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 ≥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 ≥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
• ≥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 ≥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 B1: Objective response rate (ORR)

End point title	Part B (Dose Expansion): Cohort B1: Objective response rate (ORR)[3]

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:

[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 B2: Complete response rate (CRR)

End point title	Part B (Dose Expansion): Cohort B2: Complete response rate (CRR)[5]

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:

[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:

The anti-tumor activity of sabestomig in subjects with r/r cHL was assessed.
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.
Response-evaluable set included all dosed subjects who had measurable disease at baseline.
Here, '9999' indicates that data were not analyzed due to presence of single subject during analysis as pre-specified in Statistical analysis plan (SAP).

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:

The anti-tumor activity of sabestomig in subjects with r/r cHL was assessed.
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.
Response-evaluable set included all dosed subjects who had measurable disease at baseline.
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.

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 [ClDl (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 (t½λz)

End point title	Part A (Dose Escalation): Terminal elimination half-life (t½λz)

End point description:

The t½λz 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 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[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): 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[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): 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[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): Maximum observed concentration (Cmax)

End point title	Part B (Dose Expansion): Maximum observed concentration (Cmax)

End point description:

The Cmax of sabestomig in subjects with r/r cHL was planned to be assessed.

However, Part B was not initiated, hence data for Cmax 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: ug/mL				
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): Terminal elimination half-life (t½λz)

End point title	Part B (Dose Expansion): Terminal elimination half-life (t½λz)

End point description:

The t½λz of sabestomig in subjects with r/r cHL was planned to be assessed.
However, Part B was not initiated, hence data for t½λz 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: Day				
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): 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[26]			
Units: Subjects				

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): 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[27]			
Units: Day*ug/mL				
geometric mean (geometric coefficient of variation)	()			

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

No statistical analyses for this end point

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	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	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	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			

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

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Middle ear effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	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	0 / 1 (0.00%)	0 / 5 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Acute graft versus host disease in skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vaginal discharge			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 1 (100.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	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	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 1 (100.00%)	0 / 5 (0.00%)	3 / 12 (25.00%)
occurrences (all)	1	0	3
Spinal compression fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cardiomyopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Intention tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	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	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Retinopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	3 / 12 (25.00%)
occurrences (all)	0	0	3
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	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	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 1 (100.00%)	1 / 5 (20.00%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	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	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	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	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	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	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	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	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 12 (16.67%)	2 / 12 (16.67%)	
occurrences (all)	3	2	
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Middle ear effusion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Retinopathy			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	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	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	2	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	Protocol Version 2: Revisions were made for consistency and in response to request from FDA. • 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	Protocol Version 3: • 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.

11 July 2023	Protocol Version 4: • 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 ≥ Grade 2 toxicities from prior therapies unless immune-mediated. • Added list of acceptable unresolved imAE ≥ Grade 2 • Modified the definition of washout period to 28 days. • Added description, preparation and administration guidance for liquid formulation.
07 May 2024	Protocol Version 5: • 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: