-5 Dimensions (EQ-5D-5L)

| | |
|-----------------|--|
| End point title | Change From Baseline in Health Related Quality of Life (HRQoL) as Assessed by European Quality of Life-5 Dimensions (EQ-5D-5L) |
|-----------------|--|

End point description:

The EuroQol 5D-5L a descriptive system that comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The participant is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the participant's health state.

This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

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

End point timeframe:

Every 2 Cycles (6 weeks) until End of Treatment (each cycle is 21 days)

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|--------------------------------------|-----------------------------------|---------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[26] | 0 ^[27] | 0 ^[28] | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | () | () | () | |

Notes:

[26] - No participants were enrolled under PA 2.

[27] - No participants were enrolled under PA 2.

[28] - No participants were enrolled under PA 2.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Ociperlimab

| | |
|-----------------|--|
| End point title | Serum Concentration of Ociperlimab ^[29] |
|-----------------|--|

End point description:

Serum concentrations of ociperlimab were measured for participants in the Ociperlimab + Tislelizumab + cCRT treatment group at predose (within 60 minutes before starting infusion) and postdose (within 30 minutes after the end of infusion). End of Treatment (EOT) visits occurred within 7 days after the date the investigator determined that study treatment would no longer be used, or before the initiation of a new anticancer treatment, whichever occurred first. The Pharmacokinetics (PK) Analysis Set includes all patients who receive any dose of any component of study drugs and for whom any postdose PK data are available.

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

End point timeframe:

Predose at Day 1 of Cycles 1, 2, 5, 9, and 17; postdose on Day 1 of Cycles 1, 5 and EOT visit (Each Cycle was 21 days)

Notes:

[29] - 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: Since no participants were enrolled under PA 2, no analyses of the primary or secondary endpoints were conducted. Participants enrolled under PA 1 were excluded from the primary and secondary analyses outlined for PA 2.

| End point values | Ociperlimab + Tislelizumab + cCRT | | | |
|---|-----------------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 22 | | | |
| Units: ug/ml | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cycle 1 Day 1 Predose | 18 (± 0000) | | | |
| Cycle 1 Day 1 Postdose | 312 (± 45.82) | | | |
| Cycle 2 Day 1 Predose | 34.54 (± 63.19) | | | |
| Cycle 2 Day 1 Postdose | 0 (± 0) | | | |
| Cycle 5 Day 1 Predose | 74.86 (± 61.76) | | | |
| Cycle 5 Day 1 Postdose | 339.31 (± 38.21) | | | |
| Cycle 9 Day 1 Predose | 52.4 (± 82.40) | | | |
| Cycle 9 Day 1 Postdose | 0 (± 0) | | | |
| Cycle 17 Day 1 Predose | 81.35 (± 53.83) | | | |
| Cycle 17 Day 1 Postdose | 0 (± 0) | | | |
| End of Treatment | 94.94 (± 232.05) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Tislelizumab for Participants in the Ociperlimab + Tislelizumab + cCRT Treatment Group

| | |
|-----------------|---|
| End point title | Serum Concentration of Tislelizumab for Participants in the Ociperlimab + Tislelizumab + cCRT Treatment Group ^[30] |
|-----------------|---|

End point description:

Serum concentrations of tislelizumab were collected for participants in the Ociperlimab + Tislelizumab + cCRT treatment group at predose (within 60 minutes before starting infusion) and postdose (within 30 minutes after the end of infusion). End of Treatment (EOT) visits occurred within 7 days after the date investigator determined that study treatment would no longer be used, or before the initiation of a new anticancer treatment, whichever occurred first. The Pharmacokinetics (PK) Analysis Set includes all patients who receive any dose of any component of study drugs and for whom any postdose PK data are available.

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

End point timeframe:

Predose at Day 1 of Cycles 1, 2, 5, 9, 17; postdose on Day 1 of Cycles 1 and 5, and EOT visit (each cycle was 21 days)

Notes:

[30] - 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: Since no participants were enrolled under PA 2, no analyses of the primary or secondary endpoints were conducted. Participants enrolled under PA 1 were excluded from the primary and secondary analyses outlined for PA 2.

| End point values | Ociperlimab + Tislelizumab + cCRT | | | |
|---|-----------------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 22 | | | |
| Units: ug/mL | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cycle 1 Day 1 Predose | 9999 (± 9999) | | | |
| Cycle 1 Day 1 Postdose | 72.20 (± 26.27) | | | |
| Cycle 2 Day 1 Predose | 15.91 (± 78.83) | | | |
| Cycle 2 Day 1 Postdose | 0 (± 0) | | | |
| Cycle 5 Day 1 Predose | 34.10 (± 49.67) | | | |
| Cycle 5 Day 1 Postdose | 97.08 (± 23.09) | | | |
| Cycle 9 Day 1 Predose | 30.22 (± 55.34) | | | |
| Cycle 9 Day 1 Postdose | 0 (± 0) | | | |
| Cycle 17 Day 1 Predose | 32.24 (± 156.53) | | | |
| Cycle 17 Day 1 Postdose | 0 (± 0) | | | |
| End of Treatment | 49.55 (± 89.19) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Tislelizumab for Participants in the Tislelizumab

+ cCRT Treatment Group

| | |
|-----------------|---|
| End point title | Serum Concentration of Tislelizumab for Participants in the Tislelizumab + cCRT Treatment Group ^[31] |
|-----------------|---|

End point description:

Serum concentrations of tislelizumab were collected for participants in the Tislelizumab + cCRT treatment group at predose (within 60 minutes prior to infusion initiation) and postdose (within 30 minutes after the completion of infusion). End of Treatment (EOT) visits occurred within 7 days after the date investigator determined that study treatment would no longer be used, or before the initiation of a new anticancer treatment, whichever occurred first.

PK Analysis Set; Tislelizumab concentration data are reported here for participants in the Tislelizumab + cCRT treatment group. Only participants with available data are included at each time point.

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

End point timeframe:

Predose at Day 1 of Cycles 1, 2, 5, 9, and 17; postdose on Day 1 of Cycles 1 and 5, and EOT visit (Each Cycle is 21 days)

Notes:

[31] - 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: Since no participants were enrolled under PA 2, no analyses of the primary or secondary endpoints were conducted. Participants enrolled under PA 1 were excluded from the primary and secondary analyses outlined for PA 2.

| End point values | Tislelizumab + cCRT | | | |
|---|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: ug/mL | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cycle 1 Day 1 Predose | 0000 (± 0000) | | | |
| Cycle 1 Day 1 Postdose | 73.41 (± 18.53) | | | |
| Cycle 2 Day 1 Predose | 19.69 (± 27.01) | | | |
| Cycle 2 Day 1 Postdose | 0 (± 0) | | | |
| Cycle 5 Day 1 Predose | 37.64 (± 47.00) | | | |
| Cycle 5 Day 1 Postdose | 100.26 (± 29.25) | | | |
| Cycle 9 Day 1 Predose | 36.98 (± 39.63) | | | |
| Cycle 9 Day 1 Postdose | 0 (± 0) | | | |
| Cycle 17 Day 1 Predose | 41.29 (± 55.41) | | | |
| Cycle 17 Day 1 Postdose | 0 (± 0) | | | |
| End of Treatment | 40.18 (± 139.51) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenic Responses to Ociperlimab as Assessed by the Detection of Treatment Emergent Anti-Drug Antibodies (ADAs)

| | |
|-----------------|---|
| End point title | Immunogenic Responses to Ociperlimab as Assessed by the Detection of Treatment Emergent Anti-Drug Antibodies (ADAs) ^[32] |
|-----------------|---|

End point description:

Defined as the sum of treatment-boosted and treatment-induced ADA participants as a proportion percentage of the ADA-evaluable participants population and is synonymous with 'ADA Incidence'. ADA samples were collected for participants randomized to Arm A (ociperlimab and tislelizumab). The Immunogenicity Analysis Set includes all participants who received any dose of any component of study drugs and for whom both baseline antidrug antibody (ADA) and at least 1 postbaseline ADA result were available.

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

End point timeframe:

Predose (within 60 minutes before dose) on Day 1 of Cycles 1, 2, 5, 9, 17, and the EOT Visit (Each cycle is 21 days). Maximum number of treatment cycles was 19

Notes:

[32] - 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: Since no participants were enrolled under PA 2, no analyses of the primary or secondary endpoints were conducted. Participants enrolled under PA 1 were excluded from the primary and secondary analyses outlined for PA 2.

| | | | | |
|------------------------------|-----------------------------------|--|--|--|
| End point values | Ociperlimab + Tislelizumab + cCRT | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 20 | | | |
| Units: Count of Participants | | | | |
| number (not applicable) | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenic Responses to Tislelizumab as Assessed by the Detection of Treatment Emergent Anti-Drug Antibodies (ADAs)

| | |
|-----------------|--|
| End point title | Immunogenic Responses to Tislelizumab as Assessed by the Detection of Treatment Emergent Anti-Drug Antibodies (ADAs) ^[33] |
|-----------------|--|

End point description:

Defined as the sum of treatment-boosted and treatment-induced ADA participants as a proportion percentage of the ADA-evaluable participants population and is synonymous with 'ADA Incidence'. ADA samples were collected for participants randomized to Arm A (Ociperlimab + Tislelizumab + cCRT) and Arm B (Tislelizumab + cCRT). The Immunogenicity Analysis Set includes all participants who received any dose of any component of study drugs and for whom both baseline antidrug antibody (ADA) and at least 1 postbaseline ADA result were available.

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

End point timeframe:

Predose (within 60 minutes before dose) on Day 1 of Cycles 1, 2, 5, 9, 17, and the EOT Visit (Each cycle is 21 days, maximum number of treatment cycles was 19)

Notes:

[33] - 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: Since no participants were enrolled under PA 2, no analyses of the primary or secondary endpoints were conducted. Participants enrolled under PA 1 were excluded from the primary and secondary analyses outlined for PA 2.

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | | |
|------------------------------|-----------------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 17 | | |
| Units: Count of Participants | | | | |
| number (not applicable) | 10 | 5 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Programmed Death-Ligand 1 (PD-L1) and T-cell Immunoreceptor With Ig and ITIM Domains (TIGIT) Expression in Archival and/or Fresh Tumor Tissues

| | |
|-----------------|--|
| End point title | Programmed Death-Ligand 1 (PD-L1) and T-cell Immunoreceptor With Ig and ITIM Domains (TIGIT) Expression in Archival and/or Fresh Tumor Tissues |
|-----------------|--|

End point description:

This secondary endpoint was specified in PA 2 and excludes participants enrolled under PA 1. No participants were enrolled under PA 2.

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

End point timeframe:

From randomization through to the end of study, planned duration was 20 months

| End point values | Ociperlimab + Tislelizumab + cCRT | Tislelizumab + cCRT | cCRT Followed by Durvalumab | |
|------------------------------|-----------------------------------|---------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[34] | 0 ^[35] | 0 ^[36] | |
| Units: Count of Participants | | | | |
| number (not applicable) | | | | |

Notes:

[34] - No participants were enrolled under PA 2.

[35] - No participants were enrolled under PA 2.

[36] - No participants were enrolled under PA 2.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose to 30 days after the last dose or initiation of a new anticancer therapy, whichever occurred first; through study completion data cut-off date of October 17th, 2023 (maximum time on treatment was 16 months)

Adverse event reporting additional description:

All-cause mortality is reported for all randomized participants. Serious and other adverse events include all randomized participants who received ≥ 1 dose of any study treatment.

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 26 |

Reporting groups

| | |
|-----------------------|-----------------------------------|
| Reporting group title | Ociperlimab + Tislelizumab + cCRT |
|-----------------------|-----------------------------------|

Reporting group description:

Participants enrolled in PA 1 received two cycles of ociperlimab (900 mg) and tislelizumab (200 mg) intravenously every three weeks, combined with concurrent chemoradiotherapy (cCRT). Chemotherapy regimens varied based on investigator discretion, including options such as cisplatin with etoposide, carboplatin with paclitaxel, or platinum-based regimens with pemetrexed for non-squamous histology; alongside radiotherapy. After the cCRT phase, participants continued ociperlimab and tislelizumab treatment for up to one year.

| | |
|-----------------------|-----------------------------|
| Reporting group title | cCRT Followed by Durvalumab |
|-----------------------|-----------------------------|

Reporting group description:

Participants in PA 1 received two cycles of concurrent chemoradiotherapy (cCRT), followed by durvalumab (10 mg/kg intravenously every 2 weeks, or 1500 mg every 4 weeks if locally approved). The chemotherapy regimen was chosen by the investigator and included options such as cisplatin with etoposide, carboplatin with paclitaxel, or pemetrexed with a platinum agent for non-squamous histology; alongside radiotherapy. After cCRT, participants continued durvalumab treatment for up to one year.

| | |
|-----------------------|---------------------|
| Reporting group title | Tislelizumab + cCRT |
|-----------------------|---------------------|

Reporting group description:

Participants in PA 1 received two cycles of tislelizumab (200 mg) intravenously every three weeks, combined with concurrent chemoradiotherapy (cCRT). The chemotherapy regimen was determined by the investigator and included options like cisplatin with etoposide, carboplatin with paclitaxel, or platinum-based regimens with pemetrexed for non-squamous histology; alongside radiotherapy. Following the cCRT phase, participants continued tislelizumab treatment for up to one year.

| Serious adverse events | Ociperlimab + Tislelizumab + cCRT | cCRT Followed by Durvalumab | Tislelizumab + cCRT |
|---|--------------------------------------|--------------------------------|---------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 11 / 22 (50.00%) | 8 / 22 (36.36%) | 8 / 18 (44.44%) |
| number of deaths (all causes) | 8 | 8 | 4 |
| number of deaths resulting from adverse events | 1 | 2 | 1 |
| Investigations | | | |
| Neutrophil count decreased | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transaminases increased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Infected neoplasm | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Radiation oesophagitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Radiation pneumonitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Stomatitis | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchopleural fistula | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 22 (9.09%) | 1 / 18 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 22 (0.00%) | 2 / 18 (11.11%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune-mediated lung disease | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 0 / 22 (0.00%) | 2 / 18 (11.11%) |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pathological fracture | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Type 1 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | Ociperlimab + Tislelizumab + cCRT | cCRT Followed by Durvalumab | Tislelizumab + cCRT |
|---|--------------------------------------|--------------------------------|---------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 22 / 22 (100.00%) | 22 / 22 (100.00%) | 18 / 18 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Lipoma | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cancer pain | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular disorders | | | |
| Phlebitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 2 / 22 (9.09%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 2 | 2 |
| Haematoma | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Flushing | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aortic arteriosclerosis | | | |

| | | | |
|--|-----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 4 / 22 (18.18%) | 5 / 22 (22.73%) | 1 / 18 (5.56%) |
| occurrences (all) | 4 | 5 | 1 |
| Chest discomfort | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 1 | 1 |
| Facial pain | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 | 1 |
| Chills | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 2 | 1 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 3 / 22 (13.64%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Malaise | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Influenza like illness | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 4 / 22 (18.18%) | 2 / 22 (9.09%) | 4 / 18 (22.22%) |
| occurrences (all) | 5 | 2 | 5 |
| Puncture site pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 0 / 22 (0.00%) | 4 / 18 (22.22%) |
| occurrences (all) | 5 | 0 | 7 |
| Swelling face | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Immune system disorders | | | |
| Contrast media allergy | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 2 / 18 (11.11%) |
| occurrences (all) | 1 | 0 | 2 |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infusion related hypersensitivity reaction | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 1 | 0 | 1 |
| Atelectasis | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cough | | | |
| subjects affected / exposed | 4 / 22 (18.18%) | 5 / 22 (22.73%) | 5 / 18 (27.78%) |
| occurrences (all) | 5 | 6 | 6 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Dyspnoea | | | |
| subjects affected / exposed | 4 / 22 (18.18%) | 2 / 22 (9.09%) | 2 / 18 (11.11%) |
| occurrences (all) | 4 | 2 | 2 |
| Dysphonia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 2 / 22 (9.09%) | 3 / 18 (16.67%) |
| occurrences (all) | 2 | 4 | 3 |
| Hiccups | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 3 / 22 (13.64%) | 2 / 18 (11.11%) |
| occurrences (all) | 4 | 4 | 4 |
| Hydrothorax | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune-mediated lung disease | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 1 | 1 |
| Increased viscosity of bronchial secretion | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 3 / 22 (13.64%) | 2 / 18 (11.11%) |
| occurrences (all) | 3 | 3 | 2 |

| | | | |
|--|----------------------|---------------------|----------------------|
| Pleural effusion subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 1 / 22 (4.55%) 1 | 0 / 18 (0.00%) 0 |
| Pleural thickening subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 22 (4.55%) 1 | 0 / 18 (0.00%) 0 |
| Pneumonitis subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 2 / 22 (9.09%) 2 | 1 / 18 (5.56%) 2 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 22 (4.55%) 1 | 1 / 18 (5.56%) 1 |
| Pulmonary oedema subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 22 (4.55%) 1 | 0 / 18 (0.00%) 0 |
| Productive cough subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 2 / 22 (9.09%) 2 | 2 / 18 (11.11%) 3 |
| Psychiatric disorders Tic subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 22 (0.00%) 0 | 0 / 18 (0.00%) 0 |
| Insomnia subjects affected / exposed occurrences (all) | 3 / 22 (13.64%) 4 | 1 / 22 (4.55%) 1 | 3 / 18 (16.67%) 3 |
| Depression subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 22 (4.55%) 1 | 0 / 18 (0.00%) 0 |
| Investigations Blood alkaline phosphatase increased subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 22 (4.55%) 1 | 0 / 18 (0.00%) 0 |
| Blood bilirubin increased subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 3 | 1 / 22 (4.55%) 1 | 2 / 18 (11.11%) 3 |
| Bilirubin conjugated increased | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 2 / 18 (11.11%) |
| occurrences (all) | 0 | 0 | 2 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 6 / 22 (27.27%) | 4 / 22 (18.18%) | 0 / 18 (0.00%) |
| occurrences (all) | 10 | 5 | 0 |
| Blood bilirubin unconjugated increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 8 / 22 (36.36%) | 6 / 22 (27.27%) | 0 / 18 (0.00%) |
| occurrences (all) | 15 | 9 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood creatine phosphokinase MB increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Blood chloride decreased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 4 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 2 | 1 | 4 |
| Blood fibrinogen increased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 2 / 22 (9.09%) | 1 / 18 (5.56%) |
| occurrences (all) | 4 | 3 | 2 |
| Blood creatinine decreased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |

| | | | |
|---|------------------|------------------|-----------------|
| subjects affected / exposed | 2 / 22 (9.09%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 2 | 3 | 2 |
| Blood thyroid stimulating hormone decreased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood thyroid stimulating hormone increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 | 1 |
| Blood urea increased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 2 / 18 (11.11%) |
| occurrences (all) | 3 | 0 | 4 |
| Ejection fraction decreased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 2 / 22 (9.09%) | 3 / 18 (16.67%) |
| occurrences (all) | 4 | 2 | 7 |
| Fibrin D dimer increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 2 | 2 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 5 / 22 (22.73%) | 6 / 22 (27.27%) | 5 / 18 (27.78%) |
| occurrences (all) | 7 | 10 | 5 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 14 / 22 (63.64%) | 13 / 22 (59.09%) | 5 / 18 (27.78%) |
| occurrences (all) | 31 | 29 | 13 |
| Myoglobin blood increased | | | |

| | | | |
|----------------------------------|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neutrophil count increased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Platelet count increased | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 8 / 22 (36.36%) | 10 / 22 (45.45%) | 5 / 18 (27.78%) |
| occurrences (all) | 12 | 16 | 6 |
| Occult blood positive | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Weight increased | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 3 / 22 (13.64%) | 1 / 18 (5.56%) |
| occurrences (all) | 6 | 3 | 1 |
| Weight decreased | | | |
| subjects affected / exposed | 4 / 22 (18.18%) | 4 / 22 (18.18%) | 2 / 18 (11.11%) |
| occurrences (all) | 4 | 4 | 2 |
| Troponin T increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| SARS-CoV-2 test positive | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 4 / 22 (18.18%) | 2 / 18 (11.11%) |
| occurrences (all) | 1 | 4 | 2 |
| Red blood cell count decreased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Protein total decreased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| White blood cell count increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| White blood cell count decreased | | | |

| | | | |
|--|------------------------|------------------------|------------------------|
| subjects affected / exposed occurrences (all) | 15 / 22 (68.18%) 45 | 13 / 22 (59.09%) 41 | 10 / 18 (55.56%) 25 |
| Injury, poisoning and procedural complications | | | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fall | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 3 | 1 |
| Radiation fibrosis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Radiation pneumonitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 5 / 22 (22.73%) | 2 / 18 (11.11%) |
| occurrences (all) | 0 | 7 | 2 |
| Radiation oesophagitis | | | |
| subjects affected / exposed | 6 / 22 (27.27%) | 9 / 22 (40.91%) | 3 / 18 (16.67%) |
| occurrences (all) | 6 | 10 | 3 |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Radiation skin injury | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 1 / 22 (4.55%) | 5 / 18 (27.78%) |
| occurrences (all) | 2 | 1 | 5 |
| Cardiac disorders | | | |
| Bundle branch block left | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Atrial fibrillation | | | |

| | | | |
|--------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bundle branch block right | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 | 2 |
| Sinus bradycardia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 0 | 1 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 | 1 |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Supraventricular extrasystoles | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 2 / 22 (9.09%) | 1 / 18 (5.56%) |
| occurrences (all) | 1 | 2 | 1 |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nervous system disorders | | | |
| Disturbance in attention | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 3 / 22 (13.64%) | 0 / 18 (0.00%) |
| occurrences (all) | 2 | 6 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--------------------------------------|------------------|------------------|------------------|
| Headache | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Seizure | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 12 / 22 (54.55%) | 14 / 22 (63.64%) | 10 / 18 (55.56%) |
| occurrences (all) | 14 | 20 | 15 |
| Hypercoagulation | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Hyperfibrinogenaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Leukopenia | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 22 (9.09%) | 4 / 22 (18.18%) | 2 / 18 (11.11%) |
| occurrences (all) | 4 | 9 | 7 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 22 (9.09%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 4 | 1 | 3 |
| Thrombocytosis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 0 | 1 |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 9 / 22 (40.91%) | 8 / 22 (36.36%) | 5 / 18 (27.78%) |
| occurrences (all) | 12 | 10 | 9 |
| Colitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Diarrhoea | | | |

| | | | |
|----------------------------------|-----------------|------------------|-----------------|
| subjects affected / exposed | 3 / 22 (13.64%) | 5 / 22 (22.73%) | 4 / 18 (22.22%) |
| occurrences (all) | 3 | 7 | 4 |
| Dysphagia | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 2 / 22 (9.09%) | 0 / 18 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 | 1 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingival swelling | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 0 / 22 (0.00%) | 5 / 18 (27.78%) |
| occurrences (all) | 3 | 0 | 5 |
| Nausea | | | |
| subjects affected / exposed | 6 / 22 (27.27%) | 11 / 22 (50.00%) | 7 / 18 (38.89%) |
| occurrences (all) | 7 | 18 | 8 |
| Odynophagia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 4 / 22 (18.18%) | 4 / 22 (18.18%) | 4 / 18 (22.22%) |
| occurrences (all) | 4 | 4 | 4 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Toothache | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 22 (4.55%) | 3 / 22 (13.64%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 4 / 22 (18.18%) | 1 / 18 (5.56%) |
| occurrences (all) | 2 | 5 | 1 |
| Hepatobiliary disorders | | | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 7 / 22 (31.82%) | 4 / 18 (22.22%) |
| occurrences (all) | 3 | 7 | 5 |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Decubitus ulcer | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Angioedema | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 22 (9.09%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 2 | 1 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 2 / 22 (9.09%) | 2 / 18 (11.11%) |
| occurrences (all) | 1 | 2 | 3 |
| Papule | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain of skin | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 4 / 22 (18.18%) | 2 / 22 (9.09%) | 2 / 18 (11.11%) |
| occurrences (all) | 5 | 2 | 2 |
| Skin exfoliation | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin fissures | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Renal and urinary disorders | | | |
| Renal cyst | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypothyroidism | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 4 / 22 (18.18%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 4 | 1 |
| Thyroid mass | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Thyroiditis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 2 / 22 (9.09%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Osteoporotic fracture | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Arthralgia | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 3 / 22 (13.64%) | 2 / 18 (11.11%) |
| occurrences (all) | 3 | 5 | 2 |
| Back pain | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 2 / 22 (9.09%) | 3 / 18 (16.67%) |
| occurrences (all) | 1 | 4 | 3 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 22 (9.09%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Infections and infestations | | | |
| Body tinea | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 4 / 22 (18.18%) | 2 / 18 (11.11%) |
| occurrences (all) | 0 | 4 | 2 |
| COVID-19 pneumonia | | | |

| | | | |
|-----------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 22 (9.09%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Diarrhoea infectious | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| External ear cellulitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 2 / 22 (9.09%) | 0 / 18 (0.00%) |
| occurrences (all) | 2 | 4 | 0 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 1 / 22 (4.55%) | 4 / 18 (22.22%) |
| occurrences (all) | 2 | 1 | 5 |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 3 / 22 (13.64%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Suspected COVID-19 | | | |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 2 / 22 (9.09%) | 4 / 18 (22.22%) |
| occurrences (all) | 1 | 2 | 5 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 2 / 18 (11.11%) |
| occurrences (all) | 0 | 0 | 2 |
| Metabolism and nutrition disorders | | | |
| Folate deficiency | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 2 | 0 | 1 |
| Decreased appetite | | | |
| subjects affected / exposed | 7 / 22 (31.82%) | 7 / 22 (31.82%) | 5 / 18 (27.78%) |
| occurrences (all) | 8 | 9 | 7 |
| Glucose tolerance impaired | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 1 | 1 | 2 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 2 / 22 (9.09%) | 1 / 18 (5.56%) |
| occurrences (all) | 2 | 3 | 5 |
| Hyperphosphataemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypermagnesaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 22 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Hyperlipidaemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 22 (9.09%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 1 | 1 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 5 / 22 (22.73%) | 4 / 22 (18.18%) | 1 / 18 (5.56%) |
| occurrences (all) | 14 | 8 | 1 |
| Hypochloraemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 | 1 |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 4 / 22 (18.18%) | 3 / 18 (16.67%) |
| occurrences (all) | 1 | 5 | 3 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 22 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 3 / 22 (13.64%) | 1 / 18 (5.56%) |
| occurrences (all) | 4 | 3 | 1 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 5 / 22 (22.73%) | 7 / 22 (31.82%) | 6 / 18 (33.33%) |
| occurrences (all) | 6 | 11 | 9 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 3 / 22 (13.64%) | 4 / 18 (22.22%) |
| occurrences (all) | 7 | 8 | 6 |
| Hyponatraemia | | | |
| subjects affected / exposed | 5 / 22 (22.73%) | 6 / 22 (27.27%) | 5 / 18 (27.78%) |
| occurrences (all) | 6 | 11 | 13 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypoproteinaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 22 (4.55%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|------------------------|
| 16 April 2021 | Protocol Amendment 1.0 |
| 21 April 2022 | Protocol Amendment 2.0 |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Since no participants were enrolled under PA 2, no analyses of the primary or secondary endpoints were conducted. Participants enrolled under PA 1 were excluded from the primary and secondary analyses outlined for PA 2.

Notes: