



Clinical trial results:

A Phase I/II Open-label, Multi-center Study to Assess Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of AZD7789, an Anti-PD-1 and Anti-TIM-3 Bispecific Antibody, in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2021-003569-36 |
| Trial protocol | FR IT ES DK |
| Global end of trial date | 04 September 2025 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 23 October 2025 |
| First version publication date | 23 October 2025 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | D9571C00001 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|---------------------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05216835 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | EU-CT number: 2022-502773-41-00 |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | AstraZeneca |
| Sponsor organisation address | Södertälje, Södertälje, Sweden, 151 85 |
| Public contact | Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com |
| Scientific contact | Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.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 | 30 August 2024 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 30 August 2024 |
| Global end of trial reached? | Yes |
| Global end of trial date | 04 September 2025 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main objectives of this trial were to establish the maximum tolerated dose, or optimal biological dose, and recommended Phase 2 dose in Part A; to assess the safety and tolerability of sabestomig in subjects with relapsed or refractory classical Hodgkin Lymphoma (r/rCHL) in Part A and Part B; to assess the activity of sabestomig in subjects with r/r CHL [anti-programmed cell death protein-1/programmed cell death-ligand 1 (anti-PD-1/PD-L1) exposed and naive] in Part B (B1 and B2).

Protection of trial subjects:

The study was performed in accordance with ethical principles that had their origin in the Declaration of Helsinki and were consistent with ICH GCP and the AstraZeneca policy on Bioethics and Human Biological Samples.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 18 March 2022 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Canada: 5 |
| Country: Number of subjects enrolled | Denmark: 1 |
| Country: Number of subjects enrolled | France: 5 |
| Country: Number of subjects enrolled | Italy: 19 |
| Country: Number of subjects enrolled | United Kingdom: 4 |
| Country: Number of subjects enrolled | United States: 11 |
| Worldwide total number of subjects | 45 |
| EEA total number of subjects | 25 |

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) | 37 |
| From 65 to 84 years | 8 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled in this study from 18 March 2022 (First subject in) and the analyses presented in this results form are based on a final data cut-off (DCO) of 30 August 2024.

Pre-assignment

Screening details:

Subjects who met the inclusion criteria and none of the exclusion criteria were enrolled to the study. All study assessments were performed as per the schedule of assessment.

Part B was not initiated, therefore, no subject was enrolled and analyzed for this part of the study.

Period 1

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

Arms

| | |
|------------------------------|-----------|
| Are arms mutually exclusive? | Yes |
| Arm title | Cohort A1 |

Arm description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 2mg of sabestomig.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Sabestomig |
| Investigational medicinal product code | AZD7789 |
| Other name | PD-1/TIM-3 bispecific monoclonal antibody |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects were administered sabestomig 2mg once every 3 weeks (Q3W) as an intravenous (IV) infusion.

| | |
|------------------|-----------|
| Arm title | Cohort A2 |
|------------------|-----------|

Arm description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 7mg of sabestomig.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Sabestomig |
| Investigational medicinal product code | AZD7789 |
| Other name | PD-1/TIM-3 bispecific monoclonal antibody |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects were administered sabestomig 7mg Q3W as an IV infusion.

| | |
|------------------|-----------|
| Arm title | Cohort A3 |
|------------------|-----------|

Arm description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 22.5mg of sabestomig.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|---|
| Investigational medicinal product name | Sabestomig |
| Investigational medicinal product code | AZD7789 |
| Other name | PD-1/TIM-3 bispecific monoclonal antibody |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects were administered sabestomig 22.5mg Q3W as an IV infusion. | |
| Arm title | Cohort A4 |
| Arm description: | |
| Subjects with r/r CHL previously treated with anti-PD-1/PD-L1 based therapy received 75mg of sabestomig. | |
| Arm type | Experimental |
| Investigational medicinal product name | Sabestomig |
| Investigational medicinal product code | AZD7789 |
| Other name | PD-1/TIM-3 bispecific monoclonal antibody |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects were administered sabestomig 75mg Q3W as an IV infusion. | |
| Arm title | Cohort A5 |
| Arm description: | |
| Subjects with r/r CHL previously treated with anti-PD-1/PD-L1 based therapy received 225mg of sabestomig. | |
| Arm type | Experimental |
| Investigational medicinal product name | Sabestomig |
| Investigational medicinal product code | AZD7789 |
| Other name | PD-1/TIM-3 bispecific monoclonal antibody |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects were administered sabestomig 225mg Q3W as an IV infusion. | |
| Arm title | Cohort A6 |
| Arm description: | |
| Subjects with r/r CHL previously treated with anti-PD-1/PD-L1 based therapy received 750mg of sabestomig. | |
| Arm type | Experimental |
| Investigational medicinal product name | Sabestomig |
| Investigational medicinal product code | AZD7789 |
| Other name | PD-1/TIM-3 bispecific monoclonal antibody |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects were administered sabestomig 750mg Q3W as an IV infusion. | |
| Arm title | Cohort A7 |
| Arm description: | |
| Subjects with r/r CHL previously treated with anti-PD-1/PD-L1 based therapy received 1500mg of sabestomig. | |
| Arm type | Experimental |

| | |
|---|---|
| Investigational medicinal product name | Sabestomig |
| Investigational medicinal product code | AZD7789 |
| Other name | PD-1/TIM-3 bispecific monoclonal antibody |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects were administered sabestomig 1500mg Q3W as an IV infusion. | |
| Arm title | Cohort A8 |

Arm description:

Subjects with r/r CHL previously treated with anti-PD-1/PD-L1 based therapy received 2000mg of sabestomig.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Sabestomig |
| Investigational medicinal product code | AZD7789 |
| Other name | PD-1/TIM-3 bispecific monoclonal antibody |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects were administered sabestomig 2000mg Q3W as an IV infusion.

| Number of subjects in period 1 | Cohort A1 | Cohort A2 | Cohort A3 |
|---------------------------------------|-----------|-----------|-----------|
| Started | 1 | 1 | 1 |
| Completed | 0 | 0 | 0 |
| Not completed | 1 | 1 | 1 |
| Consent withdrawn by subject | 1 | - | 1 |
| Physician decision | - | - | - |
| Study terminated by Sponsor | - | - | - |
| Other | - | 1 | - |
| Death | - | - | - |
| Ongoing as of DCO (30 Aug 2024) | - | - | - |

| Number of subjects in period 1 | Cohort A4 | Cohort A5 | Cohort A6 |
|---------------------------------------|-----------|-----------|-----------|
| Started | 1 | 5 | 12 |
| Completed | 0 | 0 | 0 |
| Not completed | 1 | 5 | 12 |
| Consent withdrawn by subject | - | 1 | - |
| Physician decision | - | - | 1 |
| Study terminated by Sponsor | - | - | - |
| Other | - | - | - |
| Death | 1 | 1 | 1 |
| Ongoing as of DCO (30 Aug 2024) | - | 3 | 10 |

| Number of subjects in period 1 | Cohort A7 | Cohort A8 |
|---------------------------------------|-----------|-----------|
|---------------------------------------|-----------|-----------|

| | | |
|---------------------------------|----|----|
| Started | 12 | 12 |
| Completed | 0 | 0 |
| Not completed | 12 | 12 |
| Consent withdrawn by subject | - | 1 |
| Physician decision | 1 | - |
| Study terminated by Sponsor | - | 1 |
| Other | - | - |
| Death | 1 | 1 |
| Ongoing as of DCO (30 Aug 2024) | 10 | 9 |

Baseline characteristics

| Reporting groups | |
|--|-----------|
| Reporting group title | Cohort A1 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 2mg of sabestomig. | |
| Reporting group title | Cohort A2 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 7mg of sabestomig. | |
| Reporting group title | Cohort A3 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 22.5mg of sabestomig. | |
| Reporting group title | Cohort A4 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 75mg of sabestomig. | |
| Reporting group title | Cohort A5 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 225mg of sabestomig. | |
| Reporting group title | Cohort A6 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 750mg of sabestomig. | |
| Reporting group title | Cohort A7 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 1500mg of sabestomig. | |
| Reporting group title | Cohort A8 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 2000mg of sabestomig. | |

| Reporting group values | Cohort A1 | Cohort A2 | Cohort A3 |
|---|-----------|-----------|-----------|
| Number of subjects | 1 | 1 | 1 |
| Age categorical | | | |
| Full analysis set included all subjects who received any amount of study intervention | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 1 | 1 | 1 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |

| | | | |
|--|----------|----------|----------|
| Age Continuous | | | |
| Full analysis set included all subjects who received any amount of study intervention. Here, for arms with a single subject, 0.999 indicates that mean data were not reported to maintain subject's confidentiality while 0.9999 indicates that standard deviation was not calculable for a single subject. | | | |
| Units: years | | | |
| arithmetic mean | 0.999 | 0.999 | 0.999 |
| standard deviation | ± 0.9999 | ± 0.9999 | ± 0.9999 |
| Sex: Female, Male | | | |
| Full analysis set included all subjects who received any amount of study intervention. For single subject in a particular gender, the data was not reported under specific category, rather a customized option was used, and the data was reported as 'All' to maintain subject's confidentiality. | | | |
| Units: Subjects | | | |
| Female | 0 | 0 | 0 |
| Male | 0 | 0 | 0 |
| All | 1 | 1 | 1 |
| Race/Ethnicity, Customized | | | |
| Full analysis set included all subjects who received any amount of study intervention. For single subject in a particular ethnicity, the data was not reported under specific category, rather a customized option was used, and the data was reported as 'Other' to maintain subject's confidentiality. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 0 | 0 | 0 |
| Missing | 0 | 0 | 0 |
| Other | 1 | 1 | 1 |

| Reporting group values | Cohort A4 | Cohort A5 | Cohort A6 |
|--|-----------|-----------|-----------|
| Number of subjects | 1 | 5 | 12 |
| Age categorical | | | |
| Full analysis set included all subjects who received any amount of study intervention | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 1 | 4 | 10 |
| From 65-84 years | 0 | 1 | 2 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous | | | |
| Full analysis set included all subjects who received any amount of study intervention. Here, for arms with a single subject, 0.999 indicates that mean data were not reported to maintain subject's confidentiality while 0.9999 indicates that standard deviation was not calculable for a single subject. | | | |
| Units: years | | | |
| arithmetic mean | 0.999 | 45.8 | 44.4 |
| standard deviation | ± 0.9999 | ± 17.6 | ± 16.0 |
| Sex: Female, Male | | | |
| Full analysis set included all subjects who received any amount of study intervention. For single subject in a particular gender, the data was not reported under specific category, rather a customized option was used, and the data was reported as 'All' to maintain subject's confidentiality. | | | |
| Units: Subjects | | | |
| Female | 0 | 3 | 3 |

| | | | |
|------|---|---|---|
| Male | 0 | 2 | 9 |
| All | 1 | 0 | 0 |

| | | | |
|---|---|---|----|
| Race/Ethnicity, Customized | | | |
| Full analysis set included all subjects who received any amount of study intervention. For single subject in a particular ethnicity, the data was not reported under specific category, rather a customized option was used, and the data was reported as 'Other' to maintain subject's confidentiality. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 0 | 3 | 12 |
| Missing | 0 | 2 | 0 |
| Other | 1 | 0 | 0 |

| Reporting group values | Cohort A7 | Cohort A8 | Total |
|--|-----------|-----------|-------|
| Number of subjects | 12 | 12 | 45 |
| Age categorical | | | |
| Full analysis set included all subjects who received any amount of study intervention | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 11 | 8 | 37 |
| From 65-84 years | 1 | 4 | 8 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous | | | |
| Full analysis set included all subjects who received any amount of study intervention. Here, for arms with a single subject, 0.999 indicates that mean data were not reported to maintain subject's confidentiality while 0.9999 indicates that standard deviation was not calculable for a single subject. | | | |
| Units: years | | | |
| arithmetic mean | 38.6 | 52.1 | |
| standard deviation | ± 14.5 | ± 21.2 | - |
| Sex: Female, Male | | | |
| Full analysis set included all subjects who received any amount of study intervention. For single subject in a particular gender, the data was not reported under specific category, rather a customized option was used, and the data was reported as 'All' to maintain subject's confidentiality. | | | |
| Units: Subjects | | | |
| Female | 2 | 6 | 14 |
| Male | 10 | 6 | 27 |
| All | 0 | 0 | 4 |
| Race/Ethnicity, Customized | | | |
| Full analysis set included all subjects who received any amount of study intervention. For single subject in a particular ethnicity, the data was not reported under specific category, rather a customized option was used, and the data was reported as 'Other' to maintain subject's confidentiality. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 10 | 10 | 35 |
| Missing | 1 | 2 | 5 |
| Other | 1 | 0 | 5 |

End points

End points reporting groups

| | |
|--|--------------|
| Reporting group title | Cohort A1 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 2mg of sabestomig. | |
| Reporting group title | Cohort A2 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 7mg of sabestomig. | |
| Reporting group title | Cohort A3 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 22.5mg of sabestomig. | |
| Reporting group title | Cohort A4 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 75mg of sabestomig. | |
| Reporting group title | Cohort A5 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 225mg of sabestomig. | |
| Reporting group title | Cohort A6 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 750mg of sabestomig. | |
| Reporting group title | Cohort A7 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 1500mg of sabestomig. | |
| Reporting group title | Cohort A8 |
| Reporting group description: Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 2000mg of sabestomig. | |
| Subject analysis set title | Part B |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Subjects with anti-PD-1/PD-L1 exposed r/r cHL were planned to receive sabestomig once the RP2D had been determined. Part B was not initiated, therefore, no subject was enrolled and analyzed for this analysis set. The total number of subjects enrolled for this study have been included for now to remove the validation error. | |

Primary: Part A (Dose Escalation): Number of subjects with adverse events (AEs)

| | |
|---|---|
| End point title | Part A (Dose Escalation): Number of subjects with adverse events (AEs) ^[1] |
| End point description: The safety and tolerability of sabestomig in subjects with r/r cHL were assessed. Safety set included all subjects who received any amount of study intervention. CTCAE = Common Terminology Criteria for Adverse Events (version 5.0); Immune-mediated AE = imAE; discontinuation = disc; including = incl. [a] = As assessed by the investigator. [b] = AE of special interest derivations were programmed based on sponsor assessment of AE terms. | |
| End point type | Primary |

End point timeframe:

From start of treatment [Cycle 1 Day 1 (C1D1) (each cycle was 28 days)] up to 90 days post last dose (approximately 2 years 5 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: No statistical analysis was performed for this endpoint.

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|--|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Subjects | | | | |
| AE | 1 | 1 | 1 | 1 |
| AE possibly related to (prt) Sabestomig [a] | 0 | 1 | 0 | 1 |
| AE of CTCAE grade 3 (G3) or higher | 0 | 0 | 0 | 0 |
| AE of CTCAE G3 or higher, prt Sabestomig [a] | 0 | 0 | 0 | 0 |
| AE with outcome = death (OD) | 0 | 0 | 0 | 0 |
| AE with OD, prt Sabestomig [a] | 0 | 0 | 0 | 0 |
| SAE (incl. events with OD) | 0 | 0 | 0 | 0 |
| SAE (incl. events with OD), prt Sabestomig [a] | 0 | 0 | 0 | 0 |
| SAE causing disc of Sabestomig | 0 | 0 | 0 | 0 |
| SAE causing disc of Sabestomig, prt Sabestomig [a] | 0 | 0 | 0 | 0 |
| AE causing disc of Sabestomig | 0 | 0 | 0 | 0 |
| AE causing disc of Sabestomig, prt Sabestomig [a] | 0 | 0 | 0 | 0 |
| AE causing cycle delay | 0 | 0 | 0 | 0 |
| AE causing cycle delay, prt Sabestomig [a] | 0 | 0 | 0 | 0 |
| AE of special interest (AESI) [b] | 0 | 1 | 0 | 1 |
| AESI [b] also considered as imAE [a] | 0 | 0 | 0 | 0 |
| AESI [b], prt Sabestomig [a] | 0 | 1 | 0 | 1 |
| AESI [b] also an imAE, prt Sabestomig [a] | 0 | 0 | 0 | 0 |
| imAE [a] | 0 | 0 | 0 | 0 |
| imAE, prt Sabestomig [a] | 0 | 0 | 0 | 0 |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|--|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 12 | 12 | 12 |
| Units: Subjects | | | | |
| AE | 4 | 12 | 10 | 12 |
| AE possibly related to (prt) Sabestomig [a] | 3 | 10 | 8 | 6 |
| AE of CTCAE grade 3 (G3) or higher | 1 | 4 | 2 | 2 |
| AE of CTCAE G3 or higher, prt Sabestomig [a] | 0 | 2 | 1 | 1 |
| AE with outcome = death (OD) | 1 | 0 | 0 | 0 |
| AE with OD, prt Sabestomig [a] | 0 | 0 | 0 | 0 |

| | | | | |
|--|---|---|---|---|
| SAE (incl. events with OD) | 3 | 2 | 2 | 0 |
| SAE (incl. events with OD), prt Sabestomig [a] | 2 | 2 | 0 | 0 |
| SAE causing disc of Sabestomig | 1 | 0 | 0 | 0 |
| SAE causing disc of Sabestomig, prt Sabestomig [a] | 0 | 0 | 0 | 0 |
| AE causing disc of Sabestomig | 1 | 1 | 0 | 1 |
| AE causing disc of Sabestomig, prt Sabestomig [a] | 0 | 1 | 0 | 1 |
| AE causing cycle delay | 0 | 5 | 4 | 3 |
| AE causing cycle delay, prt Sabestomig [a] | 0 | 2 | 1 | 0 |
| AE of special interest (AESI) [b] | 2 | 8 | 7 | 5 |
| AESI [b] also considered as imAE [a] | 0 | 3 | 2 | 2 |
| AESI [b], prt Sabestomig [a] | 2 | 6 | 4 | 2 |
| AESI [b] also an imAE, prt Sabestomig [a] | 0 | 3 | 2 | 2 |
| imAE [a] | 0 | 3 | 2 | 3 |
| imAE, prt Sabestomig [a] | 0 | 3 | 2 | 3 |

Statistical analyses

No statistical analyses for this end point

Primary: Part A (Dose Escalation): Number of subjects with dose-limiting toxicities (DLTs)

| | |
|-----------------|--|
| End point title | Part A (Dose Escalation): Number of subjects with dose-limiting toxicities (DLTs) ^[2] |
|-----------------|--|

End point description:

DLT was defined as any \geq Grade 3 AE as per NCI CTCAE version 5 unless unequivocally due to underlying malignancy or an extraneous cause.

The following conditions were considered as DLTs:

- Any death not clearly due to the underlying disease or extraneous causes
- Grade 4 imAE or anemia
- Any \geq Grade 3 non-infectious pneumonitis or colitis of any duration
- Specific liver transaminase elevation as per protocol
- Any Grade 3 imAE, including rash, pruritus, or diarrhea, that does not downgrade to Grade 2 or less within 7 days
- Grade 3 nausea, vomiting, or diarrhea that does not resolve to Grade 2 or less within 3 days of getting maximal supportive care
- \geq Grade 3 neutropenia, without fever or systemic infection, that does not improve by at least one grade within 7 days
- Grade 4 thrombocytopenia for more than 7 days or \geq Grade 3 thrombocytopenia along with Grade ≥ 2 bleeding
- Grade 4 Cytokine Release Syndrome (CRS) of any duration or Grade 3 CRS not improving to Grade ≤ 2 within 72 hours

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

End point timeframe:

From first dose [C1D1 (each cycle was 28 days)] until 28 days for each subject (within 28 days DLT period)

Notes:

[2] - 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: No statistical analysis was performed for this endpoint.

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Subjects | 0 | 0 | 0 | 0 |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 11 | 12 | 12 |
| Units: Subjects | 1 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Primary: Part B (Dose Expansion): Cohort B2: Complete response rate (CRR)

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Cohort B2: Complete response rate (CRR) ^[3] |
|-----------------|---|

End point description:

The anti-tumor activity of sabestomig in subjects with r/r cHL was planned to be assessed. The CRR was defined as the percentage of subjects with a CR as per modified Lugano criteria (Lugano 2014), with the denominator defined as the number of subjects in the response evaluable analysis set. Disease response was planned to be assessed according to Blinded Independent Central Review using modified Lugano criteria (Lugano 2014).

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

End point timeframe:

Up to approximately 2 years 90 days

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: Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint. Hence, no statistical analysis was performed.

| End point values | Part B | | | |
|----------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[4] | | | |
| Units: Percentage of Subjects | | | | |
| number (confidence interval 95%) | (to) | | | |

Notes:

[4] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Primary: Part B (Dose Expansion): Cohort B1: Objective response rate (ORR)

| | |
|-----------------|--|
| End point title | Part B (Dose Expansion): Cohort B1: Objective response rate (ORR) ^[5] |
|-----------------|--|

End point description:

The anti-tumor activity of sabestomig in subjects with r/r cHL was planned to be assessed. ORR was defined as the percentage of subjects with an objective response [Best Overall Response of a complete response (CR) or partial response (PR)] as per modified Lugano criteria (Lugano 2014), with the denominator defined as the number of subjects in the response-evaluable analysis set. Disease response was planned to be assessed according to Blinded Independent Central Review using modified Lugano criteria (Lugano 2014).

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

End point timeframe:

Up to approximately 2 years 90 days

Notes:

[5] - 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: Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint. Hence, no statistical analysis was performed.

| End point values | Part B | | | |
|----------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[6] | | | |
| Units: Percentage of Subjects | | | | |
| number (confidence interval 95%) | (to) | | | |

Notes:

[6] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Primary: Part B (Dose Expansion): Number of subjects with AEs

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Number of subjects with AEs ^[7] |
|-----------------|---|

End point description:

The safety and tolerability of sabestomig in subjects with r/r cHL was planned to be assessed.

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

End point timeframe:

Up to approximately 2 years 90 days

Notes:

[7] - 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: Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint. Hence, no statistical analysis was performed.

| End point values | Part B | | | |
|-----------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[8] | | | |
| Units: Subjects | | | | |

Notes:

[8] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Complete Response Rate (CRR)

| | |
|---|--|
| End point title | Part A (Dose Escalation): Complete Response Rate (CRR) |
| End point description: | |
| <p>The anti-tumor activity of sabestomig in subjects with r/r cHL was assessed.</p> <p>The CRR was defined as the percentage of subjects with a CR as per modified Lugano criteria (Lugano 2014) as assessed by the Investigator, with the denominator defined as the number of subjects in the response-evaluable analysis set.</p> <p>Response-evaluable set included all dosed subjects who had measurable disease at baseline.</p> <p>Here, '9999' indicates that data were not analyzed due to presence of single subject during analysis as pre-specified in Statistical analysis plan (SAP).</p> | |
| End point type | Secondary |
| End point timeframe: | |
| From start of treatment [C1D1 (each cycle was 28 days)] until first documented disease progression, or last evaluable assessment in the absence of progression (up to 2 years 5 months) | |

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|-------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Percentage of subjects | | | | |
| number (not applicable) | 9999 | 9999 | 9999 | 9999 |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|-------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 12 | 12 | 12 |
| Units: Percentage of subjects | | | | |
| number (not applicable) | 0 | 33.3 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Objective Response Rate (ORR)

| | |
|---|---|
| End point title | Part A (Dose Escalation): Objective Response Rate (ORR) |
| End point description: | |
| <p>The anti-tumor activity of sabestomig in subjects with r/r cHL was assessed.</p> <p>The ORR was defined as the percentage of subjects with an objective response (Best Overall Response of CR or PR) as per modified Lugano criteria (Lugano 2014), as assessed by the Investigator, with the denominator defined as the number of subjects in the response-evaluable analysis set.</p> <p>Response-evaluable set included all dosed subjects who had measurable disease at baseline.</p> <p>Here, '9999' indicates that data were not analyzed due to presence of single subject for analysis as pre-specified in SAP while '-9999.9' and '9999.9' indicate that the confidence interval data was not calculable.</p> | |
| End point type | Secondary |
| End point timeframe: | |
| From start of treatment [C1D1 (each cycle was 28 days)] until first documented disease progression, or last evaluable assessment in the absence of progression (up to 2 years 5 months) | |

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|----------------------------------|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|----------------------------------|-----------------------|---------------------|--------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 12 | 12 | 12 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 0 (-9999.9 to 9999.9) | 50.0 (21.1 to 78.9) | 25.0 (5.5 to 57.2) | 16.7 (2.1 to 48.4) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Duration of Response (DoR)

| | |
|-----------------|--|
| End point title | Part A (Dose Escalation): Duration of Response (DoR) |
|-----------------|--|

End point description:

The anti-tumor activity of sabestomig in subjects with r/r cHL was assessed.

The DoR was defined as the time from the date of first documented objective response (CR or PR), as assessed by Investigator, using the modified Lugano criteria (Lugano 2014), until the date of first documented disease progression or death (by any cause in the absence of disease progression).

Disease response was assessed according to Investigator assessment using modified Lugano criteria (Lugano 2014).

Response-evaluable set included all dosed subjects who had measurable disease at baseline. Number of subjects analyzed were number of subjects with objective response.

Here, '9999' indicates that data were not analyzed due to presence of single subject for analysis as pre-specified in SAP while '-9999.9' and '9999.9' indicate that the available data did not cross the 50% probability of DoR.

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

End point timeframe:

From first documented response until date of first documented disease progression or death from any cause, or data cut-off or end of study (whichever came first, assessed up to 2 years 5 months)

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|----------------------------------|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Months | | | | |
| median (confidence interval 95%) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|----------------------------------|------------------|------------------------|---------------------|-------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[9] | 6 | 3 | 2 |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | 9999.9 (2.7 to 9999.9) | 7.7 (7.1 to 9999.9) | 6.3 (-9999.9 to 9999.9) |

Notes:

[9] - There was no subject with objective response at the time of analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Duration of Complete Response (DoCR)

| | |
|-----------------|--|
| End point title | Part A (Dose Escalation): Duration of Complete Response (DoCR) |
|-----------------|--|

End point description:

The anti-tumor activity of sabestomig in subjects with r/r cHL was assessed.

The DoCR was defined as the time from first documented CR, as per modified Lugano criteria (Lugano 2014) as assessed by the Investigator, until the date of first documented relapse/progression or death due to any cause (in the absence of disease progression).

Disease response was assessed according to Investigator assessment using modified Lugano criteria (Lugano 2014).

Response-evaluable set included all dosed subjects who had measurable disease at baseline. Number of subjects analyzed were number of subjects with complete response.

Here, '9999' indicates that data (DOCR) was not calculable due to low number of responders with CR events, as pre-specified in SAP.

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

End point timeframe:

From first documented complete response until date of first documented disease progression or death from any cause, or data cut-off or end of study (whichever came first, assessed up to 2 years 5 months)

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|----------------------------------|-------------------|-------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[10] | 0 ^[11] | 0 ^[12] | 0 ^[13] |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | (to) | (to) | (to) |

Notes:

[10] - The DoCR was not assessed due to low number of CR events.

[11] - The DoCR was not assessed due to low number of CR events.

[12] - The DoCR was not assessed due to low number of CR events.

[13] - The DoCR was not assessed due to low number of CR events.

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|----------------------------------|-------------------|---------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[14] | 4 | 0 ^[15] | 0 ^[16] |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | 9999 (9999 to 9999) | (to) | (to) |

Notes:

[14] - The DoCR was not assessed due to low number of CR events.

[15] - The DoCR was not assessed due to low number of CR events.

[16] - The DoCR was not assessed due to low number of CR events.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Progression-free Survival (PFS)

| | |
|-----------------|---|
| End point title | Part A (Dose Escalation): Progression-free Survival (PFS) |
|-----------------|---|

End point description:

The anti-tumor activity of sabestomig in subjects with r/r cHL was assessed.

PFS was defined as the time from first dose until the earlier of the date of first documented disease progression, as per modified Lugano criteria (Lugano 2014) as assessed by the Investigator, or death (by any cause in the absence of disease progression or subsequent anticancer treatment).

Disease response was assessed according to Investigator assessment using modified Lugano criteria (Lugano 2014).

Full analysis set included all subjects who received any amount of study intervention.

Here, '9999' indicates that data were not analyzed due to presence of single subject for analysis as pre-specified in SAP while '9999.9' indicates that the available data did not cross the 50% probability of PFS.

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

End point timeframe:

From start of treatment [C1D1 (each cycle was 28 days)] until date of first documented disease progression or data cut-off or end of study (whichever came first, assessed up to 2 years 5 months)

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|----------------------------------|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Months | | | | |
| median (confidence interval 95%) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|----------------------------------|---------------------|-------------------|---------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 12 | 12 | 12 |
| Units: Months | | | | |
| median (confidence interval 95%) | 1.9 (1.4 to 9999.9) | 4.8 (2.4 to 11.9) | 5.7 (1.8 to 9999.9) | 2.1 (1.6 to 8.1) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Overall Survival (OS)

| | |
|-----------------|---|
| End point title | Part A (Dose Escalation): Overall Survival (OS) |
|-----------------|---|

End point description:

The anti-tumor activity of sabestomig in subjects with r/r cHL was assessed.

The OS was defined as the time from the start of treatment until death due to any cause regardless of whether subject withdraws from treatment or receives another anti-lymphoma therapy.

Full analysis set included all subjects who received any amount of study intervention.

Here, '9999' indicates that data were not analyzed due to presence of single subject for analysis as pre-specified in SAP while '9999.9' indicates that the available data did not cross the 50% probability of OS.

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

End point timeframe:

From start of treatment [CIDI (each cycle was 28 days)] until date of death due to any cause or data cut-off or end of study (whichever came first, assessed up to 2 years 5 months)

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|----------------------------------|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Months | | | | |
| median (confidence interval 95%) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|----------------------------------|------------------------|---------------------------|---------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 12 | 12 | 12 |
| Units: Months | | | | |
| median (confidence interval 95%) | 9999.9 (1.4 to 9999.9) | 9999.9 (9999.9 to 9999.9) | 9999.9 (9999.9 to 9999.9) | 9999.9 (8.4 to 9999.9) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Number of subjects with positive anti-drug antibodies (ADA) against sabestomig in serum

| | |
|---|---|
| End point title | Part A (Dose Escalation): Number of subjects with positive anti-drug antibodies (ADA) against sabestomig in serum |
| End point description: The presence of ADA for sabestomig in treated subjects with r/r cHL was assessed. Immunogenicity analysis set included all subjects who received at least 1 dose of study intervention with at least 1 reportable immunogenicity measurement. | |
| End point type | Secondary |
| End point timeframe: On C1D1, C2D1, and until end of study [up to 2 years 5 months (each cycle was 28 days)] | |

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|--|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Subjects | | | | |
| ADA prevalence | 1 | 0 | 0 | 0 |
| Treatment-induced ADA positive (+) | 1 | 0 | 0 | 0 |
| Treatment-boosted ADA | 1 | 0 | 0 | 0 |
| ADA incidence | 1 | 0 | 0 | 0 |
| ADA + at baseline and at least one post-baseline | 0 | 0 | 0 | 0 |
| ADA + at baseline and not + at post-baseline | 0 | 0 | 0 | 0 |
| ADA transient + | 0 | 0 | 0 | 0 |
| ADA persistently + | 1 | 0 | 0 | 0 |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|--|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 12 | 12 | 12 |
| Units: Subjects | | | | |
| ADA prevalence | 3 | 4 | 4 | 2 |
| Treatment-induced ADA positive (+) | 3 | 4 | 3 | 2 |
| Treatment-boosted ADA | 3 | 3 | 4 | 2 |
| ADA incidence | 3 | 4 | 4 | 2 |
| ADA + at baseline and at least one post-baseline | 0 | 0 | 1 | 0 |
| ADA + at baseline and not + at post-baseline | 0 | 0 | 0 | 0 |
| ADA transient + | 1 | 2 | 2 | 0 |
| ADA persistently + | 2 | 2 | 1 | 2 |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Maximum observed concentration (Cmax)

| | |
|---|---|
| End point title | Part A (Dose Escalation): Maximum observed concentration (Cmax) |
| End point description: The Cmax of sabestomig in subjects with r/r cHL was assessed. Pharmacokinetic (PK) set included all subjects who received at least 1 dose of study intervention with at least 1 reportable concentration. For Cohorts A1 to A4, median was not calculated for a single subject as pre-specified in the SAP. To resolve the validation error, the median is reported with the same value as min-max. | |
| End point type | Secondary |
| End point timeframe: From C1D1 [before start of infusion (SOI) and at end of infusion (EOI)] to end of study [up to 2 years 5 months (each cycle was 28 days)] | |

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|---------------------------------------|---------------------|---------------------|---------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: microgram (ug)/milliliter (mL) | | | | |
| median (full range (min-max)) | 0.14 (0.14 to 0.14) | 1.41 (1.41 to 1.41) | 5.80 (5.80 to 5.80) | 15.40 (15.40 to 15.40) |

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|---------------------------------------|------------------------|---------------------------|----------------------------|----------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 12 | 11 | 11 |
| Units: microgram (ug)/milliliter (mL) | | | | |
| median (full range (min-max)) | 52.49 (39.60 to 82.90) | 256.00 (172.00 to 430.00) | 516.00 (364.00 to 1480.00) | 695.10 (323.00 to 1400.00) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Area under the concentration-time curve (AUC)

| | |
|--|---|
| End point title | Part A (Dose Escalation): Area under the concentration-time curve (AUC) |
| End point description: The AUC of sabestomig in subjects with r/r cHL was assessed. PK set included all subjects who received at least 1 dose of study intervention with at least 1 reportable concentration. For Cohorts A2 to A4, median was not calculated for a single subject as pre-specified in the SAP. To resolve the validation error, the median is reported with the same value as min-max. | |
| End point type | Secondary |
| End point timeframe: From C1D1 (before SOI and at EOI) to end of study [up to 2 years 5 months (each cycle was 28 days)] | |

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|-------------------------------|-------------------|---------------------|------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[17] | 1 | 1 | 1 |
| Units: Day*ug/mL | | | | |
| median (full range (min-max)) | (to) | 4.24 (4.24 to 4.24) | 28.50 (28.50 to 28.50) | 88.80 (88.80 to 88.80) |

Notes:

[17] - There was no subject with reportable data at the time of analysis.

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|-------------------------------|---------------------------|------------------------------|------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 11 | 11 | 11 |
| Units: Day*ug/mL | | | | |
| median (full range (min-max)) | 273.00 (110.00 to 518.00) | 2256.00 (1710.00 to 4780.00) | 4687.00 (2740.00 to 8370.00) | 6883.00 (2560.00 to 8120.00) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Clearance (CL)

| | |
|-----------------|--|
| End point title | Part A (Dose Escalation): Clearance (CL) |
|-----------------|--|

End point description:

The CL of sabestomig in subjects with r/r cHL was assessed.

PK set included all subjects who received at least 1 dose of study intervention with at least 1 reportable concentration.

For Cohorts A2 to A4, median was not calculated for a single subject as pre-specified in the SAP. To resolve the validation error, the median is reported with the same value as min-max.

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

End point timeframe:

From C1D1 (before SOI and at EOI) to end of study [up to 2 years 5 months (each cycle was 28 days)]

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|-------------------------------|-------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[18] | 1 | 1 | 1 |
| Units: Liter (L)/Day | | | | |
| median (full range (min-max)) | (to) | 1.3200 (1.3200 to 1.3200) | 0.7210 (0.7210 to 0.7210) | 0.8160 (0.8160 to 0.8160) |

Notes:

[18] - There was no subject with reportable data at the time of analysis.

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|-------------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 11 | 9 | 11 |
| Units: Liter (L)/Day | | | | |
| median (full range (min-max)) | 0.4925 (0.2910 to 1.9800) | 0.2321 (0.1030 to 0.4200) | 0.2211 (0.1010 to 0.3180) | 0.2149 (0.1280 to 0.7020) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Dose Escalation): Terminal elimination half-life ($t_{1/2\lambda z}$)

| | |
|-----------------|---|
| End point title | Part A (Dose Escalation): Terminal elimination half-life ($t_{1/2\lambda z}$) |
|-----------------|---|

End point description:

The $t_{1/2\lambda z}$ of sabestomig in subjects with r/r CHL was assessed.

PK set included all subjects who received at least 1 dose of study intervention with at least 1 reportable concentration.

For Cohorts A2 to A4, median was not calculated for a single subject as pre-specified in the SAP. To resolve the validation error, the median is reported with the same value as min-max.

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

End point timeframe:

From C1D1 (before SOI and at EOI) to end of study [up to 2 years 5 months (each cycle was 28 days)]

| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
|-------------------------------|-------------------|------------------------|------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[19] | 1 | 1 | 1 |
| Units: Day | | | | |
| median (full range (min-max)) | (to) | 2.880 (2.880 to 2.880) | 8.980 (8.980 to 8.980) | 4.730 (4.730 to 4.730) |

Notes:

[19] - There was no subject with reportable data at the time of analysis.

| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
|-------------------------------|-------------------------|--------------------------|---------------------------|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 11 | 9 | 11 |
| Units: Day | | | | |
| median (full range (min-max)) | 9.136 (3.100 to 25.000) | 12.720 (6.680 to 42.800) | 16.440 (11.200 to 22.600) | 12.070 (5.990 to 21.000) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Duration of Response (DoR)

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Duration of Response (DoR) |
|-----------------|---|

End point description:

The DoR of sabestomig in subjects with r/r cHL was planned to be assessed.
However, Part B was not initiated, hence data for DoR was not collected and analyzed.

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

End point timeframe:

Up to approximately 2 years 90 days

| End point values | Part B | | | |
|----------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[20] | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | | | |

Notes:

[20] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Duration of Complete Response (DoCR)

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Duration of Complete Response (DoCR) |
|-----------------|---|

End point description:

The DoCR of sabestomig in subjects with r/r cHL was planned to be assessed.
However, Part B was not initiated, hence data for DoCR was not collected and analyzed.

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

End point timeframe:

Up to approximately 2 years 90 days

| End point values | Part B | | | |
|----------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[21] | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | | | |

Notes:

[21] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Progression-free Survival (PFS)

| | |
|-----------------|--|
| End point title | Part B (Dose Expansion): Progression-free Survival (PFS) |
|-----------------|--|

End point description:

The anti-tumor activity of sabestomig in subjects with r/r CHL was planned to be assessed. However, Part B was not initiated, hence data for PFS was not collected and analyzed.

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

End point timeframe:

Up to approximately 2 years 90 days

| End point values | Part B | | | |
|----------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[22] | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | | | |

Notes:

[22] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Overall Survival (OS)

| | |
|-----------------|--|
| End point title | Part B (Dose Expansion): Overall Survival (OS) |
|-----------------|--|

End point description:

The anti-tumor activity of sabestomig in subjects with r/r CHL was planned to be assessed. However, Part B was not initiated, hence data for OS was not collected and analyzed.

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

End point timeframe:

Up to approximately 2 years 90 days

| End point values | Part B | | | |
|----------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[23] | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | (to) | | | |

Notes:

[23] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Terminal elimination half-life (t_{1/2λz})

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Terminal elimination half-life (t _{1/2λz}) |
|-----------------|---|

End point description:

The t_{1/2λz} of sabestomig in subjects with r/r CHL was planned to be assessed. However, Part B was not initiated, hence data for t_{1/2λz} was not collected and analyzed.

| | |
|-------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Up to approximately 2 years 90 days | |

| End point values | Part B | | | |
|-------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[24] | | | |
| Units: Day | | | | |
| median (full range (min-max)) | (to) | | | |

Notes:

[24] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Maximum observed concentration (C_{max})

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Maximum observed concentration (C _{max}) |
|-----------------|---|

End point description:

The C_{max} of sabestomig in subjects with r/r cHL was planned to be assessed. However, Part B was not initiated, hence data for C_{max} was not collected and analyzed.

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

End point timeframe:

Up to approximately 2 years 90 days

| End point values | Part B | | | |
|-------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[25] | | | |
| Units: ug/mL | | | | |
| median (full range (min-max)) | (to) | | | |

Notes:

[25] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Area under the concentration-time curve (AUC)

| | |
|-----------------|--|
| End point title | Part B (Dose Expansion): Area under the concentration-time curve (AUC) |
|-----------------|--|

End point description:

The AUC of sabestomig in subjects with r/r cHL was planned to be assessed. However, Part B was not initiated, hence data for AUC was not collected and analyzed.

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

End point timeframe:
Up to approximately 2 years 90 days

| End point values | Part B | | | |
|---|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[26] | | | |
| Units: Day*ug/mL | | | | |
| geometric mean (geometric coefficient of variation) | () | | | |

Notes:

[26] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Number of subjects with positive ADA against sabestomig in serum

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Number of subjects with positive ADA against sabestomig in serum |
|-----------------|---|

End point description:

The presence of ADA for sabestomig in treated subjects with r/r cHL was planned to be assessed. However, Part B was not initiated, hence data for presence of ADA was not collected and analyzed.

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

End point timeframe:

Up to approximately 2 years 90 days

| End point values | Part B | | | |
|-----------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[27] | | | |
| Units: Subjects | | | | |

Notes:

[27] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Pediatric Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (Peds-PRO-CTCAE)

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Pediatric Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (Peds-PRO-CTCAE) |
|-----------------|---|

End point description:

Proportion of subjects reporting different levels of presence/magnitude/interference (as applicable) of diarrhea, rash, and fatigue over time based on peds-PRO-CTCAE was planned to be evaluated. The pediatric module included 130 items representing 62 symptomatic toxicities and permitted self-

reporting by children and adolescents aged 7 to 17 years. In this study, 17 symptomatic toxicities were planned for selection. Thus, the total number of questions that subjects would have answered ranged from 17 (assuming that no branching questions were triggered, ie, the subject answered '0' to the initial question for each symptom) to 42 items (assuming that all possible branching questions were triggered for every symptom posed to the subject).

| | |
|-------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Up to approximately 2 years 90 days | |

| End point values | Part B | | | |
|-----------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[28] | | | |
| Units: Score on a scale | | | | |

Notes:

[28] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)

| | |
|-----------------|--|
| End point title | Part B (Dose Expansion): Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) |
|-----------------|--|

End point description:

Proportion of subjects reporting different levels of presence/magnitude/interference (as applicable) of diarrhea, rash, and fatigue over time based on PRO-CTCAE was planned to be evaluated. PRO-CTCAE was a PRO measurement system developed to evaluate symptomatic toxicity in subjects on cancer clinical trials. The PRO-CTCAE Item Library included 124 items representing 78 symptomatic toxicities drawn from the CTCAE. PRO-CTCAE items were planned to evaluate the symptom attributes of frequency, severity, interference, amount, presence/absence. Each symptomatic AE was planned to be assessed by 1 to 3 attributes. Conditional branching logic was planned to be used with electronic data capture, thereby reducing respondent burden. The recall period was planned as the past 7 days and PRO-CTCAE responses were planned to score from 0 to 4 (or 0/1 for absent/present).

| | |
|-------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Up to approximately 2 years 90 days | |

| End point values | Part B | | | |
|-----------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[29] | | | |
| Units: Score on a scale | | | | |

Notes:

[29] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): Patient Global Impression of Treatment Tolerability (PGI-TT)

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): Patient Global Impression of Treatment Tolerability (PGI-TT) |
|-----------------|---|

End point description:

Proportion of subjects reporting different levels of overall side-effect bother over time based on the PGI-TT was planned to be evaluated.

For adult subjects only, the PGI-TT item was included to assess how a subject perceived the overall burden of treatment-related side effects of cancer treatment over the past 7 days. Subjects were planned to be asked to choose the response that best described the level of burden by the side effect of their cancer treatment over the past week. The planned response options were: "not at all", "a little bit", "somewhat", "quite a bit", and "very much".

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

End point timeframe:

Up to approximately 2 years 90 days

| End point values | Part B | | | |
|-----------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[30] | | | |
| Units: Score on a scale | | | | |

Notes:

[30] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Dose Expansion): European Organization for Research and Treatment of Cancer (EORTC) Item List (IL)XX QL2 [2-item global health-related quality of life (HRQoL)]

| | |
|-----------------|---|
| End point title | Part B (Dose Expansion): European Organization for Research and Treatment of Cancer (EORTC) Item List (IL)XX QL2 [2-item global health-related quality of life (HRQoL)] |
|-----------------|---|

End point description:

Proportion of subjects reporting different levels of quality of life/health over time based on the European Organization for Research and Treatment of Cancer Item List (EORTC) ILXX QL2 items was planned to be evaluated.

The EORTC QLQ-C30 was a 30-item self-administered questionnaire designed for all cancer types. Questions were grouped into 5 multi-item functional scales (physical, role, emotional, cognitive, and social), 3 multi-item symptom scales (fatigue, pain, and nausea/vomiting), a 2-item global HRQoL (QL2) scale, 5 single items assessing additional symptoms commonly reported by subjects with cancer (dyspnea, loss of appetite, insomnia, constipation, and diarrhea), and 1 item on the financial impact of the disease. Subjects were planned to answer the QLQ-C30 questions in reference to how they had been over the past week. Final scores were planned to transform to range from 0 to 100, where higher scores indicated better functioning, better HRQoL, or greater level of symptoms.

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

End point timeframe:

Up to approximately 2 years 90 days

| | | | | |
|-----------------------------|----------------------|--|--|--|
| End point values | Part B | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 0 ^[31] | | | |
| Units: Score on a scale | | | | |

Notes:

[31] - Part B was not initiated, therefore, no subject was enrolled and analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part A (Dose Escalation): Number of subjects with adverse events of special interest (AESIs)

| | |
|-----------------|--|
| End point title | Part A (Dose Escalation): Number of subjects with adverse events of special interest (AESIs) |
|-----------------|--|

End point description:

The safety and tolerability of sabestomig in subjects with r/r CHL were assessed.

An AESI was an AE of scientific and medical interest specific to understanding of a study intervention and may have required close monitoring and rapid communication to AstraZeneca by the Investigator. The AESIs for sabestomig include events with a potential inflammatory or immune-mediated mechanism and which may require more frequent monitoring and/or interventions such as steroids, immunosuppressants and/or hormone replacement therapy.

Safety set included all subjects who received any amount of study intervention.

AE of special interest derivations were programmed based on sponsor assessment of AE terms.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

From start of treatment [Cycle 1 Day 1 (C1D1) (each cycle was 28 days)] up to 90 days post last dose (approximately 2 years 5 months)

| | | | | |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| End point values | Cohort A1 | Cohort A2 | Cohort A3 | Cohort A4 |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 1 | 1 |
| Units: Subjects | 0 | 1 | 0 | 1 |

| | | | | |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| End point values | Cohort A5 | Cohort A6 | Cohort A7 | Cohort A8 |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 12 | 12 | 12 |
| Units: Subjects | 2 | 8 | 7 | 5 |

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of treatment [Cycle 1 Day 1 (C1D1) (each cycle was 28 days)] up to 90 days post last dose (approximately 2 years 5 months)

Adverse event reporting additional description:

Safety set included all subjects who received any amount of study intervention.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 27.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-----------|
| Reporting group title | Cohort A1 |
|-----------------------|-----------|

Reporting group description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 2mg of sabestomig.

| | |
|-----------------------|-----------|
| Reporting group title | Cohort A2 |
|-----------------------|-----------|

Reporting group description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 7mg of sabestomig.

| | |
|-----------------------|-----------|
| Reporting group title | Cohort A3 |
|-----------------------|-----------|

Reporting group description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 22.5mg of sabestomig.

| | |
|-----------------------|-----------|
| Reporting group title | Cohort A4 |
|-----------------------|-----------|

Reporting group description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 75mg of sabestomig.

| | |
|-----------------------|-----------|
| Reporting group title | Cohort A5 |
|-----------------------|-----------|

Reporting group description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 225mg of sabestomig.

| | |
|-----------------------|-----------|
| Reporting group title | Cohort A6 |
|-----------------------|-----------|

Reporting group description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 750mg of sabestomig.

| | |
|-----------------------|-----------|
| Reporting group title | Cohort A7 |
|-----------------------|-----------|

Reporting group description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 1500mg of sabestomig.

| | |
|-----------------------|-----------|
| Reporting group title | Cohort A8 |
|-----------------------|-----------|

Reporting group description:

Subjects with r/r cHL previously treated with anti-PD-1/PD-L1 based therapy received 2000mg of sabestomig.

| Serious adverse events | Cohort A1 | Cohort A2 | Cohort A3 |
|---|---------------|---------------|---------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |

| | | | |
|--|---------------|---------------|---------------|
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Post herpetic neuralgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Gastric perforation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Exertional rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ophthalmic herpes zoster | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Cohort A4 | Cohort A5 | Cohort A6 |
|--|---------------|----------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 3 / 5 (60.00%) | 3 / 12 (25.00%) |
| number of deaths (all causes) | 1 | 1 | 1 |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 5 (20.00%) | 0 / 12 (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 |
| Nervous system disorders | | | |
| Post herpetic neuralgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 5 (20.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Gastric perforation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 5 (20.00%) | 0 / 12 (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 |

| | | | |
|---|---------------|----------------|----------------|
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Exertional rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ophthalmic herpes zoster | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 5 (20.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Urinary tract infection | | | |

| | | | |
|---|---------------|---------------|----------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Cohort A7 | Cohort A8 | |
|--|-----------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 12 (33.33%) | 2 / 12 (16.67%) | |
| number of deaths (all causes) | 1 | 1 | |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Post herpetic neuralgia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| 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 | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |

| | | | |
|---|----------------|----------------|--|
| Gastric perforation | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Exertional rhabdomyolysis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ophthalmic herpes zoster | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Sepsis | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Cohort A1 | Cohort A2 | Cohort A3 |
|---|-----------------|-----------------|-----------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 1 / 1 (100.00%) | 1 / 1 (100.00%) |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Device related thrombosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 1 (100.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Oedema peripheral | | | |

| | | | |
|---|---------------|-----------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 1 (100.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute graft versus host disease in skin | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Vaginal discharge | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal pruritus | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------------|--------------------|----------------------|
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 1 (100.00%) 1 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Pleural effusion subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Pneumonitis subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Upper respiratory tract inflammation subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Suicidal ideation subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Amylase increased subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Blood alkaline phosphatase increased subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Aspartate aminotransferase increased | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood thyroid stimulating hormone increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| C-reactive protein increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eosinophil count increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |

| | | | |
|---|--------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Weight decreased subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Arthropod bite subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Rib fracture subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Infusion related reaction subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Spinal compression fracture subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Cardiac disorders | | | |
| Sinus tachycardia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Sinus bradycardia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Palpitations subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Cardiomyopathy subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Cardiac failure congestive subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Atrial fibrillation | | | |

| | | | |
|---|--------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Nervous system disorders | | | |
| Peripheral sensory neuropathy subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 1 (100.00%) 1 | 0 / 1 (0.00%) 0 |
| Intention tremor subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 1 (100.00%) 1 |
| Dizziness subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Post herpetic neuralgia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Sciatica subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Tremor subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Secondary cerebellar degeneration subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Lymphopenia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Thrombocytopenia | | | |

| | | | |
|--|--------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Neutropenia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Ear and labyrinth disorders Middle ear effusion subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Eye disorders Vision blurred subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Retinopathy subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Dyspepsia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Colitis subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Diarrhoea | | | |

| | | | |
|--|---------------|-----------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 1 (100.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 1 (100.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hidradenitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Autoimmune thyroiditis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia | | | |

| | | | |
|-----------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Device related infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------------|---------------|---------------|---------------|
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infected dermal cyst | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|-----------------|---------------|---------------|
| Tracheitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Steroid diabetes | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypokalaemia | | | |

| | | | |
|-----------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Cohort A4 | Cohort A5 | Cohort A6 |
|---|-----------------|----------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 4 / 5 (80.00%) | 12 / 12 (100.00%) |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 5 (20.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 1 | 2 |
| Chills | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Device related thrombosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 3 / 12 (25.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Pyrexia | | | |

| | | | |
|---|----------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 2 / 12 (16.67%) 3 |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 2 |
| Acute graft versus host disease in skin subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Reproductive system and breast disorders Vaginal discharge subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Vulvovaginal pruritus subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Lower respiratory tract inflammation subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Pleural effusion subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 5 (20.00%) 2 | 0 / 12 (0.00%) 0 |

| | | | |
|--|---------------|---------------|-----------------|
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 0 | 3 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood thyroid stimulating hormone | | | |

| | | | |
|--|-----------------|---------------|----------------|
| increased | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 1 | 0 | 1 |
| C-reactive protein increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eosinophil count increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 4 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rib fracture | | | |

| | | | |
|---|----------------------|--------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Infusion related reaction subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 0 / 5 (0.00%) 0 | 3 / 12 (25.00%) 3 |
| Spinal compression fracture subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Cardiac disorders | | | |
| Sinus tachycardia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Sinus bradycardia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Palpitations subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Cardiomyopathy subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Cardiac failure congestive subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Atrial fibrillation subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Nervous system disorders | | | |
| Peripheral sensory neuropathy subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Intention tremor subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Headache | | | |

| | | | |
|--------------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 5 (20.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 2 | 2 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Post herpetic neuralgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Secondary cerebellar degeneration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 5 (20.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 1 | 2 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Ear and labyrinth disorders | | | |
| Middle ear effusion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |

| | | | |
|--|--------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Eye disorders | | | |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Retinopathy subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 5 (20.00%) 1 | 1 / 12 (8.33%) 1 |
| Dyspepsia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 2 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Colitis subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 2 / 12 (16.67%) 2 |
| Diarrhoea subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 3 / 12 (25.00%) 3 |
| Dry mouth subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Stomatitis | | | |

| | | | |
|--|---------------|----------------|-----------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 3 / 12 (25.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Nausea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 0 | 5 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 5 (20.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hidradenitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Dry skin | | | |

| | | | |
|--|----------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Rash pruritic subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Rash maculo-papular subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Rash macular subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Renal and urinary disorders Nephrolithiasis subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Endocrine disorders Autoimmune thyroiditis subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 2 |
| Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 1 / 5 (20.00%) 1 | 1 / 12 (8.33%) 1 |
| Arthritis subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Arthralgia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Bone pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Neck pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 5 (0.00%) 0 | 1 / 12 (8.33%) 2 |
| Myalgia | | | |

| | | | |
|-----------------------------|---------------|---------------|-----------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 4 |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Device related infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 0 | 3 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infected dermal cyst | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|------------------------------------|---------------|---------------|----------------|
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Influenza | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tracheitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Metabolism and nutrition disorders | | | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypercholesterolaemia | | | |

| | | | |
|-----------------------------|-----------------|---------------|----------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Steroid diabetes | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 5 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Cohort A7 | Cohort A8 | |
|---|------------------|-------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 12 (83.33%) | 12 / 12 (100.00%) | |
| Vascular disorders | | | |
| Hypotension | | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Chills | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 12 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Device related thrombosis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 2 / 12 (16.67%) | |
| occurrences (all) | 2 | 2 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | |
| occurrences (all) | 1 | 1 | |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Acute graft versus host disease in skin | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | |
| Reproductive system and breast disorders | | | |
| Vaginal discharge | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Vulvovaginal pruritus | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lower respiratory tract inflammation | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 12 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Upper respiratory tract inflammation | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 12 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood thyroid stimulating hormone increased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Electrocardiogram QT prolonged | | | |

| | | | |
|--|-----------------|----------------|--|
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Eosinophil count increased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lipase increased | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 1 / 12 (8.33%) | |
| occurrences (all) | 2 | 1 | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | |
| occurrences (all) | 3 | 1 | |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Arthropod bite | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rib fracture | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Infusion related reaction | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Spinal compression fracture | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | |
| Cardiac disorders | | | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Sinus bradycardia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Palpitations | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Intention tremor | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Headache | | | |
| subjects affected / exposed | 4 / 12 (33.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Dizziness | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Post herpetic neuralgia | | | |

| | | | |
|---|----------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Sciatica subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | |
| Tremor subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Secondary cerebellar degeneration subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 2 / 12 (16.67%) 3 | 2 / 12 (16.67%) 2 | |
| Lymphopenia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | |
| Neutropenia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Ear and labyrinth disorders | | | |
| Middle ear effusion subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Eye disorders | | | |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Retinopathy | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Colitis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Constipation | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | |
| occurrences (all) | 3 | 2 | |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | |
| occurrences (all) | 1 | 1 | |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nausea | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 2 | |

| | | | |
|--|----------------|-----------------|--|
| Hepatobiliary disorders | | | |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Rash | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pruritus | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 2 / 12 (16.67%) | |
| occurrences (all) | 1 | 2 | |
| Hidradenitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Erythema | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dry skin | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | |
| occurrences (all) | 1 | 1 | |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rash macular | | | |

| | | | |
|--|----------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Renal and urinary disorders Nephrolithiasis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Endocrine disorders Autoimmune thyroiditis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) | 2 / 12 (16.67%) 2 | 1 / 12 (8.33%) 1 | |
| Arthritis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Arthralgia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Bone pain subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Neck pain subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Myalgia subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | |
| Musculoskeletal pain subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Muscle spasms subjects affected / exposed occurrences (all) | 2 / 12 (16.67%) 2 | 0 / 12 (0.00%) 0 | |
| Flank pain | | | |

| | | | |
|-----------------------------|----------------|-----------------|--|
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 5 / 12 (41.67%) | |
| occurrences (all) | 0 | 5 | |
| Cystitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Device related infection | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Infected dermal cyst | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 2 / 12 (16.67%) | |
| occurrences (all) | 2 | 2 | |
| Influenza | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|------------------------------------|-----------------|-----------------|--|
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 2 / 12 (16.67%) | |
| occurrences (all) | 0 | 2 | |
| Skin infection | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 12 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Tracheitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Metabolism and nutrition disorders | | | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Decreased appetite | | | |

| | | | |
|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Steroid diabetes | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | |
| occurrences (all) | 2 | 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---|
| 24 September 2021 | <p>Protocol Version 2: Revisions were made for consistency and in response to request from FDA.</p> <ul style="list-style-type: none">• The stopping criteria were expanded and described in more detail.• Inclusion criterion for Part A was modified to require that subjects failed at least 2 prior lines of systemic therapy (instead of 2 prior lines of therapy) and received at least 3 cycles of anti-PD-1/PD-L1 based therapy (instead of 1 cycle).• Added text to describe dosing criteria for Cycles ≥ 2.• Added text to clarify how subjects would be monitored during and after infusions, on Cycle 1 Day 1 and for subsequent doses.• Added text to explain that the planned dose levels may need to be adjusted depending on reported AEs and DLTs.• Added text to specify that the posterior distribution for all dose levels was Beta (1+a, 1+b), where a and b are the number of subjects with and without a DLT at the current dose level, respectively. The criteria for an unsafe dose level and dose escalation/de-escalation decision rules were adjusted.• The DLT evaluation period was changed from 21 to 28 days from the first dose of AZD7789 on Cycle 1 Day 1. The definition for an evaluable subject was aligned with revised definition of the DLT evaluation period.• The total number of subjects to be enrolled in the study and the number of subjects to be enrolled in Part B were updated.• Changed the probability percentage for dose level considered to be unsafe.• It was clarified that subjects treated at the RP2D in Part A would be included in Cohort B1.• Defined No-Go and false No-Go criteria.• Added section for Cytokine Release Syndrome (CRS).• Updated conditions to be considered as DLTs: Conditions for thrombocytopenia were updated and conditions for CRS were added. |
| 01 November 2022 | <p>Protocol Version 3:</p> <ul style="list-style-type: none">• Amended to clarify when a cohort (eg, Cohort A5, A6, A7 or A8) could fill their roster of up to 12 subjects independently of each other.• Reduction of PK sampling at later timepoints in Part A. Addition of AZD7789 PK and ADA samples at end of end of treatment (EoT).• The study stopping criteria were further clarified for each phase of the study by adding frequency and severity of the AEs.• Age range of subjects lowered from 18 to 16 years. Addition of text specifying that subjects between 16 and 18 years old need to provide assent, if required per local regulations, and their legally authorized representative must give signed written informed consent. Added wording associated with collecting agreement from a young adult subject or their legally authorized representative for participation in the study, and updated instances of "adult" to adult/young adult".• Amended the minimum threshold left ventricular ejection fraction as part of the inclusion criteria.• Addition of criterion for minimum body weight ≥ 40 kg for all subjects and "prior checkpoint inhibitor" to clarify which immunotherapy.• Specified for subjects with COVID-19 infection in the last 3 months, a negative PCR test would be needed within 72 hours prior to first dose.• Decreased the upper limit of the target toxicity interval from 35% to 33%.• DLT definition was amended to include Grade 4 anemia not related to the underlying disease or any extraneous cause (eg, bleeding).• A subsection was added to provide guidance in case pseudo-progression (eg, tumor flare due to immunomodulatory agent therapy) occurs during treatment with the study drug.• Added text to specify when disease progression should be reported as a SAE/SUSAR.• Revision of the study drug discontinuation criteria in the following sections: colitis; rash/dermatitis; neurotoxicity; peripheral neuromotor syndromes; myositis; immune-mediated liver injury; cytokine release syndrome. |

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| 11 July 2023 | <p>Protocol Version 4:</p> <ul style="list-style-type: none"> • Included objectives for quality of life / PRO assessments. • Changed eligibility of Cohort B1 from at least 3 to 2 prior cycles of anti-PD-1/ PD-L1 based therapy. • Added PRO-CTCAE (or Peds-PRO-CTCAE), PGI-TT, PROMIS PF 8c (or PROMIS Pediatric v3.0 - Mobility 7a), EORTC ILXX, PGIS, PGIC, EQ-5D-5L • Added peripheral neuropathy to the list of acceptable ongoing \geq Grade 2 toxicities from prior therapies unless immune-mediated. • Added list of acceptable unresolved imAE \geq Grade 2 • Modified the definition of washout period to 28 days. • Added description, preparation and administration guidance for liquid formulation. |
| 07 May 2024 | <p>Protocol Version 5:</p> <ul style="list-style-type: none"> • Added PTAP guidance including test assessments and samples at last study visit prior to the final study DCO. Added requirement for safety reporting to continue during PTAP. Clarified that the EoT visit would not be required for subjects entering the PTAP. • Revised time period for use of contraception and donation of sperm and ova to 90 days after last dose of sabestomig. |

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.

Part A (dose escalation) of this study was completed and Part B (dose expansion) of this study was not initiated and therefore, data were not collected and analyzed for Part B of this study.

Notes: