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Title	:	Reporting and Analysis Plan for A Phase I Open-label, Dose Escalation Study to Investigate the Safety, Tolerability, Pharmacokinetics, Immunogenicity and clinical activity of the Antibody Drug Conjugate belantamab mafodotin in Chinese Participants with Relapsed/Refractory Multiple Myeloma Who Have Failed At Least Two Lines of Previous Treatment, Containing an alkylator, a Proteasome Inhibitor and an Immunomodulatory Agent
Compound Number	:	GSK2857916
Clinical Study Identifier	:	208465/Amendment 3
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Description:

- The purpose of this RAP is to describe the planned analyses to be included in the Clinical Study Report (CSR) for Protocol 208465/Amendment 3.
- This RAP is intended to detail the planned study population, safety, tolerability, pharmacokinetics, immunogenicity and clinical activity analyses required for the study and to convey the content of the final Statistical Analysis Complete (SAC) deliverable.

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TABLE OF CONTENTS

PAGE

1. INTRODUCTION 6

2. SUMMARY OF KEY PROTOCOL INFORMATION 7
   2.1. Changes to the Protocol Defined Statistical Analysis Plan 7
   2.2. Study Objective(s) and Endpoint(s) 7
   2.3. Study Design 8
   2.4. Statistical Hypotheses / Statistical Analyses 9

3. PLANNED ANALYSES 10
   3.1. Interim Analyses 10
   3.2. Final Analyses 10

4. ANALYSIS POPULATIONS 11
   4.1. Protocol Deviations 12

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS 13
   5.1. Study Treatment & Sub-group Display Descriptors 13
   5.2. Baseline Definitions 13
   5.3. Other Considerations for Data Analyses and Data Handling Conventions 13

6. STUDY POPULATION ANALYSES 14
   6.1. Overview of Planned Study Population Analyses 14
   6.2. Participant's Disposition 14
   6.3. Demographic and Baseline Characteristics 14
   6.4. Treatment Compliance 15
   6.5. Extent of Exposure 15
   6.6. Concomitant Medications 15

7. EFFICACY ANALYSES 17
   7.1. Objective response rate (ORR) 17
      7.1.1. Derivation of Confirmed Response 17
   7.2. Duration of response (DOR) 19
   7.3. CCI [redacted] 19

8. SAFETY ANALYSES 20
   8.1. Dose Limiting Toxicity Analyses 20
   8.2. Adverse Events Analyses 20
   8.3. Adverse Events of Special Interest Analyses 21
   8.4. Serious Adverse Events 22
   8.5. SAEs are included in the listing of all adverse events. Adverse Events Leading to Discontinuation of Study Treatment and Dose Modification 22
   8.6. Pregnancies 22
   8.7. Clinical Laboratory Analyses 22
      8.7.1. Analyses of Liver Function Tests 23
   8.8. Other Safety Analyses 23
      8.8.1. Performance Status 23

8.8.2. ECG....23

9. IMMUNOGENICITY / BIOMARKER ANALYSES....24

10. PHARMACOKINETIC ANALYSES....25
10.1. Drug Concentration Measures....25
10.1.1. Non-compartmental Analysis....25
10.2. Population of Interest....26
10.3. Statistical Analyses / Methods....26
10.3.1. Statistical Methodology Specification....26

11. PHARMACOKINETIC / PHARMACODYNAMIC ANALYSES....28
11.1. Exposure-Response for Efficacy and Safety Endpoints....28
11.2. Concentration-QTc Analyses....28

12. PHARMACODYNAMIC AND BIOMARKER ANALYSES....29

13. REFERENCES....30

14. APPENDICES....31
14.1. Appendix 1: Exclusions from Per Protocol Population....31
14.2. Appendix 2: Schedule of Activities....32
14.3. Appendix 3: Assessment Windows....36
14.4. Appendix 4: Study Phases and Treatment Emergent Adverse Events....37
14.4.1. Study Phases....37
14.4.2. Treatment Emergent Flag for Adverse Events....39
14.5. Appendix 5: Data Display Standards & Handling Conventions....40
14.5.1. Reporting Process....40
14.5.2. Reporting Standards....40
14.5.3. Reporting Standards for Pharmacokinetic....41
14.6. Appendix 6: Derived and Transformed Data....42
14.6.1. General....42
14.6.2. Study Population....42
14.6.3. Efficacy....42
14.6.4. Safety....43
14.6.5. Pharmacokinetic....43
14.7. Appendix 7: Reporting Standards for Missing Data....44
14.7.1. Premature Withdrawals....44
14.7.2. Handling of Missing Data....44
14.8. Appendix 8: Values of Potential Clinical Importance....47
14.8.1. Laboratory Values....47
14.8.2. ECG Parameters and Vital Signs....47
14.9. Appendix 9: Pharmacokinetic / Pharmacodynamic Analyses....48
14.9.1. Pharmacokinetic / Pharmacodynamic Dataset Specification....48
14.9.2. Pharmacokinetic / Pharmacodynamic Methodology....48
14.10. Appendix 10: Pharmacodynamic Biomarkers and Exploratory Response Prediction Biomarkers....49
14.10.1. Pharmacodynamic Biomarkers and Exploratory Response Prediction Biomarkers Dataset Specification....49

14.10.2. Pharmacodynamic Biomarkers and Exploratory Response Prediction Biomarkers Methodology....49
14.11. Appendix 11: Abbreviations & Trade Marks....50
14.11.1. Abbreviations....50
14.11.2. Trademarks....52
14.12. Appendix 12: List of Data Displays....53
14.12.1. Data Display Numbering....53
14.12.2. Mock Example Shell Referencing....53
14.12.3. Deliverables....53
14.12.4. Study Population Tables....54
14.12.5. Study Population Figures....56
14.12.6. Efficacy Tables....57
14.12.7. Efficacy Figures....58
14.12.8. Dose Limiting Toxicity Tables....59
14.12.9. Dose Limiting Toxicity Figures....60
14.12.10. Safety Tables....61
14.12.11. Safety Figures....63
14.12.12. Immunogenicity/Biomarker Tables....64
14.12.13. Immunogenicity Figures....65
14.12.14. Pharmacokinetic Tables....66
14.12.15. Pharmacokinetic Figures....67
14.12.16. Pharmacokinetic / Pharmacodynamic Tables....68
14.12.17. Pharmacokinetic / Pharmacodynamic Figures....69
14.12.18. Pharmacodynamic Biomarkers and Exploratory Response Prediction Biomarkers Tables....70
14.12.19. Pharmacodynamic Biomarkers and Exploratory Response Prediction Biomarkers Figures....71
14.12.20. ICH Listings....72
14.12.21. Non-ICH Listings....75
14.13. Appendix 13: Example Mock Shells for Data Displays....77

1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the planned analyses to be included in the CSR for Protocol 208465/Amendment 3:

Revision Chronology:		
Original Protocol	01-Apr-2019	Original
Amendment 1	02-Nov-2019	The Centre of Drug Evaluation (CDE) China has recommended that the study participants should be sequentially entered into the 2.5 mg/kg dose group to observe participants' tolerance completely and collect PK data, based on tolerability results, the subsequent dosing plan should be adjusted as appropriate. The safety monitoring and risk management were enhanced based on the available data about the product. Ocular examination details were updated as CDE suggested to pay attention to corneal examination and collection of patient-reported symptoms during the clinical study based on the occurrence of corneal toxicity of this product. The pregnancy data collection and contraception period were revised as toxic effects on the fertility could be observed in repeat dose toxicity studies
Amendment 2	30-Oct-2020	Per current available safety and efficacy information of belantamab mafodotin studies, the 3.4 mg/kg dose cohort is converted to an optional cohort in the dose-escalation study design. It may be determined not to escalate to based on clinical data from other belantamab mafodotin studies.
Amendment 3	26-Oct-2021	The protocol has been amended to accommodate the updates based on latest information available through investigator's brochure. The study period was extended to maintain the study treatment of two ongoing participants who are benefitting from the Belantamab mafodotin treatment as judged by investigator.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

There were no changes or deviations to the originally planned statistical analysis specified in the protocol 208465/Amendment 3 (Dated: 26-Oct-2021).

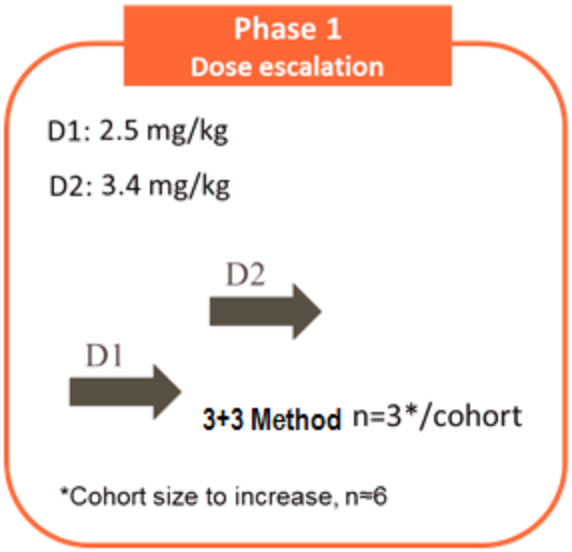
2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary	**Primary**
• To determine safety and tolerability of belantamab mafodotin in Chinese Participants with RRMM	• Adverse events (AE), i.e., number (%) of participants with DLTs, number (%) of participants with AEs
Secondary	**Secondary**
• To evaluate PK profile of belantamab mafodotin in Chinese Participants with RRMM	• ADC, total antibody and cys-mcMMAF PK parameters following IV single and repeat dose administration during dose escalation as data permit (e.g., AUC, C_{max}, t_{max})
• To evaluate safety and tolerability of belantamab mafodotin	• Changes in clinical signs and laboratory parameters, ocular findings on ophthalmic exam
• To evaluate the clinical measures of efficacy of belantamab mafodotin	• ORR, defined as the percentage of participants with a confirmed partial response (PR) or better (i.e., VGPR, CR and stringent complete response [sCR]), according to the International Myeloma Working Group (IMWG) Response Criteria.
• To assess anti-drug antibody (ADA) formation after IV single and repeat dose administration of belantamab mafodotin	• Incidence and titers of ADAs against belantamab mafodotin
• Participant self-reported symptomatic adverse effects by evaluation of tolerability of belantamab mafodotin	• Symptomatic adverse effects and related impacts as measured by the OSDI
Exploratory	**Exploratory**
CCI [redacted]	

Abbreviations: IV = intravenous; BCMA = B-cell maturation antigen; MMAF = monomethyl auristatin-F; ORR = overall response rate; CR = complete response; DLT= dose-limiting toxicity; VGPR = very good partial response; PR = partial response; sCR = Stringent complete response; PK = pharmacokinetics; AUC = area under the curve; C_{max} = maximum concentration; T_{max} = time to maximum; ADA = anti-drug antibody; OSDI = Ocular Surface Disease Index; CCI [redacted]

CCI [redacted]

2.3. Study Design

Overview of Study Design and Key Features	
 Note: De-escalation to 1.9 mg/kg will be allowed in case of ≥2 DLT at dose 2.5 mg/kg As per current available safety and efficacy information of belantamab mafodotin studies, the 3.4 mg/kg dose cohort is converted to an optional cohort in the dose-escalation study design. Escalation may not proceed if not supported by emerging clinical data from other belantamab mafodotin studies.	
Design Features	• Phase I, open-label dose-escalation study to explore safety, PK, tolerability, immunogenicity and clinical activity of belantamab mafodotin monotherapy in Chinese participants with RRMM. The study will enroll up to 12 evaluable participants. This study will include two dose cohorts. Up to six evaluable participants are expected for each cohort and the actual numbers will depend on the safety observed. Each participant will be involved in the study until participant have progressed, died, withdrawn consent, discontinued treatment due to other reasons, or have been lost to follow-up. • Based on the 3+3 dose escalation design the anticipated size will be up to 6 evaluable participants for each dose level.
Dosing	• Belantamab mafodotin will be administered via 30-60 min intravenous (IV) infusion once every three weeks (21 days = 1 cycle).
Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• Projected dose levels are 2.5 mg/kg and 3.4 mg/kg. De-escalation to 1.9 mg/kg will be allowed in case of ⩾2 DLT at dose 2.5 mg/kg. The first 3 participants in 2.5 mg/kg dose group will receive the study treatment sequentially with an observation window of 7 days, to observe acute toxicities.
Interim Analysis	• No interim analysis is planned.

2.4. Statistical Hypotheses / Statistical Analyses

Due to limited sample size and the purpose of the study, no formal statistical hypotheses are being tested. Primary objective of the study is to determine safety and tolerability of belantamab mafodotin in Chinese Participants with RRMM. Analysis of the data will only utilise descriptive methods.

3. PLANNED ANALYSES

3.1. Interim Analyses

No interim analysis is planned in this study.

3.2. Final Analyses

The final planned primary analyses will be performed after the completion of the following sequential steps:

1. All participants have completed the study as defined in the protocol, i.e., when all participants have progressed, died, withdrawn consent, discontinued treatment due to other reasons, or have been lost to follow-up.
2. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• All participants who were screened for eligibility	• Study Population
Enrolled	• All participants who passed screening and entered the study. • Note screening failures (who never passed screening even if rescreened) and participants screened but never enrolled into the study (Reserve, Not Used) are excluded from the Enrolled population as they did not enter the study.	• Study Population
All Treated	• All eligible participants who receive at least 1 dose of study treatment. An incorrect treatment schedule or drug administration or an early termination of treatment will not result in exclusion of participants from this population.	• Study Population • Safety (except the DLT analysis) • Efficacy
DLT Evaluable	• All the eligible participants who have received the 1st dose as planned, and experienced a DLT during the cycle 1 or completed the cycle 1. Participants who have been replaced during cycle 1 will be excluded from the DLT evaluable population.	• Summary of DLT
Pharmacokinetic (PK)	• All participants in the "All Treated" population from whom at least one PK sample was obtained, analyzed, and was measurable.	• PK

Refer to Appendix 12: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarised and listed.

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan (PDMP) 4.0_04Jun2021.

- Data will be reviewed prior to freezing the database to ensure all important deviations are captured and categorised on the protocol deviations dataset.
- This dataset will be the basis for the summaries and listings of protocol deviations.

A listing of all inclusion/exclusion criteria deviations will also be provided.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

There are no treatment comparisons. Analysis of the data obtained will only utilise descriptive methods.

5.2. Baseline Definitions

For all endpoints (except as noted in baseline definitions) the baseline value will be the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. If time is not collected, Day 1 assessments are assumed to be taken prior to first dose and used as baseline. For ECG analyses, participant level baseline is defined as the mean of triplicate baseline assessments.

Unless otherwise stated, if baseline data is missing no derivation will be performed and baseline will be set to missing.

Definition	Reporting Details
Change from Baseline	= Post-baseline Value – Baseline
% Change from Baseline	= 100 x [(Post-baseline Value – Baseline) / Baseline]

5.3. Other Considerations for Data Analyses and Data Handling Conventions

Other considerations for data analyses and data handling conventions are outlined in the appendices:

Section	Component
Section 14.3	Appendix 3: Assessment Windows
Section 14.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
Section 14.5	Appendix 5: Data Display Standards & Handling Conventions
Section 14.6	Appendix 6: Derived and Transformed Data
Section 14.7	Appendix 7: Reporting Standards for Missing Data
Section 14.8	Appendix 8: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population analyses will be based on the "All Treated" population, unless otherwise specified. The summary of screening failures and reasons for screening failure will be based on the "Screened" population, unless otherwise specified.

Study population analyses including analyses of participant's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 12: List of Data Displays.

6.2. Participant's Disposition

A summary of the number of participants in each of the analysis populations described in Section 4 will be provided using "Screened" population.

A summary of participant status and reason for study withdrawal will be provided. This display will show the number and percentage of participants who withdrew from the study, including the primary reasons for study withdrawal. Reasons for study withdrawal will be presented in the order they are displayed in the eCRF.

A summary of study treatment status will be provided. This display will show the number and percentage of participants who are ongoing or discontinued study treatment and a summary of the primary reasons for discontinuation of study treatment. Reasons for study treatment discontinuation will be presented in the order they are displayed in the eCRF. A listing of study treatment discontinuation will be generated. The listing will include last dose date, and reasons for study treatment discontinuation.

6.3. Demographic and Baseline Characteristics

The demographic characteristics (e.g., age, race, ethnicity, sex, baseline height, baseline body weight, and baseline BMI) will be summarized and listed. Age, height, weight and BMI will be summarized using mean, standard deviation, median, minimum, and maximum. The count and percentage will be computed for sex and ethnicity.

Disease history and characteristics (e.g. time since initial diagnosis in years, stage at initial diagnosis, date of initial diagnosis) at initial diagnosis and screening will be listed. Summaries of disease characteristics at initial diagnosis and screening will be provided. Disease characteristics at screening, including stage, type of multiple myeloma, myeloma light chain, and immunoglobulin, and whether or not have extramedullary disease and lytic bone lesions will be summarized and listed.

Genetic characteristics and Cytogenetic risk for multiple myeloma participants at screening will be summarized. Genetic characteristics will be listed. A participant is considered as having high cytogenetic risk if the participant has any of the following cytogenetics: t(4;14), del17p, t(14;16).

Current medical conditions, such as liver disease medical conditions, cardiovascular risk factors and other medical conditions will be summarized and will be sorted by decreasing overall frequency. A by-participant listing of medical conditions will also be provided.

Prior anti-cancer therapy will be listed.

Prior anti-cancer therapy for multiple myeloma participants will also be summarized by type of therapy, and drug class. A summary of multiple myeloma participants' refractory to prior anti-cancer therapy by drug class will be provided.

6.4. Treatment Compliance

Summaries of study treatment exposure and dose modifications (e.g., number of dose reductions, number of dose delays) will further characterize compliance. These analyses are described in Section 6.5 'Extent of Exposure'.

6.5. Extent of Exposure

Extent of exposure to Belantamab Mafodotin will be summarized.

The number of cycles administered to study treatment will be summarised with mean, median, standard deviation, minimum, and maximum. The number and percentage of participants who received a given number of cycles (<4, 4, and >4 cycles) will be reported. The duration of exposure to study treatment in days (from first day to last day of treatment) will be calculated and summarized using mean, median, standard deviation, minimum, and maximum. A horizontal bar graph of duration of treatment will be produced that displays duration of treatment in months for each participant.

A by participant summary listing of data on exposure to all study treatments will be produced.

Dose reductions will be summarised by number of reductions and reasons for reductions. Dose delays will be summarised by number of delays, reasons for the delays, and delay duration (days). The number and percentage of the delays for intervals of 1-21, 22-42 and >42 days will be computed.

Duration of delays is defined as period from the expected start date of dose to actual start date of current dose. Calculation: (actual start date of current dose - expected start date of dose). Expected start date of dose = actual start date of previous dose + 21.

The summaries of dose modifications will be provided. All the dose reductions and dose delays will be listed.

6.6. Concomitant Medications

Concomitant medications will be coded using GSK Drug coding dictionary, summarized, and listed. The summary of concomitant medications will show the number and percentage of participants taking concomitant medications by Ingredient. Multi-ingredient products will be summarized by their separate ingredients rather than as a combination of ingredients. Anatomical Therapeutic Chemical (ATC) classification Level 1 (Body

System) information will be included in the dataset created but will not appear on the listing or summary.

In the summary of concomitant medications, each participant is counted once within each unique ingredient. For example, if a participant takes Amoxycillin on two separate occasions, the participant is counted only once under the ingredient “Amoxycillin”. In the summary of concomitant medications, the ingredients will be summarized by the base only, using CMBASECD and CMBASE. Note: In order to be considered a concomitant medication, the concomitant medication must have been taken at some point during the on-treatment window.

Blood products or blood supportive care products with onset date within the on-therapy window will be included in the summary tables. The frequency and percentage of subjects using blood products and blood supportive care products after the start of study medication will be provided. Supporting listings will also be provided.

7. EFFICACY ANALYSES

The efficacy analyses will be based on the All Treated population, unless otherwise specified.

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, the following endpoints / variables will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.1. Objective response rate (ORR)

ORR is defined as the percentage of participants with a confirmed partial response (PR) or better (i.e., VGPR, CR and stringent complete response [sCR]) as assessed according to IMWG Uniform Response Criteria for Multiple Myeloma 2016 (See Protocol Appendix 6) by the Investigator.

ORR and the associated 2-sided 95% exact confidence intervals will be provided. A list of investigator-assessed response at each visit will be listed.

The following rule of confirmation will be used to confirm the response (i.e., PR, VGPR, CR and sCR):

- PR: two consecutive response of PR or better at any time before starting any new therapy.
- VGPR: two consecutive responses of VGPR or better at any time before starting any new therapy.
- CR: two consecutive response of CR or better (i.e. sCR) at any time before starting any new therapy.
- sCR: two consecutive responses of sCR at any time before starting any new therapy.

7.1.1. Derivation of Confirmed Response

The derivation of confirmed response shall be based on the algorithm specified in Table 1. The date of the first of the two consecutive assessments will be used as the date of the confirmed response.

Table 1 Response confirmation algorithm

#	Response at the First Time Point	Response at Subsequent Disease Assessment[1]	Confirmed Response at the First Time Point
1	sCR	sCR	sCR
2	sCR	CR	CR
3	CR	sCR/CR	
4	sCR/CR	VGPR	VGPR
5	VGPR	sCR/CR/VGPR	
6	sCR/CR/VGPR	PR	PR
7	PR	sCR/CR/VGPR/PR	

#	Response at the First Time Point	Response at Subsequent Disease Assessment[1]	Confirmed Response at the First Time Point
8	sCR/CR/VGPR/PR	MR	MR
9	MR	sCR/CR/VGPR/PR/MR	
10	sCR/CR/VGPR/PR/MR	SD	SD
11	sCR/CR/VGPR/PR/MR	PD (any reason) OR No subsequent disease assessment: **subject died or discontinued study or started new anti-cancer therapy** before further adequate disease assessment	NE
12	PD (due to reasons other than imaging, i.e., plasmacytoma or bone lesion)	PD (any reason) including PD after initiation of new anti-cancer therapy OR No subsequent disease assessment: subject **died due to PD** before further adequate disease assessment (including death due to PD after initiation of new anti-cancer therapy)	PD
13	PD (due to reasons other than imaging, i.e., plasmacytoma or bone lesion)	sCR/CR/VGPR/PR/MR/SD OR No subsequent disease assessment: subject died **due to reasons other than PD** before further adequate disease assessment OR No subsequent disease assessment: subject **discontinued study** before further adequate disease assessment	NE
14	sCR/CR/VGPR/PR/MR/PD (due to reasons other than imaging, i.e., plasmacytoma or bone lesion)	No subsequent disease assessment: subject has not died, discontinued from study or (except for PD) started new anti-cancer therapy; but as yet has no further adequate disease assessments	Unconfirmed sCR/CR/VGPR/PR/MR/PD. Will be categorized as NE for final ORR analysis. For ORR analysis in IA, the UC response (PR or better) will be counted as responder.
15	SD	Any	SD

#	Response at the First Time Point	Response at Subsequent Disease Assessment[1]	Confirmed Response at the First Time Point
		OR No subsequent disease assessment	
16	PD due to imaging (plasmacytoma or bone lesion)	Any OR No subsequent disease assessment	PD
17	NE or missing	Any OR No subsequent disease assessment	NE

1. Subsequent disease assessment is defined as the next adequate (not missing or NE) disease assessment following the first timepoint before (or on the same date of) start of new anti-cancer therapy except for confirmation of PD, for which PD or death due to PD after new anti-cancer therapy are considered for confirmation of PD. No minimal time interval is required for the subsequent disease assessment, but a different sample is required for confirmation.
2. PD due to imaging (i.e., plasmacytoma or bone lesion) does not need to be confirmed.
3. Where criteria are not mutually exclusive, take the first that applies.

7.2. Duration of response (DOR)

DOR is defined as the duration from the time documented evidence of confirmed PR or better is first met until the first date that progressive disease or death due to PD, whichever occurs first, among participants who achieve a response (i.e. confirmed PR or better).

DOR will be summarized using Kaplan-Meier curves if applicable. If there are a sufficient number of progressions or death due to PD among the responders, median DOR, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A listing of DOR time will also be provided.

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8. SAFETY ANALYSES

The primary endpoints are adverse events, i.e., the number (%) of participants with DLTs, and the number (%) of participants with AEs.

The DLT analyses will be based on the DLT Evaluable population, unless otherwise specified.

The safety analyses (except the DLT analysis) will be based on the All Treated population, unless otherwise specified.

8.1. Dose Limiting Toxicity Analyses

The DLTs is one of the primary endpoints, the number and proportion of participants in the DLT population who experienced DLT during the Cycle 1 of study treatment will be presented. Details of the planned displays are presented in Appendix 12: List of Data Displays.

8.2. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), serious adverse events (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 12: List of Data Displays.

An overview summary of AEs, including counts and percentages of participants with any AE, AEs related to study treatment, Grade 3 or 4 AEs, Grade 3 or 4 AEs related to study treatment, AEs leading to permanent discontinuation of study treatment, AE leading to dose reductions, AEs leading to dose delays OR interruptions, SAEs, SAEs related to study treatment, fatal SAEs, and fatal SAEs related to study treatment will be produced.

A summary of non-serious AEs will be provided. The summary will be displayed by PT.

The relationship between PT and Verbatim Text will be displayed.

Adverse events (AEs) will be coded using the standard Medical Dictionary for Regulatory Activities (MedDRA). Severity of corneal events will be graded using the scale provided in Table 7 of the Study Protocol. The severity of other AEs will be graded by the investigator according to the National Cancer Institute-Common Toxicity Criteria for Adverse Events (NCI-CTCAE) (version 5.0).

A summary of number and percentage of participants with any adverse events by maximum grade will be produced. AEs will be sorted by Preferred term (PT) in descending order of total incidence. The summary will use the following algorithms for counting the participant:

- **Preferred term row**: Participants experiencing the same AE preferred term several times with different grades will only be counted once with the maximum grade.

- **Any event row**: Each participant with at least one adverse event will be counted only once at the maximum grade no matter how many events they have.

In addition, the frequency and percentage of AEs (all grades) will be summarized and displayed in descending order of total incidence by PT only.

A separate summary will be provided for study treatment-related AEs. A study treatment-related AE is defined as an AE for which the investigator classifies the relationship to study treatment as "Yes". A worst-case scenario approach will be taken to handle missing relatedness data, i.e. the summary table will include events with the relationship to study treatment as 'Yes' or missing. The summary table will be displayed by maximum grade sorted by PT in descending order of total incidence.

In addition, AEs of maximum grade of 3 or higher will be summarized separately by PT.

All AEs will be listed. Additionally, a listing of participant IDs for each individual AE will be produced.

The details of the planned displays are provided in Appendix 12: List of Data Displays.

8.3. Adverse Events of Special Interest Analyses

Adverse events of special interest (AESI) for belantamab mafodotin are corneal events, thrombocytopenia and infusion related reactions.

Summaries of the number and percentage of participants with these events will be provided for each type of events separately by preferred term and maximum grade. The time of onset and duration of first occurrence of corneal events will be summarized using summary statistics mean, standard deviation, median, minimum value, and maximum. The number and percentage of participants who have time of onset of first occurrence (1-21, 22-42, 43-63, >63 days) will be reported. The number and percentage of participants who have duration of first occurrence (1-21, 22-42, >42 days) will be reported.

The summary of event characteristics of corneal events and thrombocytopenia will also be provided, including number of participants with any event, number of events, number of participants with any event that is serious, number of participants with any event that is related to study treatment, number of occurrences (One, Two, Three or more), maximum grade and the action taken for the event. The percentage will be calculated in two ways, one with number of participants with event as the denominator and the other with total number of participants as the denominator. The worst-case approach will be applied at participant level for the maximum grade, i.e. a participant will only be counted once as the worst case from all the events experienced by the participant. For action taken to an event, participant will be counted once under each action, e.g. if a participant has an event leading to both study treatment discontinuation and dose reduction, the participant will be counted once under both actions.

A comprehensive list of MedDRA terms based on clinical review will be used to identify each type of event. The details of the planned displays are provided in Appendix 12: List of Data Displays.

8.4. Serious Adverse Events

All SAEs will be tabulated based on the number and percentage of participants who experienced the event. Separate summaries will also be provided for study treatment-related SAEs. The summary tables will be displayed in descending order by PT.

A study treatment-related SAE is defined as an SAE for which the investigator classifies the relationship to study treatment as "Yes". A worst-case scenario approach will be taken to handle missing data, i.e. the summary table will include events with the relationship to study treatment as 'Yes' or missing.

8.5. SAEs are included in the listing of all adverse events. Adverse Events Leading to Discontinuation of Study Treatment and Dose Modification

The following categories of AEs will be summarized by PT and separate supportive listings will be generated with participant level details for those participants:

- AEs Leading to Permanent Discontinuation of Study Treatment
- AEs Leading to Dose Interruptions or Delays
- AEs Leadings to Dose Reductions

8.6. Pregnancies

While pregnancy itself is not considered to be an AE or SAE, any pregnancy complication or elective termination of a pregnancy for medical reasons will be recorded as an AE or SAE as described in the protocol. If participants and participants' partner become pregnant while on the study, the information will be included in the narratives and no separate table or listing will be produced.

8.7. Clinical Laboratory Analyses

Only local laboratory evaluations including the analyses of Chemistry laboratory tests, Haematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 12: List of Data Displays.

Summaries of worst case grade increase from baseline grade will be provided for all the lab tests that are gradable by CTCAE v5.0. These summaries will display the number and percentage of participants with a maximum post-baseline grade increasing from their baseline grade. Any increase in grade from baseline will be summarized along with any increase to a maximum grade of 3 and any increase to a maximum grade of 4. Missing baseline grade will be assumed as grade 0. For laboratory tests that are graded for both low and high values, summaries will be done separately and labelled by direction, e.g., sodium will be summarized as hyponatremia and hypernatremia.

Separate summary tables for haematology, and chemistry laboratory tests will be produced. Liver function laboratory tests will be included with chemical chemistry.

A supporting listing of laboratory data for subjects with abnormalities of potential clinical concern will be provided. A separate listing of laboratory data with character values will also be provided. For lab test values that can be graded, values of grade 1 or above are defined as values of potential clinical concern. For lab test values that cannot be graded, values out of the normal range are defined as values of potential clinical concern.

Detailed derivation of baseline assessment is specified in Section 5.2.

Unless otherwise specified, the denominator in percentage calculation at each scheduled visit will be based on the number of participants with non-missing value at each particular visit.

8.7.1. Analyses of Liver Function Tests

Summaries of hepatobiliary laboratory events including possible Hy's law cases will be provided in addition to what has been described above.

8.8. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs, ECHOs, Ocular findings and vital signs will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 12: List of Data Displays.

Unless otherwise specified, the denominator in percentage calculation at each scheduled visit will be based on the number of participants with non-missing value at each particular visit.

8.8.1. Performance Status

A ECOG performance status listing will also be provided.

8.8.2. ECG

A summary of the number and percentage of participants who had normal and abnormal (clinically significant and not clinically significant) ECG findings will be displayed by scheduled visits as well as for the worst case post-baseline.

The QTc values based on Fridericia formula will be rounded to the integer and the values will be categorized into the following CTCAE grade and ranges: Grade 0 CCI [redacted] Grade 1 CCI [redacted] Grade 2 CCI [redacted] and Grade 3 CCI [redacted] Summaries of grade increase will be provided. These summaries will display the number and percentage of participants with any grade increase, increase to grade 2 and increase to grade 3 in the worst case post-baseline only.

A listing of QTc values of potential clinical importance will be provided.

The summaries and listing of QTc will use the collected values based on Fridericia formula.

9. IMMUNOGENICITY / BIOMARKER ANALYSES

For each participant, the anti-belantamab mafodotin (drug) antibody results, titers, and also ADC and total antibody concentration will be listed for each assessment time point. The frequency and percentage of participants with positive and negative anti-drug antibody will be summarized for each assessment time and overall for each participant. The conclusive results will be based on the total antibody concentration. The details of the planned displays are presented in Appendix 12: List of Data Displays.

Summary of biomarker change from baseline by scheduled visits using mean, median, standard deviation, minimum and maximum will be provided. A listing of biomarker will be provided. The details of the planned displays are presented in Appendix 12: List of Data Displays.

10. PHARMACOKINETIC ANALYSES

The pharmacokinetic analyses will be based on the "Pharmacokinetic (PK)" population, unless otherwise specified.

Concentration-time data collected under protocol amendment 3 will be analysed using standard non-compartmental methods; some parameters will be determined for all participants and cycles. Full details are presented in Appendix 12: List of Data Displays.

10.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 14.5.3)

10.1.1. Non-compartmental Analysis

- Pharmacokinetic parameters described in Table 2 below, will be determined separately for each analyte, as data permit.
- The pharmacokinetic parameters under protocol amendment 3 or later will be calculated by standard non-compartmental analysis according to current working practices and using Phoenix WinNonlin, version 6.3 or later, as data permit.
- The pharmacokinetic parameters CEOI and Ctrough will be determined directly from the concentration-time dataset for the other cycles under protocol amendment 3 and for participants enrolled prior to protocol amendment 3, as data permit.

  Note: For the dosing occasions with only predose and end of infusion samples, the end of infusion concentration (CEOI) will not be identified as Cmax.
- All calculations of non-compartmental parameters will be based on actual sampling times.

Table 2 Derived Pharmacokinetic Parameters

Parameter	Parameter Description
AUC(0-t)	Area under the concentration-time curve from time zero to the time of the last quantifiable concentration (C(t)) will be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid
AUC(0-τ)	Area under the concentration-time curve during the dosing interval (τ=504h, this parameter will be calculated only for ADC and total antibody)
AUC(0-168)	Area under the concentration-time curve from time 0 to 168h (This parameter will be calculated only for cys-mcMMAF)
AUC(0-∞)	Area under the concentration-time curve extrapolated to infinity will be calculated as: **AUC = AUC(0-t) + C(t) / lambda_z**
%AUCex	The percentage of AUC (0-∞) obtained by extrapolation (%AUCex) will be calculated as: **[AUC(0-inf) – AUC(0-t)] / AUC(0-inf) x 100**
Cmax	Maximum observed concentration, determined directly from the concentration-time data for each cycle. Cmax will not be derived when only predose and EOI samples were collected.
tmax	Time to reach Cmax, determined directly from the concentration-time data for each cycle

Parameter	Parameter Description
Cτ, Ctrough	Trough concentration prior to the next dose for each cycle
CEOI	Observed plasma concentration at the end of infusion
t½	Apparent terminal half-life will be calculated as: **t½ = ln(2) / lambda_z**
tlast	Time of last observed quantifiable concentration
CL	Clearance (This parameter will be calculated only for ADC and total antibody)
CL/weight	CL normalized by body weight (This parameter will be calculated only for ADC and total antibody)
Vss	Volume of distribution at steady state (This parameter will be calculated only for ADC and total antibody)
Vss/weight	Vss normalized by body weight (This parameter will be calculated only for ADC and total antibody)
λz, lambda_z	Terminal phase rate constant

10.2. Population of Interest

The pharmacokinetic analyses will be based on the PK population, unless otherwise specified.

10.3. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12: List of Data Displays, based on GSK data standards and statistical principles. Unless otherwise specified, endpoints / variables defined in Section 10.1.1 will be summarised using descriptive statistics descriptively (mean, standard deviation, median, minimum, maximum, geometric mean, and the standard deviation, CV%, and 95% CI of parameters values) by cycle, graphically presented (where appropriate) and listed.

10.3.1. Statistical Methodology Specification

The following pharmacokinetic statistical analyses will only be performed if sufficient data are available.

10.3.1.1. Concentration-Time Data

Concentration-time data will be summarized (when appropriate) using mean, median, standard deviation, minimum, and maximum, i.e. by planned time point and dose level for belantamab mafodotin (ADC, total antibody and cys-mcMMAF).

Linear and semi-logarithmic individual concentration-time profiles, and mean and median profiles (when appropriate) will be plotted for belantamab mafodotin (ADC, total antibody and cys-mcMMAF).

10.3.1.2. Pharmacokinetic Parameters

To assess the extent of accumulation following belantamab mafodotin repeat dosing, the observed accumulation ratio (Ro) for belantamab mafodotin, total antibody, and cys-mcMMAF will be determined as ratio of CEOI and Ctrough at Cycle 4 to CEOI and Ctrough at Cycle 1, respectively, using the data collected under Protocol 208465/Amendment 3.

Previous studies indicate that the pharmacokinetics for the third consecutive dose given at the planned interval will be at steady state. Therefore, based on the planned sampling scheme, accumulation ratios will be derived using the CEOI at Cycle 4 for Ro(CEOI) and Ctrough at Cycle 3 (predose at C4D1) for Ro(Ctrough). Participants must receive the same dose without delay or change for the first three cycles to derive Ro(Ctrough) and for the first four cycles to derive Ro(CEOI) (i.e., with dosing delays of ≤3 days).

Ro(CEOI) = CEOI at C4D1 / CEOI at C1D1;

Ro(Ctrough) = Cycle 3 trough / Cycle 1 trough

Accumulation ratios of CEOI and Ctrough, and other Pharmacokinetic Parameters in Table 2 will be summarised using descriptive statistics for belantamab mafodotin (ADC, total antibody and cys-mcMMAF) by planned initial dose level, graphically presented (where appropriate) and listed.

CCI

11. PHARMACOKINETIC / PHARMACODYNAMIC ANALYSES

11.1. Exposure-Response for Efficacy and Safety Endpoints

If deemed appropriate and if data permit, exposure-response relationships between belantamab mafodotin exposure (e.g., dose, dose intensity, concentration, Cmax, or AUC) and clinical activity and/or toxicity (e.g., response, corneal event, AESIs) may be explored using population methods. If data permit, the effects of covariates may be explored. Details of these analyses will be reported under a separate RAP, and the results of this analysis will be provided in a separate report.

11.2. Concentration-QTc Analyses

For each ECG assessment, the individual participant's QTcF change from baseline will be calculated and will be merged with time-matched PK concentration values for the timepoints at which they are available. QTcF change from baseline (y-axis) will be plotted against the PK concentration data (x-axis) separately for each analyte (ADC, total mAb, and cys-mc-MMAF). If appropriate, linear regression analyses may be performed for each analyte-ΔQTcF plot.

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[redacted]

13. REFERENCES

NA.

14. APPENDICES

14.1. Appendix 1: Exclusions from Per Protocol Population

This study does not have per protocol population.

14.2. Appendix 2: Schedule of Activities

Study Assessments	Screen[1]	Cycle 1 Day 1[2]	Cycle 1 Day 2	Cycle 1 Day 4	Cycle 1 Day 8	Cycle 1 Day 15	Treatment Period[3] Cycle = 21 days D1 of C2 - CX	End of Treatment Follow-up[4]	PD Follow-up[5]
Informed Consent	X								
Baseline Demographics	X								
Medical History including disease history and characteristics	X								
Physical Exam	X	X					X every 3 weeks	X	X
Safety									
Ocular Exam	X[6]						X[7]	X[7]	X[8]
ECOG Performance Status	X						X every 3 weeks	X	
Vital Signs (BP, HR, Body Temperature) [9, 10]	X	X			X	X	X	X	
Weight[9] and Height	X	Weight only					Weight only	Weight only	
Hematology[11]	X	X		X	X	X	X every 3 weeks	X	
Clinical chemistry[11]	X	X	X	X	X	X	X every 3 weeks	X	X[11]
Urine Dipstick[11]	X	X					X every 3 weeks	X	X
eGFR (by MDRD formula- see Appendix 8)	X	X					X every 3 weeks	X	
Spot urine for creatinine/albumin ratio[12]	X	X					Cycle: 3, 5, 7 and Every other cycle thereafter	X	
CRP	X						X every 3 weeks	X	
HBsAg, HBcAb, and hepatitis C Ab.[13]	X								
Troponin I[14]	X								
BNP[15]	X								
Pregnancy Test [9, 16]	X	X					X	X	X[16]
ECHO[17]	X						as clinically indicated		
12-lead ECG[9, 18]	X	X[18]	X[18]	X[18]	X[18]	X[18]	X.	X	
PK and ADA									
PK[19]		X[19]	X[19]	X[19]	X[19]	X[19]	X[19]	X[20]	
ADA[21]		X[21]					X[21]	X[21]	
Disease Evaluation									
β_2 Microglobulin	X								
Response assessment[22]							X every 3 weeks	X[23]	X
Skeletal survey[24]	X						As clinically indicated [25]		
Imaging for Extramedullary disease[26]	X						C5, C9, C13 and C17, every12 weeks then as clinically indicated [26]	X [27]	X
UPEP (Urine Protein Electrophoresis) 24 hr urine collection	X						X every 3 weeks	X	X
Urine Immunofixation	X						At time of first achieving CR or suspected PD after CR or sCR	At time of first achieving CR or suspected PD after CR or sCR	At time of first achieving CR or suspected PD after CR or sCR

Study Assessments	Screen[1]	Cycle 1 Day 1[2]	Cycle 1 Day 2	Cycle 1 Day 4	Cycle 1 Day 8	Cycle 1 Day 15	Treatment Period[3] Cycle = 21 days D1 of C2 - CX	End of Treatment Follow-up[4]	PD Follow-up[5]
SPEP (Serum Protein Electrophoresis)	X						X every 3 weeks	X	X
Serum immunofixation	X						At time of CR or suspected PD after CR or sCR	At time of CR or suspected PD after CR or sCR	At time of CR or suspected PD after CR or sCR
Serum Kappa, lambda free LC, FLC ratio	X						X every 3 weeks	X	X
Calcium corrected for albumin (serum)	X						X every 3 weeks	X	X
IgG, IgM, IgA	X	X					X every 3 weeks	X	X
IgD/E[28]	X	X					X every 3 weeks	X	X
Bone Marrow Aspiration / biopsy									
FISH testing on bone marrow[29]	X								
CCI									
BM for disease assessment[31]	X						At the time of CR (always) or at time of suspected PD (only if not evident otherwise)	Only if CR has been achieved by this visit, or suspected PD not evident otherwise	Only if CR has been achieved by this visit, or suspected PD not evident otherwise
Bone marrow to assess sCR by (IHC)[32]							X[32]	Only if CR has been achieved on this visit.	Only if CR have been achieved on this visit
Biomarker									
CCI									
Study treatment									
Premedication if needed		X					X		
Belantamab mafodotin administration[34]		X					X		
Preservative-free artificial tears[35]		X					Everyday until end of Study treatment		
Adverse Events[36]		X	X	X	X	X	X		
Concomitant Medications	X	X	X		X	X	X		
Health Outcomes									
OSDI[37]	X	X					X every 3 weeks	X	X

Abbreviations:
ADA = Anti-drug Antibody; ALP = alkaline phosphatase; BM = bone marrow; BNP = B-type natriuretic peptide; BP = blood pressure; C1D1 = Cycle 1 Day 1, etc.; CK = creatine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FISH = fluorescence in situ hybridization; FLC = free light chain; HR= heart rate; Ig = immunoglobulin; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis; OSDI = Ocular Surface Disease Index.

1. All Screening assessments must be performed within 21 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed. Screening Assessment do not need to be repeated on C1D1 unless otherwise specified.
2. Assessments scheduled on days of dosing must be done prior to drug administration, unless otherwise specified. All other assessments can be done ±3 days unless otherwise specified.
3. Belantamab mafodotin will be administered intravenously on Day 1 (D1) of every 21-day cycle until disease progression, death, unacceptable toxicity, withdrawal of consent or end of study.
4. The End of treatment (EOT) follow-up visit is to assess any residual AEs or toxicities associated with Study treatment. The visit should occur -within 45 days after last dose or before the start any new anti-cancer therapy.
5. PD follow-up once every 21 days: Participants who discontinue IP for a reason other than PD, disease evaluations will continue to be performed once every 21 days (±7 days) until confirmed PD, death, start of a new anticancer treatment, withdrawal of consent, or end of the study whichever occurs first.
6. Screening examination will be performed by an ophthalmologist (or an optometrist if an ophthalmologist is not available) within 21 days prior to first dose. See Protocol Section 8.3.9 for the list of ophthalmic exam procedures.
7. On-study ophthalmic exams to be performed by an ophthalmologist (or an optometrist if an ophthalmologist is not available) pre-dose every 3 weeks (schedule of assessment window should be within 5 days prior to dosing, all efforts should be made to schedule as close to dosing as possible). After the 6th dose of belantamab mafodotin (no schedule of assessment window needed): If there are no significant (Grade 2 or above) ocular symptoms or vision changes the frequency of ophthalmologic exams may be decreased to every 3 months until

end of treatment. In case of persistent ocular exam findings, newly developed ocular symptoms or vision changes, further ocular exams should be performed at least every cycle until resolution (to Grade 1 or baseline) or more frequently as clinically indicated by the qualified eye care specialist(Protocol Appendix 9). See Protocol Section 8.3.9 for the list of ophthalmic exam procedures.

8. Additional exams may be performed by the ophthalmologist (an optometrist if an ophthalmologist is not available), as clinically indicated.
9. If a participant's belantamab mafodotin dose is not administered at a given visit, the following activities do not need to be performed at that visit unless clinically indicated: ECG, weight, vitals, pregnancy test. Please follow the visit schedule in the SOA above, and perform these activities prior to a belantamab mafodotin infusion.
10. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to start of infusion(SOI)), +10 minutes after SOI, end of infusion (EOI), and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), and at EOI. On days where vital sign time points align with PK sampling time points, vital signs must be assessed prior to PK samples being drawn. On days where vital signs are measured multiple times, temperature does not need to be repeated unless clinically indicated.
11. Refer to Protocol Table 9 for a comprehensive list of lab tests that must be collected for all participants. If labs are completed within 72 hours prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Creatinine only is required at PD visits (not a full chemistry).
12. Creatinine / albumin ratios (spot urine from first void) at screening and C1, C3, C5, C7 and every other cycle thereafter (local labs or central if local not available).
13. Hepatitis: If the participant is hepatitis C virus (HCV) positive by serology, an additional Hep C RNA testing may be done to determine participant eligibility (if negative- participant is eligible).
14. Troponin I will be measured at the local lab or by central laboratory if not available locally. If cardiac workup is required due to safety concerns during the study, troponin must be measured.
15. B-type natriuretic peptide (BNP) to be measured locally, or by a central laboratory if not available locally, at screening; if cardiac workup is required due to safety concerns during the study, BNP must be measured.
16. Perform only in women of childbearing potential. A serum pregnancy test must be performed at screening, and subsequent pregnancy tests may be either serum or urine. If test is completed within 72 hours prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1.
    For questionable cases, follicle stimulating hormone (FSH) and estradiol (as needed in women of non-child bearing potential only) should be performed at local lab. See Protocol Section 5.1, Section 8.3.5, and Appendix 4 for more details.
    a. Final pregnancy test (serum or urine) must be performed in women of childbearing potential at the EOT Visit, and 8 months after the last dose of study treatment may be via a urine pregnancy test kit mailed to the participant's home with results reported by telephone.
17. Echocardiography for LVEF performed within 3 months of screening are acceptable as screening value. For participants with an abnormal LVEF (per institutional standards), the participant is to follow-up with a cardiologist.
18. ECGs on dosing days: Triplicate ECGs to be performed at pre-dose (within 30 minutes prior to SOI) and EOI at cycle 1. Triplicate ECGs should be collected prior to PK sample on Cycle 1 Day 2, Day 4, Day 8 and Cycle 1 Day 15. Single ECG at screening, at all other cycles, and End of Study Treatment On days where ECG time points align with PK sampling time points, ECGs must be performed within 30 minutes prior to PK samples being drawn (PK sample must be taken at the exact nominal time). ECGs will be collected and stored at site. See SRM for details on collection regarding ECGs.
19. PK samples to be taken in all participants for belantamab mafodotin ADC, total antibody and cys-mcMMAF measurements on:
    - C1D1 at pre-dose (within 30 minutes prior to SOI), at the end of infusion (EOI) (+5 min), 2 h post-SOI (±15 min), 4 h post-SOI (±15 min), 8 h post-SOI (±1 h), 24 h post-SOI (±2 h);
    - C1D4 anytime (±1 day);
    - C1D8 anytime (±1 day);
    - C1D15 anytime (±1 day);
    - C1D22 anytime (±1 day) (collect one PK sample only if the dose for the next cycle is delayed; this sample will combined)
    - For C2D1, C4D1, C6D1, C9D1, and C12D1, collect samples at pre-dose (within 30 min prior to SOI) and at the EOI (+5 min);
    - For every six cycles after C12 (e.g., C18, C24, etc.), collect one sample at pre-dose (within 30 min prior to SOI). However, one year after the first dose of last subject, PK samples will only be collected for the interpretation of ADA results in the following visits.
20. Collect 1 PK sample at each participant's final visit.
21. All ADA samples will be collected prior to each infusion at C1, C2, C4, C6, C9, C12, and every 6 cycles thereafter (C18, C24, etc.) until end of treatment (dosing days only) and at the last visit.
22. Disease Response Assessment: Response assessment must be conducted Q3W based on standard disease laboratory tests (serum and urine M protein test, FLC, IgD/E, if applicable), Ca corrected for albumin, bone marrow aspirate (in case of CR, or suspected PD if not evident otherwise). Assessment based on imaging has to be included in participants with extramedullary disease at indicated time points. Response evaluation will be performed according to the IMWG Uniform Response Criteria for Multiple Myeloma 2016.
23. For participants who are discontinuing IP due to PD the confirmation must performed on a different date from a different blood collection within 14 days of the original disease progression. This may be performed at the at EOT follow-up visit.
24. Skeletal Survey: Imaging of bones for lytic lesions by a method aligned with the institutional guidance (X-ray, CT, or [Computed tomography], or MRI [Magnetic resonance imaging]). Skeletal survey results within 30 days prior to C1D1 are acceptable.
25. Only if clinically indicated or if worsening clinical symptoms suggest PD.
26. Imaging is only required for participants with extramedullary disease (CT, MRI, or PET [Positron Emission Tomography]//CT can be applied per local guidance). Screening assessment may be performed up to 30 days prior to C1D1. The same modality should be used throughout the study (i.e., if PET scan was used as baseline, participant needs to be followed by PET scans). Plasmacytoma measurements should be taken from the CT portion of the PET/CT, or MRI scans, or dedicated CT scans where applicable. For participants with skin only involvement, skin lesions should be measured with a ruler. Measurement of tumor size will be determined by the Sum of the Products of the maximal perpendicular diameters of measured lesions (SPD). Evaluations should be performed by the same method as at screening.
27. In participants with extramedullary MM, if the last radiographic assessment occurred $\geqslant$8 weeks prior to the participant's withdrawal from study treatment, and progressive disease has NOT been documented –then a new assessment (presence or absence extramedullary disease) should be obtained at the time the participants withdrew from study treatment.
28. Only required for participants with IgD/E myeloma, where serum m-component cannot be followed otherwise
29. FISH testing at least for: t (4;14), t (14;16), 17p13del, and +1q21. FISH results from samples taken within 60 days prior to first dose are acceptable. If this cannot be performed at a local lab the samples can be sent to the central lab

30. CCI [redacted]
31. Bone Marrow for disease assessment performed within 14 days prior to first dose is acceptable.
32. Bone marrow biopsy for IHC to confirm sCR after achieving a CR.
33. CCI [redacted]
34. Belantamab mafodotin administration: Study drug administration ±3-day window.
35. Corneal management information:
    a. Prophylactic preservative-free artificial tears must be administered in each eye at least 4-8 times daily beginning on Cycle 1 Day 1 until end of treatment.
    b. At the start of each infusion, participants may apply cooling eye masks to their eyes for approximately 1 hour or as long as tolerated.
36. All related SAEs are to be collected from consent through PD follow-up.
37. Additional assessments may be conducted for those participants who experience a worsening in visual function. Participants who discontinue participation in the study will continue to be assessed during follow-up until resolution of visual symptoms. Continue to follow up with participants via telephone who are still experiencing visual symptoms even after discontinuation

14.3. Appendix 3: Assessment Windows

All assessments on study must be performed on a calendar schedule in Appendix 2: Schedule of Activities and must not be affected by dose interruptions/delays. For post-baseline assessments, a window of ±3 days is permitted to allow for flexible scheduling, and PD follow-up visits have a ±7 days window.

For analysis endpoints, the analysis visit will be re-mapped by the assessment time windows. In general, the summary tables will only be displayed by planned time points and visits, unless otherwise specified.

14.4. Appendix 4: Study Phases and Treatment Emergent Adverse Events

14.4.1. Study Phases

Assessments and events will be classified according to the time of occurrence relative to the start and/or stop date of the study treatment. The earliest and latest exposure treatment start and stop dates will be used to determine whether an assessment or event was pre-treatment, on-treatment or post-treatment. If it is not possible to tell whether an assessment or event was on-treatment or not it will be considered as on-treatment.

Study Phase	Definition
Pre-Treatment	Date ≤ Study Treatment Start Date
On-Treatment	Study Treatment Start Date < Date ≤ Study Treatment Stop Date + 70 days
Post-Treatment	Date > Study Treatment Stop Date + 70 days

NOTES:

- Time of study treatment dosing and assessments and events should be considered, if collected, then the study phases will be re-defined as following:
  Pre-Treatment: Date < Study Treatment Start Date
  On-Treatment: Study Treatment Start Date ≤ Date ≤ Study Treatment Stop Date + 70 days
  Post- Treatment: Date > Study Treatment Stop Date + 70 days

Concomitant Medication start and end dates will be assigned to study time periods in relation to first dose of study treatment as defined below. The start date references time flag variables and end date reference time flag variables will be added to the concomitant medication datasets, respectively.

- **Start relative to treatment:** Assign to 'BEFORE' if start date is prior to study treatment start date or if subject has not taken any study treatment or (start date is missing and end date is before study treatment start date). Else assign to 'DURING' if the start date falls into the on-treatment period as defined above or if subject is ongoing (not all study treatment discontinuation records completed) or start date is missing. Else assign to 'AFTER' if start date is after the on-treatment period.
- **End relative to** treatment: Assign to 'BEFORE' if end date is prior to study treatment start date or if subject has not taken any study treatment. Else assign to 'DURING' if start date falls into the on-treatment period or if subject is ongoing (not all study treatment discontinuation records completed) or (end date is missing and start relative to treatment not 'AFTER'). Else assign to 'AFTER' if start date is after the on-treatment period or (end date is missing and start relative to treatment='AFTER').

Concomitant medication starts relative to treatment and end relative to treatment flags are used to select data to include in the Concomitant Medication summaries as follows:

- Summary of Concomitant Medications: This summary will contain medications including those with start date prior to study treatment start date and continue (missing end date or end date after study treatment start date) on therapy. Note that any medications with start date and end date prior to study treatment start date will be excluded. In addition, any medication that was started during post-therapy will be

excluded. Include concomitant medication records where start relative to treatment in ('BEFORE','DURING') and end relative to treatment in ('DURING','AFTER').

- Summary of Concomitant Medications with On-Therapy Onset: This summary will contain medications with start date after study treatment start date. In addition, any medication that was started during post-therapy (see above for definition of post-therapy) will be excluded. Include concomitant medication records where start relative to treatment in ('DURING') and end relative to treatment in ('DURING','AFTER').

14.4.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent	• Study Treatment Start Date ≤ AE Start Date ≤ Study Treatment Stop Date + 70 days.

NOTES:

- If the study treatment stop date is missing, then the AE will be considered to be On-Treatment.
- Time of study treatment dosing and start/stop time of AEs should be considered, if collected.

14.5. Appendix 5: Data Display Standards & Handling Conventions

14.5.1. Reporting Process

Software	
• The currently supported versions of SAS software 9.4 will be used.	
Reporting Area	
HARP Server	: us 1salx00259
HARP Compound	: GSK2857916/mid208465
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards	
Generation of RTF Files	
• Rich Text Format (RTF) files will be generated for the final reporting effort for use in writing the CSR.	

14.5.2. Reporting Standards

General

• The current GSK Statistical Display Standards in the GSK Standards Library (IDSL) will be applied for reporting, unless otherwise stated (Library Location: https://spope.gsk.com/sites/IDSLLibrary/SitePages/Home.aspx):
  • 4.03 to 4.23: General Principles
  • 5.01 to 5.08: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics
• Do not include participant level listings in the main body of the GSK Clinical Study Report. All participant level listings should be located in the modular appendices as ICH or non-ICH listings

Formats
• GSK Statistical Display Principles (5.03 & 6.06.3) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected, unless otherwise stated. • Numeric data will be reported at the precision collected on the eCRF. • The reported precision from non eCRF sources will follow the GSK Standard Statistical Display Principles but may be adjusted to a clinically interpretable number of DP's.
Planned and Actual Time

• Reporting for tables, figures and formal statistical analyses:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to GSK Standard Statistical Display Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the participant's listings.

Unscheduled Visits
• Unscheduled visits will not be included in summary tables and/or figures that need to be summarized by visits. • All unscheduled visits will be included in listings.

Descriptive Summary Statistics	
Continuous Data	Refer to GSK Standard Statistical Display Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to GSK Standard Statistical Display Principals 7.01 to 7.13.	

14.5.3. Reporting Standards for Pharmacokinetic

Pharmacokinetic Concentration Data	
PC Windows Non-Linear (WNL) File	PC WNL file (CSV format) for the non compartmental analysis by Clinical Pharmacology Modelling and Simulation function will be created according to Standards for the Transfer and Reporting of PK Data document. Note: Concentration values will be imputed as per GUI_51487
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to the GSK Standard PK Display Standard. Refer to the GSK Standard Statistical Display Principle 6.06.1. Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.
NONMEM/Pop PK File	Not applicable.
NONMEM/PK/PD File	Not applicable.
Pharmacokinetic Parameter Derivation	
PK Parameter to be Derived by Programmer	The following PK parameter will be derived by the Programmer: • Accumulation ratios based on Cycle 1 and Cycle 4 CEOI and Ctrough values
Pharmacokinetic Parameter Data	
Is NQ impacted PK Parameters Rule Being Followed	Yes, refer to [Standards for Handling NQ Impacted PK Parameters].
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to GSK Standard PK Display Standard.

14.6. Appendix 6: Derived and Transformed Data

14.6.1. General

Multiple Measurements at One Analysis Time Point
• If there are two or more values within a time window (as per Section 14.3) the value closest to the target day for that window will be used for summary tables. If values are the same distance from the target, then the mean will be taken, but if listed, all data will be presented. • Participants having both High and Low values for Normal Ranges at any post-baseline visit for safety parameters will be counted in both the High and Low categories of "Any visit post-baseline" row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Study Day

• Calculated as the number of days from First Dose Date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < First Dose Date → Study Day = Ref Date – First Dose Date
  • Ref Data ≥ First Dose Date → Study Day = Ref Date – (First Dose Date) + 1

14.6.2. Study Population

Age
• Age will be calculated based on the date of first dose. • Only year of birth is collected on the eCRF, therefore day and month of birth are imputed as '30JUN' in order to derive age. • Birth date will be presented in listings as 'YYYY'.
Body Mass Index (BMI)
• Calculated as Weight (kg) / [Height $(m)^2$]
Extent of Exposure
• Number of days of exposure to study drug will be calculated based on the formula: **Duration of Exposure in Days = min(Last infusionDate+20, Death date) – First infusion Date + 1** • Participants who were enrolled but did not report a treatment start date will be categorised as having zero days of exposure. • The cumulative dose will be based on the formula: **Cumulative Dose (mg/kg) = Sum of Dose at Each Cycle** • Dose intensity will be calculated based on the formula: • **Dose intensity (mg/kg/3 week) = Cumulative Dose/((last infusion date – first infusion date + 21)/21)**

14.6.3. Efficacy

Objective Response Rate ORR
• ORR will be calculated based on the formula: **ORR = Number of Participants with a Confirmed Partial Response (PR) or Better / Number of Participants in All Treated Population**

14.6.4. Safety

Adverse Events of Special Interest (AESI)
• AESI includes corneal events, thrombocytopenia and infusion related reactions
Laboratory Parameters
• If a laboratory value which is expected to have a numeric value for summary purposes, has a non-detectable level reported in the database, where the numeric value is missing, but typically a character value starting with '<x' or '>x' (or indicated as less than x or greater than x in the comment field) is present, the number of significant digits in the observed values will be used to determine how much to add or subtract in order to impute the corresponding numeric value. • Example 1: 2 Significant Digits = '< x ' becomes x – 0.01 • Example 2: 1 Significant Digit = '> x' becomes x + 0.1 • Example 3: 0 Significant Digits = '< x' becomes x – 1

14.6.5. Pharmacokinetic

PK
• Plasma sample analysis will be performed under the control of GSK Bioanalysis Immunogenicity and Biomarkers (BIB) group, the details of which will be included in the Study Reference Manual (SRM). Belantamab mafodotin, total antibody, and cys-mcMMAF plasma concentrations will be determined using the currently validated methodology. The actual sampling times, if different from protocol, will be used in the PK calculations. Please refer to the rules in Section 14.7.2 for the plasma concentrations below Limit of quantification (LOQ). • Belantamab mafodotin, total antibody, and cys-mcMMAF plasma concentration-time data will be analyzed by non-compartmental methods with WinNonlin 6.3 or above and derived PK parameters will be summarised and listed. Derived Pharmacokinetic parameters will be summarized by cycle and dose level. Mean, standard deviation, median, minimum, maximum, geometric mean, and the standard deviation, CV%, and 95% CI of parameters values will be provided; Individual concentration, linear and semi-logarithmic individual concentration-time profiles, and mean and median profiles (when appropriate) will be provided.

14.7. Appendix 7: Reporting Standards for Missing Data

14.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Participant study completion (i.e. as specified in the protocol) was defined as completed all scheduled visit and completed exit visit. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified. • The Withdrawal visit will be slotted as per Appendix 3: Assessment Windows or will be summarised as the withdrawal visit.

14.7.2. Handling of Missing Data

<table>
<tr><th>Element</th><th>Reporting Detail</th></tr>
<tr><td>General</td><td>• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument:
○ These data will be indicated by the use of a “blank” in participant listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table.
○ Answers such as “Not applicable” and “Not evaluable” are not considered to be missing data and should be displayed as such.</td></tr>
<tr><td>Outliers</td><td>• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.</td></tr>
<tr><td>PK</td><td>• Concentrations which are below the LLQ (“lower limit of quantification” for the analyte in question) are listed as NQ in the raw concentration data provided by DMPK. Several derived variables exist for the imputation of these concentrations.
• The following variables exist in the PKCNC dataset for different imputations of the raw concentration data;
PCORRES: Original result
PCSTRESN: Original result in standard units
PCSTIMPN: Imputed result for use in the calculation of summary statistics
PCSTIMSN: Imputed result for individual concentration plots
PCWNLN: Imputed result for use in WinNonlin analysis
• The imputation of NQs for variables in the PKCNC file will be based on that defined in GUI_51487, under the section “How to Handle Values Below the Quantification Limit”. A brief summary is provided in the table below.
<table>
<tr><th>Variable</th><th>Leading NQ</th><th>Single NQ between measurable concentrations</th><th>More than one consecutive NQ between measurable concentrations</th><th>Measurable concentrations after more than one consecutive mid-profile NQ*</th><th>Trailing NQ (consecutive NQs in the tail)</th></tr>
<tr><td>PCSTIMPN</td><td>0</td><td>NULL</td><td>0</td><td>NULL</td><td>0</td></tr>
<tr><td>PCSTIMSN</td><td>0</td><td>NULL</td><td>0</td><td>No Action</td><td>NULL</td></tr>
<tr><td>PCWNLN</td><td>0</td><td>NULL</td><td>NULL</td><td>NULL</td><td>NULL</td></tr>
</table>
</td></tr>
</table>

Element	Reporting Detail
	* a mid-profile NQ is defined as any NQ where measurable concentrations exist both before and after that NQ in the profile

14.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in participant listing displays. • Imputed partial dates will not be used to derive study day, duration (e.g. duration of adverse events), or elapsed time variables. In addition, imputed dates are not used for deriving the last contact date in the overall survival analysis dataset. • Imputed dates will not be displayed in listings. However, where necessary, display macros may impute dates as temporary variables for the purpose of sorting data in listings only. In addition, partial dates may be imputed for 'slotting' data to study time periods or for specific analysis purposes as outlined below.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. ○ Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment Emergent Adverse Events. ○ Missing Stop Day: Last day of the month will be used. • Completely missing start dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing. • Completely missing end dates will remain missing, with no imputation applied. Consequently, duration of such events will be missing.
Concomitant Medications/Medical History	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month ○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. • The recorded partial date will be displayed in listings.
Covariates for efficacy analysis (Date of initial diagnosis/ Last recurrence/ Last progression)	• If both month and day are missing, first of January will be used • If only day is missing, first of the month will be used
Treatment end date	• If there is more than one study treatment, imputation of missing treatment end date will be applied to all applicable treatments following rules below and treatment end date is the latest treatment end date across all study treatments. In general, completely missing end dates are not imputed, with the following exceptions for imputation of missing treatment end date at interim analyses. • For imputation of missing exposure end date at an interim analysis when participants are still on treatment, the following conventions will be applied:

Element	Reporting Detail
	○ If the missing end date is in the last exposure record, the earliest of: the date of the data cut-off, the date of withdrawal from the study, or the death date will be used ○ If the missing end date is not in the last exposure record, treatment start date for the record will be used • The imputed treatment end date will be used to calculate cumulative dose and duration of treatment as specified in Section 14.6.2. • If treatment end date is missing for a cycle, treatment start date for the cycle will be used.

14.8. Appendix 8: Values of Potential Clinical Importance

14.8.1. Laboratory Values

Reference ranges for all laboratory parameters collected throughout the study are provided by the laboratory. A laboratory value that is outside the reference range is considered either high abnormal (value above the upper limit of the reference range) or low abnormal (value below the lower limit of the reference range). Note: a high abnormal or low abnormal laboratory value is not necessarily of clinical concern. The laboratory reference ranges will be provided on the listings of laboratory data. Clinical laboratory test results outside of the reference range will be flagged in the listings.

To identify laboratory values of potential clinical importance, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE v5.0) will be used to assign grades to the relevant laboratory parameters. NCI-CTCAE v5.0 can be found at http://ctep.cancer.gov/reporting/ctc.html.

For laboratory data which are not listed in the NCI CTCAE v5.0, a summary of values outside the normal range will be provided.

14.8.2. ECG Parameters and Vital Signs

For ECG and vital signs, outputs per the most updated IDSL standard up to the RAP effective date will be provided.

Unless otherwise specified, ECG displays will be based on central reading.

14.9. Appendix 9: Pharmacokinetic / Pharmacodynamic Analyses

14.9.1. Pharmacokinetic / Pharmacodynamic Dataset Specification

If deemed appropriate and if data permit, dose/exposure - objective response relationships between belantamab mafodotin dose/exposure and clinical activity may be explored based on pooled data from Study 208465 and overseas studies using population methods. Dose/exposure will be assessed based on dose intensity, duration of exposure in days, Cmax and AUC. Clinical activity will be assessed based on objective response which is defined as the confirmed stringent complete response (sCR), complete response (CR), very good partial response (VGPR), and partial response (PR) as assessed by IMWG. The response is a binary term (e.g., 0 or 1, 1 = confirmed partial response (PR) or better; 0 = other response or NE).

If deemed appropriate and if data permit, dose/exposure - toxicity relationships between belantamab mafodotin dose/exposure and safety activity may be explored using above method. Safety activity will be assessed based on Dose-Limiting Toxicity (DLT). The response is also a binary term (e.g., 0 or 1, 1 = experienced DLT; 0 = non-experienced DLT).

If data permit, the effects of covariates (e.g., race, age, body weight) may also be explored.

The analyses will be based on the PK population, unless otherwise specified.

14.9.2. Pharmacokinetic / Pharmacodynamic Methodology

If deemed appropriate and if data permit, dose/exposure- safety/clinical activity relationships will be analysed using logistic regression. Generalized linear mixed model (GLMM) will be used which includes the terms of response of safety/clinical activity, dose intensity, duration of exposure in days, Cmax and AUC, If data permit, the effects of covariates (e.g., race, age, body weight) may also be included.

In order to determine which terms impact the response of safety/clinical activity significantly, the step-by-step method will be used to select the statistical significant terms.

The results of analyses based on the final model will be presented as estimated effect of selected terms, 2-sided 95% confidence intervals (CI), and associated p-values.

14.10. Appendix 10: Pharmacodynamic Biomarkers and Exploratory Response Prediction Biomarkers

CCI

14.11. Appendix 11: Abbreviations & Trade Marks

14.11.1. Abbreviations

Abbreviation	Description
ADA	Anti-drug antibodies
ADC	Antibody drug conjugate
AE	Adverse Event
AUC	Area under the curve
BCMA	B-cell maturation antigen
BM	Bone marrow
BNP	B-type natriuretic peptide
BP	Blood Pressure
C1D1	Cycle 1 Day 1
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence interval
CK	Creatine kinase
CL	Clearance
C_{max}	Maximum observed concentration
CR	Complete response
CRF	Case Report Form
CRP	C-reactive protein
CSR	Clinical study report
CT	Computed tomography
Ctrough	Trough plasma concentration after repeat dose
CV	Coefficient of variation
DLT	Dose limiting toxicities
DP's	Decimal Places
ECG	Electrocardiogram
ECHO	Echocardiogram
ECOG	Eastern Cooperative Oncology Group
EOI	End of Infusion
eCRF	Electronic case report form
eGFR	Estimated glomerular filtration rate
EOT	End of treatment
FISH	Fluorescence in situ hybridization
FLC	Free light chain
FSH	Follicle stimulating hormone
GFR	Glomerular filtration rate
GSK	GlaxoSmithKline
HCV	Hepatitis C virus
HR	Heart rate
ICH	International Conference on Harmonization
IDSL	Integrated Data Standards Library (GSK Standards Library)
IHC	Immunohistochemistry
IgA	Immunoglobulin A

Abbreviation	Description
IgD	Immunoglobulin D
IgE	Immunoglobulin E
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IMWG	International Myeloma Working Group
IV	Intravenous
LC	Light chain
LVEF	Left ventricular ejection fraction
MDRD	Modified diet in renal disease
MMAF	Monomethyl auristatin-F
CCI [redacted]	
MRI	Magnetic resonance imaging
NE	Not Evaluable
ORR	Objective Response Rate
OSDI	Ocular Surface Disease Index
PD	Progressive disease
PDMP	Protocol Deviation Management Plan
PET	Positron Emission Tomography
PK	Pharmacokinetics
PR	Partial response
Q3W	Once every 3 weeks
QID	Four times a day
QTc	Corrected QT interval (ECG)
QTcF	Corrected QT interval Fridericia
RAP	Reporting and Analysis Plan
RNA	Ribonucleic acid
RRMM	Relapsed / refractory multiple myeloma
RTF	Rich Text Format
SAC	Statistical Analysis Complete
SAE	Serious adverse event
sCR	Stringent Complete Response
SCT	Stem cell transplant
SoA	Schedule of activities
SOI	Start of infusion
SOP	Standard operating procedure
SPD	Sum of the products of the maximal perpendicular diameters of measured lesions
SPEP	Serum Protein Electrophoresis
SRM	Study Reference Manual
t½	Terminal phase half-life
T_{max}	Time of maximum observed concentration
UPEP	Urine protein electrophoresis
V	Volume of distribution
VGPR	Very good partial response

14.11.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
HARP

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS
WinNonlin

14.12. Appendix 12: List of Data Displays

All data displays will use the term "subject" rather than "participant" in accordance with CDSIC and GSK Statistical Display Standards.

14.12.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.010 to 1.xxx	1.010 to 1.xxx
Efficacy	2.010 to 2.xxx	2.010 to 2.xxx
Dose Limiting Toxicity	3.010 to 3.xxx	3.010 to 3.xxx
Safety	4.010 to 4.xxx	4.010 to 4.xxx
Immunogenicity	5.010 to 5.xxx	5.010 to 5.xxx
Pharmacokinetic / Biomarker	6.010 to 6.xxx	6.010 to 6.xxx
Section	**Listings**	
ICH Listings	1.010 to xxx	
Other Listings	30.010 to 30.xxx	

14.12.2. Mock Example Shell Referencing

Non IDSL pecifications will be referenced as indicated and if required example mock-up displays provided in Appendix 13: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Dose Limiting Toxicity	DLT_Fn	DLT_Tn	DLT_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Immunogenicity	ADA_Fn	ADA_Tn	ADA_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
Pharmacokinetic / Pharmacodynamic	PKPD_Fn	PKPD_Tn	PK/PD_Ln
CCI			

NOTES:

- Non-Standard displays are indicated in the 'GSK Statistical Display Standard / Example Shell' or 'Programming Notes' column as '[Non-Standard] + Reference.'

14.12.3. Deliverables

Delivery [Priority] [1]	Description
SAC [1]	Final Statistical Analysis Complete

NOTES:

1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort

14.12.4. Study Population Tables

Study Population Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.010	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal		SAC [1]
1.020	Screened	ES6	Summary of Screening Status and Screening Failures		SAC [1]
1.030	All Treated	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment		SAC [1]
Protocol Deviation					
1.040	All Treated	DV1	Summary of Important Protocol Deviations		SAC [1]
Population Analysed					
1.050	Screened	SP1	Summary of Study Populations		SAC [1]
Demographic and Baseline Characteristics					
1.060	All Treated	DM1	Summary of Demographic Characteristics		SAC [1]
Disease Characteristics					
1.070	All Treated	DC2	Summary of Disease Characteristics		SAC [1]
1.080	All Treated	POP_T1	Summary of Genetic Characteristics and Cytogenetics Risk at Screening		SAC [1]
Medical Conditions					
1.090	All Treated	MH1	Summary of Current Medical Conditions		SAC [1]
Prior and Follow-Up Anti-Cancer Therapy					

Study Population Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.100	All Treated	POP_T3	Summary of Prior Anti-Cancer Therapy by Drug Class of Agents		SAC [1]
1.110	All Treated	POP_T4	Summary of Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class		SAC [1]
Extent of Exposure					
1.120	All Treated	EX1 / EX5	Summary of Exposure to Belantamab Mafodotin		SAC [1]
1.130	All Treated	OEX6	Summary of Dose Reductions of Belantamab Mafodotin		SAC [1]
1.140	All Treated	OEX6	Summary of Dose Delays of Belantamab Mafodotin		SAC [1]
1.150	All Treated	Non-Standard	Summary of Dose Modifications of Belantamab Mafodotin		SAC [1]
Prior and Concomitant Medications					
1.160	All Treated	CM8	Summary of Concomitant Medications		SAC [1]
1.170	All Treated	CM8	Summary of Blood Products		SAC [1]
1.180	All Treated	CM8	Summary of Blood Supportive Care Products		SAC [1]

14.12.5. Study Population Figures

No figures of study population analysis.

14.12.6. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
2.010	All Treated	Non-Standard	Summary of Objective Response Rate		SAC [1]
Time-to Event Endpoint					
2.020	All Treated	TTE1a	Summary of Duration of Response		SAC [1]
CCI [redacted]					

14.12.7. Efficacy Figures

No figures of efficacy data analysis.

14.12.8. Dose Limiting Toxicity Tables

Dose Limiting Toxicity: Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Dose Limiting Toxicity (DLT)					
3.010	DLT Evaluable	AE19	Summary of Dose Limiting Toxicity During the Cycle 1 of Study Treatment		SAC [1]

14.12.9. Dose Limiting Toxicity Figures

No figures of dose limiting toxicity.

14.12.10. Safety Tables

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
4.010	All Treated	AE13	Adverse Event Overview		SAC [1]
4.020	All Treated	AE3	Summary of All Adverse Events by Preferred Term		SAC [1]
4.030	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade		SAC [1]
4.040	All Treated	OAE07	Summary of All Treatment-Related Adverse Events by Preferred Term and Maximum Grade		SAC [1]
4.050	All Treated	OAE07	Summary of Non-Serious Adverse Events by Preferred Term and Maximum Grade		SAC [1]
4.060	All Treated	AE3	Summary of Adverse Events of Maximum Grade 3 or Higher by Preferred Term		SAC [1]
Adverse Events of Special Interest					
4.070	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade		SAC [1]
4.080	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and Maximum Grade		SAC [1]
4.090	All Treated	OAE07	Summary of Infusion Related Reactions by Preferred Term and Maximum Grade		SAC [1]
4.100	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events		SAC [1]
4.110	All Treated	ESI1	Summary of Characteristics of Corneal Events		SAC [1]
4.120	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia		SAC [1]
4.130	All Treated	AE3	Summary of Corneal Events Leading to Dose Modification by Preferred Term		SAC [1]
Serious and Other Significant Adverse Events					
4.140	All Treated	AE3	Summary of Serious Adverse Events by Preferred Term		SAC [1]
4.150	All Treated	AE3	Summary of All Treatment-Related Serious Adverse Events by Preferred Term		SAC [1]

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.160	All Treated	AE1	Summary of Adverse Events Leading to Dose Modification by System Organ Class and Preferred Term		SAC [1]
Laboratory: Chemistry					
4.170	All Treated	OLB9B	Summary of Chemistry Worst Grade Changes from Baseline Grade		SAC [1]
Laboratory: Hematology					
4.180	All Treated	OLB9B	Summary of Hematology Worst Grade Changes from Baseline Grade		SAC [1]
Laboratory: Hepatobiliary (Liver)					
4.190	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities		SAC [1]
ECG					
4.200	All Treated	EG1	Summary of ECG Findings		SAC [1]
4.210	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc		SAC [1]

14.12.11. Safety Figures

No figures of safety data analysis.

14.12.12. Immunogenicity/Biomarker Tables

Immunogenicity/Biomarker: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Immunogenicity					
5.010	All Treated	SAFE_T5	Summary of Anti-Belantamab Mafodotin Antibodies (ADA)		SAC [1]
CCI [redacted]					

14.12.13. Immunogenicity Figures

No figures of immunogenicity.

14.12.14. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK Concentration Data					
6.010	PK	PK01	Summary of Plasma Belantamab Mafodotin (ADC) PK Concentration-Time Data		SAC [1]
6.011	PK	PK01	Summary of Plasma Belantamab Mafodotin (Total Antibody) PK Concentration-Time Data		SAC [1]
6.012	PK	PK01	Summary of Plasma cys-mcMMAF PK Concentration-Time Data		SAC [1]
PK Parameter Data					
6.020	PK	PK06	Summary of Derived Belantamab Mafodotin (ADC) PK Parameters	PK06 with both transformed and untransformed values.	SAC [1]
6.021	PK	PK06	Summary of Derived Belantamab Mafodotin (Total Antibody) PK Parameters	PK06 with both transformed and untransformed values.	SAC [1]
6.022	PK	PK06	Summary of Derived cys-mcMMAF PK Parameter	PK06 with both transformed and untransformed values.	SAC [1]
Accumulation Ratio					
6.023	PK	PK05	Summary of Results of Accumulation Ratio Assessment for Belantamab Mafodotin (ADC)	Include Ro(CEOI) and Ro(Ctrough) with 95%CI in one table.	SAC [1]
6.024	PK	PK05	Summary of Results of Accumulation Ratio Assessment for Belantamab Mafodotin (Total Antibody)	Include Ro(CEOI) and Ro(Ctrough) with 95%CI in one table.	SAC [1]
6.025	PK	PK05	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF	Include Ro(CEOI) and Ro(Ctrough) with 95%CI in one table.	SAC [1]

14.12.15. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK Concentration Data					
6.010	PK	PK16	Individual Plasma Belantamab Mafodotin (ADC) Concentration-Time Plots (Linear and Semi-Log)		SAC [1]
6.011	PK	PK16	Individual Plasma Belantamab Mafodotin (Total Antibody) Concentration-Time Plots (Linear and Semi-Log)		SAC [1]
6.012	PK	PK16	Individual Plasma cys-mcMMAF Concentration-Time Plots (Linear and Semi-Log)		SAC [1]
6.020	PK	PK17	Mean Plasma Belantamab Mafodotin (ADC) Concentration-Time Plots (Linear and Semi-Log)		SAC [1]
6.021	PK	PK17	Mean Plasma Belantamab Mafodotin (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log)		SAC [1]
6.022	PK	PK17	Mean Plasma Belantamab Mafodotin (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log)		SAC [1]
6.030	PK	PK18	Median Plasma Belantamab Mafodotin (ADC) Concentration-Time Plots (Linear and Semi-Log)		SAC [1]
6.031	PK	PK18	Median Plasma Belantamab Mafodotin (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log)		SAC [1]
6.032	PK	PK18	Median Plasma Belantamab Mafodotin (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log)		SAC [1]

14.12.16. Pharmacokinetic / Pharmacodynamic Tables

No tables of Pharmacokinetic / Pharmacodynamic.

14.12.17. Pharmacokinetic / Pharmacodynamic Figures

No figures of Pharmacokinetic / Pharmacodynamic.

CCI

[redacted]

CCI

[redacted]

14.12.20. ICH Listings

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.010	All Treated	ES2	Listing of Reasons for Study Withdrawal		SAC [1]
1.020	All Treated	SD2	Listing of Reasons for Study Treatment Discontinuation		SAC [1]
1.030	All Treated	CP_RA1p	Listing of Planned and Actual Treatments		SAC [1]
Protocol Deviations					
1.040	All Treated	DV2	Listing of Important Protocol Deviations		SAC [1]
1.050	All Treated	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations		SAC [1]
Demographic and Baseline Characteristics					
1.060	All Treated	DM2	Listing of Demographic Characteristics		SAC [1]
Prior and Concomitant Medications					
1.070	All Treated	CM3	Listing of Prior and Concomitant Medications		SAC [1]
Exposure and Treatment Compliance					
1.080	All Treated	EX3	Listing of Exposure Data		SAC [1]
1.090	All Treated	ODMOD10A	Listing of Dose Reduction		SAC [1]
1.100	All Treated	ODMOD12A	Listing of Dose Delays		SAC [1]
Response					
1.110	All Treated	Non-	Listing of Investigator-Assessed Responses		SAC [1]
1.120	All Treated	TT9	Listing of Duration of Response		SAC [1]
Adverse Events					
1.130	All Treated	AE8	Listing of All Adverse Events		SAC [1]

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.140	All Treated	AE7	Listing of Subject Numbers for Individual Adverse Events		SAC [1]
1.150	All Treated	AE2	Listing of Relationship Between Adverse Event Preferred Term and Verbatim Text		SAC [1]
Serious and Other Significant Adverse Events					
1.160	All Treated	OAE4	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment		SAC [1]
1.170	All Treated	OAE4	Listing of Adverse Events Leading to Dose Reduction of Study Treatment		SAC [1]
1.180	All Treated	OAE4	Listing of Adverse Events Leading to Dose Interruptions of Study Treatment		SAC [1]
1.190	All Treated	OAE4	Listing of Serious Adverse Events		SAC [1]
1.200	All Treated	OAE4	Listing of Corneal Events		SAC [1]
1.210	All Treated	OAE4	Listing of Thrombocytopenia		SAC [1]
All Laboratory					
1.220	All Treated	OLB13	Listing of Laboratory Data with Character Results		SAC [1]
1.221	All Treated	LB5	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance		SAC [1]
ECOG					
1.230	All Treated	PS5A	Listing of ECOG Performance Status		SAC [1]
PK					
1.240	PK	PK07	Listing of Plasma Belantamab Mafodotin (ADC) Pharmacokinetic Concentration-Time Data		SAC [1]
1.250	PK	PK07	Listing of Plasma Belantamab Mafodotin (Total Antibody) Pharmacokinetic Concentration-Time Data		SAC [1]

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.260	PK	PK07	Listing of Plasma cys-mcMMAF Pharmacokinetic Concentration-Time Data		SAC [1]
1.270	PK	PK03	Listing of Derived Belantamab Mafodotin (ADC) PK Parameters (Untransformed)		SAC [1]
1.280	PK	PK03	Listing of Derived Belantamab Mafodotin (Total Antibody) PK Parameters (Untransformed)		SAC [1]
1.290	PK	PK03	Listing of Derived cys-mcMMAF PK Parameters (Untransformed)		SAC [1]
1.300	PK	PK15	Listing of Belantamab Mafodotin (ADC) CEOI and Ctrough Accumulation Ratio		SAC [1]
1.310	PK	PK15	Listing of Belantamab Mafodotin (Total Antibody) CEOI and Ctrough Accumulation Ratio		SAC [1]
1.320	PK	PK15	Listing of cys-mcMMAF CEOI and Ctrough Accumulation Ratio		SAC [1]

14.12.21. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
30.010	Screened	ES7	Listing of Reasons for Screening Failure		SAC [1]
Medical Conditions					
30.020	All Treated	MH3	Listing of Medical Conditions		
Anti-Cancer Therapy, Radiotherapy and Surgical Procedures					
30.030	All Treated	AC6	Listing of Prior Anti-Cancer Therapy		SAC [1]
Disease Characteristics					
30.040	All Treated	DC4	Listing of Disease Characteristics		SAC [1]
ECG					
30.050	All Treated	OECG5A	Listing of Fridericia's QTc Values of Potential Clinical Importance		SAC [1]
Vital Signs					
30.060	All Treated	VS4	Listing of Vital Signs		SAC [1]
Anti-Drug Antibody					
30.070	All Treated	SAFE_L3	Listing of Anti-Belantamab Mafodotin Antibody Results		SAC [1]
CCI [redacted]					
Genetic Characteristics					
30.090	All Treated	Non-Standard	Listing of Genetic Characteristics		SAC [1]
Prior and Concomitant Medications					

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.100	All Treated	Non-Standard	Listing of Blood Products		SAC [1]
30.110	All Treated	Non-Standard	Listing of Blood Supportive Care Products		SAC [1]

14.13. Appendix 13: Example Mock Shells for Data Displays

The data display mock shells will be contained in separate documents which will be available on request.