



Clinical trial results:

A Phase 1/2 Open-label, Multi-center Study of the Safety and Efficacy of IMCgp100 using the Intra-patient Escalation Dosing Regimen in Patients with Advanced Uveal Melanoma

Summary

EudraCT number	2015-004222-34
Trial protocol	GB DE ES
Global end of trial date	17 October 2022

Results information

Result version number	v1 (current)
This version publication date	20 May 2023
First version publication date	20 May 2023

Trial information

Trial identification

Sponsor protocol code	IMCgp100-102
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02570308
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Immunocore Ltd.
Sponsor organisation address	92 Park Drive, Milton Park, Abindgon, Oxfordshire, United Kingdom, OX14 4RY
Public contact	Nicola McKelvie, Immunocore Ltd., +44 1235438600, nicola.mckelvie@immunocore.com.com
Scientific contact	Nicola McKelvie, Immunocore Ltd., +44 1235438600, nicola.mckelvie@immunocore.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	20 March 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 March 2020
Global end of trial reached?	Yes
Global end of trial date	17 October 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

IMCgp100-102 is a Phase I/II study of the weekly intra-patient escalation dose regimen with IMCgp100 as a single agent in participants with metastatic uveal melanoma (mUM). According to this regimen, all participants in the trial received 2 weekly doses of IMCgp100 at a dose level below the identified weekly recommended Phase II dose (RP2D-QW) and then a dose escalation commenced at the third weekly dose at C1D15. The Phase I testing of the intra-patient escalation dosing regimen is designed to achieve a higher exposure and maximal plasma concentration of IMCgp100 after doses at Cycle 1 Day 15 (C1D15) and thereafter.

The Phase I portion of the study was a standard 3+3 dose escalation design. The recommended Phase II dose of the intra-patient escalation dose regimen (RP2D-IE) was identified and expansion cohorts in metastatic uveal melanoma was accrued based on prior therapy.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice (GCP) standards and applicable regulations regarding ethical use of human subjects in medical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 February 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 19
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	United Kingdom: 17
Country: Number of subjects enrolled	United States: 91
Worldwide total number of subjects	146
EEA total number of subjects	19

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)	92
From 65 to 84 years	53
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Adult participants with metastatic Stage 4 uveal melanoma (HLA-A*0201 subtype) with any prior systemic therapy were recruited.

Pre-assignment

Screening details:

Participants were enrolled at study centers located in Canada, Germany, Spain, United Kingdom, and United States.

Period 1

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

Blinding implementation details:

This was an open-label study.

Arms

Are arms mutually exclusive?	Yes
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Arm title	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp
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Arm description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 54 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Arm type	Experimental
Investigational medicinal product name	IMCgp100
Investigational medicinal product code	
Other name	Tebentafusp, Kimmtrak
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bispecific soluble HLA-A2 restricted gp100-specific T-cell receptor fused to anti-CD3.

Arm title	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp
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Arm description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 64 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Arm type	Experimental
Investigational medicinal product name	IMCgp100
Investigational medicinal product code	
Other name	Tebentafusp, Kimmtrak
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bispecific soluble HLA-A2 restricted gp100-specific T-cell receptor fused to anti-CD3.

Arm title	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp
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Arm description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 73 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

beyond (each cycle is 28 days).

Arm type	Experimental
Investigational medicinal product name	IMCgp100
Investigational medicinal product code	
Other name	Tebentafusp, Kimmtrak
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bispecific soluble HLA-A2 restricted gp100-specific T-cell receptor fused to anti-CD3.

Arm title	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
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Arm description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 68 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Arm type	Experimental
Investigational medicinal product name	IMCgp100
Investigational medicinal product code	
Other name	Tebentafusp, Kimmtrak
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bispecific soluble HLA-A2 restricted gp100-specific T-cell receptor fused to anti-CD3.

Arm title	Phase 2 Dose Expansion: 68 mcg Tebentafusp
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Arm description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 68 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Arm type	Experimental
Investigational medicinal product name	IMCgp100
Investigational medicinal product code	
Other name	Tebentafusp, Kimmtrak
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bispecific soluble HLA-A2 restricted gp100-specific T-cell receptor fused to anti-CD3.

Number of subjects in period 1	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp
Started	3	6	4
Completed	2	1	0
Not completed	1	5	4
Consent withdrawn by subject	-	-	-
Death	1	5	4
Unspecified	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp	Phase 2 Dose Expansion: 68 mcg Tebentafusp
Started	6	127
Completed	2	53
Not completed	4	74
Consent withdrawn by subject	-	1
Death	4	69
Unspecified	-	2
Lost to follow-up	-	2

Baseline characteristics

Reporting groups

Reporting group title	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp
Reporting group description: Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 54 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).	
Reporting group title	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp
Reporting group description: Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 64 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).	
Reporting group title	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp
Reporting group description: Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 73 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).	
Reporting group title	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
Reporting group description: Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 68 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).	
Reporting group title	Phase 2 Dose Expansion: 68 mcg Tebentafusp
Reporting group description: Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 68 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).	

Reporting group values	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp
Number of subjects	3	6	4
Age categorical 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)	2	4	2
From 65-84 years	1	2	2
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	61.3	54.7	56.5
standard deviation	± 6.03	± 11.99	± 18.41

Gender categorical Units: Subjects			
Female	2	3	2
Male	1	3	2
Race Units: Subjects			
White	3	6	4
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	3	5	4

Reporting group values	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp	Phase 2 Dose Expansion: 68 mcg Tebentafusp	Total
Number of subjects	6	127	146
Age categorical 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)	4	120	132
From 65-84 years	2	6	13
85 years and over	0	1	1
Age continuous Units: years			
arithmetic mean	55.8	56.5	
standard deviation	± 9.24	± 11.37	-
Gender categorical Units: Subjects			
Female	3	64	74
Male	3	63	72
Race Units: Subjects			
White	6	126	145
Other	0	1	1
Ethnicity Units: Subjects			
Hispanic or Latino	0	4	5
Not Hispanic or Latino	6	123	141

Subject analysis sets

Subject analysis set title	Phase 1 Dose Escalation
Subject analysis set type	Per protocol

Subject analysis set description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8),

followed by
weekly (QW) doses per cohort administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group values	Phase 1 Dose Escalation		
Number of subjects	19		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	12		
From 65-84 years	7		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±		
Gender categorical			
Units: Subjects			
Female			
Male			
Race			
Units: Subjects			
White			
Other			
Ethnicity			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			

End points

End points reporting groups

Reporting group title	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 54 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group title	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 64 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group title	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 73 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group title	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 68 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group title	Phase 2 Dose Expansion: 68 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 68 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Subject analysis set title	Phase 1 Dose Escalation
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Subject analysis set type	Per protocol
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Subject analysis set description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) doses per cohort administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Primary: Number of Participants With a Dose Limiting Toxicity (DLT) in Phase 1

End point title	Number of Participants With a Dose Limiting Toxicity (DLT) in Phase 1 ^{[1][2]}
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End point description:

Number of participants with a dose limiting toxicity, defined as an adverse event (AE) or abnormal laboratory value assessed as having a suspected relationship to study drug, and unrelated to disease, disease progression, inter-current illness, or concomitant medications that occurs within the first cycle of treatment and meets any of the pre-specified criteria. The Safety Analysis Set (SAS) included all participants who received at least 1 full or partial dose of tebentafusp.

End point type	Primary
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End point timeframe:

Up to 49 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: Per protocol, only descriptive statistics are presented.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	4	6
Units: Participants	0	1	2	0

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate in Phase 2

End point title	Objective Response Rate in Phase 2 ^{[3][4]}
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End point description:

Objective response rate (ORR) is defined as the percentage of participants with measurable disease with at least 1 visit response of complete response (CR) or partial response (PR) that is confirmed at least 4 weeks later, as defined in RECIST v.1.1 and assessed by an independent central review (ICR). The denominator in the calculation of the ORR is the number of participants in the full analysis set with measurable disease at baseline. The Full Analysis Set (FAS) included all participants who received at least 1 full or partial dose of tebentafusp.

End point type	Primary
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End point timeframe:

Up to 38 months

Notes:

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

Justification: Per protocol, only descriptive statistics are presented.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Percentage of participants				
number (confidence interval 95%)	4.7 (1.8 to 10.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate in Phase 1

End point title	Objective Response Rate in Phase 1
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End point description:

ORR is defined as the percentage of participants with measurable disease with at least 1 visit response of CR or PR that is confirmed at least 4 weeks later, as defined in RECIST v.1.1 and assessed by an investigator. The denominator in the calculation of the ORR is the number of participants in the full analysis set with measurable disease at baseline. The Full Analysis Set (FAS) included all participants who received at least 1 full or partial dose of tebentafusp. The analysis was pre-specified to be a pooled analysis of all Phase 1 cohort participants (irrespective of dose); therefore, data by individual dose were not analyzed.

End point type	Secondary
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End point timeframe:

Up to 49 months

End point values	Phase 1 Dose Escalation			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: Percentage of participants				
number (confidence interval 95%)	15.8 (3.4 to 39.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival

End point title	Progression-free Survival ^[5]
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End point description:

Progression-free survival is defined as the time in months from first dose of study drug until the date of disease progression or death (by any cause in the absence of disease progression) as assessed by RECIST v1.1 by the investigator for Phase 1 and ICR for Phase 2. The Full Analysis Set (FAS) included all participants who received at least 1 full or partial dose of tebentafusp. The analysis was pre-specified to be a pooled analysis of all Phase 1 cohort participants (irrespective of dose); therefore, data by individual dose were not analyzed.

End point type	Secondary
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End point timeframe:

Up to 49 months

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp	Phase 1 Dose Escalation		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	127	19		
Units: Months				
median (confidence interval 95%)	2.8 (2.0 to 3.7)	7.4 (1.2 to 14.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate

End point title	Disease Control Rate ^[6]
End point description:	
Disease control rate (DCR) is defined as the percentage of participants with a best overall response of CR or PR or stable disease (SD) recorded at least 24 weeks (\pm 1 week) after commencement of study drug and prior to any progressive disease (PD) event, as assessed by RECIST v1.1 by the investigator for Phase 1 and ICR for Phase 2. The Full Analysis Set (FAS) included all participants who received at least 1 full or partial dose of tebentafusp. The analysis was pre-specified to be a pooled analysis of all Phase 1 cohort participants (irrespective of dose); therefore, data by individual dose were not analyzed.	
End point type	Secondary
End point timeframe:	
24 weeks	

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp	Phase 1 Dose Escalation		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	127	19		
Units: Percentage of participants				
number (confidence interval 95%)	22.8 (15.9 to 31.1)	47.4 (24.4 to 71.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response ^[7]
End point description:	
Duration of response (DOR) is defined as the time in months from the date of first documented objective response (CR or PR) until the date of documented disease progression or death by any cause in the absence of disease progression as assessed by RECIST v1.1 by the investigator for Phase 1 and ICR for Phase 2. The analysis population included all participants who received at least 1 full or partial dose of	

tebentafusp and who achieved a response. The analysis was pre-specified to be a pooled analysis of all Phase 1 cohort participants (irrespective of dose); therefore, data by individual dose were not analyzed.

End point type	Secondary
End point timeframe:	
Up to 49 months	
Notes:	
[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Per protocol, only descriptive statistics are presented.	

End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp	Phase 1 Dose Escalation		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	6	3		
Units: Months				
median (confidence interval 95%)	8.706 (5.552 to 24.542)	7.425 (3.713 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response

End point title	Time to Response ^[8]
End point description:	
Time to response (TTR) is defined as the time in months from the date of first dose of study drug until the date of first documented objective response as assessed by RECIST v1.1 by the investigator for Phase 1 and ICR for Phase 2. The analysis population included all participants who received at least 1 full or partial dose of tebentafusp and who achieved a response. The analysis was pre-specified to be a pooled analysis of all Phase 1 cohort participants (irrespective of dose); therefore, data by individual dose were not analyzed.	
End point type	Secondary
End point timeframe:	
Up to 49 months	
Notes:	
[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Per protocol, only descriptive statistics are presented.	

End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp	Phase 1 Dose Escalation		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	6	3		
Units: Months				
arithmetic mean (standard deviation)	7.0 (± 6.9)	5.5 (± 1.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival ^[9]
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End point description:

Overall survival (OS) is defined as the time in months from the date of first dose of study drug until death due to any cause in general. The Full Analysis Set (FAS) included all participants who received at least 1 full or partial dose of tebentafusp. The analysis was pre-specified to be a pooled analysis of all Phase 1 cohort participants (irrespective of dose); therefore, data by individual dose were not analyzed.

End point type	Secondary
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End point timeframe:

Up to 49 months

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp	Phase 1 Dose Escalation		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	127	19		
Units: Months				
median (confidence interval 95%)	16.8 (12.9 to 21.3)	29.6 (10.9 to 42.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Minor Response Rate

End point title	Minor Response Rate ^[10]
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End point description:

Rate of minor response (or better) is defined as the proportion of participants with a confirmed CR, PR, or minor response (MinR) as assessed by RECIST v1.1 by the investigator for Phase 1 or ICR for Phase 2, where MinR is a reduction from baseline in sum of diameters between 10%-29%. The sum of diameters is defined as per RECIST v1.1 as the sum of longest diameters or short axis of target lesions (mm). The Full Analysis Set (FAS) included all participants who received at least 1 full or partial dose of tebentafusp. The analysis was pre-specified to be a pooled analysis of all Phase 1 cohort participants (irrespective of dose); therefore, data by individual dose were not analyzed.

End point type	Secondary
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End point timeframe:

Up to 49 months

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp	Phase 1 Dose Escalation		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	127	19		
Units: Percentage of participants				
number (confidence interval 95%)	11.0 (6.2 to 17.8)	26.3 (9.1 to 51.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment Dose Interruptions or Reductions

End point title	Number of Participants With Treatment Dose Interruptions or Reductions
End point description:	
Tolerability of study treatment was assessed by summarizing the number of participants with dose interruptions or reductions that occurred during the treatment period. The Safety Analysis Set (SAS) included all participants who received at least 1 full or partial dose of tebentafusp.	
End point type	Secondary
End point timeframe:	
Up to 49 months	

End point values	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	4
Units: Participants	2	4	3	4

End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Participants	49			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-Time Curve (AUC) of Tebentafusp

End point title	Area Under the Plasma Concentration-Time Curve (AUC) of Tebentafusp ^[11]
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End point description:

Area under the plasma concentration-time curve (AUC) in dose escalation cohorts. All participants who received at least 1 full or partial dose of tebentafusp and with detectable serum concentrations are included.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 and Cycle 1 Day 15: predose, end of infusion, and 4 and 8 hours postdose

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	4	6
Units: hr*pg/mL				
geometric mean (standard deviation)				
Cycle 1 Day 1	28550 (± 27.0)	36530 (± 23.3)	32920 (± 18.2)	33030 (± 16.5)
Cycle 1 Day 15	81310 (± 33.7)	98660 (± 34.8)	106800 (± 11.6)	109800 (± 23.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum plasma concentration (Cmax) of Tebentafusp

End point title	Maximum plasma concentration (Cmax) of Tebentafusp ^[12]
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End point description:

The maximum observed plasma drug concentration after single dose administration in dose escalation cohorts. All participants who received at least 1 full or partial dose of tebentafusp and with detectable serum concentrations are included.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 and Cycle 1 Day 15: predose, end of infusion, and 4 and 8 hours postdose

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	4	6
Units: pg/mL				
geometric mean (standard deviation)				
Cycle 1 Day 1	3050 (± 15.1)	3294 (± 22.7)	3041 (± 21.7)	3640 (± 23.3)
Cycle 1 Day 15	8885 (± 17.2)	9523 (± 23.0)	11300 (± 11.7)	11520 (± 25.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Plasma Concentration (Tmax) of Tebentafusp

End point title	Time to Maximum Plasma Concentration (Tmax) of Tebentafusp ^[13]
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End point description:

The Tmax of tebentafusp in the phase 1 dose escalation cohorts is reported. All participants who received at least 1 full or partial dose of tebentafusp and with detectable serum concentrations are included.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 and Cycle 1 Day 15: predose, end of infusion, and 4 and 8 hours postdose

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	4	6
Units: Hours				
median (full range (min-max))				
Cycle 1 Day 1	0.50 (0.50 to 0.50)	0.50 (0.50 to 0.50)	0.50 (0.50 to 0.50)	0.50 (0.50 to 0.50)
Cycle 1 Day 15	0.50 (0.50 to 0.50)	0.50 (0.50 to 0.50)	0.50 (0.50 to 0.50)	0.50 (0.50 to 0.50)

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent terminal plasma half-life (t_{1/2}) of tebentafusp

End point title	Apparent terminal plasma half-life (t _{1/2}) of tebentafusp ^[14]
End point description: The apparent t _{1/2} of tebentafusp is reported in phase 1 dose escalation cohorts. All participants who received at least 1 full or partial dose of tebentafusp and with detectable serum concentrations are included.	
End point type	Secondary
End point timeframe: Cycle 1 Day 1 and Cycle 1 Day 15: predose, end of infusion, and 4 and 8 hours postdose	

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Per protocol, only descriptive statistics are presented.

End point values	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	4	6
Units: Hours				
median (full range (min-max))				
Cycle 1 Day 1	6.635 (5.40 to 6.67)	7.591 (6.03 to 11.3)	6.442 (5.82 to 7.63)	6.273 (5.59 to 10.1)
Cycle 1 Day 15	6.897 (6.78 to 8.03)	7.532 (6.57 to 10.5)	7.519 (6.36 to 9.24)	7.488 (5.70 to 11.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Anti-IMCgp100 Antibody Formation

End point title	Percentage of Participants With Anti-IMCgp100 Antibody Formation
End point description: The Full Analysis Set (FAS) included all participants who received at least 1 full or partial dose of tebentafusp and with evaluable data; two participants were excluded from ADA evaluation due to lack of sampling after dosing.	
End point type	Secondary
End point timeframe: Up to 49 months	

End point values	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	4	6
Units: Percentage of participants				

number (not applicable)	66.7	16.7	25.0	33.3
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End point values	Phase 2 Dose Expansion: 68 mcg Tebentafusp			
Subject group type	Reporting group			
Number of subjects analysed	125			
Units: Percentage of participants				
number (not applicable)	33.6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 49 months

Adverse event reporting additional description:

All treated participants are included.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 54 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group title	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 64 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group title	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 73 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group title	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 68 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Reporting group title	Phase 2 Dose Expansion: 68 mcg Tebentafusp
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Reporting group description:

Fixed low doses of 20 mcg tebentafusp at Cycle 1 Day 1 (C1D1) and 30 mcg at Cycle 1 Day 8 (C1D8), followed by weekly (QW) 68 mcg dose administered intravenously at Cycle 1 Day 15 (C1D15) and beyond (each cycle is 28 days).

Serious adverse events	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	3 / 4 (75.00%)
number of deaths (all causes)	1	5	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Hypertensive crisis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Multiple organ system dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Pulmonary edema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 physical condition decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Injury, poisoning and procedural complications			
Infusion-related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Cardiac failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Left ventricular dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Aphasia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Spinal cord compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Abdominal pain upper			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Diarrhea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Biliary colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Hyperbilirubinemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Jaundice cholestatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Skin and subcutaneous tissue disorders			

Rash maculopapular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Bone pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Arthritis infective			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Biliary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Metabolism and nutrition disorders			
Hypophosphatemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (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

Serious adverse events	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp	Phase 2 Dose Expansion: 68 mcg Tebentafusp	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	42 / 127 (33.07%)	
number of deaths (all causes)	4	69	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor pain			

subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Multiple organ system dysfunction syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	9 / 127 (7.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 6 (16.67%)	4 / 127 (3.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnea			

subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary edema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical condition decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion-related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			

subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infarction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemorrhage intracranial			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			

subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

Rash maculopapular			
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			

subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypophosphatemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Phase 1 Dose Escalation Cohort 1: 54 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 2: 64 mcg Tebentafusp	Phase 1 Dose Escalation Cohort 3: 73 mcg Tebentafusp
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor inflammation			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 3	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Tumor pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 3	1 / 6 (16.67%) 4	0 / 4 (0.00%) 0
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 6 (33.33%) 2	2 / 4 (50.00%) 3
Vascular disorders Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 2	0 / 4 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 4 (25.00%) 1
Hypotension subjects affected / exposed occurrences (all)	3 / 3 (100.00%) 8	4 / 6 (66.67%) 5	2 / 4 (50.00%) 4
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 5	0 / 4 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 3	3 / 6 (50.00%) 14	4 / 4 (100.00%) 48
Diverticulitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Edema peripheral			
subjects affected / exposed	3 / 3 (100.00%)	5 / 6 (83.33%)	3 / 4 (75.00%)
occurrences (all)	3	6	12
Face edema			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	4
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	5 / 6 (83.33%)	4 / 4 (100.00%)
occurrences (all)	9	16	6
Feeling hot			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Generalized edema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Impaired healing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Infusion site hematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Localized infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Nodule			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	3 / 4 (75.00%)
occurrences (all)	15	16	16
Temperature regulation disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vulvovaginal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	3	8	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dyspnea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	3	4
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	2 / 4 (50.00%)
occurrences (all)	4	6	4
Oropharyngeal pain			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
Pleuritic pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	3	3
Pulmonary congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Pulmonary edema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Rhinorrhea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Sinus pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 6 (16.67%) 1	1 / 4 (25.00%) 1
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	1 / 4 (25.00%) 1
Confusional state subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
Depressed mood subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	1 / 4 (25.00%) 1
Insomnia subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	3 / 6 (50.00%) 3	0 / 4 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 6 (33.33%) 2	2 / 4 (50.00%) 3
Amylase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	1	6	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Blood cholesterol increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Fall			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Ligament injury			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	11	5
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	6	0
Sunburn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Wound			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
Cardiomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypertensive heart disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Tachycardia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
Nervous system disorders			
Aphasia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Ataxia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
Cerebral arteriosclerosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 4 (25.00%) 1
Disturbance in attention subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	2 / 6 (33.33%) 4	2 / 4 (50.00%) 4
Dysgeusia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	1 / 4 (25.00%) 2
Headache subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 3	3 / 6 (50.00%) 6	2 / 4 (50.00%) 2
Memory impairment subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	3 / 4 (75.00%) 3
Neuropathy peripheral subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Paresthesia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 6 (16.67%) 4	2 / 4 (50.00%) 3
Syncope			

subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otorrhea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Parasthesia ear			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vertigo			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Eye inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eyelash hypopigmentation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ocular hyperemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Periorbital edema			
subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	3 / 4 (75.00%)
occurrences (all)	2	13	9
Vision blurred			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 4 (50.00%)
occurrences (all)	0	1	4
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	3 / 4 (75.00%)
occurrences (all)	1	9	7
Abdominal pain lower			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	2 / 4 (50.00%)
occurrences (all)	1	4	5
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Diarrhea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	3 / 4 (75.00%)
occurrences (all)	0	13	7
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Dysphagia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Eructation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastric ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastrointestinal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Hemorrhoidal hemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	5 / 6 (83.33%)	4 / 4 (100.00%)
occurrences (all)	7	21	18
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rectal hemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	3 / 4 (75.00%)
occurrences (all)	0	13	5
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hepatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	4
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	3 / 4 (75.00%)
occurrences (all)	0	0	3
Blister			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Dermatitis acneiform			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	2 / 4 (50.00%)
occurrences (all)	1	5	3
Ephelides			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	3 / 4 (75.00%)
occurrences (all)	1	20	19
Generalized erythema			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	2 / 4 (50.00%)
occurrences (all)	1	3	4
Hair color changes			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	1	2	2
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nail discoloration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Palmar-plantar erythrodysesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	9	0

Photosensitivity reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 4 (50.00%)
occurrences (all)	0	1	4
Pruritus			
subjects affected / exposed	3 / 3 (100.00%)	4 / 6 (66.67%)	4 / 4 (100.00%)
occurrences (all)	6	25	18
Pruritus generalized			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Purpura			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 4 (50.00%)
occurrences (all)	0	1	4
Rash erythematous			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Rash generalized			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	2 / 4 (50.00%)
occurrences (all)	2	9	15
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	5	12

Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sensitive skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin fissures			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin hyperpigmentation			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	2 / 4 (50.00%)
occurrences (all)	1	3	2
Skin hypopigmentation			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Skin irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin mass			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	0 / 4 (0.00%)
occurrences (all)	2	11	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Ligament sprain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	3 / 4 (75.00%)
occurrences (all)	1	7	6
Back pain			
subjects affected / exposed	2 / 3 (66.67%)	5 / 6 (83.33%)	4 / 4 (100.00%)
occurrences (all)	6	24	5
Bone pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	9	5	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 4 (50.00%)
occurrences (all)	0	4	2
Musculoskeletal pain			

subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	10	2
Myalgia			
subjects affected / exposed	3 / 3 (100.00%)	3 / 6 (50.00%)	1 / 4 (25.00%)
occurrences (all)	5	8	5
Neck pain			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	1	3	3
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	3 / 4 (75.00%)
occurrences (all)	1	19	10
Pain in jaw			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Nail infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Otitis media			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Tinea pedis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Tooth infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 4 (25.00%) 1
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	1 / 6 (16.67%) 3	1 / 4 (25.00%) 2
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	4 / 6 (66.67%) 4	0 / 4 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 4 (25.00%) 2
Hyperglycemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 4 (25.00%) 2
Hyperkalemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 2	0 / 4 (0.00%) 0
Hypermagnesemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Hypoalbuminemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
Hypocalcemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 6 (16.67%) 2	0 / 4 (0.00%) 0
Hypoglycemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypomagnesemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphatemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	2	0

Non-serious adverse events	Phase 1 Dose Escalation Cohort 4: 68 mcg Tebentafusp	Phase 2 Dose Expansion: 68 mcg Tebentafusp	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	127 / 127 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Tumor pain			
subjects affected / exposed	0 / 6 (0.00%)	8 / 127 (6.30%)	
occurrences (all)	0	11	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	7 / 127 (5.51%)	
occurrences (all)	0	9	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	1 / 6 (16.67%)	16 / 127 (12.60%)	
occurrences (all)	2	20	
Hot flush			
subjects affected / exposed	1 / 6 (16.67%)	14 / 127 (11.02%)	
occurrences (all)	2	26	

Hypertension			
subjects affected / exposed	1 / 6 (16.67%)	18 / 127 (14.17%)	
occurrences (all)	1	53	
Hypotension			
subjects affected / exposed	5 / 6 (83.33%)	53 / 127 (41.73%)	
occurrences (all)	10	115	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	9 / 127 (7.09%)	
occurrences (all)	0	20	
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences (all)	0	2	
Chills			
subjects affected / exposed	5 / 6 (83.33%)	84 / 127 (66.14%)	
occurrences (all)	20	282	
Diverticulitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)	
occurrences (all)	1	0	
Edema peripheral			
subjects affected / exposed	5 / 6 (83.33%)	44 / 127 (34.65%)	
occurrences (all)	7	86	
Face edema			
subjects affected / exposed	2 / 6 (33.33%)	78 / 127 (61.42%)	
occurrences (all)	4	134	
Facial pain			
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)	
occurrences (all)	1	2	
Fatigue			
subjects affected / exposed	6 / 6 (100.00%)	78 / 127 (61.42%)	
occurrences (all)	21	134	
Feeling hot			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			

subjects affected / exposed	1 / 6 (16.67%)	1 / 127 (0.79%)
occurrences (all)	1	1
Gait disturbance		
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)
occurrences (all)	0	0
Generalized edema		
subjects affected / exposed	0 / 6 (0.00%)	8 / 127 (6.30%)
occurrences (all)	0	12
Hyperbilirubinemia		
subjects affected / exposed	1 / 6 (16.67%)	10 / 127 (7.87%)
occurrences (all)	1	16
Impaired healing		
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)
occurrences (all)	0	0
Infusion site hematoma		
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)
occurrences (all)	0	1
Localized infection		
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)
occurrences (all)	1	0
Malaise		
subjects affected / exposed	1 / 6 (16.67%)	9 / 127 (7.09%)
occurrences (all)	1	10
Nodule		
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)
occurrences (all)	0	0
Non-cardiac chest pain		
subjects affected / exposed	0 / 6 (0.00%)	4 / 127 (3.15%)
occurrences (all)	0	4
Pain		
subjects affected / exposed	0 / 6 (0.00%)	10 / 127 (7.87%)
occurrences (all)	0	13
Peripheral swelling		
subjects affected / exposed	1 / 6 (16.67%)	1 / 127 (0.79%)
occurrences (all)	1	1
Pyrexia		

subjects affected / exposed occurrences (all) Temperature regulation disorder subjects affected / exposed occurrences (all)	6 / 6 (100.00%) 21 0 / 6 (0.00%) 0	103 / 127 (81.10%) 417 0 / 127 (0.00%) 0	
Immune system disorders Cytokine release syndrome subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	10 / 127 (7.87%) 45	
Reproductive system and breast disorders Breast pain subjects affected / exposed occurrences (all) Vulvovaginal dryness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 127 (0.00%) 0 0 / 127 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dysphonia subjects affected / exposed occurrences (all) Dyspnea subjects affected / exposed occurrences (all) Hiccups subjects affected / exposed occurrences (all) Hypoxia subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all) Oropharyngeal pain	5 / 6 (83.33%) 9 0 / 6 (0.00%) 0 2 / 6 (33.33%) 6 0 / 6 (0.00%) 0 1 / 6 (16.67%) 1 1 / 6 (16.67%) 4	29 / 127 (22.83%) 49 0 / 127 (0.00%) 0 24 / 127 (18.90%) 34 0 / 127 (0.00%) 0 4 / 127 (3.15%) 4 10 / 127 (7.87%) 13	

subjects affected / exposed	1 / 6 (16.67%)	13 / 127 (10.24%)	
occurrences (all)	1	16	
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Productive cough			
subjects affected / exposed	1 / 6 (16.67%)	3 / 127 (2.36%)	
occurrences (all)	1	4	
Pulmonary congestion			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences (all)	0	2	
Pulmonary edema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)	
occurrences (all)	0	3	
Rhinitis allergic			
subjects affected / exposed	1 / 6 (16.67%)	3 / 127 (2.36%)	
occurrences (all)	1	4	
Rhinorrhea			
subjects affected / exposed	0 / 6 (0.00%)	7 / 127 (5.51%)	
occurrences (all)	0	8	
Sinus pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 127 (0.79%)	
occurrences (all)	3	1	
Upper-airway cough syndrome			
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)	
occurrences (all)	1	2	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	13 / 127 (10.24%)	
occurrences (all)	0	13	
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	8 / 127 (6.30%)	
occurrences (all)	0	13	

Depressed mood subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 127 (0.00%) 0	
Depression subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	6 / 127 (4.72%) 6	
Insomnia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	20 / 127 (15.75%) 23	
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	19 / 127 (14.96%) 33	
Amylase increased subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	7 / 127 (5.51%) 8	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	23 / 127 (18.11%) 36	
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	3 / 6 (50.00%) 3	13 / 127 (10.24%) 19	
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 127 (0.79%) 1	
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	4 / 127 (3.15%) 4	
Cardiac murmur subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 127 (0.00%) 0	
Lipase increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	12 / 127 (9.45%) 19	
Weight decreased			

subjects affected / exposed	1 / 6 (16.67%)	20 / 127 (15.75%)	
occurrences (all)	1	20	
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	5 / 127 (3.94%)	
occurrences (all)	0	5	
Fall			
subjects affected / exposed	0 / 6 (0.00%)	7 / 127 (5.51%)	
occurrences (all)	0	8	
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences (all)	0	2	
Ligament injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	8 / 127 (6.30%)	
occurrences (all)	0	8	
Scratch			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Skin abrasion			
subjects affected / exposed	1 / 6 (16.67%)	5 / 127 (3.94%)	
occurrences (all)	1	11	
Skin laceration			
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)	
occurrences (all)	1	3	
Sunburn			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences (all)	0	4	
Wound			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 127 (0.79%) 1	
Cardiac disorders			
Cardiomegaly			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Hypertensive heart disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Pericardial effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	1 / 6 (16.67%)	12 / 127 (9.45%)	
occurrences (all)	3	15	
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	15 / 127 (11.81%)	
occurrences (all)	0	22	
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Dizziness			

subjects affected / exposed	3 / 6 (50.00%)	21 / 127 (16.54%)	
occurrences (all)	3	25	
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	12 / 127 (9.45%)	
occurrences (all)	0	13	
Headache			
subjects affected / exposed	4 / 6 (66.67%)	42 / 127 (33.07%)	
occurrences (all)	12	91	
Memory impairment			
subjects affected / exposed	1 / 6 (16.67%)	1 / 127 (0.79%)	
occurrences (all)	1	1	
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)	
occurrences (all)	0	3	
Paresthesia			
subjects affected / exposed	1 / 6 (16.67%)	10 / 127 (7.87%)	
occurrences (all)	2	15	
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)	
occurrences (all)	0	3	
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	2 / 6 (33.33%)	17 / 127 (13.39%)	
occurrences (all)	2	21	
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	4 / 127 (3.15%)	
occurrences (all)	0	4	
Neutropenia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)	
occurrences (all)	1	3	
Ear and labyrinth disorders			
Ear discomfort			

subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Ear pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 127 (0.79%)	
occurrences (all)	2	1	
Hyperacusis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)	
occurrences (all)	1	0	
Otorrhea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Parasthesia ear			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	1 / 6 (16.67%)	3 / 127 (2.36%)	
occurrences (all)	1	4	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	9 / 127 (7.09%)	
occurrences (all)	0	12	
Eye inflammation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)	
occurrences (all)	1	0	
Eyelash hypopigmentation			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences (all)	0	2	
Lacrimation increased			
subjects affected / exposed	1 / 6 (16.67%)	4 / 127 (3.15%)	
occurrences (all)	1	4	
Ocular hyperemia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)	
occurrences (all)	0	3	

Periorbital edema subjects affected / exposed occurrences (all)	4 / 6 (66.67%) 9	34 / 127 (26.77%) 69	
Vision blurred subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	6 / 127 (4.72%) 7	
Visual impairment subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	2 / 127 (1.57%) 2	
Gastrointestinal disorders			
Abdominal distension subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	14 / 127 (11.02%) 16	
Abdominal pain subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 7	45 / 127 (35.43%) 71	
Abdominal pain lower subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 2	2 / 127 (1.57%) 4	
Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 3	30 / 127 (23.62%) 45	
Constipation subjects affected / exposed occurrences (all)	3 / 6 (50.00%) 4	30 / 127 (23.62%) 45	
Dental caries subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 127 (0.00%) 0	
Diarrhea subjects affected / exposed occurrences (all)	4 / 6 (66.67%) 11	33 / 127 (25.98%) 50	
Dyspepsia subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 5	15 / 127 (11.81%) 21	
Dysphagia			

subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Eructation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Gastric ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	1 / 6 (16.67%)	6 / 127 (4.72%)	
occurrences (all)	1	6	
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	16 / 127 (12.60%)	
occurrences (all)	0	23	
Gastrointestinal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Hemorrhoidal hemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	5 / 6 (83.33%)	86 / 127 (67.72%)	
occurrences (all)	14	247	
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)	
occurrences (all)	0	2	
Rectal hemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	4 / 6 (66.67%)	52 / 127 (40.94%)	
occurrences (all)	11	141	
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	

Hepatic pain subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	7 / 127 (5.51%) 10	
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	12 / 127 (9.45%) 12	
Blister subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	2 / 127 (1.57%) 3	
Dermatitis acneiform subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	8 / 127 (6.30%) 13	
Dermatitis allergic subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	2 / 127 (1.57%) 3	
Dry skin subjects affected / exposed occurrences (all)	5 / 6 (83.33%) 9	52 / 127 (40.94%) 68	
Ephelides subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 127 (1.57%) 2	
Erythema subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 8	22 / 127 (17.32%) 33	
Generalized erythema subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	20 / 127 (15.75%) 59	
Hair color changes subjects affected / exposed occurrences (all)	3 / 6 (50.00%) 7	34 / 127 (26.77%) 38	
Hyperhidrosis subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	4 / 127 (3.15%) 4	
Miliaria			

subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)
occurrences (all)	0	0
Nail discoloration		
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)
occurrences (all)	0	0
Night sweats		
subjects affected / exposed	1 / 6 (16.67%)	3 / 127 (2.36%)
occurrences (all)	2	3
Pain of skin		
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)
occurrences (all)	0	3
Palmar-plantar erythrodysesthesia syndrome		
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)
occurrences (all)	1	2
Papule		
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)
occurrences (all)	0	1
Photosensitivity reaction		
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)
occurrences (all)	1	3
Pruritus		
subjects affected / exposed	6 / 6 (100.00%)	87 / 127 (68.50%)
occurrences (all)	26	206
Pruritus generalized		
subjects affected / exposed	0 / 6 (0.00%)	22 / 127 (17.32%)
occurrences (all)	0	70
Psoriasis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)
occurrences (all)	0	0
Purpura		
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)
occurrences (all)	0	0
Rash		
subjects affected / exposed	2 / 6 (33.33%)	42 / 127 (33.07%)
occurrences (all)	6	88

Rash erythematous subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	6 / 127 (4.72%) 7
Rash generalized subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	30 / 127 (23.62%) 63
Rash macular subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 5	0 / 127 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 4	51 / 127 (40.16%) 121
Rash papular subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	1 / 127 (0.79%) 2
Rash pruritic subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	5 / 127 (3.94%) 18
Scab subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 127 (1.57%) 2
Sensitive skin subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 127 (0.00%) 0
Skin exfoliation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	28 / 127 (22.05%) 32
Skin fissures subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 127 (0.79%) 1
Skin hyperpigmentation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	21 / 127 (16.54%) 22
Skin hypopigmentation subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 4	25 / 127 (19.69%) 31

Skin irritation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Skin lesion			
subjects affected / exposed	1 / 6 (16.67%)	6 / 127 (4.72%)	
occurrences (all)	1	6	
Skin mass			
subjects affected / exposed	1 / 6 (16.67%)	11 / 127 (8.66%)	
occurrences (all)	1	15	
Skin ulcer			
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)	
occurrences (all)	1	0	
Vitiligo			
subjects affected / exposed	2 / 6 (33.33%)	7 / 127 (5.51%)	
occurrences (all)	2	7	
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	2 / 6 (33.33%)	3 / 127 (2.36%)	
occurrences (all)	2	4	
Nocturia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Ligament sprain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Arthralgia			
subjects affected / exposed	1 / 6 (16.67%)	33 / 127 (25.98%)	
occurrences (all)	2	45	
Back pain			
subjects affected / exposed	2 / 6 (33.33%)	41 / 127 (32.28%)	
occurrences (all)	4	57	
Bone pain			

subjects affected / exposed	2 / 6 (33.33%)	3 / 127 (2.36%)	
occurrences (all)	2	3	
Flank pain			
subjects affected / exposed	1 / 6 (16.67%)	4 / 127 (3.15%)	
occurrences (all)	1	5	
Muscle tightness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)	
occurrences (all)	11	0	
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	5 / 127 (3.94%)	
occurrences (all)	0	6	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	6 / 127 (4.72%)	
occurrences (all)	0	8	
Musculoskeletal pain			
subjects affected / exposed	1 / 6 (16.67%)	12 / 127 (9.45%)	
occurrences (all)	2	23	
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	23 / 127 (18.11%)	
occurrences (all)	3	33	
Neck pain			
subjects affected / exposed	1 / 6 (16.67%)	11 / 127 (8.66%)	
occurrences (all)	2	14	
Pain in extremity			
subjects affected / exposed	2 / 6 (33.33%)	19 / 127 (14.96%)	
occurrences (all)	3	33	
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Nail infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	13 / 127 (10.24%)	
occurrences (all)	0	18	

Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	3 / 127 (2.36%)	
occurrences (all)	0	3	
Otitis media			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 127 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	1 / 6 (16.67%)	7 / 127 (5.51%)	
occurrences (all)	1	7	
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Tinea pedis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 127 (0.00%)	
occurrences (all)	2	0	
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 127 (0.79%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	11 / 127 (8.66%)	
occurrences (all)	0	16	
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	16 / 127 (12.60%)	
occurrences (all)	1	18	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	32 / 127 (25.20%)	
occurrences (all)	3	45	
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	5 / 127 (3.94%)	
occurrences (all)	0	5	
Hyperglycemia			

subjects affected / exposed	0 / 6 (0.00%)	2 / 127 (1.57%)
occurrences (all)	0	3
Hyperkalemia		
subjects affected / exposed	3 / 6 (50.00%)	4 / 127 (3.15%)
occurrences (all)	3	4
Hypermagnesemia		
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)
occurrences (all)	1	2
Hypoalbuminemia		
subjects affected / exposed	0 / 6 (0.00%)	5 / 127 (3.94%)
occurrences (all)	0	6
Hypocalcemia		
subjects affected / exposed	0 / 6 (0.00%)	10 / 127 (7.87%)
occurrences (all)	0	13
Hypoglycemia		
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)
occurrences (all)	2	4
Hypokalemia		
subjects affected / exposed	1 / 6 (16.67%)	2 / 127 (1.57%)
occurrences (all)	1	4
Hypomagnesemia		
subjects affected / exposed	0 / 6 (0.00%)	13 / 127 (10.24%)
occurrences (all)	0	22
Hypophosphatemia		
subjects affected / exposed	1 / 6 (16.67%)	14 / 127 (11.02%)
occurrences (all)	1	25

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 December 2015	Amendment 1 was issued to implement dosing changes in the intra-patient dose-escalation regimen in response to hypotension observed in the ongoing first-in-human (FIH) study.
11 January 2016	Amendment 2 was issued to implement monitoring changes for hypotension in the intra-patient dose escalation regimen.
23 May 2016	Amendment 3 was issued to implement a change in the definition of dose limiting toxicity (DLT) with respect to recent observations of transient elevations of hepatic transaminases, alanine aminotransferase (ALT), and aspartate aminotransferase (AST), in patients with uveal melanoma (UM) in the 2 ongoing Phase 1 trials with IMCgp100, the first-in-human (FIH) study (IMCgp100-01) and this UM Phase 1 study.
07 September 2016	Amendment 4 was issued to only enroll participants with HLA-A*0201 allele determined centrally.
11 April 2017	Amendment 5 was issued to update the nomenclature of the dose levels and the recommended Phase 2 dose (RP2D) of IMCgp100 utilizing the intra-patient escalation.
15 December 2017	Amendment 6 was issued primarily to transition the dose expansion cohort of the study to more formal Phase 2 testing in participants with metastatic uveal melanoma who are treated in the second or third line setting in this trial.
26 November 2018	Amendment 7 was issued to clarify the interim and final analysis that will be done to assess the efficacy of IMCgp100 in the Phase 2 expansion phase.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported