Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)

Title	:	Reporting and Analysis Plan for A Phase I/II Single Arm Open-Label Study to Explore Safety and Clinical Activity of Belantamab Mafodotin Administered in Combination with Pembrolizumab in Subjects with Relapsed/Refractory Multiple Myeloma (DREAMM 4)
Compound Number	:	GSK2857916
Effective Date	:	29 Aug 2022

Description:

- The purpose of this RAP is to influence and impact protocol development and other documents and support key operational/data management study set-up activities for Protocol of study 205207 (DREAMM 4) [GSK Document Number.: TMF-14344600, Dated: 22-FEB-2022].
- This RAP is intended to describe the safety, tolerability, pharmacokinetics, and efficacy analyses required for the study.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

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1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the Clinical Study Report for Protocol 205207.

All data displays (Tables, Figures & Listings) will use the term "Subject" which reflects CDISC and GSK Data Display Standards terminology.

Revision Chronology:		
2016N273410_00	11-MAY-2017	Original
2016N273410_01	26-SEP-2018	Amendment 01 The protocol had been amended to address feedback from regulatory agencies. The lowest dose level (1.92 mg/kg) in dose escalation phase is removed. To accommodate these changes, the statistical model in dose escalation is revised from Bayesian Logistic Regression Model to modified mTPI and the overall sample size and related analytical methods have been changed. Part 2 stopping criteria has been added for continuous safety monitoring.
2016N273410_02	26-FEB-2020	Amendment 02 The protocol had been amended to address feedback from regulatory agencies, inclusions of items noted in protocol clarification letters, revisions due to discrepancies, revision of study drug related language and other clarifications. DLT evaluable population is included to analysis population to further define Part 1 population.
TMF-12902367	27-AUG-2021	Amendment 03 The protocol had been amended to update pembrolizumab safety, ECI-overdose language, and standard text based on latest IB update for pembrolizumab (2021) and belantamab mafodotin (2021). Addition of the primary analysis at approximately 15 months follow-up from LSLV. Update on planned derived PK parameters and PK/PD analyses, update to data monitoring language, medical monitoring information, and SAE reporting.
TMF-14344600	21-FEB-2022	Amendment 04 The protocol has been amended to provide updates including the addition of the end of study definition Section and continued access to study intervention after the end of the study Section (Post Analysis Continued Treatment [PACT]). Additional contents for risk assessment and mitigation strategy and updated PK and PD Section.

1.1. RAP Amendments

Revision chronology:

RAP Section	Amendment Details
Reporting and Analysis Plan_Study205207_Final_V1 27-OCT-2021	
Reporting and Analysis Plan_Study205207_Amendment_Final_V1 05-AUG-2022	
8.2.1.1 Eye Disorders, Thrombocytopenia, and Infusion Related Reactions	• Updated onset and duration of first occurrence language
8.7 Clinical Laboratory Analyses	• Included additional summary of worst case urinalysis results from baseline
8.8.4 Immunogenicity Analyses	• Included additional summary of immunogenicity incidence
10 Population Pharmacokinetic Analyses	• Removed dataset specifications language
16.9. Appendix 9 Population Pharmacokinetic (PopPK) Analyses	• Removed PopPK dataset specifications
16.11.3 Deliverables	• Updated SAC deliverables for primary and final analyses
16.11.5 Efficacy Tables	• Updated time-to-event displays to include GSK2857916 2.5 mg/kg + Pembro 200 mg Escalation and GSK2857916 2.5 mg/kg + Pembro 200 mg Overall treatment arms
16.11.6 Efficacy Figures	• Updated time-to-event displays to include GSK2857916 2.5 mg/kg + Pembro 200 mg Escalation and GSK2857916 2.5 mg/kg + Pembro 200 mg Overall treatment arms
16.11.7 Safety Tables	• Updated negative ADA results in Anti-GSK2857916 Antibodies (ADA) displays • Included Table 3.0094 "GSK2857916 Immunogenicity Incidence and Summary" • Included Table 3.0067 "Summary of Worst Case Urinalysis Results Post-Baseline Relative to Baseline"
16.11.14 ICH-Listings	• Updated time-to-event displays to include GSK2857916 2.5 mg/kg + Pembro 200 mg Escalation and GSK2857916 2.5 mg/kg + Pembro 200 mg Overall treatment arms
16.11.15 Non-ICH Listings	• The following listings were requested by CPMS to remove: Listing 1.0068 "Listing of Derived Plasma GSK2857916 (ADC) Secondary Pharmacokinetic Parameters", Listing 1.0069 "Listing of Derived Plasma GSK2857916 (Total Antibody) Secondary Pharmacokinetic Parameters", Listing 1.0070 "Listing of Derived Plasma GSK2857916 (cyc-mcMMAF) Secondary Pharmacokinetic Parameters"
16.12. Appendix 12 Example Mock Shells for Data Displays	• Removed mock shells as per current GSK disclosure process

RAP Section	Amendment Details
Reporting and Analysis Plan_Study205207_Amendment 2_Final_V1 [Refer to Document Date]	
16.11 Appendix 11 List of Data Displays	• Updated final analysis deliverable to include some additional data displays that were planned for primary analysis only

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 amendment 4 GSK Document Number TMF-14344600 (Dated: 21/FEB/2022).

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

Part 1: Dose Escalation

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To determine safety, tolerability and to establish the recommended Phase 2 dose (RP2D) of the combination of belantamab mafodotin and pembrolizumab in subjects with RRMM	• Percent of subjects with adverse events (AEs), changes in clinical signs and laboratory parameters • Number of subjects with dose limiting toxicities (DLTs)
Secondary Objectives	**Secondary Endpoints**
• To evaluate clinical activity of the combination of belantamab mafodotin and pembrolizumab in subjects with RRMM	• Overall Response Rate (ORR), defined as the percentage of subjects with a confirmed partial response (PR) or better (i.e., PR, very good partial response [VGPR], complete response [CR] and stringent complete response [sCR]), according to the International Myeloma Working Group (IMWG) Response Criteria [Kumar, 2016].
• To evaluate the pharmacokinetic profile of belantamab mafodotin when administered intravenously in combination with pembrolizumab[1]	• Pharmacokinetic (PK) parameters following IV administration as data permit.
• To assess anti-drug antibodies (ADAs) against belantamab mafodotin[1]	• Incidence and titers of ADAs against belantamab mafodotin
Exploratory Objectives	**Exploratory Endpoints**
• To assess Minimal Residual Disease (MRD) in participants who achieve ≥VGPR or better	• Minimal Residual Disease (MRD) negativity rate, defined as: the percentage of subjects who are MRD negative in subjects who achieve VGPR or CR
• To characterize the relationship between clinical response and other biologic characteristics	• BCMA expression levels on malignant cells, serum sBCMA levels, serum cytokines, and immune cell characterization and their relationship to clinical response (Protein, RNA, DNA analysis)
• To investigate the relationship between genetic variants in the host and response to belantamab mafodotin in combination with pembrolizumab	• Possible relationship between host genetic variation and response to belantamab mafodotin in combination with pembrolizumab
• To evaluate the tolerability of belantamab mafodotin in combination with pembrolizumab based on patient	• Symptomatic adverse effects as measured by the Patient-reported outcome version of the Common Term Criteria for Adverse Events (PRO-CTCAE)

Objectives	Endpoints
self-report of symptomatic adverse effects	• Impact of ocular adverse effects on quality of life as measured by the Visual Function questionnaire(s): National Eye Institute 25-item Visual Function Questionnaire (NEI-VFQ-25) and Ocular Surface Disease Index (OSDI)
• To evaluate disease and treatment related symptoms and associated impacts on function and health-related quality of life	• Exit Interview

[1] PK and ADA samples for pembrolizumab will be collected and stored during the trial. The analysis will be triggered only in case of unexpected clinical findings.

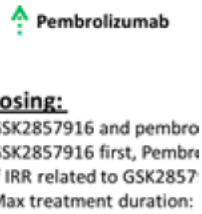
Part 2: Expansion

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To assess the clinical activity of the combination treatment with belantamab mafodotin and pembrolizumab in subjects with RRMM	• Overall Response Rate (ORR), defined as the percentage of subjects with a confirmed PR or better (i.e., PR, VGPR, CR and sCR), according to the IMWG Response Criteria [Kumar, 2016].
Secondary Objectives	**Secondary Endpoints**
• To further evaluate the safety of belantamab mafodotin administered in combination with pembrolizumab in subjects with RRMM	• Number (percent) of subjects with AEs, changes in clinical signs and laboratory parameters • Ocular finding on ophthalmic exam
• To further assess the clinical activity of the combination treatment with belantamab mafodotin and pembrolizumab in subjects with RRMM	• Clinical benefit rate (CBR), defined as the percentage of participants with a confirmed minimal response (MR) or better per IMWG • Duration of response (DoR), defined as: the time from first documented evidence of PR or better, to the time when disease progression (PD) is documented per IMWG; or death due to PD occurs among subjects who achieve an overall response, i.e. confirmed PR or better • Time to response (TTR), defined as: the time between the date of first dose and the first documented evidence of response (PR or better) among participants who achieved a confirmed response of PR or better • Time to best response, defined as the time between the date of first dose and the first best documented response (PR or better) among subjects who achieved a confirmed response of PR or better • Progression-free survival (PFS), defined as: the time from first dose until the earliest date of PD per IMWG, or death due to any cause • Time to disease progression (TTP), defined as: the time from first dose until the earliest date of PD per IMWG, or death due to PD • Overall Survival (OS), defined as the time from first dose until death due to any cause
• To evaluate the pharmacokinetic	• Pharmacokinetic (PK) parameters following IV

Objectives	Endpoints
profile of belantamab mafodotin when administered intravenously in combination with pembrolizumab[1]	administration as data permit.
• To assess ADAs against belantamab mafodotin[1]	• Incidence and titer of ADA to belantamab mafodotin
Exploratory Objectives	**Exploratory Endpoints**
• To assess Minimal Residual Disease (MRD) in participants who achieve ≥VGPR or better	• Minimal Residual Disease (MRD) negativity rate, defined as: the percentage of subjects who are MRD negative in subjects who achieve VGPR or CR
• To characterize the relationship between clinical response and other biologic characteristics	• BCMA expression levels on malignant cells, serum sBCMA levels, serum cytokines, and immune cell characterization and their relationship to clinical response (Protein, RNA, DNA analysis).
• To investigate the relationship between genetic variants in the host and response to belantamab mafodotin in combination with pembrolizumab	• Possible relationship between host genetic variation and response to belantamab mafodotin administered in combination with pembrolizumab
• To explore the effect of belantamab mafodotin in combination with pembrolizumab on symptoms and health-related quality of life in subjects with RRMM	• Changes from baseline in symptoms and health-related quality of life as measured by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire 30-item Core Module (EORTCQLQ-C30) and European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire 20-item Multiple Myeloma Module (EORTC-QLQ-MY20)
• To evaluate the tolerability of belantamab mafodotin in combination with pembrolizumab based on patient self-report of symptomatic adverse effects	• Symptomatic adverse effects as measured by the PRO-CTCAE • Impact of ocular adverse effects on quality of life as measured by the Visual Function questionnaire(s): NEI-VFQ-25 and OSDI
• To evaluate disease and treatment related symptoms and associated impacts on function and health-related quality of life	• Exit Interview

[1] PK and ADA samples for pembrolizumab will be collected and stored during the trial. The analysis will be triggered if unexpected clinical findings have been identified.

2.3. Study Design

Overview of Study Design and Key Features	
	
Design Features	Population: Subjects with relapsed/refractory MM who have undergone stem cell transplant, or are considered transplant ineligible, and who have been previously treated with at least 3 prior lines that include the following: an IMiD (i.e. lenalidomide or pomalidomide), proteasome inhibitor (i.e. bortezomib, ixazomib or carfilzomib) and an anti-CD38 antibody alone or in combination. • **Part 1 Dose Escalation (n = ~ 12 subjects)** o Objective: characterize the safety, tolerability, PK, and immunogenicity of escalating doses of belantamab mafodotin in combination with 200 mg pembrolizumab to establish the RP2D. • **Part 2 Expansion Cohort(s) (n=~28 subjects)** o Objective: Further evaluate the safety, PK, immunogenicity, and clinical activity of belantamab mafodotin at the RP2 dose in combination with 200 mg pembrolizumab identified in Part 1 and to detect if meaningful overall response rate (ORR) can be achieved.
Dosing	• **Part 1 Dose Escalation** o Escalating doses of belantamab mafodotin (2.5 mg/kg, 3.4 mg/kg) will be administered first as an IV infusion once every three weeks (21 days = 1 cycle) in combination with the fixed dose of 200 mg pembrolizumab as an IV infusion to establish the RP2D. o Belantamab mafodotin will be administered first, as an IV infusion, followed by at least 1 hour rest. o Provided there is no infusion related reaction (IRR) warranting a prolonged interval between dosing, pembrolizumab will be administered as second drug over approximately 30 min via IV infusion. • **Part 2: Dose Expansion Phase** • Subjects enrolled in Part 2 dose expansion phase will be administered belantamab mafodotin at recommended phase 2 dose (RP2D) established in combination with the fixed dose of 200 mg pembrolizumab based on Part 1 outcomes.
Time &	• Refer to Appendix 2: Schedule of Activities

Overview of Study Design and Key Features	
Events	
Treatment Assignment	• This is a non-randomized, single arm, open label, two-part study.
Interim Analysis	• **Part 1: Dose Escalation Phase** o During the dose escalation, no formal interim analysis is planned for Part 1. Data will be reviewed through data visualization tool to inform dose escalation decisions. The mTPI design will be utilized to guide dose escalation/de-escalation decisions. o After the last cohort of subjects in Part 1 complete the DLT observation period, a formal interim analysis will be performed to support the RP2D decision, except for scenarios where RP2D is clearly defined by the toxicity profile. • **Part 2: Dose Expansion Phase** o Treatment-related Grade 4 or higher AEs will be continuously monitored starting from when 5 subjects are dosed. If observed toxicity level is significantly higher than 12% at 1-sided alpha of 0.025, the study may be terminated early based on totality of safety data. The 12% threshold is chosen based on 11% Grade 4 or higher AE observed in study BMA117159. o Futility analyses for ORR will start when 10 subjects are evaluable. Enrollment may stop if the stopping rule is met based on totality of data. Stopping rules are provided in Section 3.1.2.1 of RAP. • **Primary Analysis** o The primary analysis will take place approximately 15 months from the last subject first visit (LSFV). • Further details can be referred to in Section 3 of RAP and Section 9.6 of the protocol (version: GSK Document Number TMF-14344600)

2.4. Statistical Hypotheses / Statistical Analyses

2.4.1. Part 1: Dose Escalation Phase

No formal statistical hypotheses are being tested in Part 1. Analysis of the data obtained from Part 1 will only utilize descriptive methods.

2.4.2. Part 2: Expansion Cohort

The primary goal of Part 2 is to characterize clinical activity of the combination and to detect if meaningful response rate (ORR) can be achieved. Based on historical information [Lokhorst, 2015] and clinical judgement, the null hypothesis has been defined as ORR $\leq$ 40%. The alternative hypothesis has been defined as ORR $\geq$60% based on clinically meaningful improvement of 20%.

In Part 2, treatment-related Grade 4 or higher AEs will be continuously monitored starting from when 5 participants are dosed. Based on the 11% Grade 4 or higher AEs observed in the FTIH study (BMA117159), it is considered that the combination treatment has unacceptable toxicity if observed treatment-related Grade 4 or higher AEs is significantly higher than 12% at 1-sided alpha of 0.025.

3. PLANNED ANALYSES

3.1. Interim Analyses

3.1.1. Part 1: Dose Escalation Phase

During dose escalation, no formal interim analysis will be performed. Data will be reviewed through data visualization tool to inform dose escalation decisions. The mTPI (modified Toxicity Probability Interval) design will be utilized to guide dose escalation/de-escalation decisions which is described in Section 3.1.1.1.

After the last cohort of patients in Part 1 complete the DLT observation period (21 days), a formal interim analysis will be performed to support the RP2D decision, except for scenarios where RP2D is clearly defined by the toxicity profile. Data considered to support RP2D decision will include but not limited to safety, available PK profile and observed signs of clinical activity. Details of the planned displays for RP2D are provided in a separate RAP.

3.1.1.1. Description of the Modified Toxicity Probability Interval

The mTPI design assumes the true underlying toxicity rate for maximum tolerated dose (MTD) of belantamab mafodotin falls within the range from 25% to 35% and centered at 30%. The monitoring rules for guiding dose escalations are provided in Table 1. Columns provide the numbers of subjects treated at the current dose level, and rows provide the corresponding numbers of subjects experiencing toxicity. The entries of the table are dose-finding decisions (i.e., E, S, and D) representing escalating the dose, staying at the same dose, and de-escalating the dose. In addition, decision U means that the current dose level is unacceptable because of high toxicity; the current dose level and any higher dose level should be excluded from the trial. For example, when one of three subject's experiences toxicity, the decision can be located at row 1 and column 3, which is S – to stay at the current dose level. Consequently, the next cohort of subjects will be treated at the same dose level currently being used. If 0 of 3 subjects experiences toxicity, the decision is at row 0 and column 3, which is E – to escalate. Thus, the next cohort of subjects will be treated at the next-higher dose level. If three of three subjects experiences toxicity, the decision is DU – to de-escalate to the next-lower dose level, and exclude the current dose and any higher dose from the trial, because the high toxicity level is unacceptable. In dose escalation (E)/de-escalation (D), no dose skipping is allowed.

Table 1 Dose-Escalation Monitoring Rules for Part 1 Using the mTPI Method

Number of TDLTs	Number of Patients treated at current dose					
	1	2	3	4	5	6
0	E	E	E	E	E	E
1	D	S	S	S	S	E
2		DU	D	S	S	S
3			DU	DU	D	S
4				DU	DU	DU
5					DU	DU
6						DU

The Table was generated based on a beta/binomial model and precalculated before trial initiation. The letters in different colors are computed based on the decision rules under the mTPI method and represent different dose-finding actions. In addition to actions de-escalate the dose (D), stay at the same dose (S), and escalate the dose (E), the Table includes action unacceptable toxicity (DU), which is defined as the execution of the dose-exclusion rule in mTPI. Excerpted from Ji et al [Ji, 2010]

3.1.1.2. Displays To Be Created For Dose Escalation Review By Request

Review of preliminary data will be performed after completion of each dosing cohort in Part 1. Preliminary safety and study population data may include, if requested, a demographic characteristics summary, exposure of study drugs summary, adverse event (AE) summary by systems organ class (SOC) and preferred term (PT) and maximum grade, AE related to study treatment summary by maximum grade, AEs leading to dose modification by PT summary, serious adverse events (SAE) summary by SOC and PT, and listing of laboratory assessments with NCI-CTCAE Grade 3 and 4. Spreadsheets containing study data will be supplied by the study data manager.

Dose escalation/de-escalation decisions will take into account all available safety and tolerability data. The decisions will be informed by the mTPI approach and will occur following review of these data and joint discussion by the GSK Study Team and investigators. The details of the planned displays, if requested, are provided in Appendix 11: List of Data Displays.

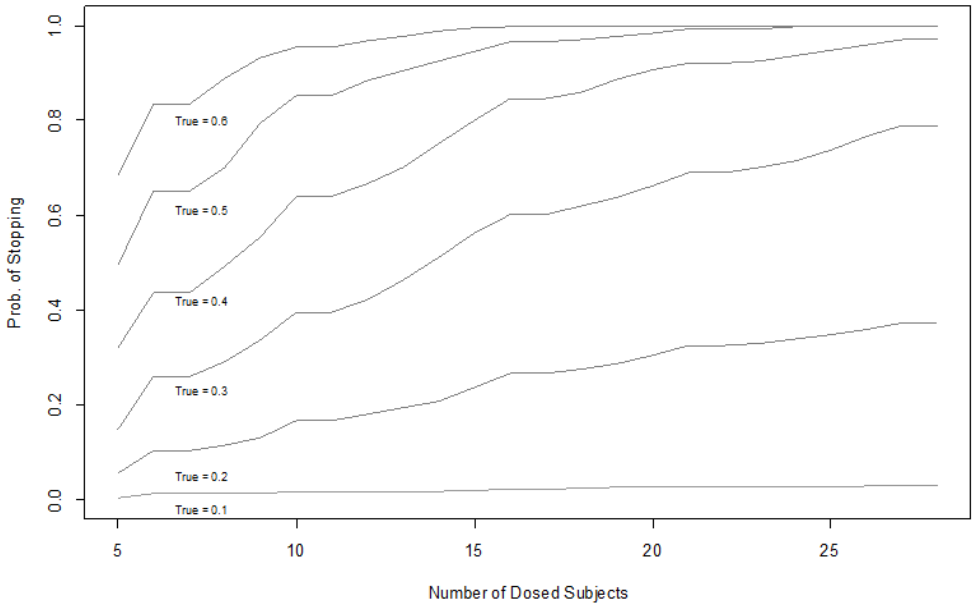
3.1.2. Part 2 Dose Expansion Phase

Continuous safety monitoring will be conducted for the expansion cohort starting from when 5 subjects are dosed. The observed number of treatment-related Grade 4 or higher AEs will be compared against the safety stopping rule in Table 2 . Enrollment may stop if the safety stopping rule is met based on totality of safety data. For example, if there are 3 events out of 5 dosed subjects, enrollment may stop after review of all safety data; if there is 2 or fewer events out of 5 dosed subjects, enrollment will continue. Operating characteristics for the safety stopping rule are provided in Figure 1. The iSRC will review and may implement Part 2 safety stopping rules, if pre-specified criteria are met. Details of the planned analyses for the iSRC data review meetings, including subject demographic, subject disposition, AE and SAE data, are documented in a separate RAP.

Table 2 Safety Stopping Rules for the Expansion Cohort

Number of dosed subjects	Stop if treatment related Grade 4 or higher AEs larger or equal to this this number
5	3
6-10	4
11-14	5
15-19	6
20-25	7
26-28	8

Figure 1 Operating Characteristics of Safety Stopping Rule for Expansion Cohort



Interim analyses for ORR will start when at least 10 subjects are evaluable as defined in Section 4. Subjects who initially received RP2D in Part 1 may also be included. The observed number of subjects with unconfirmed response of PR or better will be compared with the stopping boundary in Table 3. Enrolment may stop if the stopping rule is met. Final decision will be based on the totality of data. For example, if there are 2 unconfirmed responses out of 10 evaluable subjects, enrolment may stop after review of all available data; if there are 3 or more unconfirmed responses out of 10 evaluable subjects, enrolment will continue. More details of the operating characteristics for futility analysis are provided in Section 3.1.2.1.

3.1.2.1. Operating Characteristics of the Stopping Rules for Futility

The futility stopping rule in Table 3 is based on the methodology of Lee et al. [Lee, 2008]. The optimal design has a maximum sample size of 28 and a type I error rate of 0.10 and power of 80.6%. The expansion cohort may be stopped early for futility if the predicted probability of success is less than 1.5%. Under the null hypothesis, if the true ORR is 40%, the expected sample size of the design is 20 subjects and probability of early termination is 86.1%. Under the alternative hypothesis, if the true ORR is 60%, the expected sample size is 28 and the probability of early termination is 15.6%.

Table 3 Decision Making Criteria for Futility Analysis

Number of Evaluable Subjects	≤This Number of Responses to Stop Early for Futility	Probability of continuing enrolling when ORR=0.4	Probability of continuing enrolling when ORR=0.6
10	2	83.3%	98.8%
11	2	83.3%	98.8%
12	3	75.5%	98.1%
13	3	75.5%	98.1%
14	4	68.6%	97.5%
15	4	68.6%	97.5%
16	5	62.3%	96.9%
17	6	52.9%	95.7%
18	6	52.9%	95.7%
19	7	46.7%	94.9%
20	7	46.7%	94.9%
21	8	41.6%	94.2%
22	9	34.6%	92.8%
23	9	34.6%	92.8%
24	10	30.2%	91.9%
25	11	24.4%	90.2%
26	12	18.8%	87.7%
27	13	13.9%	84.5%
28	14	0.0%	0.0%

3.2. Primary and Final Analyses

The primary and 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.
2. All required database cleaning activities have been completed and final database lock (DBL) has been declared by Data Management.

Data from the two parts may be combined for some analyses at 15 months from LSFV and at the end of the trial, as appropriate.

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. Included are: Run-in Failures; Randomized Participants; in non-randomized study and participants who were assigned a treatment in a non-randomised 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 participants who received at least one dose of study treatment(s).	• Efficacy, Safety, Study Population based on actual treatment received
COVID-19	• All participants in the All Treated population who had a confirmed, probable or suspected COVID-19 case diagnosis.	• Baseline Characteristics, Medical History, Laboratory Data, and Safety
DLT Evaluable	• Participants fulfilling the 'All Treated' population criteria during part 1 (Dose Escalation) and are followed up for a 21-day period or withdrawn within 21 days due to an AE meeting the definition of a DLT as defined in Section 4.2.3.1 of protocol.	• Summary of DLT for Part 1 only
All Evaluable	• It is considered when at least 10 subjects are evaluable if all the first 10 treated participants in the All Treated population meet at least one of the criteria below: o if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR o had at least one disease assessment on or after day 60 OR o had an unconfirmed response of PR/CR or better,	• Futility Analyses for the expansion cohort (for part 2 participants and part 1 participants who initially received the RP2D)

Population	Definition / Criteria	Analyses Evaluated
	OR ○ progressed, OR ○ died, OR ○ discontinued treatment due to other reasons • No skipping of participant is allowed, e.g., if the 11th treated participant does not meet one of the criteria above, the 12th treated participant will not be included even if one of the criteria is met for the 12th subject.	
Pharmacokinetic (PK)	• Participants in the All Treated population from whom at least one PK sample was obtained and analysed for belantamab mafodotin.	• PK
Pharmacodynamic (PD)	• Participants in the All Treated population from whom at least one biomarker sample was obtained and analysed.	• PD/biomarker

Refer to Appendix 11: 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 [Version 3, dated 16-JUN-2021].

- Data will be reviewed prior to locking 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 separate summary and listing of all inclusion/exclusion criteria deviations will also be provided. This summary will be based on data as recorded on the inclusion/exclusion page of the eCRF.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Data Displays for Reporting [1]			
Code	**Description**		**Order in TLF**
A	Part 1: Dose Escalation	GSK2857916 2.5 mg/kg + Pembro 200 mg Escalation	1
B		GSK2857916 1.92 mg/kg + Pembro 200 mg Escalation[2]	2
C		GSK2857916 3.4 mg/kg + Pembro 200 mg Escalation	3
D	Part 2: Dose Expansion	GSK2857916 2.5 mg/kg + Pembro 200 mg Expansion	4
E	Part 2: Futility Interim Analyses[3]	GSK2857916 2.5 mg/kg + Pembro 200 mg Escalation	5
F		GSK2857916 2.5 mg/kg + Pembro 200 mg Expansion	6
G		GSK2857916 2.5 mg/kg + Pembro 200 mg Overall	7
H	Part 1 and Part 2	GSK2857916 2.5 mg/kg + Pembro 200 mg Overall	8

Notes:
[1] No treatment assignment schedule nor randomization schedule is planned for this multi-part, single-arm, open label study.
[2] Dose level 1.92 mg/kg may be tested if dose level 2.5 mg/kg is not cleared.
[3] These treatment codes will be applied for futility interim analyses (IA) in part 2 only

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. If no central lab value is available, the latest non-missing pre-dose value from local lab will be used. If there are multiple assessments on the same day, the mean will be used as the baseline value.

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

5.3. Examination of Covariates, Other Strata and Subgroups

5.3.1. Examination of Subgroups

The list of subgroups may be used in descriptive summaries and statistical analyses. Additional subgroups of clinical interest may also be considered.

- If the percentage of subjects is small within a particular subgroup, then the subgroup categories may be refined.
- If the category cannot be refined further, then descriptive rather than statistical comparisons may be performed for the particular subgroup.

Subgroup	Categories
Age	18 to <65, 65 to <75, >=75
Sex	Male, Female
Ethnic Background	White, Other
ISS Staging at Screening & at Initial Diagnosis	I, II, III, Other (Unknown or Missing)
Number of prior lines of therapy	<=3,4-5, >5
Type of myeloma	IgG, Non-IgG
Extramedullary disease	No, Yes, Missing

Refractory to prior anti-cancer therapy	• Any Proteasome Inhibitor (PI)
	  ○ Bortezomib
	  ○ Carfilzomib
	  ○ Ixazomib
	• Any Immunomodulator (IMiD)
	  ○ Thalidomide
	  ○ Lenalidomide
	  ○ Pomalidomide
	• Monoclonal Antibodies
	  ○ Anti-CD38 [2]
	  ○ Anti-CD38 in combination [3]
	• PI+IMiD
	• Anti-CD38+PI+IMiD
	• Penta-refractory [4]

Subgroup	Categories
Cytogenetics Risk [1]	High, Other (non-high risk, not done, or missing)
Prior anti-cancer therapy of interest	• With prior Anti-CD38 Treatment and IMiD and Proteasomes Inhibitors. • Without prior Anti-CD38 Treatment. • With prior IMiD and Proteasomes Inhibitors. • With prior Anti-BCMA, Anti-CD38, or Daratumumab Treatment
Renal Impairment per eGFR (mL/min/ 1.73 m2)	• Normal: >=90, Mild: >=60, <90, Moderate: >=30, <60, Severe: 0, <30, Missing

NOTES:

- [1] A subject is considered as high risk if the subject has any of at least of the following cytogenetics: t(4;14), t(14;16), and 17p13del (Kastritis, 2017).
- [2] Defined as prior CTX regimen with Anti-CD38 (i.e. Daratumumab, Isatuximab) as the only drug.
- [3] Defined as prior CTX regimen with Anti-CD38 (i.e. Daratumumab, Isatuximab) and other drugs.
- [4] Defined as refractory to: Bortezomib, AND Carfilzomib AND Lenalidomide AND Pomalidomide AND Daratumumab.

5.4. 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
Section16.3	Appendix 3: Assessment Windows
Section16.3	Appendix 4: Study Phases and Treatment Emergent Adverse Events
Section16.5	Appendix 5: Data Display Standards & Handling Conventions
Section16.6	Appendix 6: Derived and Transformed Data
Section16.7	Appendix 7: Reporting Standards for Missing Data
Section16.8	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.

Study population analyses including analyses of subject's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, disease characteristics at initial diagnosis and at screening, prior and follow-up anti-cancer therapy, surgical/medical procedures, substance use, duration of follow up, exposure and treatment compliance will be based on GSK Core and Oncology Data Standards. Details of the planned displays are presented in Appendix 11: List of Data Displays.

6.2. Disposition of Subjects

A summary of the number of subjects in each of the analysis populations described in Section 4 will be provided (for final analysis, Evaluable population will not be included). In addition, the number of subjects enrolled by centre will be summarized by dose level using the "Enrolled" population. A listing of subjects excluded from each study population will also be provided (for primary analysis, Evaluable population will not be included) using the following rationales for exclusions.

Population	Rationale for Exclusion
All Treated	• Enrolled into study, but did not receive study treatment(s)
COVID-19	• Received study treatment(s), but are not suspected, probable, or suspected COVID-19 case diagnosis
DLT Evaluable	• Enrolled in Part 1 and received study treatment(s), but did not meet the DLT evaluable criteria
All Evaluable	• Received study treatment(s), but did not meet the All evaluable criteria
Pharmacokinetic (PK)	• Received study treatment(s), but did not have at least one PK sample obtained
Pharmacodynamic (PD)	• Received study treatment(s), but did not have at least one biomarker sample obtained

A summary of subject status and reason for study withdrawal will be provided. This display will show the number and percentage of subjects who withdrew from the study, including 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 subjects 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, and baseline body weight and baseline BMI) will be summarized. Age, height, weight and BMI will be summarized using the mean, standard deviation, minimum, median, and maximum. The count and percentage will be computed for sex and ethnicity.

Race and racial combinations will be summarized.

Disease history and characteristics (e.g. time since initial diagnosis in years, date of initial diagnosis) at initial diagnosis and screening will be listed. Separate 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 myeloma immunoglobulin, extramedullary disease, lytic bone lesion, renal impairment per eGFR, and genetic characteristics (including high cytogenetic risk) will be summarized and listed.

Medical conditions collected at screening will be summarized by past and current separately.

Substance use, including smoking history and alcohol use will be summarized. Smoking Pack Years which is calculated as (number of cigarettes smoked per day/20) x number of years smoked will be provided.

Prior anti-cancer therapy will be coded using GSK Drug coding dictionary, then summarized by type of therapy and listed. A listing of prior anti-cancer therapy will show the relationship between ATC Level 1, Ingredient, and verbatim text. A summary of the number of prior anti-cancer therapy regimens will also be produced.

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

Anti-cancer radiotherapy will be listed. Prior cancer and non-cancer related surgeries will be summarized. Prior and on treatment cancer and non-cancer related surgeries will be listed.

6.4. Treatment Compliance

Summaries of study treatment exposure and dose modifications (e.g., number of dose reductions, number of dose interruptions) will further characterize compliance. These analyses are described in Section 6.4.1 'Extent of Exposure'.

6.4.1. Extent of Exposure

Extent of exposure to belantamab mafodotin and pembrolizumab will be summarized and listed separately for each component.

The number of cycles administered to study treatment will be summarised with mean, median, standard deviation, minimum, and maximum.

Dose delivered per cycle (mg/kg/cycle) will be summarized using mean, median, standard deviation, minimum, and maximum by cycle and overall.

- the dose intensity for belantamab mafodotin (mg/kg/3 weeks) which is calculated as the actual cumulative dose (mg/kg) divided by expected duration of exposure in 3 weeks (last infusion date– first infusion date + 21)/21
- the dose intensity for pembrolizumab (mg/3 weeks), which is calculated as the actual cumulative dose (mg) divided by expected duration of exposure in 3 weeks (last infusion date– first infusion date + 21)/21

A by subject 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. Infusion interruptions will be summarised by number of interruptions and reasons for interruptions. Dose delays will be summarised by number of 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. Primary reasons for dose reductions and infusion interruptions will also be summarized by cycle.

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. Because the protocol allows a window of ± 3 days for administration of study treatment after Cycle 1, a dose will only be considered delayed if it is 4 or more days after the scheduled dose date.

The summaries of dose modifications will be provided. A plot showing the number and percentage of subjects treated at different dose levels over time will be provided.

The duration of exposure to study treatment (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 subject.

6.5. Concomitant Medications

Concomitant medications will be coded using GSK Drug coding dictionary and summarized. The summary of concomitant medications will show the number and percentage of subjects 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 summary.

In the summary of concomitant medications, each subject is counted once within each unique ingredient. For example, if a subject takes Amoxycillin on two separate occasions, the subject 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.

6.6. Subsequent Anti-Cancer Therapies

The number and percentage of subjects that received chemotherapy, immunotherapy, hormonal therapy, biologic therapy, radioactive therapy, small molecule targeted therapy, as post study treatment anti-cancer therapy will be summarized. Time from study treatment discontinuation to the first post study treatment anti-cancer therapy will also be included in this summary Table, if available.

Follow-up anti-cancer therapy will be coded using GSK Drug coding dictionary, then summarized by ingredient. A listing of the type of follow-up anti-cancer therapy received (chemotherapy, immunotherapy, hormonal therapy, biologic therapy, radioactive therapy, and small molecule targeted therapy for each subject will be provided).

7. EFFICACY ANALYSES

7.1. Part 1: Dose Escalation

7.1.1. Secondary Efficacy Analyses

7.1.1.1. Endpoint / Variables

BOR

Best Overall Response **(**BOR) is defined as the best confirmed response (stringent Complete Response [sCR] > Complete Response [CR] > Very Good Partial Response [VGPR] > Partial Response [PR] > Minimal Response [MR] > Stable Disease [SD] > Progressive Disease [PD] > Not Evaluable [NE]) from treatment start date until disease progression or initiation of new anti-cancer therapy, whichever is earlier, as assessed by the investigator per IMWG (2016). Details on derivation of confirmed response are provided in Table 4.

ORR

Overall Response Rate (ORR), defined as the percentage of participants with a confirmed PR or better as the BOR (i.e., Partial Response [PR], Very Good Partial Response [VGPR], Complete Response [CR], and stringent Complete Response [sCR]), as assessed by the investigator per IMWG (2016).

ORR at interim analysis will be analysed based on confirmed responses, if available. However, in case a participant has achieved a response of PR or better at data cut, which was not confirmed due to the time constraints (too short timeframe for the next assessment), but with a potential to be confirmed through subsequent assessments after interim, the participant will also be considered as a responder; if the participant dies or discontinues study or starts other anti-cancer therapy prior to confirming the response, the participant will not be considered as a responder at IA.

Only the assessments from the start of treatment up to the earlier of confirmed disease progression or the start of new anti-cancer therapy will be considered. Only new systemic anti-cancer drugs taken are considered as anti-cancer therapy (radiotherapy and surgeries are not considered as systemic anti-cancer therapy for the purpose of this analysis).

Subjects with only assessments of Not Evaluable or missing response will be treated as non-responders; i.e. they will be included in the denominator when calculating the percentage.

Details on derivation of confirmed response are provided in Table 4.

Table 4 Derivation of Confirmed Response

	Response at the First Time Point	Response at Subsequent Time Point[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	
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	SD
12	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 ORR analysis. For ORR analysis in IA, the UC response (PR or better) will be counted as responder.
13	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	PD

	Response at the First Time Point	Response at Subsequent Time Point[1]	Confirmed Response at the First Time Point
		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)	
14	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
15	SD	Any OR No subsequent disease assessment	SD
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 SD does not need to be confirmed.
3 PD due to imaging (i.e., plasmacytoma or bone lesion) does not need to be confirmed.
Where criteria are not mutually exclusive, take the first that applies.

7.1.1.2. Summary Measure

ORR

The number and percentage of participants with the BOR in the following response categories at timepoint will be summarized: sCR, CR, VGPR, PR, overall response (sCR+CR+VGPR+PR), minimal response (MR), stable disease (SD), progressive disease (PD), and not evaluable (NE). The corresponding exact 95% CI for ORR will also be provided. Participants with unknown or missing responses will be treated as non-responders, i.e., these participants will be included in the denominator when calculating percentages of response. A list of investigator-assessed response at each visit will be listed.

A waterfall plot showing the maximum percent reduction from baseline in Serum M protein, or Urine M-protein, or difference between two types Serum FLC [Kappa light chain (Kappa LC) and Lambda light chain (Lambda LC)] for each subject will be produced using by dose level. The plot will be color-coded for M-protein types and Serum FLC, etc. Indication of the best overall response will be provided below the plot. Only the assessments from the start of treatment up to the start of new anti-cancer therapy will be considered. Only new systemic anti-cancer drugs taken are considered as anti-cancer cancer therapy (radiotherapy and surgeries are not considered as systemic anti-cancer therapy for the purpose of this analysis).

The maximum percent reduction will be plotted in the following hierarchical order:

[1] Plot Serum M-protein maximum percent reduction from baseline if data is available;

[2] If [1] is not feasible, plot Urine M-protein maximum percent reduction from baseline if data is available;

[3] If both [1] and [2] are not feasible, plot maximum percent reduction from baseline for difference between two types of Serum FLC if data is available;

Difference between two types of Serum FLC

The percent change from baseline for difference between two types of Serum FLC is defined as:

(post-baseline difference-baseline difference) / baseline difference *100%

To calculate the difference, the “involved” and “non-involved” light chains must be determined at first based on the ratio of non-missing values for Serum Kappa LC protein and Serum Lambda LC protein at baseline.

The detailed algorithm is provided as below:

- If the baseline ratio of (Kappa LC/Lambda LC)>1.65, then Kappa LC is defined as involved FLC, and Lambda LC is defined as non-involved FLC. Then
    - Difference between involved and uninvolved = Kappa LC-Lambda LC
- If the baseline ratio of (kappa/lambda) <0.26, then Lambda light chain is defined as involved FLC, and Kappa light chain is defined as non-involved FLC
    - Difference between involved and uninvolved = Lambda LC-Kappa LC
- If the baseline ratio of (Kappa LC/Lambda LC) ≤1.65 and ≥0.26, then "involved" and "non-involved" FLC can not be determined (ratio is normal), and maximum percent reduction from baseline for difference between two types of Serum FLC won't be available.

7.1.1.3. Population of Interest

The secondary efficacy analysis of ORR will be based on the All Treated population, unless otherwise specified.

7.1.1.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 11: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.1.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.1.2. Exploratory Efficacy Analyses

7.1.2.1. Endpoint / Variables

MRD Negativity Rate

Minimal Residual Disease (MRD) negativity rate, defined as the percentage of participants who are MRD negative (with threshold 10^{-5}) and achieve confirmed VGPR or CR from treatment start date until disease progression or initiation of new anti-cancer therapy, whichever is earlier, as assessed by next generation sequencing (NGS) per IMWG (2016).

For analysis purposes, subjects in the All Treated population without MRD assessment will be considered as having positive MRD.

7.1.2.2. Summary Measure

MRD Negativity Rate

MRD negativity rate at any timepoint will be summarized. the number and percentage of participants who have achieved MRD negativity will be summarized by dose level. The corresponding 95% exact CI will be provided. Information of MRD will be included in the listing of response. For analysis purposes, subjects in the All Treated population without MRD assessment will be considered as having positive MRD.

7.1.2.3. Population of Interest

The MRD negative rate analyses will be based on the All Treated population, unless otherwise specified.

7.1.2.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 11: List of Data Display, based on GSK data standards.

Unless otherwise specified, endpoints / variables defined in Section 7.1.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.2. Part 2: Dose Expansion

7.2.1. Primary Efficacy Analyses

7.2.1.1. Endpoint / Variables

BOR

The definition of BOR is provided in Section 7.1.1.1. Details on derivation of confirmed response are provided in Table 4.

ORR

The definition of ORR is provided in Section 7.1.1.1. Details on derivation of confirmed response are provided in Table 4.

7.2.1.2. Summary Measure

ORR

The summary measure of ORR is provided in Section 7.1.1.2.

7.2.1.3. Population of Interest

At futility interim, the primary efficacy analysis of ORR will be based on the All Evaluable population.

Otherwise, the primary efficacy analysis of ORR will be based on the All Treated population, unless otherwise specified.

7.2.1.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 11: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.2.2. Secondary Efficacy Analyses

7.2.2.1. Endpoint / Variables

CBR

Clinical Benefit Rate (CBR), defined as the percentage of participants with a confirmed MR or better (i.e., MR, PR, VGPR, CR and sCR) as the BOR assessed by the investigator per IMWG (2016).

DOR

Duration of response (DoR), defined as the interval of time (in months) from first documented evidence of confirmed PR or better to the time when disease progression is documented assessed by the investigator per IMWG (2016), or death due to PD among participants with a confirmed PR or better as the BOR. Responders without confirmed PD will be censored at the censoring time point for time to progression as specified in Table 6.

TTR

Time to response (TTR), defined as the interval of time (in months) between the date of first dose and the first documented evidence of response (PR or better) among participants with a confirmed PR or better as the BOR assessed by the investigator per IMWG (2016).

TTBR

Time to best response (TTBR), defined as the interval of time (in months) between the date of first dose and the earliest date of achieving BOR among participants with a confirmed PR or better as the BOR assessed by investigator per IMWG (2016).

PFS

Progression-free survival (PFS), defined as the interval of time (in months) from first dose until the earlier date of disease progression per IMWG (2016), or the date of death due to any cause. Determination of dates of PFS events and dates for censoring are described in Table 5.

TTP

Time to disease progression (TTP), defined as the interval of time (in months) from first dose until the earlier date of PD per IMWG (2016), or the date of death due to PD. Determination of dates of TTP events and dates for censoring are described in Table 6.

OS

Overall Survival (OS), defined as the interval of time (in months) from first dose to the date of death due to any cause. Participants who withdraw consent from the study or are lost to follow-up will be censored at the time of withdrawal or lost to follow-up. Participants who do not have a death record at the clinical cut-off date for the analysis will be censored at the last known alive date. The last contact date will be determined by

the maximum collection/assessment date from among selected data domains within the clinical database.

Table 5 Assignments of Progression and Censoring Dates for PFS Analysis

Situation	Date of Event (Progression/Death) or Censored[1]	Event (Progression/Death) Or Censored
No adequate baseline assessments[4] and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the Table)	First dose	Censored
No post-baseline assessments and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the Table)	First dose	Censored
Progression documented between scheduled visits	Date of assessment of progression	Event
With post-baseline assessment but no progression (or death)	Date of last 'adequate' assessment of response[2]	Censored
No adequate post-baseline assessment before start of new anticancer therapy	First dose	Censored
With adequate post-baseline assessment and new anticancer treatment started (prior to documented disease progression).[3]	Date of last 'adequate' assessment of response[2] (on or prior to starting anti-cancer therapy)	Censored
Death before first scheduled assessment (or Death at baseline or without any adequate assessments)	Date of death	Event
Death between adequate assessment visits	Date of death	Event
Death or progression after more than three missed scheduled assessment	Date of last 'adequate' assessment of response[2] (prior to missed assessments): If the disease assessment is every 3 weeks, a window of 66 days (9 weeks + 3 day window) will be used to determine whether there is extended time without adequate assessment. If the time difference between PD/death and last adequate disease assessment is more than 66 days, PFS will be censored at the last adequate disease assessment prior to PD/death.	Censored

[1] Event or censored are based on confirmed responses.
[2] An adequate assessment is defined as an unconfirmed assessment where the investigator assessed response is sCR, CR, PR, VGPR, MR, or SD.
[3] If PD and New anti-cancer therapy occur on the same day assume the progression was documented first e.g., outcome is progression and the date is the date of the assessment of progression).
[4] Adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein ≥0.5 g/dL (≥5 g/L) or b. Urine M-protein ≥200 mg/24h or c. Serum FLC assay: Involved FLC level ≥10 mg/dL (≥100 mg/L) and an abnormal serum free light chain ratio (<0.26 or >1.65).

Table 6 Assignments for Progression and Censoring Dates for TTP Analysis

Situation	Date of Event (Progression/Death due to PD) or Censored[1]	Event (Progression/Death due to PD) Or Censored
No adequate baseline assessments[4] and the subject has not died (if the subject has died due to PD follow the rules for death indicted at the bottom of the Table)	First dose	Censored
No post-baseline assessments and the subject has not died (if the subject has died due to PD follow the rules for death due to PD indicted at the bottom of the Table)	First dose	Censored
Progression documented between scheduled visits	Date of assessment of progression	Event
With post-baseline assessment but no progression (or death due to PD)	Date of last 'adequate' assessment of response[2]	Censored
No adequate post-baseline assessment before start of new anticancer therapy	First dose	Censored
With adequate post-baseline assessment and new anticancer treatment started (prior to documented disease progression).[3]	Date of last 'adequate' assessment of response[2] (on or prior to starting anti-cancer therapy)	Censored
Death due to PD before first scheduled assessment (or Death at baseline or without any adequate assessments)	Date of death	Event
Death due to PD between adequate assessment visits	Date of death	Event
Death from causes other than PD before first scheduled assessment (or Death at baseline or without any adequate assessments)	Date of death	Censored
Death from causes other than PD between adequate assessment visits	Date of death	Censored
Death due to PD or progression after more than three missed scheduled assessment	Date of last 'adequate' assessment of response[2] (prior to missed assessments): If the disease assessment is every 3 weeks, a window of 66 days (9 weeks + 3 day window) will be used to determine whether there is extended time without adequate assessment. If the time difference between PD/death due to PD and last adequate disease assessment is	Censored

Situation	Date of Event (Progression/Death due to PD) or Censored[1]	Event (Progression/Death due to PD) Or Censored
	more than 66 days, PFS will be censored at the last adequate disease assessment prior to PD/death due to PD.	

[1] Event or censored are based on confirmed responses.
[2] An adequate assessment is defined as an assessment where the investigator assessed response is sCR, CR, PR, VGPR, MR, or SD .
[3] If PD and New anti-cancer therapy occur on the same day assume the progression was documented first e.g., outcome is progression and the date is the date of the assessment of progression).
[4] Adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein ≥0.5 g/dL (≥5 g/L) or b. Urine M-protein ≥200 mg/24h or c. Serum FLC assay: Involved FLC level ≥10 mg/dL (≥100 mg/L) and an abnormal serum free light chain ratio (<0.26 or >1.65).

7.2.2.2. Summary Measure

CBR

The number and percentage of participants with the BOR in the following response categories will be summarized by dose level: sCR, CR, VGPR, PR, MR, clinical benefit response (sCR+CR+VGPR+PR+MR), SD, PD, and NE. The corresponding exact 95% CI for CBR will also be provided. Participants with unknown or missing responses will be treated as non-responders, i.e., these participants will be included in the denominator when calculating percentages of response.

DOR

If there are sufficient number of responders who subsequently progress or die due to PD, distribution of DOR will be summarized using the Kaplan-Meier method. The median, 25th and 75th percentiles of DOR will be estimated and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (1982). A Figure and listing of DoR time will also be provided.

TTR

If there are sufficient number of responses by dose level, time to response at will be summarized descriptively using median(s) and quartiles in the subset of subjects with a confirmed response of PR or better as the BOR and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (1982). A Figure and listing of TTR time will also be provided.

TTBR

If there are sufficient number of responses by dose level, time to best response at will be summarized descriptively using median(s) and quartiles in the subset of subjects with a confirmed response of PR or better as the BOR and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (1982). A Figure and listing of TTBR time will also be provided.

PFS

The distribution of PFS for each dose level will be estimated using the Kaplan-Meier method. If there is a sufficient number of progressions or death due to PD, the median, 25th and 75th percentiles of PFS will be estimated and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (1982). PFS rate at 6, 9, 12, 15, and 18 months and corresponding 95% CI will also be estimated from the Kaplan-Meier analysis. A Figure and listing of PFS time will also be provided.

OS

The distribution of OS for each dose level will be estimated using the Kaplan-Meier method. If there are a sufficient number of deaths, then the median, 25th and 75th percentiles of OS will be estimated and corresponding 95% confidence intervals will be

estimated using the Brookmeyer-Crowley method (1982). A graph of survival curves and a listing of survival times will also be provided. In addition, pending on maturity of data, the survival probability at 6, 9, 12, 15, and 18 months with 95% CI will be estimated using Kaplan-Meier method.

TTP

The distribution of TTP will be estimated using the Kaplan-Meier method. The median, 25th and 75th percentiles of TTP will be estimated and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (1982). A Figure and listing of TTP time will also be provided.

7.2.2.3. Population of Interest

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

7.2.2.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 11: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.2.3. Exploratory Efficacy Analyses

7.2.3.1. Endpoint / Variables

MRD Negativity Rate

MRD negativity rate is defined in Section 7.1.2.1.

7.2.3.2. Summary Measure

MRD Negativity Rate

The summary measure of MRD negativity rate is provided at Section 7.1.2.2.

7.2.3.3. Population of Interest

The MRD negative rate analyses will be based on the All Treated population, unless otherwise specified.

7.2.3.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 11: List of Data Display, based on GSK data standards.

Unless otherwise specified, endpoints / variables defined in Section 7.1.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.3. Other Efficacy Analyses

7.3.1. Endpoint / Variables

Time to Next Treatment

Time to next treatment (TTNT) is defined as the time from the date of first dose of study treatment to the date of next subsequent treatment for relapse refractory multiple myeloma due to any reasons. Subjects who have not started the next subsequent anti-cancer treatment will be censored at the date of last contact or at death. Subjects who do not have a documented start date of first dose of study treatment will be excluded from this analysis.

Rate of VGPR or Better

Rate of VGPR or better, defined as the percentage of participants with a confirmed VGPR or better as the BOR (i.e., VGPR, CR and sCR), per IMWG (2016).

7.3.2. Summary Measure

Time to Next Treatment

If there are sufficient number of responders who started new anti-cancer treatment due to any reasons by dose level, time to next treatment will be summarized descriptively using median(s) and quartiles.

Rate of VGPR or Better

The number and percentage of participants with the BOR in the following response categories will be summarized: sCR, CR, and VGPR. The corresponding exact 95% CI for rate of VGPR or better will also be provided. Participants with unknown or missing responses will be treated as non-responders, i.e., these participants will be included in the denominator when calculating percentages of response.

7.3.3. Population of Interest

Time to next treatment and rate of VGPR or better analyses will be based on the All Treated population, unless otherwise specified.

8. SAFETY ANALYSES

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

8.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs), ir (immune-related) AEs associated with pembrolizumab, and other significant AEs and serious and other significant irAEs will be based on GSK Core Data Standards. Details on treatment emergent AEs are provided in Section 16.4.1.2. Dose modifications (dose interruptions, dose reduction, and dose delays) and dose limiting toxicity (DLT) will also be summarized and listed according to GSK Oncology Data Standards. The details of the planned displays are provided in Appendix 11: List of Data Displays.

A summary of non-serious adverse events that occurred in strictly 5% of the subjects or above will be provided (no rounding for the percentage will be used in terms of 5% threshold, e.g., event with 4.99% incidence rate should not be included in this Table). The summary will be displayed by SOC and PT.

Adverse events (AEs) and immune-related adverse events (irAEs) will be graded by the investigator according to the National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE), Version 4.03 [NCI, 2010]. Adverse events will be coded using the Medical Dictionary for Regulatory Affairs (MedDRA dictionary) and grouped by system organ class (SOC). Immune-related adverse events will be coded using the Medical Dictionary for Regulatory Affairs (MedDRA dictionary) and grouped by preferred terms (PT). In addition, corneal findings will also be graded using the GSK scale for corneal events.

A summary of number and percentage of subjects with any adverse events and immune-related adverse events by maximum grade will be produced. AEs and irAEs will be sorted by Preferred term (PT) in descending order of total incidence. The summary will use the following algorithms for counting the subject (this applies also for subjects with irAEs):

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

- **Any event row**: Each subject 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) and irAEs (all grades) will be summarized and displayed in two ways: 1) in descending order of total incidence by PT only and 2) in descending order of total incidence by System Organ Classes (SOC) and PT and Maximum Grade for AEs and irAEs. In the SOC row, the number of subjects with multiple events under the same system organ class will be counted once. Otherwise, if AEs and irAEs are not listed in the NCI-CTCAE (version 4.03, [NCI, 2010]), then the AEs and irAEs will be summarized by maximum intensity.

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 in descending order of total incidence by SOC and PT and Maximum Grade for AEs.

All AEs and irAEs will be listed. Additionally, a listing of subject IDs for each individual AE and a listing of subject IDs for each individual irAE will be produced.

A summary of the number of patients experiencing DLTs will be provided. Grade 3 or above corneal events based on the GSK scale for corneal events associated with belantamab mafodotin should be used for evaluation of DLT.

8.2. Adverse Events of Special Interest Analyses

Characteristics (e.g. number of occurrences, action taken, grade, etc) of the following AEs of special interest and identified risk for belantamab mafodotin and AEs of special interest for pembrolizumab will be summarized separately:

- **Belantamab Mafodotin (AESIs)**
  - Corneal events (GSK Scale)
  - Eye Disorders (CTCAE)
  - Thrombocytopenia
  - Infusion related reactions
- **Belantamab Mafodotin (Identified Risk)**
  - Neutropenia
- **Pembrolizumab (AESIs)**
  - Overdose

8.2.1. Belantamab Mafodotin

8.2.1.1. Eye Disorders, Thrombocytopenia, and Infusion Related Reactions

The severity of all AESI will be graded utilizing the National Cancer Institute Common Toxicity Criteria for Adverse Events (NCI-CTCAE) v.4.03 [NCI, 2010]. For thrombocytopenia, in addition to events identified and collected in eCRF, a comprehensive list of MedDRA terms based on clinical review will be used to identify each type of event. Changes to the MedDRA dictionary may occur between the start of the study and the time of reporting and/or emerging data from on-going studies may highlight additional adverse events of special interest, therefore the list of terms to be used for each event of interest and the specific events of interest will be based on the safety review team (SRT) agreements in place at the time of reporting. For infusion related reactions (IRR), events are only considered IRR if the preferred term = "Infusion related reaction" or event was reported on an infusion day after the start of infusion or within 24 hours following end of infusion and led to a temporary interruption or prolongation of infusion time or treatment withdrawal. For keratopathy events (CTCAE) under eye disorders, events are considered keratopathy events if the synonym =

"keratopathy/keratitis". The details of the planned displays are provided in Appendix 11: List of Data Displays.

Summaries of the number and percentage of subjects 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 each type of events will be summarized using summary statistics mean, standard deviation, median, minimum value, and maximum. The number and percentage of subjects who have time of onset of first occurrence and the number and percentage of subjects who have duration of first occurrence will be reported in the following:

Thrombocytopenia and Eye Disorders:

- Time of first occurrence: 1-21, 22-42, 43-63, >63 days
- Duration of first occurrence: 1-21, 22-42, >42 days

Infusion Related Reactions:

- Time of first occurrence: 0-6, >6-12, >12-18, >18-24 hours
- Duration of first occurrence: 0-12, >12-24, >24 hours

The summary of event characteristics will also be provided, including number of subjects with any event, number of events, number of subjects with any event that is serious, number of subjects 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. Distinct occurrences require at least one day (or hour for IRR) gap between the resolution of all events from first course to the onset of second course. Overlapping occurrences of events are treated as the same occurrence. The percentage will be calculated in two ways, one with number of subjects with event as the denominator and the other with total number of subjects as the denominator. The worst-case approach will be applied at subject level for the maximum grade, i.e. a subject will only be counted once as the worst case from all the events experienced by the subject. For action taken to an event, subject will be counted once under each action, e.g. if a subject has an event leading to both study treatment discontinuation and dose reduction, the subject will be counted once under both actions.

8.2.1.2. Corneal Events (GSK Scale)

After discussions with regulatory agencies, GSK developed a grading scale to capture both corneal examination findings and visual acuity changes in participants treated with belantamab mafodotin. This GSK scale differs from the CTCAE criteria for eye disorders which relies mainly on patient's symptoms and patient's ability to attend to 'activities of daily living' for grading of events.

Severity of belantamab mafodotin treatment related corneal events will also be graded using the GSK scale for corneal events and should be used for evaluation of DLT.

Summaries of the number and percentage of subjects with these events will be provided for each type of grade separately by visit. The time of onset and duration of first

occurrence of grade 2 or above events, and the event characteristics will be summarized similarly as the AESIs for belantamab mafodotin provided in Section 8.2.1.1.

In addition to the listing, the following outputs will be provided for corneal events graded using the GSK scale:

1. Overview for corneal event (GSK scale)

2. Summary of actions taken with study treatment (e.g. dose reduction/delay/study treatment withdrawn)

The details of the planned displays are provided in Appendix 11: List of Data Displays.

8.2.1.3. Identified Risks: Neutropenia

Characteristics (e.g., number of occurrences, action taken, grade, etc.) of the important identified risk, neutropenia, will be summarized separately. The severity of neutropenia will be graded utilizing the NCI-CTCAE v.4.03 [NCI, 2010].

A comprehensive list of MedDRA preferred terms for neutropenia based on clinical review will be used to identify each type of event similarly as the AESIs for belantamab mafodotin provided in Section 8.2.1.1. The details of the planned displays are provided in Appendix 11: List of Data Displays.

Summaries of the number and percentage of subjects 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 each type of events in days, and the event characteristics will be summarized similarly as the AESI for belantamab mafodotin provided in Section 8.2.1.1.

8.2.2. Pembrolizumab

8.2.2.1. Overdose

For pembrolizumab, an overdose as defined in Section 6.10 of protocol that is not associated with clinical symptoms or abnormal laboratory results is an AESI.

A comprehensive list of MedDRA preferred terms for overdose based on clinical review will be used to identify each type of event similarly as the AESIs for belantamab mafodotin provided in Section 8.2.1.1. The details of the planned displays are provided in Appendix 11: List of Data Displays.

8.3. Deaths and Serious Adverse Events

All deaths will be summarised based on the number and percentage of subjects. This summary will classify subjects by time of death relative to the last dose of medication (>30 days or ≤30 days) and primary cause of death (disease under study, SAE related to

study treatment, or other). A supportive listing will be generated to provide subject-specific details on subjects who died and have fatal SAEs and fatal serious irAEs.

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

SAEs are included in the listing of all adverse events and immune-related adverse events. Separate supportive listings with subject-level details will be generated for

- Non-Fatal SAEs.
- Non-Fatal serious irAEs

8.4. Adverse Events Leading to Discontinuation of Study Treatments and Other Significant Adverse Events

The following categories of AEs will be summarized for separately in descending order of total incidence by SOC and PT and separate supportive listings will be generated with subject level details for those subjects:

- AEs Leading to Permanent Discontinuation of Study Treatment (belantamab mafodotin and pembrolizumab)
- AEs Leading to Dose Interruptions (belantamab mafodotin and pembrolizumab)
- AEs Leadings to Dose Reductions (belantamab mafodotin)
- All Treatment-related Serious Adverse Events (belantamab mafodotin and pembrolizumab)

8.4.1. Immune-Related Adverse Events Leading to Discontinuation of Study Treatments and Other Significant Adverse Events

The following categories of irAEs will be summarized for separately in descending order of total incidence by SOC and PT and separate supportive listings will be generated with subject level details for those subjects:

- irAEs Leading to Dose Interruptions (Pembrolizumab)

8.5. Ocular Findings from Ophthalmic Exam (Part 2)

As outlined in study protocol (GSK Document Number.: TMF-14344600) Schedule of Activities (Table 7- Table 10 of Section 7), ophthalmic exams are scheduled at screening, during the study, end of treatment, and follow-up period. The ocular findings from ophthalmic exams will be analysed as described below.

1. From baseline to last follow-up, the following analysis will be performed:

   a. Visual Acuity:
      i. The best corrected visual acuity (BCVA) summary will be based on the Logarithm of the Minimum Angle of Resolution (logMAR score), where:

         $$\text{logMAR score} = -\log_{10}(\text{Snellen Acuity Score})$$

         The following categories of logMAR score changes from baseline are defined:
         - No change/improved vision is defined as a change from baseline <0.12;
         - A possible worsened vision is defined as a change from baseline >=0.12 to <0.3;
         - a definite worsened vision is defined as a change from baseline >=0.3 logMAR score.

      ii. A summary of characteristics of definite worsen vision as defined above by subject will be provided, including time to onset of first occurrence; outcome and duration of first occurrence; number of occurrences based on subjects with definite worsen vision; outcome post treatment exposure; time to resolution post-treatment exposure

      iii. In addition, a summary of worst change from baseline (based on the eye with worst change) in BCVA score (logMAR score) will be provided for the following categories:
         - Increase >=0.12 to < 0.3
         - Increase >=0.3 to < 0.6
         - Increase >= 0.6

      iv. Number (%) of subjects with a decline in BCVA to 'light perception' (LP) or 'no light perception' (NLP) anytime post-baseline will also be provided.

   b. Corneal Exam
      i. Shift table from baseline to worst post-baseline by eye (R/L) and subject (worse eye, defined as the eye with the maximum worsening change from baseline) for corneal epithelium findings:
         - Corneal epithelium (Normal to Abnormal), Corneal ulcer (No to Yes), Epithelial microcystic edema (No to Yes), Subepithelial haze (No to Yes), Corneal neovascularization (No to Yes), and Microcysts without edema (No to Yes)

ii. For punctate keratopathy, summary Table of worst grade post-baseline and most frequent grade post-baseline across ocular exams by eye (R/L) and subject (worse eye)

c. Lens

i. Shift Table from baseline to worst post-baseline by eye (R/L) and subject (worse eye, defined as the eye with the maximum worsening changes from baseline) for lens findings:

- Lens: Clear (No to Yes), Pseudophakia (No to Yes); and Types of cataract (Nuclear Sclerosis, Cortical Cataract, Posterior Subcapsular Cataract).

The details of the planned displays are provided in Appendix 11: List of Data Displays.

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 subjects and subjects' 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

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 11: List of Data Displays.

Summary of change from baseline by scheduled visits using mean, median, standard deviation, minimum and maximum will be provided.

Summaries of worst case grade increase from baseline grade will be provided for all the lab tests that are gradable by CTCAE v4.03. These summaries will display the number and percentage of subjects 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. The 'Any Grade Increase' column will include all cases where the worst-case grade is 1 or higher and the baseline grade is missing. Likewise the Increase to Grade X (where X=3 or 4) will include cases that are worst-case grade X and the baseline grade is missing. 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.

For lab tests that are not gradable by CTCAE v4.03, summaries of worst case changes from baseline with respect to normal range will be generated. Decreases to low, changes to normal or no changes from baseline, and increases to high will be summarized for the worst case post-baseline. If a subject has a decrease to low and an increase to high during

the same time interval, then the subject is counted in both the "Decrease to Low" categories and the "Increase to High" categories.

For urinalysis laboratory tests results, occult blood, proteins, ketones, and glucose dipstick tests will be summarized. If the subject has a discrete value greater than 0 or a character value that is positive, then the subject is counted in the "Presence" category. Otherwise, the subject is counted in the "Absence" category.

The number of subjects with worst case urinalysis laboratory tests results will be summarized by the combination of specimen, method, test, and category. Subjects with a missing baseline value are to be assumed to have a negative baseline value.

- If the subject with "Presence" or "Absence" category at baseline does not change post-baseline, then the subject is counted in the "No Change" category.
- If the subject with "Presence" category at baseline changed to "Absence" category post-baseline, then the subject is counted in the "Decreased" category.
- If the subject with "Absence" category at baseline changed to "Presence" category post-baseline, then the subject is counted in the "Any Increase" category

Separate summary tables for hematology, chemistry, urinalysis, and hepatobiliary laboratory tests will be produced. Liver function laboratory tests will be included with hepatobiliary laboratory tests.

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 can not 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 subjects with non-missing value at each particular visit.

8.7.1. Analyses of Liver Function Tests

A summary of Liver Monitoring/Stopping Event Reporting will be provided. A Liver event profile which includes medical conditions data for subjects with liver stopping events, substance use data for subjects with liver stopping events, liver biopsy results for subjects and recorded outcomes of liver imaging assessments for subjects will be listed.

Summaries of hepatobiliary laboratory abnormalities including possible Hy's law cases will be provided. A summary of liver restart/re-challenge timings will be provided.

Plots of maximum total bilirubin versus maximum ALT, maximum ALT versus baseline ALT, maximum AST versus maximum LDH, maximum AST versus maximum Creatinine Kinase, and maximum LDH versus maximum Creatinine Kinase will be generated. A plot of maximum albumin/creatinine ratio (greater than 2000 mg/g) versus

concomitant serum concomitant will be provided. Serum creatinine will be considered as concomitant only if the start date is within ±7 days of the ongoing lab event.

8.8. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs and vital signs will be based on GSK Core Data Standards, unless otherwise specified. LVEF and Performance status will be summarized and listed based on GSK Oncology Data Standard. The details of the planned displays are presented in Appendix 11: List of Data Displays.

8.8.1. Performance Status

ECOG performance status will be summarized at baseline and each post-baseline scheduled visit. Summaries will use frequency and percentage of subjects at each planned assessment time. A summary of change from baseline by scheduled visits will be performed, as well as the worst case post-baseline and the best case post-baseline changes during the study (improved, no change, deteriorated).

8.8.2. ECG

A summary of the number and percentage of subjects 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 ranges: Grade 0 CCI , Grade 1 CCI , Grade 2 CCI , and Grade 3 CCI . Summaries of grade increase will be provided. These summaries will display the number and percentage of subjects with any grade increase.

The changes in QTc values will be categorized into the clinical concern ranges which are specific to changes in QTc: 31-60 and >60 msec. A summary of change in QTc value will display the number and percentage of subjects with a change within each range in the worst case post-baseline only. Subjects with missing baseline values will be excluded from this summary.

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.

A Figure plotting the baseline QTc and the worst-case post-baseline values will be produced. The Figure will have reference lines at 480 and 500 msec for both the ordinate and the abscissa axes. There will be diagonal reference lines at equality (i.e. a 45 degree line), at equality plus 30 msec, and at equality plus 60 msec.

8.8.3. LVEF

Absolute change from baseline in LVEF will be summarized in the worst case post-baseline only. Only the post-baseline assessments that used the same method (ECHO or MUGA) as the baseline assessments will be used to derive the change from baseline. The change from baseline will be categorized as follows:

- No change or any increase
- Any decrease
  - >0-<10 decrease
  - 10-19 decrease
  - >=20 decrease
  - >=10 decrease and >= LLN
  - >=10 decrease and < LLN
  - >=20 decrease and >= LLN
  - >=20 decrease and < LLN

8.8.4. Immunogenicity Analyses

For each subject, the results and titers of anti-belantamab mafodotin binding antibodies and neutralizing antibody assay results will be listed for each assessment time point, along with ADC and total antibody concentration. The frequency and percentage of subjects with positive and negative anti-drug antibody and neutralizing antibody assay results will be summarized for each assessment time and overall for each subject by dose cohort.

The number and percentage of subjects with baseline anti-drug antibody results, overall and split by negative and positive samples in each treatment group will be provided. A further summary of subjects with post-baseline anti-drug antibody and neutralizing antibody results, anti-drug antibody negative (overall and for treatment-unaffected only), and treatment-emergent anti-drug antibody results (overall and split by treatment-induced and treatment-boosted) in each treatment group will be presented. Treatment-emergent anti-drug antibody is the sum of treatment-induced anti-drug antibody subjects and treatment-boosted anti-drug antibody positive subjects. Treatment unaffected anti-drug antibody is defined as a subject with an ADA-positive sample at baseline, in which post-baseline sample titer results are less than or equal to a four-fold increase in titer values relative to the baseline titer value (titer ≤ 4x baseline titer) or was ADA negative anytime post baseline.

For treatment-induced and treatment-boosted subjects, a summary of all their titer values will be presented. Treatment-induced anti-drug antibody is defined as a subject with at least one post-baseline anti-drug antibody positive sample and an anti-drug antibody negative or missing baseline sample. Treatment-boosted anti-drug antibody is defined as a subject with an anti-drug antibody positive baseline sample in which at least one post-baseline sample titer value is four-fold greater than the baseline titer value (titer > 4x

baseline titer) or if titer result is missing at baseline or missing at all post-baseline assessments.

8.8.5. Profile Plot

A profile plot for subjects will be produced. This plot will display the duration of study treatment in days for each subject, along with an indication of each subject's actual dose over time, investigator assessed confirmed response, highlighting responders versus non-responders, and those ongoing on belantamab mafodotin study treatment.

9. PHARMACOKINETIC ANALYSES

Concentration-time data collected in Cycle 1 will be analyzed using standard non-compartmental methods; some parameters will be determined for all participants and cycles, as data permit. The concentration-time data for belantamab mafodotin, total mAb, and/or cys-mcMMAF may be combined with data from other studies and analyzed in a population approach using nonlinear mixed effects modeling.

9.1. Drug Concentration Measures

Linear and semi-logarithmic individual concentration-time profiles will be plotted for belantamab mafodotin, total mAb, cys-mcMMAF, and pembrolizumab (if tested) in Part 1 and Part 2. Mean and median profiles (when applicable) will be plotted for each analyte by study part and belantamab dose cohort. Plasma concentrations of belantamab mafodotin, total mAb, cys-mcMMAF, and pembrolizumab (if tested) will be listed for each subject and summarized (when appropriate) by study part, belantamab mafodotin dose cohort, and planned time point. Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 16.5.3 Reporting Standards for Pharmacokinetic)

9.2. Derived Pharmacokinetic Parameters

Concentration-time data for belantamab mafodotin, total mAb, cys-mcMMAF, and pembrolizumab (if measured) will be used.

The following pharmacokinetic parameters will be determined separately for each analyte, as data permit:

- Belantamab mafodotin and total mAb: Cmax, C-EOI, tmax, Ctrough, tlast, and AUC(0-τ)
- cys-mcMMAF: Cmax, C-EOI, tmax, tlast, and AUC(0-168)
- Pembrolizumab (if measured): Cmax, tmax, AUC(0-τ)

The pharmacokinetic parameters 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, or by population pharmacokinetic analysis (Section 10). Calculations of pharmacokinetic parameter values will be based on the actual sampling times recorded during the study.

The pharmacokinetic parameters C-EOI and Ctrough will be determined directly from the concentration-time dataset. Notes: For the dosing occasions with only predose and end of infusion samples, the end of infusion sample will not be identified as Cmax.

Table 7 Description of 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
AUC(0-168)	Area under the concentration-time curve from time zero to 168 h after the start of the infusion
C-EOI	Concentration at the end of infusion
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
Ctrough	Trough concentration prior to the next dose for each cycle
t½	Apparent terminal half-life will be calculated as: **t½ = ln(2) / lambda_z** (only from population PK analysis of belantamab mafodotin, if performed)
tlast	Time of last observed quantifiable concentration
CL	Clearance (only from population PK analysis of belantamab mafodotin, if performed)
Vss	Volume of distribution at steady state (only from population PK analysis of belantamab mafodotin, if performed)
λz, lambda_z	Terminal phase rate constant (only from population PK analysis of belantamab mafodotin, if performed)

NOTES:

- Only C-EOI and Ctrough may be derived when only predose and EOI samples were collected.
- Additional parameters may be included as required.

9.3. Summary Measure

Parameters listed in Section 9.2 will be summarized.

9.4. Population of Interest

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

9.5. Statistical Analyses / Methods

Unless otherwise specified, pharmacokinetic parameters defined in Section 9.2 will be listed and summarized descriptively (mean, standard deviation, median, minimum, maximum, geometric mean, and the standard deviation, CV% and 95% confidence interval of log-transformed parameters) by analyte, study part, and dose cohort and may be graphically presented, where appropriate. Summaries of pharmacokinetic parameter values from both Part 1 and Part 2 at the same belantamab mafodotin dose cohort may be generated.

Details of the planned displays are provided in Appendix 11: List of Data Displays and will be based on GSK Data Standards and statistical principles.

10. POPULATION PHARMACOKINETIC (POPPK) ANALYSES

Belantamab mafodotin, total mAb, and/or cys-mcMMAF concentration-time data may be analysed using a population pharmacokinetic approach. The planned population PK analysis will use the then-current population pharmacokinetic model(s) to generate *post hoc* pharmacokinetic parameter estimates (e.g., CL, Vss, t½, AUC(0-τ)) for the individual participants in this study on certain dosing occasions, data permitting. These parameter values will be listed and summarized as described in Section 9.5.

Based on the individual *post hoc* parameter values, dosing information, and sample collection times, drug concentrations at the time of sample collection will be predicted for each participant. Model evaluation will consist of comparison of model-predicted and observed concentrations. If necessary, model estimation will be performed.

Results of this analysis may be provided in a separate report.

To support this analysis, a population PK dataset will be generated. Detailed population PK methodology is also presented in Appendix 9: Population Pharmacokinetic (PopPK) Analyses.

11. PHARMACOKINETIC / PHARMACODYNAMIC ANALYSES

If deemed appropriate and if data permit, exposure-response relationships between belantamab mafodotin exposure (e.g., concentration, Cmax, or AUC) and clinical activity and/or toxicity (e.g., response, AESIs) may be explored using population methods. If data permit, the effects of covariates may be explored.

If done, the analysis will be performed by, or under the direct auspices of, Clinical Pharmacology Modelling and Simulation (CPMS), GlaxoSmithKline, using the currently supported versions of all software packages. These analyses will be performed using R (The R Foundation for Statistical Computing), NONMEM (ICON Solutions) with PsN (Perl Speaks NONMEM), or another software platform deemed appropriate.

The results of this analysis may be provided in a separate report.

12. BIOMARKER ANALYSES

Description of exploratory biomarker data is intended for hypothesis generation in relation to the pharmacodynamics of belantamab mafodotin and/or combinations, for potential prognostic or predictive biomarker evaluation and/or for patient monitoring. Different shapes, colors, symbols and split plots will be used as appropriate to denote patient cohort, response group, dose group or other characteristics. On-treatment measurements may be visualized as percent or fold changes from baseline or as absolute values, as appropriate. Subjects may be plotted individually or in groups, as appropriate. Linear, semi-logarithmic, or logarithmic scales will be used for data visualization where appropriate. Linear interpolation will be used to visually connect measurements from individual subjects to aid interpretations, where appropriate.

If deemed appropriate and if data permit, relationships between biomarkers and/or pharmacodynamic markers and clinical activity and/or toxicity (e.g., response, AESIs) may be explored. If data permit, the effects of covariates may be explored. Details of these analyses will be reported either within the main clinical study report (CSR) or in a separate report.

Data measured from the following samples will be assessed in this RAP:

- Serum samples collected at pre- and post-belantamab mafodotin infusion and/or on-treatment to determine soluble BCMA (sBCMA) concentration by an electrochemiluminescent (ECL)-based MesoScale Discovery (MSD) immunoassays designed to detect GSK2857916 bound and free sBCMA.

12.1. Data processing

- Any out of range values defined by BISTRESC = BLQ or ALQ will be imputed respectively as LLOQ/3 or ULOQ and marked as out of range using distinct colors, shapes, or similar demarcation.

- Duplicate measurements for collections (same collection date/time) will be averaged across the duplicate measurements, when applicable.

- In cases where there are multiple pre-infusion collections (i.e. different collection date/time), the most recent measurement will be used as the baseline measurement.

12.2. Visualization and Tables

12.2.1. Exploratory Objective: To evaluate PD markers in MM after treatment with belantamab mafodotin in combination with pembrolizumab.

Endpoint: sBCMA concentration at baseline and on-treatment in subjects with MM and in relationship to clinical response.

12.2.1.1. Population of Interest

The biomarker/pharmacodynamic analyses will be based on the pharmacodynamic population in the All treated population, unless otherwise specified.

12.2.1.2. sBCMA

- Box plot showing absolute free sBCMA serum concentrations (log scale) measured at baseline in all participants, marked or separated by dose level and categorized by responders (participants with a best confirmed response (partial response (PR) or better)), non-responders (participants with best confirmed response (minimal response (MR), stable disease (SD) or progressive disease (PD)), and participants with best confirmed response of not evaluable (NE). Plots will illustrate the data gathered in Part 1 and Part 2 of this study.
- Spider plot showing absolute free sBCMA serum concentrations (log scale) measured at baseline and while on treatment versus the corresponding treatment cycle number or timepoint in all participants, marked or separated by dose level and categorized by responders (participants with a best confirmed response (partial response (PR) or better)), non-responders (participants with best confirmed response (minimal response (MR), stable disease (SD) or progressive disease (PD)), and participants with best confirmed response of not evaluable (NE). Plots will illustrate the data gathered in Part 1 and Part 2 of this study.
- Spider plot showing fold and/or percentage (%) change from baseline in free sBCMA serum concentrations (log scale) while on treatment versus the corresponding treatment cycle number or timepoint in all participants, marked or separated by dose level and categorized by responders (participants with a best confirmed response (partial response (PR) or better)), non-responders (participants with best confirmed response (minimal response (MR), stable disease (SD) or progressive disease (PD)), and participants with best confirmed response of not evaluable (NE). Plots will illustrate the data gathered in Part 1 and Part 2 of this study.
- Box plot showing absolute free sBCMA serum concentrations in relation to other disease burden markers, including but not limited to β2 microglobulin, kappa/lambda free light chain, M-protein, etc. (log scale), measured at baseline in all participants, marked or separated by dose level and categorized by responders (participants with a best confirmed response (partial response (PR) or better)), non-responders (participants with best confirmed response (minimal response (MR), stable disease (SD) or progressive disease (PD)), and participants with best confirmed response of not evaluable (NE), and extramedullary disease. Plots will illustrate the data gathered in Part 1 and Part 2 of this study.

Table 8 below provides an overview of all the planned interim exploratory biomarker analyses in this RAP. Pre-defined assay parameters (e.g., dynamic range) will be used to identify and exclude from further analysis invalid biomarker data. Other biomarker variables may be examined in relation to other clinical variables, laboratory values, biomarkers, or safety endpoints, as deemed necessary.

Table 8 Overview of Planned Exploratory Analyses

[Endpoint /Parameter]	Untransformed or log-transformed														
	Absolute							% Change from Baseline							
	Statistical Analysis			Summary		Individual		Statistical Analysis			Summary		Individual		
	T	F	L	T	F	F	L	T	F	L	T	F	F	L	
sBCMA levels in subjects with MM															
Free sBCMA						Y							Y		

NOTES :

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
- Summary = Represents TF related to any summaries (descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.
- Either untransformed or log transformed analysis results will be presented, depending upon which is most appropriate for the data and analysis.

13. PATIENT REPORTED OUTCOMES ANALYSES

All questionnaires will be collected electronically as Electronic Patient Reported Outcomes (ePRO). The EORTC QLQ-C30 (version 3.0), EORTC QLQ-MY20, and the PRO-CTCAE are three oncology-specific Health-Related Quality-of-Life (HRQoL) assessments that will be analysed in this study.

In addition, the impact of potential corneal event on function and health-related quality-of-life will be assessed with the use of two visual function questionnaires, the NEI-VFQ-25 and Ocular Surface Disease Index (OSDI).

The analyses for EORTC QLQ-C30, EORTC QLQ-MY20, PRO-CTCAE, NEI-VFQ-25, and OSDI will be based on the All Treated population, unless otherwise specified.

13.1. Patient-Reported Outcome Version of the Common Term Criteria for Adverse Events (PRO-CTCAE)

The PRO-CTCAE is a patient-reported outcome measure developed to evaluate symptomatic toxicity in subjects on cancer clinical trials [Basch, 2014]. The PRO-CTCAE was designed to be used as a companion to the CTCAE, the standard lexicon for adverse event reporting in cancer trials. The PRO-CTCAE includes an item library of 124 items representing 78 symptomatic toxicities drawn from the CTCAE. PRO-CTCAE provides a systematic yet flexible tool for descriptive reporting of symptomatic treatment side effects in cancer clinical trials. In the present study, a subset of items selected from the PRO-CTCAE Version 1.0 Item library will be administered. The levels and related code values for PRO-CTCAE are shown below.

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

For each selected item from the library: proportion of PRO-CTCAE scores for attributes (frequency, severity and/or interference) will be presented with stacked bar charts by visit. Maximum PRO-CTCAE score at post-baseline for each item attribute will be summarized by counts and proportions. Proportion of patients with a maximum score of 3 or 4 for each item attribute (severe or very severe, frequently or almost constantly, quite a bit or very much) will also be reported. Proportions will be based on the number of patients with available data and subject with missing response will be excluded from analysis. A listing of the PRO-CTCAE score will be provided for each attribute (frequency, severity, interference, presence).

13.2. Visual Function Questionnaires

13.2.1. National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25)

The NEI-VFQ-25 consists of a base set of 25 vision-targeted questions representing 11 vision-related constructs, plus an additional single-item general health rating question [Mangione, 2001]. The NEI-VFQ-25 generates the following vision-targeted sub-scales: global vision rating, difficulty with near vision activities; difficulty with distance vision activities; limitations in social functioning due to vision; role limitations due to vision; dependency on others due to vision; mental health symptoms due to vision; driving difficulties; limitations with peripheral vision, limitations with color vision; and ocular pain. Details of deriving domain scores and overall composite score can be found in Section 16.6.5.3.

For each of 11 sub-scale scores, the descriptive summary of the actual value and change from baseline by visit will be provided. The overall composite score and 11-sub-scale scores will be listed.

13.2.2. Ocular Surface Disease Index

The Ocular Surface Disease Index (OSDI) is a 12-item questionnaire designed to assess both the frequency of dry eye symptoms and their impact on vision-related functioning [Schiffman, 2000]. The OSDI has demonstrated good reliability, validity, sensitivity, and specificity, and can be used as a complement to other clinical and subjective measures of dry eye disease by providing a quantifiable assessment of dry eye symptom frequency and the impact of these symptoms on vision-related functioning.

For the OSDI, the total score will be calculated as well as scores for the three subscales (ocular symptom: item 1-3; vision-related function: item 4-9; and environmental triggers: item 10-12).

The total OSDI score = ([sum of scores for all questions answered × 100]/[total number of questions answered ×4]). Subscale scores are computed similarly with only the questions from each subscale used to generate its own score. Subscale scores are computed similarly with only the questions from each subscale used to generate its own score. A score of 100 corresponds to complete disability (a response of "all of the time" to all questions answered), while a score of 0 corresponds to no disability (a response of "none of the time" to all questions answered). Therefore, decrease in score from baseline means improvement.

For each of the three sub-scales, the descriptive summary of the actual value and change from baseline at selected time points will be provided. For the Vision-Related Functioning domain, the number and percentage of participants with post-baseline score worsening of ≥ 12.5 from baseline score will be summarized at selected time points. Additionally, a time to event analysis of time to meaningful worsening based on the ≥ 12.5 threshold will be summarized with frequency of number of patients with event (N, %). Time to first event and duration of event will also be calculated (median days, range). Additionally, recovery from first event defined as ≥ 12.5 decrease from the first worst score will be summarized.

Plots of mean change from baseline (including baseline) and 95% confidence interval over time by visit, and at end of study treatment, last follow-up, and worst case post-baseline for individual domains will also be provided. The overall total score and sub-scale scores will be listed.

13.3. Value Evidence and Outcome (Part 2 only)

13.3.1. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30-item Core module (EORTC QLQ-C30)

The EORTC QLQ-C30 is a 30-item questionnaire containing both single- and multi-item measures [Aaronson, 1993]. These include five functional scales (Physical, Role, Cognitive, Emotional, and Social Functioning), three symptom scales (Fatigue, Pain, and Nausea/Vomiting), a Global Health Status/QoL scale, and six single items (Constipation, Diarrhea, Insomnia, Dyspnea, Appetite Loss, and Financial Difficulties). Scores for each scale and single-item measure are averaged and transformed linearly to a score ranging from 0–100. Details of deriving domain scores (9 scales and 6 single items) and summary score can be found in Section 16.6.5.1.

A high score for functional scales and for Global Health Status/QoL represent better functioning ability or Health-Related Qualify of Life (HRQoL), (higher score indicates improvement) whereas a high score for symptom scales and single items represents significant symptomatology [Proskorovsky 2014]. (lower score indicates improvement)

Descriptive summaries (mean, SD, median, min and max) of the actual value and change from baseline at selected time points will be provided for EORTC QLQ-C30 summary score and each domain score.

Plots of mean change from baseline (including baseline) and 95% confidence interval over time by visit, and at end of study treatment, last follow-up, and worst case post-baseline for individual domains will also be provided. The overall summary score and 11-sub-scale scores will be listed.

13.3.2. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 20-item Multiple Myeloma module (EORTC QLQ-MY20)

The EORTC QLQ-MY20 is a supplement to the QLQ-C30 instrument used in patients with multiple myeloma [Aaronson, 1993; Cocks, 2007]. The module comprises 20 questions that address four myeloma-specific HRQoL domains: Disease Symptoms, Side Effects of Treatment, Future Perspective, and Body Image. Three of the four QLQ-MY20 domains are multi-item scales: Disease Symptoms (includes bone aches or pain, back pain, hip pain, arm or shoulder pain, chest pain, and pain increasing with activity); Side Effects of Treatment (includes drowsiness, thirst, feeling ill, dry mouth, hair loss, upset by hair loss, tingling hands or feet, restlessness/agitation, acid indigestion/heartburn, and burning or sore eyes); and Future Perspective (includes worry about death and health in the future, and thinking about illness). The Body Image scale is a single-item scale that addresses physical attractiveness. Details of deriving domain scores can be found in Section 16.6.5.2.

For each of four domain scores, a descriptive summary of the actual value and change from baseline by visit will be provided:

Plots of mean change from baseline (including baseline) and 95% confidence interval over time by visit, and at end of study treatment, last follow-up, and worst case post-baseline for individual domains will also be provided. The 4-domain scores will be listed.

13.4. Compliance of OSDI, EORTC QLQ-C30, and EORTC-QLQ-MY20

Tables to summarize the compliance of OSDI (Part 1 and Part 2) and EORTC QLQ-C30 and EORTC-QLQ-MY20 (Part 2 only) by visit will be provided. The Tables will include number of subjects remaining in study, number and percentage of participants with OSDI summary score, QLQ-C30 summary score, and QLQ-MY20 summary score. The percentage is calculated using number of participants remaining in the study at given timepoint as denominator.

14. ADDITIONAL ANALYSES DUE TO THE COVID-19 PANDEMIC

14.1. Study Population

14.1.1. Subject Disposition

A summary of recruitment by country and site, relative to COVID-19 Pandemic measures will be produced. For the definition of the phases of the COVID-19 pandemic measures see Section 16.4.1.4.

A country level listing of the dates of the COVID-19 Pandemic measures, will be produced. The 'Summary of Subject Status and Reason for Study Withdrawal' and the 'Summary of Treatment Status and Reasons for Discontinuation of Study Treatment' will be repeated, with the reason for withdrawal/discontinuation categorised as due to the COVID-19 pandemic, or non-due to the COVID-19 pandemic based on information collected on the COVID-19 Pandemic Study Impact form. The summaries will be based on GSK Core Data Standards, and details are provided in Appendix 11: List of Data Displays.

14.1.2. Protocol Deviations

In addition to the overall summary of important protocol deviations, separate summaries will be produced of important protocol deviations related to COVID-19, and non-important protocol deviations related to COVID-19. A listing of important protocol deviations related to COVID-19 will also be produced.

The summaries will be based on GSK Core Data Standards, and details are provided in Appendix 11: List of Data Displays.

14.1.3. Additional Displays for Participants with a COVID-19 Infection

A participant is defined as having a suspected, probable or confirmed COVID-19 infection during the study if the answer is "Confirmed", "Probable" or "Suspected" to the case diagnosis question from the COVID-19 coronavirus infection assessment eCRF.

Summaries and listings of the numbers of participants with a suspected, probable or confirmed COVID-19 infection, and of COVID-19 test results will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 11: List of Data Displays.

Additionally, if greater than 5 participants have a suspected, probable of confirmed COVID-19 infection, the following data displays will be produced:

- Summary of COVID-19 Assessments for Subjects with Suspected, Probable or Confirmed COVID-19 Case Diagnosis

- Summary of COVID-19 Symptoms for Subjects with Suspected, Probable or Confirmed COVID-19 Case Diagnosis

All of the above displays will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 11: List of Data Displays.

14.2. Safety

14.2.1. Assessment of COVID-19 AEs

A Standardised MedDRA Query (SMQ) will be used to identify all COVID-19 AEs.

The incidence of AEs of COVID-19, and COVID-19 AEs leading to study drug discontinuation will be obtained from standard AE summaries.

If >5% participants report ≥1 COVID-19 AEs, then the following data displays will be produced:

- Summary of COVID-19-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade
- Summary of COVID-19 Adverse Events Leading to Permanent Discontinuation of Study Treatment by Overall Frequency
- Listing of COVID-19 Adverse Events
- Listing of COVID-19 Assessments and Symptom Assessments for Subjects with COVID-19 Adverse Events

All of the above displays will be based on All of the above displays will be GSK Core Data Standards. The details of the planned displays are provided in Appendix 11: List of Data Displays.

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16. APPENDICES

16.1. Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population

This study does not have per protocol population.

16.2. Appendix 2: Schedule of Activities

16.2.1. Protocol Defined Schedule of Events

Refer to Section 7 of Protocol (Version: GSK Document Number TMF-14344600).

16.3. Appendix 3: Assessment Windows

No assessment windows will be applied.

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

16.4.1. Study Phases

Assessments and events will be classified according to the time of occurrence relative to Screening Assessment, On Study Assessment Completed Independent of Dosing, On study Assessment with Dosing Days (Cycles), and End of Study and Follow-up Assessment.

Study Phase	Definition
Pre-Treatment	Date ≤ Study Treatment Start Date
On-Treatment	Study Treatment Start Date < Date ≤ Study Treatment Stop Date + 30 days For interim analyses when subjects are still on treatment, Study Treatment Stop Date will be imputed following rules specified in Section 16.7.2.1
Post-Treatment	Date > Study Treatment Stop Date + 30 days

16.4.1.1. Study Phases for Concomitant Medication

Study Phase	Definition
Prior	End Date < Study Treatment Start Date
Post-Treatment	Start Date > Study Treatment Stop Date + 30 days For interim analyses when subjects are still on treatment, Study Treatment Stop Date will be imputed following rules specified in Section 16.7.2.1.
Concomitant	If the medication is not Prior nor Post-treatment

NOTES:

- Please refer to Appendix 7: Reporting Standards for Missing Data for handling of missing and partial dates for concomitant medication. Use the rules in this Table if concomitant medication date is missing.

16.4.1.2. Study Phases for Vital signs, ECG and Laboratory Values

Study Phase	Definition
Pre-Treatment	Date ≤ Study Treatment Start Date (if time is collected then Date/time ≤ Study Treatment Start Date/time)
On-Treatment	Study Treatment Start Date < Date (if time is collected then Date/time > Study Treatment Start Date/time)

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 vital signs, ECG, and laboratory values should be considered, if collected.

16.4.1.3. End of Treatment Exposure

Study Phase	Definition
Post-Treatment	Date > Study Treatment Stop Date + 20 days

16.4.1.4. Phases of COVID-19 Pandemic Measures

Pandemic measures began in different countries at different times. A dataset containing the date when pandemic measures began, as determined by the GSK country Issue Management Teams (IMT), and available within the HARP reporting environment (arcomn folder), will be used to determine the start date of pandemic measures within each country. A copy of this dataset will be taken at the time of database lock (DBL).

Adverse events will be summarised according to whether the onset date was before or after the start of the COVID-19 pandemic measures.

Pandemic Measures Phase	Definition
Before	AE onset date < pandemic measures start date
After	Pandemic measures start date ≤ AE onset date

16.4.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent	• If AE onset date is on or after treatment start date or missing o Study Treatment Start Date ≤ AE Start Date ≤ Study Treatment Stop Date + 45 days o AE Start Date is missing

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.

16.5. Appendix 5: Data Display Standards & Handling Conventions

16.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: US1SALX00259
HARP Compound	: arprod\gsk2859716\mid205207\
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.2 & ADaM IG Version 1.1). If the Study Data Standardization Plan (SDSP) exists for a study, ensure the CDISC versions are consistent.	
Generation of RTF Files	
• RTF files will be generated for SAC deliverable.	

16.5.2. Reporting Standards

General

• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated (IDSL Standards 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 subject level listings in the main body of the GSK Clinical Study Report. All subject level listings should be located in the modular appendices as ICH or non-ICH listings
• Note: All displays (TFL) will use the term 'Subjects' to reflect GSK Display Standards and CDISC SDTM/ADaM standards

Formats
• GSK IDSL Statistical 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 IDSL statistical 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 IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the subject's listings.

Unscheduled Visits	
• Unscheduled visits will not be included in summary Tables and/or Figures. o For by planned time analysis, unscheduled visits will not be included; o For worst-case analysis, unscheduled visits will be included. • All unscheduled visits will be included in listings.	
Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

16.5.3. 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 SOP_314000: Non-Compartment Analysis of Clinical Pharmacokinetic Data [Note: Concentration values will be imputed as per GUI_51487
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. Refer to IDSL Statistical 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	Pop-PK file (CSV format) for the POP-PK analysis by Clinical Pharmacology Modelling and Simulation function will be created according to the data specification detailed in Appendix 9.
NONMEM/PK/PD File	Not applicable.
Pharmacokinetic Parameter Derivation	
PK Parameter to be Derived by Programmer	The following PK parameters will be derived by the Programmer: Ctrough (predose) and C-EOI at certain cycles. Note: C-EOI will not be designated as Cmax
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 IDSL PK Display Standards.]
Untransformed PK parameters	tmax (TMAX), tlast (TLST)

16.6. Appendix 6: Derived and Transformed Data

16.6.1. General

Multiple Measurements at One Analysis Time Point
• Mean of the measurements will be calculated and used in any derivation of summary statistics 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 Date ≥ First Dose Date → Study Day = Ref Date – (First Dose Date) + 1

Change from Baseline
• Change from Baseline = Post-Baseline Visit Value – Baseline • % Change from Baseline= 100 x (Post-Baseline Visit Value – Baseline) / Baseline • Maximum Increase/Decrease from Baseline = maximum (Increase/Decrease from Baseline) • If either the Baseline or Post-Baseline Visit Value is missing, Change from Baseline and % Change from Baseline is set to missing
Date of Response
• For post-baseline disease assessments, the date of response (PR or better) is assigned to the latest date of disease assessments; for other response categories (MR, SD, NE, PD), the date of response is assigned to the earliest date of disease assessments.
Date of New Anti-Cancer Therapy
• Derived as the earliest date of new anti-cancer therapy, radiotherapy (where applicable) or cancer-related surgical procedure (where applicable) • after date of study treatment discontinuation (date of last dose of study treatment). Missing or partial dates will be imputed for derivation of new anti-cancer therapy following rules specified in Section 16.7.2.1.

16.6.2. Study Population

Extent of Exposure

- Missing treatment stop date will be imputed following rules specified in Section 16.7.2.1.
- Combination Treatments
- Extent of exposure will be calculated for each treatment component
  - **Non-Continual Drugs**
    - Extent of exposure will be calculated based on treatment cycles derived based on cycle start dates in the exposure dataset
- Duration of treatment will be calculated based on the formula:

  Duration on study treatment is calculated as the minimum of
  - Maximum of (treatment stop date + lag time) – minimum of first treatment start date
    - for continual treatments, lag time = 1
    - for non-continual treatments, lag time = duration of one cycle
- Data cut-off date – minimum of (first treatment start date) + 1
- Date of death – minimum of (first treatment start date) + 1
- Last contact date– minimum of (first treatment start date) + 1 (only applies for those lost to follow up/withdrew consent; does not apply for those who are still on study including follow-up)
  - The last contact date is determined for each by selecting the latest date of all dates available in the database, and is derived as follows:
    - Date of death if the subject has died (DM.DTHDTC).
    - Else latest date from all other SDTM datasets. Partial and missing dates will not be imputed for the purpose of deriving date of last contact
  - The following dates below need to be removed from consideration. Note that if a participant has withdrawn consent from the study, then do not consider any dates in the database after the date of withdrawn consent.
    - DM.RFPENDTC, SV.SVENDTC, SV.SVSTDTC, SUPPAE.QNAM = "SASAEDTC", SUPPC1.QNAM="CMDSCRDT", SUPPCM.QNAM="CMDSCRDT".
    - DS.DSSTDTC where DS.DSCAT="DISPOSITION EVENT" and DS.DSSCAT in ("STUDY CONCLUSION" ="STUDY TREATMENT DISCONTINUATION") and DS.DSDECOD not equal to "WITHDRAWAL BY SUBJECT"
- Participants who were randomized but did not report a treatment start date will be categorized as having zero days of exposure
- Dose intensity will be calculated based on the formula:
  - **Belantamab mafodotin:**
    - **Actual dose (mg/kg) = Actual dose of belantamab mafodotin (mg)/ Weight at baseline (kg)**
      - If the change of body weight is greater than 10%, the dose should be re-calculated based on the actual body weight on the day of dosing
    - **Cumulative Dose (mg/kg) = Sum of individual actual dose of belantamab mafodotin at all cycles**
    - **Dose intensity (mg/kg/3 week) = Cumulative Dose/((last infusion date – first infusion date + 21)/21)**
  - **Pembrolizumab:**
    - **Actual dose (mg) = Actual dose of pembrolizumab (mg)**
    - **Cumulative Dose (mg) = Sum of individual actual dose of pembrolizumab at all cycles**
    - **Dose intensity (mg/3 week) = Cumulative Dose/((last infusion date – first infusion date + 21)/21)**

Treatment Cycle
• Actual Treatment Cycle will be derived based on cycle start date in exposure data to distinguish from assessment cycle.
Actual Treatment
• Subject's actual treatment will be derived from exposure data. If a subject's actual treatment is the same as assigned treatment, actual treatment is the assigned treatment; if a subject received treatment different from assigned treatment for the entire duration of treatment, actual treatment is different from assigned treatment.   ◦ Refer to the adjustments due to body weight in Section 6.4.1 of protocol. • If time is not available for at least one of the study treatments, then GSK2857916 will be selected over pembrolizumab.
Time since Initial Diagnosis

• Calculated as the number of Days from the Date of Initial Diagnosis:
  ◦ First Dose Date = Missing → Elapse Time = Missing
  ◦ Date of Initial Diagnosis = Completely/partially Missing → Elapse Time = Missing
  ◦ Otherwise → Elapse Time = First Dose Date – Date of Initial Diagnosis + 1

16.6.3. Efficacy

Laboratory Parameters: Serum M-protein, Urine M-protein, Serum FLC

• 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

16.6.4. Safety

Adverse Events
AE'S of Special Interest (belantamab mafodotin)
• Corneal events (GSK Scale): collected in eCRF • Eye Disorders (CTCAE) • Thrombocytopenia • Infusion related reactions
AE'S of Special Interest (pembrolizumab)
• Overdose

Duration of AE

• Calculated as the number of days from AE Start Date to AE Stop Date:
  • AE Start Date = Missing → Elapse Time = Missing
  • AE Stop Date = Missing → Elapse Time = Missing
  • Otherwise → Elapsed Time = AE Stop Date – AE Start Date + 1

ECHO/MUGA
• Change from Baseline for cardiac data, e.g., Left Ventricular Ejection Fraction (LVEF), will be calculated based on the same modality (ECHO or MUGA) throughout the study for each subject. Post-baseline assessments with a different cardiac scan modality will not be used to calculate change from Baseline.

DLT
DLT Evaluable
• Participant is considered DLT evaluable if they fulfilled the 'All Treated' population criteria during part 1 (Dose Escalation) and are followed up for a 21-day period or withdrawn within 21 days due to an AE meeting the definition of a DLT as defined in Section 4.2.3.1 of protocol.

16.6.5. Patient Reported Outcomes

16.6.5.1. EORTC QLQ-C30

The EORTC QLQ-C30 is a 30-item questionnaire containing both single- and multi-item measures [Aaronson, 1993]. These include five functional scales (Physical, Role, Cognitive, Emotional, and Social Functioning), three symptom scales (Fatigue, Pain, and Nausea/Vomiting), a Global Health Status/QoL scale, and six single items (Constipation, Diarrhea, Insomnia, Dyspnea, Appetite Loss, and Financial Difficulties). The below image shows the details.


CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

Technical Summary

In practical terms, if items $I_1, I_2, \ldots I_n$ are included in a scale, the procedure is as follows:

Raw score
Calculate the raw score
$RawScore = RS = (I_1 + I_2 + ... + I_n)/n$

Linear transformation
Apply the linear transformation to 0-100 to obtain the score S,

Functional scales: $S = \left\{1 - \frac{(RS-1)}{range}\right\} \times 100$

Symptom scales / items: $S = \{(RS-1)/range\} \times 100$

Global health status / QoL: $S = \{(RS-1)/range\} \times 100$

Range is the difference between the maximum possible value of *RS* and the minimum possible value. The QLQ-C30 has been designed so that all items in any scale take the same range of values. Therefore, the range of *RS* equals the range of the item values. Most items are scored 1 to 4, giving *range* = 3. The exceptions are the items contributing to the global health status / QoL, which are 7-point questions with *range* = 6, and the initial yes/no items on the earlier versions of the QLQ-C30 which have *range* = 1.

Scoring of the QLQ-C30 Summary Score

The EORTC QLQ-C30 Summary Score is calculated from the mean of 13 of the 15 QLQ-C30 scales (the Global Quality of Life scale and the Financial Impact scale are not included). Prior to calculating the mean, the symptom scales need to be reversed to obtain a uniform direction of all scales. The summary score should only be calculated if all of the required 13 scale scores are available.

QLQ-C30 Summary Score = [Physical Functioning+ Role Functioning+ Social Functioning+ Emotional Functioning+ Cognitive Functioning+ (100 - Fatigue) + (100 - Pain) + (100 -Nausea_Vomiting) + (100 - Dyspnoea) + (100 - Sleeping Disturbances) + (100 - Appetite Loss) + (100 - Constipation) + (100 - Diarrhoea)]/13.

Handling of missing items

Single-item measures: if the item is missing, the score S will be set to missing.

Scales requiring multiple items: if at least half of the items from the scale are available, the score S will be calculated based on available items. If more than half of the items from the scale are missing, the score S will be set to missing (Fayers et. al., The EORTC QLQ-C30 Scoring Manual (3rd Edition) 2001).

Minimal Important Difference (MID)

In a sample of patients who received chemotherapy for either breast cancer or small-cell lung cancer (n=246, n=80 respectively), the mean change in EORTC QLQ-C30 score

between baseline and follow-up was about 5 to 10 points on a 0-100 scale for patients who indicated "a little" change on the Subjective Significance Questionnaire (SSQ), either for better or for worse (Osoba, 1998).

16.6.5.2. EORTC QLQ-MY20

For EORTC QLQ-MY20, the raw scores from the following multi-item scales and single-item measures raw scores will be calculated by averaging the items that contribute to the scale or single item: disease symptom scales (includes bone aches or pain, back pain, hip pain, arm or shoulder pain, chest pain, and pain increasing with activity), side effects of treatments (including drowsiness, thirst, feeling ill, dry mouth, hair loss, upset by hair loss, tingling hands or feet, restlessness/agitation, acid indigestion/heartburn, and burning or sore eyes), future perspective (includes worry about death and health in the future, and thinking about illness), and body image scale is a single-item scale that addresses physical attractiveness.

1.) Raw Score

For each multi-item scale, calculate the average of the corresponding items.

$$\text{Raw Score} = \text{RS} = \left\{\frac{(I_1 + I_2 + \cdots + I_n)}{n}\right\}$$

For the single-item measure, the score of the concerning item corresponds to the raw score.

2.) Linear Transformation

To obtain the Score S, standardize the raw score to a 0 – 100 range following the appropriate transformation:

Functional scales: $S = \left\{1 - \frac{(RS-1)}{range}\right\} x\ 100$

Symptom scales: $S = \left\{\frac{(RS-1)}{range}\right\} x\ 100$

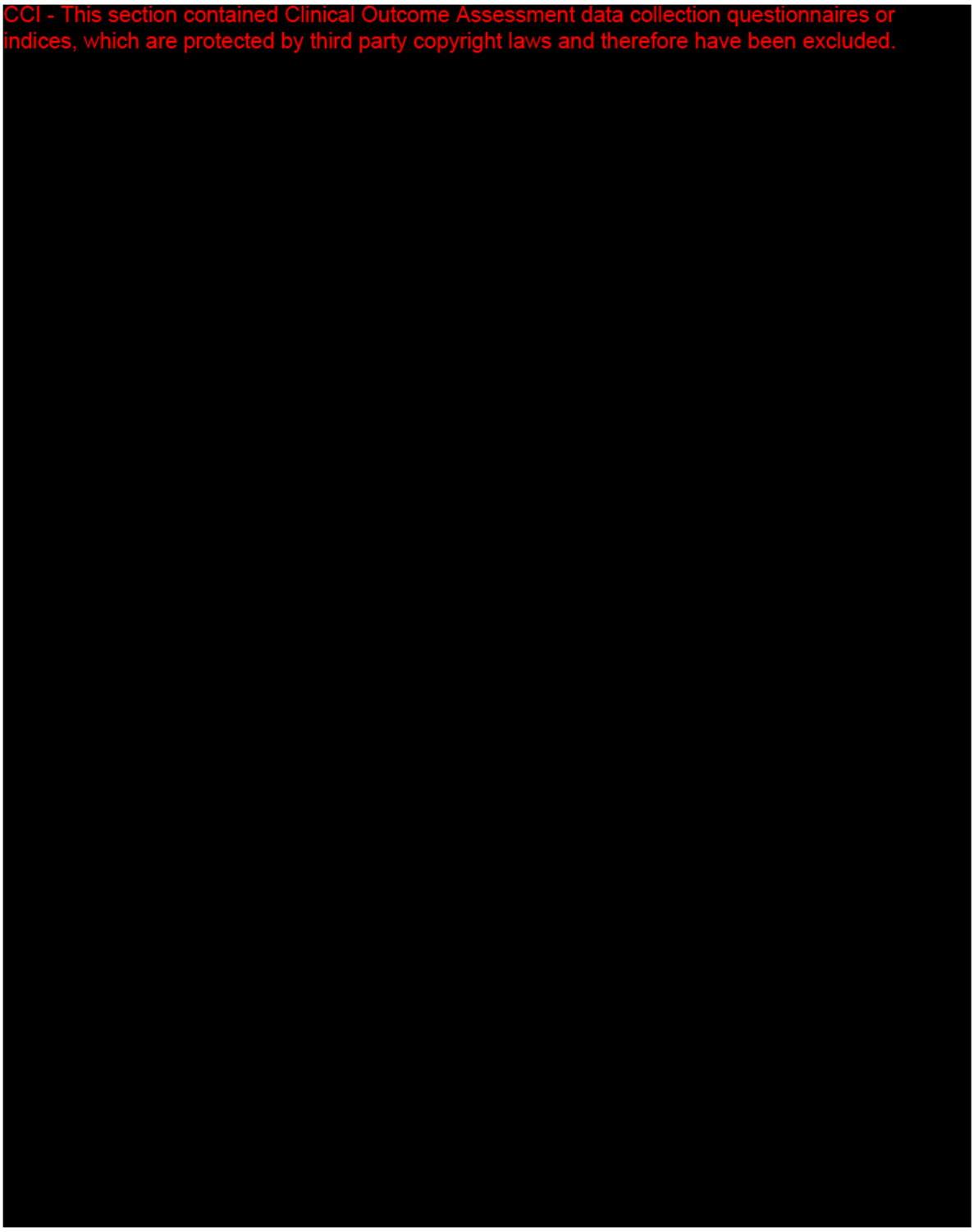
A high score for Disease Symptoms and Side Effects of Treatment represents a high level of symptomatology or problems, whereas a high score for Future Perspective and Body Image represents better outcomes [Proskorovsky, 2014].

Missing items can be handled similarly to EORTC QLQ-C30 as described in Section 16.6.5.1.

16.6.5.3. NEI-VFQ-25

The NEI-VFQ-25 consists of a base set of 25 vision-targeted questions representing 11 vision-related constructs, plus an additional single-item general health rating question [Mangione, 2001]. The NEIVFQ-25 generates the following 11 vision-targeted sub-scales: global vision rating, difficulty with near vision activities; difficulty with distance vision activities; limitations in social functioning due to vision; role limitations due to vision; dependency on others due to vision; mental health symptoms due to vision; driving difficulties; limitations with peripheral vision, limitations with color vision; and corneal pain.

The following two Tables (from the NEI-VFQ-25 User Manuals) provide the details of converting the original response category to the recorded values, and items of which recorded values need to be averaged to generate the VFQ-25 sub-scales. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Hence scores represent the average for all items in the sub-scale that the respondent answered. Sub-scales with at least one item answered can be used to generate a sub-scale score. To calculate an overall composite score for the VFQ-25, simply average the 11 vision-targeted sub-scale scores.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16.7. Appendix 7: Reporting Standards for Missing Data

16.7.1. Premature Withdrawals

Element	Reporting Detail

General	• Subject study completion (i.e. as specified in the protocol) was defined as:
	  ○ For Part 1 and Part 2, a subject is considered to have completed the study if they received at least 1 cycle of combination study treatment, and:
	  ▪ The subject is followed until death, or
	  ▪ The subject is followed until the end of study
	  ○ The end of study (defined as last subject's last visit) is defined as when all subjects have either died, progressed, withdrawn consent, or have been followed for a minimum of 24 months from the last subject first dose (LSFD). Following 24 months post LSFD, PACT will be implemented. At this time, the collection of data for all recruited participants who no longer receive study treatment will stop entirely and clinical trial database will be closed.
	• Withdrawn subjects for other reasons other than toxicity, but prior to completion of DLT period will be replaced in the study for Part 1.
	• 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.
	• Withdrawal visits will be slotted as per Appendix 3: Assessment Windows or will be summarised as withdrawal visits.

16.7.2. Handling of Missing Data

Element	Reporting Detail

General	• 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 subject 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.

Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.
Responder Analysis	• For endpoints which determine the percentage of responders, subjects with unknown/not evaluable or missing best overall response will be assumed to be non-responders and will be included in the denominator when calculating the percentages.
Time to Event	• Because study treatment is dependent on the study endpoints (e.g., progression, i.e. not a fixed treatment duration), the length of treatment for each subject will depend on the efficacy and toxicity of the treatment, so the duration of treatment will vary across subjects. Similarly, the duration of follow up will also vary. All available time-to-event data will be analysed using suitable statistical methods; subjects with shorter treatment and follow-up due to the natural history of their disease or medical necessities of the treatment of their disease will not be considered to have missing time-to-event data.

16.7.2.1. Handling of Missing and Partial Dates

<table>
<tr><th>Element</th><th>Reporting Detail</th></tr>
<tr><td>General</td><td>

Partial dates will be displayed as captured in participant listing displays.
Imputed partial dates will not be used to derive study day, time to onset or duration (e.g., time to onset or duration of adverse events), or elapsed time variables (e.g., time since diagnosis). In addition, imputed dates are not used for deriving the last contact date in 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.

</td></tr>
<tr><td>Age</td><td>

The eCRF collects year of birth only. Day and Month will be imputed by Data Management using a '30' for the day and 'June' for the month
Age will then be derived referenced to the Screening Date
A footnote to say that age has been imputed will be included in any outputs containing age.

</td></tr>
<tr><td>Adverse Events</td><td>

Imputations in the adverse events dataset are used for slotting events to the appropriate study time periods and for sorting in data listings.
Partial dates for AE recorded in the CRF will be imputed using the following conventions:

<table>
<tr><td>Missing start day</td><td>

If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = 1st of month.
Else if study treatment start date is not missing:

If month and year of start date = month and year of study treatment start date then

If stop date contains a full date and stop date is earlier than study treatment start date then set start date= 1st of month.
Else set start date = study treatment start date.

Else set start date = 1st of month.

</td></tr>
<tr><td>Missing start day and month</td><td>

If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = January 1.
Else if study treatment start date is not missing:

If year of start date = year of study treatment start date then

If stop date contains a full date and stop date is earlier than study treatment start date then set start date = January 1.
Else set start date = study treatment start date.

Else set start date = January 1.

</td></tr>
<tr><td>Missing stop day</td><td>Last day of the month will be used.</td></tr>
<tr><td>Missing stop day and month</td><td>No Imputation</td></tr>
<tr><td>Completely missing start/end date</td><td>No imputation</td></tr>
</table>
</td></tr>
<tr><td>Concomitant Medications/ Blood Supportive</td><td>

Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention:

</td></tr>
</table>

<table>
<tr><th>Element</th><th>Reporting Detail</th></tr>
<tr><td>Products</td><td>
<table>
<tr><td>Missing start day</td><td>• If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = 1st of month.
• Else if study treatment start date is not missing:
o If month and year of start date = month and year of study treatment start date then
▪ If stop date contains a full date and stop date is earlier than study treatment start date then set start date= 1st of month.
▪ Else set start date = study treatment start date.
o Else set start date = 1st of month.</td></tr>
<tr><td>Missing start day and month</td><td>• If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = January 1.
• Else if study treatment start date is not missing:
o If year of start date = year of study treatment start date then
▪ If stop date contains a full date and stop date is earlier than study treatment start date then set start date = January 1.
▪ Else set start date = study treatment start date.
• Else set start date = January 1.</td></tr>
<tr><td>Missing end day</td><td>A '28/29/30/31' will be used for the day (dependent on the month and year)</td></tr>
<tr><td>Missing end day and month</td><td>A '31' will be used for the day and 'Dec' will be used for the month.</td></tr>
<tr><td>Completely missing start/end date</td><td>No imputation</td></tr>
</table>
</td></tr>
<tr><td>New Anti-Cancer Therapy/ Radiotherapy/ Surgical Procedures for Efficacy Evaluation (e.g., response rate, time to event)</td><td>• Completely missing start dates will remain missing, with no imputation applied;
• Partial start dates will be imputed using the following convention:
• If both month and day are missing, no imputation will be applied;
• If only day is missing:
o If the month of partial date is the same as the month of last dosing date, minimum of (last dosing date + 1, last day of the month) will be used for the day;
o If the month of partial date is the same as the month of last disease assessment and the last disease assessment is PD, minimum of (last date of disease assessment + 1, last day of the month) will be used for the day;
o If both conditions above are met, the later date will be used for the day;
o Otherwise, a '01' will be used for the day;
• Completely or partial missing end dates will remain missing, with no imputation applied;</td></tr>
<tr><td>Covariates for efficacy analysis (Date of initial diagnosis/ Last recurrence/ Last progression)</td><td>• 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</td></tr>
<tr><td>Treatment end</td><td>• If there is more than one study treatment, imputation of missing treatment end</td></tr>
</table>

Element	Reporting Detail

date	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.
	• If treatment end date is missing for a cycle, treatment start date for the cycle will be used.
	• For imputation of missing exposure end date at an interim analysis when subjects are still on treatment, the following conventions will be applied:
	  ○ 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.
	• If treatment end date is missing for a cycle, treatment start date for the cycle will be used.

16.8. Appendix 8: Values of Potential Clinical Importance

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 v4.03) will be used to assign grades for relevant laboratory parameters. NCI-CTCAE v4.03 can be found at http://ctep.cancer.gov/reporting/ctc.html.

For laboratory data which are not listed in the NCI CTCAE v4.03, a summary of values outside the normal range will be provided.

16.8.1. 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.

16.9. Appendix 9: Population Pharmacokinetic (PopPK) Analyses

16.9.1. Population Pharmacokinetic (PopPK) Methodology

Belantamab mafodotin, total mAb, and/or cys-mcMMAF plasma concentration-time data may be analyzed by population PK methods using a nonlinear mixed-effects modelling approach.

The key objective of this analysis is to:

- Predict individual pharmacokinetic parameter values for belantamab mafodotin, total mAb, and/or cys-mcMMAF

16.9.1.1. Systems

The population PK analysis will be performed using NONMEM (ICON Solutions) and PsN (Perl Speaks NONMEM) or another software platform deemed appropriate. Graphical displays and data summary will be produced using R (The R Foundation for Statistical Computing). The analysis will be performed by, or under the direct auspices of, Clinical Pharmacology Modelling and Simulation (CPMS), GlaxoSmithKline using the currently supported versions of all software packages.

16.9.1.2. Data Assembly

Participant data will be collected in the electronic CRF and will be transmitted into a validated database by GSK data management. Derived/processed variables will be provided by or under the guidance of Clinical Programming. Plasma samples will be analyzed using approved analytical methodology. Data will be transferred electronically to data managers to be processed and stored in the GSK database. GSK or a designated third party will generate the NONMEM input dataset.

Previously combined belantamab mafodotin, total mAb, and/or cys-mcMMAF PK data may be merged with the PK data in Study 205207 in order to provide a pooled NONMEM data set.

16.9.1.3. Model Development

The analysis will use the then-current population pharmacokinetic model for each compound analyzed.

Initially, empirical Bayes estimates will be derived applying the current population PK model to the Study 205207 dataset with the MAXEVAL=0 option. If the corresponding model diagnostics indicate that this population PK model is appropriate to represent the belantamab mafodotin, total mAb, and/or cys-mcMMAF data from Study 205207, then individual PK parameter estimates will be based on the current population PK parameter values.

If the parameter set of the current population PK model applied to the Study 205207 dataset results in substantial bias or if a further exploration of the covariate effect in the Study 205207 population is deemed necessary, the parameters of the current population

PK model will be re-estimated for the Study 205207 PK data alone and/or for a pooled dataset before generating the individual PK parameter estimates. Certain parameter values may be fixed to the value in the current population PK model, if they cannot be estimated with sufficient precision within the Study 205207 PK population. Covariates not available for the Study 205207 PK population but present in the current population PK model may be removed from the Study 205207 population PK model. Lastly, a model refinement step, if needed, will include, but may not be limited to, a qualification and possible modification of the model's random effect structure.

16.9.1.4. Model Qualification

Any model development will be supported and the final model will be qualified using the following criteria where appropriate:

- Scientific plausibility of parameter estimates
- Goodness of fit plots
- Relative standard errors (RSE) of the parameter estimates
- Objective function value
- Distribution and shrinkage of random effects;
- Successful minimization and execution of covariance step
- Condition number (ratio of the largest and smallest eigenvalue of the covariance matrix
- Visual predictive check
- Bootstrap (if deemed necessary/feasible)

16.10. Appendix 10: Abbreviations & Trade Marks

16.10.1. Abbreviations

Abbreviation	Description
ADA	Anti-Drug Antibodies
ADC	Anti-drug Conjugate
ADaM	Analysis Data Model
AE	Adverse Event
AESI	Adverse Event of Special Interest
ALT	Alanine aminotransferase
A&R	Analysis and Reporting
AUC	Area under the curve
AUC(0-t)	Area under the concentration-time curve
AUC(0-τ)	Area under the concentration-time curve during the dosing interval
AUC(0-168)	Area under the concentration-time curve from time zero to 168 h after the start of the infusion
BMI	Body mass index
BCMA	B cell maturation antigen
BCVA	Best Corrected Visual Acuity
BOR	Best Overall Response
CBR	Clinical benefit rate
CDISC	Clinical Data Interchange Standards Consortium
C-EOI	Concentration at the end of infusion
cfDNA	Circulating Cell Free deoxyribonucleic acid
CI	Confidence Interval
CL	Clearance
Cmax	Maximum observed plasma drug concentration
CPMS	Clinical Pharmacology Modelling & Simulation
CR	Complete response
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
Ctrough	Concentration observed prior to the next dose
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
Cys-mcMMAF	Cysteine-maleimidocaproyl monomethyl auristatin F
DBL	Database Lock
DNA	Deoxyribonucleic acid
DLT	Dose limiting toxicity
DOB	Date of Birth
DOR	Duration of response
DP	Decimal Places
ECG	Electrocardiogram
ECHO	Echocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Record Form

Abbreviation	Description
eGFR	Estimated glomerular filtration rate
EOI	End of infusion
EORTC	European Organization for Research and Treatment of Cancer
EOT	End of treatment
EMA	European Medicines Agency
ePRO	Electronic Patient Reported Outcomes
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
FLC	Free light chain
FTIH	First Time in Human Trial
GSK	GlaxoSmithKline
HRQoL	Health-Related Quality-of-Life
IA	Interim Analysis
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IgG	ImmunoglobulinG
IMMS	International Modules Management System
IMWG	International Myeloma Working Group
IMT	Issue Management Team
IP	Investigational Product
irAE	Immune-related Adverse Event
iSRC	Internal Safety Review Committee
ISS	International Staging System
LFT	Liver function tests
LVEF	Left ventricular ejection fraction
LSFV	Last Subject First Visit
LSVD	Last Subject First Dose
mAb	Monoclonal antibody
MedDRA	Medical Dictionary for Regulatory Affairs
MM	Multiple Myeloma
MMAF	Monomethyl auristatin F
MR	Minimal response
MRD	Minimal Residual Disease
MTD	Maximum Tolerated Dose
mTPI	modified Toxicity Probability Interval
MUGA	Multigated acquisition scan
NCI	National Cancer Institute
NCI-CTCAE	National Cancer Institute Common Toxicity Criteria for Adverse Events
NEI-VFQ-25	National Eye Institute Visual Functioning Questionnaire - 25
NONMEM	Nonlinear mixed effects modelling
ORR	Overall response rate
OS	Overall survival
OSDI	Ocular Surface Disease Index
PACT	Post Analysis Continued Treatment

Abbreviation	Description
PCI	Potential Clinical Importance
PD	Pharmacodynamics
PD	Progressive disease
PDMP	Protocol Deviation Management Plan
PFS	Progression-free survival
PK	Pharmacokinetics
PP	Per Protocol
PR	Partial response
PopPK	Population PK
PRO-CTCAE	Patient-Reported Outcome Version of the Common Term Criteria for Adverse Events
PT	Preferred Term
QC	Quality Control
QTcF	QT Interval Corrected for Heart Rate by Fridericia's Method
QTcB	QT Interval Corrected for Heart Rate by Bazett's Methos
QoL	Quality of life
QLQ-C30	Quality of Life Questionnaire 30-item Core module
QLQ-MY20	Quality of Life Questionnaire 20-item Multiple Myeloma module
RAP	Reporting & Analysis Plan
RAMOS	Randomization & Medication Ordering System
RNA	Ribonucleic acid
RP2D	Recommended Phase 2 Dose
RRMM	Relapsed/refractory multiple myeloma
SAC	Statistical Analysis Complete
SAE	Serious Adverse Event
sBCMA	Soluble B-cell maturation antigen
sCR	Stringent complete response
SDSP	Study Data Standardization Plan
SD	Stable disease
SDTM	Study Data Tabulation Model
SMQ	Standardised MedDRA Query
SOC	System Organ Classes
SOI	Start of infusion
SOP	Standard Operation Procedure
SPEP	Serum protein electrophoresis
SRM	Study Reference Manual
SRT	Safety Review Team
t½	Terminal phase half-life
TA	Therapeutic Area
TFL	Tables, Figures & Listings
tmax	Time of maximum drug concentration
TTNT	Time to next treatment
tlast	Time of last observed quantifiable concentration
TTBR	Time to best response
TTP	Time to progression

Abbreviation	Description
TTR	Time to response
ULN	Upper limit normal
UPEP	Urine protein electrophoresis
VGPR	Very Good Partial Response
Vss	Volume of distribution at steady state

16.10.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
NONE

Trademarks not owned by the GlaxoSmithKline Group of Companies
MedDRA
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16.11. Appendix 11: List of Data Displays

16.11.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.0000 to 1.n	1.0000 to 1.n
Efficacy	2.0000 to 2.n	2.0000 to 2.n
Safety	3.0000 to 3.n	3.0000 to 3.n
Pharmacokinetic	4.0000 to 4.n	4.0000 to 4.n
Biomarker	5.0000 to 5.n	5.0000 to 5.n
Health Outcomes	6.0000 to 6.n	6.0000 to 6.n
Section	**Listings**	
ICH Listings	1.0010 to x	
Other Listings	1.0010 to z	

16.11.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Section 16.12: 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
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
Biomarker	BIO_Fn	BIO_Tn	BIO_Ln
Health Outcomes	PRO_Fn	PRO_Tn	PRO_Ln

NOTES:

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

16.11.3. Deliverables

Delivery [Priority] [1]	Description
IA [1]	Interim Analysis
HDL [2]	Headline results for Primary SAC
P-SAC [3]	Statistical Analysis Complete for Primary Analysis
F-SAC [4]	Statistical Analysis Complete for Final Analysis

NOTES:

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

16.11.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.001	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total; Add the following footnote: "Subject PPD PPD and PP are continuing to Post Analysis Continued Treatment (PACT)."	P-SAC [3], F-SAC [4]
1.002	All Treated	ES8	Summary of Reason for Study Withdrawal by Relationship to COVID-19 Pandemic	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total; summarise by related to COVID-19 and not related to COVID-19;	P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.003	All Treated	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total; Add the following footnote: "Subject PPD PPD and PP are continuing to Post Analysis Continued Treatment (PACT)."	HDL [2], P-SAC [3], F-SAC [4]
1.004	All Treated	SD1	Summary of Reasons for Discontinuation of Study Treatment by Relationship to COVID-19 Pandemic	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available). summarise by related to COVID-19 and not related to COVID-19; Total;	P-SAC [3], F-SAC [4]
1.005	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available).	P-SAC [3], F-SAC [4]
1.006	Enrolled	NS1	Summary of Number of Subjects by Country and Site ID	Report for: Part 1, Part 2, and combined Part 1 and Part 2; (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.007	Screened	BIMO1	Summary of Subject Status in the Study by Country and Site ID	Report for: Part 1, Part 2, and combined Part 1 and Part 2; (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
1.008	Enrolled	NS1	Summary of Number of Subjects by Country and Site ID Relative to COVID-19 Pandemic Measures	Report for: Part 1, Part 2, and combined Part 1 and Part 2; summarise by before and after implementation of pandemic measures; Total	P-SAC [3], F-SAC [4]
Protocol Deviation					
1.009	All Treated	DV1	Summary of Important Protocol Deviations	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available); Total	P-SAC [3], F-SAC [4]
1.0010	All Treated	DV1	Summary of Important Protocol Deviations by Relationship to COVID-19	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) summarise by important related to COVID-19 and important not related to COVID-19; Total	P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0011	All Treated	DV1	Summary of Non-Important COVID-19 Related Protocol Deviations	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available); Total	P-SAC [3], F-SAC [4]
1.0012	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available); Total	P-SAC [3], F-SAC [4]
Population Analysed					
1.0013	Enrolled	SP1A	Summary of Study Populations	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Total	P-SAC [3], F-SAC [4]
Demographic and Baseline Characteristics					
1.0014	All Treated	DM1	Summary of Demographic Characteristics	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	HDL [2], P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0015	All Evaluable	DM1	Summary of Demographic Characteristics	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level). Add the following footnote: A subject is evaluable for interim analysis if the subject fulfils the criteria for 'All Treated' population with adequate baseline assessment and measurable disease meet at least one of the following criteria: if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR had an unconfirmed response of PR/CR or better, progressed, OR died, OR discontinued treatment due to other reasons	IA [1]
1.0016	Enrolled	DM11	Summary of Age Ranges	Include columns "No Treatment", "Part 1", "Part 2", "All Treated", "Total"	P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0017	All Treated	DM6	Summary of Race and Racial Combinations	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
Prior and Concomitant Medications					
1.0018	All Treated	MH1	Summary of Current Medical Conditions	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
1.0019	All Treated	MH1	Summary of Past Medical Conditions	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
1.0020	All Treated	CM8	Summary of Concomitant Medications by Ingredient	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure and Treatment Compliance					
1.0021	All Treated	EX5	Summary of Exposure to Study Treatment	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Create separate Tables for GSK2857916 and pembrolizumab. Note: to derive actual cumulative dose, use baseline/screening weight in order to capture patients who incorrectly receive the wrong dose for the study treatment .	HDL [2], P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0022	All Evaluable	EX5	Summary of Exposure to Study Treatment	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level) Add the following footnote: A subject is evaluable for interim analysis if the subject fulfils the criteria for 'All Treated' population with adequate baseline assessment and measurable disease meet at least one of the following criteria: if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR had an unconfirmed response of PR/CR or better, progressed, OR died, OR discontinued treatment due to other reasons	IA [1]
1.0023	All Treated	OEX9	Summary Listing of Overall Exposure and Dose Modifications	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Disease Characteristics					
1.0024	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
1.0025	All Evaluable	DC1	Summary of Disease Characteristics at Initial Diagnosis	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level) Add the following footnote: A subject is evaluable for interim analysis if the subject fulfils the criteria for 'All Treated' population with adequate baseline assessment and measurable disease meet at least one of the following criteria: if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR had an unconfirmed response of PR/CR or better, progressed, OR died, OR discontinued treatment due to other reasons	IA [1]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0026	All Treated	DC2	Summary of Disease Characteristics at Screening	Report for: Part 1 and Part 2 and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total; See Table 1.2101 in 205678 (primary_02) and include footnote for cytogenetics. Include eGFR using DREAMM-2 RE internal_05 T1.11060 (eGFR) collected at baseline with the following categories for eGFR: • Normal: >=90 • Mild: >=60, <90 • Moderate: >=30, <60 • Severe: 0, <30 • Missing	HDL [2], P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0027	All Evaluable	DC2	Summary of Disease Characteristics at Screening	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level) Add the following footnote: A subject is evaluable for interim analysis if the subject fulfils the criteria for 'All Treated' population with adequate baseline assessment and measurable disease meet at least one of the following criteria: if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR had an unconfirmed response of PR/CR or better, progressed, OR died, OR discontinued treatment due to other reasons	IA [1]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Anti-Cancer Therapy					
1.0028	All Treated	AC2	Summary of Prior Anti-Cancer Therapy	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_08) Table 1.0190 for guidance.	P-SAC [3], F-SAC [4]
1.0029	All Treated	AC2	Summary of Subjects Refractory to Prior Anti-Cancer Therapy	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_08) Table 1.0200 for guidance.	P-SAC [3], F-SAC [4]
1.0030	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Table 1.0220 for guidance.	P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0031	All Treated	FAC1	Summary of Follow-up Anti-Cancer Therapy	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_08) Table 1.0240 for guidance.	P-SAC [3], F-SAC [4]
Surgical/Medical Procedures					
1.0032	All Treated	PR1	Summary of Prior Non-Cancer Related Surgical Procedures	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total..	P-SAC [3], F-SAC [4]
Substance Use					
1.0033	All Treated	SU1	Summary of Substance Use	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Follow-up					
1.0034	All Treated	FAC2	Summary of Duration of Follow-up	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	HDL [2], P-SAC [3], F-SAC [4]
Blood and Blood Supportive Care Products					
1.0035	All Treated	BP1A	Summary of Blood Products	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
1.0036	All Treated	BP1B	Summary of Blood Supportive Care Products	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

16.11.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Responses.					
2.001	All Treated	RE1a	Summary of Investigator Assessed Best Response (With Confirmation) (IMWG 2016)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available); Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Rate of Very Good Partial Response or better: (sCR+CR+VGPR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR).	HDL [2], P-SAC [3], F-SAC [4]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Include: Overall Response Rate, Rate of VGPR or better and Clinical Benefit Rate (include p-value for the overall response rate for part 2 P-SAC deliverable only) in one table. Include the following footnotes for P-SAC and F-SAC deliverables: "Note: The 95% Confidence Interval is based on Exact method." Include the following footnotes for P-SAC deliverable: "(1) Probability under the null hypothesis: p=10% of an outcome at least as extreme as that observed."	
2.002	All Evaluable	RE1a	Summary of Investigator Assessed Best Response (for Interim Futility Analyses) (IMWG 2016)	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level) Add the following footnote: A subject is evaluable for interim analysis if the subject fulfils the criteria for 'All Treated' population	IA [1]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				with adequate baseline assessment and measurable disease meet at least one of the following criteria: if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR had an unconfirmed response of PR/CR or better, progressed, OR died, OR discontinued treatment due to other reasons.	
2.003	All Treated	See programming notes	Summary of MRD Negativity Rate by Investigator Assessed Best Response	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available). MRD negativity will be based on test result with sensitivity of 10^5. Refer to mid205678 (primary_01) Table 2.0040 for guidance. Include the following footnote: "Note: Minimal Residual Disease (MRD) negativity rate is defined as: the percentage of participants who are MRD negative by Next Generation Sequencing (NGS). Subjects without MRD assessment	P-SAC [3], F-SAC [4]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				will be considered as having positive MRD."	
Time-to-Event Endpoints					
2.004	All Treated	TTE1	Summary of Duration of Response by Investigator (IMWG 2016) (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level	HDL [2], P-SAC [3], F-SAC [4]
2.005	All Treated	TTE1	Summary of Time to Response by Investigator (IMWG 2016) (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level	P-SAC [3], F-SAC [4]
2.006	All Treated	TTE1	Summary of Time to Best Response by Investigator (IMWG 2016) (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level	P-SAC [3], F-SAC [4]
2.007	All Treated	TTE1	Summary of Progression Free Survival by Investigator (IMWG 2016) (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level; use mid205678(primary_01) T2.0080 for guidance	HDL [2], P-SAC [3], F-SAC [4]
2.008	All Treated	TTE1	Summary of Time to Progression by Investigator (IMWG 2016) (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for	P-SAC [3], F-SAC [4]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				dose level	
2.009	All Treated	TTE1	Summary of Overall Survival (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level; use mid205678(primary_01) T2.0150 for guidance	P-SAC [3], F-SAC [4]
2.0010	All Treated	TTE1	Summary of Time to Next Treatment (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level	P-SAC [3], F-SAC [4]

16.11.6. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
2.001	All Treated	Programming Note	Forest Plot – Overall Response Rate (ORR) Based on Investigator-Assessed Response	Report for Part 1 and Part 2, and combined Part 1 and Part 2: Similar to Figure 12.012 in BMA117159 (primary_02).	P-SAC [3], F-SAC [4]
2.002	All Treated	RE8b	Investigator Assessed Maximum Percent Reduction from Baseline in M-Protein (or FLC) Measurement	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Figure 2.0030 for guidance	P-SAC [3], F-SAC [4]
Time-to-Event Endpoints					
2.003	All Treated	TTE10	Graph of Kaplan Meier Survival Curves for Duration of Response (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
2.004	All Treated	TTE10	Graph of Kaplan Meier Survival Curves for Time to Response (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
2.005	All Treated	TTE10	Graph of Kaplan Meier Survival Curves for Time to Best Response (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only	P-SAC [3], F-SAC [4]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				code A, code D, and code H for dose level;	
2.006	All Treated	TTE10	Graph of Kaplan Meier Survival Curves for Progression Free Survival (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
2.007	All Treated	TTE10	Graph of Kaplan Meier Survival Curves for Time to Progression (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
2.008	All Treated	TTE10	Graph of Kaplan Meier Survival Curves for Overall Survival (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]

16.11.7. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.001	All Treated	AE5B	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.002	All Treated	AE5B	Summary of All Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.003	COVID-19	AE5B	Summary of All COVID-19 Adverse Events by System Organ Class and Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. only if greater than 5 participants with COVID-19 infection; If less than 5 participants, produce listing instead;	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.004	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.005	All Treated	AE13	Adverse Event Overview	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Table 3.0010 for guidance. Include the following additional categories under "Any AE": • AEs leading to drug interruption and/or dose reduction; • AEs related to study treatment and lead to permanent discontinuation of study treatment • Grade 3 or 4 AEs • For the "Grade 3 or 4 AEs related to study treatment", replace with the following two subcategories: "Grade 3 or 4 AEs related to GSK2857916" and "Grade 3 or 4 AEs related to pembrolizumab"	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.006	All Treated	See programming notes	Overview of Corneal Events (GSK Scale)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Include category 'dose interruption and/or dose reduction'; Refer to mid205678 (primary_01) Table 3.0900 for guidance.	P-SAC [3], F-SAC [4]
3.007	All Treated	AE13	Overview of Eye Disorders (CTCAE)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Table 3.0900 for guidance. Include the following additional categories under "Any AE": • AEs leading to drug interruption and/or dose reduction; • AEs related to study treatment and lead to permanent discontinuation of study treatment • Grade 3 or 4 AEs	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.008	All Evaluable	AE13	Adverse Event Overview	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level) Add the following footnote: A subject is evaluable for interim analysis if the subject fulfils the criteria for 'All Treated' population with adequate baseline assessment and measurable disease meet at least one of the following criteria: if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR had an unconfirmed response of PR/CR or better, progressed, OR died, OR discontinued treatment due to other reasons	IA [1]
3.009	All Treated	AE3	Summary of All Adverse Events by Preferred Term	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0010	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0011	All Treated	AE5B	Summary All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0012	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total..	P-SAC [3], F-SAC [4]
3.0013	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0014	All Treated	AE3	Summary of Non-Serious Drug-Related Adverse Events by Overall Frequency	Report for: Part 1 Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0015	All Treated	AE5B	Summary of Adverse Events by Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total.; Do not include SOC	HDL [2], P-SAC [3], F-SAC [4]
3.0016	All Treated	AE5B	Summary of Adverse Events Related to Study Treatment by Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total.; Do not include SOC	P-SAC [3], F-SAC [4]
3.0017	All Treated	AE5B	Summary of Adverse Events by Maximum Grades 3-5	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Include Any Grade column with footnote as defined as "The 'Any Grade' column includes events with Grade 1-5 or missing grade."; Exclude Grade 1, Grade 2, Unknown, and Total column; Do not include SOC	P-SAC [3], F-SAC [4]
3.0018	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions by Preferred Term	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0019	All Treated	AE3	Summary of Adverse Events Leading to Drug Interruptions by Preferred Term	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Immune-Related Adverse Events: Pembrolizumab					
3.0020	All Treated	AE5B	Summary of All Immune-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0021	All Treated	AE13	Immune-Related Adverse Events Overview	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Table 3.0010 for guidance; Include the following Any AE subcategory, Replace "AE" with "irAE" and "SAE" with "serious irAE" Include the following subcategories: • irAEs leading to dose interruption and/or dose reduction; • irAEs related to study treatment and lead to permanent discontinuation of study treatment • Grade 2 irAEs • Grade 3 or 4 irAEs related to study treatment	P-SAC [3], F-SAC [4]
3.0022	All Treated	AE3	Summary of Immune-Related Adverse Events Leading to Drug Interruptions by Preferred Term	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events of Special Interest: belantamab mafodotin					
3.0023	All Treated	ESI1	Summary of Characteristics of Corneal Events (GSK scale)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Summary based on both all subjects and subjects with events.	HDL [2], P-SAC [3], F-SAC [4]
3.0024	All Treated	ESI1	Summary of Characteristics of Eye Disorders (CTCAE)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Summary based on both all subjects and subjects with events.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0025	All Evaluable	ESI1	Summary of Characteristics of Eye Disorders (CTCAE)	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level) Add the following footnote: A subject is evaluable for interim analysis if the subject fulfils the criteria for 'All Treated' population with adequate baseline assessment and measurable disease meet at least one of the following criteria: if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR had an unconfirmed response of PR/CR or better, progressed, OR died, OR discontinued treatment due to other reasons.	IA [1]
3.0026	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Summary based on both all subjects and subjects with events.	HDL [2], P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0027	All Evaluable	ESI1	Summary of Characteristics of Thrombocytopenia	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level) Add the following footnote: A subject is evaluable for interim analysis if the subject fulfils the criteria for 'All Treated' population with adequate baseline assessment and measurable disease meet at least one of the following criteria: if the planned assessment is every 3 weeks and at least three assessments are required, the time from the first dose to the time of data cut-off is more than 66 days, OR had an unconfirmed response of PR/CR or better, progressed, OR died, OR discontinued treatment due to other reasons.	IA [1]
3.0028	All Treated	ESI1	Summary of Characteristics of Infusion Related Reactions	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Summary based on both all subjects and subjects with events.	HDL [2], P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0029	All Treated	See programming notes	Summary of Keratopathy Events (CTCAE) Characteristics II	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Refer to mid205678 (primary_01) Table 3.0200 for guidance.	P-SAC [3], F-SAC [4]
3.0030	All Treated	ESI2a	Summary of Onset and Duration of the First Occurrence of Grade 2 or Above Corneal Events (GSK scale)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	P-SAC [3], F-SAC [4]
3.0031	All Treated	ESI2a	Summary of Onset and Duration of the First Occurrence of Eye Disorders (CTCAE)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	P-SAC [3], F-SAC [4]
3.0032	All Treated	ESI2a	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0033	All Treated	ESI2a	Summary of Onset and Duration of the First Occurrence of Infusion Related Reactions	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	P-SAC [3], F-SAC [4]
3.0034	All Treated	See programming notes	Summary of Corneal Events (GSK scale) by Grade and Visit	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Include Worst-case baseline visit.; Refer to mid205678 (primary_01) Table 3.0340 for guidance.	P-SAC [3], F-SAC [4]
3.0035	All Treated	AE5B	Summary of Eye Disorders (CTCAE) by Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total; Do not include SOC	P-SAC [3], F-SAC [4]
3.0036	All Treated	AE5B	Summary of Thrombocytopenia by Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; Do not include SOC	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0037	All Treated	AE5B	Summary of Infusion Related Reactions by Preferred Term and Maximum Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; Do not include SOC	P-SAC [3], F-SAC [4]
3.0038	All Treated	See programming notes	Summary of Time to Re-initiation of Study Treatment Post First Treatment Interruption/Delay due to Corneal Events (GSK Scale)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Table 3.0430 for guidance.	P-SAC [3], F-SAC [4]
3.0039	All Treated	See programming notes	Summary of Action Taken with Study Treatment for Corneal Events (GSK Scale) by Visit and Grade	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Table 3.0380 for guidance.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Identified Risks: belantamab mafodotin					
3.0040	All Treated	ESI1	Summary of Characteristics of Neutropenia	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Summary based on both all subjects and subjects with events.	P-SAC [3], F-SAC [4]
3.0041	All Treated	ESI2a	Summary of Onset and Duration of the First Occurrence of Neutropenia	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	P-SAC [3], F-SAC [4]
3.0042	All Treated	AE5B	Summary of Neutropenia by Preferred Term and Maximum Grade	Report for: Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total.; Do not include SOC	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious and Other Significant Adverse Events					
3.0043	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0044	All Treated	AE3	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by Overall Frequency	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0045	All Treated	AE3	Summary of Serious Adverse Events	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0046	All Treated	AE3	Summary of Serious Drug-Related Adverse Events by Overall Frequency	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0047	All Treated	AE3	Summary of Fatal Adverse Events	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0048	COVID-19	AE3	Summary of COVID-19 Adverse Events Leading to Permanent Discontinuation of Study Treatment by Overall Frequency	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total. only if greater than 5 participants with COVID-19 infection	P-SAC [3], F-SAC [4]
Serious and Other Significant Immune-related Adverse Events: pembrolizumab					
3.0049	All Treated	AE3	Summary of Fatal Immune-Related Adverse Events	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Ocular Findings					
3.0050	All Treated	See programming notes	Shift in Corneal Epithelium Exam Results from Baseline to Worst Post-Baseline for Other Exams	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; Refer to mid205678 (primary_01) Table 3.0852 for guidance. Include the following corneal exams: Microcyst without Edema, Subepithelial Haze, Corneal Neovascularization, Epithelial Microcystic Edema, Corneal Ulcer Add the following footnote: Note: Baseline percentage is based on N. Percentage for worst post-Baseline value is based on Baseline n.	P-SAC [3], F-SAC [4]
3.0051	All Treated	See programming notes	Shift in Corneal Epithelium Exam Results from Baseline to Worst Post-Baseline for Corneal Epithelium	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; Refer to mid205678 (primary_01) Table 3.0850 for guidance. Include the following corneal exams: Corneal Epithelium Add the following footnote: Note: Baseline percentage is based on N. Percentage for worst post-Baseline value is based on Baseline n.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0052	All Treated	See programming notes	Summary of Characteristics II of Worsening in Best Corrected Visual Acuity (BCVA) Score (logMAR Score)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; Refer to mid205678 (primary_07) Table 3.12060 for guidance. Add the following footnotes: [1] Duration is the time from onset of any visual acuity event (change from baseline logMAR score >= 0.3 in either eye) until the event is resolved (change from baseline logMAR score < 0.3 in both eyes). It requires at least a one day gap between the resolution of all events from first occurrence to the onset of second occurrence. [2] Snellen acuity response of "no equivalent value" will be set to a logMAR value of 1000 to indicate a worsening in result if there is a corresponding Non-Snellen acuity response. [3] If a subject has both a Snellen acuity and Non-Snellen acuity recorded at a visit, the Snellen acuity value will be selected. [4] The end of treatment exposure is defined as last infusion date +20 days.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0053	All Treated	See programming notes	Summary of Findings for Punctate Keratopathy	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by dose level (refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available; Total; Refer to mid205678 (internal_05) Table 3.0860 for guidance. Add the following footnote: Note: n reflects the number of eyes with punctate keratopathy worse than baseline at any post-baseline ocular exam.	P-SAC [3], F-SAC [4]
3.0054	All Treated	See programming notes	Shift in Lens Exam Results from Baseline to Worst Post-Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by dose level (refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available; Total; Refer to mid205678 (primary_01) Table 3.1000 and Table 3.1020 for guidance. Categories are "No" and "Yes"; Include the following lens exams: Lens Clear, Pseudophakia, Nuclear Sclerosis, Cortical Cataract, Posterior Subcapsular Cataract Add the following footnote: Note: Baseline percentage is based on N. Percentage for worst post-Baseline value is based on Baseline n.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0055	All Treated	See programming notes	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; Refer to mid205678 (primary_01) Table 3.0730 for guidance.	P-SAC [3], F-SAC [4]
3.0056	Safety	See programming notes	Number (%) of Subjects with a Decline in Best Corrected Visual Acuity (BCVA) to LP or NLP due Anytime Post-Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; Refer to mid205678 (primary_01) Table 3.0740 for guidance.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0057	Safety	Mock-up SAFE_T1	Summary of Worst Post-Baseline Best Corrected Visual Acuity (BCVA) Change in Snellen Results	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; Percentages should be computed out of big N. Add the following footnotes: [1]: Number of lines change from baseline is defined as the following: Improved BCVA equates to a negative change in logMAR from baseline BCVA. <=2 Lines decline in Visual Acuity equates to logMAR change from baseline <=0.37 (or CCI [redacted] decline as defined by GSK Scale). >=3 Lines decline in Visual Acuity equates to logMAR change from baseline >=0.38 (or CCI [redacted] decline as defined by GSK Scale. Note: 'n' denotes subjects who have any post-baseline Best Corrected Visual acuity (BCVA) score.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Deaths					
3.0058	All Treated	DD1	Summary of Deaths	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Use ranges '<= 30 days' and '> 30 days' for "time to death from last dose"	P-SAC [3], F-SAC [4]
Laboratory: Chemistry					
3.0059	All Treated	LB1	Summary of Chemistry Changes from Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Include baseline values; .	P-SAC [3], F-SAC [4]
3.0060	All Treated	LB16	Summary of Worst Case Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; For categories, use only "Any Grade Increase", "Increase to Grade 3" and "Increase to Grade 4"	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0061	All Treated	LB15	Summary of Worst Case Chemistry Results Relative to Normal Range Post-Baseline Relative to Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; For categories, use "Decrease to Low", "Change to Normal or No Change", and "Increase to High"	P-SAC [3], F-SAC [4]
Laboratory: Hematology					
3.0062	All Treated	LB1	Summary of Hematology Changes from Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Include baseline values;	P-SAC [3], F-SAC [4]
3.0063	All Treated	LB16	Summary of Worst Case Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.; For categories, use only "Any Grade Increase", "Increase to Grade 3" and "Increase to Grade 4"	P-SAC [3], F-SAC [4]
3.0064	All Treated	LB15	Summary of Worst Case Hematology Results Relative to Normal Range Post-Baseline Relative to Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.;For categories, use "Decrease to Low", "Change to Normal or No Change", and "Increase to High"	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Urinalysis					
3.0065	All Treated	LB1	Summary of Urine Concentration Changes from Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; ; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Include baseline values	P-SAC [3], F-SAC [4]
3.0066	All Treated	OUR1B	Summary of Urinalysis Results (Discrete or Character Values) by Visit	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. For protein, occult blood, ketones, and glucose dipstick tests, remove “increase” columns and “Worst-case post baseline” row for dose levels and add “presence” and “absence” columns.	P-SAC [3], F-SAC [4]
3.0067	All treated	UR1	Summary of Worst Case Urinalysis Results Post Baseline Relative to Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Include only ‘n’, ‘No Change/Decreased’ and ‘Any Increase’ categories	F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Hepatobiliary (Liver)					
3.0068	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. If less than 5 participants, produce listing instead.	P-SAC [3], F-SAC [4]
3.0069	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0070	All Treated	LIVER11	Summary of Liver Restart/Re-Challenges	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
ECG					
3.0071	All Treated	EG1	Summary of ECG Findings	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0072	All Treated	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total;. For categories, use only "Any Grade Increase", "Increase to Grade 2" and "Increase to Grade 3"; Worst case post-baseline only	P-SAC [3], F-SAC [4]
3.0073	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0074	All Treated	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total; Worst case post-baseline only.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Vital Signs					
3.0075	All Treated	VS1	Summary of Change from Baseline in Vital Signs	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0076	All Treated	VS6	Summary of Worst Case Vital Signs Results by Maximum Grade Increase Post-Baseline Relative to Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total	P-SAC [3], F-SAC [4]
3.0077	All Treated	VS3	Summary of Worst Case Vital Signs Results Relative to Normal Range Post-Baseline Relative to Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total;	P-SAC [3], F-SAC [4]
LVEF					
3.0078	All Treated	LVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Worst case post-baseline only Footnote: LLN: Normal Range Lower Limit.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Dose Modifications					
3.0079	All Treated	ODMOD1	Summary of Dose Reductions of GSK2857916	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total;	P-SAC [3], F-SAC [4]
3.0080	All Evaluable	ODMOD1	Summary of Dose Reductions of GSK2857916	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level); Include the following footnote: "Note: A subject is evaluable for interim analysis if they meet at least one of these criteria: (More than 66 days in study and had at least three disease assessments) OR had at least one disease assessment on or after day 60 OR had an unconfirmed response of PR/CR or better OR progressed OR died OR discontinued treatment."	IA [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0081	All Treated	ODMOD3	Summary of Dose Delays of GSK2857916	Report for: Part 1 and Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Include summary statistics. Include the following footnote: "Note: The protocol allows a window of ± 3 days for administration of study treatment after Cycle 1 so a dose will only be considered delayed if it is 4 or more days after the scheduled dose date."	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0082	All Evaluable	ODMOD3	Summary of Dose Delays of GSK2857916	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level); Include summary statistics. Include the following footnote(s): "Note: The protocol allows a window of ± 3 days for administration of study treatment after Cycle 1 so a dose will only be considered delayed if it is 4 or more days after the scheduled dose date." "Note: A subject is evaluable for interim analysis if they meet at least one of these criteria: (More than 66 days in study and had at least three disease assessments) OR had at least one disease assessment on or after day 60 OR had an unconfirmed response of PR/CR or better OR progressed OR died OR discontinued treatment."	IA [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0083	All Treated	ODMOD3	Summary of Dose Delays of Pembrolizumab	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total; Include summary statistics. Include the following footnote: "Note: The protocol allows a window of ± 3 days for administration of study treatment after Cycle 1 so a dose will only be considered delayed if it is 4 or more days after the scheduled dose date."	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0084	All Evaluable	ODMOD3	Summary of Dose Delays of Pembrolizumab	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level); Include summary statistics. Include the following footnote(s): "Note: The protocol allows a window of ± 3 days for administration of study treatment after Cycle 1 so a dose will only be considered delayed if it is 4 or more days after the scheduled dose date." "Note: A subject is evaluable for interim analysis if they meet at least one of these criteria: (More than 66 days in study and had at least three disease assessments) OR had at least one disease assessment on or after day 60 OR had an unconfirmed response of PR/CR or better OR progressed OR died OR discontinued treatment."	IA [1]
3.0085	All Treated	ODMOD16	Summary of Infusion Interruptions of GSK2857916	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total;	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0086	All Evaluable	ODMOD16	Summary of Infusion Interruptions of GSK2857916	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level).Include the following footnote: "Note: A subject is evaluable for interim analysis if they meet at least one of these criteria: (More than 66 days in study and had at least three disease assessments) OR had at least one disease assessment on or after day 60 OR had an unconfirmed response of PR/CR or better OR progressed OR died OR discontinued treatment."	IA [1]
3.0087	All Treated	ODMOD16	Summary of Infusion Interruptions of Pembrolizumab	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available), Total;	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0088	All Evaluable	ODMOD16	Summary of Infusion Interruptions of Pembrolizumab	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D (Refer to Section 5.1 for ordering of dose level).Include the following additional footnote for IA only: "Note: A subject is evaluable for interim analysis if they meet at least one of these criteria: (More than 66 days in study and had at least three disease assessments) OR had at least one disease assessment on or after day 60 OR had an unconfirmed response of PR/CR or better OR progressed OR died OR discontinued treatment.	IA [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Dose Limiting Toxicity (DLT)					
3.0089	DLT Evaluable	AE19	Summary of Dose-Limiting Toxicities during the Determinative Period (Part 1)	Report for: Part 1; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) An event will be considered a DLT if meets at least one of the criteria defined from Section 4.2.3.1 of the protocol and is considered by the investigator to be clinically relevant and attributed (definitely, probably, or possibly) to the study therapy during the 21 day DLT observation period. Add footnote, "Withdrawn subjects for other reasons other than toxicity, but prior to completion of DLT period were replaced in the study"	P-SAC [3], F-SAC [4]
Performance Status					
3.0090	All Treated	PS1A	Summary of ECOG Performance Status	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]
3.0091	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Anti-Drug Antibody					
3.0092	All Treated	See programming notes	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Table 3.0710 for guidance. For all time points, under the "Subjects with Screening ADA Results", replace "negative conclusive" and "negative inconclusive" with "Negative"; Include titer value summary statistics for confirmed positive; Include the following footnotes: Note: A subject is considered to have a positive ADA result if they have a positive screening assay, a positive confirmation assay and a titer value. A baseline ADA result is the closest ADA sample (i.e. either Screening Visit or Cycle 1 Day 1 Visit) prior to the subject receiving the first dose of GSK2857916. Only confirmed ADA positive samples were tested in the Neutralizing Antibody assay."Note: ADA sample was collected at the time of start of infusion without PK sample." Note: Negative are subjects with all negative results or confirmed negative results.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0093	All Treated	See programming notes	Summary of Anti-GSK2857916 Antibodies (ADA)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Refer to mid205678 (primary_01) Table 3.0720 for guidance. For the results relating to negative post-baseline ADA results, combine both sub-categories and classify the results as "negative" and remove total antibody concentration threshold and missing statements; Include the following footnotes: Note: A subject is considered to have a positive ADA result if they have a positive screening assay, a positive confirmation assay and a titer value. A baseline ADA result is the closest ADA sample (i.e. either Screening Visit or Cycle 1 Day 1 Visit) prior to the subject receiving the first dose of GSK2857916. Only confirmed ADA positive samples were tested in the Neutralizing Antibody assay. Note: ADA sample was collected at the time of start of infusion without PK sample.	P-SAC [3], F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0094	All Treated	IMM4	GSK2857916 Immunogenicity Incidence and Summary	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total. Do not include optional rows, 'Persistent ADA' and 'Transient ADA'.	F-SAC [4]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
COVID-19 Assessments					
3.0095	COVID-19	PAN1A	Summary of COVID-19 Assessments for Subjects with Suspected, Probable or Confirmed COVID-19 Case Diagnosis	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total; only if greater than 5 participants with COVID-19 infection; If less than 5 participants with COVID-19 infection, produce listing instead; For footnote 1, use 20-Mar-2020 date as per COVID-19 Case Definition for Trials and Event Reporting Guidance	P-SAC [3], F-SAC [4]
3.0096	COVID-19	PAN3A	Summary of COVID-19 Symptoms for Subjects with Suspected, Probable or Confirmed COVID-19 Case Diagnosis	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Total; only if greater than 5 participants with COVID-19 infection; If less than 5 participants with COVID-19 infection, produce listing instead;	P-SAC [3], F-SAC [4]

16.11.8. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory					
3.001	All Treated	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Create plot per treatment group	P-SAC [3], F-SAC [4]
3.002	All Treated	LIVER9	Scatter Plot of Maximum Bilirubin vs. Maximum ALT – eDISH	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Create plot per treatment group	P-SAC [3], F-SAC [4]
3.003	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum LDH - eDISH Plot	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Create plot per treatment group	P-SAC [3], F-SAC [4]
3.004	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum Creatinine Kinase - eDISH Plot	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Create plot per treatment group	P-SAC [3], F-SAC [4]
3.005	All Treated	LIVER9	Scatter Plot of Maximum LDH vs Maximum Creatinine Kinase - eDISH Plot	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Create plot per treatment group	P-SAC [3], F-SAC [4]
3.006	All Treated	LIVER9	Scatter Plot of Maximum Albumin/Creatinine Ratio (> 2000 mg/g) vs. Concomitant Values of Serum Creatinine	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Create plot per treatment group; Concomitant window = ± 7 days; If more than 3 participants	P-SAC [3], F-SAC [4]
Exposure					
3.007	All Treated	OEX12	Plot of Duration of Study Treatment by Response	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Add	P-SAC [3], F-SAC [4]

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				the following footnote: "Subject PPD PPD and PP are continuing to Post Analysis Continued Treatment (PACT)."	

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG					
3.008	All Treated	OECG4	Fridericia's QTc Shifts from Baseline to Worst-case Post Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2;	P-SAC [3], F-SAC [4]
Profile Plot					
3.009	All Treated	See programming notes	Profile Plot for Subjects	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Refer to mid205678 (primary_01) Figure 3.0031 for guidance	P-SAC [3], F-SAC [4]

16.11.9. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK					
4.001	PK	PK01	Summary of Plasma GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (ng/mL)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Include the following footnote: Note: Samples collected as End of Infusion Pembrolizumab are included in the SOI + 2hr time point.	P-SAC [3], F-SAC [4]
4.002	PK	PK01	Summary of Plasma GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (ng/mL)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Include the following footnote: Note: Samples collected as End of Infusion Pembrolizumab are included in the SOI + 2hr time point.	P-SAC [3], F-SAC [4]
4.003	PK	PK01	Summary of Plasma GSK2857916 (cys-mcMMAF) Pharmacokinetic Concentration-Time Data (pg/mL)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Include the following footnote: Note: Samples collected as End of Infusion Pembrolizumab are included in the SOI + 2hr time point.	P-SAC [3], F-SAC [4]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.004	PK	PK04	Summary of Derived Plasma GSK2857916 (ADC) Pharmacokinetic Parameters	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Report only Cycle 1 Day 1; Include the following footnotes: Note: PK parameters labelled 'Cycle 1 Day 1' are based on the full first cycle duration. Note: AUC(0-tau) represents AUC during Cycle 1.	P-SAC [3]
4.005	PK	PK04	Summary of Derived Plasma GSK2857916 (Total Antibody) Pharmacokinetic Parameters	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Report only Cycle 1 Day 1; Include the following footnotes: Note: PK parameters labelled 'Cycle 1 Day 1' are based on the full first cycle duration. Note: AUC(0-tau) represents AUC during Cycle 1.	P-SAC [3], F-SAC [4]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.006	PK	PK04	Summary of Derived Plasma GSK2857916 (cys-mcMMAF) Pharmacokinetic Parameters	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Report only Cycle 1 Day 1; Include the following footnotes: Note: PK parameters labelled 'Cycle 1 Day 1' are based on the full first cycle duration.	P-SAC [3], F-SAC [4]
4.007	PK	PK13	Listing of Derived Plasma GSK2857916 (ADC) Pharmacokinetic Parameters (non-transformed)	Report for: Part 1 and Part 2; Include the following footnotes: Note: PK parameters labelled 'Cycle 1 Day 1' are based on the full first cycle duration. Note: AUC(0-tau) represents AUC during Cycle 1.	P-SAC [3]
4.008	PK	PK13	Listing of Derived Plasma GSK2857916 (Total Antibody) Pharmacokinetic Parameters (non-transformed)	Report for: Part 1 and Part 2; Include the following footnotes: Note: PK parameters labelled 'Cycle 1 Day 1' are based on the full first cycle duration. Note: AUC(0-tau) represents AUC during Cycle 1.	P-SAC [3], F-SAC [4]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.009	PK	PK13	Listing of Derived Plasma GSK2857916 (cys-mcMMAF) Pharmacokinetic Parameters (non-transformed)	Report for: Part 1 and Part 2; Include the following footnotes: Note: PK parameters labelled 'Cycle 1 Day 1' are based on the full first cycle duration.	P-SAC [3], F-SAC [4]

16.11.10. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK					
4.001	PK	PK16a	Individual Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1 and Part 2	P-SAC [3], F-SAC [4]
4.002	PK	PK16a	Individual Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1 and Part 2	P-SAC [3], F-SAC [4]
4.003	PK	PK16a	Individual Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1 and Part 2	P-SAC [3], F-SAC [4]
4.004	PK	PK17	Cycle 1 Mean Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1, Part 2, and combined Part 1 and Part 2;	P-SAC [3], F-SAC [4]
4.005	PK	PK17	Cycle 1 Mean Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1, Part 2, and combined Part 1 and Part 2;	P-SAC [3], F-SAC [4]
4.006	PK	PK17	Cycle 1 Mean Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1, Part 2, and combined Part 1 and Part 2;	P-SAC [3], F-SAC [4]
4.007	PK	PK18	Cycle 1 Median Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1, Part 2, and combined Part 1 and Part 2;	P-SAC [3], F-SAC [4]
4.008	PK	PK18	Cycle 1 Median Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1, Part 2, and combined Part 1 and Part 2;	P-SAC [3], F-SAC [4]
4.009	PK	PK18	Cycle 1 Median Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-log)	Report for: Part 1, Part 2, and combined Part 1 and Part 2;	P-SAC [3], F-SAC [4]

16.11.11. Biomarker Figures

Biomarker: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
sBCMA					
5.001	PD	BIO_F1	Absolute Free sBCMA Versus Cycle and Timepoint by Best Confirmed Response (Log Scale)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Categorize best overall response in the following: Response (subjects with PR or better), Non-Response (subjects with MR, SD, or PD) and NE (subjects with NE)	P-SAC [3], F-SAC [4]
5.002	PD	BIO_F1	Fold Change from Baseline in Free sBCMA Versus Cycle and Timepoint by Best Confirmed Response (Log Scale)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Categorize best overall response in the following: Response (subjects with PR or better), Non-Response (subjects with MR, SD, or PD) and NE (subjects with NE)	P-SAC [3], F-SAC [4]
5.003	PD	BIO_F2	Boxplot of Baseline sBCMA by Best Confirmed Response (Log Scale)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Categorize best overall response in the following: Response (subjects with PR or better), Non-Response (subjects with MR, SD, or PD) and NE (subjects with NE)	P-SAC [3], F-SAC [4]
5.004	PD	BIO_F3	Boxplot of Baseline sBCMA and Other Disease Burden Markers (e.g., β2M, FLC, M-protein) Versus Best Confirmed Response and Extramedullary Disease (Log Scale)	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Categorize best overall response in	P-SAC [3], F-SAC [4]

Biomarker: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				the following: Response (subjects with PR or better), Non-Response (subjects with MR, SD, or PD) and NE (subjects with NE); Categorize EMD in the following: EMD No (subjects without EMD), EMD Yes (subjects with EMD),	

16.11.12. Health Outcomes Tables

Health Outcomes: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PRO-CTCAE					
6.001	All Treated	See programming notes	Summary of Maximum Post-Baseline PRO-CTCAE Score	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Refer to mid205678 (primary_01) Table 8.0090 for guidance. For each selected item from PRO-CTCAE library: create summary Table for maximum post-baseline PRO-CTCAE score for each of 3 attributes (frequency, severity and/or interference). Presence/Absence will only be listed.	P-SAC [3], F-SAC [4]
OSDI					
6.002	All Treated	See programming notes	Summary of Change in OSDI Subscale Scores from Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available) Refer to mid205678 (primary_01) Table 8.00130 for guidance; Additional	P-SAC [3], F-SAC [4]

Health Outcomes: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				timepoints includes EOT visit, last follow-up visit, and worst change from baseline.	
6.003	All Treated	See programming notes	Summary of Subjects with a 12.5 Point or Greater Deterioration from Baseline in the OSDI Vision-Related Function Subscale Score	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available); Refer to mid205678 (present_2020_04) Table 8.0160 for guidance. Include the following footnotes: (1) Improvement is defined as a decrease from the worst subscale score of at least 12.5 points. (2) Time to 12.5 point deterioration assessed only for those subjects experiencing a first worsening of at least one 12.5 unit as compared to the baseline score with complete onset date. (3) Time to improvement is defined as time from the onset of first worsening of at least one 12.5 unit as compared to the baseline score to the first time of resolution based on 12.5 improvement from the first worst subscale score during the event.	P-SAC [3], F-SAC [4]

Health Outcomes: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				It requires at least one day gap between the resolution of worsening from first course to the onset of second course.	
NEI-VFQ-25					
6.004	All Treated	See programming notes	Summary of Change in NEI-VFQ-25 Subscale Scores from Baseline	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available). Refer to mid205678 (primary_01) Table 8.0110 for guidance. Including 11 subscale score. Additional timepoints includes EOT visit, last follow-up visit, and worst change from baseline; include both investigator and subject assessed data	P-SAC [3], F-SAC [4]
EORTC QLQ-C30					
6.005	All Treated	See programming notes	Summary of Change in EORTC QLQ-C30 Domain Scores from Baseline (Part 2)	Report for: Part 2; Refer to mid205678 (primary_01) Table 8.0020 for guidance. Including score for 15 domains and Improvement in EORTC QLQ-C30 domain score >=10	P-SAC [3], F-SAC [4]

Health Outcomes: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
EORTC QLQ-MY20					
6.006	All Treated	See programming notes	Summary of Change in EORTC QLQ-MY20 Domain Scores from Baseline (Part 2)	Report for: Part 2; Refer to mid205678 (primary_01) Table 8.0070 for guidance. Including score for 4 domains and Improvement in EORTC QLQ-MY20 domain score >=10	P-SAC [3], F-SAC [4]
Compliance of PRO-CTCAE, OSDI, and EORTC QLQ-C30					
6.007	All Treated	See programming notes	Summary of Compliance of OSDI by Visit	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available). Refer to mid205678 (primary_08) Table 8.10011 for guidance. Include number and percentage of subjects for each assessment. Footnote: Note: percentage is calculated using number of subject remaining in the study at given timepoint as denominator.	P-SAC [3], F-SAC [4]
6.008	All Treated	See programming notes	Summary of Compliance of EORTC QLQ-C30 and EORTC QLQ-MY20 by Visit (Part 2)	Report for: Part 2; Refer to mid205678 (primary_08) Table 8.10010 for guidance. Include number and percentage	P-SAC [3], F-SAC [4]

Health Outcomes: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				of subjects for each assessment. Footnote: Note: percentage is calculated using number of subject remaining in the study at given timepoint as denominator.	

16.11.13. Health Outcomes Figures

Health Outcomes: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PRO-CTCAE					
6.001	All Treated	See programming notes	Stacked Bar Chart of PRO-CTCAE Score by Attributes and Visit	Report for: Part 1, Part 2, and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available). Refer to mid205678 (primary_01) Figure 8.0010 for guidance. For each selected item from PRO-CTCAE library: create 5 sets of stacked bar charts per dose cohort for PRO-CTCAE score for each of 3 attributes (frequency, severity and/or interference).	P-SAC [3], F-SAC [4]

Health Outcomes: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
OSDI					
6.002	All Treated	See programming notes	Plot of Change from Baseline and Confidence Interval of OSDI Ocular Symptom Subscale Score by Visit	Report for: Part 2 and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available). Refer to mid205678 (primary_07) Figure 8.10023 for guidance. Add a dashed line at y axis=0. In addition to treatment visits, also include end of treatment, worst case post treatment and last follow-up visits. Add arrows showing direction of change from baseline: “deterioration” “improvement”. Add the following footnotes: Note 1: Interval shown represents 95% confidence limits around mean at each planned time. Note 2: “BSLN” represents “Baseline”; “EOT” represents “End of Treatment”; "WCPB" represents "Worst Case Post-baseline"; "LFU" represents "Last Follow-up".	P-SAC [3], F-SAC [4]

Health Outcomes: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.003	All Treated	See programming notes	Plot of Change from Baseline and Confidence Interval of OSDI Vision-Related Functioning Subscale Score by Visit	Report for: Part 2 and combined Part 1 and Part 2; Summarize by: dose level (Refer to Section 5.1 for ordering of dose level and omit 1.92 mg/kg if data is not available). Refer to mid205678 (primary_07) Figure 8.10023 for guidance. Add a dashed line at y axis=0. In addition to treatment visits, also include end of treatment, worst case post treatment and last follow-up visits. Add arrows showing direction of change from baseline: “deterioration” “improvement”. Add the following footnotes: Note 1: Interval shown represents 95% confidence limits around mean at each planned time. Note 2: “BSLN” represents “Baseline”; “EOT” represents “End of Treatment”; "WCPB" represents "Worst Case Post-baseline"; "LFU" represents "Last Follow-up".	P-SAC [3], F-SAC [4]

Health Outcomes: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
EORTC QLQ-C30					
6.004	All Treated	See programming notes	Plot of Change from Baseline and Confidence Interval of EORTC QLQ-C30 Fatigue Domain Score by Visit (Part 2)	Report for: Part 2; Refer to mid205678 (primary_07) Figure 8.10038 for guidance. Add a dashed line at y axis=0. In addition to treatment visits, also include end of treatment, worst case post treatment and last follow-up visits. Add arrows showing direction of change from baseline: “deterioration” “improvement”. Add the following footnotes: Note 1: Interval shown represents 95% confidence limits around mean at each planned time. Note 2: “BSLN” represents “Baseline”; “EOT” represents “End of Treatment”; "WCPB" represents "Worst Case Post-baseline"; "LFU" represents "Last Follow-up".	P-SAC [3], F-SAC [4]

Health Outcomes: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.005	All Treated	See programming notes	Plot of Change from Baseline and Confidence Interval of EORTC QLQ-C30 Global Health Status / QoL Domain Score by Visit (Part 2)	Report for: Part 2; Refer to mid205678 (primary_07) Figure 8.10039 for guidance. Add a dashed line at y axis=0. In addition to treatment visits, also include end of treatment, worst case post treatment and last follow-up visits. Add arrows showing direction of change from baseline: “deterioration” “improvement”. Add the following footnotes: Note 1: Interval shown represents 95% confidence limits around mean at each planned time. Note 2: “BSLN” represents “Baseline”; “EOT” represents “End of Treatment”; "WCPB" represents "Worst Case Post-baseline"; "LFU" represents "Last Follow-up".	P-SAC [3], F-SAC [4]

Health Outcomes: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.006	All Treated	See programming notes	Plot of Change from Baseline and Confidence Interval of EORTC QLQ-C30 Physical Functioning Domain Score by Visit (Part 2)	Report for: Part 2; Refer to mid205678 (primary_07) Figure 8.10037 for guidance. Add a dashed line at y axis=0. In addition to treatment visits, also include end of treatment, worst case post treatment and last follow-up visits. Add arrows showing direction of change from baseline: “deterioration” “improvement”. Add the following footnotes: Note 1: Interval shown represents 95% confidence limits around mean at each planned time. Note 2: “BSLN” represents “Baseline”; “EOT” represents “End of Treatment”; "WCPB" represents "Worst Case Post-baseline"; "LFU" represents "Last Follow-up".	P-SAC [3], F-SAC [4]

Health Outcomes: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.007	All Treated	See programming notes	Plot of Change from Baseline and Confidence Interval of EORTC QLQ-MY20 Disease Symptoms Domain Score by Visit (Part 2)	Report for: Part 2; Refer to mid205678 (primary_07) Figure 8.10037 for guidance. Add a dashed line at y axis=0. In addition to treatment visits, also include end of treatment, worst case post treatment and last follow-up visits. Add arrows showing direction of change from baseline: “deterioration” “improvement”. Add the following footnotes: Note 1: Interval shown represents 95% confidence limits around mean at each planned time. Note 2: “BSLN” represents “Baseline”; “EOT” represents “End of Treatment”; "WCPB" represents "Worst Case Post-baseline"; "LFU" represents "Last Follow-up".	P-SAC [3], F-SAC [4]

16.11.14. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.001	All Treated	ES2	Listing of Reasons for Study Withdrawal		P-SAC [3], F-SAC [4]
1.002	All Treated	SD2	Listing of Reasons for Study Treatment Discontinuation		P-SAC [3], F-SAC [4]
1.003	All Treated	TA1	Listing of Planned and Actual Treatments		P-SAC [3], F-SAC [4]
1.004	All Treated	PAN5	Country Level Listing of Start Dates of COVID-19 Pandemic Measures		P-SAC [3], F-SAC [4]
Protocol Deviations					
1.005	All Treated	DV2	Listing of Important Protocol Deviations		P-SAC [3], F-SAC [4]
1.006	All Treated	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	Include the protocol version column	P-SAC [3], F-SAC [4]
1.007	All Treated	DV2	Listing of Important Protocol Deviations by Relationship to COVID-19		P-SAC [3], F-SAC [4]
Populations Analysed					
1.008	Enrolled	SP3	Listing of Subjects Excluded from Any Population		P-SAC [3], F-SAC [4]
Demographic and Baseline Characteristics					
1.009	All Treated	DM2	Listing of Demographic Characteristics		P-SAC [3], F-SAC [4]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Prior and Concomitant Medications					
1.0010	All Treated	CM3	Listing of Concomitant Medications		P-SAC [3], F-SAC [4]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure and Treatment Compliance					
1.0011	All Treated	OEX8A	Listing of Exposure to GSK2857916		P-SAC [3], F-SAC [4]
1.0012	All Treated	OEX8B	Listing of Exposure to Pembrolizumab		P-SAC [3], F-SAC [4]
Response					
1.0013	All Treated	See programming notes	Listing of Investigator Assessed Responses With Confirmation) (IMWG 2016)	Include MRD information, genetics at screening, cytogenetics at screening and extramedullary disease at screening information; Refer to mid205678 (primary_01) listing 1.0400 for guidance.;	P-SAC [3], F-SAC [4]
Time to Event					
1.0014	All Treated	TTE9	Listing of Duration of Response based on Investigator-Assessed Responses (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
1.0015	All Treated	TTE9	Listing of Time to Response based on Investigator-Assessed Responses (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
1.0016	All Treated	TTE9	Listing of Time to Best Response based on Investigator-Assessed Responses (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0017	All Treated	TTE9	Listing of Progression Free Survival based on Investigator-Assessed Responses (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
1.0018	All Treated	TTE9	Listing of Time to Progression based on Investigator-Assessed Responses (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
1.0019	All Treated	TTE9	Listing of Overall Survival (GSK2857916 2.5 mg/kg)	Report for: 2.5 mg/kg doses only; Refer to Section 5.1 and use only code A, code D, and code H for dose level;	P-SAC [3], F-SAC [4]
Adverse Events					
1.0020	All Treated	AE8	Listing of All Adverse Events		P-SAC [3], F-SAC [4]
1.0021	COVID-19	AE8	Listing of COVID-19 Adverse Events		P-SAC [3], F-SAC [4]
1.0022	All Treated	AE7	Listing of Subject Numbers for Individual Adverse Events		P-SAC [3], F-SAC [4]
1.0023	COVID-19	PAN12	Listing of COVID-19 Assessments and Symptom Assessments for Subjects with COVID-19 Adverse Events	Only if less than 5 participants with COVID-19 infection;	P-SAC [3], F-SAC [4]
Immune-Related Adverse Events: pembrolizumab					
1.0024	All Treated	AE8	Listing of All Immune-Related Adverse Events		P-SAC [3], F-SAC [4]
1.0025	All Treated	AE7	Listing of Subject Numbers for Individual Immune-Related Adverse Events		P-SAC [3], F-SAC [4]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events of Special Interest: belantamab mafodotin					
1.0026	All Treated	AE8	Listing of Eye Disorders (CTCAE)		P-SAC [3], F-SAC [4]
1.0027	All Treated	AE8	Listing of Thrombocytopenia		P-SAC [3], F-SAC [4]
1.0028	All Treated	AE8	Listing of Infusion Related Reactions		P-SAC [3], F-SAC [4]
Identified Risks: belantamab mafodotin					
1.0029	All Treated	AE8	Listing of Neutropenia		P-SAC [3], F-SAC [4]
Adverse Events of Special Interest: pembrolizumab					
1.0030	All Treated	AE8	Listing of Overdose		P-SAC [3], F-SAC [4]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious and Other Significant Adverse Events					
1.0031	All Treated	AE8	Listing of Non-Fatal Serious Adverse Events		P-SAC [3], F-SAC [4]
1.0032	All Treated	AE14	Listing of Reasons for Considering as a Serious Adverse Event		P-SAC [3], F-SAC [4]
1.0033	All Treated	AE8	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment		P-SAC [3], F-SAC [4]
Serious and Other Significant Immune-related Adverse Events: pembrolizumab					
1.0034	All Treated	AE8	Listing of Non-Fatal Serious Immune-Related Adverse Events		P-SAC [3], F-SAC [4]
1.0035	All Treated	AE14	Listing of Reasons for Considering as a Serious Immune-Related Adverse Event		P-SAC [3], F-SAC [4]
1.0036	All Treated	AE8	Listing of Immune-Related Adverse Events Leading to Permanent Discontinuation of Study Treatment		P-SAC [3], F-SAC [4]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Deaths					
1.0037	All Treated	DD3	Subject Profile of Death	Include the time from last dose in the listing and Number of Cycles; Include fatal serious immune-related SAEs related to pembrolizumab	P-SAC [3], F-SAC [4]
Hepatobiliary (Liver)					
1.0038	All Treated	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events		P-SAC [3], F-SAC [4]
1.0039	All Treated	SU2	Listing of Substance Use for Subjects with Liver Stopping Events		P-SAC [3], F-SAC [4]
1.0040	All Treated	LIVER15	Liver Stopping Event Profile		P-SAC [3], F-SAC [4]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
All Laboratory					
1.0041	All Treated	LB5A	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance		P-SAC [3], F-SAC [4]
1.0042	All Treated	LB14	Listing of Laboratory Data with Character Results		P-SAC [3], F-SAC [4]
1.0043	All Treated	UR2	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance		P-SAC [3], F-SAC [4]
ECG					
1.0044	All Treated	ECG3	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance	Use QTcF Interval, Aggregate column instead of QTcB Interval, Aggregate column; Include timepoint; Exclude RR interval;	P-SAC [3], F-SAC [4]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Vital Signs					
1.0045	All Treated	VS4	Listing of All Vital Signs for Subjects with Any Value of Potential Clinical Importance	Include timepoint, present PCI category/grades instead of H/L flags; Include the following footnotes: "Note: Clinical Importance is defined as Grade 2 or higher for blood pressure, as Decrease to <60 or Increase to >100 for pulse rate and as Decrease to <= 35 or Increase to => 38 for temperature. Note: SOI = Start of Infusion, EOI = End of Infusion.""	P-SAC [3], F-SAC [4]

16.11.15. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Disease Characteristics					
1.0046	All Treated	DC3	Listing of Disease Characteristics at Initial Diagnosis		P-SAC [3], F-SAC [4]
1.0047	All Treated	DC4	Listing of Disease Characteristics at Screening	Include genetic characteristics and renal impairment per eGFR;	P-SAC [3], F-SAC [4]
Anti-Cancer Therapy					
1.0048	All Treated	AC6	Listing of Prior Anti-Cancer Therapy		P-SAC [3], F-SAC [4]
1.0049	All Treated	AC6	Listing of Subjects Refractory to Prior Anti-Cancer Therapy		P-SAC [3], F-SAC [4]
1.0050	All Treated	AC7	Listing of Prior Anti-Cancer Radiotherapy	Include best response to the most recent prior anti-cancer therapy column;	P-SAC [3], F-SAC [4]
1.0051	All Treated	FAC3	Listing of Follow-Up Anti-Cancer Therapy		P-SAC [3], F-SAC [4]
Surgical Procedures					
1.0052	All Treated	PR2	Listing of Prior Non-Cancer Related Surgical Procedures	Refer to mid205678 (primary_01) listing 30.0080 for guidance.; Exclude classification column; Include the following footnote:	P-SAC [3], F-SAC [4]
Blood and Blood Supportive Care Products					

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0053	All Treated	BP4	Listing of Blood Products		P-SAC [3], F-SAC [4]
1.0054	All Treated	BP5	Listing of Blood Supportive Care Products		P-SAC [3], F-SAC [4]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
1.0055	All Evaluable	RE12	Listing of Investigator-Assessed Best Response for Interim Review by First Dose Date	Report for: futility interim analyses for part 2 participants and part 1 participants who initially received the RP2D	IA [1]
Corneal Events (GSK Scale)					
1.0056	All Treated	See programming notes	Listing of Corneal Events (GSK Scale)	Refer to mid205678 (primary_01) listing 30.0190 for guidance	P-SAC [3], F-SAC [4]
Ocular Exam					
1.0057	All Treated	See programming note	Listing of Visual Acuity and Abnormal Corneal Exam Results	Refer to mid205678 (primary_01) listing 30.0210 for guidance.;	P-SAC [3], F-SAC [4]
1.0058	All Treated	See programming note	Listing of Abnormal Slit Lamp Lens Exam Results	Refer to mid205678 (primary_01) listing 30.0230 for guidance.;	P-SAC [3], F-SAC [4]
Health Outcomes					
1.0059	All Treated	See programming note	Listing of EORTC QLQ-C30 Scores (Part 2)	Refer to mid205678 (primary_01) listing 30.0250 for guidance.; Use the same layout as the shell indicated and include the following columns in order listed: “Site ID/Unique Subj ID.”, “Age (YEARS)/Sex/Race Detail”, “Domain/Summary Score”, “Visit”, “Date”, “Study Day”, “Score”.;	P-SAC [3], F-SAC [4]
1.0060	All Treated	See programming	Listing of EORTC QLQ-MY20 Scores (Part 2)	Refer to mid205678 (primary_01)	P-SAC [3], F-

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
		note		listing 30.0260 for guidance. Use the same layout as the shell indicated and include the following columns in order listed: “Site ID/Unique Subj ID.”, “Age (YEARS)/Sex/Race Detail”, “Domain/Summary Score”, “Visit”, “Date”, “Study Day”, “Score”;	SAC [4]
1.0061	All Treated	See programming note	Listing of PRO-CTCAE response	Refer to mid205678 (primary_01) listing 30.0270 for guidance. Use the same layout as the shell indicated and include the following columns in order listed: “Site ID/Unique Subj ID.”, “Age (YEARS)/Sex/Race”, “Item”, “Visit”, “Date”, “Study Day”, “Frequency”, “Interference”, “Severity”, “Present/Absent”;	P-SAC [3], F-SAC [4]
1.0062	All Treated	See programming note	Listing of NEI-VFQ-25 Scores	Refer to mid205678 (primary_01) listing 30.0280 for guidance. Use the same layout as the shell indicated and include the following columns in order listed: “Site	P-SAC [3], F-SAC [4]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				ID/Unique Subj ID.", "Age (YEARS)/Sex/Race", "Subscale/Composite Score", "Visit", "Date", "Study Day", "Score".;	
1.0063	All Treated	See programming note	Listing of OSDI Scores	Refer to mid205678 (primary_01) listing 30.0290 for guidance. Use the same layout as the shell indicated and include the following columns in order listed: "Site ID/Unique Subj ID", "Age (YEARS)/Sex/Race", "Subscale/Total Summary Score", "Visit", "Date", "Study Day", "Score".;	P-SAC [3], F-SAC [4]
Anti-Drug Antibody					
1.0064	All Treated	See programming note	Listing of Human Anti-GSK2857916 Antibody Results	Refer to mid205678 (primary_01) listing 30.0180 for guidance. Use the same layout as the shell indicated and include the following columns in order listed: "Site ID/Unique Subj ID.", "Age (YEARS)/Sex/Race", "Visit", "Study Date/Day", "Screening Assay", "Confirming Assay", "Titer", "Neutralizing Antibody	P-SAC [3], F-SAC [4]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Assay", "GSK2857916 Concentration (ADC) (ng/mL)", "GSK2857916 Concentration (Total mAb) (ng/mL)". Include the following footnotes: Note: Neutralizing Antibody Assay was only applied to confirmed ADA positive samples. Note: Study Day is calculated as the number of days from the first dose date. Note: ADA sample was collected at the time of start of infusion without PK sample.	

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK					
1.0065	PK	PK07	Listing of Plasma GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data		P-SAC [3], F-SAC [4]
1.0066	PK	PK07	Listing of Plasma GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data		P-SAC [3], F-SAC [4]
1.0067	PK	PK07	Listing of Plasma GSK2857916 (cys-mcMMAF) Pharmacokinetic Concentration-Time Data		P-SAC [3], F-SAC [4]

16.12. Appendix 12: Example Mock Shells for Data Displays

All data displays are available upon request.

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Reason for signing: Approved	Name: PPD Role: Approver Date of signature: 29-Aug-2022 13:33:25 GMT+0000

Reason for signing: Approved	Name: PPD Role: Approver Date of signature: 29-Aug-2022 18:41:38 GMT+0000

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