ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: January 9, 2024

ClinicalTrials.gov ID: NCT06160609

Study Identification

Unique Protocol ID:	208887 Sub Study 1
Brief Title:	Platform Sub-study of Belantamab Mafodotin (GSK2857916) in Combination With aOX40 (GSK3174998) in Participants With RRMM
Official Title:	A Phase I/II, Randomized, Open-label Platform Study Utilizing a Master Protocol to Study Belantamab Mafodotin (GSK2857916) as Monotherapy and in Combination With Anti-Cancer Treatments in Participants With Relapsed/Refractory Multiple Myeloma (RRMM)-DREAMM5. Sub-study 1 - Belantamab Mafodotin and aOX40 (GSK3174998) in Combination
Secondary IDs:	2019-001138-32 [EudraCT Number]

Study Status

Record Verification:	January 2024
Overall Status:	Terminated [The study was terminated due to lack of efficacy.]
Study Start:	October 7, 2019 [Actual]
Primary Completion:	January 9, 2023 [Actual]
Study Completion:	January 9, 2023 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	Yes
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDER IND/IDE Number: 136133 Serial Number: Has Expanded Access: Yes [NCT03763370]
Human Subjects Review:	Board Status: Approved Approval Number: 08/20/2019 Board Name: St Vincent's Hospital Board Affiliation: Independent Review Board Phone: 9231 2211 Email: Address: 41 Victoria Parade Fitzroy VIC 3065 PO Box 2900 Fitzroy VIC 3065
Data Monitoring:	No
FDA Regulated Intervention:	Yes

Study Description

Brief Summary:	The primary purpose is to determine the safety and tolerability of belantamab mafodotin in combination with other anti-cancer treatments (in each sub-study), and to establish the recommended Phase 2 dose for each combination treatment to explore in the cohort expansion phase. This study is the sub study of the Master protocol (NCT04126200).
Detailed Description:	

Conditions

Conditions:	Relapsed/Refractory Multiple Myeloma
Keywords:	

Study Design

Study Type:	Interventional

Primary Purpose:	Treatment
Study Phase:	Phase 1/Phase 2
Interventional Study Model:	Single Group Assignment
Number of Arms:	1
Masking:	None (Open Label)
Allocation:	N/A
Enrollment:	9 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Belantamab mafodotin + GSK3174998	Drug: Belantamab Mafodotin Belantamab Mafodotin will be administered. Other Names: • GSK2857916 Drug: GSK3174998 GSK3174998 will be administered. Other Names: • aOX40

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

• Participant must be 18 years of age inclusive or older, at the time of signing the informed consent.

- Participants must have histologically or cytologically confirmed diagnosis of Multiple Myeloma (MM), as defined by the IMWG.
- Participants having at least 3 prior lines of prior anti-myeloma treatments including an immunomodulating agent (IMID) a proteasome inhibitor (PI) and an anti-CD38 monoclonal antibody.
- Participants with a history of autologous stem cell transplant are eligible for study participation when, transplant was >100 days prior to study enrolment and with no active infection(s).
- Participants with Eastern Cooperative Oncology Group (ECOG) performance status of 0-1, unless ECOG less than equal to (<=)2 is due solely to skeletal complications and/or skeletal pain due to MM.
- Participants with measurable disease defined as at least one of the following: Serum M-protein greater than equal to (>=)0.5 gram per deciliter (>=5 gram per liter) or Urine M-protein >=200 milligrams (mg) per 24 hours or Serum free light chain (FLC) assay: Involved FLC level >=10 mg per deciliter (>=100 mg per Liter) and an abnormal serum FLC ratio (<0.26 or >1.65).
- Participants who have tested positive for Hepatitis B core antibody (HBcAb) can be enrolled if the following criteria are met: Serology result HBcAb+, Hepatitis B surface antigen (HBsAg)-; HBV deoxyribonucleic acid (DNA) undetectable during screening.
- Participants who are currently receiving physiological doses oral steroids (<10 mg/day), inhaled steroids or ophthalmological steroids.

Exclusion Criteria:

- Participants with current corneal epithelial disease except mild punctate keratopathy.
- Participants with evidence of cardiovascular risk.
- Participants with known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to belantamab mafodotin or any of the components of the study treatment. History of severe hypersensitivity to other mAb.
- Participants with active infection requiring antibiotic, antiviral, or antifungal treatment.
- Participants with other monoclonal antibodies within 30 days or systemic anti-myeloma therapy within <14 days.
- Participants with prior radiotherapy within 2 weeks of start of study therapy.
- Participants with prior allogeneic transplant are prohibited.
- Participants who have received prior Chimeric Antigen T cell therapy (CAR-T) therapy with lymphodepletion with chemotherapy within 3 months of screening.
- Participants with any major surgery (other than bone-stabilizing surgery) within the last 30 days.
- Participants with prior treatment with an investigational agent within 14 days or 5 half-lives of receiving the first dose of study drugs, whichever is shorter.
- Participants with >=grade 3 toxicity considered related to prior check-point inhibitors and that led to treatment discontinuation.
- Participants who have received transfusion of blood products within 2 weeks before the first dose of study drug.
- Participants must not receive live attenuated vaccines within 30 days prior to first dose of study treatment or whilst receiving belantamab mafodotin +- partner agent in any sub-study arm of the platform trial and for at least 70 days following last study treatment.
- Participants with presence of active renal condition (infection, requirement for dialysis or any other condition that could affect participant's safety). Participants with isolated proteinuria resulting from MM.
- Participants with known human immunodeficiency virus (HIV) infection, unless the participant can meet all criteria: a) established anti-retroviral therapy for at least 4 weeks and HIV viral load<400 copies/milliliter (mL) b) cluster of differentiation 4 plus (CD4+) T-cell (CD4+) counts >= 350 cells/microliter (µL) c) No history of Acquired immunodeficiency syndrome (AIDS)-defining opportunistic infections within the last 12 months in which case the participant would be eligible for CE Phase only.

- Participants with autoimmune disease (current or history) or syndrome that required systemic treatment within the past 2 years.
- Exclusion for a recent (within the past 6 months) history of symptomatic pericarditis.

Contacts/Locations

Central Contact Person: US GSK Clinical Trials, Call Center
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IPDSharing

Plan to Share IPD: Yes
IPD for this study will be made available via the Clinical Study Data Request site.

Supporting Information:
Study Protocol
Statistical Analysis Plan (SAP)

Informed Consent Form (ICF)
Clinical Study Report (CSR)

Time Frame:
IPD will be made available within 6 months of publishing the results of the primary endpoints, key secondary endpoints and safety data of the study.

Access Criteria:
Access is provided after a research proposal is submitted and has received approval from the Independent Review Panel and after a Data Sharing Agreement is in place. Access is provided for an initial period of 12 months but an extension can be granted, when justified, for up to another 12 months.

URL: http://clinicalstudydatarequest.com

References

Citations:

Links:

Available IPD/Information:

Documents

Study Protocol
Document Date: February 14, 2020
Uploaded: 01/05/2024 04:42

Statistical Analysis Plan
Document Date: August 24, 2022
Uploaded: 01/05/2024 04:44

Study Results

Participant Flow

Recruitment Details	This is a sub-study of the master study NCT04126200. This sub study was terminated due to lack of efficacy. The study was planned to include two phases - Dose Escalation (DE) and Cohort Expansion (CE) and no participants were enrolled in CE phase as study was early terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with Relapsed/Refractory Multiple Myeloma (RRMM) received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Overall Study

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Started	6	3
Completed [1]	6 [2]	3 [3]
Not Completed	0	0

[1] Participants who completed follow-up or who died were considered to have completed the study.
[2] 1 participant completed the follow-up and 5 participants died
[3] 1 participant completed the follow-up and 2 participants died

Baseline Characteristics

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Baseline Measures

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Total
Overall Number of Participants	6	3	9

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Total
Age, Continuous Mean (Standard Deviation) Unit of measure: Years	Number Analyzed	6 participants	3 participants	9 participants
		69.0 (11.15)	73.3 (2.31)	70.4 (9.15)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	6 participants	3 participants	9 participants
	Female	1 16.67%	0 0%	1 11.11%
	Male	5 83.33%	3 100%	8 88.89%
Race/Ethnicity, Customized Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	6 participants	3 participants	9 participants
Not Hispanic or Latino		6 100%	3 100%	9 100%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	DE Phase: Number of Participants With Dose Limiting Toxicities (DLT)
Measure Description	Criteria for dose-limiting toxicity (DLT) included hematologic indicators such as Grade 3-5 febrile neutropenia and thrombocytopenia with bleeding. Non-hematologic criteria, excluding corneal toxicity, comprise Grade 3-5 toxicities, with exceptions for manageable nausea, vomiting, or diarrhea, controlled Grade 3 hypertension, and events linked to disease progression. Tumor lysis syndrome (TLS) of Grade 3 or 4, successfully managed within 7 days without end-organ damage, is considered. Corneal toxicity, assessed by the GSK corneal grading scale at Grade 4, is a DLT. Other organ-specific toxicities, notably liver toxicity meeting GSK stopping criteria, also qualify as DLTs.
Time Frame	Up to 21 days

Analysis Population Description

DLT Evaluable Population included participants in DE phase who received the first course of treatment containing both agents within a sub-study and followed up within cycle 1 (Each cycle is of 21 days) or withdrew within cycle 1 due to an AE meeting the definition of a DLT.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3
DE Phase: Number of Participants With Dose Limiting Toxicities (DLT) Measure Type: Count of Participants Unit of measure: participants	0 0%	0 0%

2. Primary Outcome Measure:

Measure Title	DE Phase: Number of Participants With Adverse Events (AEs)
Measure Description	An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.

	Description
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3
DE Phase: Number of Participants With Adverse Events (AEs) Measure Type: Count of Participants Unit of measure: participants	6 100%	3 100%

3. Primary Outcome Measure:

Measure Title	DE Phase: Number of Participants With Worst-Case Hematology Results by Maximum Grade Increase Post - Baseline Relative to Baseline
Measure Description	Blood samples were collected for the analysis of following hematology parameters: eosinophils, anemia, hemoglobin increased, lymphocyte count decreased, lymphocyte count increased, neutrophil count decreased, platelet count decreased, leukocytosis and white blood cell decreased. The laboratory parameters were graded according to Common Terminology Criteria for Adverse Events (CTCAE) version 5. Grade 1 (G1): mild; Grade 2 (G2): moderate; Grade 3 (G3: severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade. Any worst-case post baseline increase to G1, G2 and G3 are presented.
Time Frame	Baseline (Day 1) and up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.

	Description
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3
DE Phase: Number of Participants With Worst-Case Hematology Results by Maximum Grade Increase Post - Baseline Relative to Baseline Measure Type: Count of Participants Unit of measure: participants		
Eosinophils, Increase to G1	0 0%	0 0%
Eosinophils, Increase to G2	0 0%	0 0%
Eosinophils, Increase to G3	0 0%	0 0%
Anemia, Increase to G1	0 0%	2 66.67%
Anemia, Increase to G2	2 33.33%	0 0%
Anemia, Increase to G3	1 16.67%	0 0%
Hemoglobin Increased, Increase to G1	0 0%	0 0%
Hemoglobin Increased, Increase to G2	1 16.67%	0 0%
Hemoglobin Increased, Increase to G3	0 0%	0 0%
Lymphocyte Count Decreased, Increase to G1	1 16.67%	2 66.67%
Lymphocyte Count Decreased, Increase to G2	1 16.67%	0 0%
Lymphocyte Count Decreased, Increase to G3	1 16.67%	0 0%
Lymphocyte Count Increased, Increase to G1	0 0%	0 0%
Lymphocyte Count Increased, Increase to G2	0 0%	0 0%
Lymphocyte Count Increased, Increase to G3	0 0%	0 0%
Neutrophil Count Decreased, Increase to G1	0 0%	0 0%
Neutrophil Count Decreased, Increase to G2	2 33.33%	0 0%
Neutrophil Count Decreased, Increase to G3	0 0%	0 0%

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Platelet Count Decreased, Increase to G1	2 33.33%	2 66.67%
Platelet Count Decreased, Increase to G2	2 33.33%	0 0%
Platelet Count Decreased, Increase to G3	2 33.33%	0 0%
Leukocytosis, Increase to G1	0 0%	0 0%
Leukocytosis, Increase to G2	0 0%	0 0%
Leukocytosis, Increase to G3	0 0%	0 0%
White Blood Cell Decreased, Increase to G1	1 16.67%	0 0%
White Blood Cell Decreased, Increase to G2	3 50%	0 0%
White Blood Cell Decreased, Increase to G3	0 0%	0 0%

4. Primary Outcome Measure:

Measure Title	DE Phase: Number of Participants With Worst-Case Chemistry Results by Maximum Grade Increase Post - Baseline Relative to Baseline
Measure Description	Blood samples were collected for the analysis of following chemistry parameters: Hypoglycemia, hypoalbuminemia, alkaline phosphatase (ALP) increased, alanine aminotransferase (ALT) increased, aspartate aminotransferase (AST) increased, blood bilirubin increased, creatine kinase (CPK) increased, creatinine increased, gamma glutamyl transferase (GGT) increased, hyperkalemia, blood lactate dehydrogenase (LDH) increased, hypermagnesemia, hypomagnesemia, hypernatremia, hypercalcemia, hypocalcemia and Serum OR Plasma Glomerular Filtration Rate (GFR) from creatinine adjusted for body surface area (BSA) SA (mL/sec/1.73m^2)/chronic kidney disease. The laboratory parameters were graded according to CTCAE version 5. G1: mild; G2: moderate; G3: severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade. Any worst-case post baseline increase to G1, G2 and G3 are presented.
Time Frame	Baseline (Day 1) and up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3
DE Phase: Number of Participants With Worst-Case Chemistry Results by Maximum Grade Increase Post - Baseline Relative to Baseline Measure Type: Count of Participants Unit of measure: participants		
Hypoglycemia, Increase to G1	0 0%	0 0%
Hypoglycemia, Increase to G2	0 0%	0 0%
Hypoglycemia, Increase to G3	0 0%	1 33.33%
Hypoalbuminemia, Increase to G1	1 16.67%	0 0%
Hypoalbuminemia, Increase to G2	2 33.33%	0 0%
Hypoalbuminemia, Increase to G3	1 16.67%	0 0%
ALP Increased, Increase to G1	4 66.67%	0 0%
ALP Increased, Increase to G2	0 0%	1 33.33%
ALP Increased, Increase to G3	0 0%	0 0%
ALT Increased, Increase to G1	1 16.67%	1 33.33%
ALT Increased, Increase to G2	0 0%	0 0%
ALT Increased, Increase to G3	0 0%	0 0%
AST Increase, Increase to G1	4 66.67%	1 33.33%
AST Increase, Increase to G2	0 0%	1 33.33%

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
AST Increase, Increase to G3	0 0%	0 0%
Blood bilirubin Increased, Increase to G1	0 0%	0 0%
Blood bilirubin Increased, Increase to G2	0 0%	0 0%
Blood bilirubin Increased, Increase to G3	0 0%	0 0%
CPK Increased, Increase to G1	2 33.33%	1 33.33%
CPK Increased, Increase to G2	0 0%	1 33.33%
CPK Increased, Increase to G3	0 0%	0 0%
Creatinine Increased, Increase to G1	3 50%	0 0%
Creatinine Increased, Increase to G2	1 16.67%	1 33.33%
Creatinine Increased, Increase to G3	0 0%	0 0%
GGT Increased, Increase to G1	3 50%	1 33.33%
GGT Increased, Increase to G2	1 16.67%	1 33.33%
GGT Increased, Increase to G3	0 0%	0 0%
Hyperkalemia, Increase to G1	1 16.67%	1 33.33%
Hyperkalemia, Increase to G2	0 0%	0 0%
Hyperkalemia, Increase to G3	0 0%	0 0%
LDH increased, Increase to G1	2 33.33%	2 66.67%
LDH increased, Increase to G2	0 0%	0 0%
LDH increased, Increase to G3	0 0%	0 0%
Hypermagnesemia, Increase to G1	0 0%	1 33.33%
Hypermagnesemia, Increase to G2	0 0%	0 0%
Hypermagnesemia, Increase to G3	1 16.67%	0 0%
Hypomagnesemia, Increase to G1	1 16.67%	1 33.33%
Hypomagnesemia, Increase to G2	0 0%	0 0%
Hypomagnesemia, Increase to G3	1 16.67%	0 0%
Hypernatremia, Increase to G1	0 0%	0 0%
Hypernatremia, Increase to G2	0 0%	0 0%

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Hypernatremia, Increase to G3	0 0%	0 0%
Hypercalcemia, Increase to G1	1 16.67%	1 33.33%
Hypercalcemia, Increase to G2	1 16.67%	0 0%
Hypercalcemia, Increase to G3	0 0%	0 0%
Hypocalcemia, Increase to G1	0 0%	0 0%
Hypocalcemia, Increase to G2	0 0%	0 0%
Hypocalcemia, Increase to G3	0 0%	0 0%
GFR from creatinine/Chronic Kidney Disease, Increase to G1	0 0%	0 0%
GFR from creatinine/Chronic Kidney Disease, Increase to G2	1 16.67%	0 0%
GFR from creatinine/Chronic Kidney Disease, Increase to G3	1 16.67%	0 0%

5. Primary Outcome Measure:

Measure Title	Cohort Expansion (CE) Phase: Overall Response Rate (ORR)
Measure Description	Overall Response Rate (ORR) was defined as the percentage of participants with a confirmed PR or better as the best overall response (i.e., Partial Response [PR], Very Good Partial Response [VGPR], Complete Response [CR], and stringent Complete Response [sCR]), as assessed by the investigator per international myeloma working group (IMWG) (2016). CR defined as negative immunofixation of serum and urine AND disappearance of any soft tissue plasmacytomas AND <5% plasmacytomas in the bone marrow; sCR defined as CR as above PLUS normal serum free light-chain (FLC) assay ratio and absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence; VGPR defined as serum and urine M-component detectable by immunofixation but not on electrophoresis OR ≥ 90% reduction in serum M-component plus urine M-component <100 mg/24 h; PR defined as ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 h.
Time Frame	Up to 170 weeks

Analysis Population Description

Intent to Treat (ITT) population included all the enrolled participants. No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

6. Secondary Outcome Measure:

Measure Title	DE Phase: Overall Response Rate (ORR)
Measure Description	ORR was defined as the percentage of participants with a confirmed partial response (PR) or better (i.e., PR, very good partial response [VGPR], complete response [CR] and stringent complete response [sCR]), according to the International Myeloma Working Group (IMWG) Response Criteria. CR = negative immunofixation of serum and urine AND disappearance of any soft tissue plasmacytomas AND <5% plasmacytomas in the bone marrow; sCR=stringent complete response, CR as above PLUS normal serum free light-chain (FLC) assay ratio and absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence; VGPR = serum and urine M-component detectable by immunofixation but not on electrophoresis OR ≥ 90% reduction in serum M-component plus urine M-component <100 mg/24 h; PR = ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 h.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.

	Description
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3
DE Phase: Overall Response Rate (ORR) Measure Type: Number Unit of measure: Percentage of participants	0	0

7. Secondary Outcome Measure:

Measure Title	CE Phase: Clinical Benefit Rate (CBR)
Measure Description	Clinical benefit rate was defined as the percentage of participants with a confirmed minimal response (MR) or better according to the IMWG Response Criteria. MR is >= 25% but < 49% reduction of serum M-protein and reduction in 24-hour urinary M-protein by 50-89%.
Time Frame	Up to 170 weeks

Analysis Population Description

Intent to Treat (ITT) population included all the enrolled participants. No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

8. Secondary Outcome Measure:

Measure Title	DE Phase: Percentage of Participants Achieving Stringent Complete Response (SCR), Complete Response (CR), Very Good Partial Response (VGPR) and Partial Response (PR)
Measure Description	Partial Response [PR], Very Good Partial Response [VGPR], Complete Response [CR], and stringent Complete Response [sCR] as assessed by the investigator per IMWG (2016). CR = negative immunofixation of serum and urine AND disappearance of any soft tissue plasmacytomas AND <5% plasmacytomas in the bone marrow; sCR=stringent complete response, CR as above PLUS normal serum free light-chain (FLC) assay ratio and absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence; VGPR = serum and urine M-component detectable by immunofixation but not on electrophoresis OR ≥ 90% reduction in serum M-component plus urine M-component <100 mg/24 h; PR = ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 h.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
DE Phase: Percentage of Participants Achieving Stringent Complete Response (SCR), Complete Response (CR), Very Good Partial Response (VGPR) and Partial Response (PR) Measure Type: Number Unit of measure: Percentage of participants		
Stringent Complete Response (sCR)	0	0
Complete response (CR)	0	0
Very Good Partial Response (VGPR)	0	0
Partial response (PR)	0	0

9. Secondary Outcome Measure:

Measure Title	CE Phase: Percentage of Participants Achieving SCR, CR, VGPR and PR
Measure Description	Partial Response [PR], Very Good Partial Response [VGPR], Complete Response [CR], and stringent Complete Response [sCR] as assessed by the investigator per IMWG (2016). CR = negative immunofixation of serum and urine AND disappearance of any soft tissue plasmacytomas AND <5% plasmacytomas in the bone marrow; sCR=stringent complete response, CR as above PLUS normal serum free light-chain (FLC) assay ratio and absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence; VGPR = serum and urine M-component detectable by immunofixation but not on electrophoresis OR ≥ 90% reduction in serum M-component plus urine M-component <100 mg/24 h; PR = ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 h.
Time Frame	Up to 170 weeks

Analysis Population Description

Intent to Treat (ITT) population included all the enrolled participants. No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.

	Description
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

10. Secondary Outcome Measure:

Measure Title	DE Phase: Plasma Concentrations of Belantamab Mafodotin Antibody-Drug Conjugate (ADC)
Measure Description	Blood samples were collected for PK analysis of belantamab mafodotin Antibody-Drug Conjugate (ADC).
Time Frame	Up to Day 1 (End of Infusion) of Cycle 6 (Each Cycle consist of 21 days)

Analysis Population Description

Pharmacokinetic population included all participants in the safety population from whom at least one PK sample has been obtained and analysed.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
DE Phase: Plasma Concentrations of Belantamab Mafodotin Antibody-Drug Conjugate (ADC) Median (Full Range) Unit of measure: nanogram/ millilitre (ng/mL)	[Not specified]		
Cycle 1 Day 1, Pre-Dose	Number Analyzed	4 participants	3 participants
		0.0 (0 to 0)	0.0 (0 to 0)
Cycle 1 Day 1, End Of Infusion	Number Analyzed	6 participants	3 participants
		30100.0 (25900 to 36400)	43400.0 (31400 to 50000)
Cycle 1 Day 1, 2 hours	Number Analyzed	6 participants	3 participants
		29450.0 (25100 to 32100)	39700.0 (29800 to 45800)
Cycle 1 Day 1, 24 hours	Number Analyzed	6 participants	3 participants
		18300.0 (13700 to 27800)	30900.0 (20000 to 31000)
Cycle 1 Day 4	Number Analyzed	6 participants	3 participants
		9925.0 (6240 to 15500)	10700.0 (9420 to 15500)
Cycle 1 Day 8	Number Analyzed	5 participants	3 participants
		3880.0 (3530 to 4880)	7180.0 (5170 to 8220)
Cycle 1 Day 22	Number Analyzed	1 participants	1 participants
		1060.0 (--- to ---)	3130.0 (--- to ---)
Cycle 2 Day 1, Pre-Dose	Number Analyzed	4 participants	3 participants
		1415.0 (878 to 1700)	1390.0 (679 to 2720)
Cycle 2 Day 1, End Of Infusion	Number Analyzed	5 participants	3 participants
		27700.0 (24100 to 33000)	42900.0 (32500 to 54000)
Cycle 4 Day 1, Pre-Dose	Number Analyzed	2 participants	1 participants
		2635.0 (2190 to 3080)	2190.0 (--- to ---)
Cycle 4 Day 1, End Of Infusion	Number Analyzed	2 participants	1 participants

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
		28200.0 (27200 to 29200)	29900.0 (--- to ---)
Cycle 6 Day 1, Pre-Dose	Number Analyzed	1 participants	1 participants
		3600.0 (--- to ---)	2800.0 (--- to ---)
Cycle 6 Day 1, End Of Infusion	Number Analyzed	1 participants	1 participants
		32100.0 (--- to ---)	27500.0 (--- to ---)

11. Secondary Outcome Measure:

Measure Title	CE Phase: Plasma Concentrations of Belantamab Mafodotin Antibody-Drug Conjugate (ADC)
Measure Description	Blood samples were collected for PK analysis of Belantamab Mafodotin Antibody-Drug Conjugate (ADC).
Time Frame	Up to Day 1 (End of Infusion) of Cycle 6 (Each Cycle consist of 21 days)

Analysis Population Description

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

12. Secondary Outcome Measure:

Measure Title	DE Phase: Plasma Concentration of Belantamab Mafodotin Total Antibody
Measure Description	Blood samples were collected for PK analysis of Belantamab mafodotin total antibody.
Time Frame	Up to Day 1 (End of Infusion) of Cycle 6 (Each Cycle consist of 21 days)

Analysis Population Description

Pharmacokinetic population included all participants in the safety population from whom at least one PK sample has been obtained and analysed.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed		6	3
DE Phase: Plasma Concentration of Belantamab Mafodotin Total Antibody Median (Full Range) Unit of measure: ng/mL	[Not specified]		
Cycle 1 Day 1, Pre-Dose	Number Analyzed	3 participants	2 participants
		0.0 (0 to 0)	0.0 (0 to 0)
Cycle 1 Day 1, End Of Infusion	Number Analyzed	6 participants	3 participants
		32650.0 (29600 to 36400)	49500.0 (38200 to 56800)
Cycle 1 Day 1, 2 hours	Number Analyzed	6 participants	3 participants
		34500.0 (30000 to 37000)	46000.0 (37800 to 53000)
Cycle 1 Day 1, 24 hours	Number Analyzed	6 participants	3 participants

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
		23650.0 (18500 to 32900)	36700.0 (26600 to 41000)
Cycle 1 Day 4	Number Analyzed	6 participants	3 participants
		15900.0 (9950 to 22000)	21500.0 (16300 to 25100)
Cycle 1 Day 8	Number Analyzed	5 participants	3 participants
		9770.0 (7460 to 10400)	18300.0 (10600 to 21500)
Cycle 1 Day 22	Number Analyzed	1 participants	0 participants
		2620.0 (--- to ---)	---
Cycle 2 Day 1, Pre-Dose	Number Analyzed	4 participants	3 participants
		4105.0 (2600 to 5170)	3740.0 (3070 to 8680)
Cycle 2 Day 1, End Of Infusion	Number Analyzed	5 participants	3 participants
		34000.0 (29300 to 41800)	52000.0 (40800 to 56200)
Cycle 4 Day 1, Pre-Dose	Number Analyzed	3 participants	1 participants
		6910.0 (4560 to 11800)	5430.0 (--- to ---)
Cycle 4 Day 1, End Of Infusion	Number Analyzed	3 participants	1 participants
		40500.0 (39100 to 40900)	33200.0 (--- to ---)
Cycle 6 Day 1, Pre-Dose	Number Analyzed	1 participants	1 participants
		13100.0 (--- to ---)	8720.0 (--- to ---)
Cycle 6 Day 1, End Of Infusion	Number Analyzed	1 participants	1 participants
		47500.0 (--- to ---)	40400.0 (--- to ---)

13. Secondary Outcome Measure:

Measure Title	CE Phase: Plasma Concentration of Belantamab Mafodotin Plasma Total Antibody
Measure Description	Blood samples were collected for PK analysis of Belantamab mafodotin plasma total antibody.
Time Frame	Up to Day 1 (End of Infusion) of Cycle 6 (Each Cycle consist of 21 days)

Analysis Population Description

Pharmacokinetic population included all participants in the safety population from whom at least one PK sample has been obtained and analysed. No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

14. Secondary Outcome Measure:

Measure Title	DE Phase: Plasma Concentrations of Belantamab Mafodotin Cys- Monomethyl Auristatin-F (Cys-mcMMAF)
Measure Description	Blood samples were collected for PK analysis of belantamab mafodotin cys- monomethyl auristatin-F (cys-mcMMAF).
Time Frame	Up to Day 1 (End of Infusion) of Cycle 6 (Each Cycle consist of 21 days)

Analysis Population Description

Pharmacokinetic population included all participants in the safety population from whom at least one PK sample has been obtained and analysed.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed		6	3
DE Phase: Plasma Concentrations of Belantamab Mafodotin Cys- Monomethyl Auristatin-F (Cys-mcMMAF) Median (Full Range) Unit of measure: ng/mL	[Not specified]		
Cycle 1 Day 1, Pre-Dose	Number Analyzed	6 participants	3 participants
		0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)
Cycle 1 Day 1, End Of Infusion	Number Analyzed	6 participants	3 participants
		404.00 (352.0 to 741.0)	623.00 (343.0 to 735.0)
Cycle 1 Day 1, 2 hours	Number Analyzed	6 participants	3 participants
		489.00 (338.0 to 811.0)	527.00 (515.0 to 832.0)
Cycle 1 Day 1, 24 hours	Number Analyzed	6 participants	3 participants
		766.50 (449.0 to 1760.0)	1020.00 (722.0 to 1050.0)
Cycle 1 Day 4	Number Analyzed	6 participants	3 participants
		360.50 (288.0 to 752.0)	492.00 (309.0 to 615.0)
Cycle 1 Day 8	Number Analyzed	5 participants	3 participants
		120.00 (107.0 to 235.0)	234.00 (172.0 to 292.0)
Cycle 1 Day 22	Number Analyzed	1 participants	1 participants
		0.00 (--- to ---)	0.00 (--- to ---)
Cycle 2 Day 1, Pre-Dose	Number Analyzed	5 participants	3 participants
		0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)
Cycle 2 Day 1, End Of Infusion	Number Analyzed	5 participants	3 participants
		384.00 (262.0 to 676.0)	625.00 (353.0 to 796.0)
Cycle 4 Day 1, Pre-Dose	Number Analyzed	3 participants	1 participants

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
		0.00 (0.0 to 0.0)	0.00 (--- to ---)
Cycle 4 Day 1, End Of Infusion	Number Analyzed	3 participants	1 participants
		548.00 (268.0 to 679.0)	268.00 (--- to ---)
Cycle 6 Day 1, Pre-Dose	Number Analyzed	1 participants	1 participants
		0.00 (--- to ---)	0.00 (--- to ---)
Cycle 6 Day 1, End Of Infusion	Number Analyzed	1 participants	1 participants
		291.00 (--- to ---)	179.00 (--- to ---)

15. Secondary Outcome Measure:

Measure Title	CE Phase: Plasma Concentrations of Belantamab Mafodotin Cys- Monomethyl Auristatin-F (Cys-mcMMAF)
Measure Description	Blood samples were collected for PK analysis of Belantamab Mafodotin Cys- Monomethyl Auristatin-F (Cys-mcMMAF)
Time Frame	Up to Day 1 (End of Infusion) of Cycle 6 (Each Cycle consist of 21 days)

Analysis Population Description

Pharmacokinetic population included all participants in the safety population from whom at least one PK sample has been obtained and analysed.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

16. Secondary Outcome Measure:

Measure Title	DE Phase: OX40 Concentration When Administered in Combination With Belantamab Mafodotin
Measure Description	Blood samples were collected for PK analysis of OX40 when administered intravenously in combination with belantamab mafodotin.
Time Frame	Up to Day 1 (End of Infusion) of Cycle 6 (Each Cycle consist of 21 days)

Analysis Population Description

Pharmacokinetic population included all participants in the safety population from whom at least one PK sample has been obtained and analysed.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed		6	3
DE Phase: OX40 Concentration When Administered in Combination With Belantamab Mafodotin Median (Full Range) Unit of measure: ng/mL	[Not specified]		
Cycle 1 Day 1, Pre-Dose	Number Analyzed	6 participants	3 participants
		0.0 (0 to 0)	0.0 (0 to 0)
Cycle 1 Day 1, End Of Infusion	Number Analyzed	6 participants	3 participants

		1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
		1199.5 (0 to 1478)	1759.0 (1746 to 2671)
Cycle 1 Day 1, 24 hours	Number Analyzed	6 participants	3 participants
		1078.0 (712 to 1305)	1540.0 (1427 to 1974)
Cycle 1 Day 1, 2-4 hours	Number Analyzed	6 participants	3 participants
		1576.0 (1137 to 1659)	1888.0 (1785 to 1889)
Cycle 1 Day 4	Number Analyzed	6 participants	3 participants
		576.5 (428 to 770)	889.0 (751 to 1087)
Cycle 1 Day 8	Number Analyzed	5 participants	3 participants
		358.0 (0 to 545)	737.0 (487 to 874)
Cycle 1 Day 22	Number Analyzed	1 participants	1 participants
		0.0 (--- to ---)	326.0 (--- to ---)
Cycle 2 Day 1, Pre-Dose	Number Analyzed	5 participants	3 participants
		0.0 (0 to 0)	0.0 (0 to 0)
Cycle 4 Day 1, Pre-Dose	Number Analyzed	3 participants	1 participants
		0.0 (0 to 551)	0.0 (--- to ---)
Cycle 6 Day 1, Pre-Dose	Number Analyzed	1 participants	1 participants
		0.0 (--- to ---)	346.0 (--- to ---)

17. Secondary Outcome Measure:

Measure Title	CE Phase: OX40 Concentration When Administered in Combination With Belantamab Mafodotin
Measure Description	Blood samples were collected for PK analysis of OX40 when administered intravenously in combination with belantamab mafodotin.
Time Frame	Up to Day 1 (End of Infusion) of Cycle 6 (Each Cycle consist of 21 days)

Analysis Population Description

Pharmacokinetic population included all participants in the safety population from whom at least one PK sample has been obtained and analysed.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

18. Secondary Outcome Measure:

Measure Title	DE Phase: Number of Participants With Post-baseline Positive Anti-drug Antibodies (ADAs) Against Belantamab Mafodotin
Measure Description	Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were tested in screening assay, and positive samples were further characterized for antibody titers.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3
DE Phase: Number of Participants With Post-baseline Positive Anti-drug Antibodies (ADAs) Against Belantamab Mafodotin Measure Type: Count of Participants Unit of measure: participants	0 0%	0 0%

19. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With Post-baseline Positive ADAs Against Belantamab Mafodotin
Measure Description	Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were tested in screening assay, and positive samples were further characterized for antibody titers.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

20. Secondary Outcome Measure:

Measure Title	DE Phase: Number of Participants With Post-baseline Positive ADAs Against OX40
Measure Description	Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were tested in screening assay, and positive samples were further characterized for antibody titers.
Time Frame	Up to 170 weeks

Analysis Population Description

Data was not collected.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

21. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With Post-baseline Positive ADAs Against OX40
Measure Description	Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were tested in screening assay, and positive samples were further characterized for antibody titers.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

22. Secondary Outcome Measure:

Measure Title	DE Phase: Concentration of ADAs Against Belantamab Mafodotin
Measure Description	Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were to be further tested in screening assay, and positive samples were further to be characterized for antibody titers.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy. No participants were found positive for ADAs, hence participants were not analyzed for concentration of ADAs.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

23. Secondary Outcome Measure:

Measure Title	CE Phase: Concentration of ADAs Against Belantamab Mafodotin
Measure Description	Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were to be further tested in screening assay, and positive samples were further to be characterized for antibody titers.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

24. Secondary Outcome Measure:

Measure Title	DE Phase: Concentration of ADAs Against OX40 When Administered in Combination With Belantamab Mafodotin

Measure Description	Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were to be further tested in screening assay, and positive samples were further to be characterized for antibody titers.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

There were no participants with positive ADA results. Hence participants were not analyzed for the concentration of ADA.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

25. Secondary Outcome Measure:

Measure Title	CE Phase: Concentration of ADAs Against OX40 When Administered in Combination With Belantamab Mafodotin
Measure Description	Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were to be further tested in screening assay, and positive samples were further to be characterized for antibody titers.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

26. Secondary Outcome Measure:

Measure Title	DE Phase: Number of Participants With Adverse Events of Special Interest (AESI)
Measure Description	An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that; results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations judged by physician, is associated with liver injury and impaired liver function. Adverse Events of Special Interest (whether serious or non serious) were collected.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.

	Description
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3
DE Phase: Number of Participants With Adverse Events of Special Interest (AESI) Measure Type: Count of Participants Unit of measure: participants	6 100%	3 100%

27. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With AESI
Measure Description	An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that; results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations judged by physician, is associated with liver injury and impaired liver function.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

28. Secondary Outcome Measure:

Measure Title	DE Phase: Number of Participants With Any Corneal Events by Maximum Grade as Per CTCAE Grade
Measure Description	The corneal events were graded according to CTCAE version 5. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade. Results are presented for number of participants with any corneal events by maximum grade as per CTCAE grade.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	6	3
DE Phase: Number of Participants With Any Corneal Events by Maximum Grade as Per CTCAE Grade Measure Type: Count of Participants Unit of measure: participants		

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Grade 1	1 16.67%	0 0%
Grade 2	3 50%	1 33.33%
Grade 3	0 0%	1 33.33%

29. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With Any Corneal Events by Maximum Grade as Per CTCAE Grade
Measure Description	Corneal Events were examined.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

30. Secondary Outcome Measure:

Measure Title	CE Phase: Progression-free Survival (PFS)

Measure Description	PFS is defined as the time from randomization until the earliest date of confirmed progressive disease (PD) per IMWG, or death due to any cause.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

31. Secondary Outcome Measure:

Measure Title	CE Phase: Duration of Response (DoR)
Measure Description	DoR is defined as the time from first documented evidence or PR or better until progressive disease per IMWG or death due to progressive disease among participants who achieve confirmed partial response or better.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

32. Secondary Outcome Measure:

Measure Title	CE Phase: Time to Response (TTR)
Measure Description	TTR is defined as the time between the date of randomization and the first documented evidence of response (PR or better), among participants who achieve a response (confirmed PR or better).
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

33. Secondary Outcome Measure:

Measure Title	CE Phase: Overall Survival (OS)
Measure Description	OS is defined as the time from randomization until death due to any cause.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

34. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With AEs and SAEs
Measure Description	AEs and SAEs were collected.

Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

35. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With AEs Leading to Discontinuation
Measure Description	Number of participants with AEs leading to discontinuation were evaluated.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

36. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With Dose Reduction or Delay
Measure Description	Number of participants with dose reduction or delay were evaluated.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

37. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With Clinically Significant Changes in Hematology Lab Parameters
Measure Description	Blood samples were collected for the analysis of following hematology parameters: eosinophils, anemia, hemoglobin increased, lymphocyte count decreased, lymphocyte count increased, neutrophil count decreased, platelet count decreased, leukocytosis and white blood cell decreased. The laboratory parameters were graded according to Common Terminology Criteria for Adverse Events (CTCAE) version 5. Grade 1 (G1): mild; Grade 2 (G2): moderate; Grade 3 (G3: severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

38. Secondary Outcome Measure:

Measure Title	CE Phase: Number of Participants With Clinically Significant Changes in Clinical Chemistry Lab Parameters
Measure Description	Blood samples were collected for the analysis of following chemistry parameters: Hypoglycemia, hypoalbuminemia, alkaline phosphatase (ALP) increased, alanine aminotransferase (ALT) increased, aspartate aminotransferase (AST) increased, blood bilirubin increased, creatine kinase (CPK) increased, creatinine increased, gamma glutamyl transferase (GGT) increased, hyperkalemia, blood lactate dehydrogenase (LDH) increased, hypermagnesemia, hypomagnesemia, hypernatremia, hypercalcemia, hypocalcemia and chronic kidney disease. The laboratory parameters were graded according to CTCAE version 5. G1: mild; G2: moderate; G3: severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade.
Time Frame	Up to 170 weeks

Analysis Population Description

Safety Population included all participants who received at least 1 dose of any component of the combination therapy.

No participants were enrolled in CE Phase as study got terminated.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

Measured Values

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40	2.5 mg/kg Belantamab Mafodotin + 8mg OX40
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	All cause mortality, non-serious adverse events (Non-SAEs) and serious adverse events (SAEs) were collected maximum up to 170 weeks.

Adverse Event Reporting Description	Safety set included all participants who received at least one dose of any component of the combination therapy in the combination arm.

Reporting Groups

	Description
1.9 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 1.9 milligram (mg)/kilogram (kg) belantamab mafodotin intravenous (IV) infusion as powder for solution once every 3 weeks (Q3W) infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin end of infusion (EOI) on day 1 of 21-day cycles.
2.5 mg/kg Belantamab Mafodotin + 8mg OX40	Participants with RRMM received 2.5 mg/kg belantamab mafodotin IV infusion as powder for solution Q3W infused over 30- 60 minutes on day 1 of 21-day cycles in combination with 8 mg OX40 IV solution 1 hour after belantamab mafodotin EOI on day 1 of 21-day cycles.

All-Cause Mortality

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40		2.5 mg/kg Belantamab Mafodotin + 8mg OX40	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total All-Cause Mortality	5/6 (83.33%)		2/3 (66.67%)	

Serious Adverse Events

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40		2.5 mg/kg Belantamab Mafodotin + 8mg OX40	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	6/6 (100%)		1/3 (33.33%)	
Infections and infestations				
Parainfluenzae virus infection [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Pneumonia [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Staphylococcal infection [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Urosepsis [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Injury, poisoning and procedural complications				
Fall [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Femur fracture [A] †	1/6 (16.67%)	2	0/3 (0%)	0
Infusion related reaction [A] †	1/6 (16.67%)	1	0/3 (0%)	0

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40		2.5 mg/kg Belantamab Mafodotin + 8mg OX40	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Subdural haemorrhage [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Musculoskeletal and connective tissue disorders				
Musculoskeletal chest pain [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Nervous system disorders				
Haemorrhage intracranial [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Vascular disorders				
Peripheral vascular disorder [A] †	0/6 (0%)	0	1/3 (33.33%)	1

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA v25.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40		2.5 mg/kg Belantamab Mafodotin + 8mg OX40	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	6/6 (100%)		3/3 (100%)	
Blood and lymphatic system disorders				
Neutropenia [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Thrombocytopenia [A] †	4/6 (66.67%)	4	0/3 (0%)	0
Cardiac disorders				
Atrioventricular block first degree [A] †	0/6 (0%)	0	1/3 (33.33%)	1
Eye disorders				
Conjunctival haemorrhage [A] †	1/6 (16.67%)	2	0/3 (0%)	0
Dry eye [A] †	1/6 (16.67%)	1	1/3 (33.33%)	2
Exophthalmos [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Eye inflammation [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Eye pain [A] †	1/6 (16.67%)	1	0/3 (0%)	0

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40		2.5 mg/kg Belantamab Mafodotin + 8mg OX40	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Keratitis [A] †	0/6 (0%)	0	1/3 (33.33%)	1
Keratopathy [A] †	2/6 (33.33%)	2	2/3 (66.67%)	7
Ocular hypertension [A] †	0/6 (0%)	0	1/3 (33.33%)	1
Photophobia [A] †	0/6 (0%)	0	1/3 (33.33%)	1
Punctate keratitis [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Vision blurred [A] †	1/6 (16.67%)	2	1/3 (33.33%)	3
Visual acuity reduced [A] †	1/6 (16.67%)	1	1/3 (33.33%)	1
Gastrointestinal disorders				
Abdominal pain upper [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Constipation [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Nausea [A] †	0/6 (0%)	0	1/3 (33.33%)	2
General disorders				
Mass [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Infections and infestations				
Conjunctivitis [A] †	0/6 (0%)	0	1/3 (33.33%)	2
Sinusitis [A] †	0/6 (0%)	0	1/3 (33.33%)	7
Urinary tract infection [A] †	0/6 (0%)	0	1/3 (33.33%)	1
Investigations				
Alanine aminotransferase increased [A] †	0/6 (0%)	0	1/3 (33.33%)	1
Aspartate aminotransferase increased [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Metabolism and nutrition disorders				
Hyponatraemia [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Iron deficiency [A] †	0/6 (0%)	0	1/3 (33.33%)	1

	1.9 mg/kg Belantamab Mafodotin + 8mg OX40		2.5 mg/kg Belantamab Mafodotin + 8mg OX40	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Musculoskeletal and connective tissue disorders				
Osteonecrosis of jaw [A] †	0/6 (0%)	0	1/3 (33.33%)	1
Rotator cuff syndrome [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Spinal pain [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Nervous system disorders				
Seizure [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Psychiatric disorders				
Insomnia [A] †	0/6 (0%)	0	1/3 (33.33%)	1
Renal and urinary disorders				
Renal impairment [A] †	1/6 (16.67%)	1	0/3 (0%)	0
Skin and subcutaneous tissue disorders				
Photosensitivity reaction [A] †	1/6 (16.67%)	1	0/3 (0%)	0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA v25.1

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single site data not precede the primary publication of the entire clinical trial.

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