Clinical trial results:
A Phase 1/2 Open-label Study to Investigate the Safety and Tolerability, Efficacy, Pharmacokinetics, and Immunogenicity of Modakafusp Alfa (TAK-573) as a Single Agent in Patients With Relapsed Refractory Multiple Myeloma

Summary

EudraCT number	2021-006038-37
Trial protocol	NO DE FR IE ES GR IT
Global end of trial date	07 November 2024

Results information

Result version number	v1 (current)
This version publication date	11 May 2025
First version publication date	11 May 2025

Trial information

Trial identification

Sponsor protocol code	TAK-573-1501

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03215030
WHO universal trial number (UTN)	U1111-1195-8134

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Ave, Lexington, MA, United States, 02421
Public contact	Study Director, Takeda, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, TrialDisclosures@takeda.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	07 November 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 November 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main aim of this study was to evaluate the safety and tolerability, efficacy, pharmacokinetics, and immunogenicity of modakafusp alfa in participants with relapsed refractory multiple myeloma (RRMM).

Protection of trial subjects:

Each participant signed an informed consent form (ICF) before participating in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 October 2017
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: 11
Country: Number of subjects enrolled	Puerto Rico: 1
Country: Number of subjects enrolled	France: 17
Country: Number of subjects enrolled	Greece: 8
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	Japan: 5
Country: Number of subjects enrolled	Norway: 6
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	China: 11
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Türkiye: 4
Country: Number of subjects enrolled	Israel: 10
Country: Number of subjects enrolled	Ireland: 10
Country: Number of subjects enrolled	United States: 173
Worldwide total number of subjects	268
EEA total number of subjects	50

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)	111
From 65 to 84 years	156
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at various investigative sites globally from 4 October 2017 to 7 November 2024.

Pre-assignment

Screening details:

Participants with diagnosis of RRMM were enrolled in this study consisting of Part 1 (Dose Escalation), Part 2 (Dose Expansion), Part 3 (Dose Extension), & Japan Safety Lead-in to receive modakafusp alfa with/without dexamethasone. 4 participants enrolled in study but discontinued without receiving TAK-573 dosing and are thus not presented below.

Period 1

Period 1 title	Part 1: Dose Escalation
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1 (Dose Escalation) Schedule A

Arm description:

Participants received modakafusp alfa 0.001 up to 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by Q2W on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use, Infusion

Dosage and administration details:

Modakafusp alfa 0.001 up to 14 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Arm title	Part 1 (Dose Escalation) Schedule B

Arm description:

Participants received modakafusp alfa 0.20 up to 0.30 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use, Infusion

Dosage and administration details:

Modakafusp alfa 0.20 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Arm title	Part 1 (Dose Escalation) Schedule C

Arm description:

Participants received modakafusp alfa 0.40 up to 0.75 mg/kg, infusion, IV, once every 3 weeks (Q3W) on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Arm title	Part 1 (Dose Escalation) Schedule D

Arm description:

Participants received modakafusp alfa 1.5 up to 6.0 mg/kg, infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 1.5 mg/kg, infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Number of subjects in period 1[1]	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C
Started	20	8	7
Completed	2	1	1
Not completed	18	7	6
Adverse event, serious fatal	15	6	6
Consent withdrawn by subject	2	-	-
Reason Not Specified	-	-	-
Lost to follow-up	1	1	-

Number of subjects in period 1[1]	Part 1 (Dose Escalation) Schedule D
Started	21
Completed	7
Not completed	14
Adverse event, serious fatal	8
Consent withdrawn by subject	2
Reason Not Specified	3
Lost to follow-up	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Only Part 1: Dose Escalation was considered as the baseline reporting period. The groups for the other periods are presented as subject analysis sets.

Period 2

Period 2 title	Part 2: Dose Expansion
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa

Arm description:

Participants received modakafusp alfa 0.400 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 0.400 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Arm title	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone

Arm description:

Participants received modakafusp alfa 0.400 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 0.400 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Arm title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa

Arm description:

Participants received modakafusp alfa 1.500 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Arm type	Experimental

Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 1.5 mg/kg, infusion, IV, Q4W on Days 1 of each 28-day treatment cycle until treatment discontinuation.

Arm title	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone

Arm description:

Participants received modakafusp alfa 1.500 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 1.5 mg/kg infusion, IV, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Number of subjects in period 2	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part2(Dose Expansion):Schedule C:Modakafusp Alfa+Dexamethasone	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa
Started	8	3	25
Completed	4	1	11
Not completed	4	2	14
Adverse event, serious fatal	3	1	5
Consent withdrawn by subject	1	1	5
Reason Not Specified	-	-	4
Study Terminated by Sponsor	-	-	-

Number of subjects in period 2	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Started	25
Completed	16
Not completed	9

Adverse event, serious fatal	4
Consent withdrawn by subject	2
Reason Not Specified	2
Study Terminated by Sponsor	1

Period 3

Period 3 title	Part 3: Dose Extension
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Part 3 (Dose Extension): Modakafusp Alfa 120 mg

Arm description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Arm title	Part 3 (Dose Extension): Modakafusp Alfa 240 mg

Arm description:

Participants received modakafusp alfa 240 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 240 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Number of subjects in period 3	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg
Started	71	75
Completed	5	7
Not completed	66	68
Adverse event, serious fatal	19	20
Consent withdrawn by subject	6	7
Reason Not Specified	3	-
Study Terminated by Sponsor	38	39
Lost to follow-up	-	2

Period 4

Period 4 title	Japan Safety Lead-In
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Japan Lead-in: Modakafusp Alfa 60 mg

Arm description:

Participants received modakafusp alfa 60 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 60 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Arm title	Japan Lead-in: Modakafusp Alfa 120 mg

Arm description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

Modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Number of subjects in period 4	Japan Lead-in: Modakafusp Alfa 60 mg	Japan Lead-in: Modakafusp Alfa 120 mg
Started	3	2
Completed	0	0
Not completed	3	2
Study Terminated by Sponsor	3	2

Baseline characteristics

Reporting groups	
Reporting group title	Part 1 (Dose Escalation) Schedule A
Reporting group description:	
Participants received modakafusp alfa 0.001 up to 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by Q2W on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 1 (Dose Escalation) Schedule B
Reporting group description:	
Participants received modakafusp alfa 0.20 up to 0.30 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 1 (Dose Escalation) Schedule C
Reporting group description:	
Participants received modakafusp alfa 0.40 up to 0.75 mg/kg, infusion, IV, once every 3 weeks (Q3W) on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 1 (Dose Escalation) Schedule D
Reporting group description:	
Participants received modakafusp alfa 1.5 up to 6.0 mg/kg, infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	

Reporting group values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C
Number of subjects	20	8	7
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	60.3	61.1	60.4
standard deviation	± 10.56	± 7.00	± 10.47
Gender categorical Units: Subjects			
Female	10	3	2
Male	10	5	5
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	19	8	6
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	3	1
White	20	4	6
More than one race	0	0	0
Unknown or Not Reported	0	1	0

Reporting group values	Part 1 (Dose Escalation) Schedule D	Total	
Number of subjects	21	56	
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	64.7		
standard deviation	± 10.34	-	
Gender categorical Units: Subjects			
Female	10	25	
Male	11	31	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	2	
Not Hispanic or Latino	21	54	
Unknown or Not Reported	0	0	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	1	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	5	9	
White	14	44	
More than one race	0	0	
Unknown or Not Reported	1	2	

Subject analysis sets

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-

day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule B: Modakafusp alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received Modakafusp alfa 0.2 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received Modakafusp alfa 0.3 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received Modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1(Dose Escalation) Schedule C: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received Modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1(Dose Escalation) Schedule D: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received Modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1 (Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received Modakafusp alfa 1.5 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.3 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg

Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule D: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg

Subject analysis set title	Part1(Dose Escalation)Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule A: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day

treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation)Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule A: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment

discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation)Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment

discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment

cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4

	mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2: (Dose Expansion) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description: Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment	

cycle until treatment discontinuation.

Subject analysis set title	Part2: Schedule D: Modakafusp alfa 1.5 mg/kg + Dex 40 mg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2: Schedule C: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2: Schedule C: Modakafusp alfa 0.4 mg/kg + Dex 40 mg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2: Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2: Schedule D: Modakafusp alfa 1.5 mg/kg + Dex 40 mg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received modakafusp alfa 0.400 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received modakafusp alfa 0.400 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received modakafusp alfa 1.500 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Arm: Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received modakafusp alfa 1.500 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 3 (Dose Extension): Modakafusp Alfa 120 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Subject analysis set title	Part 3 (Dose Extension): Modakafusp Alfa 240 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 240 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Subject analysis set title	Japan Lead-in: Modakafusp Alfa 60 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 60 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Subject analysis set title	Japan Lead-in: Modakafusp Alfa 120 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Reporting group values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg
Number of subjects	3	6	3
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.75 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Number of subjects	3	3	6
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1(Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg	Part1(Dose Escalation) Schedule B: Modakafusp alfa 0.2 mg/kg	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.3 mg/kg
Number of subjects	3	4	4
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White			

More than one race Unknown or Not Reported			

Reporting group values	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.4 mg/kg	Part1(Dose Escalation) Schedule C: Modakafusp alfa 0.75 mg/kg	Part1(Dose Escalation) Schedule D: Modakafusp alfa 0.75 mg/kg
Number of subjects	3	2	3
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part1 (Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Number of subjects	3	3	6
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.75 mg/kg	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.2 mg/kg
Number of subjects	3	3	4
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Number of subjects	4	4	2

Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part1(Dose Escalation) Schedule D: Modakafusp alfa 0.75 mg/kg	Part 1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg	Part1(Dose Escalation)Schedule A: Modakafusp alfa 0.01 mg/kg
Number of subjects	3	3	3
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian			

Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Part 1(Dose Escalation) Schedule A: Modakafusp Alfa 0.75 mg/kg
Number of subjects	6	3	3
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Number of subjects	1	2	1
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			

Male			

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg	Part 1(Dose Escalation)Schedule D:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Number of subjects	2	4	3
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part1(Dose Escalation) Schedule A: Modakafusp alfa	Part1(Dose Escalation) Schedule A: Modakafusp alfa	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa

	0.01 mg/kg	0.1 mg/kg	0.4 mg/kg
Number of subjects	3	6	3
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1(Dose Escalation) Schedule A: Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Number of subjects	3	4	4
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			

American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Number of subjects	4	2	6
Age Categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Number of subjects	3	2	3
Age Categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±

Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Number of subjects	3	1	2
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1 (Dose	Part 1 (Dose	Part 1 (Dose

	Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg	Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Number of subjects	1	2	4
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Number of subjects	3	3	2
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB)			

Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Number of subjects	3	3	1
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Number of subjects	2	1	2
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±

Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation)Schedule D:Modakafusp Alfa 0.75 mg/kg	Part1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Number of subjects	4	3	3
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1 (Dose	Part 1 (Dose	Part 1 (Dose

	Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg	Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Number of subjects	2	3	3
Age Categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Number of subjects	1	2	1
Age Categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race (NIH/OMB)			

Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Number of subjects	2	4	3
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Number of subjects	3	2	3
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±

Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Number of subjects	3	1	2
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1 (Dose	Part 1(Dose	Part 1 (Dose

	Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg	Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Number of subjects	1	2	4
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Number of subjects	3	3	7
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Number of subjects	3	21	6
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Number of subjects	7	3	21
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Number of subjects	6	7	3
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American			

White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Number of subjects	21	6	3
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Number of subjects	2	19	6
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2: (Dose Expansion) Schedule D: Modakafusp alfa 1.5 mg/kg
Number of subjects	3	2	19
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	± 	± 	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Number of subjects	6	3	2

Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Number of subjects	21	6	3
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian			

Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part2: Schedule D: Modakafusp alfa 1.5 mg/kg + Dex 40 mg
Number of subjects	2	19	6
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2: Schedule C: Modakafusp alfa 0.4 mg/kg	Part 2: Schedule C: Modakafusp alfa 0.4 mg/kg + Dex 40 mg	Part 2: Schedule D: Modakafusp alfa 1.5 mg/kg
Number of subjects	3	2	21
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			

Male			

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			

Reporting group values	Part 2: Schedule D: Modakafusp alfa 1.5 mg/kg + Dex 40 mg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone
Number of subjects	6	8	3
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 ±	 61.9 ± 8.63	 65.7 ± 12.58
Gender categorical Units: Subjects			
Female		1	2
Male		7	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino		0	0
Not Hispanic or Latino		8	3
Unknown or Not Reported		0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native		0	0
Asian		1	0
Native Hawaiian or Other Pacific Islander		0	0
Black or African American		1	0
White		6	3
More than one race		0	0
Unknown or Not Reported		0	0

Reporting group values	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa	Arm: Part 2: Schedule D: Modakafusp Alfa+Dexamethasone	Part 3 (Dose Extension): Modakafusp Alfa 120 mg
Number of subjects	25	25	71
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	64.1	70.2	66.2
standard deviation	± 12.17	± 7.77	± 9.76
Gender categorical Units: Subjects			
Female	12	10	34
Male	13	15	37
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	4
Not Hispanic or Latino	24	23	51
Unknown or Not Reported	1	1	16
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	0	5
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	8	10
White	20	17	38
More than one race	0	0	0
Unknown or Not Reported	1	0	18

Reporting group values	Part 3 (Dose Extension): Modakafusp Alfa 240 mg	Japan Lead-in: Modakafusp Alfa 60 mg	Japan Lead-in: Modakafusp Alfa 120 mg
Number of subjects	75	3	2
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	66.5	66.66	66.00
standard deviation	± 9.61	± 9.71	± 11.31
Gender categorical Units: Subjects			
Female	39	2	0
Male	36	1	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	0	0
Not Hispanic or Latino	57	3	2
Unknown or Not Reported	15	0	0

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	9	3	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	0	0
White	51	0	0
More than one race	0	0	0
Unknown or Not Reported	11	0	0

End points

End points reporting groups

Reporting group title	Part 1 (Dose Escalation) Schedule A
Reporting group description:	
Participants received modakafusp alfa 0.001 up to 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by Q2W on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 1 (Dose Escalation) Schedule B
Reporting group description:	
Participants received modakafusp alfa 0.20 up to 0.30 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 1 (Dose Escalation) Schedule C
Reporting group description:	
Participants received modakafusp alfa 0.40 up to 0.75 mg/kg, infusion, IV, once every 3 weeks (Q3W) on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 1 (Dose Escalation) Schedule D
Reporting group description:	
Participants received modakafusp alfa 1.5 up to 6.0 mg/kg, infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa
Reporting group description:	
Participants received modakafusp alfa 0.400 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Reporting group title	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone
Reporting group description:	
Participants received modakafusp alfa 0.400 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa
Reporting group description:	
Participants received modakafusp alfa 1.500 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Reporting group description:	
Participants received modakafusp alfa 1.500 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 3 (Dose Extension): Modakafusp Alfa 120 mg
Reporting group description:	
Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.	
Reporting group title	Part 3 (Dose Extension): Modakafusp Alfa 240 mg
Reporting group description:	
Participants received modakafusp alfa 240 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.	
Reporting group title	Japan Lead-in: Modakafusp Alfa 60 mg
Reporting group description:	
Participants received modakafusp alfa 60 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.	
Reporting group title	Japan Lead-in: Modakafusp Alfa 120 mg
Reporting group description:	
Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.	

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule B: Modakafusp alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received Modakafusp alfa 0.2 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received Modakafusp alfa 0.3 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received Modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1(Dose Escalation) Schedule C: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received Modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1(Dose Escalation) Schedule D: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received Modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1 (Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received Modakafusp alfa 1.5 mg/kg, infusion, IV, Q1W on Days 1 and 8.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.2

	mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.3 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule D: Modakafusp alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg

Subject analysis set title	Part1(Dose Escalation)Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule A: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation)Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule A: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-

day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation)Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.1 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.2 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.3 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day

treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.75 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.01 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by once on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by once on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2: (Dose Expansion) Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5

	mg/kg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part2: Schedule D: Modakafusp alfa 1.5 mg/kg + Dex 40 mg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2: Schedule C: Modakafusp alfa 0.4 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 0.4 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2: Schedule C: Modakafusp alfa 0.4 mg/kg + Dex 40 mg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 0.4 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2: Schedule D: Modakafusp alfa 1.5 mg/kg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 1.5 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2: Schedule D: Modakafusp alfa 1.5 mg/kg + Dex 40 mg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received modakafusp alfa 1.5 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received modakafusp alfa 0.400 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Subject analysis set title	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received modakafusp alfa 0.400 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received modakafusp alfa 1.500 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Arm: Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received modakafusp alfa 1.500 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Subject analysis set title	Part 3 (Dose Extension): Modakafusp Alfa 120 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Subject analysis set title	Part 3 (Dose Extension): Modakafusp Alfa 240 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 240 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Subject analysis set title	Japan Lead-in: Modakafusp Alfa 60 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 60 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Subject analysis set title	Japan Lead-in: Modakafusp Alfa 120 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Primary: Part 1: Percentage of Participants Reporting one or More Treatment Emergent Adverse Events (TEAEs)

End point title	Part 1: Percentage of Participants Reporting one or More Treatment Emergent Adverse Events (TEAEs)[1]

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a participants administered a pharmaceutical product; the untoward medical occurrence does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product whether or not it is related to the medicinal product. A TEAE is defined as any AE either reported for the first time or worsening of a pre-existing event after first dose of study drug and within 30 days of the last administration of study drug. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573.

End point type	Primary

End point timeframe:

Up to 54.3 months in Part 1

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: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	7	21
Units: percentage of participants				
number (not applicable)	100	100	100	100

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Participants With Dose-limiting Toxicities (DLTs)

End point title	Part 1: Number of Participants With Dose-limiting Toxicities (DLTs)[2]

End point description:

DLTs were evaluated as per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0. Nonhematologic TEAEs of NCI CTCAE Grade ≥3 clearly unrelated to the underlying disease and occurring during the first cycle were considered DLTs. The DLT-evaluable Analysis Set included participants who received all Cycle 1 doses of modakafusp alfa or experienced a DLT in Cycle 1 in the Part 1 Dose Escalation portion of the study.

End point type	Primary

End point timeframe:

Up to Cycle 1 (cycle length was 28 days for Schedule A, B and D; 21 days for Schedule C)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	6	7	21
Units: percentage of participants				
number (not applicable)	4	3	0	3

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Percentage of Participants Reporting one or More Grade 3 or Higher TEAEs

End point title	Part 1: Percentage of Participants Reporting one or More Grade 3 or Higher TEAEs[3]

End point description:

An AE is defined as any untoward medical occurrence in a participants administered a pharmaceutical product; the untoward medical occurrence does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product whether or not it is related to the medicinal product. TEAEs grades were

evaluated as per NCI CTCAE, Version 5.0. Grade 1 scaled as mild; Grade 2 scaled as moderate; Grade 3 scaled as severe or medically significant but not immediately life-threatening; Grade 4 scaled as life-threatening consequences; and Grade 5 scaled as death related to AE. Percentages were rounded off to the nearest decimal. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573.

End point type	Primary

End point timeframe:

Up to 54.3 months in Part 1

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: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	7	21
Units: percentage of participants				
number (not applicable)	95	100	85.7	95.2

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Percentage of Participants Reporting one or More Serious Treatment-emergent Adverse Events (Serious TEAEs)

End point title	Part 1: Percentage of Participants Reporting one or More Serious Treatment-emergent Adverse Events (Serious TEAEs)[4]

End point description:

AE: any untoward medical occurrence in participants administered a pharmaceutical product; untoward medical occurrence does not necessarily have causal relationship with this treatment. AE can therefore be any unfavorable&unintended sign (including an abnormal laboratory finding), symptom/disease temporally associated with use of medicinal (investigational) product whether or not it is related to medicinal product. TEAE:any AE either reported for first time/worsening of pre-existing event after first dose of study drug&within 30 days of last administration of study drug. Serious TEAEs:any untoward medical occurrence that:results in death,is life-threatening,requires inpatient hospitalization or prolongation of existing hospitalization,results in persistent/significant disability/incapacity,leads to congenital anomaly/birth defect in offspring of participant/is medically important event. Percentages were rounded off to nearest decimal. Analysis population: SAS.

End point type	Primary

End point timeframe:

Up to approximately 54.3 months in Part 1

Notes:

[4] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	7	21
Units: percentage of participants				
number (not applicable)	40	75	28.6	61.9

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Percentage of Participants Who Discontinued the Treatment Because of TEAE

End point title	Part 1: Percentage of Participants Who Discontinued the Treatment Because of TEAE[5]

End point description:

An AE is defined as any untoward medical occurrence in a participants administered a pharmaceutical product; the untoward medical occurrence does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product whether or not it is related to the medicinal product. A TEAE is defined as any AE either reported for the first time or worsening of a pre-existing event after first dose of study drug and within 30 days of the last administration of study drug. Percentages were rounded off to the nearest decimal. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573.

End point type	Primary

End point timeframe:

Up to 54.3 months in Part 1

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	7	21
Units: percentage of participants				
number (not applicable)	15	25	0	14.3

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Percentage of Participants With TEAEs Resulting in Dose Modifications: Dose Delay

End point title	Part 1: Percentage of Participants With TEAEs Resulting in Dose Modifications: Dose Delay[6]

End point description:

Percentages were rounded off to the nearest decimal. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573.

End point type	Primary

End point timeframe:

Up to 54.3 months in Part 1

Notes:

[6] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	7	21
Units: percentage of participants				
number (not applicable)	30	12.5	57.1	9.5

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Percentage of Participants With TEAEs Resulting in Dose Modifications: Dose Reductions

End point title	Part 1: Percentage of Participants With TEAEs Resulting in Dose Modifications: Dose Reductions[7]

End point description:

Percentages were rounded off to the nearest decimal. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573.

End point type	Primary

End point timeframe:

Up to 54.3 months in Part 1

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	7	21
Units: percentage of participants				
number (not applicable)	10	12.5	0	9.5

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Percentage of Participants With TEAEs Resulting in Dose Modifications: Dose Interruptions

End point title	Part 1: Percentage of Participants With TEAEs Resulting in Dose Modifications: Dose Interruptions[8]

End point description:

Percentages were rounded off to the nearest decimal. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573.

End point type	Primary

End point timeframe:

Up to 54.3 months in Part 1

Notes:

[8] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	7	21
Units: percentage of participants				
number (not applicable)	15	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Percentage of Participants With Clinically Significant Vital Signs Measurements

End point title	Part 1: Percentage of Participants With Clinically Significant Vital Signs Measurements[9]

End point description:

Vital signs included temperature, pulse, respiratory rate, oxygen saturation, and blood pressure. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573. The protocol pre-specified categorization of vital sign values to 'Clinically Significant' or 'Non-significant', planned to be done by Investigator, could not be performed due to early termination of the study.

End point type	Primary

End point timeframe:

Up to 54.3 months in Part 1

Notes:

[9] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[10]	0[11]	0[12]	0[13]
Units: percentage of participants				
number (not applicable)				

Notes:

[10] - No participants analysed due to early termination of study.

[11] - No participants analysed due to early termination of study.

[12] - No participants analysed due to early termination of study.

[13] - No participants analysed due to early termination of study.

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Percentage of Participants With Clinically Significant Laboratory Values

End point title	Part 1: Percentage of Participants With Clinically Significant Laboratory Values[14]

End point description:

Laboratory values included hematology, chemistry, and urinalysis and were assessed per investigator's interpretation. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573. The protocol pre-specified categorization of vital sign values to 'Clinically Significant' or 'Non-significant', planned to be done by Investigator, could not be performed due to early termination of the study.

End point type	Primary

End point timeframe:

Up to 54.3 months in Part 1

Notes:

[14] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[15]	0[16]	0[17]	0[18]
Units: percentage of participants				
number (not applicable)				

Notes:

[15] - No participants analysed due to early termination of study.

[16] - No participants analysed due to early termination of study.

[17] - No participants analysed due to early termination of study.

[18] - No participants analysed due to early termination of study.

Statistical analyses

No statistical analyses for this end point

Primary: Part 3: Overall Response Rate (ORR) Assessed by Independent Review Committee (IRC)

End point title	Part 3: Overall Response Rate (ORR) Assessed by Independent Review Committee (IRC)[19]

End point description:

ORR: percentage of participants who achieved PR rate or better (sCR + CR + VGPR + PR) during the study as defined by IMWG uniform response criteria. PR :≥50% reduction of serum M-protein &reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 hours. CR:negative immunofixation of serum& urine, disappearance of any soft tissue plasmacytomas, and <5% plasma cells in bone marrow. Scr: CR+normal FLC ratio &absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR:serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥90% reduction in serum M-protein plus urine M-protein <100 mg/24 hours. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. Due to early termination, IRC was disbanded prior to completing its evaluation and could not be utilized for the assessment, therefore the data for this outcome measure is not available.

End point type	Primary

End point timeframe:

Up to 20.5 months in Part 3

Notes:

[19] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[20]	0[21]		
Units: percentage of participants				
number (confidence interval 95%)	(to)	(to)		

Notes:

[20] - No participants analysed for this endpoint due to early termination of the study.

[21] - No participants analysed for this endpoint due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Primary: Part 2: Overall Response Rate (ORR)

End point title	Part 2: Overall Response Rate (ORR)[22]

End point description:

ORR was defined as the percentage of participants who achieved a partial response (PR) rate or better (stringent complete response [sCR] + complete response [CR] + very good partial response [VGPR] + PR) during the study as defined by international myeloma working group (IMWG) uniform response criteria. PR: ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 hours. CR: negative immunofixation of serum and urine, disappearance of any soft tissue plasmacytomas, and <5% plasma cells in bone marrow. sCR: CR+normal free light chain (FLC) ratio and absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR:serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥90% reduction in serum M-protein plus urine M-protein <100 mg/24 hours. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573 and with measurable disease at baseline.

End point type	Primary

End point timeframe:

Up to 34.7 months in Part 2

Notes:

[22] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	25	25
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 36.94)	0 (0.00 to 70.76)	48 (27.80 to 68.69)	32 (14.95 to 53.50)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Percentage of Participants With Dose-limiting Toxicities (DLTs)- Like Events

End point title	Parts 1 and 2: Percentage of Participants With Dose-limiting Toxicities (DLTs)- Like Events

End point description:

Percentage of participants with TEAEs meeting DLT definition were reported. Toxicity was evaluated as per the NCI CTCAE, Version 5.0. The hematologic TEAEs of Grade ≥3 clearly unrelated to the underlying disease and occur during the first cycle that are considered DLTs: Grade ≥3 hemolysis; Grade 4 neutropenia for >7 consecutive days; Grade 4 thrombocytopenia for >14 consecutive days; Grade 3 thrombocytopenia with clinically significant bleeding; Any other Grade ≥4 hematologic toxicity except for Grade 4 lymphopenia. An incomplete recovery from treatment-related toxicity causing >2-week delay in the next scheduled infusion before the initiation of Cycle 2 were considered a DLT. Percentages were rounded off to the nearest decimal. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573. Subjects analysed is the number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Up to 54.3 months in Part 1; Up to 34.7 months in Part 2

End point values	Part 1 (Dose Escalation) Schedule A	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part 1 (Dose Escalation) Schedule B	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	8	3
Units: percentage of participants				
number (not applicable)	10	12.5	0	66.7

End point values	Part 1 (Dose Escalation) Schedule C	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa	Part 1 (Dose Escalation) Schedule D	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	25	21	8
Units: percentage of participants				
number (not applicable)	0	24	9.5	25

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Cmax: Maximum Observed Serum Concentration for Modakafusp alfa

End point title	Part 1: Cmax: Maximum Observed Serum Concentration for

	Modakafusp alfa

End point description:

As per planned analysis, data for this outcome measure was collected and reported dose-wise for each treatment schedule. The Pharmacokinetic (PK) Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subject analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point. '99999' denotes geometric coefficient of variation was not estimable for a single participant. '9999' denotes geometric mean was not available for the specified time-point as no participants were analysed at that time-point. '999999' denotes geometric coefficient of variation was not available for the specified time-point as no participants were analysed at that time-point.

End point type	Secondary

End point timeframe:

Part 1:Schedule A:Day 1&15 in Cycles 1&2; Schedule B: Day1&15 in Cycles 1&2; Schedule C:Day1 in Cycles 1&2; Schedule D: Day 1 in Cycles 1&2: Pre-infusion&at multiple times post-infusion (cycle length was 28 days for Schedule A, B&D;21 days for Schedule C)

End point values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	6	3	3
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,6,3,3,4,4,4,2,6,3)	14.7 (± 47.6)	154 (± 95.5)	2980 (± 29.0)	11800 (± 33.5)
Cycle 1 Day 15 (n=3,4,3,2,3,3,0,0,0,0)	16.9 (± 75.4)	289 (± 71.8)	2750 (± 18.1)	11900 (± 40.8)
Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	47.5 (± 175.1)	158 (± 99999)	3030 (± 10.1)	9999 (± 999999)
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	9999 (± 999999)	9999 (± 999999)	9999 (± 999999)	9999 (± 999999)

End point values	Part1(Dose Escalation) Schedule B: Modakafusp alfa 0.2 mg/kg	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.3 mg/kg	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.4 mg/kg	Part1(Dose Escalation) Schedule C: Modakafusp alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	4	4	2
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,6,3,3,4,4,4,2,6,3)	1260 (± 106.1)	2230 (± 53.8)	2460 (± 38.6)	15000 (± 20.0)
Cycle 1 Day 15 (n=3,4,3,2,3,3,0,0,0,0)	1030 (± 183.5)	2600 (± 37.9)	9999 (± 999999)	9999 (± 999999)
Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	9999 (± 999999)	1970 (± 99999)	2490 (± 41.5)	15100 (± 2.3)
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	1730 (± 99999)	1270 (± 99999)	9999 (± 999999)	9999 (± 999999)

End point values	Part1(Dose Escalation) Schedule D: Modakafusp alfa 0.75 mg/kg	Part1 (Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	3		
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,6,3,3,4,4,4,2,6,3)	11600 (± 30.9)	15900 (± 27.1)		
Cycle 1 Day 15 (n=3,4,3,2,3,3,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		
Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	9690 (± 21.3)	16800 (± 31.3)		
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Tmax: Time to Reach the Cmax for Modakafusp alfa

End point title	Part 1: Tmax: Time to Reach the Cmax for Modakafusp alfa

End point description:

As per planned analysis, data for this outcome measure was collected and reported dose-wise for each treatment schedule. The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point. '999' denotes median and full range were not available for the specified time-point as no participants were analysed at that time-point.

End point type	Secondary

End point timeframe:

Part 1:Schedule A:Day 1&15 in Cycles 1&2; Schedule B: Day1&15 in Cycles 1&2; Schedule C:Day1 in Cycles 1&2; Schedule D: Day 1 in Cycles 1&2: Pre-infusion&at multiple times post-infusion (cycle length was 28 days for Schedule A, B&D;21 days for Schedule C)

End point values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg	Part1 (Dose Escalation) Schedule A: Modakafusp alfa 0.4 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	6	3	3
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (n=3,6,3,3,4,4,4,2,6,3)	4.03 (3.97 to 4.15)	3.99 (1.95 to 4.25)	4.40 (3.92 to 6.10)	4.27 (4.00 to 6.28)

Cycle 1 Day 15 (n=3,4,3,2,3,3,0,0,0,0)	3.93 (2.02 to 4.05)	4.02 (3.93 to 4.20)	4.25 (4.08 to 4.35)	5.87 (5.78 to 5.95)
Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	2.97 (1.97 to 3.98)	4.23 (4.23 to 4.23)	3.98 (3.90 to 4.05)	999 (999 to 999)
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)

End point values	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.2 mg/kg	Part1 (Dose Escalation) Schedule B: Modakafusp alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	4	4	2
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (n=3,6,3,3,4,4,4,2,6,3)	4.75 (3.97 to 5.60)	4.03 (4.00 to 4.10)	4.78 (3.87 to 6.05)	3.07 (2.07 to 4.07)
Cycle 1 Day 15 (n=3,4,3,2,3,3,0,0,0,0)	4.28 (4.15 to 6.17)	4.00 (4.00 to 4.10)	999 (999 to 999)	999 (999 to 999)
Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	999 (999 to 999)	4.45 (4.45 to 4.45)	4.00 (3.90 to 5.92)	3.21 (2.23 to 4.18)
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	5.65 (5.65 to 5.65)	4.00 (4.00 to 4.00)	999 (999 to 999)	999 (999 to 999)

End point values	Part1(Dose Escalation) Schedule D: Modakafusp alfa 0.75 mg/kg	Part 1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	3		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (n=3,6,3,3,4,4,4,2,6,3)	4.94 (4.00 to 6.02)	4.03 (3.77 to 7.65)		
Cycle 1 Day 15 (n=3,4,3,2,3,3,0,0,0,0)	999 (999 to 999)	999 (999 to 999)		
Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	4.13 (3.90 to 5.95)	5.52 (3.98 to 7.05)		
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	999 (999 to 999)	999 (999 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: AUC∞: Area Under the Serum Concentration-time Curve from Time 0 to Infinity for Modakafusp alfa

End point title	Part 1: AUC∞: Area Under the Serum Concentration-time Curve from Time 0 to Infinity for Modakafusp alfa

End point description:

As per planned analysis, data for this outcome measure was collected and reported dose-wise for each treatment schedule. The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point. '99999' denotes geometric coefficient of variation was not estimable for a single participant. '9999' denotes geometric mean was not available for the specified time-point as no participants were analysed at that time-point. '999999' denotes geometric coefficient of variation was not available for the specified time-point as no participants were analysed at that time-point.

End point type	Secondary

End point timeframe:

Part1:Schedule A:Day 1 in Cycles1&2&Day15 in Cycle1;Schedule B: Day1&15 in Cycle 1;Schedule C:Day1 in Cycles1&2; Schedule D:Day 1 in Cycles1&2: Pre-infusion&at multiple times post-infusion (cycle length= 28 days for Schedule A, B&D;21 days for Schedule C)

End point values	Part1(Dose Escalation)Schedule A: Modakafusp alfa 0.01 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Part 1(Dose Escalation) Schedule A: Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[23]	2	3	3
Units: hour*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	()	9999 (± 999999)	14900 (± 99999)	209000 (± 83.4)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	()	2410 (± 21.3)	24000 (± 38.0)	286000 (± 66.5)
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	()	9999 (± 999999)	28000 (± 49.3)	9999 (± 999999)

Notes:

[23] - No participants were analysed.

End point values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	2	1	2
Units: hour*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	9999 (± 999999)	20500 (± 33.2)	14100 (± 99999)	288000 (± 44.5)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	24300 (± 99999)	20100 (± 21.7)	9999 (± 999999)	9999 (± 999999)
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	9999 (± 999999)	9999 (± 999999)	73600 (± 99999)	333000 (± 54.0)

End point values	Part 1(Dose Escalation)Schedule D:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	3		
Units: hour*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	199000 (± 104.4)	240000 (± 109.7)		
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	243000 (± 54.5)	215000 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: AUClast: Area Under the Serum Concentration-time Curve from Time 0 to the Time of the Last Quantifiable Concentration for Modakafusp alfa

End point title	Part 1: AUClast: Area Under the Serum Concentration-time Curve from Time 0 to the Time of the Last Quantifiable Concentration for Modakafusp alfa

End point description:

As per planned analysis, data for this outcome measure was collected and reported dose-wise for each treatment schedule. The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point. '99999' denotes geometric coefficient of variation was not estimable for a single participant. '9999' denotes geometric mean was not available for the specified time-point as no participants were analysed at that time-point. '999999' denotes geometric coefficient of variation was not available for the specified time-point as no participants were analysed at that time-point.

End point type	Secondary

End point timeframe:

Part1:Schedule A:Day 1 in Cycles1&2&Day15 in Cycle1;Schedule B: Day1&15 in Cycle 1;Schedule C:Day1 in Cycles1&2; Schedule D:Day 1 in Cycles1&2: Pre-infusion&at multiple times post-infusion (cycle length= 28 days for Schedule A, B&D;21 days for Schedule C)

End point values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Part 1(Dose Escalation) Schedule A: Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	3	3
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=2,6,3,3,4,4,4,2,6,3)	29.5 (± 19.0)	550 (± 111.6)	30100 (± 67.9)	208000 (± 83.2)
Cycle 1 Day 15 (n=2,4,3,2,3,3,0,0,0,0)	76.3 (± 34.8)	1270 (± 88.4)	23900 (± 38.2)	285000 (± 66.1)
Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	128 (± 113.1)	584 (± 99999)	27700 (± 48.5)	9999 (± 999999)
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	9999 (± 999999)	9999 (± 999999)	9999 (± 999999)	9999 (± 999999)

End point values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	4	4	2
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=2,6,3,3,4,4,4,2,6,3)	7090 (± 263.7)	10600 (± 98.0)	17900 (± 106.8)	287000 (± 44.5)
Cycle 1 Day 15 (n=2,4,3,2,3,3,0,0,0,0)	8710 (± 514.0)	19200 (± 17.0)	9999 (± 999999)	9999 (± 999999)
Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	9999 (± 999999)	6020 (± 99999)	15600 (± 225.4)	332000 (± 54.0)
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	22200 (± 99999)	5090 (± 99999)	9999 (± 999999)	9999 (± 999999)

End point values	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg	Part 1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	3		
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=2,6,3,3,4,4,4,2,6,3)	197000 (± 83.9)	229000 (± 107.7)		
Cycle 1 Day 15 (n=2,4,3,2,3,3,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		

Cycle 2 Day 1 (n=2,1,2,0,0,1,3,2,5,2)	190000 (± 77.5)	582000 (± 250.5)		
Cycle 2 Day 15 (n=0,0,0,0,1,1,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: λz: Terminal Disposition Rate Constant for Modakafusp alfa

End point title	Part 1: λz: Terminal Disposition Rate Constant for Modakafusp alfa

End point description:

As per planned analysis, data for this outcome measure was collected and reported dose-wise for each treatment schedule. The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point. '99999' denotes geometric coefficient of variation was not estimable for a single participant. '9999' denotes geometric mean was not available for the specified time-point as no participants were analysed at that time-point. '999999' denotes geometric coefficient of variation was not available for the specified time-point as no participants were analysed at that time-point.

End point type	Secondary

End point timeframe:

Part1:Schedule A:Day 1 in Cycles1&2&Day15 in Cycle1;Schedule B: Day1&15 in Cycle 1;Schedule C:Day1 in Cycles1&2; Schedule D:Day 1 in Cycles1&2: Pre-infusion&at multiple times post-infusion (cycle length= 28 days for Schedule A, B&D;21 days for Schedule C)

End point values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[24]	2	3	3
Units: per hour (1/hour)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	()	9999 (± 999999)	0.309 (± 99999)	0.0933 (± 26.2)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	()	0.162 (± 4.3)	0.207 (± 34.6)	10.0852 (± 20.6)
Cycle 2 Day 1(n=0,0,2,0,0,0,1,2,4,1)	()	9999 (± 999999)	0.197 (± 12.7)	9999 (± 999999)

Notes:

[24] - No participants were analysed.

End point values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75 mg/kg

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	2	1	2
Units: per hour (1/hour)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	9999 (± 999999)	0.294 (± 3.1)	0.265 (± 99999)	0.0924 (± 0.5)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	0.115 (± 99999)	0.179 (± 59.7)	9999 (± 999999)	9999 (± 999999)
Cycle 2 Day 1(n=0,0,2,0,0,0,1,2,4,1)	9999 (± 999999)	9999 (± 999999)	0.0907 (± 99999)	0.0528 (± 10.1)

End point values	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	3		
Units: per hour (1/hour)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	0.107 (± 88.7)	0.113 (± 117.8)		
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		
Cycle 2 Day 1(n=0,0,2,0,0,0,1,2,4,1)	0.0828 (± 14.6)	0.0961 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: T1/2z: Terminal Elimination Phase Half-life for Modakafusp alfa

End point title	Part 1: T1/2z: Terminal Elimination Phase Half-life for Modakafusp alfa

End point description:

As per planned analysis, data for this outcome measure was collected and reported dose-wise for each treatment schedule. The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point. '99999' denotes geometric coefficient of variation was not estimable for a single participant. '9999' denotes geometric mean was not available for the specified time-point as no participants were analysed at that time-point. '999999' denotes geometric coefficient of variation was not available for the specified time-point as no participants were analysed at that time-point.

End point type	Secondary

End point timeframe:

Part1:Schedule A:Day 1 in Cycles1&2&Day15 in Cycle1;Schedule B: Day1&15 in Cycle 1;Schedule C:Day1 in Cycles1&2; Schedule D:Day 1 in Cycles1&2: Pre-infusion&at multiple times post-infusion (cycle length= 28 days for Schedule A, B&D;21 days for Schedule C)

End point values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[25]	2	3	3
Units: hours				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	()	9999 (± 999999)	2.24 (± 99999)	7.43 (± 26.2)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	()	4.28 (± 4.3)	3.36 (± 34.6)	8.14 (± 20.6)
Cycle 2 Day 1(n=0,0,2,0,0,0,1,2,4,1)	()	9999 (± 999999)	3.52 (± 12.8)	9999 (± 999999)

Notes:

[25] - No participants were available for analyses.

End point values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	2	1	2
Units: hours				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	9999 (± 999999)	2.36 (± 3.1)	2.61 (± 99999)	7.50 (± 0.4)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	6.01 (± 99999)	3.87 (± 59.7)	9999 (± 999999)	9999 (± 999999)
Cycle 2 Day 1(n=0,0,2,0,0,0,1,2,4,1)	9999 (± 999999)	9999 (± 999999)	7.64 (± 99999)	13.1 (± 10.1)

End point values	Part 1 (Dose Escalation)Schedule D:Modakafusp Alfa 0.75 mg/kg	Part1(Dose Escalation) Schedule D: Modakafusp alfa 1.5 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	3		
Units: hours				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	6.51 (± 88.6)	6.16 (± 117.7)		
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		
Cycle 2 Day 1(n=0,0,2,0,0,0,1,2,4,1)	8.37 (± 14.6)	7.22 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: CL: Clearance for Modakafusp alfa

End point title	Part 1: CL: Clearance for Modakafusp alfa

End point description:

Clearance is defined as a quantitative measure of the rate at which a drug substance is removed from the body. CL = dose/AUC. As per planned analysis, data for this outcome measure was collected and reported dose-wise for each treatment schedule. The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point. '99999' denotes geometric coefficient of variation was not estimable for a single participant. '9999' denotes geometric mean was not available for the specified time-point as no participants were analysed at that time-point. '999999' denotes geometric coefficient of variation was not available for the specified time-point as no participants were analysed at that time-point.

End point type	Secondary

End point timeframe:

Part1:Schedule A:Day 1 in Cycles1&2&Day15 in Cycle1;Schedule B: Day1&15 in Cycle 1;Schedule C:Day1 in Cycles1&2; Schedule D:Day 1 in Cycles1&2: Pre-infusion&at multiple times post-infusion (cycle length= 28 days for Schedule A, B&D;21 days for Schedule C)

End point values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[26]	2	3	3
Units: liters per hour per kilogram (L/h/kg)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	()	9999 (± 999999)	0.0268 (± 99999)	0.00358 (± 83.7)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	()	0.0415 (± 21.3)	0.0167 (± 37.9)	0.00261 (± 66.5)
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	()	9999 (± 999999)	0.0143 (± 49.2)	9999 (± 999999)

Notes:

[26] - No participants were available for analyses.

End point values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule C:Modakafusp Alfa 0.75

				mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	2	1	2
Units: liters per hour per kilogram (L/h/kg)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	9999 (± 999999)	0.0147 (± 32.9)	0.0283 (± 99999)	0.00258 (± 45.3)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	0.00820 (± 99999)	0.0149 (± 22.0)	9999 (± 999999)	9999 (± 999999)
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	9999 (± 999999)	9999 (± 999999)	0.00540 (± 99999)	0.00226 (± 52.1)

End point values	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	3		
Units: liters per hour per kilogram (L/h/kg)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	0.00380 (± 102.9)	0.00628 (± 108.4)		
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	0.00306 (± 55.3)	0.00700 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Vss: Volume of Distribution at Steady State for Modakafusp alfa

End point title	Part 1: Vss: Volume of Distribution at Steady State for Modakafusp alfa

End point description:

Volume of distribution: theoretical volume in which total amount of drug would need to be uniformly distributed to produce desired serum concentration of a drug. V(ss)=(dose/AUC)*MRT, where MRT is mean residence time. As per planned analysis, data for this outcome measure was collected&reported dose-wise for each treatment schedule. PK Analysis Set: participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed: participants with data available for analysis. 'n' denotes number of participants with data available for analysis during specified time-point. '99999' denotes geometric coefficient of variation was not estimable for a single participant. '9999' denotes geometric mean was not available for specified time-point as no participants were analysed at that time-point. '999999' denotes geometric coefficient of variation was not available for the specified time-point as no participants were analysed at that time-point.

End point type	Secondary

End point timeframe:

Part1:Schedule A:Day 1 in Cycles1&2&Day15 in Cycle1;Schedule B: Day1&15 in Cycle 1;Schedule C:

End point values	Part1(Dose Escalation) Schedule A: Modakafusp alfa 0.01 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.1 mg/kg	Part 1 (Dose Escalation) Schedule A: Modakafusp Alfa 0.4 mg/kg	Part 1 (Dose Escalation) Schedule A:Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[27]	2	3	3
Units: liters/kg				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	()	9999 (± 999999)	0.104 (± 99999)	0.0352 (± 23.4)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	()	0.150 (± 24.6)	0.0675 (± 36.9)	0.0319 (± 43.3)
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	()	9999 (± 999999)	0.0678 (± 31.1)	9999 (± 999999)

Notes:

[27] - No participants were available for analyses.

End point values	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.2 mg/kg	Part 1 (Dose Escalation) Schedule B: Modakafusp Alfa 0.3 mg/kg	Part 1 (Dose Escalation) Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 1(Dose Escalation) Schedule C: Modakafusp Alfa 0.75 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	2	1	2
Units: liters/kg				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	9999 (± 999999)	0.0575 (± 26.4)	0.117 (± 99999)	0.0329 (± 32.1)
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	0.0660 (± 99999)	0.0624 (± 14.2)	9999 (± 999999)	9999 (± 999999)
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	9999 (± 999999)	9999 (± 999999)	0.0640 (± 99999)	0.0456 (± 36.9)

End point values	Part 1 (Dose Escalation) Schedule D:Modakafusp Alfa 0.75 mg/kg	Part 1 (Dose Escalation) Schedule D: Modakafusp Alfa 1.5 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	3		
Units: liters/kg				
geometric mean (geometric coefficient of variation)				

Cycle 1 Day 1 (n=0,0,1,3,0,2,1,2,4,3)	0.0390 (± 27.1)	0.0536 (± 24.3)		
Cycle 1 Day 15 (n=0,2,3,2,1,2,0,0,0,0)	9999 (± 999999)	9999 (± 999999)		
Cycle 2 Day 1 (n=0,0,2,0,0,0,1,2,4,1)	0.0404 (± 26.8)	0.0716 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1, 2 and 3: Percentage of Participants with Positive Anti-drug Antibody (ADA) at any Scheduled and Unscheduled Post-Baseline Visit

End point title	Parts 1, 2 and 3: Percentage of Participants with Positive Anti-drug Antibody (ADA) at any Scheduled and Unscheduled Post-Baseline Visit

End point description:

ADA samples scoring equal to or above the cut-point (titer of 75) were defined as ADA positive. Percentages were rounded off to the nearest decimal. The Immunogenicity-evaluable Analysis Set included participants from the SAS with a baseline assessment and at least 1 postbaseline immunogenicity assessment. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 54.3 months in Part 1; Up to 34.7 months in Part 2; Up to 20.5 months in Part 3

End point values	Part 1 (Dose Escalation) Schedule A	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 1 (Dose Escalation) Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	7	65	6
Units: percentage of participants				
number (not applicable)	41.2	57.1	52.3	83.3

End point values	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone	Part 3 (Dose Extension): Modakafusp Alfa 240 mg	Part 1 (Dose Escalation) Schedule C	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	65	6	21
Units: percentage of participants				
number (not applicable)	66.7	61.5	83.3	61.9

End point values	Part 1 (Dose Escalation) Schedule D	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	7		
Units: percentage of participants				
number (not applicable)	66.7	14.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Overall Response Rate (ORR)

End point title	Part 1: Overall Response Rate (ORR)

End point description:

ORR was defined as the percentage of participants who achieved a PR rate or better (sCR + CR + VGPR + PR) during the study as defined by IMWG uniform response criteria. PR: ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 hours. CR: negative immunofixation of serum and urine, disappearance of any soft tissue plasmacytomas, and <5% plasma cells in bone marrow. sCR: CR+normal FLC ratio and absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR: serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥90% reduction in serum M-protein plus urine M-protein <100 mg/24 hours. Percentages were rounded off to the nearest decimal. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573 and with measurable disease at baseline. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 54.3 months in Part 1

End point values	Part 1 (Dose Escalation) Schedule A	Part 1 (Dose Escalation) Schedule B	Part 1 (Dose Escalation) Schedule C	Part 1 (Dose Escalation) Schedule D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	8	7	21
Units: percentage of participants				
number (confidence interval 95%)	15.8 (3.8 to 39.58)	0 (0.00 to 36.94)	0 (0.00 to 40.96)	23.8 (8.22 to 47.17)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Clinical Benefit Rate (CBR)

End point title	Parts 1 and 2: Clinical Benefit Rate (CBR)

End point description:

CBR: percentage of participants with confirmed response of sCR,CR,VGPR,PR/minimal response(MR) during study per investigator assessment as per by IMWG Uniform Response Criteria. PR:≥50%

reduction of serum M-protein&reduction in 24-hour urinary M-protein by ≥90%/to <200 mg/24 hours. CR:negative immunofixation of serum&urine, disappearance of any soft tissue plasmacytomas,&<5% plasma cells in bone marrow.sCR:CR+normal FLC ratio&absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR:serum&urine M-protein detectable by immunofixation but not on electrophoresis,or≥90% reduction in serum M-protein plus urine M-protein<100 mg/24 hours.MR:≥25% but≤49% reduction of serum M-protein&reduction in 24-hour urine M-protein by 50% to 89%. Percentages were rounded off to nearest decimal.SAS: all enrolled subjects who received at least 1 dose,even if incomplete,of TAK-57&with measurable disease at baseline. Subjects analysed: number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Up to 54.3 months in Part 1; Up to 34.7 months in Part 2

End point values	Part 1 (Dose Escalation) Schedule A	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part 1 (Dose Escalation) Schedule B	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	8	8	3
Units: percentage of participants				
number (confidence interval 95%)	15.8 (3.38 to 39.58)	0 (0.00 to 36.94)	0 (0.00 to 36.94)	0 (0.00 to 70.76)

End point values	Part 1 (Dose Escalation) Schedule C	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa	Part 1 (Dose Escalation) Schedule D	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	25	21	25
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 40.96)	52.0 (31.31 to 72.20)	38.1 (18.11 to 61.56)	32.0 (14.95 to 53.50)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Disease Control Rate (DCR)

End point title	Parts 1 and 2: Disease Control Rate (DCR)

End point description:

DCR:proportion of participants with confirmed response of sCR,CR,VGPR,PR,MR,or stable disease(SD) during study per investigator assessment as defined by IMWG Uniform Response Criteria.PR:≥50% reduction of serum M-protein&reduction in 24-hour urinary M-protein by≥90%/ to <200 mg/24 hours.CR:negative immunofixation of serum&urine, disappearance of any soft tissue plasmacytomas,&<5% plasma cells in bone marrow.sCR:CR+normal FLC ratio&absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR:serum&urine M-protein detectable by immunofixation but not on electrophoresis/≥90% reduction in serum M-protein plus urine M-protein<100 mg/24 hours.MR:≥25% but ≤49% reduction of serum M-protein&reduction in 24-hour

known evidence of progressive or new bone lesions if radiographic studies were performed. Percentages were rounded off to nearest decimal.Analysis population:SAS.Subjects analysed:number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Up to 54.3 months in Part 1; Up to 34.7 months in Part 2

End point values	Part 1 (Dose Escalation) Schedule A	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part 1 (Dose Escalation) Schedule B	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	8	8	3
Units: percentage of participants				
number (confidence interval 95%)	57.9 (33.50 to 79.75)	62.5 (24.49 to 91.48)	37.5 (8.52 to 75.51)	66.7 (9.43 to 99.16)

End point values	Part 1 (Dose Escalation) Schedule C	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa	Part 1 (Dose Escalation) Schedule D	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	25	21	25
Units: percentage of participants				
number (confidence interval 95%)	42.9 (9.90 to 81.59)	64.0 (42.52 to 82.03)	61.9 (38.44 to 81.89)	68.0 (46.50 to 85.05)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1, 2, and 3: Duration of Response (DOR)

End point title	Parts 1, 2, and 3: Duration of Response (DOR)

End point description:

DOR was defined as the time from the date of first documentation of response PR or better (sCR + CR + VGPR + PR) to the time of disease progression or death, whichever occurs first. PR: ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 hours. CR: negative immunofixation of serum and urine, disappearance of any soft tissue plasmacytomas, and <5% plasma cells in bone marrow. sCR: CR+normal FLC ratio and absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR: serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥90% reduction in serum M-protein plus urine M-protein <100 mg/24 hours. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573. Subjects analysed is the number of participants with data available for analyses. '9.99' denotes median was not estimable due to low number of participants with events.

End point type	Secondary

End point timeframe:

Up to 54.3 months in Part 1; Up to 34.7 months in Part 2; Up to 20.5 months in Part 3

End point values	Part 1 (Dose Escalation) Schedule A	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 1 (Dose Escalation) Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	0[28]	6	0[29]
Units: months				
median (full range (min-max))	2.1 (2.0 to 12.0)	(to)	9.99 (2.07 to 13.57)	(to)

Notes:

[28] - No participants analysed due to early termination of study.

[29] - No participants analysed due to early termination of study.

End point values	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone	Part 3 (Dose Extension): Modakafusp Alfa 240 mg	Part 1 (Dose Escalation) Schedule C	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[30]	13	0[31]	7
Units: months				
median (full range (min-max))	(to)	9.2 (0.76 to 16.82)	(to)	24.4 (1.0 to 39.7)

Notes:

[30] - No participants analysed due to early termination of study.

[31] - No participants analysed due to early termination of study.

End point values	Part 1 (Dose Escalation) Schedule D	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	3		
Units: months				
median (full range (min-max))	7.4 (2.8 to 24.8)	10.3 (1.0 to 17.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Time to Response

End point title	Parts 1 and 2: Time to Response

End point description:

Time to response was defined as the time from first dose to the date of first documentation of response (PR or better [sCR + CR + VGPR + PR]) PR: ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 hours. CR: negative immunofixation of serum and urine, disappearance of any soft tissue plasmacytomas, and <5% plasma cells in bone marrow. sCR:

CR+normal FLC ratio and absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR: serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥90% reduction in serum M-protein plus urine M-protein <100 mg/24 hours. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 54.3 months in Part 1; Up to 34.7 months in Part 2

End point values	Part 1 (Dose Escalation) Schedule A	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part 1 (Dose Escalation) Schedule B	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	0[32]	0[33]	0[34]
Units: months				
median (full range (min-max))	1.15 (1.0 to 3.0)	(to)	(to)	(to)

Notes:

[32] - No participants analysed due to early termination of study.

[33] - No participants analysed due to early termination of study.

[34] - No participants analysed due to early termination of study.

End point values	Part 1 (Dose Escalation) Schedule C	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa	Part 1 (Dose Escalation) Schedule D	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[35]	12	5	8
Units: months				
median (full range (min-max))	(to)	1.07 (0.8 to 5.8)	1.87 (0.9 to 3.7)	1.08 (1.0 to 10.0)

Notes:

[35] - No participants analysed due to early termination of study.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Cmax: Maximum Observed Serum Concentration for Modakafusp alfa

End point title	Part 2: Cmax: Maximum Observed Serum Concentration for Modakafusp alfa

End point description:

The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Schedule C and D: Pre-infusion and at multiple times post-infusion on Day 1 of Cycles 1 and 2: (cycle

length was 21 days for Schedule C and 28 days for Schedule D)

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	3	21	6
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=7,3,21,6)	3540 (± 83.7)	4330 (± 23.7)	32100 (± 25.4)	35700 (± 20.0)
Cycle 2 Day 1 (n=6,3,16,4)	3450 (± 51.2)	3870 (± 26.6)	34200 (± 24.6)	36100 (± 25.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 2 and 3: Overall Survival (OS)

End point title	Parts 2 and 3: Overall Survival (OS)

End point description:

The OS was defined as the time from the date of first dose to the date of death due to any cause. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. Subjects analysed is the number of participants with data available for analyses. '9.99' indicates that median was not estimable due to censoring.

End point type	Secondary

End point timeframe:

Up to 34.7 months in Part 2; Up to 20.5 months in Part 3

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone	Part 3 (Dose Extension): Modakafusp Alfa 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	3	2
Units: months				
median (full range (min-max))	9.99 (1.5 to 19.9)	9.99 (1.7 to 15.2)	9.99 (0.5 to 22.3)	3.4 (1.0 to 3.7)

End point values	Part 2 (Dose Expansion): Schedule D:	Part 2: Schedule D: Modakafusp		

	Modakafusp Alfa	Alfa+Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	17		
Units: months				
median (full range (min-max))	9.99 (1.08 to 17.25)	9.99 (0.39 to 19.81)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1, 2, and 3: Progression Free Survival (PFS)

End point title	Parts 1, 2, and 3: Progression Free Survival (PFS)

End point description:

PFS was defined as the time from the date of enrollment until the date of progressive disease (PD) or death due to any cause, whichever occurs first as defined by IMWG Criteria. Per IMWG criteria, PD: serum M-component increase ≥0.5 g/dl or urine M-component increase ≥ 200 mg/24-hour/ difference between involved and uninvolved FLC levels increase >10 mg/dl or bone marrow plasma cell ≥10%/ development of new/ increase in size of existing bone lesions or soft tissue plasmacytoma or development of hypercalcemia. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. Subjcets analysed is the number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Up to 54.3 months in Part 1; Up to 34.7 months in Part 2; Up to 20.5 months in Part 3

End point values	Part 1 (Dose Escalation) Schedule A	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 1 (Dose Escalation) Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	7	43	7
Units: months				
median (full range (min-max))	2.6 (0.0 to 13.1)	1.1 (0.5 to 2.3)	4.1 (0.03 to 15.44)	1.5 (0.2 to 5.4)

End point values	Part2(Dose Expansion):ScheduleC:Modakafusp Alfa+Dexamethasone	Part 3 (Dose Extension): Modakafusp Alfa 240 mg	Part 1 (Dose Escalation) Schedule C	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	44	6	18
Units: months				
median (full range (min-max))	1.4 (0.7 to 1.4)	5.3 (0.03 to 19.81)	1.4 (0.1 to 6.2)	8.0 (0.0 to 40.4)

End point values	Part 1 (Dose Escalation) Schedule D	Part 2: Schedule D: Modakafusp Alfa+Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	13		
Units: months				
median (full range (min-max))	3.6 (0.0 to 26.5)	3.4 (0.0 to 22.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: AUC∞: Area Under the Serum Concentration-time Curve from Time 0 to Infinity for Modakafusp alfa

End point title	Part 2: AUC∞: Area Under the Serum Concentration-time Curve from Time 0 to Infinity for Modakafusp alfa

End point description:

The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Schedule C and D: Pre-infusion and at multiple times post-infusion on Day 1 of Cycles 1 and 2: (cycle length was 21 days for Schedule C and 28 days for Schedule D)

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part2: Schedule D: Modakafusp alfa 1.5 mg/kg + Dex 40 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	19	6
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,2,19,6)	24900 (± 77.1)	42700 (± 19.2)	1020000 (± 89.1)	1280000 (± 70.4)
Cycle 2 Day 1 (n=2,2,16,3)	37200 (± 35.4)	43700 (± 118.5)	1520000 (± 60.7)	2070000 (± 33.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: λz: Terminal Disposition Rate Constant for Modakafusp alfa

End point title	Part 2: λz: Terminal Disposition Rate Constant for Modakafusp alfa

End point description:

The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Schedule C and D: Pre-infusion and at multiple times post-infusion on Day 1 of Cycles 1 and 2: (cycle length was 21 days for Schedule C and 28 days for Schedule D)

End point values	Part 2: Schedule C: Modakafusp alfa 0.4 mg/kg	Part 2: Schedule C: Modakafusp alfa 0.4 mg/kg + Dex 40 mg	Part 2: Schedule D: Modakafusp alfa 1.5 mg/kg	Part 2: Schedule D: Modakafusp alfa 1.5 mg/kg + Dex 40 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	21	6
Units: 1/h				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,2,21,6)	0.114 (± 67.0)	0.111 (± 31.0)	0.0478 (± 63.6)	0.0468 (± 62.8)
Cycle 2 Day 1 (n=2,2,16,4)	0.127 (± 80.1)	0.171 (± 64.0)	0.0381 (± 36.9)	0.0276 (± 54.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: AUClast: Area Under the Serum Concentration-time Curve from Time 0 to the Time of the Last Quantifiable Concentration for Modakafusp alfa

End point title	Part 2: AUClast: Area Under the Serum Concentration-time Curve from Time 0 to the Time of the Last Quantifiable Concentration for Modakafusp alfa

End point description:

The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Schedule C and D: Pre-infusion and at multiple times post-infusion on Day 1 of Cycles 1 and 2: (cycle length was 21 days for Schedule C and 28 days for Schedule D)

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	3	21	6
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=7,3,21,6)	40800 (± 93.6)	34600 (± 40.0)	975000 (± 90.8)	1280000 (± 70.4)
Cycle 2 Day 1 (n=6,3,16,4)	42300 (± 64.8)	45600 (± 74.7)	1510000 (± 62.5)	1650000 (± 56.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Tmax: Time to Reach the Cmax for Modakafusp alfa

End point title	Part 2: Tmax: Time to Reach the Cmax for Modakafusp alfa

End point description:

The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants with data available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Schedule C and D: Pre-infusion and at multiple times post-infusion on Day 1 of Cycles 1 and 2: (cycle length was 21 days for Schedule C and 28 days for Schedule D)

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	3	21	6
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (n=7,3,21,6)	5.70 (4.08 to 7.73)	3.27 (2.60 to 9.00)	1.18 (0.93 to 3.00)	1.68 (1.07 to 6.57)
Cycle 2 Day 1(n=6,3,16,4)	5.68 (3.88 to 6.68)	3.30 (1.12 to 9.00)	1.29 (0.90 to 4.88)	1.63 (1.10 to 3.00)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: CL: Clearance for Modakafusp alfa

End point title	Part 2: CL: Clearance for Modakafusp alfa

End point description:

Clearance is defined as a quantitative measure of the rate at which a drug substance is removed from the body. CL = dose/AUC. The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analyses. 'n' denotes the number of participants with data available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Schedule C and D: Pre-infusion and at multiple times post-infusion on Day 1 of Cycles 1 and 2: (cycle length was 21 days for Schedule C and 28 days for Schedule D)

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	19	6
Units: L/h/kg				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,2,19,6)	0.0160 (± 77.4)	0.00937 (± 19.0)	0.00147 (± 89.9)	0.00119 (± 67.9)
Cycle 2 Day 1 (n=2,2,16,3)	0.0107 (± 35.6)	0.00912 (± 118.7)	0.000995 (± 61.2)	0.000737 (± 36.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Vss: Volume of Distribution at Steady State for Modakafusp alfa

End point title	Part 2: Vss: Volume of Distribution at Steady State for Modakafusp alfa

End point description:

Volume of distribution is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired serum concentration of a drug. V(ss) = (dose/AUC)*MRT, where MRT is mean residence time. The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analyses. 'n' denotes the number of participants with data available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Schedule C and D: Pre-infusion and at multiple times post-infusion on Day 1 of Cycles 1 and 2: (cycle length was 21 days for Schedule C and 28 days for Schedule D)

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2: (Dose Expansion) Schedule D: Modakafusp alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	19	6
Units: L/kg				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,2,19,6)	0.114 (± 32.8)	0.0646 (± 4.7)	0.0260 (± 67.6)	0.0276 (± 16.7)
Cycle 2 Day 1(n=2,2,16,3)	0.0779 (± 32.2)	0.0501 (± 41.8)	0.0289 (± 39.6)	0.0260 (± 13.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: T1/2z: Terminal Elimination Phase Half-life for Modakafusp alfa

End point title	Part 2: T1/2z: Terminal Elimination Phase Half-life for Modakafusp alfa

End point description:

The PK Analysis Set included participants from the SAS who had sufficient data to calculate at least 1 PK parameter for modakafusp alfa. Subjects analysed is the number of participants with data available for analyses. 'n' denotes the number of participants with data available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Schedule C and D: Pre-infusion and at multiple times post-infusion on Day 1 of Cycles 1 and 2: (cycle length was 21 days for Schedule C and 28 days for Schedule D)

End point values	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule C: Modakafusp Alfa 0.4 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg	Part 2 (Dose Expansion): Schedule D: Modakafusp Alfa 1.5 mg/kg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	21	6
Units: hours				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,2,21,6)	6.08 (± 67.0)	6.22 (± 31.0)	14.5 (± 63.6)	14.8 (± 62.8)
Cycle 2 Day 1 (n=2,2,16,4)	5.46 (± 80.1)	4.07 (± 64.0)	18.2 (± 36.9)	25.1 (± 54.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Disease Control Rate (DCR) by IRC and Investigator Assessment

End point title	Part 3: Disease Control Rate (DCR) by IRC and Investigator Assessment

End point description:

DCR:proportion of participants with confirmed response of sCR,CR, VGPR,PR,MR/SD during study per investigator assessment as defined by IMWG Uniform Response Criteria. PR:≥50% reduction of serum M-protein&reduction in 24-hour urinary M-protein by ≥90%/to<200 mg/24 hours. CR:negative immunofixation of serum&urine,disappearance of any soft tissue plasmacytomas,&<5% plasma cells in bone marrow.sCR:CR+normal FLC ratio&absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR: serum&urine M-protein detectable by immunofixation but not on electrophoresis,or ≥90% reduction in serum M-protein plus urine M-protein<100 mg/24 hours.MR:≥25% but ≤49% reduction of serum M-protein&reduction in 24-hour urine M-protein by 50% to 89%. SD:no known evidence of progressive/new bone lesions if radiographic studies were performed. Percentages were rounded off to nearest decimal. The FAS: all subjects who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in Part 3.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	75		
Units: percentage of participants				
number (confidence interval 95%)	74.6 (62.92 to 84.23)	68.0 (56.22 to 78.311)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Duration of Clinical Benefit

End point title	Part 3: Duration of Clinical Benefit

End point description:

Duration of clinical benefit was defined as the time from first documented evidence of confirmed MR or better until the earliest date of a confirmed PD per IMWG, or death among participants who achieve a confirmed MR or better. MR: ≥25% but ≤49% reduction of serum M-protein and reduction in 24-hour urine M-protein by 50% to 89%. Per IMWG criteria, PD: serum M-component increase ≥0.5 g/dl or urine M-component increase ≥ 200 mg/24-hour/ difference between involved and uninvolved FLC levels increase >10 mg/dl or bone marrow plasma cell ≥10%/ development of new/ increase in size of existing bone lesions or soft tissue plasmacytoma or development of hypercalcemia. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. Subjects analysed is the number of participants with data available for analyses. Participants with no post baseline response assessment were censored.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	25		
Units: months				
median (confidence interval 95%)	6.5 (0.03 to 14.52)	5.6 (0.03 to 18.89)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Clinical Benefit Rate (CBR) by IRC and Investigator assessment

End point title	Part 3: Clinical Benefit Rate (CBR) by IRC and Investigator assessment

End point description:

CBR: percentage of participants with confirmed response of sCR, CR, VGPR, PR, or minimal response (MR) during the study per investigator assessment as defined by IMWG Uniform Response Criteria. PR: ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 hours. CR: negative immunofixation of serum and urine, disappearance of any soft tissue plasmacytomas, and <5% plasma cells in bone marrow. sCR: CR+normal FLC ratio and absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR: serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥90% reduction in serum M-protein plus urine M-protein <100 mg/24 hours. MR: ≥25% but ≤49% reduction of serum M-protein and reduction in 24-hour urine M-protein by 50% to 89%. Percentages were rounded off to nearest decimal. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	75		
Units: percentage of participants				
number (confidence interval 95%)	38.0 (26.76 to 50.33)	48.0 (36.31 to 59.85)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Objective Response Rate (ORR) by Investigator Assessment

End point title	Part 3: Objective Response Rate (ORR) by Investigator

	Assessment

End point description:

ORR was defined as the percentage of participants who achieved a PR rate or better (sCR + CR + VGPR + PR) during the study as defined by IMWG uniform response criteria. PR :≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 hours. CR:negative immunofixation of serum and urine, disappearance of any soft tissue plasmacytomas, and <5% plasma cells in bone marrow. sCR: CR+normal FLC ratio and absence of clonal cells in bone marrow biopsy by immunohistochemistry. VGPR:serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥90% reduction in serum M-protein plus urine M-protein <100 mg/24 hours. Percentages were rounded off to the nearest decimal. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	75		
Units: percentage of participants				
number (confidence interval 95%)	32.4 (21.76 to 44.55)	41.3 (30.08 to 53.30)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Time to Progression (TTP) by IRC and Investigator Assessment

End point title	Part 3: Time to Progression (TTP) by IRC and Investigator Assessment

End point description:

TTP was defined as the time from the date of the first dose until the earliest date of confirmed PD per IMWG, or death due to PD. Per IMWG criteria, PD: serum M-component increase ≥0.5 g/dl or urine M-component increase ≥200 mg/24-hour/ difference between involved and uninvolved FLC levels increase >10 mg/dl or bone marrow plasma cell ≥10%/ development of new/ increase in size of existing bone lesions or soft tissue plasmacytoma or development of hypercalcemia. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	39		
Units: months				
median (full range (min-max))	4.7 (0.03 to 15.44)	5.5 (0.03 to 19.81)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Number of Participants at Baseline and at Worst Post-baseline Status as Categorized by Eastern Cooperative Oncology Group (ECOG) Performance Status

End point title	Part 3: Number of Participants at Baseline and at Worst Post-baseline Status as Categorized by Eastern Cooperative Oncology Group (ECOG) Performance Status

End point description:

ECOG performance status was measured at baseline and over time. ECOG performance status was measured on a 6 point scale: Grade 0: Normal activity, Grade 1: Symptoms but ambulatory, Grade 2: In bed <50% of the time, Grade 3: In bed >50% of the time, Grade 4: 100% bedridden, Grade 5: Dead. Reported here is the baseline status and the worst post-baseline status measured. A decrease in grade from baseline indicates an improvement. Only categories for which there was at least 1 participant are reported. The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	75		
Units: participants				
Baseline: 0; Worst Post-baseline: 0	11	6		
Baseline: 0; Worst Post-baseline: 1	5	12		
Baseline: 0; Worst Post-baseline: 2	2	1		
Baseline: 0; Worst Post-baseline: 3	0	1		
Baseline: 1; Worst Post-baseline: 0	1	0		
Baseline: 1; Worst Post-baseline: 1	31	25		
Baseline: 1; Worst Post-baseline: 2	6	12		
Baseline: 1; Worst Post-baseline: 3	3	1		
Baseline: 1; Worst Post-baseline: 4	1	0		
Baseline: 2; Worst Post-baseline: 2	6	4		
Baseline: 2; Worst Post-baseline: 3	1	1		
Baseline: 2; Worst Post-baseline: 4	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Percentage of Participants With Clinically Significant Laboratory Values

End point title	Part 3: Percentage of Participants With Clinically Significant Laboratory Values

End point description:

Laboratory values included hematology, chemistry, and urinalysis as interpreted by the investigator. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. The protocol pre-specified categorization of laboratory values to 'Clinically Significant' or 'Non-significant', planned to be done by Investigator, could not be performed due to early termination of the study.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[36]	0[37]		
Units: percentage of participants				
number (not applicable)				

Notes:

[36] - No participants were analysed due to early termination of the study.

[37] - No participants were analysed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Percentage of Participants With Serious Treatment-emergent Adverse Events (Serious TEAEs)

End point title	Part 3: Percentage of Participants With Serious Treatment-emergent Adverse Events (Serious TEAEs)

End point description:

AE:any untoward medical occurrence in participants administered pharmaceutical product;untoward medical occurrence does not necessarily have causal relationship with this treatment. AE can therefore be any unfavorable&unintended sign(including abnormal laboratory finding),symptom/disease temporally associated with use of medicinal (investigational) product whether/not it is related to medicinal product.TEAE:any AE either reported for first time/worsening of pre-existing event after first dose of study drug&within 30 days of last administration of study drug.Serious TEAEs:any untoward medical occurrence that:results in death,is life-threatening,requires inpatient hospitalization/prolongation of existing hospitalization,results in persistent/significant disability/incapacity,leads to congenital anomaly/birth defect in offspring of participant/is medically

important event. Percentages were rounded off to nearest decimal. Analysis population: FAS.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	75		
Units: percentage of participants				
number (not applicable)	39.4	44.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Duration of Disease Control

End point title	Part 3: Duration of Disease Control

End point description:

Duration of disease control was defined as the time from first documented evidence of SD or better until the earliest date of a confirmed PD per IMWG, or death among participants who achieved a SD or better. SD: no known evidence of progressive or new bone lesions if radiographic studies were performed. Per IMWG criteria, PD: serum M-component increase ≥0.5 g/dl or urine M-component increase ≥200 mg/24-hour/ difference between involved and uninvolved FLC levels increase >10 mg/dl or bone marrow plasma cell ≥10%/ development of new/ increase in size of existing bone lesions or soft tissue plasmacytoma or development of hypercalcemia. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	25		
Units: months				
median (full range (min-max))	6.5 (0.03 to 14.52)	5.6 (0.03 to 18.89)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Rate of Minimal Residual Disease (MRD) Negativity Status at a Sensitivity of 10^-5 in Participants Achieving CR

End point title	Part 3: Rate of Minimal Residual Disease (MRD) Negativity Status at a Sensitivity of 10^-5 in Participants Achieving CR

End point description:

MRD negativity rate at a sensitivity of 10^-5 was defined as participants who were MRD negative at a sensitivity of 10^-5 in participants achieving suspected complete response (CR). CR was defined as negative immunofixation of serum and urine, disappearance of any soft tissue plasmacytomas, and <5% plasma cells in bone marrow; in participants for whom only measurable disease is by serum FLC level, normal FLC ratio of 0.26 to 1.65 in addition to CR criteria was required. The Intent-to-Treat (ITT) Analysis Set included all randomized participants regardless of whether they received study drug or adhered to the assigned dose. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	1		
Units: participants	3	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Duration of MRD Negativity Status at a Sensitivity of 10^-5 in Participants Achieving CR

End point title	Part 3: Duration of MRD Negativity Status at a Sensitivity of 10^-5 in Participants Achieving CR

End point description:

Duration of MRD negativity (10^-5) was defined as the time from the first MRD negative status (10^-5) to the earliest date of the MRD positive status (10^-5), confirmed PD per IMWG or death. Due to early termination of the study the complete data for pre-planned analysis of duration of MRD was not collected based on sponsor decision.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[38]	0[39]		
Units: months				

Notes:

[38] - Duration of MRD was not collected based on sponsor decision due to early termination of the study.

[39] - Duration of MRD was not collected based on sponsor decision due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Percentage of Participants With Treatment -emergent Adverse Events (TEAEs)

End point title	Part 3: Percentage of Participants With Treatment -emergent Adverse Events (TEAEs)

End point description:

An AE is defined as any untoward medical occurrence in a participants administered a pharmaceutical product; the untoward medical occurrence does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product whether or not it is related to the medicinal product. A TEAE is defined as any AE either reported for the first time or worsening of a pre-existing event after first dose of study drug and within 30 days of the last administration of study drug. Percentages were rounded off to the nearest decimal. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	75		
Units: percentage of participants				
number (not applicable)	98.6	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Health Care Utilization: Number of Participants With at Least One Medical Encounter

End point title	Part 3: Health Care Utilization: Number of Participants With at Least One Medical Encounter

End point description:

Medical encounters included hospitalizations, emergency room stays, or outpatient visits. The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	57		
Units: participants				
Hospitalizations	29	31		
Emergency Room Stays	7	8		
All Outpatient Visits	10	18		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Percentage of Participants With Neutralizing Antibodies (NAb) at Any Scheduled and Unscheduled Post-Baseline Visit

End point title	Part 3: Percentage of Participants With Neutralizing Antibodies (NAb) at Any Scheduled and Unscheduled Post-Baseline Visit

End point description:

Percentages were rounded off to the nearest decimal. Immunogenicity-Evaluable Set Analysis included participants with a baseline assessment and at least 1 post-baseline immunogenicity assessment. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	65		
Units: percentage of participants				
number (not applicable)	47.7	44.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Health Care Utilization: Length of Hospital Stays

End point title	Part 3: Health Care Utilization: Length of Hospital Stays

End point description:

The FAS included all participants who received at least 1 dose, even an incomplete dose, of modakafusp alfa, in the Part 3 extension cohorts. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 20.5 months in Part 3

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	75		
Units: days				
median (full range (min-max))	14 (2 to 240)	11 (1 to 158)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Patient-reported Outcome (PRO): Change From Baseline to Cycle 9 in Instrument European Organisation for Research and Treatment of Cancer QLQ Questionnaire Multiple Myeloma Module (EORTC QLQ-MY20)

End point title	Part 3: Patient-reported Outcome (PRO): Change From Baseline to Cycle 9 in Instrument European Organisation for Research and Treatment of Cancer QLQ Questionnaire Multiple Myeloma Module (EORTC QLQ-MY20)

End point description:

EORTC QLQ-MY20 is a myeloma-specific module developed by the EORTC group specifically to assess quality of life in participants with multiple myeloma. It contains 20 items which can be grouped into a disease symptom subscale (6 items), side effects of treatment subscale (10 items), body image (1 item) and future perspective subscale (3 items). All transformed scale scores range from 0 to 100 with higher scores indicating worse symptoms (Disease Symptoms and Side Effects of Treatment) or better support/functioning (Future Perspective and Body Image). The PRO Analysis Set included all participants with a baseline and at least one post-baseline measurement of any PRO measure (EORTC QLQ-MY20 or EQ-5D-5L).Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Baseline, Cycle 9 Day 8 [cycle length was 28 days] (up to 7.7 months)

End point values	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: score on a scale				
arithmetic mean (standard deviation)				
Disease Symptoms	-7.9 (± 22.63)	-7.4 (± 10.93)		
Side Effects of Treatment	4.7 (± 11.62)	7.0 (± 5.45)		
Body Image	4.8 (± 35.63)	0.0 (± 21.06)		
Future Perspective	11.1 (± 9.06)	7.4 (± 34.92)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 54.3 months in Part 1; Up to 34.7 months in Part 2; Up to 20.5 months in Part 3

Adverse event reporting additional description:

The SAS included all enrolled participants who received at least 1 dose, even if incomplete, of TAK-573.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Japan Lead-in: Modakafusp alfa 60 mg

Reporting group description:

Participants received modakafusp alfa 60 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Reporting group title	Part 3 (Dose Extension): Modakafusp Alfa 240 mg

Reporting group description:

Participants received modakafusp alfa 240 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Reporting group title	Part 1 (Dose Escalation) Schedule A

Reporting group description:

Participants received modakafusp alfa 0.001 up to 0.75 mg/kg, infusion, IV, Q1W on Days 1, 8, 15 and 22 of each 28-day treatment cycle up to 2 cycles, followed by Q2W on Days 1 and 15 of each 28-day treatment cycle up to 4 cycles, followed by Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Reporting group title	Part 1 (Dose Escalation) Schedule B

Reporting group description:

Participants received modakafusp alfa 0.20 up to 0.30 mg/kg, infusion, IV, Q2W on Days 1 and 15 of each 28-day treatment cycle until treatment discontinuation.

Reporting group title	Part 3 (Dose Extension): Modakafusp Alfa 120 mg

Reporting group description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Reporting group title	Japan Lead-in: Modakafusp alfa 120 mg

Reporting group description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W, for each 28-day treatment cycle until disease progression or treatment discontinuation.

Reporting group title	Part 2 (Dose Expansion): Schedule D: Modakafusp alfa

Reporting group description:

Participants received modakafusp alfa 1.500 mg/kg infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Reporting group title	Part 2: Schedule D: Modakafusp alfa + Dexamethasone

Reporting group description:

Participants received modakafusp alfa 1.500 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Reporting group title	Part 2 (Dose Expansion): Schedule C: Modakafusp alfa

Reporting group description:

Participants received modakafusp alfa 0.400 mg/kg infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.

Reporting group title	Part 1 (Dose Escalation) Schedule D

Reporting group description:

Participants received modakafusp alfa 1.5 up to 6.0 mg/kg, infusion, IV, Q4W on Day 1 of each 28-day treatment cycle until treatment discontinuation.

Reporting group title	Part 1 (Dose Escalation) Schedule C
Reporting group description:	
Participants received modakafusp alfa 0.40 up to 0.75 mg/kg, infusion, IV, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	
Reporting group title	Part 2: Schedule C: Modakafusp alfa + Dexamethasone
Reporting group description:	
Participants received modakafusp alfa 0.400 mg/kg infusion, IV, and dexamethasone 40 mg, orally, Q3W on Day 1 of each 21-day treatment cycle until treatment discontinuation.	

Serious adverse events	Japan Lead-in: Modakafusp alfa 60 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg	Part 1 (Dose Escalation) Schedule A
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	37 / 75 (49.33%)	8 / 20 (40.00%)
number of deaths (all causes)	0	20	15
number of deaths resulting from adverse events	0	5	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Plasmacytoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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	0 / 3 (0.00%)	2 / 75 (2.67%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Sudden death			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Obliterative bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Pneumonitis aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 alveolar haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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%)	1 / 75 (1.33%)	0 / 20 (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
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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

Ejection fraction decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Electrophoresis protein abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Light chain analysis increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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			
Accidental overdose			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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

Febrile nonhaemolytic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Femoral neck fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Tibia fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 / 75 (0.00%)	0 / 20 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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

Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 congestive			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Cerebral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Haemorrhage intracranial			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Haemorrhagic stroke			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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%)	1 / 75 (1.33%)	0 / 20 (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
Stupor			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Methaemoglobinaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dieulafoy's vascular malformation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Gastric ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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			
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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			
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Haemarthrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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

Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 3 (0.00%)	7 / 75 (9.33%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	6 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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 / 75 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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			
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (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
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (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
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1 (Dose Escalation) Schedule B	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Japan Lead-in: Modakafusp alfa 120 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	29 / 71 (40.85%)	0 / 2 (0.00%)
number of deaths (all causes)	6	19	0
number of deaths resulting from adverse events	2	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myelodysplastic syndrome			

subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Plasmacytoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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			
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Sudden death			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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

Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Obliterative bronchiolitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Pneumonitis aspiration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 alveolar haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Respiratory failure			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Delirium			

subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Mental status changes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Electrophoresis protein abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Light chain analysis increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 abnormal			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Troponin increased			

subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Fall			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile nonhaemolytic transfusion reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Femoral neck fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Femur fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Tibia fracture			

subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 arrest			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Myocardial infarction			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Supraventricular tachycardia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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			
Encephalopathy			
subjects affected / exposed	2 / 8 (25.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Haemorrhagic stroke			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	1 / 8 (12.50%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stupor			

subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Methaemoglobinaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	4 / 71 (5.63%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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			
Anal incontinence			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (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

Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Dieulafoy's vascular malformation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Gastric ulcer			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Odynophagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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			

Cholelithiasis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	4 / 71 (5.63%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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			
Arthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Back pain			
subjects affected / exposed	2 / 8 (25.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (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
Haemarthrosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Bronchiolitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 sepsis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Device related bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Clostridium difficile infection			

subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	6 / 71 (8.45%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (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			
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2 (Dose	Part 2: Schedule D:	Part 2 (Dose

	Expansion): Schedule D: Modakafusp alfa	Modakafusp alfa + Dexamethasone	Expansion): Schedule C: Modakafusp alfa
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 25 (28.00%)	9 / 25 (36.00%)	1 / 8 (12.50%)
number of deaths (all causes)	5	6	3
number of deaths resulting from adverse events	0	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Myelodysplastic syndrome			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (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
Plasmacytoma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Hypertension			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (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
Hypotension			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Fatigue			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 health deterioration			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Mucosal inflammation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Sudden death			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (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
Pain			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (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
Dyspnoea			

subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Pleural effusion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Obliterative bronchiolitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Pneumonitis aspiration			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 alveolar haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Respiratory failure			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Stridor			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Mental status changes			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Ejection fraction decreased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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

Electrophoresis protein abnormal			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Light chain analysis increased			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Troponin increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Accidental overdose			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Fall			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Febrile nonhaemolytic transfusion reaction			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Femoral neck fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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

Femur fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Infusion related reaction			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Tibia fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 arrest			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Myocardial infarction			

subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Encephalopathy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Cerebral haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Haemorrhagic stroke			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Headache			

subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (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
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 / 25 (0.00%)	1 / 25 (4.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stupor			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (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
Febrile neutropenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Methaemoglobinaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Thrombocytopenia			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Anal incontinence			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Diarrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Dieulafoy's vascular malformation			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (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
Gastric ulcer			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	2 / 25 (8.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Vomiting			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Odynophagia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Cholelithiasis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Pruritus			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Haematuria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Arthritis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Back pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Haemarthrosis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (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
Muscular weakness			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Bacteraemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Bronchiolitis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 sepsis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 bacteraemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 25 (12.00%)	4 / 25 (16.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Pseudomonal sepsis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Respiratory tract infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Septic shock			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Sinusitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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			
Hypercalcaemia			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Hypokalaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (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
Metabolic acidosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1 (Dose Escalation) Schedule D	Part 1 (Dose Escalation) Schedule C	Part 2: Schedule C: Modakafusp alfa + Dexamethasone
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 21 (61.90%)	2 / 7 (28.57%)	1 / 3 (33.33%)
number of deaths (all causes)	8	6	1
number of deaths resulting from adverse events	2	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Plasmacytoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Hypertension			

subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Fatigue			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Mucosal inflammation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (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
Sudden death			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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	2 / 21 (9.52%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	2 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Dyspnoea			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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
Pneumonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Pleural effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Obliterative bronchiolitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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
Pneumonitis aspiration			

subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (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
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Respiratory failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Stridor			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Delirium			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Mental status changes			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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
Investigations			

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Ejection fraction decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Electrophoresis protein abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Light chain analysis increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Troponin increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Accidental overdose			

subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Fall			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Febrile nonhaemolytic transfusion reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Femoral neck fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Femur fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Infusion related reaction			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Tibia fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 arrest			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 congestive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Encephalopathy			

subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Cerebral haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Haemorrhagic stroke			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Headache			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Stupor			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Febrile neutropenia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Methaemoglobinaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Thrombocytopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Anal incontinence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Diarrhoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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

Dieulafoy's vascular malformation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Gastric ulcer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Cholelithiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			

Pruritus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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 and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Back pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (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
Haemarthrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Muscular weakness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Bacterial infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Bronchiolitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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
Device related sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Pneumocystis jirovecii pneumonia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	4 / 21 (19.05%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	3 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Septic shock			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (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
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Hypokalaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Metabolic acidosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (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

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

Non-serious adverse events	Japan Lead-in: Modakafusp alfa 60 mg	Part 3 (Dose Extension): Modakafusp Alfa 240 mg	Part 1 (Dose Escalation) Schedule A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	74 / 75 (98.67%)	20 / 20 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypoperfusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	3 / 75 (4.00%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Shock haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Infusion site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	8 / 75 (10.67%)	0 / 20 (0.00%)
occurrences (all)	0	11	0
Fatigue			

subjects affected / exposed	0 / 3 (0.00%)	29 / 75 (38.67%)	8 / 20 (40.00%)
occurrences (all)	0	36	11
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	0 / 20 (0.00%)
occurrences (all)	0	6	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	1 / 20 (5.00%)
occurrences (all)	0	4	2
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	16 / 75 (21.33%)	0 / 20 (0.00%)
occurrences (all)	1	18	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	0	6	0

Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	22 / 75 (29.33%)	5 / 20 (25.00%)
occurrences (all)	0	28	6
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	2 / 20 (10.00%)
occurrences (all)	0	4	4
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	14 / 75 (18.67%)	2 / 20 (10.00%)
occurrences (all)	0	20	2
Laryngeal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	2 / 20 (10.00%)
occurrences (all)	0	7	2
Respiratory distress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Respiratory symptom			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 3 (33.33%)	5 / 75 (6.67%)	0 / 20 (0.00%)
occurrences (all)	1	5	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	2 / 20 (10.00%)
occurrences (all)	0	8	2
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 20 (5.00%)
occurrences (all)	0	1	2
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	2 / 20 (10.00%)
occurrences (all)	0	6	2
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	11 / 75 (14.67%)	5 / 20 (25.00%)
occurrences (all)	0	29	6
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	11 / 75 (14.67%)	5 / 20 (25.00%)
occurrences (all)	0	21	7
Activated partial thromboplastin time prolonged			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	2 / 20 (10.00%)
occurrences (all)	0	6	3
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	2 / 20 (10.00%)
occurrences (all)	0	5	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood uric acid decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	9 / 20 (45.00%)
occurrences (all)	0	14	17
Staphylococcus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	0 / 20 (0.00%)
occurrences (all)	0	8	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Infusion related reaction			

subjects affected / exposed	1 / 3 (33.33%)	11 / 75 (14.67%)	1 / 20 (5.00%)
occurrences (all)	2	16	1
Road traffic accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	1 / 3 (33.33%)	5 / 75 (6.67%)	2 / 20 (10.00%)
occurrences (all)	1	8	2
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	0 / 20 (0.00%)
occurrences (all)	0	5	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block first degree			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Brain fog			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	8 / 75 (10.67%)	1 / 20 (5.00%)
occurrences (all)	0	9	1
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Headache			
subjects affected / exposed	2 / 3 (66.67%)	11 / 75 (14.67%)	1 / 20 (5.00%)
occurrences (all)	2	12	1
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	3 / 3 (100.00%)	55 / 75 (73.33%)	6 / 20 (30.00%)
occurrences (all)	24	181	11
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	32 / 75 (42.67%)	5 / 20 (25.00%)
occurrences (all)	1	62	5
Leukopenia			
subjects affected / exposed	2 / 3 (66.67%)	25 / 75 (33.33%)	10 / 20 (50.00%)
occurrences (all)	11	106	20
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	0	7	0

Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 3 (66.67%)	63 / 75 (84.00%)	16 / 20 (80.00%)
occurrences (all)	22	291	37
Eye disorders			
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	13 / 75 (17.33%)	6 / 20 (30.00%)
occurrences (all)	0	16	7
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	0 / 20 (0.00%)
occurrences (all)	0	6	0
Abdominal pain upper			
subjects affected / exposed	1 / 3 (33.33%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Haematochezia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	22 / 75 (29.33%)	4 / 20 (20.00%)
occurrences (all)	0	35	4
Noninfective gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	2 / 20 (10.00%)
occurrences (all)	0	6	2
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cholecystitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Acute hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 3 (33.33%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	2	4	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	6 / 75 (8.00%)	1 / 20 (5.00%)
occurrences (all)	2	7	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	3 / 20 (15.00%)
occurrences (all)	0	5	3
Back pain			
subjects affected / exposed	2 / 3 (66.67%)	10 / 75 (13.33%)	4 / 20 (20.00%)
occurrences (all)	2	14	4
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	1 / 20 (5.00%)
occurrences (all)	0	4	1
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	1 / 20 (5.00%)
occurrences (all)	0	6	1
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	8 / 75 (10.67%)	2 / 20 (10.00%)
occurrences (all)	0	9	2
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	1 / 20 (5.00%)
occurrences (all)	0	4	2
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	1 / 20 (5.00%)
occurrences (all)	0	6	1
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	5 / 20 (25.00%)
occurrences (all)	0	7	7
Infections and infestations			

Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	13 / 75 (17.33%)	2 / 20 (10.00%)
occurrences (all)	0	15	2
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	7 / 75 (9.33%)	0 / 20 (0.00%)
occurrences (all)	0	8	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	12 / 75 (16.00%)	2 / 20 (10.00%)
occurrences (all)	0	16	4
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
Skin candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 20 (0.00%)
occurrences (all)	0	6	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	14 / 75 (18.67%)	0 / 20 (0.00%)
occurrences (all)	0	21	0
Diabetes mellitus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	0 / 20 (0.00%)
occurrences (all)	0	7	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	5 / 20 (25.00%)
occurrences (all)	0	1	12
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 20 (5.00%)
occurrences (all)	0	1	2
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	9 / 75 (12.00%)	4 / 20 (20.00%)
occurrences (all)	0	17	5
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	4 / 20 (20.00%)
occurrences (all)	0	13	5
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	1 / 20 (5.00%)
occurrences (all)	0	5	1
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	3 / 20 (15.00%)
occurrences (all)	0	8	3
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	8 / 20 (40.00%)
occurrences (all)	0	3	12
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	2 / 20 (10.00%)
occurrences (all)	0	5	4
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	6 / 20 (30.00%)
occurrences (all)	0	4	11

Non-serious adverse events	Part 1 (Dose Escalation) Schedule B	Part 3 (Dose Extension): Modakafusp Alfa 120 mg	Japan Lead-in: Modakafusp alfa 120 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	70 / 71 (98.59%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 8 (0.00%)	5 / 71 (7.04%)	0 / 2 (0.00%)
occurrences (all)	0	11	0
Haematoma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Shock			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypoperfusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	4 / 71 (5.63%)	0 / 2 (0.00%)
occurrences (all)	1	4	0

Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	7 / 71 (9.86%)	0 / 2 (0.00%)
occurrences (all)	0	11	0
Shock haemorrhagic			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Infusion site extravasation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	7 / 71 (9.86%)	0 / 2 (0.00%)
occurrences (all)	0	12	0
Fatigue			
subjects affected / exposed	2 / 8 (25.00%)	21 / 71 (29.58%)	0 / 2 (0.00%)
occurrences (all)	4	25	0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Chills			
subjects affected / exposed	0 / 8 (0.00%)	7 / 71 (9.86%)	0 / 2 (0.00%)
occurrences (all)	0	10	0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Chest discomfort			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	5 / 71 (7.04%)	0 / 2 (0.00%)
occurrences (all)	0	9	0
Pain			

subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	8 / 71 (11.27%)	0 / 2 (0.00%)
occurrences (all)	0	12	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Cough			
subjects affected / exposed	0 / 8 (0.00%)	12 / 71 (16.90%)	0 / 2 (0.00%)
occurrences (all)	0	15	0
Dysphonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	5	0
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Dyspnoea			

subjects affected / exposed	1 / 8 (12.50%)	7 / 71 (9.86%)	0 / 2 (0.00%)
occurrences (all)	1	9	0
Laryngeal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 8 (0.00%)	4 / 71 (5.63%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Respiratory distress			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory symptom			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	4 / 71 (5.63%)	0 / 2 (0.00%)
occurrences (all)	0	5	0
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	0	2	0

Confusional state			
subjects affected / exposed	2 / 8 (25.00%)	5 / 71 (7.04%)	0 / 2 (0.00%)
occurrences (all)	2	6	0
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	7 / 71 (9.86%)	0 / 2 (0.00%)
occurrences (all)	1	10	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	6 / 71 (8.45%)	0 / 2 (0.00%)
occurrences (all)	0	9	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased			
subjects affected / exposed	1 / 8 (12.50%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	2	7	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
International normalised ratio increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood uric acid decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	5 / 71 (7.04%)	0 / 2 (0.00%)
occurrences (all)	0	20	0
Staphylococcus test positive			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	16 / 71 (22.54%)	0 / 2 (0.00%)
occurrences (all)	0	34	0
Road traffic accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 8 (0.00%)	4 / 71 (5.63%)	0 / 2 (0.00%)
occurrences (all)	0	9	0
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	4 / 71 (5.63%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Atrioventricular block first degree			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Nervous system disorders			
Brain fog			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	7 / 71 (9.86%)	0 / 2 (0.00%)
occurrences (all)	0	8	0
Dysarthria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 8 (0.00%)	13 / 71 (18.31%)	1 / 2 (50.00%)
occurrences (all)	0	22	1
Seizure			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	0	2	0

Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	4 / 8 (50.00%)	48 / 71 (67.61%)	1 / 2 (50.00%)
occurrences (all)	8	171	4
Anaemia			
subjects affected / exposed	5 / 8 (62.50%)	31 / 71 (43.66%)	1 / 2 (50.00%)
occurrences (all)	9	50	4
Leukopenia			
subjects affected / exposed	2 / 8 (25.00%)	18 / 71 (25.35%)	1 / 2 (50.00%)
occurrences (all)	2	64	2
Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Febrile neutropenia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Thrombocytopenia			
subjects affected / exposed	8 / 8 (100.00%)	52 / 71 (73.24%)	2 / 2 (100.00%)
occurrences (all)	16	238	10
Eye disorders			
Vitreous floaters			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Periorbital oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	15 / 71 (21.13%)	0 / 2 (0.00%)
occurrences (all)	2	21	0
Constipation			
subjects affected / exposed	1 / 8 (12.50%)	5 / 71 (7.04%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
Abdominal pain upper			

subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Inguinal hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 8 (12.50%)	11 / 71 (15.49%)	0 / 2 (0.00%)
occurrences (all)	1	17	0
Noninfective gingivitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			

Hypertransaminasaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Cholecystitis acute			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Acute hepatic failure			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Cold sweat			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Rash maculo-papular			

subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Pruritus			
subjects affected / exposed	1 / 8 (12.50%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 8 (12.50%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Renal failure			
subjects affected / exposed	1 / 8 (12.50%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 8 (25.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
Back pain			
subjects affected / exposed	2 / 8 (25.00%)	7 / 71 (9.86%)	0 / 2 (0.00%)
occurrences (all)	2	17	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	5 / 71 (7.04%)	0 / 2 (0.00%)
occurrences (all)	0	5	0
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			

subjects affected / exposed	1 / 8 (12.50%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	5 / 71 (7.04%)	0 / 2 (0.00%)
occurrences (all)	0	6	0
Myalgia			
subjects affected / exposed	1 / 8 (12.50%)	7 / 71 (9.86%)	0 / 2 (0.00%)
occurrences (all)	1	9	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	6 / 71 (8.45%)	0 / 2 (0.00%)
occurrences (all)	0	7	0
Ear infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Device related infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	5 / 71 (7.04%)	0 / 2 (0.00%)
occurrences (all)	0	5	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	6 / 71 (8.45%)	1 / 2 (50.00%)
occurrences (all)	1	10	1
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Streptococcal bacteraemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 8 (12.50%)	8 / 71 (11.27%)	0 / 2 (0.00%)
occurrences (all)	1	10	0
Diabetes mellitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
Hyperglycaemia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 8 (25.00%)	6 / 71 (8.45%)	0 / 2 (0.00%)
occurrences (all)	2	9	0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	1	7	0
Hyperphosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			

subjects affected / exposed	1 / 8 (12.50%)	1 / 71 (1.41%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 71 (4.23%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
Metabolic acidosis			
subjects affected / exposed	1 / 8 (12.50%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Lactic acidosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 71 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Hyponatraemia			
subjects affected / exposed	4 / 8 (50.00%)	2 / 71 (2.82%)	0 / 2 (0.00%)
occurrences (all)	5	5	0

Non-serious adverse events	Part 2 (Dose Expansion): Schedule D: Modakafusp alfa	Part 2: Schedule D: Modakafusp alfa + Dexamethasone	Part 2 (Dose Expansion): Schedule C: Modakafusp alfa
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 25 (96.00%)	24 / 25 (96.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Haematoma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hot flush			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Shock			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoperfusion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	2 / 25 (8.00%)	2 / 25 (8.00%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Hypertension			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Shock haemorrhagic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Infusion site extravasation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	7 / 25 (28.00%)	6 / 25 (24.00%)	3 / 8 (37.50%)
occurrences (all)	7	6	3
Influenza like illness			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Chills			
subjects affected / exposed	5 / 25 (20.00%)	1 / 25 (4.00%)	2 / 8 (25.00%)
occurrences (all)	7	1	3
Chest pain			

subjects affected / exposed	3 / 25 (12.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	4	0	1
Chest discomfort			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	2 / 25 (8.00%)	2 / 25 (8.00%)	1 / 8 (12.50%)
occurrences (all)	2	3	1
Pain			
subjects affected / exposed	3 / 25 (12.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	3	1	0
Oedema peripheral			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	7 / 25 (28.00%)	3 / 25 (12.00%)	0 / 8 (0.00%)
occurrences (all)	8	4	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	7 / 25 (28.00%)	4 / 25 (16.00%)	0 / 8 (0.00%)
occurrences (all)	11	4	0
Dysphonia			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Dyspnoea exertional			
subjects affected / exposed	3 / 25 (12.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	4	1	0
Epistaxis			
subjects affected / exposed	0 / 25 (0.00%)	3 / 25 (12.00%)	0 / 8 (0.00%)
occurrences (all)	0	5	0
Dyspnoea			
subjects affected / exposed	5 / 25 (20.00%)	5 / 25 (20.00%)	1 / 8 (12.50%)
occurrences (all)	7	5	1
Laryngeal inflammation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	2	0	1
Respiratory distress			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Respiratory symptom			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	2 / 25 (8.00%)	2 / 25 (8.00%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Oropharyngeal pain			

subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Wheezing			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 25 (4.00%)	3 / 25 (12.00%)	2 / 8 (25.00%)
occurrences (all)	2	5	2
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 25 (16.00%)	4 / 25 (16.00%)	1 / 8 (12.50%)
occurrences (all)	6	7	2
Alanine aminotransferase increased			
subjects affected / exposed	3 / 25 (12.00%)	2 / 25 (8.00%)	1 / 8 (12.50%)
occurrences (all)	3	2	2
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	2 / 8 (25.00%)
occurrences (all)	2	1	5
Blood lactate dehydrogenase increased			

subjects affected / exposed	2 / 25 (8.00%)	4 / 25 (16.00%)	0 / 8 (0.00%)
occurrences (all)	2	4	0
International normalised ratio increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Blood uric acid decreased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	7 / 25 (28.00%)	7 / 25 (28.00%)	6 / 8 (75.00%)
occurrences (all)	11	7	9
Staphylococcus test positive			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	8 / 25 (32.00%)	3 / 25 (12.00%)	3 / 8 (37.50%)
occurrences (all)	16	4	3
Road traffic accident			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fall			

subjects affected / exposed	2 / 25 (8.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	11	1	0
Contusion			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block first degree			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Brain fog			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 25 (4.00%)	2 / 25 (8.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Headache			

subjects affected / exposed	7 / 25 (28.00%)	3 / 25 (12.00%)	2 / 8 (25.00%)
occurrences (all)	9	5	2
Seizure			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Tremor			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	18 / 25 (72.00%)	15 / 25 (60.00%)	5 / 8 (62.50%)
occurrences (all)	35	59	8
Anaemia			
subjects affected / exposed	14 / 25 (56.00%)	11 / 25 (44.00%)	3 / 8 (37.50%)
occurrences (all)	25	19	4
Leukopenia			
subjects affected / exposed	12 / 25 (48.00%)	12 / 25 (48.00%)	5 / 8 (62.50%)
occurrences (all)	27	16	10
Lymphopenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	19 / 25 (76.00%)	20 / 25 (80.00%)	6 / 8 (75.00%)
occurrences (all)	49	80	9
Eye disorders			
Vitreous floaters			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Periorbital oedema			
subjects affected / exposed	1 / 25 (4.00%)	2 / 25 (8.00%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 25 (4.00%)	6 / 25 (24.00%)	3 / 8 (37.50%)
occurrences (all)	1	6	3
Constipation			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Abdominal pain upper			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 25 (0.00%)	2 / 25 (8.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Inguinal hernia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2

Nausea			
subjects affected / exposed	7 / 25 (28.00%)	5 / 25 (20.00%)	2 / 8 (25.00%)
occurrences (all)	8	7	2
Noninfective gingivitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 25 (12.00%)	4 / 25 (16.00%)	0 / 8 (0.00%)
occurrences (all)	3	4	0
Toothache			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cholecystitis acute			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Acute hepatic failure			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cold sweat			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Urticaria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Pruritus			
subjects affected / exposed	2 / 25 (8.00%)	2 / 25 (8.00%)	1 / 8 (12.50%)
occurrences (all)	7	2	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Haematuria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	5 / 25 (20.00%)	3 / 25 (12.00%)	1 / 8 (12.50%)
occurrences (all)	7	3	2
Back pain			
subjects affected / exposed	7 / 25 (28.00%)	2 / 25 (8.00%)	1 / 8 (12.50%)
occurrences (all)	7	2	1
Muscle spasms			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Bone pain			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Musculoskeletal chest pain			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	3	1	0
Pain in extremity			
subjects affected / exposed	2 / 25 (8.00%)	2 / 25 (8.00%)	2 / 8 (25.00%)
occurrences (all)	2	2	2
Myalgia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Ear infection			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 25 (8.00%)	5 / 25 (20.00%)	0 / 8 (0.00%)
occurrences (all)	2	6	0
Sinusitis			
subjects affected / exposed	2 / 25 (8.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Skin candida			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Diabetes mellitus			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 25 (0.00%)	2 / 25 (8.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Hyperglycaemia			
subjects affected / exposed	4 / 25 (16.00%)	4 / 25 (16.00%)	5 / 8 (62.50%)
occurrences (all)	5	4	5

Hyperkalaemia			
subjects affected / exposed	1 / 25 (4.00%)	2 / 25 (8.00%)	0 / 8 (0.00%)
occurrences (all)	1	3	0
Hypokalaemia			
subjects affected / exposed	4 / 25 (16.00%)	5 / 25 (20.00%)	1 / 8 (12.50%)
occurrences (all)	4	5	2
Hypoglycaemia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Hypocalcaemia			
subjects affected / exposed	9 / 25 (36.00%)	2 / 25 (8.00%)	4 / 8 (50.00%)
occurrences (all)	9	3	6
Hyperphosphataemia			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	2 / 25 (8.00%)	2 / 25 (8.00%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Hypoalbuminaemia			
subjects affected / exposed	3 / 25 (12.00%)	4 / 25 (16.00%)	1 / 8 (12.50%)
occurrences (all)	3	5	2
Metabolic acidosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	8 / 25 (32.00%)	2 / 25 (8.00%)	0 / 8 (0.00%)
occurrences (all)	10	2	0
Hyponatraemia			
subjects affected / exposed	4 / 25 (16.00%)	3 / 25 (12.00%)	1 / 8 (12.50%)
occurrences (all)	4	3	1

Non-serious adverse events	Part 1 (Dose Escalation) Schedule D	Part 1 (Dose Escalation) Schedule C	Part 2: Schedule C: Modakafusp alfa + Dexamethasone
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 21 (100.00%)	7 / 7 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Haematoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Shock			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoperfusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	1
Hypertension			
subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Shock haemorrhagic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Infusion site extravasation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	8 / 21 (38.10%)	2 / 7 (28.57%)	1 / 3 (33.33%)
occurrences (all)	10	2	2
Influenza like illness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	6 / 21 (28.57%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	8	1	0
Chest pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	4 / 21 (19.05%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	5	0	1

Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Cough			
subjects affected / exposed	4 / 21 (19.05%)	2 / 7 (28.57%)	0 / 3 (0.00%)
occurrences (all)	4	2	0
Dysphonia			
subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Hypoxia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	5 / 21 (23.81%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	5	0	0
Dyspnoea			
subjects affected / exposed	4 / 21 (19.05%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	6	1	0
Laryngeal inflammation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory distress			

subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory symptom			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Anxiety			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Confusional state			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	2 / 3 (66.67%)
occurrences (all)	2	0	2
Investigations			
Aspartate aminotransferase increased			

subjects affected / exposed	6 / 21 (28.57%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	7	1	0
Alanine aminotransferase increased			
subjects affected / exposed	3 / 21 (14.29%)	2 / 7 (28.57%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased			
subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Blood uric acid decreased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	11 / 21 (52.38%)	1 / 7 (14.29%)	2 / 3 (66.67%)
occurrences (all)	23	1	4
Staphylococcus test positive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	6 / 21 (28.57%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	26	1	0
Road traffic accident			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	4 / 21 (19.05%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Contusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Atrioventricular block first degree			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	4 / 21 (19.05%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Nervous system disorders			

Brain fog			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Burning sensation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysarthria			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	5 / 21 (23.81%)	0 / 7 (0.00%)	2 / 3 (66.67%)
occurrences (all)	6	0	2
Seizure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypoaesthesia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	16 / 21 (76.19%)	5 / 7 (71.43%)	3 / 3 (100.00%)
occurrences (all)	36	15	6
Anaemia			

subjects affected / exposed	15 / 21 (71.43%)	3 / 7 (42.86%)	3 / 3 (100.00%)
occurrences (all)	24	4	6
Leukopenia			
subjects affected / exposed	15 / 21 (71.43%)	5 / 7 (71.43%)	3 / 3 (100.00%)
occurrences (all)	34	19	10
Lymphopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	16 / 21 (76.19%)	6 / 7 (85.71%)	3 / 3 (100.00%)
occurrences (all)	30	24	9
Eye disorders			
Vitreous floaters			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 21 (19.05%)	1 / 7 (14.29%)	3 / 3 (100.00%)
occurrences (all)	5	1	3
Constipation			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Inguinal hernia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	7 / 21 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	7	0	0
Noninfective gingivitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	1
Toothache			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Cholecystitis acute			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acute hepatic failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Alopecia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Night sweats			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	2 / 21 (9.52%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	5	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pruritus			

subjects affected / exposed	4 / 21 (19.05%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	5	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 21 (19.05%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	5	0	0
Back pain			
subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Muscle spasms			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	13	0	0
Bone pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			

subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Pain in extremity			
subjects affected / exposed	3 / 21 (14.29%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Myalgia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Pneumonia			
subjects affected / exposed	3 / 21 (14.29%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Ear infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 21 (14.29%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	3	1	1
Sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 21 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Diabetes mellitus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	9 / 21 (42.86%)	5 / 7 (71.43%)	2 / 3 (66.67%)
occurrences (all)	24	7	6
Hyperkalaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 21 (9.52%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	5	1	3
Hypoglycaemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypocalcaemia			
subjects affected / exposed	5 / 21 (23.81%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	10	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	3 / 21 (14.29%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	5	1	2
Hypomagnesaemia			

subjects affected / exposed	4 / 21 (19.05%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	5	0	1
Hypoalbuminaemia			
subjects affected / exposed	6 / 21 (28.57%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	8	0	0
Metabolic acidosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lactic acidosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	2
Hyponatraemia			
subjects affected / exposed	3 / 21 (14.29%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	3	1	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 April 2017	The following changes were made as per Amendment 01: 1. The compound name was updated to TAK-573 and the study number was updated accordingly. 2. The number of participants for phase 1 and 2a were revised. 3. The definitions of PK, biomarker, and pharmacodynamic measurements were updated.
07 November 2017	The following changes were made as per Amendment 02: 1. Changed at time of "enrollment" and "randomization" to "first dose." 2. Modified triplicate ECG measurement time points.
29 June 2018	The following changes were made as per Amendment 03: 1. Removed test dose. 2. Reduced number of dose escalation levels to remove possible subtherapeutic doses. 3. Removed baseline visit (Day -1) associated with test dose administration. 4. Added the possibility of defining an optimal biologic dose (OBD) on the basis of pharmacodynamic endpoints as an alternative to the maximum tolerated dose (MTD) based on DLTs as a possible dose for future studies. 4. Revised PK sample collection schedule. 5. Changed the ECOG performance status requirement from 0-2 to 0-1.
22 October 2018	The following changes were made as per Amendment 04: 1. Added 3 schedules (Schedule B, C and D) to the original schedule (Schedule A) to be evaluated during the dose escalation phase. 2. Modified hematologic TEAEs to be considered DLTs. 3. Added subsequent anticancer therapy to AE and SAE reporting timelines. 4. Added option for eligible participants for intra-participants dose escalation to continue in a different schedule.
03 July 2019	The following changes were made as per Amendment 05: 1. Reduced the infusion time for modakafusp alfa. 2. Removed the requirement for preinfusion and postinfusion medication. 3. Added combination cohort(s) with dexamethasone during the phase 2 expansion phase. 4. Updated the expected number of cohorts and patients for phase 2. 5. Changed phase 2a to phase 2 throughout. 6. Replaced "monotherapy" with "single agent" throughout. 7. Added "relapsed" to the description of the study population. 8. Added a Clinical Safety section. 9. Added a definition of "DLT-like." 10. Increased the frequency of PFS follow-up to 4 weeks for participants who discontinued for reasons other than PD. 11. Updated inclusion criterion for females of childbearing potential and male participants. 12. Added guidance regarding discontinuation of dexamethasone for the combination arm. 13. Revised the end-of-study description. 13. Added a Posttrial Access section. 14. Revised exclusion criterion regarding severe allergic or anaphylactic reactions.
16 October 2020	The following changes were made as per Amendment 06: 1. Added new safety data. 2. Added CBR and DCR as a secondary endpoint for phase 1 and a primary endpoint for phase 2, respectively. 3. Removed OS as a secondary endpoint. 4. Updated the number of study sites and expected study duration. 4. Defined IRRs and treatment of IRRs. 5. Added oxygen saturation to vital signs. 6. Defined AESIs. 7. Added response-evaluable analysis set. 8. Revised the planned sample size for phase 2.
01 March 2022	The following changes were made as per Amendment 08: 1. Increased the number of planned study sites to 100. 2. Revised eligibility criteria regarding disease characteristics required for Part 3. 3. Added a second interim analysis for Part 3. 4. Removed CR as a reason for discontinuation (already covered under "other"). 5. Updated study monitoring guidelines to allow for COVID-19 circumstances.

02 August 2023	The following changes were made as per Amendment 09: 1. The IND No. and Abbreviated European Union Drug Regulating Authorities Clinical Trials (EUDRACT) number were added to the cover page. 2. "Immunogenicity" was added to description of assessments. 3. The purpose, enrollment plan, and number of participants for the China cohort were described. 4. Serum creatinine was removed as an inclusion criterion. 5. Participants may be treated after disease progression if the investigator considers it in the best interest of the participants and with approval by the sponsor. 6. Evaluation of neutralizing antibodies was added to ADA assessments and endpoints in Parts 1 and 2. 7. Intensive pharmacokinetic (PK) sampling endpoints for the China cohort were added to Part 3 Secondary Objectives and Part 3 Secondary Endpoints, along with a corresponding PK table in the appendix. 8. The exclusion criterion for hepatitis infection was revised; hepatitis testing for the Japan safety lead-in Part 3 was added. 9. Previous treatment with modakafusp alfa was added as an exclusion criterion. 10. Procedures for reporting SAEs were updated. 11. IMWG criteria were updated to 2016 version.
03 April 2024	The following changes were made as per Amendment 10: 1. Implemented new dose modification guidelines in cases of bleeding treatment-emergent adverse events (TEAEs) as an urgent safety measure. 2. Changed the Primary Objective and Endpoint for the Part 3 Dose Extension part of the study to investigator-assessed ORR.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
07 November 2024	The study was terminated by the sponsor for strategic reasons.	-

Notes:

Limitations and caveats

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

The study was terminated early due to discontinuation of development of modakafusp alfa for strategic reasons. The February 9 2024 data cut comprises the final full dataset for safety and efficacy.

Notes: