Clinical trial results:
A Phase 1/2a Open-label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of Modakafusp Alfa in Combination With Daratumumab Subcutaneous in Patients With Relapsed or Refractory Multiple Myeloma

Summary

EudraCT number	2022-002169-14
Trial protocol	HU ES
Global end of trial date	22 May 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-573-2001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05590377
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Avenue, Lexington, Massachusetts, 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	22 May 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 May 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to determine the safety and tolerability of modakafusp alfa in combination with daratumumab subcutaneous (SC) in Phase 1 Dose Escalation.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator:

NA

Actual start date of recruitment	23 January 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 7
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Korea, Republic of: 4
Worldwide total number of subjects	15
EEA total number of subjects	4

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)	8
From 65 to 84 years	6
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 9 investigative sites globally from 23 January 2023 to 22 May 2024.

Pre-assignment

Screening details:

Participants with multiple myeloma were enrolled in Phase 1 (Dose Escalation) to receive modakafusp alfa (80 milligrams [mg], 120 mg or 240 mg) + daratumumab. No participants were enrolled in Phase 2a (Dose Finding) as the study was terminated by the Sponsor due to strategic reasons.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab

Arm description:

Participants received modakafusp alfa 80 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 60 weeks.

Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	Darzalex
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression.

Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Powder for concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Modakafusp alfa 80 mg, IV once Q4W in each 28-day treatment cycle until disease progression.

Arm title	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab

Arm description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 48 weeks.

Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	Darzalex
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details: Daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression.	
Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Powder for concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details: Modakafusp alfa 120 mg, IV, Q4W in each 28-day treatment cycle until disease progression.	
Arm title	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab
Arm description: Participants received modakafusp alfa 240 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 36 weeks.	
Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	Darzalex
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression.	
Investigational medicinal product name	Modakafusp Alfa
Investigational medicinal product code	TAK-573
Other name	
Pharmaceutical forms	Powder for concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details: Modakafusp alfa 240 mg, infusion, IV, Q4W in each 28-day treatment cycle until disease progression.	

Number of subjects in period 1	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab
Started	3	6	6
Completed	0	0	0
Not completed	3	6	6
Adverse event, serious fatal	1	1	2
Consent withdrawn by subject	1	-	-
Study Terminated by Sponsor	1	5	4

Baseline characteristics

Reporting groups	
Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab
Reporting group description:	
Participants received modakafusp alfa 80 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 60 weeks.	
Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab
Reporting group description:	
Participants received modakafusp alfa 120 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 48 weeks.	
Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab
Reporting group description:	
Participants received modakafusp alfa 240 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 36 weeks.	

Reporting group values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab
Number of subjects	3	6	6
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
arithmetic mean	71.7	63.7	59.2
standard deviation	± 18.34	± 11.64	± 12.02
Gender categorical Units: Subjects			
Female	2	2	2
Male	1	4	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	4	0
Native Hawaiian or Other Pacific Islander	0	0	0

Black or African American	0	0	2
White	3	0	1
More than one race	0	0	0
Unknown or Not Reported	0	2	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	3	4	3
Unknown or Not Reported	0	2	2

Reporting group values	Total		
Number of subjects	15		
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years arithmetic mean standard deviation	--		
Gender categorical Units: Subjects			
Female	6		
Male	9		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	4		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	2		
White	4		
More than one race	0		
Unknown or Not Reported	5		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1		
Not Hispanic or Latino	10		
Unknown or Not Reported	4		

End points

End points reporting groups

Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab

Reporting group description:

Participants received modakafusp alfa 80 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 60 weeks.

Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab

Reporting group description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 48 weeks.

Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab

Reporting group description:

Participants received modakafusp alfa 240 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 36 weeks.

Subject analysis set title	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab
Subject analysis set type	Per protocol

Subject analysis set description:

Participants were planned to receive modakafusp alfa at dose level 1 (DL1) [selected from Phase 1 Dose Escalation] with daratumumab SC 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression. However, the study terminated prior to initiation of Phase 2 and no participants were enrolled in Phase 2 of the study. "15" is added as a placeholder value for "0" in the "number of subjects in subject analysis set" field due to database limitations.

Subject analysis set title	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab
Subject analysis set type	Per protocol

Subject analysis set description:

Participants were planned to receive modakafusp alfa at dose level 2 (DL2) [selected from Phase 1 Dose Escalation] with daratumumab SC 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression. However, the study terminated prior to initiation of Phase 2 and no participants were enrolled in Phase 2 of the study. "15" is added as a placeholder value for "0" in the "number of subjects in subject analysis set" field due to database limitations.

Primary: Phase 1: Number of Participants Reporting one or More TEAEs and Per Severity

End point title	Phase 1: Number of Participants Reporting one or More TEAEs and Per Severity[1]

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a clinical investigation participant administered a drug; it does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (e.g., a clinically significant abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, whether or not it is considered related to the drug. A TEAE is defined as an adverse event with an onset that occurs after receiving study drug. Severity grades for TEAEs were evaluated as per the NCI CTCAE Version 5.0. The Safety Population included all participants who received at least 1 dose, even an incomplete dose, of any study drug.

End point type	Primary

End point timeframe:

Phase 1: Up to 15.9 months

Notes:

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

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	6	
Units: participants				
Grade 1	1	0	0	
Grade 2	0	2	1	
Grade 3	2	4	3	
Grade 4	0	0	1	
Grade 5	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants with Dose Limiting Toxicities (DLT)

End point title	Phase 1: Number of Participants with Dose Limiting Toxicities (DLT)[2]

End point description:

DLT was defined as any of the treatment-emergent adverse events (TEAEs) that occurred during Cycle 1 and were considered by the investigator to be at least possibly related to modakafusp alfa. Toxicity was evaluated according to national cancer institute common terminology criteria for adverse events (NCI CTCAE) Version 5.0. The Dose Limiting Toxicity (DLT)-evaluable Population included all participants from the Phase 1 dose escalation portion who experienced a DLT in Cycle 1 in the treatment phase of the study or had completed the Cycle 1 dose of modakafusp alfa and at least 75% of the planned dose of daratumumab SC.

End point type	Primary

End point timeframe:

Phase 1: Cycle 1 (cycle length=28 days)

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 analyses were planned for this endpoint.

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	6	
Units: participants	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2a: Overall Response Rate (ORR)

End point title	Phase 2a: Overall Response Rate (ORR)[3]

End point description:

ORR is defined as the percentage of participants who achieve a confirmed partial response (PR) or better during the study in the safety population. ORR will be assessed by the investigator per International Myeloma Working Group (IMWG) criteria. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons. Thus, no participants were enrolled for Phase 2a and no data was collected for this outcome measure due to study termination.

End point type	Primary

End point timeframe:

Phase 2a: Up to 15.9 months

Notes:

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

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[4]	0[5]		
Units: participants				

Notes:

[4] - Due to early study termination no participants were enrolled in Phase 2a of the study.

[5] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Cmax: Single-Dose Maximum Observed Serum Concentration for Modakafusp Alfa

End point title	Phase 1: Cmax: Single-Dose Maximum Observed Serum Concentration for Modakafusp Alfa

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[6]	0[7]	0[8]	
Units: ng/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[6] - Data was not collected for this outcome measure as planned because the study was terminated early.
[7] - Data was not collected for this outcome measure as planned because the study was terminated early.
[8] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Tmax: Time to First Occurrence of Maximum Serum Concentration (Cmax) for Modakafusp Alfa

End point title	Phase 1: Tmax: Time to First Occurrence of Maximum Serum Concentration (Cmax) for Modakafusp Alfa

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[9]	0[10]	0[11]	
Units: hours				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[9] - Data was not collected for this outcome measure as planned because the study was terminated early.
[10] - Data was not collected for this outcome measure as planned because the study was terminated early.
[11] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: AUC∞: Area Under the Serum Concentration-time Curve From Time 0 to Infinity for Modakafusp Alfa

End point title	Phase 1: AUC∞: Area Under the Serum Concentration-time Curve From Time 0 to Infinity for Modakafusp Alfa

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[12]	0[13]	0[14]	
Units: nanogram*hour per milliliter (ng*hr/mL)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[12] - Data was not collected for this outcome measure as planned because the study was terminated early.
[13] - Data was not collected for this outcome measure as planned because the study was terminated early.
[14] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Apparent Serum Terminal Disposition Rate Constant for Modakafusp Alfa

End point title	Phase 1: Apparent Serum Terminal Disposition Rate Constant for Modakafusp Alfa

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[15]	0[16]	0[17]	
Units: hour				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[15] - Data was not collected for this outcome measure as planned because the study was terminated early.
[16] - Data was not collected for this outcome measure as planned because the study was terminated early.
[17] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: AUClast: Area Under the Serum Concentration-time Curve from Time 0 to Time of the Last Quantifiable Concentration

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

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[18]	0[19]	0[20]	
Units: ng*hr/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[18] - Data was not collected for this outcome measure as planned because the study was terminated early.
[19] - Data was not collected for this outcome measure as planned because the study was terminated early.
[20] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Total Clearance After Intravenous Administration for

Modakafusp Alfa	
End point title	Phase 1: Total Clearance After Intravenous Administration for Modakafusp Alfa

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[21]	0[22]	0[23]	
Units: L/hr				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[21] - Data was not collected for this outcome measure as planned because the study was terminated early.
[22] - Data was not collected for this outcome measure as planned because the study was terminated early.
[23] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Apparent Serum Terminal Disposition Phase Half-life for Modakafusp Alfa

End point title	Phase 1: Apparent Serum Terminal Disposition Phase Half-life for Modakafusp Alfa

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[24]	0[25]	0[26]	
Units: hour				

arithmetic mean (standard deviation)	()	()	()	

Notes:

[24] - Data was not collected for this outcome measure as planned because the study was terminated early.
[25] - Data was not collected for this outcome measure as planned because the study was terminated early.
[26] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Volume of Distribution at Steady State After Intravenous (IV) Administration for Modakafusp Alfa

End point title	Phase 1: Volume of Distribution at Steady State After Intravenous (IV) Administration for Modakafusp Alfa

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[27]	0[28]	0[29]	
Units: liters				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[27] - Data was not collected for this outcome measure as planned because the study was terminated early.
[28] - Data was not collected for this outcome measure as planned because the study was terminated early.
[29] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Tmax: Time to First Occurrence of Maximum Serum Concentration (Cmax) for Daratumumab

End point title	Phase 1: Tmax: Time to First Occurrence of Maximum Serum Concentration (Cmax) for Daratumumab

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[30]	0[31]	0[32]	
Units: hours				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[30] - Data was not collected for this outcome measure as planned because the study was terminated early.
[31] - Data was not collected for this outcome measure as planned because the study was terminated early.
[32] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Cmax: Single-Dose Maximum Observed Serum Concentration for Daratumumab

End point title	Phase 1: Cmax: Single-Dose Maximum Observed Serum Concentration for Daratumumab

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[33]	0[34]	0[35]	
Units: ng/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[33] - Data was not collected for this outcome measure as planned because the study was terminated early.
[34] - Data was not collected for this outcome measure as planned because the study was terminated early.

[35] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Ctrough: Single-Dose and Multiple-dose Observed Concentration at the End of a Dosing Interval for Daratumumab

End point title	Phase 1: Ctrough: Single-Dose and Multiple-dose Observed Concentration at the End of a Dosing Interval for Daratumumab

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[36]	0[37]	0[38]	
Units: micrograms/milliliter (mcg/mL)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[36] - Data was not collected for this outcome measure as planned because the study was terminated early.
[37] - Data was not collected for this outcome measure as planned because the study was terminated early.
[38] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: AUC∞: Area Under the Serum Concentration-time Curve from Time 0 to Infinity for Daratumumab

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

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[39]	0[40]	0[41]	
Units: ng*hr/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[39] - Data was not collected for this outcome measure as planned because the study was terminated early.
[40] - Data was not collected for this outcome measure as planned because the study was terminated early.
[41] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Data was not collected for this outcome measure as planned because the study was terminated by the sponsor due to strategic reasons (no safety concerns).

End point type	Secondary

End point timeframe:

Phase 1: Days 1, 8, 15, and 22 of Cycles 1 and 2: Pre-dose, and at multiple time points up to 4 hours post-dose; Day 2 of Cycles 1 and 2: Post-dose (cycle length=28 days)

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[42]	0[43]	0[44]	
Units: ng*hr/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[42] - Data was not collected for this outcome measure as planned because the study was terminated early.
[43] - Data was not collected for this outcome measure as planned because the study was terminated early.

[44] - Data was not collected for this outcome measure as planned because the study was terminated early.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Overall Response Rate (ORR)

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

End point description:

ORR is defined as the percentage of participants who achieved a confirmed PR or better during the study in the safety population. ORR will be assessed by the investigator per IMWG criteria. The Response-evaluable Population included all participants who received at least 1 dose, even an incomplete dose, of any study drug, have a disease assessment at screening (baseline evaluation), and at least 1 postbaseline disease assessment.

End point type	Secondary

End point timeframe:

Phase 1: Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	6	
Units: percentage of participants				
number (confidence interval 95%)	33.3 (0.84 to 90.57)	66.7 (22.28 to 95.67)	50.0 (11.81 to 88.19)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and Phase 2a: Progression Free Survival (PFS)

End point title	Phase 1 and Phase 2a: Progression Free Survival (PFS)

End point description:

PFS is defined as the time from the date of the first dose administration of any study drug to the first documentation of confirmed progressive disease or death due to any cause, whichever occurs first. PFS will be assessed by the investigator as per IMWG criteria. Due to the early study termination, the short follow-up of the participants, and the small population, the pre-planned efficacy analysis could not be adequately interpreted for Phase 1. Furthermore, for strategic reasons, the sponsor decided not to proceed with Phase 2a. Thus, no participants were enrolled in Phase 2a, and no data was collected for this outcome measure.

End point type	Secondary

End point timeframe:

Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[45]	0[46]	0[47]	0[48]
Units: months				

Notes:

[45] - The pre-planned efficacy analysis could not be adequately interpreted for Phase 1.

[46] - The pre-planned efficacy analysis could not be adequately interpreted for Phase 1.

[47] - The pre-planned efficacy analysis could not be adequately interpreted for Phase 1.

[48] - Due to early study termination no participants were enrolled in Phase 2a of the study.

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab			
Subject group type	Subject analysis set			
Number of subjects analysed	0[49]			
Units: months				

Notes:

[49] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and Phase 2a: Duration of Response (DOR)

End point title	Phase 1 and Phase 2a: Duration of Response (DOR)

End point description:

DOR is defined as the time from the date of first documentation of a confirmed PR or better to the date of first documentation of confirmed progressive disease or death due to any cause, whichever occurs first. DOR will be calculated for confirmed responders only (PR or better). DOR will be assessed by the investigator as per IMWG criteria. Due to the early study termination, the short follow-up of the participants, and the small population, the pre-planned efficacy analysis could not be adequately interpreted for Phase 1. Furthermore, for strategic reasons, the sponsor decided not to proceed with Phase 2a. Thus, no participants were enrolled in Phase 2a, and no data was collected for this outcome measure.

End point type	Secondary

End point timeframe:

Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[50]	0[51]	0[52]	0[53]
Units: months				

Notes:

[50] - The pre-planned efficacy analysis could not be adequately interpreted for Phase 1.

[51] - The pre-planned efficacy analysis could not be adequately interpreted for Phase 1.

[52] - The pre-planned efficacy analysis could not be adequately interpreted for Phase 1.

[53] - Due to early study termination no participants were enrolled in Phase 2a of the study.

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab			
Subject group type	Subject analysis set			
Number of subjects analysed	0[54]			
Units: months				

Notes:

[54] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and Phase 2a: Overall Survival (OS)

End point title	Phase 1 and Phase 2a: Overall Survival (OS)

End point description:

OS is defined as the time from the date of the first dose administration of any study drug to the documentation of death due to any cause. OS will be assessed by the investigator as per IMWG criteria. Due to the early study termination, the short follow-up of the participants, and the small population, the pre-planned efficacy analysis could not be adequately interpreted for Phase 1. Furthermore, for strategic reasons, the sponsor decided not to proceed with Phase 2a. Thus, no participants were enrolled in Phase 2a, and no data was collected for this outcome measure.

End point type	Secondary

End point timeframe:

Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[55]	0[56]	0[57]	0[58]
Units: months				

Notes:

[55] - The preplanned efficacy analysis could not be adequately interpreted for Phase 1.

[56] - The preplanned efficacy analysis could not be adequately interpreted for Phase 1.

[57] - The preplanned efficacy analysis could not be adequately interpreted for Phase 1.

[58] - Due to early study termination no participants were enrolled in Phase 2a of the study.

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab			
Subject group type	Subject analysis set			
Number of subjects analysed	0[59]			
Units: months				

Notes:

[59] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and Phase 2a: Titer of Anti-drug Antibodies

End point title	Phase 1 and Phase 2a: Titer of Anti-drug Antibodies

End point description:

Due to early termination and small evaluable population, the pre-planned immunogenicity measurements of serum titers were not performed for Phase 1. Furthermore, for strategic reasons, the sponsor decided not to proceed with Phase 2a. Thus, no participants were enrolled in Phase 2a, and no data was collected for this outcome measure.

End point type	Secondary

End point timeframe:

Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[60]	0[61]	0[62]	0[63]
Units: percentage of participants				

Notes:

[60] - The preplanned immunogenicity measurements of serum titers were not performed for Phase 1.

[61] - The preplanned immunogenicity measurements of serum titers were not performed for Phase 1.

[62] - The preplanned immunogenicity measurements of serum titers were not performed for Phase 1.

[63] - Due to early study termination no participants were enrolled in Phase 2a of the study.

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab			
Subject group type	Subject analysis set			
Number of subjects analysed	0[64]			
Units: percentage of participants				

Notes:

[64] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and Phase 2a: Number of Participants With Anti-drug Antibodies (ADA)

End point title	Phase 1 and Phase 2a: Number of Participants With Anti-drug Antibodies (ADA)

End point description:

After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons and hence no participants were enrolled for Phase 2a. Immunogenicity-evaluable Population included participants who received at least 1 dose of modakafusp alfa in combination with daratumumab SC (partial or complete) with a baseline assessment & at least 1 postbaseline immunogenicity assessment. No data was collected for this outcome measure due to study termination. Subjects analyzed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	0[65]	
Units: participants	3	2		

Notes:

[65] - No participant in this arm group had data available for analyses at the specified time point.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and Phase 2a: Number of Participants With Neutralizing Antibodies (NAb) Against Study Drug

End point title	Phase 1 and Phase 2a: Number of Participants With Neutralizing Antibodies (NAb) Against Study Drug

End point description:

Immunogenicity-evaluable Population. After Phase 1 Dose Escalation, the sponsor decided not to proceed with Phase 2a due to strategic reasons. Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination. Subjects analyzed=participants with data available for analyses.

End point type	Secondary

End point timeframe:

Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3	6	0[66]	0[67]
Units: participants	1	0		

Notes:

[66] - No participant had the data available for analysis at the specified time point.

[67] - No participants were enrolled in Phase 2a due to early study termination.

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab			
Subject group type	Subject analysis set			
Number of subjects analysed	0[68]			
Units: participants				

Notes:

[68] - No participants were enrolled in Phase 2a due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and Phase 2a: Rate of Measurable [Minimal] Residual Disease Negative (MRD[-]) Complete Response (CR)

End point title	Phase 1 and Phase 2a: Rate of Measurable [Minimal] Residual Disease Negative (MRD[-]) Complete Response (CR)

End point description:

MRD[-] CR rate is defined as the percentage of participants who achieve confirmed CR assessed by the investigator and MRD[-] status using a threshold of 10^-5. The analysis will be based on the response-evaluable population. No participants had sCR or CR in Phase 1 thus the subjects analyzed is zero. Only participants who had a confirmed stringent CR (sCR) or complete response (CR) were to be analyzed for this outcome measure. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons. Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[69]	0[70]	0[71]	0[72]
Units: percentage of participants				

Notes:

[69] - No participant had sCR or CR in Phase 1 thus the subjects analysed is zero.

[70] - No participant had sCR or CR in Phase 1 thus the subjects analysed is zero.

[71] - No participant had sCR or CR in Phase 1 thus the subjects analysed is zero.

[72] - Due to early study termination no participants were enrolled in Phase 2a of the study.

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab			
Subject group type	Subject analysis set			
Number of subjects analysed	0[73]			
Units: percentage of participants				

Notes:

[73] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and Phase 2a: Duration of Measurable [Minimal] Residual Disease (MRD) Negativity

End point title	Phase 1 and Phase 2a: Duration of Measurable [Minimal] Residual Disease (MRD) Negativity

End point description:

Duration of MRD negativity for participants achieving MRD negativity is defined as the time from the date of first documentation of MRD negativity to the first documentation of MRD positivity or confirmed progressive disease, whichever occurs first. It will be calculated for participants achieving MRD negativity only. No participants had sCR or CR in Phase 1 thus the subjects analyzed is zero.

End point type	Secondary

End point timeframe:

Up to 15.9 months

End point values	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[74]	0[75]	0[76]	0[77]
Units: months				

Notes:

[74] - No participant had sCR or CR in Phase 1 thus the subjects analyzed is zero.

[75] - No participant had sCR or CR in Phase 1 thus the subjects analyzed is zero.

[76] - No participants had sCR or CR in Phase 1 thus the subjects analyzed is zero.

[77] - Due to early study termination no participants were enrolled in Phase 2a of the study.

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab			
Subject group type	Subject analysis set			
Number of subjects analysed	0[78]			
Units: months				

Notes:

[78] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2a: Clinical Benefit Rate (CBR)

End point title	Phase 2a: Clinical Benefit Rate (CBR)

End point description:

CBR is defined as the percentage of participants who had a confirmed response of stringent complete response (sCR), complete response (CR), very good partial response (VGPR), partial response (PR), or minimal response based on investigators' disease assessment per IMWG criteria. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons. Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Phase 2a: Up to 15.9 months

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[79]	0[80]		
Units: percentage of participants				

Notes:

[79] - Due to early study termination no participants were enrolled in Phase 2a of the study.

[80] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2a: Duration of Clinical Benefit (DCB)

End point title	Phase 2a: Duration of Clinical Benefit (DCB)

End point description:

DCB is defined as the time from the date of first documentation of a minimal response or better to the date of first documentation of confirmed progressive disease or death due to any cause, whichever

occurs first. DCB will be calculated for only participants who achieved a minimal response or better. DCB will be assessed by the investigator as per IMWG criteria. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons (no safety concerns). Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Phase 2a: Up to 15.9 months

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[81]	0[82]		
Units: months				

Notes:

[81] - Due to early study termination no participants were enrolled in Phase 2a of the study.

[82] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2a: Time to Next Treatment (TTNT)

End point title	Phase 2a: Time to Next Treatment (TTNT)

End point description:

TTNT is defined as the time from the date of first dose administration of any study drug to the date of the first dose initiation of the next line of anticancer therapy for any reason or death from any cause, whichever comes first. Participants who have not started the next-line therapy will be censored at the date last known to be alive before subsequent anticancer therapy. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons (no safety concerns). Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Phase 2a: Up to 15.9 months

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[83]	0[84]		
Units: days				
median (full range (min-max))	(to)	(to)		

Notes:

[83] - Due to early study termination no participants were enrolled in Phase 2a of the study.

[84] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2a: Disease Control Rate (DCR)

End point title	Phase 2a: Disease Control Rate (DCR)

End point description:

DCR is defined as the percentage of participants with a confirmed response of sCR, CR, VGPR, PR, minimal response, or stable disease (SD) based on investigators' disease assessment per IMWG criteria. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons (no safety concerns). Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Phase 2a: Up to 15.9 months

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[85]	0[86]		
Units: percentage of participants				

Notes:

[85] - Due to early study termination no participants were enrolled in Phase 2a of the study.

[86] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2a: Duration of Disease Control

End point title	Phase 2a: Duration of Disease Control

End point description:

Duration of disease control is defined as the time from date of first documentation of SD or better to the date of first documentation of confirmed progressive disease or death due to any cause. Duration of disease control will be calculated for only patients who achieved SD or better. It will be assessed by the investigator per IMWG criteria. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons (no safety concerns). Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Phase 2a: Up to 15.9 months

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[87]	0[88]		
Units: months				

Notes:

[87] - Due to early study termination no participants were enrolled in Phase 2a of the study.

[88] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2a: Time to Progression (TTP)

End point title	Phase 2a: Time to Progression (TTP)

End point description:

TTP is defined as the time from the date of randomization to the first documentation of confirmed progressive disease as defined by IMWG criteria, assessed by the investigator. Participants without documentation of confirmed progression will be censored at the date of last adequate disease assessment. The analysis will be based on the intent-to-treat (ITT) population. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons (no safety concerns). Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Phase 2a: Up to 15.9 months

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[89]	0[90]		
Units: months				

Notes:

[89] - Due to early study termination no participants were enrolled in Phase 2a of the study.

[90] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2a: Time to Response (TTR)

End point title	Phase 2a: Time to Response (TTR)

End point description:

TTR is defined as time from the date of first dose administration of any study drug to the date of the first documentation of a confirmed PR or better. TTR will be calculated for responders only. TTR will be assessed by the investigator per IMWG criteria. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons (no safety concerns). Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Phase 2a: Up to 15.9 months

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[91]	0[92]		
Units: months				

Notes:

[91] - Due to early study termination no participants were enrolled in Phase 2a of the study.

[92] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2a: Number of Participants Reporting one or More TEAEs and Per Severity

End point title	Phase 2a: Number of Participants Reporting one or More TEAEs and Per Severity

End point description:

An AE is defined as any untoward medical occurrence in a clinical investigation participant administered a drug; it does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (e.g., a clinically significant abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, whether or not it is considered related to the drug. A TEAE is defined as an adverse event with an onset that occurs after receiving study drug. Severity grades for TEAEs will be evaluated as per the NCI CTCAE Version 5.0. After completion of Phase 1 Dose Escalation of this study the sponsor decided not to proceed with Phase 2a due to strategic reasons (no safety concerns). Thus, no participants were enrolled for Phase 2a & no data was collected for this outcome measure due to study termination.

End point type	Secondary

End point timeframe:

Phase 2a: Up to 15.9 months

End point values	Phase 2a Dose Finding: Modakafusp Alfa (DL1) + Daratumumab	Phase 2a Dose Finding: Modakafusp Alfa (DL2) + Daratumumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[93]	0[94]		
Units: participants				

Notes:
[93] - Due to early study termination no participants were enrolled in Phase 2a of the study.
[94] - Due to early study termination no participants were enrolled in Phase 2a of the study.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Phase 1: Up to 15.9 months

Adverse event reporting additional description:

The Safety Population was defined as all participants who received at least 1 dose, even an incomplete dose, of any study drug. The sponsor decided not to proceed with Phase 2a after phase 1 completion due to strategic reasons. Thus, no participants were enrolled & no adverse events were reported for Phase 2a.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab

Reporting group description:

Participants received modakafusp alfa 80 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 60 weeks.

Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab

Reporting group description:

Participants received modakafusp alfa 240 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 36 weeks.

Reporting group title	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab

Reporting group description:

Participants received modakafusp alfa 120 mg, infusion, IV, Q4W with daratumumab 1800 mg, SC, QW in Cycles 1 and 2, Q2W in Cycles 3 to 6, and Q4W thereafter in each 28-day treatment cycle until disease progression or up to 48 weeks.

Serious adverse events	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events	0	1	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (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			

Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (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
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (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
Hyperthermia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (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
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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	Phase 1 (Dose Escalation) Modakafusp Alfa 80 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 240 mg + Daratumumab	Phase 1 (Dose Escalation) Modakafusp Alfa 120 mg + Daratumumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	6 / 6 (100.00%)
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Chills			

subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	2
Pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	7	2	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Upper respiratory tract congestion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Anxiety			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Investigations			
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	7	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Fall			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Atrial fibrillation			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Nervous system disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 6 (66.67%)	1 / 6 (16.67%)
occurrences (all)	0	4	2
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Thrombocytopenia			
subjects affected / exposed	2 / 3 (66.67%)	4 / 6 (66.67%)	3 / 6 (50.00%)
occurrences (all)	2	8	11
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	3 / 6 (50.00%)
occurrences (all)	1	10	5
Eye disorders			
Lacrimation increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vision blurred			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Dry mouth			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypogonadism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 3 (100.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Muscular weakness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	3	0

Rash pustular			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypercreatininaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hyperphagia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 April 2024	The following changes were made as per Amendment 01: 1. Removed the criteria related to Grade 4 life threatening TEAEs. 2. Modified phase name to indicate "dose escalation" rather than "safety lead-in".

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
22 May 2024	No participants were enrolled in Phase 2a (Dose Finding) and data for the outcome measures related to progression-free survival (PFS), overall survival (OS), duration of response (DOR), pharmacokinetic (PK) parameters and pharmacodynamic (PD)/antidrug antibodies (ADAs) was not collected or analysed as planned because the study was terminated by the sponsor due to strategic reasons.	-

Notes:

Limitations and caveats

None reported