Clinical trial results:
A Phase 1b Open-label Study to Evaluate the Safety and Tolerability of Intravenous Modakafusp Alfa as Part of Combination Therapy in Adult Patients With Multiple Myeloma

Summary

EudraCT number	2022-001418-20
Trial protocol	ES
Global end of trial date	04 June 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-573-1502

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05556616
WHO universal trial number (UTN)	-

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	04 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 June 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objectives of the trial were to determine the safety and tolerability of modakafusp alfa and lenalidomide combination therapy as maintenance in adult patients with newly diagnosed multiple myeloma (NDMM) after autologous stem cell transplant (ASCT), modakafusp alfa as part of 2-drug combination therapy in adult patients with relapsed/refractory multiple myeloma (RRMM) and modakafusp alfa as part of 3-drug combination therapy in adult patients with RRMM; to determine the recommended Phase 2 dose (RP2D) of the combination therapy with modakafusp alfa, modakafusp alfa (recommended doses of the doublet combinations) for RRMM Doublet Combinations (Doublets) and modakafusp alfa (recommended doses of the triplet combinations) for RRMM Triplet Combinations (Triplets).

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	12 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	Belgium: 2
Country: Number of subjects enrolled	United States: 12
Worldwide total number of subjects	14
EEA total number of subjects	2

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)	4
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at various investigative sites globally from 12 January 2023 to 04 June 2024.

Pre-assignment

Screening details:

Participants with a diagnosis of multiple myeloma (MM) enrolled;those newly diagnosed with MM(NDMM) received modakafusp alfa + lenalidomide; participants with relapsed/refractory MM(RRMM)received modakafusp alfa+pomalidomide/carfilzomib. Due to early termination, no participants enrolled in Group2 Arm 4:modakafusp alfa+bortezomib and Group 3 arms.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg

Arm description:

Participants received 80 milligrams (mg) modakafusp alfa, infusion intravenously (IV), once on Day 1, once every 4 weeks (Q4W), in combination with 10 mg lenalidomide capsules orally once daily continuously on Days 1 to 28, in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or to a maximum of 2 years for measurable/minimal residual disease-negative (MRD [-]) participants, whichever occurred first.

Arm type	Experimental
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:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W, in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or to a maximum of 2 years for MRD [-] negative participants, whichever occurred first.

Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received 10 mg lenalidomide capsules orally once daily continuously on Days 1 to 28, in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or to a maximum of 2 years for MRD [-] negative participants, whichever occurred first.

Arm title	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg

Arm description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 2 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Arm type	Experimental

Investigational medicinal product name	Pomalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received 2 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

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:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Arm title	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg

Arm description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 4 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Pomalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received 4 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

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:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Arm title	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2

Arm description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 20/70 milligrams per meter square (mg/m^2) carfilzomib IV, on Day 1, 8 and 15 of a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Arm type	Experimental

Investigational medicinal product name	Carfilzomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 20/70 milligrams per meter square (mg/m^2) carfilzomib IV, on Day 1, 8 and 15 of a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

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:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W of a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Number of subjects in period 1	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg
Started	3	4	4
Completed	2	1	2
Not completed	1	3	2
Adverse event, serious fatal	-	-	2
Consent withdrawn by subject	1	-	-
Study Terminated by Sponsor	-	3	-

Number of subjects in period 1	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2
Started	3
Completed	2
Not completed	1
Adverse event, serious fatal	1
Consent withdrawn by subject	-
Study Terminated by Sponsor	-

Baseline characteristics

Reporting groups	
Reporting group title	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg
Reporting group description:	
Participants received 80 milligrams (mg) modakafusp alfa, infusion intravenously (IV), once on Day 1, once every 4 weeks (Q4W), in combination with 10 mg lenalidomide capsules orally once daily continuously on Days 1 to 28, in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or to a maximum of 2 years for measurable/minimal residual disease-negative (MRD [-]) participants, whichever occurred first.	
Reporting group title	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg
Reporting group description:	
Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 2 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.	
Reporting group title	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg
Reporting group description:	
Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 4 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.	
Reporting group title	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2
Reporting group description:	
Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 20/70 milligrams per meter square (mg/m^2) carfilzomib IV, on Day 1, 8 and 15 of a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.	

Reporting group values	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg
Number of subjects	3	4	4
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	62.3	64.3	71.3
standard deviation	± 18.50	± 11.00	± 2.63
Gender categorical Units: Subjects			
Female	2	0	2
Male	1	4	2
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	1	1	2
White	2	1	2
More than one race	0	0	0
Unknown or Not Reported	0	2	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	2	4
Unknown or Not Reported	1	2	0

Reporting group values	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	Total	
Number of subjects	3	14	
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	57.3		
standard deviation	± 12.06	-	
Gender categorical Units: Subjects			
Female	0	4	
Male	3	10	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	1	5	
White	2	7	
More than one race	0	0	
Unknown or Not Reported	0	2	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	3	11	
Unknown or Not Reported	0	3	

End points

End points reporting groups

Reporting group title	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg

Reporting group description:

Participants received 80 milligrams (mg) modakafusp alfa, infusion intravenously (IV), once on Day 1, once every 4 weeks (Q4W), in combination with 10 mg lenalidomide capsules orally once daily continuously on Days 1 to 28, in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or to a maximum of 2 years for measurable/minimal residual disease-negative (MRD [-]) participants, whichever occurred first.

Reporting group title	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg

Reporting group description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 2 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Reporting group title	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg

Reporting group description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 4 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Reporting group title	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2

Reporting group description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 20/70 milligrams per meter square (mg/m^2) carfilzomib IV, on Day 1, 8 and 15 of a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

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

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

End point description:

DLT was defined by national cancer institute common terminology criteria for adverse events (NCI CTCAE) version 5.0: Grade 5 AE; Hematologic toxicity: Nonfebrile Grade 4 neutropenia lasting more than 7 consecutive days/Grade greater than or equal to (>=) 3 febrile neutropenia; Grade 4 thrombocytopenia lasting more than 14 consecutive days, Grade 3 thrombocytopenia with clinically significant bleeding; any other Grade 4 with exceptions; Nonhematologic Grade 3 or higher toxicities unrelated to the underlying disease with exceptions. The DLT-evaluable Analysis Set included participants who experienced a DLT in Cycle 1 in the treatment phase of the study or completed Cycle 1 procedures and received a full Cycle 1 dose of modakafusp alfa and at least 75% of the planned dose of the combination partner. Due to early termination of the study no participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms, thus they are not presented here.

End point type	Primary

End point timeframe:

Cycle 1 (Cycle length is 28 days)

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 was planned for this endpoint.

End point values	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	4	2
Units: participants	0	1	1	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With one or More Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Participants With one or More Treatment Emergent Adverse Events (TEAEs)[2]

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 was 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 participants who had received at least 1 dose, even if incomplete, of any study drug. Due to early termination of the study no participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms, thus they are not presented here.

End point type	Primary

End point timeframe:

Up to 16.7 months

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 was planned for this endpoint.

End point values	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	4	3
Units: participants	3	3	4	3

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

PFS:time from date of 1st dose of study drug administration to date of 1st documentation of confirmed progression of disease(PD)/death due to any cause,whichever occurs first.PD:determined by International Myeloma Working Group(IMWG)criteria.PD:≥25%increase from lowest response value in≥1of:serum M-component increase≥0.5gram per deciliter(g/dL)/urine M-component increase≥200mg/24-hour;difference between involved & uninvolved free light chains(FLC)levels increase must be>10mgperdeciliter;bone marrow plasma cell≥10%;definite development of new bone lesions/soft tissue plasmacytomas/definite increase in size of existing bone lesions/soft tissue plasmacytomas;development of hypercalcemia that can be attributed solely to plasma cell proliferative disorder.Due to early study termination,short follow-up & small population data could not be adequately interpreted.No participants enrolled in Group2Arm4:modakafusp alfa+bortezomib&Group3 arms due to early study termination,thus not presented.

End point type	Secondary

End point timeframe:

Up to 16.7 months

End point values	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[3]	0[4]	0[5]	0[6]
Units: months				

Notes:

[3] - The pre-planned efficacy analysis could not be adequately interpreted due to early termination.

[4] - The pre-planned efficacy analysis could not be adequately interpreted due to early termination.

[5] - The pre-planned efficacy analysis could not be adequately interpreted due to early termination.

[6] - The pre-planned efficacy analysis could not be adequately interpreted due to early termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR)

End point title	Overall Response Rate (ORR)[7]

End point description:

ORR was defined as the percentage of participants who achieved a confirmed partial response rate (PR) or better (stringent complete response [sCR] + complete response [CR] + very good partial response [VGPR] + PR) during the study as defined by IMWG uniform response criteria and as determined by the investigator. PR: >=50% reduction of serum M-protein and >=90% reduction in urine M-protein or less than (<) 200 mg/24 hour, or >=50% decrease in uninvolved FLC or >=50% reduction in plasma cells. At baseline, a >=50% decrease in size of soft tissue plasmacytomas was required. Percentages were rounded off to the nearest single decimal place.The Response-Evaluable Analysis Set was a subset of SAS including participants with measurable disease at baseline and at least 1 post-baseline efficacy evaluation. Due to early termination of the study no participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	4	3	
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 60.24)	50 (6.76 to 93.24)	33.3 (0.84 to 90.57)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

DOR:time from1st documentation of confirmed PR/better(sCR+CR+VGPR+PR)to1st documentation of PD/death due to any cause.PR:≥50%reduction(serum M-protein)&≥90%reduction(urine M-protein)/<200mg/24hr/≥50%decrease(uninvolved FLC)/≥50%reduction(plasma cells).At BL,≥50%decrease(size of soft tissue plasmacytomas).PD:≥25%increase from lowest response value in any one/more of:serum M-component increase≥0.5 g/dL/urine M-component increase≥200mg/24-hour;difference between involved&>10mg/dLincrease in uninvolved FLC levels; ≥10%bone marrow plasma cell;definite development(new bone lesions)/soft tissue plasmacytomas/definite increase in size of existing bone lesions/soft tissue plasmacytomas;development of hypercalcemia that can be attributed solely to plasma cell proliferative disorder.Due to early termination,short follow-up&small population,pre-planned efficacy analysis was not adequately interpreted.No participants enrolled in Group2Arm4&Group 3 arms due to termination,thus not presented.

End point type	Secondary

End point timeframe:

Up to 16.7 months

End point values	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[8]	0[9]	0[10]	0[11]
Units: months				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[8] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

[9] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

[10] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[11] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 2 and 3: Disease Control Rate (DCR)

End point title	Groups 2 and 3: Disease Control Rate (DCR)[12]

End point description:

DCR was defined as the percentage of participants who achieved a stable disease (SD) or better during the study based on the investigator's disease assessment as defined by IMWG uniform response criteria. SD was defined as no known evidence of progressive disease or new bone lesions. Percentages were rounded off to the nearest single decimal place. The Response-Evaluable Analysis Set was a subset of SAS including participants with measurable disease at baseline and at least 1 post-baseline efficacy evaluation. Due to early termination of the study no participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms, thus they are not presented here. Also, no participants in Group 1 fulfilled the criteria for the Response-Evaluable Analysis Set and hence are not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	4	3	
Units: percentage of participants				
number (confidence interval 95%)	75.0 (19.41 to 99.37)	50.0 (6.76 to 93.24)	66.7 (9.43 to 99.16)	

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 2 and 3: Time to Next Treatment (TTNT)

End point title	Groups 2 and 3: Time to Next Treatment (TTNT)[13]

End point description:

TTNT was defined as the time from the date of first dose administration to the date of the first dose initiation of the next line of antineoplastic therapy, for any reason. Due to early study termination, the short follow-up of the participants and the small population, the pre-planned efficacy analysis could not

be adequately interpreted. No participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms due to early study termination, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[14]	0[15]	0[16]	
Units: months				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[14] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[15] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[16] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

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

End point title	Groups 2 and 3: Overall Survival (OS)[17]

End point description:

OS was defined as the time from the first dose of administration to the date of death, due to any cause. Participants without documentation of death at the time of analysis were censored at the date last known to be alive. Due to early study termination, the short follow-up of the participants and the small population, the pre-planned efficacy analysis could not be adequately interpreted. No participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms due to early study termination, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[18]	0[19]	0[20]	
Units: months				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[18] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[19] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[20] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 2 and 3: Time to Progression (TTP)

End point title	Groups 2 and 3: Time to Progression (TTP)[21]

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. PD: increase of >=25% from lowest response value in any one or more of the following: 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 must be >10 mg/dL; bone marrow plasma cell >=10%; definite development of new bone lesions or soft tissue plasmacytomas or definite increase in the size of existing bone lesions or soft tissue plasmacytomas; development of hypercalcemia that can be attributed solely to plasma cell proliferative disorder. Due to early study termination, the short follow-up of the participants and the small population, the pre-planned efficacy analysis could not be adequately interpreted. No participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms due to early study termination, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[22]	0[23]	0[24]	
Units: months				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[22] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[23] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[24] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 2 and 3: Percentage of Participants with MRD Negativity CR Status at a Threshold of 10^-5 in Participants Achieving CR Assessed by the Investigator

End point title	Groups 2 and 3: Percentage of Participants with MRD Negativity CR Status at a Threshold of 10^-5 in Participants Achieving CR Assessed by the Investigator[25]

End point description:

Rate of MRD negativity CR status a sensitivity of 10^-5 was defined as the percentage of participants who have achieved MRD negative CR status in participants achieving CR. CR is 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 is required. Due to early study termination, the short follow-up of the participants and the small population, the pre-planned efficacy analysis could not be adequately interpreted. No participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms due to early study termination, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 2 years after CR confirmation

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[26]	0[27]	0[28]	
Units: percentage of participants				
number (not applicable)				

Notes:

[26] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[27] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[28] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 2 and 3: Event-free Survival (EFS)

End point title	Groups 2 and 3: Event-free Survival (EFS)[29]

End point description:

EFS:time from date of 1st dose of study drug administration to date of 1st documentation of event that may include confirmed PD,discontinuation of treatment for AE(related/not related),or death due to any cause,whichever occurs first.PD:determined by IMWG criteria.PD:increase of ≥25% from lowest response value in ≥1 of:serum M-component increase ≥0.5g/dL/urine M-component increase ≥200mg/24-hour;difference between involved & uninvolved FLC levels increase must be >10mg/dL;bone marrow plasma cell ≥10%;definite development of new bone lesions/soft tissue plasmacytomas/definite increase in the size of existing bone lesions/soft tissue plasmacytomas;development of hypercalcemia that can be attributed solely to plasma cell proliferative disorder.Due to early study termination,short follow-up & small population data could not be adequately interpreted.No participants enrolled in Group2Arm4:modakafusp alfa+bortezomib & Group3 arms due to early study termination,thus not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[30]	0[31]	0[32]	
Units: months				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[30] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[31] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[32] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 2 and 3: Time to Response (TTR)

End point title	Groups 2 and 3: Time to Response (TTR)[33]

End point description:

TTR was defined as the time from the date of the first dose administration to the date of the first documentation of objective confirmed response as defined by IMWG criteria. Due to early study termination, the short follow-up of the participants and the small population, the pre-planned efficacy analysis could not be adequately interpreted. No participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms due to early study termination, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[34]	0[35]	0[36]	
Units: months				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[34] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[35] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[36] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Group 1: Percentage of Participants with MRD Negativity Status at a Threshold of 10^-5

End point title	Group 1: Percentage of Participants with MRD Negativity Status at a Threshold of 10^-5[37]

End point description:

Rate of MRD negativity at a sensitivity of 10^-5 was defined as the percentage of participants who achieved MRD negative status in the MRD-evaluable analysis set. Due to early study termination, the short follow-up of the participants and the small population, the pre-planned efficacy analysis could not be adequately interpreted.

End point type	Secondary

End point timeframe:

At 6 months, 1 year, and 2 years after the start of treatment

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg			
Subject group type	Reporting group			
Number of subjects analysed	0[38]			
Units: percentage of participants				
number (not applicable)				

Notes:

[38] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive Anti-drug Antibodies (ADA) and Neutralizing Antibody (NAb)

End point title	Number of Participants With Positive Anti-drug Antibodies (ADA) and Neutralizing Antibody (NAb)

End point description:

Due to early study termination, the short follow-up of the participants and the small population, the pre-planned analysis could not be adequately interpreted. No participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms due to early study termination, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

End point values	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[39]	0[40]	0[41]	0[42]
Units: participants				

Notes:

[39] - Immunogenicity not interpreted adequately due to study termination,short follow-up,small population.
[40] - Immunogenicity not interpreted adequately due to study termination,short follow-up,small population.
[41] - Immunogenicity not interpreted adequately due to study termination,short follow-up,small population.
[42] - Immunogenicity not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 2 and 3: Duration of MRD Negativity Status at a Sensitivity Threshold of 10^-5 in Participants Achieving MRD Negativity

End point title	Groups 2 and 3: Duration of MRD Negativity Status at a Sensitivity Threshold of 10^-5 in Participants Achieving MRD Negativity[43]

End point description:

Duration of MRD negativity (10^-5) was defined as time from date of first documentation of MRD[-] to

first documentation of MRD positivity or confirmed PD or death due to any cause, whichever occurred first.PD: increase of ≥25% from lowest response value in any one or more of the following: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 must be >10 mg/dL; bone marrow plasma cell ≥10%;definite development of new bone lesions or soft tissue plasmacytomas or definite increase in the size of existing bone lesions or soft tissue plasmacytomas;development of hypercalcemia that can be attributed solely to plasma cell proliferative disorder.Due to early study termination,short follow-up & small population,the pre-planned efficacy analysis could not be adequately interpreted.No participants were enrolled in Group2Arm4 & Group 3 arms due to early study termination, thus are not reported

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[44]	0[45]	0[46]	
Units: months				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[44] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[45] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[46] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Group 2 and 3: Percentage of Participants with MRD Negativity Status at a Threshold of 10^-5

End point title	Group 2 and 3: Percentage of Participants with MRD Negativity Status at a Threshold of 10^-5[47]

End point description:

Rate of MRD negativity at a sensitivity of 10^-5 was defined as the percentage of participants who have achieved MRD negative status. Due to early study termination, the short follow-up of the participants and the small population, the pre-planned efficacy analysis could not be adequately interpreted. No participants were enrolled in Group 2 Arm 4: modakafusp alfa + bortezomib and Group 3 arms due to early study termination, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 16.7 months

Notes:

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive analyses was planned for this endpoint.

End point values	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[48]	0[49]	0[50]	
Units: percentage of participants				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[48] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[49] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[50] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of MRD Negativity Status at a Threshold of 10^-5 in Participants Achieving MRD Negativity

End point title	Duration of MRD Negativity Status at a Threshold of 10^-5 in Participants Achieving MRD Negativity

End point description:

Duration of MRD negativity (10^-5):time from the date of 1st documentation of MRD[-] to 1st documentation of MRD positivity or confirmed PD or death due to any cause,whichever occurred first.PD:increase of ≥25% from lowest response value in any one or more of the following:serum M-component increase ≥0.5g/dL or urine M-component increase ≥200mg/24-hour;difference between involved & uninvolved FLC levels increase must be >10mg/dL;bone marrow plasma cell ≥10%;definite development of new bone lesions or soft tissue plasmacytomas or definite increase in size of existing bone lesions or soft tissue plasmacytomas;development of hypercalcemia that can be attributed solely to plasma cell proliferative disorder.Due to early study termination,short follow-up & small population,the pre-planned efficacy analysis could not be adequately interpreted.No participants enrolled in Group2Arm4:modakafusp alfa+bortezomib and Group 3 arms due to early study termination, thus they are not presented here.

End point type	Secondary

End point timeframe:

Up to 2 years after treatment

End point values	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg	Group 2 (RRMM Doublets): Modakafusp alfa +Pomalidomide 4 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[51]	0[52]	0[53]	0[54]
Units: months				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[51] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[52] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[53] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.
[54] - Efficacy was not interpreted adequately due to study termination,short follow-up,small population.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 16.7 months

Adverse event reporting additional description:

The SAS included all participants who had received at least 1 dose, even if incomplete, of any study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg

Reporting group description:

Participants received 80 milligrams (mg) modakafusp alfa, infusion intravenously (IV), once on Day 1, once every 4 weeks (Q4W), in combination with 10 mg lenalidomide capsules orally once daily continuously on Days 1 to 28, in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or to a maximum of 2 years for measurable/minimal residual disease-negative (MRD [-]) participants, whichever occurred first.

Reporting group title	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2

Reporting group description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 20/70 milligrams per meter square (mg/m^2) carfilzomib IV, on Day 1, 8 and 15 of a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Reporting group title	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 4 mg

Reporting group description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 4 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Reporting group title	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg

Reporting group description:

Participants received 80 mg modakafusp alfa, infusion IV, once on Day 1, Q4W in combination with 2 mg pomalidomide capsules orally once daily on Days 1 to 21 in a 28-day (4-week) treatment cycle until disease progression, unacceptable toxicity, or until any other discontinuation criterion was met, whichever occurred first.

Serious adverse events	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	3 / 3 (100.00%)	1 / 4 (25.00%)
number of deaths (all causes)	0	1	2
number of deaths resulting from adverse events	0	0	0

Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (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%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic microangiopathy			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 4 (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
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (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
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (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
Renal haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia influenzal			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombotic microangiopathy			

subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia influenzal			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Group 1 (NDMM): Modakafusp alfa + Lenalidomide 10 mg	Group 2(RRMM Doublets):Modakafusp alfa+Carfilzomib 20/70mg/m^2	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 4 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	4 / 4 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haematoma			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	2
Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Suprapubic pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Upper-airway cough syndrome			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypoxia			

subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	0	9	4
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			

Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bundle branch block left			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	3 / 3 (100.00%)	3 / 4 (75.00%)
occurrences (all)	3	11	3
Leukopenia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	13	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 3 (66.67%)	3 / 3 (100.00%)	3 / 4 (75.00%)
occurrences (all)	9	14	16
Neutropenia			
subjects affected / exposed	3 / 3 (100.00%)	0 / 3 (0.00%)	3 / 4 (75.00%)
occurrences (all)	15	0	17
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	9
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Anal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Mouth haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Noninfective sialoadenitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Hepatobiliary disorders			
Portal hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Sacral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Salmonella bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Group 2 (RRMM Doublets): Modakafusp alfa + Pomalidomide 2 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)		
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Haematoma			

subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)		
occurrences (all)	2		
Inflammation			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Suprapubic pain			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hypoxia			

subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Delirium			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			

Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Cardiac disorders Bradycardia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Bundle branch block left subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Palpitations subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Right ventricular dysfunction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Tachycardia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Dizziness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Somnolence subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0		
Paraesthesia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Neuropathy peripheral			

subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 4 (50.00%)		
occurrences (all)	3		
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	3 / 4 (75.00%)		
occurrences (all)	7		
Neutropenia			
subjects affected / exposed	3 / 4 (75.00%)		
occurrences (all)	11		
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Anal incontinence			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Mouth haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Noninfective sialoadenitis			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Portal hypertension			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Sacral pain			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Limb discomfort			

subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Clostridium difficile colitis			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Gastroenteritis salmonella			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Rhinitis			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Salmonella bacteraemia			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			

subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hyperphosphataemia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Hypophosphataemia			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 May 2022	The following changes were made as per Amendment 01: Added an exclusion criterion for patients who had previously received modakafusp alfa. 2. Revised several procedures in the schedules of events.
17 August 2022	The following changes were made as per Amendment 02: 1. Removed modakafusp alfa and daratumumab arm (Arm 5 in Group 2 RRMM Doublets). 2. Removed secondary objectives relating to daratumumab pharmacokinetics (PK). 3. Reduced the modakafusp alfa starting dose. 4. Revised the prior therapy inclusion criterion. 5.Updated pregnancy testing timepoints and modalities, and contraception language (period of contraception and method). 6. Updated imaging assessment schedules. 7. Removed baseline human immunodeficiency (HIV) and hepatitis C virus testing.
13 June 2023	The following changes were made as per Amendment 03: 1. Revised the study design. 2. Updated clinical data from ongoing modakafusp alfa studies. 3. Added event-free survival (EFS) as a secondary endpoint. 4. Closed the combination arm with carfilzomib and added contraindications to concurrent carfilzomib and modakafusp alfa treatment. 5. Revised the pomalidomide and bortezomib dosing schedules.
03 April 2024	The following change was made as per Amendment 04: 1. Added new modakafusp alfa dose modification guidelines.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to early termination of study for strategic reasons no participants enrolled in Group 2Arm4:modakafusp alfa+bortezomib &Group 3 arms.Endpoint data related toPFS,OS,DOR,TTP,TTNT,EFS,TTR,&MRD not collected as planned&thus not reported.

Notes: