Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)
Title	:	Reporting and Analysis Plan for Reporting and Analysis Plan for A Phase 1b/2a Pilot Study to Evaluate the Safety and Tolerability of Autologous T-Cells Expressing Enhanced TCRs (T-Cell Receptors) Specific for NY-ESO-1/LAGE-1a (GSK3377794) Alone, or in Combination with Pembrolizumab in HLA-A2+ Participants with NY-ESO-1- or LAGE-1a-Positive Advanced or Recurrent Non-Small Cell Lung Cancer
Compound Number	:	GSK3377794
Clinical Study Identifier	:	Study Number 208471
Effective Date	:	21 Jun 2022

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the final Clinical Study Report for Protocol 208471.
- This RAP is intended to describe the planned efficacy, safety, and tolerability analyses required for the study.
- This RAP will be provided to the study team members to convey the content of interim analysis deliverables as well as the Statistical Analysis Complete (SAC)] content.

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TABLE OF CONTENTS

PAGE

1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the interim (if applicable) and final Clinical Study Report for Protocol:

Revision Chronology:		
Original/ 2018N358002_00	11-JUL-2018	Original
Amendment 01/ 2018N358002_01	17-OCT-2018	Changes made to the protocol were requested by Regulatory Agency as a result of safety events which included 2 reports of Guillain-Barré syndrome in subjects who have received chemotherapy and GSK3377794 during clinical trials.
Amendment 02/ 2018N358002_02	13-FEB-2019	Changes made to the protocol were requested by a Regulatory Agency after its review of Amendment 1 and a third treatment arm was added to the study.
Amendment 03/ 2018N358002_05	01-OCT-2019	The overall rationale for this amendment is the removal of randomization to Arm A and Arm B, clarification of aspects related to participant enrollment and clarification regarding study stopping and pausing rules. These additions included modification of lymphodepleting regimen for older articipants, modification of dose range and changes related to Health Canada requests including updates to both the Encephalopathy (now Immune Effector Cell-Associated Neurotoxicity or ICANS) and the CRS grading and management criteria.
Amendment 04/ 2018N358002_06	29-OCT-2019	The overall rationale for this amendment is the addition of fresh biopsy collection in order to perform antigen expression screening, in absence of archival tumor tissue.
Amendment 05/ 2018N358002_08	21-FEB-2020	The overall rationale for this amendment is to add clarification regarding measurable lesion, to remove docetaxel as exclusion criterion and add platinum-based combination chemotherapy as an inclusion criterion. Docetaxel therapy as supportive therapy between leukapheresis and the start of lymphodepletion is removed.
Amendment 06/ 2018N358002_09	17-MAY-2021	The overall rationale for this amendment is to: • Simplify/enhance screening and enrolment efforts • Broaden patient eligibility • Include additional safety tests and measures
Amendment 07/ TMF-14132100	04-NOV-2021	The overall rationale for this amendment is to: • Implementation of additional safety monitoring measures in accordance with a recent Dear Investigator Letter and safety events for lete-cel. • For participants treated as of protocol amendment 7, the upper end of the target dose range of transduced T-cells was increased from $8x10^9$ to $15x10^9$ in order to

		maximize the delivery of cells for participants whose manufacture yields >8x10^9 transduced T-cells.

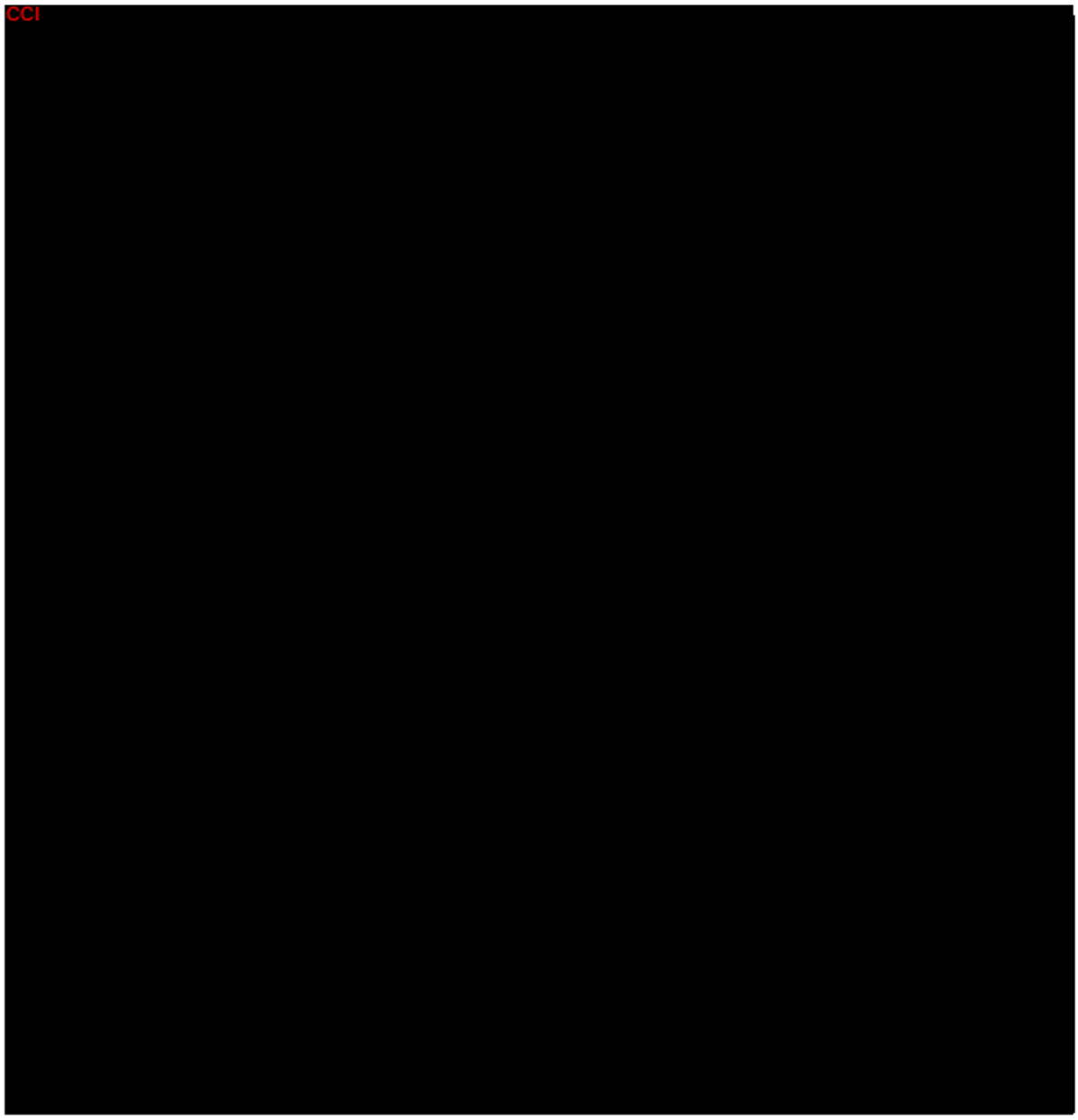
2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

At the time of finalization of this document, it is unlikely that the study will reach the number of patients dosed necessary to perform the planned interim analyses. In the case where the interim analysis trigger point is not reached, no interim analyses will be performed and the only planned analysis will be the final analysis.

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

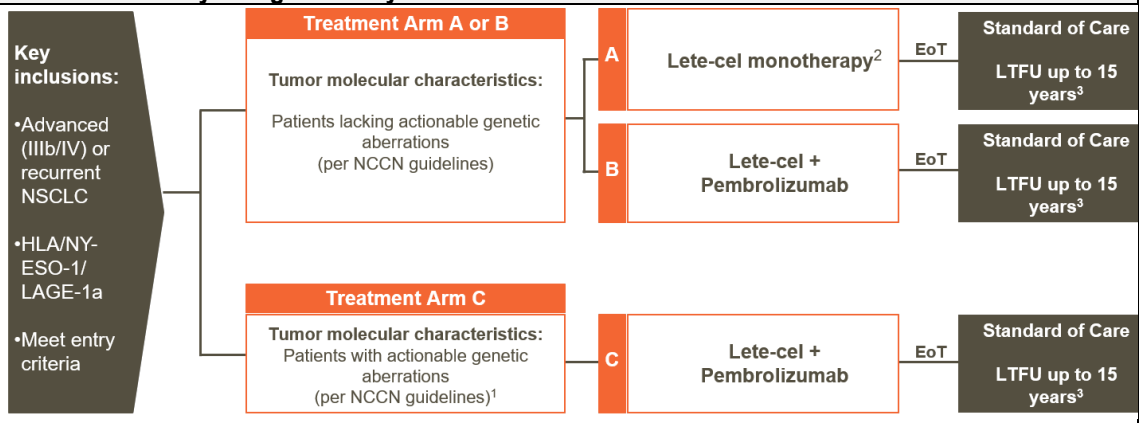
Objectives	Estimands / Endpoints
Primary	**Primary**
• To evaluate the safety and tolerability of autologous genetically modified T-cells (GSK3377794) in human leukocyte antigen (HLA) HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 positive participants with NY-ESO-1 and/or LAGE1a-positive advanced NSCLC alone [Arm A] or lete-cel in combination with pembrolizumab in participants with NSCLC lacking actionable genetic aberrations [Arm B] and participants with NSCLC with an actionable genetic aberration [Arm C]	• Frequency and severity of AEs, serious adverse events (SAEs) and AEs of special interest (AESI; as defined in protocol) • AE/SAEs leading to dose delays and/or withdrawals in participants who received GSK3377794 alone or in combination with pembrolizumab
• To determine the response to lete-cel alone [Arm A] or lete-cel in combination with pembrolizumab in participants with NSCLC lacking actionable genetic aberrations [Arm B] and participants with NSCLC with actionable genetic aberrations [Arm C]	• Overall Response Rate (ORR) (investigator assessed according to RECIST v1.1)
Secondary	**Secondary**
• To further investigate the anti-tumor activity of lete-cel according to RECIST v1.1 criteria	• Progression-Free Survival (PFS) • Disease Control Rate (DCR) • Duration of Response (DoR) • Time to Response (TTR)
• To characterize in vivo cellular PK profile (levels, expansion, persistence) of NY-ESO-1 specific (c259) T cells	• Maximum transgene expansion (Cmax) • Time to Cmax (Tmax) • Area under the time curve from zero to time t AUC(0-t), as data permit.
CCI [redacted]	



Abbreviations:
AE = adverse event/s; AUC(0-t) = area under the time curve from zero to time t; Cmax = maximum persistence; ; DCR = disease control rate; DoR = duration of response (ECG = electrocardiogram; ECOG PS = Eastern Cooperative Oncology Group performance status; eCRF = electronic case report form; G-CSF = granulocyte colony stimulating factor; HLA = human leukocyte antigen; IL = interleukin; LAGE-1a = cancer testis antigen 2; NSCLC = non-small cell lung cancer; NY-ESO-1 = New York esophageal squamous cell carcinoma 1; ORR = overall response rate ( ); ; PD-L1 = programmed death protein 1 ligand; PET = positron emission tomography; PFS = progression-free survival (; PRO-CTCAE = Patient-Reported Outcomes version of Common Terminology Criteria for Adverse Events; RECIST = Response Evaluation Criteria In Solid Tumors ( ); ; SAE = serious adverse event; ; Tmax = time to Cmax; TTR = time to response; WT = wild-type.

2.3. Study Design

Overview of Study Design and Key Features

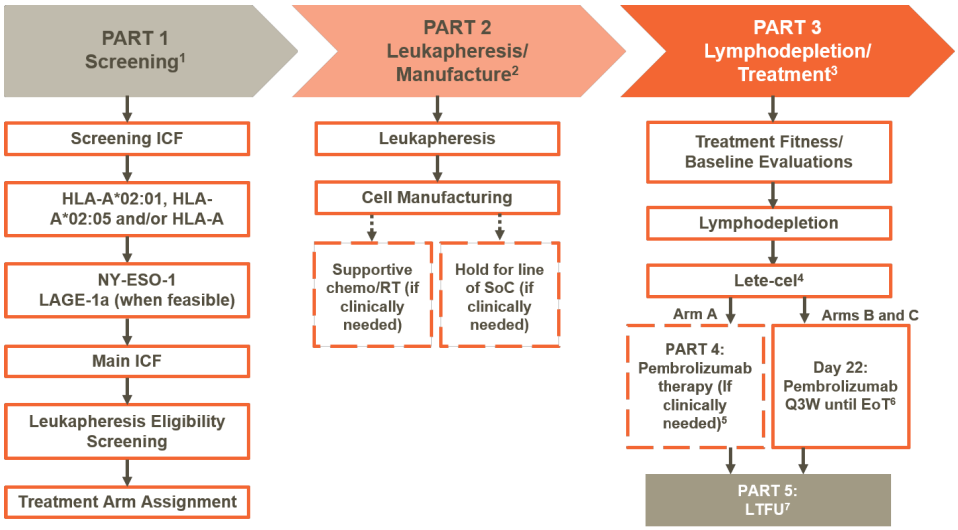


Abbreviations: EoT = end of treatment; HLA = human leukocyte antigen; LAGE-1a = cancer testis antigen 2; NCCN = National Comprehensive Cancer Network; NSCLC = non-small cell lung cancer; NY-ESO-1 = New York esophageal squamous cell carcinoma 1; PD-1 = programmed death protein 1; PD-L1 = PD-1 ligand; LTFU = long--term follow--up.

1. NSCLC patients with actionable genetic aberrations may receive treatment as part of Arm C only following treatment with targeted standard of care therapy (NCCN or equivalent country-guidelines (e.g., ESMO, NICE, etc.), as applicable).
2. Option of pembrolizumab therapy at time of disease progression following lete-cel administration and based on benefit-risk evaluation with Sponsor's Medical Monitor (or designee) approval.
3. LTFU requires participant enrollment in a dedicated LTFU protocol (GSK Study 208750). If not yet enrolled in the LTFU protocol, participants will be followed per LTFU schedule under this protocol (Part 5) until enrolled in the separate LTFU protocol.

Design Features	• This is a multi-arm, open-label study of letetresgene autoleucel (lete-cel, GSK3377794) in HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 adults whose tumors express NY-ESO-1 and/or LAGE-1a. • Enrolled participants includes participants who have unresectable Stage IIIb or Stage IV NSCLC and also fit criteria outlined in eligibility. • Up to 54 participants will be enrolled to achieve at least 15 evaluable participants per arm. At least 30 participants (15 per each arm) with NSCLC lacking actionable genetic aberrations will be assigned to lete-cel alone (Arm A) or in combination with pembrolizumab (Arm B). Assignment of participants to Arm A or B will be determined upon agreement with the Sponsor. Participants with NSCLC lacking actionable genetic aberrations will be assigned to Arm A first and then to Arm B. At least 15 evaluable participants with NSCLC with actionable genetic aberrations will be assigned to treatment with lete-cel in combination with pembrolizumab (Arm C). Note: As enrollment into Arm B was never opened, there are no patients assigned to Arm B per study design, thus no analysis of Arm B will be performed. • This study is divided into five distinct parts: 1) Screening, 2) Leukapheresis/manufacture, 3) Lymphodepletion/Treatment (Interventional Phase), 4) Pembrolizumab Therapy Following Disease Progression after GSK3377794 Infusion, for Arm A only, 5) Long-Term Follow-Up.

Participant Flow



Abbreviations: CRS = cytokine release syndrome; EoT = end of treatment; HLA = human leukocyte antigen; ICF = informed consent form; I/E = inclusion/exclusion; LAGE-1a = cancer testis antigen 2; NSCLC = non-small cell lung cancer; NY-ESO-1 = New York esophageal squamous cell carcinoma 1; PD = progressive disease; Q3W = once every 3 weeks; RT = radiotherapy; SoC = standard of care.

1. Screening may start at any time after diagnosis of advanced Stage IIIb or IV or recurrent NSCLC.
2. Leukapheresis may start once the eligibility criteria are fulfilled. Wash-out times as indicated in Protocol Table 12 may apply.
3. Lymphodepletion starts at clinical and / or radiographic disease progression. Wash-out times as indicated in Protocol Table 12 may apply.
4. Participants will receive a single dose of lete-cel five (5) days after completing the lymphodepleting chemotherapy (this is considered Day 1).
5. Participants in Arm A who have PD following treatment with lete-cel at or before the scheduled Week 25 scan may be offered pembrolizumab therapy (Part 4) following assessment of eligibility for pembrolizumab treatment, benefit-risk evaluation, and approval by the Sponsor's Medical Monitor (or designee). (see Section 6.4.4 of Protocol).
6. In Arms B and C, the first pembrolizumab administration is on Day 22 (Week 4 Day 1). If toxicities that preclude pembrolizumab treatment, including such as CRS Grade ≥2, are present at Day 22, infusion of pembrolizumab will start on Week 7 Day 1. In either case, pembrolizumab will then be administered Q3W up to 35 cycles or PD as described in Section 6.5 of Protocol.
7. LTFU requires participant enrollment in a dedicated LTFU protocol (GSK Study 208750). If not yet enrolled in the LTFU protocol, participants will be followed per LTFU schedule under this protocol (Part 5) until enrolled in the LTFU protocol (see Table 8 of Protocol).

Note: Dashed boxes and arrows indicate activities that may be performed based on clinical need.

- Participants will undergo stepwise enrolment on the study followed by treatment according to protocol-defined phases within this study which will include:

Overview of Study Design and Key Features	
	○ Part 1: Screening ▪ Target expression screening for the presence of HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 positivity and tumour expression of NY-ESO-1 and, when feasible LAGE-1a expression. ▪ Leukapheresis screening phase to determine eligibility for undergoing leukapheresis within 42 days prior to the day of the scheduled leukapheresis procedure. ▪ Participants screened or enrolled in other GSK studies may be considered for enrollment to this study, where it is IRB/IEC approved, on a case-by-case scenario following risk/benefit evaluation between the Investigator and Sponsor Medical Monitor (or designee). ○ Part 2: Leukapheresis/Manufacture ▪ Participants who fulfil the leukapheresis eligibility criteria can undergo the leukapheresis procedure. Following leukapheresis, lete-cel manufacture can begin. ○ Part 3: Lymphodepletion/Treatment ▪ Following clinical and/or radiographic evidence of disease progression, baseline eligibility criteria will be reconfirmed and baseline tumor assessments (scan and biopsy) obtained prior to initiating the lymphodepleting chemotherapy. ▪ The interventional phase includes Lymphodepletion from Days -8 to -5, lete-cel infusion on Day 1, Pembrolizumab administration beginning on Day 22 then Q3W up to 35 cycles (Arms B and C only), and follow-up until the patient completes the interventional phase (per Protocol section 4.4) . ○ Part 4: Pembrolizumab therapy following disease progression after GSK3377794 infusion (Arm A only) ▪ Participants in Arm A who have PD following treatment with lete-cel at or before the scheduled Week 25 scan, may be offered pembrolizumab therapy following assessment of eligibility for pembrolizumab treatment, benefit-risk evaluation, and approval by the Sponsor's Medical Monitor. ○ Part 5: All participants who are alive and have either ended the interventional phase or withdrawn early from the interventional phase will be followed for the observation of delayed AEs and survival during the 15 years post-infusion in the long-term follow-up (LTFU) protocol (GSK Study 208750) in accordance with FDA regulations [FDA, 2020b] (Section 8.1.2 of Protocol). If not yet enrolled in Study 208750, there is a short-term provision (≤6 months) to follow participants according to the LTFU schedule under this protocol (reproduced on Table 8 in Protocol) until enrolled in the 208750 study. Participants who fail to consent to the 208750 study within this period will be withdrawn from Study 208471.

Overview of Study Design and Key Features	
	• Participants who do not receive pembrolizumab will be considered to have ended the interventional phase of the study when one of the following occurs (whichever is sooner): o Participant has been on study until Week 106 post GSK3377794 infusion o Participant has CCI [redacted] o Participant dies • Participants who do receive pembrolizumab will be considered to have ended the interventional phase when one of the following occurs (whichever is sooner): o Participant completes 35 cycles of pembrolizumab o Participant has CCI [redacted] (Arms B and C) or further progressive disease (Arm A Part 4) o Participant dies • All participants who are alive and have either ended the interventional phase or have withdrawn early from the interventional phase will be followed for the observation of delayed AEs and survival during the 15 years post-infusion in the LTFU protocol (GSK Study 208750). • The primary completion of the study is defined as the date when at least 70% of all participants who received GSK3377794 infusion (mITT) have progressed or died or have been lost to follow-up. The study ends when all participants have moved to the LTFU protocol, declined LTFU, have been lost to follow-up, withdrew early, or died. Note that as the study is early terminated, the analyses described here are for the final study CSR at the end of the study.
Dosing	• All eligible participants will receive a single dose of lete-cel by IV infusion five (5) days after completing the lymphodepleting chemotherapy (this is considered Day 1). A target dose range of $1x10^9$ to $15x10^9$ total transduced T-cells was chosen. • On Day 1, In Arm A, lete-cel will be administered as a single intravenous (IV) infusion of 1 to 15 $x10^9$ transduced cells. There will be no re-treatment. Participants who subsequently progress may optionally receive therapy with pembrolizumab 200 mg Q3W for up to 35 cycles or until disease progression, at which point participants may enter the LTFU phase (following the LTFU schedule under this protocol (Part 5) until enrolled into a separate LTFU protocol (GSK Study 208750)). • In Arms B and C, participants will also receive a single IV infusion of 1 to 15 $x10^9$ lete-cel transduced cells on Day 1 followed by pembrolizumab 200 mg starting on Day 22 (Week4 Day 1). Pembrolizumab will be administered for up to 35 cycles Q3W or until disease progression, at which point participants may enter the LTFU phase (following the LTFU schedule under this protocol (Part 5) until enrolled into the LTFU protocol (GSK Study 208750).
Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• This is a multi-arm, open-label study with 3 arms, Arm A, Arm B, and Arm C, described above under Design Features
Interim Analysis	• Separate interim analyses may be conducted when at least 10 participants become evaluable for Arms A, B, and C. • Futility interim analysis decision rules for the 10^{th} evaluable participants are described below under Section 3.1

2.4. Statistical Analyses

This is a Phase 1b/2a study focused on the safety, tolerability, clinical activity, and whether HLA and antigen expression biomarkers can identify a population of participants with advanced NSCLC that could benefit from lete-cel administered alone or in combination with pembrolizumab.

No formal statistical hypotheses are being tested in this study.

3. PLANNED AND AD HOC ANALYSES

3.1. Ad hoc Analyses

An ad hoc analysis was performed using a data cutoff of August 30, 2021 as part of the study monitoring and to inform further development of the lete-cel NSCLC program. A set of data listings and figures for the first ten dosed patients (5 from Arm A and 5 from Arm C) were generated. This analysis is prior to the protocol-specified interim analysis detailed below. Based on the analysis of efficacy data from this unplanned interim analysis and given active parallel enrolment in NSCLC of a next-gen NYESO-targeting TCR-T cell therapy with a CD8a modification which may provide enhanced efficacy over lete-cel, the study stopped its further enrolment .

A second ad hoc analysis was performed using a data cutoff of February 24, 2022 for the purpose of internal strategic discussion. An updated set of data listings and figures for the first thirteen dosed patients (7 from Arm A and 6 from Arm C) were generated. Based on additional cumulative data, the study will allow enrolled patients who are eligible to receive the T-cell infusion to be dosed until 18 November 2022.

More details on each analysis can be found in the filenotes archived in electronic Trial Master File (eTMF).

3.2. Interim Analyses

For the primary purpose of informing future lete-cel development, separate interim analyses are planned for each arm after at least 10 evaluable participants are available in that arm. Evaluable participants are defined as participants who received a T-cell infusion and have either progressed, withdrawn from the study treatment, were lost to follow-up, or are ongoing and have completed at least two post-treatment disease assessments. If enrollment is still open at the time of the interim analysis, enrollment into a treatment arm may be stopped early for toxicity or lack of efficacy (futility) based on the results of an interim analysis.

The sample size for each arm was determined using a Bayesian predictive adaptive design that allows the study to be monitored more frequently while maintaining the desired Type I error and power. The sample size is based on testing the hypothesis for each arm separately and not for a comparison between arms. For all three arms, clinical response will be defined as investigator-assessed ORR per RECIST v1.1. An interim analysis after the 10th participant becomes evaluable will be employed for Arms A, B, and C, separately.

Participants with NSCLC lacking actionable genetic aberrations will be assigned to Arm A and Arm B such that at least 15 participants receive T-cell infusion within the target dose range (lete-cel) in Arm A and at least 15 participants receive T-cell infusion within the target dose range and pembrolizumab in Arm B. Participants with NSCLC with actionable genetic aberrations will be assigned to Arm C such that at least 15 participants receive T- cell infusion and pembrolizumab. Assuming around 15% of the participants enrolled will discontinue from the study prior to lete-cel infusion, up to approximately 18

participants will be enrolled in each arm to ensure at least 15 evaluable participants will receive T-cell infusion within the target dose range. Enrollment will proceed continuously with no scheduled enrollment pause while conducting the interim analysis. Upon completion of the interim analysis, this protocol may be amended to allow for expansion beyond 15 participants.

Analyses will be conducted for Arms A, B, and C independently. An end of study threshold is defined such that meeting this threshold may warrant continuing development in the population of interest. For each arm, Bayesian statistics will be employed to calculate the predictive probability of meeting the end of study threshold at the interim analysis (after the 10th enrolled participant per arm has received T-cell infusion (modified Intent-to-Treat [mITT] population) and has completed at least 2 post-baseline disease assessments since infusion or discontinued earlier) given the responses that have already been observed assuming a beta prior for the binomially distributed data. A weak prior of beta (0.02, 0.08) is used, which is equivalent to the information present in 0.1 participant.

At the interim analysis for each arm, further enrollment into the arm is recommended to be stopped due to futility if the predictive probability of meeting the threshold at the final analysis is less than 2.8%. Here, this threshold is defined as the posterior probability that the ORR is greater than 10% at the end of the arm is larger than 95%. This predictive probability aligns with observing at least 2 responders out of 10 participants, and if not met, serves as strong statistical evidence to stop further development of the treatment for the target population.

Futility interim analysis decision guidelines for each arm, specifying the number of participants with a confirmed response needed for continuing enrollment or stopping for futility is presented in Table 1.

Table 1 Decision-Making Criteria for Futility for Arms A, B, and C at the Interim Analysis Conducted with 10 Evaluable Participants/Arm

Arm (N=10/Arm)	Stop Enrollment for Futility if the Number of Confirmed Responses is Less Than or Equal to this Number	Probability of Continuing Enrollment under H0 (10%)	Probability of Continuing Enrollment under Ha (30%)
Arm A or B or C	1	0.2639	0.8507

Based on interim analysis results, enrollment for all treatment arms (Arm A, B, or C) may be stopped due to futility if ≤1 confirmed response is observed in the first 10 evaluable participants within the arm, i.e., the predictive probability that rejecting H0 at end of study is small (e.g., less than 2.8% chance to have at least 4 confirmed responders out of 15 participants who received T-cell infusion in the treatment arm). The above criteria are intended as guidelines. Final decisions with respect to study conduct, including pausing enrollment, will be based on a comprehensive review of the totality of the data including safety, DCR, DoR, CR rate, and PFS as warranted by the data.

3.3. Final Analyses

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

1. All participants that have received lete-cel infusion (mITT) have moved to the separate LTFU protocol, declined LTFU, have been lost to follow-up, withdrew early, or died.
2. All required database cleaning activities have been completed and final database release (DBR) and database lock(DBL) have been declared by Data Management.

For Arms A, B, and C, clinical response will be defined as ORR per RECIST v1.1.

If 4 responses out of 15 are observed at the final analysis, this will serve as evidence in favor of further development in this arm. Operating characteristics for a range of true population ORR are given in Table 2. The probability of reaching the continuing development criteria at the final analysis, given a true ORR of 30% is 68.1%. The inference from the Bayesian predictive probabilities of clinical activity in participants in each treatment arm is intended to drive decision making. Actual decisions will depend on the totality of the data including clinical activity, safety, PK, and biomarker data.

Table 2 Operating Characteristics for Interim and Final Analyses for Arms A, B, and C

True ORR	Probability of passing futility at interim (n=10)	Probability of reaching end of study threshold at final analysis (n=15)
10%	0.265	0.054
20%	0.625	0.334
30%	0.850	0.681
40%	0.953	0.896
50%	0.988	0.976

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• All participants who signed an ICF to participate in the study.	• Study Population
Enrolled	• All participants who started the leukapheresis procedure.	• Study Population
Intent-To-Treat (ITT) Population	• All participants who started the leukapheresis procedure.	• Study Population, Safety, Efficacy
Lymphodepletion Population	• All participants who received any dose of lymphodepleting chemotherapy.	• Safety
Modified ITT (mITT) Population	• All participants who received lete-cel infusion.	• Study Population, Safety, Efficacy
Pembrolizumab	• All participants in the mITT population who received at least one infusion of pembrolizumab.	• Study Population, Safety, Efficacy
Evaluable Population	• All participants in the mITT population with at least 2 post-baseline radiological disease assessments or have progressed, died, permanently withdrawn from the study, or (if relevant) permanently withdrawn from pembrolizumab.	• Interim Futility Analyses
Pharmacokinetic (PK) Population	• All participants in the mITT population from whom at least one persistence sample was obtained, analysed, and was measurable.	• PK

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

4.1. Protocol Deviations

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

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan Version 4 (26 May 2022) .

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

A 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

This is a multi-arm, non-randomized study, in which the participant will receive either lete-cel alone (Arm A) or in combination with pembrolizumab (Arms B and C). Data will be listed and summarized according to GSK reporting standards, where applicable.

Study population summaries will be displayed with separate columns for each arm, as well as an "Overall" column, without regard to actual treatment received. Efficacy summaries will be displayed with separate columns for each arm, according to planned treatment. An "overall" column will not be produced for the efficacy summaries. Safety summaries will be displayed according to actual treatment received within each arm, see Section 8 for details of planned safety displays.

Post-pembrolizumab safety data from patients who received pembrolizumab therapy following disease progression after GSK3377794 infusion will be summarized separately, as detailed in Sections 8.1 and Section 13.4. Efficacy data after pembrolizumab therapy for these patients will be listed separately.

		Treatment Group Descriptions		
RandAll NG			Data Displays for Reporting	
Code	Description	Tumor Characteristics	Description	Order in TLF
A	GSK3377794 monotherapy 1x10^9-6x10^9 transduced T-cells	Patients lacking actionable genetic aberrations	Arm A	1
B	GSK3377794 1x10^9 - 6x10^9 transduced T-cells followed by 200 mg of pembrolizumab Q3W up to 35 cycles*	Patients lacking actionable genetic aberrations	Arm B	2
		Patients with actionable genetic aberrations	Arm C	3

*Note: The description for Code B shows a target dose of 1x10^9 -6x10^9 transduced T-cells. However, as of PA7, the target dose has been expanded to 1x10^9 -15x10^9. The description has not been updated in RandAll NG at the study team's discretion.

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, prior to initiating lymphodepletion regardless of how close it is to the lymphodepletion date, albeit per protocol, baseline assessments should occur less than 10 days prior to initiating lymphodepletion.. If time is not collected, assessments taken on the day of lymphodepleting chemotherapy are assumed to be taken prior to lymphodepletion and used as baseline.

For summaries of laboratory data by CTCAE grade, missing baseline grade will be assumed as grade 0.

For participants who did not receive study treatment during the study, baseline will be defined as the latest, non-missing collected value.

Participants may receive either a single ECG at baseline or a triplicate. For ECG analyses, participant level baseline QTc is defined as the mean of triplicate QTc baseline assessments, if more than one ECG is present. If only a single ECG is present, this value will be used.

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

Baseline Assessment: Participants Assigned to Arm A who progress after receiving lete-cel and Receive Anti-PD-1 Rescue with Pembrolizumab

If the CT/MRI has been obtained at the progressive disease (PD) confirmatory scan within 4 weeks (28 days) prior to pembrolizumab rescue therapy initiation, this can be considered as baseline measurement for disease assessment during the Pembrolizumab Therapy Following Disease Progression Phase (see Section 13.4.1 for phase definitions).

For other endpoints, the same baseline definitions described above for the entire analysis population with the exception that the window for baseline being within (<=) 28 days prior to the initiation of pembrolizumab rescue therapy will be applied to all assessments deemed necessary as the baseline re-evaluation for these participants during the pembrolizumab rescue phase

5.3. Multicentre Studies

- Data from all participating centres will be pooled prior to analysis.
- It is anticipated that participant accrual will be spread thinly across centres and summaries of data by centre would be unlikely to be informative and will not, therefore, be provided.

5.4. Examination of Covariates, Other Strata and Subgroups

5.4.1. Covariates and Other Strata

No covariates or stratification will be used in any of the analyses.

5.4.2. Examination of Subgroups

No subgroup analyses will be performed due to small sample size.

5.5. Multiple Comparisons and Multiplicity

No formal statistical testing for between-treatment comparisons will be performed; therefore, no adjustments for multiple comparisons or multiplicity are planned.

5.6. Other Considerations for Data Analyses and Data Handling Conventions

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

Section	Component
Section 13.3	Appendix 3: Assessment Windows
Section 13.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
Section 13.5	Appendix 5: Data Display Standards & Handling Conventions
Section 13.6	Appendix 6: Derived and Transformed Data
Section 13.7	Appendix 7: Reporting Standards for Missing Data
Section 13.8	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 modified Intent-to-Treat (mITT) and Intent-to-Treat (ITT) population, unless otherwise specified. Some study population analyses will be performed using both the mITT and ITT populations. If the mITT and ITT populations are identical, then results planned for both populations will only be reported for the mITT population. Some study population analyses will be performed on the Pembrolizumab Population, where applicable.

All listings will be based on the ITT population, unless otherwise specified.

Study population analyses including analyses of participant's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, disease characteristics at initial diagnosis and at screening, prior and on study anti-cancer therapy, surgical/medical procedures, disease burden at baseline and study treatment exposure will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 12: List of Data Displays.

Summaries will present the study population data with separate columns for each arm, as well as with an overall column, where applicable.

6.2. Disposition of Participants

A summary of the number of participants in each of the analysis populations described in Section 4 above will be provided. A listing of participants excluded from analysis populations will also be provided.

A summary of screening status and screen failures will be provided using the screened population. Per GSK reporting standards, participants who were rescreened will appear once in these displays according to their final status.

A summary of interventional phase status will be produced, with reasons for completion and study withdrawal summarized in the order they are displayed in the CRF. Participant status will be displayed with the categories and subcategories: Completed study (death, progressive disease), ongoing, or did not complete interventional phase (with reasons from the CRF).

Overall study disposition, including long term follow up, will be summarized for the mITT population. An additional table will be created to summarize the number of participants in the ITT population who did and did not receive lete-cel, as well as the reason for not receiving the lete-cel infusion. A supporting listing of reason for study withdrawal will be created.

The number of participants in the Enrolled Population and mITT population will be summarized by country and study site ID.

A summary of study treatment discontinuation for pembrolizumab will be produced for the Pembrolizumab Population only, for each arm separately. The number of participants ongoing on pembrolizumab, discontinued, and reason for discontinuation will be summarized in the order they are displayed in the eCRF. A supporting listing of reasons for Pembrolizumab discontinuation will also be provided

6.3. Demographic and Baseline Characteristics

The demographic characteristics (e.g., race, age, ethnicity, sex, height and body weight at leukapheresis eligibility screening visit, the derived body mass index (BMI) according to baseline body weight and height at screening visit, and body surface area (BSA) per the DuBois & DuBois formula (Dubois & Dubois, 1916)) will be summarized and listed per GSK standards. A supportive listing of race and demographic characteristics will be produced.

A summary of disease characteristics at initial diagnosis will be provided, including stage of lung cancer at initial diagnosis and enrollment, time from initial diagnosis to leukapheresis eligibility screening in months, histology and histology grade at initial diagnosis. A supporting listing will be provided, with date of initial diagnosis. Refer to Section 13.6.2 for time since initial diagnosis derivation rules.

A summary of disease characteristics at screening will be provided, as collected in the CRF. Example categories may include disease stage at screening, , HLA-A/NY-ESO-1/LAGE-1a status, status of measurable disease at baseline as assessed by investigator, status of visceral/non-visceral disease, non-target lesions and measurable disease, tumor-node-metastasis (TNM) staging at baseline, time from last progression to leukapheresis eligibility screening (if applicable), and time from last recurrence to leukapheresis eligibility screening. A supporting listing will be provided.

A summary of disease burden at baseline will be provided, including number of organs involved and location of disease at baseline. Both target and non-target lesions at baseline, including both the number of organs, and their locations, will be included.

Medical conditions present at screening will be listed and summarized by past and current categories, separately for the ITT and mITT populations. All medical conditions recorded will be summarized, even if they are not pre-specified in the CRF.

Substance use including smoking history, smokeless tobacco use, betel quid/areca nut use, and alcohol use (data collected at onset of liver event only) will be summarized and listed.

6.4. Concomitant Medications

All concomitant medications will be coded using GSK Drug coding dictionary and will be summarized using the mITT population. Concomitant medications usage during the study will be summarized and listed. The summary of concomitant medications will show the number and percentage of participants taking concomitant medication 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 based on GSK Drug dictionary will be included in the dataset created but will not appear on the listing or summary.

In the summary of concomitant medications, each participant is counted once within each unique ingredient. For example, if a participant takes Amoxycillin on two separate occasions, the participant is counted only once under the ingredient 'Amoxycillin'. In the summary of concomitant medications, the ingredients will be summarized by the base only.

Refer to Section 13.4.1.1 for prior and concomitant medicine definition.

Summary of blood products or blood supportive care products ongoing at the time of lymphodepletion or initiated on or after lymphodepletion will be produced for the mITT population with supportive listings.

6.5. Study Treatment Exposure

A listing of study treatment will be provided, including overall lete-cel infusion start and stop date/time over all bags and for each bag separately, average vector copy number per cell in the cell product, total number of transduced cells, transduction efficiency, and route of synthesis (i.e. A6, B1, or B2). The listing will also include information pertaining to why a bag was partially infused and reason for pausing or discontinuing infusion. The total number of transduced T-cells will be summarized for the mITT population using mean, standard deviation, median, min and max. The total number of transduced T-cells will be categorized into <1, ≥ 1 to ≤ 8, and >8 to ≤ 15, and >15 (x 10^9 cells), cumulative cyclophosphamide dose will be categorized into ≤ 1800, >1800 to ≤ 2400, >2400 (mg/m^2), and cumulative fludarabine dose will be categorized into ≤ 60, >60 to ≤ 80, >80 to ≤ 90, >90 to ≤ 120, and >120 (mg/m^2). Time from leukapheresis to T-cell infusion will also be summarized.

All dose administration data for lymphodepletion, including cyclophosphamide and fludarabine, for lete-cel infusion will be presented by participant in a data listing. Supportive listings to report dose reductions and delay of lymphodepletion chemotherapy, as well as reason for dose reduction and delay, will be provided.

Duration of lymphodepletion dose delays over planned consecutive days is defined as the period from the expected start date of dose to actual start date of current dose. The calculation of duration of delay is actual start date of current dose – expected start date of dose. Expected start date of dose = actual start date of previous dose + 1.

A summary of exposure to pembrolizumab will be provided for the Pembrolizumab Population, including number of doses (n, mean, SD, median, min, max), time on study (days) and cumulative actual dose (mg). All exposure to pembrolizumab will also be listed by participant. All dose modifications (i.e. delays/interruptions and completed/stopped early and not completed) of pembrolizumab will also be summarized and listed as collected in the eCRF.

Total on-study treatment follow-up time will be summarized using descriptive statistics. The on-study treatment follow-up time is defined as the last contact date minus T-cell infusion date plus 1 and will be expressed in months.

6.6. Anti-Cancer Therapies and Surgery

Anti-cancer therapies include systemic therapy (coded using the GSK Drug coding dictionary), radiotherapy, and cancer-related surgery.

Anti-cancer systemic therapies will be classified into prior, bridging, and on-study phases as described below. Therapies will be identified using the corresponding CRF pages.

Type of Systemic Therapy	Definition
Prior	Prior therapy is defined as any line of systemic therapy (including intermediate therapy after leukapheresis), radiotherapy, and cancer-related surgeries given before start of lymphodepletion.
Bridging	Bridging therapies (supportive chemotherapy) are defined as systemic therapy given between leukapheresis and start of lymphodepletion to maintain disease control (not considered a line of therapy)
On-Study/Follow-up	On-study and follow-up therapies are defined as systemic therapy, radiotherapy, or cancer related surgery given on or after the start of T-cell infusion.

6.6.1. Prior Anti-Cancer Therapies

Systemic anti-cancer therapy regimens initiated between leukapheresis and lymphodepletion (as defined in Appendix 4) are categorized as either bridging (regimens administered to maintain/stabilize the participant until T-cell infusion) or full lines (regimens administered with the intent of disease effect, i.e. intermediate therapy after leukapheresis). Full lines of therapy administered after leukapheresis are considered prior therapy.

Anti-cancer therapy will be coded using GSK Drug coding dictionary. The number of participants receiving prior anti-cancer therapies will be summarized by ATC Level 1 and ingredient. Bridging therapies will be similarly summarized.

A breakdown of the number of participants who received each category of anti-cancer therapy (surgery, radiotherapy, chemotherapy, etc…) in the advanced/metastatic setting will be summarized.

A summary of the number of prior anti-cancer therapy regimens in the advanced/metastatic setting will be produced.

A listing of systemic therapy will be provided and labelled as prior, bridging, or on-study. Radiotherapies and cancer-related surgical procedures will be listed separately and labelled as prior or on-study.

6.6.2. On-study Anti-Cancer Therapies

On-study anti-cancer therapies will be summarized using the mITT population. The number and percentage of participants that received any on-study systemic anti-cancer therapy, radiotherapy, or cancer related surgery will be summarized together with the time from T-cell infusion to first post-treatment anti-cancer therapy. For the Pembrolizumab population, time from study treatment discontinuation (pembrolizumab) to start of subsequent anti-cancer therapy will also be included. On-study systemic therapies will be coded using GSK Drug coding dictionary and summarized by ingredient. On-study anti-cancer therapy will be listed.

Palliative radiotherapy is permitted on study and will not be considered an On-study Anti-Cancer Therapy for the purpose of censoring.

7. EFFICACY ANALYSES

Tumor assessments for response and progression will be evaluated by the investigator per RECIST v1.1 (Eisenhauer, 2009).

All efficacy summaries will be presented with a separate column for each treatment arm, using planned treatment. More specifically, patients from Arm C who received Lete-cel, but discontinued treatment before receiving any pembrolizumab will still be pooled with all other Arm C patients who received planned pembrolizumab Q3W. Efficacy for Part 4 participants after treatment with salvage pembrolizumab will be listed separately and shall not be included in efficacy tables or figures. An "overall" column will not be included for any efficacy summary.

7.1. Final Efficacy Analyses

The final analysis will be conducted when all participants who received lete-cel infusion (mITT) have moved to the separate LTFU protocol, declined LTFU, have been lost to follow-up, withdrew from the study, or died.

7.1.1. Endpoint / Variables

ORR

Overall Response Rate (ORR), defined as the percentage of participants with a confirmed PR or CR relative to the total number of participants within the analysis population, as assessed by the investigator per RECIST 1.1 Criteria.

Best Overall Response **(**BOR) is defined as the best confirmed response (Complete Response [CR] > Partial Response [PR] > Stable Disease [SD] [or non-CR/non-PD] > Progressive Disease [PD] > Not Evaluable [NE]) from letetresgene autoleucel (lete-cel, GSK3377794 infusion date until disease progression or initiation of new anti-cancer therapy, whichever is earlier, as assessed by the investigator per RECIST 1.1 Criteria.

RECIST (version 1.1) criteria

With respect to best overall responses, RECIST will be derived on local investigator assessed overall response at each visit:

- To be assigned a status of PR, or CR, a confirmatory disease assessment should be performed no less than 4 weeks (28 days) after the criteria for response are first met
- To be assigned a status of SD, follow-up disease assessment must have met the SD criteria at least once after the first dose at a minimum of 4 (28 days) weeks (Protocol section 10.10.1)
- If the minimum of 4 weeks (28 days) for SD is not met, best response will depend on the subsequent assessments. For example, if an assessment of PD follows the assessment of SD and SD does not meet the minimum 4-week requirement the best response will be PD. Alternatively, participants lost to follow-up after an SD

assessment not meeting the minimum time criteria will be considered not evaluable

- Responses of CR/PR that do not meet the requirements of confirmed CR/PR are still eligible to be considered SD if it has met the SD criteria.
- If PR assessments are separated by more than one SD assessment (e.g. PR-SD-SD-PR), the PR is not considered confirmed. PR separated by only one SD assessment (PR-SD-PR) will be considered a confirmed PR.
- Assessments that are not done or not evaluable should be disregarded.
- Disease assessments after new on-study anti-cancer therapy, will not be considered when deriving best overall response. On-study anti-cancer therapy is defined in Section 6.6.2 No disease assessments after initiation of the rescue pembrolizumab will be considered when deriving the best overall responses.
- The date of disease progression is defined as the date of radiological disease progression based on imaging data per RECIST v1.1. For cases where non-radiological progression is documented by the investigator, the derived overall response based on RECIST v1.1 tumor assessment data, not the non-radiological progression, will be utilized for investigator assessment.
- If time is not collected and anti-cancer therapy starts on the same day as the disease assessment, it is assumed that the disease assessment occurred first.
- Inclusion criteria 16 requires participants to have measurable disease according to RECIST v1.1 criteria prior to lymphodepletion. If this is violated and a participant has no measurable disease at baseline, then the participant will be treated as a non-responder and included in the denominator when calculating ORR. Participants with no disease assessments on study will be also treated as a non-responder and included in the denominator when calculating ORR.

7.1.2. Summary Measure

ORR

The number and percentage of participants with the BOR in the following response categories will be summarized by treatment arm: CR, PR, SD, PD, NE and overall response rate (CR+PR). The observed confirmed ORR will be reported along with 95% Clopper-Pearson exact confidence interval. Analysis will be based on mITT and ITT population.

Change in target lesions from baseline over time will be shown in a spider plot. A waterfall plot showing the maximum percent reduction from baseline in tumor measurement will be also produced for each treatment arm.

An overall listing of participant response data will be provided for the ITT population. The listing will include all response evaluations, the best confirmed response, whether the participant is ongoing in the study (for interim or final analysis), and whether the participant is in the mITT population. All supporting lesion data will be listed.

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

7.1.3. Population of Interest

The efficacy analyses will be based on the modified Intent-To-Treat (mITT) population. ORR will be reported in the Evaluable and mITT populations at the time of the interim and final analyses, respectively. The Intent-To-Treat (ITT) is the sensitivity analysis population for the efficacy endpoint. If the mITT and ITT populations are identical, only results associated with the mITT population will be reported.

7.1.4. Strategy for Intercurrent (Post-Randomization) Events

In the analysis of ORR and BOR in the protocol specified population, there are two types of intercurrent events, i.e., missed response assessments and other anticancer therapy. To address the missed response assessment as an intercurrent event, a composite strategy will be followed for participants who experience death prior to response assessments, or have only missing responses or not-evaluable assessments, or have non-measurable disease at baseline. These participants will be treated as non-responders (NE) ; i.e. they will be included in the denominator when calculating the percentage.

Start of new anti-cancer therapy as a second type of intercurrent event, is addressed with while-on-treatment strategy, as the interest lies in the treatment effect of the investigational treatments before start of new anti-cancer therapy.

7.1.5. Statistical Analyses / Methods

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

Unless otherwise specified, endpoints / variables defined in Section 7.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

A listing of investigator-assessed target, non-target, and new lesions assessments will be provided, as well as a listing of investigator-assessed response at each visit. Assessments that occur during pembrolizumab rescue therapy for Arm A, as defined in Section 13.4.1, will be flagged. ORR will not be calculated for assessments during pembrolizumab rescue therapy.

7.2. Secondary Efficacy Analyses

7.2.1. Endpoint / Variables

Disease Control Rate (DCR)

DCR, is defined as the percentage of participants with a confirmed CR, PR, or SD with minimal 6 months (168 days) duration relative to the total number of participants within the analysis population at the time of the analysis (interim or final) as determined by local investigators per RECIST v1.1. DCR will be analysed based on mITT population. The observed DCR will be reported along with 95% Clopper-Pearson exact confidence interval (CI).

A BOR of SD will be considered to have had a duration of at least 6 months (SD durability) if there is at least one follow-up disease assessment that has met the RECIST 1.1 SD, PR or CR Criteria on or after Week 24 (Day 168), but before disease progression or initiation of new anti-cancer therapy.

Inclusion criteria 16 requires participants to have measurable disease according to RECIST v1.1 criteria. If this is violated and a participant has no measurable disease at baseline, then the participant will be treated as a non-responder and included in the denominator when calculating DCR. Participants with no disease assessments on study will be also treated as a non-responder and included in the denominator when calculating DCR.

Progression-Free Survival (PFS)

PFS is defined as the interval of time (in months) from the date of T-cell infusion to the earliest date of radiological progression of disease (PD) as assessed by investigator per RECIST v1.1, or death due to any cause. Determination of dates of PFS events and dates for censoring are described in Table 3.

The date of disease progression is defined as the date of radiological disease progression based on imaging data per RECIST v1.1.

For the analysis of PFS, if the participant received subsequent anti-cancer therapy prior to the date of documented events, PFS will be censored at the last adequate disease assessment (e.g., assessment when visit level response was CR, PR, or SD) prior to the initiation of the new anticancer therapy. If a participant does not have any adequate post-baseline disease assessments on or beforethe date of initiation of anti-cancer therapy, PFS will be censored at the date of the T-cell infusion.

PFS will be censored for participants who have radiological progression or die after missing two or more scheduled radiological disease assessments. Specifically, if there are two or more consecutive scheduled radiological assessments which are missing followed by radiological progression or death, PFS will be censored at the last adequate radiological assessment prior to radiological progression or death. If a participant does not have an adequate post-baseline disease assessment prior to the date of radiological progression or death, PFS will be censored at the date of the T-cell infusion. Refer to the

section below to identify Extended Loss to Follow-Up at selected time points in the study.

If a participant has neither progressed nor died nor started new anti-cancer therapy, PFS will be censored at the date of the last adequate disease assessment. Acceptable imaging modalities for this study include:

- Diagnostic-quality CT scan with oral and/or IV iodinated contrast of the chest and abdomen/pelvis (CT is the preferred modality for tumor assessments)
- MRI of the abdomen/pelvis acquired before and after gadolinium contrast agent administration
- Non-contrast enhanced CT of chest/abdomen/pelvis if a participant is contraindicated for both CT and MRI contrast or if they have renal compromise
- Additional scans (CT/MRI) should be acquired for any other areas of suspected/known disease per site SoC, if clinically indicated
- Digital photographs of skin lesions including a ruler for estimating the size of the lesion

If the start date of anticancer therapy is partial, the imputation rules described in Appendix 7: Reporting Standards for Missing Data will be applied. If new anti-cancer therapy occur on the same day as a radiological disease assessment, assume the disease assessment was performed first.

Extended Loss to Follow-up

Since missing scheduled radiological disease assessments prior to radiological progression or death increases the uncertainty when the event actually occurs, PFS will be censored for participants who have radiological progression or die after missing two or more scheduled radiological disease assessments. Specifically, if there are two or more scheduled radiological assessments which are missing followed by radiological progression or death, PFS will be censored at the last adequate radiological assessment prior to radiological progression or death. If a participant does not have an adequate post-baseline disease assessment prior to the date of radiological progression or death, PFS will be censored at the date of the T-cell infusion date.

As the assessment schedule and windows change through the course of the study (i.e., every 6 weeks during the first 24 weeks, an assessment 9 weeks at Wk34D1 , and then every 12 weeks thereafter), the following rules will be used for identifying extended loss to follow up.

- If the PFS event is prior to Day 176 (Week 25 + 7 day window), then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment or T-cell infusion during the time period of 98 days (12 weeks + 1 week window + 1 week window) prior to PFS event

- Else if the PFS event is after Day 176 (Week 25 + 7 day window) and on or before Day 239 (Week 34 + 7 day window) then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment during the time period of 119 days (6 weeks + 9 weeks + 2 week window)

- Else if the PFS event is after Day 239 (Week 34 + 7 day window) and on or before Day 323 (Week 46 + 7 day window) then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment during the time period of 161 days (9 weeks + 12 weeks + 2 week window)

- Else if the PFS event is after Day 323 (Week 46 + 7 day window) then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment during the time period of 182 days (12 weeks + 12 weeks + 2 week window)

The "month" used in these algorithms is 30.4375 days long (365.25/12=30.4375) and rounded to the closest integer.

If the participant has a missing or incomplete baseline assessment and dies before missing two scheduled disease assessments, the death will be considered an event.

A summary of the assignments for progression and censoring dates for PFS are specified in REF _Ref105524333 \h .

Table 3 Assignments for Progression and Censoring Dates for PFS Analysis

Situation	Date of Event (Progression/Death) or Censored	Event (Progression/Death) Or Censored
No or incomplete baseline tumor assessments or no measurable disease at baseline and the participants has not died	Date of T cell infusion	Censored
No adequate post-baseline disease assessments before start of new anti-cancer therapy and the participant has not died	Date of T cell infusion	Censored
Progression documented between scheduled visits	Date of radiological assessment of progression[1]	Event
With adequate post-baseline assessment but no progression (or death)	Date of last adequate radiological disease assessment of response[2]	Censored
With adequate post-baseline assessment and new anticancer treatment started (prior to documented disease progression) [3]	Date of last adequate radiological disease assessment of response[2] (on or prior to starting anti-cancer therapy)	Censored
Death before first scheduled assessment	Date of death	Event

Situation	Date of Event (Progression/Death) or Censored	Event (Progression/Death) Or Censored
Death (regardless of having baseline assessment) before missing two schedule assessments and no progression	Date of death (Use rule above to determine missing two scheduled assessments)	Event
Death (regardless of having baseline assessment) or progression after two or more consecutive missed adequate disease assessment[4]	Date of last adequate radiological disease assessment of response[2] (prior to missed assessments)	Censored

[1] The earliest of (i) Date of radiological assessment showing new lesion (if progression is based on new lesion); or (ii) Date of radiological assessment showing unequivocal progression in non-target lesions, or (iii) Date of last radiological assessment of measured lesions (if progression is based on increase in sum of measured lesions)
[2] An adequate assessment is defined as an assessment where the Investigator determined response is CR, PR, 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] Refer to Section 7.2.1 for details of extended time without an adequate assessment

Duration of Response (DOR)

DOR is defined as the time (in months) from first documented evidence of confirmed PR or CR to the date of disease progression, as assessed by RECIST v1.1 or death due to any cause in the subset of participants with a confirmed CR or PR as assessed by local investigators per RECIST v1.1. Censoring rules and analysis details will follow those for PFS as specified in Table 3.

Time to Response (TTR)

TTR is defined as the time between T cell infusion to initial date of confirmed response (PR or CR) as assessed by investigator per RECIST v1.1 in the subset of participants who achieved a confirmed PR or CR.

7.2.2. Summary Measure

DCR

The number and percentage of participants with the BOR in the following response categories will be summarized: CR, PR, SD ≥ 6 months, clinical benefit response (CR+PR+SD ≥ 6 months), PD and NE. The corresponding Clopper-Pearson exact 95% CI for DCR 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 DCR percentages. DCR will be summarized for the ITT and mITT population.

PFS

The distribution of PFS will be estimated using the Kaplan-Meier method if data warrant, separately for each study arm. The median, 25^{th} and 75^{th} percentiles of PFS will be estimated and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (Brookmeyer & Crowley, 1982) using the SAS default (loglog transformation in PROC LIFETEST). A Kaplan-Meier curve will be produced

with 95% confidence bands, if data warrant. PFS rate at timepoints every 3 months and corresponding 95% CI will also be estimated from the Kaplan-Meier analysis. A supporting listing will be provided.

The follow-up time for PFS will also be estimated based on reverse KM estimate, i.e., treating the patients who have had progression or died as censored, and those who continue to follow-up as event. The reverse KM estimates suggest the follow-up time for patients and provide context for the interpretation of the PFS estimates.

DOR

If there is a sufficient number of responses at time of analysis, the distribution of DOR will be estimated using the Kaplan-Meier method by study arm. The median, 25th and 75th percentiles of DOR will be estimated and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (Brookmeyer & Crowley, 1982) using the SAS default (loglog transformation in PROC LIFETEST). A Kaplan-Meier curve will be produced with 95% confidence bands, if data warrant. DOR will be summarized among the participants with confirmed response of PR or CR as the BOR. A supporting listing will be provided.

TTR

If there is a sufficient number of responses at time of analysis, time to response will be summarized descriptively by study arm using median, min, max and quartiles in the subset of participants with a confirmed response of PR or CR as the BOR. A supportive listing will be provided.

7.2.3. Population of Interest

The secondary efficacy analyses will be based on the mITT population, unless otherwise specified. The ITT is the sensitivity analysis population for DCR. If the mITT and ITT populations are identical, only results associated with the mITT population will be reported.

7.2.4. Strategy for Intercurrent (Post-Randomization) Events

For DCR:

A composite strategy will be followed for participants who experience death prior to response assessments, or have only missing responses or not-evaluable assessments, or have non-measurable disease at baseline. These participants will be treated as non-responders (NE) ; i.e. they will be included in the denominator when calculating the percentage.

Start of new anti-cancer therapy is addressed with a while-on-treatment strategy, as the interest lies in the treatment effect of the investigational treatments before start of new anti-cancer therapy.

For PFS and DOR:

New anti-cancer therapy started before documented PD or death is addressed with the hypothetical strategy, because the interest lies in the treatment effect attributable to the investigational treatments and not confounded by other anti-cancer therapies. Palliative radiotherapy is not considered an anti-cancer therapy since it is permitted per protocol.

Refer to Table 3 for censoring rules and intercurrent event strategy.

7.2.5. Statistical Analyses / Methods

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

Unless otherwise specified, endpoints / variables defined in Section 7.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

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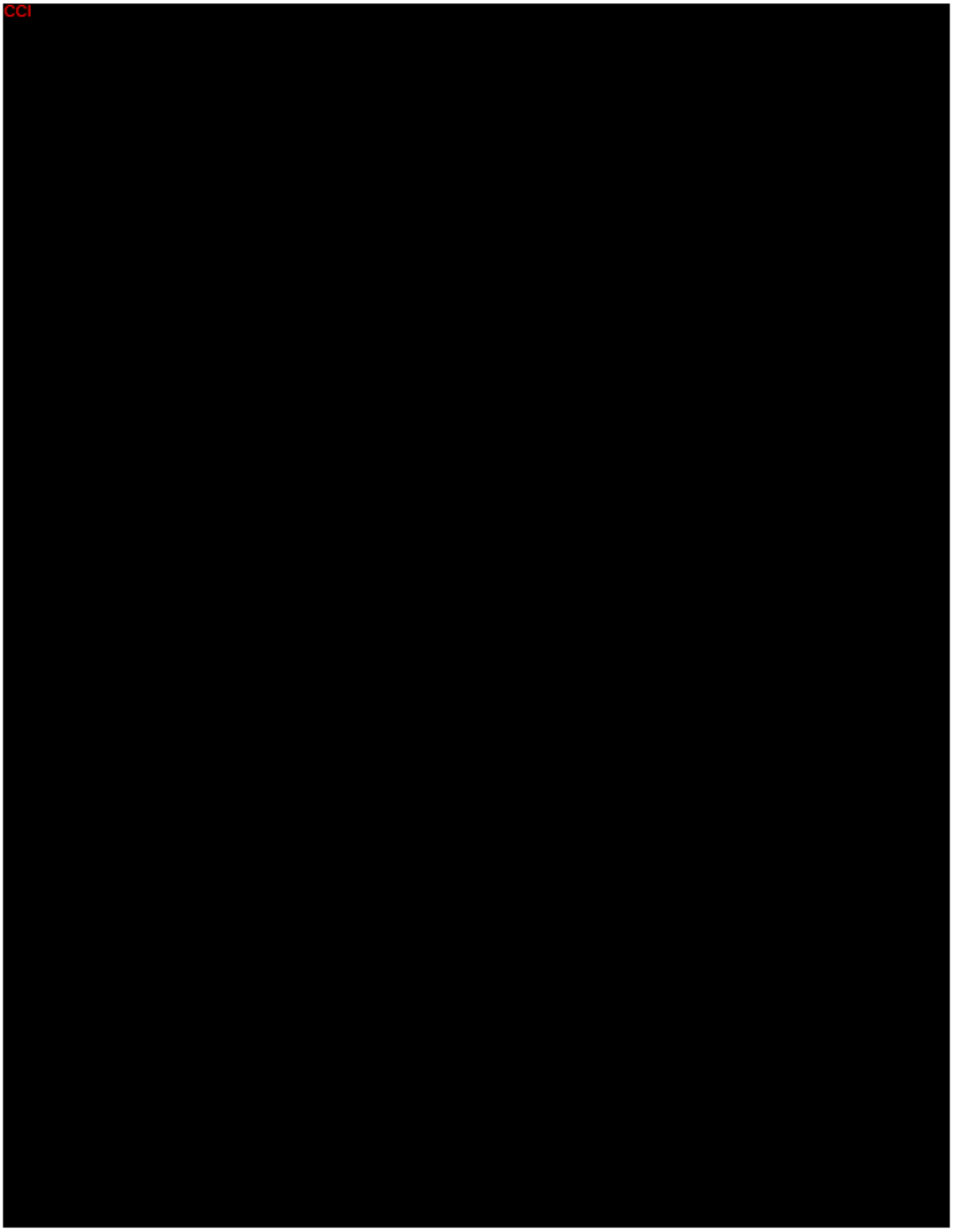

8. SAFETY ANALYSES

The safety analyses will be based on the mITT population, unless otherwise specified. Additional analyses will be presented using the Intent-to-Treat and Lymphodepletion populations. The Pembrolizumab Population will be used as needed to describe the safety and tolerability of pembrolizumab after T-cell infusion in the exposed populations.

Arm C participants are expected to receive lete-cel in combination with pembrolizumab, however, since there is a 3 week time period between lete-cel infusion and the first scheduled dose of pembrolizumab, it is possible that Arm C participants may not receive any dose of pembrolizumab (e.g. if the participant withdraws from the study or dies after receiving lete-cel but before receiving any dose of pembrolizumab). To account for this, all safety displays for Arm C in the T-cell infusion phase will be presented in a single table with three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab), and Arm C (Total). By study design, participants who didn't receive pembrolizumab in Arm C have shorter follow-up times compared to the participants who received pembrolizumab, i.e., they are mostly followed shorter than 3 weeks and discontinued the study before the first dose of pembrolizumab. The results of the two split columns need to be interpreted with caution. Participants will be slotted into these columns based on actual treatment received. Displays in the Pre-Lymphodepletion and Lymphodepletion phases will use planned treatment to display data separately by arm.

Note that within the Arm A Pembrolizumab Population, all safety events (including AEs, SAEs, labs, etc) which occur after the first dose of Pembrolizumab therapy following disease progression (see phase definition in Appendix 13.4.1) should be excluded from the main safety summary tables. Safety data which is collected after the first dose of pembrolizumab in Arm A will be listed. The only exception will be summaries of Replication Competent Lentivirus and Integration Site Analysis, which will include all patient data without excluding data collected after the first dose of pembrolizumab.

8.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious AEs (SAEs), AEs related to study-treatment (lymphodepleting chemotherapy, T-cell infusion, pembrolizumab), SAEs related to study treatment (lymphodepleting chemotherapy, T-cell infusion, pembrolizumab) and other significant AEs will be based on GSK Core Data Standards. AEs leading to dose modifications for Pembrolizumab (dose interruptions, dose reduction and dose delays) will also be summarized and listed according to GSK Oncology Data Standards for the Pembrolizumab population, as needed. The details of the planned displays are provided in Appendix 12: List of Data Displays.

AEs will be graded according to National Cancer Institute-Common Toxicity Criteria for Adverse Events (NCI-CTCAE) version 4.03 unless otherwise specified in the protocol. For instance, the grading of AE-related Cytokine Release Syndrome (CRS) and ICANS will be performed using ASTCT grading criteria (Lee, Santomasso, & Locke, 2019); see protocol Section 10.9.5 and 10.9.8.1. For the grading of Graft versus Host Disease (GVHD) associated AEs, see protocol Section 10.9.6.2. AEs will be coded to the level of

Preferred Term (PT) using the latest version of the Medical Dictionary for Regulatory Affairs (MedDRA).

Per GSK standard, Adverse Events that have grade changes over the course of the event are entered in the same record, with grade changes indicated within. Other attributes of the event (e.g. seriousness, relatedness) are attributed to the full event.

For specific adverse event displays, Preferred Terms are combined and will be reported together as one term. The combined terms for MedDRA Version 24.1 are listed in Appendix 6. 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 combined terms, therefore the list of combined preferred terms will be based on the safety review team (SRT) agreements in place at the time of reporting. A table showing the relationship between the combined preferred term and contributing preferred terms will be produced. Tables that summarize AEs by SOC and PT will use MedDRA preferred terms. Most other AE tables will summarize AEs by the combined terms in Appendix 6, unless otherwise specified.

AEs will be summarized in the following phases among participants which have entered the phase.

Phase	Definition	Population
Pre-Lymphodepletion Phase	AEs which start prior to lymphodepletion chemotherapy	Intent-to-Treat Population
Lymphodepletion Phase	AEs which start or worsen on or after the start of lymphodepletion chemotherapy until prior to T-cell infusion	Lymphodepletion Population
T-cell Infusion Phase (Treatment-Emergent)	AEs which start or worsen on or after T-cell infusion up until Pembrolizumab Therapy Following Disease Progression after lete-cel Infusion (if applicable)	mITT Population
Pembrolizumab Therapy Following Disease Progression after GSK3377794 Infusion Phase	AEs which start or worsen on or after first dose of Pembrolizumab Rescue Therapy (Arm A only)	Pembrolizumab Population (Arm A only)

These periods are defined in more detail in Section 13.4.2.

AEs which start within the phase or worsen after initiation of the phase (maximum grade after initiation of the phase is larger than the maximum grade before initiation of the phase) will qualify to be summarized in the phase. AEs may be summarized in multiple phases (ex: A Grade 2 AE after lymphodepletion increases to Grade 3 after T-cell infusion and is summarized as a Grade 2 in the lymphodepletion phase and a Grade 3 in the T-cell Infusion Phase).

The primary analysis of adverse events will be performed for AEs which started or worsened during the T-cell Infusion Phase i.e. treatment-emergent AEs. However additional analyses will be performed in the periods above.

All AEs collected in the Intent-to-Treat population will be listed and the phase assigned to the AE will be indicated in the listing. AEs which led to study treatment withdrawal, interruption, delay, or reduction of any study treatment (cyclophosphamide, fludarabine, T-cell infusion, or Pembrolizumab) will be flagged in the listing as collected in the CRF. Additionally, a listing of participant IDs for each individual AE will be produced.

SAEs will be included in the listing of all AEs, but also separate supportive listings with participant-level details will be generated for:

- Non-fatal SAEs
- Reasons for considering AE as serious

AEs will be summarized and displayed in descending order of total incidence by SOC and PT. In the SOC row, the number of participants with multiple events under the same system organ class will be counted once.

Summaries of number and percentage of participants with adverse events by maximum grade will also be produced. AEs will be sorted by combined PT in descending order of total incidence. The summary will use the following algorithms for counting the participant:

- **Combined preferred term row**: Participants experiencing the same combined preferred term several times with different grades will only be counted once with the maximum grade.
- **Any event row**: Each participant with at least one adverse event will be counted only once at the maximum grade no matter how many events they have.

Summaries will be provided for lymphodepletion-related and T cell-related AEs separately. Another separate summary by maximum grade will be provided for AEs related to pembrolizumab (Pembrolizumab Population). 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.

Analyses for AEs in the Pre-Lymphodepletion Phase will include:

- Summary of AEs by System Organ Class and Preferred Term (using PT term)
    - AEs
- Summary by maximum grade
    - AEs
    - SAEs

Analyses for AEs in the Lymphodepletion Phase will include:

- Summary of AEs by System Organ Class and Preferred Term (using PT term)
  - AEs
- Summary by maximum grade
  - AEs
  - SAEs
  - Lymphodepletion-related AEs

Analyses for treatment-emergent AEs will include:

- Summary of AEs by System Organ Class and Preferred Term (using PT term)
  - AEs
  - SAEs
  - T-cell related
  - Pembrolizumab related
  - Common non-serious AEs (number of subjects and occurrences)
  - SAEs (number of subjects and occurrences)
- Summary by maximum grade
  - AEs
  - SAEs
  - T-cell related AEs
  - Pembrolizumab related AEs
  - Lymphodepletion related AEs
  - T-cell related SAEs
  - Pembrolizumab related SAEs
  - Lymphodepletion related SAEs
- Descending frequency (using Preferred Term)
  - Non serious T-cell related AEs
  - Serious fatal and non-fatal T-cell related AE

As displayed above, a summary of common non-serious treatment-emergent AEs that occurred in 5% of the participants or above will be provided (no rounding for the percentage will be used in terms of 5% threshold, e.g. events with 4.9% incidence rate should not be included in this table). This summary will contain the number of subjects and occurrences of participants with common non-serious adverse events. The summary table will be displayed by SOC and PT. A summary of All Treatment-Emergent Serious Adverse Events by System Organ Class (SOC) and Preferred Term (PT) will also be created to detail the number of participants and occurrences of each event.

Delayed AEs as defined in the FDA 2020 Guidance- Long Term Follow-Up After Administration of Human Gene Therapy Products (FDA, 2020) are identified through sponsor adjudication as the primary method of reporting. Sponsor adjudication will focus on AEs starting 90 days after administration of T-cell therapy that fall into one of following categories:

- New malignancies

- New incidence or exacerbation of a pre-existing neurological disorder
- New incidence or exacerbation of a prior rheumatologic or other autoimmune disorder
- New incidence of immune-related hematologic disorder
- Serious infections (including opportunistic)
- Unanticipated illness or hospitalization deemed related to gene modified cell therapy

Events that meet the criteria above, are study-treatment related events, and are serious and/or Grade ≥ 3 will be the primary focus of sponsor adjudication, although adjudication is not limited to these criteria. A listing of delayed AEs as adjudicated by the sponsor by delayed AE category will be produced.

Delayed AEs are also identified by the investigator and captured in the CRF. Delayed AEs as adjudicated by the sponsor (provided from external data source) and identified by the investigator will be listed separately.

8.2. Adverse Events of Special Interest Analyses

Adverse events of special interest (AESIs) evaluated in this RAP include:

- Cytokine release syndrome (CRS)
- Pneumonitis/pneumonia
- Graft vs host disease (GvHD)
- Guillain Barre syndrome (GBS) or acute inflammatory demyelinating polyneuropathy (AIDP)
- Pancytopenia/Aplastic anemia (including analysis of all hematopoietic cytopenias)
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
- Treatment-related inflammatory response at tumor site(s)

All analysis of AESIs will be performed in the T-cell Infusion Phase using the mITT population, unless otherwise stated.

A focused list of MedDRA terms based on clinical review will be used to identify each type of event. In addition, a comprehensive list of MedDRA terms aligning with MedDRA SMQ list will also be used for AESI reporting. 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. The details of the planned displays are provided in Appendix 12: List of Data Displays.

The protocol-identified AESI, Treatment-related inflammatory response at tumor site, is non-specific and will not be identified using the focused or comprehensive list. Investigator identified AEs which may be related to this event will be used to characterize this AESI.

The number and percentage of participants with treatment-emergent AESIs will be summarized by categories of AESI, combined preferred term, and grade using both the comprehensive list and focused list (if applicable). Hematopoeitic cytopenias will only be summarized using the focused list, and presented overall, as well as by cell line.

A summary of AEs linked to the AESI identified by the investigator will be summarized by AESI and maximum grade. A summary of the concomitant medications linked to the AESI will also be provided by AESI.

A summary of event characteristics for each category of AESI will be provided, including number of participants with any event, number of events, number of participants with any event that is serious, number of participants with any event that is related to study treatment, the outcome of the event, maximum grade and the action taken for the event. The percentage will be calculated in 2 ways, one with number of participants with event as the denominator and the other with total number of participants as the denominator. The worst-case approach will be applied at participant level for the event outcome and maximum grade, i.e. a participant will only be counted once as the worst case from all the events experienced by the participant. For action taken to an event, participant will be counted once under each action, e.g. if a participant has an event leading to both study treatment discontinuation and dose reduction, the participant will be counted once under both actions. This summary will only be created if there are a sufficient number of events.

Cytokine Release Syndrome

The following analyses will be provided:

- Summary of event characteristics (as detailed above) using the focused list
- Among participants which experienced CRS, a summary of onset and duration of the first occurrence of CRS identified using the focused list will be provided.
- Time to onset and duration of serious events, if at least 5 events
- Summary of the procedures and medications associated with CRS from the CRS eCRF page
- Cumulative total doses per patient that received tocilizumab for CRS

A supporting CRS listing profile will be provided to detail the CRS adverse event, display the procedures and medications received to treat CRS, display symptoms associated with the event.

Haematopoetic cytopenias

The following analyses will be provided:

- Summary of event characteristics of treatment-emergent cytopenias using the focused list (as detailed above).
- Summary of onset and duration of the first occurrence of febrile neutropenia

A supporting Pancytopenia listing profile will be provided to detail these events

Pneumonitis/pneumonia

The following analyses will be provided:
- Summary of event characteristics using the focused list (as detailed above).
- Summary of onset and duration of the first occurrence of pneumonitis/pneumonia identified using the focused list

Supporting pneumonitis and pneumonia profile listings will be provided to detail these events

Graft versus Host Disease (GvHD) The following analyses will be provided:
- Summary of event characteristics using the focused list (as detailed above).
- Summary of onset and duration of the first occurrence of GvHD identified using the focused list

A supporting GvHD listing profile will be provided to detail these events

Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)

The following analyses will be provided:
- Summary of event characteristics using the focused list (as detailed above).
- Summary of onset and duration of the first occurrence of ICANS identified using the focused list

A supporting ICANS listing profile will be provided to detail these events

Guillain-Barre Syndrome (GBS)

A supporting GBS listing profile will be provided to detail these events

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

8.3. 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 12: List of Data Displays.

Laboratory Assessments	**Parameters**			
Hematology	Platelet Count RBC Count Hemoglobin Hematocrit	RBC Indices: • MCV • MCH • Reticulocytes		WBC count with Differential: • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils
Flow Cytometry	T-Lymphocytes	CD3/CD4/CD8		
Clinical Chemistry	BUN[b]	Potassium	AST (SGOT)	Total and direct bilirubin
	Creatinine	Sodium	ALT (SGPT)	Total Protein
	Glucose [Indicate if fasting, or nonfasting]	Calcium	Alkaline phosphatase	Chloride
	Albumin	Phosphorus	LDH	Urea[a]
		Magnesium	Bicarbonate	
Coagulation	INR, PT, aPTT and Fibrinogen			
Routine Urinalysis	• Specific gravity • pH, glucose, protein, blood, ketones, bilirubin, urobilinogen, nitrite, leukocyte, and esterase by dipstick • Microscopic examination (if blood or protein is abnormal)			
Other Tests	• CMV IgG and PCR • TSH with free T4 • CRP • Uric acid • GFR or 24-hour urine collection • Follicle-stimulating hormone and estradiol (as needed in women of non-childbearing potential only) • Highly sensitive serum or urine hCG pregnancy test (as needed for women of childbearing potential)[c] • HIV, HBV, HCV, HTLV, EBV, and syphilis (spirochete bacterium). • Ferritin • Serum troponin • NT-proBNP / BNP			

a. Details of liver chemistry monitoring criteria and required actions and follow-up assessments after liver monitoring event are given in Section 7.1.1 and Table 17 of study protocol. All events of ALT ≥ 3 × ULN and bilirubin ≥ 2 × ULN (>35% direct bilirubin) or ALT≥ 3 × ULN and INR >1.5, if INR measured, which may indicate severe liver injury (possible Hy's Law), must be reported as an SAE.
b. Either BUN or UREA tests are acceptable
c. Local urine testing will be standard for the protocol unless serum testing is required by local regulation or IRB/IEC.

Laboratory grades will be reported using CTCAE v4.03.

Summary of post-baseline change of laboratory values by visit will be provided. Separate summary tables for haematology, chemistry, and urinalysis laboratory tests will be produced. Unless otherwise specified, the denominator in percentage calculation at each scheduled visit will be based on the number of participants with non-missing value at each particular visit.
Supporting line graphs of neutrophils, platelets, hemoglobin, and lymphocytes over time will also be produced. Plots will be produced by type of lab value.

Summaries of worst case grade increase from baseline grade will be provided for all the laboratory tests that are gradable by CTCAE v4.03. These summaries will display the number and percentage of participants with a maximum post-baseline grade increasing from their baseline grade, as well as post-baseline increase at all planned visits for hematology parameters. 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 labeled by direction, e.g. sodium will be summarized as hyponatremia and hypernatremia.

For laboratory tests that are not gradable by CTCAE v4.03., summaries of worst case changes from baseline with respect to normal range will be generated. The worst case will be chosen from all available tests, including scheduled and unscheduled visits. 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 participant has a decrease to low and an increase to high during the same time interval, then the participant is counted in both the "Decrease to Low" categories and the "Increase to High" categories. Missing baseline grade will be assumed to be normal.

The number of participants with worst case protein or occult blood urinalysis (discrete or character) results will be summarized by the combination of specimen, method and test and category.

8.3.1. Analysis of Liver Function Test (LFT)

A summary of liver monitoring/stopping event reporting will be provided, with a corresponding listing.

A listing of subjects meeting hepatobiliary laboratory abnormalities aligned with the Protocol liver monitoring criteria will be provided. The intent of this listing is to identify subjects, in particular possible Hy's Law subjects, for clinical review. A summary of subjects meeting hepatobiliary laboratory abnormalities may be provided if enough subjects have events. Details can be found in the IDSL Liver standard document.

The percentage of participants that met the following criteria will be summarized : ALT $\geq$3xULN and BIL $\geq$2xULN, ALT $\geq$3xULN and INR >1.5, ALT $\geq$3xULN and BIL $\geq$2xULN and (ALP <2xULN), Hepatocellular injury, Hepatocellular injury and BIL $\geq$2xULN, ALT $\geq$3xULN, ALT $\geq$5xULN, ALT $\geq$8xULN, ALT $\geq$10xULN, ALT $\geq$20xULN

- To be counted in the denominator, the participant must have at least one post-baseline lab chemistry measurement for the specified lab tests (e.g. in the 'ALT $\geq$3xULN and BIL $\geq$2xULN' category, the denominator should include participants who had both a post-baseline ALT value AND a post-baseline BIL value that was up to 28 days after ALT).
- Categories are not mutually exclusive. For example, a participant with ALT 20xULN will be included in each of the 3x, 5x, 8x, 10x, and 20x categories.

- If Direct Bilirubin is available on the same day, then Direct Bilirubin as a portion of total bilirubin must be ≥35% when total Bilirubin is ≥ 2xULN, in order to satisfy the criteria. If all criteria for Hy's law are satisfied except Direct Bilirubin exists and is < 35% then the record will not be considered a possible Hy's Law event. The total Bilirubin elevation must occur on or up to 28 days after the ALT elevation (as this is the standard for DILI cases of Hy's Law). This was deemed an acceptable window through discussion with the GSK Hepatic Safety Panel.
- **Note:** In the rare event that total Bilirubin value is not provided within 28 days on or after ALT value, Direct Bilirubin cannot be used in place of total Bilirubin in the Hy's law criteria therefore a separate optional category can be included if needed to analyse these cases.
- Hepatocellular injury is defined as ((ALT/ALT ULN)/(ALP/ALP ULN)) ≥5 and ALT ≥3xULN. ALT and ALP values must occur on the same day. The denominator should include participants who had both a post-baseline ALT and ALP on the same day. In addition, the denominator for Hepatocellular injury and BIL ≥2xULN should include participants who had both a post-baseline ALT and ALP on the same day as well as BIL on or up to 28 days of that day.
- For the row 'ALT >3xULN and BIL >2xULN and (ALP <2xULN)', the ALP value must occur on or up to 28 days after the ALT elevation.

An additional liver stopping event profile will be provided to facilitate medical review of participants with liver stopping events.

A scatter plot of maximum total bilirubin versus maximum ALT will be generated, as well as a scatter plot of maximum vs baseline for ALT.

8.4. 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 and these tests are gradable by CTCAE v4.03.. The details of the planned displays are presented in Appendix 12: List of Data Displays.

8.4.1. Deaths

All deaths will be summarized based on the number and percentage of participants. This summary will classify participants by time of death relative to the date of T cell infusion as a categorical (>30 days or ≤30 days) and primary cause of death displayed in the order it appears in the CRF.

An individual participant profile for patients who died will be generated, which will report fatal SAEs.

8.4.2. Performance Status

The frequency and percentage of participant's ECOG score (0,1,2,3,4-5) at Baseline and the Last Assessment Post-Infusion) will be provided in addition to a summary of change in ECOG performance score from baseline for each planned assessment time, including worst case post-baseline and best case post-baseline.

8.4.3. ECG

The QTc values based on the Fridericia formula (QTcF) will be categorized into the following CTCAE v5.0 grade and ranges: Grade 0 (<450 milliseconds [msec]), Grade 1 (>=450 to <481 msec), Grade 2 (>=481 to <501 msec), and Grade 3 (≥501 msec) at baseline. Summaries of worst-case grade increase will be provided. These summaries will display the number and percentage of participants with no change or improvement, any grade increase, increase to Grade 1, increase to Grade 2 and increase to Grade 3 for worst case post-baseline only. Participants with missing baseline grade will be assumed to be Grade 0 at baseline.

The changes in QTcF values will be categorized into the clinical concern ranges which are specific to changes in QTcF from baseline: Increase of <=30 msec, increase of 31 to 60 msec, and increase of >60 msec. A summary of change in QTc value will display the number and percentage of participants with a change within each range for worst case post-baseline only. Participants with missing baseline values will be excluded from this summary.

If QTcF is missing, it will be calculated using the formula in Section 13.6.4. QTcB values will only be listed.

QRS Durations will be categorized into the following categories approximately based on the limits determined by Ramirez et al. (Ramirez, 2011): Low (<70 msec), Normal (>=70 msec to <= 105 msec) and High (>105 msec). Additionally these summaries will display the number and percentage of participants with no change or improvement to Normal, worsening to Low and worsening to High for the worst case (both minimum and maximum) post-baseline values only. Participants with missing baseline QRS duration will be assumed to be Normal at baseline.

A listing of Left Ventricular Ejection Fraction results will be provided

8.4.4. Vital Signs

A summary of change in vital signs (heart rate, diastolic blood pressure, systolic blood pressure, pulse oximetry, temperature) from baseline by worst-case change post-baseline only will be provided by categories of potential clinical importance. PCI criteria are detailed in Section 13.8.3.

8.4.5. Pregnancies

The investigator will report all pregnancies immediately to the Sponsor. If participants or participants' partner become pregnant while on the study, the information will be

included in the narratives. A supportive listing of participants or partners of participants who became pregnant during the study will be produced to support the case narratives.

8.4.6. Cardiovascular Events

As required by the GSK Global Safety Board, profile displays for following ten cardiovascular events will be produced if an event occurs and the appropriate CV event form has been completed.

- Arrythmias
- Congestive Heart Failure
- Cerebrovascular Events, Stroke and Transient Ischemic Attack
- Deep Vein Thrombosis/Pulmonary Embolism
- Unstable Angina / Myocardial Infarction
- Peripheral Arterial Thromboembolism
- Pulmonary Hypertension
- RevascularisationValvulopathy

8.4.7. Replication Competent Lentivirus and Integration Site Analysis

The results of Replication Competent Lentivirus (RCL) and Integration Site Analysis (ISA) will be summarized descriptively. Note that all available data should be included in summaries for RCL and ISA, i.e. for the Arm A cohort patients who received Pembrolizumab following progression after lete-cel infusion data will not be excluded from summaries, even if after the first dose of pembrolizumab.

Replication Competent Lentivirus (RCL)

The proportion of participants who are RCL positive will also be summarized, if data warrant. RCL results will also be presented in a data listing.

The proportion of participants showing >1% gene marked PBMCs one-year post-infusion will be summarized. Percentage will be based on the participants with persistence value available one-year or later post-infusion.

For any patient who has greater than 1% gene marked PBMCs at least 1 year or beyond post-infusion, integration site analysis will be performed on PBMCs to assess clonality and possible insertional oncogenesis.

Integration Site Analysis

For participants that undergo Integration Site Analysis, a supportive listing will be provided to report the data. Two diversity indices, Shannon diversity index and Gini index (GI), will be reported in the data listing. Shannon diversity is a measurement that represents the uncertainty about the identity of a single species within a population. Therefore, the greater number of unique species within a population, the less certain the measure is of the “identity” of any one species, resulting in a higher value of Shannon diversity. Likewise, the less complex the population, the lower the value of Shannon diversity. When Shannon diversity is calculated it takes into account the number of

distinct clones ("species") as well as the abundance of each clone. A low value of Shannon diversity has been previously reported in the literature as being associated with clonal expansion and a reduction in overall clonal diversity Braun, 2014).

The GI is a measure for detecting inequality in the distribution of clone sizes. A GI value of 0 indicates complete equality across the population i.e., all clones have the same abundance. A value of 1 would indicate complete inequality i.e., one clone is much more abundant than the others. Therefore, as GI approaches 1 this indicates that one clone is highly abundant. It has previously been used for insertion site analysis (as the oligoclonality index (Gillet, 2011)) to describe clonal populations where the dominance of a single clone is seen (e.g., leukaemia).

9. PHARMACOKINETIC ANALYSES

9.1. Primary Pharmacokinetic Analyses

There are no primary pharmacokinetic analyses planned for this study.

9.2. Secondary Pharmacokinetic Analyses

9.2.1. Endpoint / Variables

Evaluation of peak expansion of NY-ESO-1^{c259}T cells over time is a secondary objective. All analyses will be performed separately for each treatment arm.

9.2.1.1. Cell Expansion

Lete-cel T-cell vector copies (expansion/persistence) in the peripheral blood will be measured in participants either by quantitation of transduced cells by PCR of transgene from DNA extracted from frozen PBMC or quantitation of transduced cells by flow cytometry from frozen PBMC. Expansion will be measured to establish the relationships with response to lete-cel as well as a long-term safety measure. For all PK analyses, expansion of the engineered T-cells will be applied in lieu of "concentration" to derive PK parameters.

Spider plots will be used to graphically summarize persistence over time for each participant by responders and non-responders.

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 13.5.3 Reporting Standards for Pharmacokinetic)

9.2.1.2. Derived Pharmacokinetic Parameters

Pharmacokinetic parameters will be calculated by the Clinical Pharmacology Modelling and Simulation (CPMS) group using standard non-compartmental analysis according to current working practices and using appropriate software. All calculations of non-compartmental parameters will be based on actual sampling times. Pharmacokinetic parameters listed will be determined from the expansion-time data, as data permits.

Peak cell expansion during the study (Cmax), time to peak expansion (Tmax), and as data permit, $AUC_{0\text{-}28d}$ will be summarized overall and for responders and non-responders using descriptive statistics and dot plots.

The area under the plasma concentration-time curve to day 28 ($AUC_{0\text{-}28d}$) will be determined using the linear trapezoidal rule for increasing concentrations and the logarithmic trapezoidal rule for decreasing concentrations.

Parameter	Parameter Description
$AUC_{0\text{-}28d}$	Area under the expansion-time curve from time zero to 28 days will be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.
Cmax	Maximum observed persistence, determined directly from the persistence-time data.
Tmax	Time to reach Cmax, determined directly from the persistence-time data.

NOTES:

- Additional parameters may be included as required.

9.2.2. Summary Measure

For each of these parameters, except Tmax, the following summary statistics will be calculated: n, median, minimum, maximum, arithmetic mean, 95% confidence interval for the arithmetic mean, standard deviation, coefficient of variation (coefficient of variation (CV) = 100*(sqrt (exp(SD^2) - 1))) [NOTE: SD = SD of log transformed data]), geometric mean, 95% confidence interval for the geometric mean and standard deviation of logarithmically transformed data. Data will be summarized by treatment arm and overall.

For Tmax, calculations will include median, maximum, minimum, arithmetic mean, 95% confidence interval, and standard deviation. Data will be summarized by treatment arm and overall.

Spider plots will be used to graphically summarize persistence (copies/µg gDNA) over time for each participant.

A listing of persistence will be provided and will include coefficient of variation, number of positive replicates, copies/cell, copies/µg DNA, percent gene marked cells of PBMCs (%), interpretive result, duration of detectible persistence, time to loss of 25%/50%/75% peak expansion, and $AUC_{0\text{-}28d}$.

Time to loss of 25% of peak expansion will be calculated as the time since T-cell infusion corresponding to observing at least 25% loss of peak expansion. If time to 25% loss of peak expansion is not observed, the last observed time will be reported with a "+". The same procedure will be followed for 50% and 75%.

The following calculations will be performed:

- copies/cell is calculated with the following formula:
  copies/cell=(copies/µg) x (0.0000063 µg gDNA/cell)
- Percent gene-marked cells of peripheral blood mononuclear cells (PBMCs) = (copies/cell) x 100

The final reported result of copies/µg gDNA is calculated as follows:

copies/µg DNA=copies per well/µg gDNA per well

For persistence value below LLOQ, the following rules will be applied:

Reported Copies per cell Result	Reported Copies per ug gDNA Result	Reported Result	Set Value for Copies per cell	Set Value for Copies per ug gDNA
<0.0003	<50.0	Negative	0	0
<0.0003	<50.0	Detectable, <LLOQ	0.0003	50

Note, sometimes values for copies per cell and copies per ug DNA might be different than above as it depends on the input of DNA, but rule would be the same:

- If interpretive reported result is negative, then set values to 0.
- If interpretive reported result is "Detectable, <LLOQ", set values to LLOQ (If <XXX, set at XXX)

The unit for persistence will be "Copies/ug of gDNA"

All PK parameters will be reported to at least 3 significant digits, but to no more significant digits than the precision of the original data.

Duration of detectable persistence is defined as time from T-cell infusion until persistence is no longer detectable. Persistence above the assay limit of detection but below the lower limit of quantitation is considered for the duration determination, i.e. the time window from infusion until the first instance persistence falls below the detection limit and the interpretive reported result is "Negative." If persistence for a given participant remains detectable ("Positive" or "Detectable, LLOQ") at their last sample collection timepoint, the last observed time is reported and considered as right-censored with a "+" appended to the numerical result. Note, transduced T-cells frequently persist beyond the follow-up period, and hence, the reported duration is directly influenced by length of time the participant is on-study

9.2.3. Population of Interest

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

9.2.4. Statistical Analyses / Methods

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

CCI [redacted]

10. BIOMARKER ANALYSES

Details of the exploratory biomarker analyses will be reported under a separate Biomarker Clinical Study Plan.

11. ADDITIONAL ANALYSES DUE TO THE COVID-19 PANDEMIC

11.1. Study Population

11.1.1. Subject Disposition

A country level listing of the dates of the COVID-19 Pandemic measures will be produced. For the definition of the phases of the COVID-19 pandemic measures see Section 13.4.1.2.

The 'Summary of Subject Status and Subject Disposition for the Study Conclusion Record' will be repeated, with the reason for withdrawal/discontinuation categorised as due to versus not due to the COVID-19 pandemic based on information collected on the COVID-19 Pandemic Study Impact form. The summary will be based on GSK Core Data Standards, and details are provided in Appendix 12: List of Data Displays. Study treatment that is discontinued due to the COVID-19 pandemic will be flagged in the listing.

11.1.2. 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 important protocol deviations not related to COVID-19. A listing of non-important protocol deviations related to COVID-19 will also be produced.

Visits and assessments missed due to the COVID-19 pandemic, together with visits conducted remotely, will be listed by participant. The summaries will be based on GSK Core Data Standards, and details are provided in Appendix 12: List of Data Displays.

11.1.3. 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.

Analysis 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.

A summary of COVID-19 assessments for participants with COVID-19 AEs will be provided, if the data warrant. A comprehensive profile listing of COVID-19 assessments and symptom assessments for participants with COVID-19 adverse events will be provided.

More detailed summaries of additional COVID-19 assessments and symptoms may be produced if enough COVID-19 Adverse Events are observed in the ITT population.

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

11.2. Efficacy

The impact of the COVID-19 pandemic on the efficacy results has been accounted for within the estimand definitions and interccurent event strategy, defined in Section 7.

11.3. Safety

11.3.1. Assessment of COVID-19 AEs

A Standardised MedDRA Query (SMQ) will be used to identify all COVID-19 AEs. COVID-19 AEs will either be listed or summarized by overall frequency, depending on the number of COVID-19 AEs observed in the ITT population.

The incidence of AEs and SAEs (Fatal and Non-Fatal) of COVID-19 will be obtained from standard AE and SAE summaries. COVID-19 AEs leading to study drug discontinuation and study withdrawal can be found in the associated listing.

Additional analyses of COVID-19 AEs and laboratory results for participants with COVID-19 AEs may be provided, if enough COVID-19 AEs are observed.

All of the above displays will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 12: List of Data Displays.

12. REFERENCES

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13. APPENDICES

13.1. Appendix 1: Exclusions from Per Protocol Population

This study does not include a Per-Protocol population.

13.2. Appendix 2: Schedule of Activities

13.2.1. Protocol Defined Schedule of Events

Table 6 Schedule of Activities - Screening (Part 1) and Leukapheresis (Part 2)

	Screening Phase[1]		Leuka-pheresis[4]	Notes
Day (D) / Week (W)	**Target Expression Screening[2]**	**Leukapheresis Eligibility Screening (Within 42 days prior to Leukapheresis)[3]**		
Informed Consent for Screening	X			1. Written informed consent must be obtained prior to performing any study assessments or procedures, except for those collected as SoC and considered acceptable for the study (footnote 11) or as part of other GSK studies (per Protocol Section 4.1.1). 2. Target Expression Screening may be performed under a separate protocol, if applicable, per Protocol Section 4.1.1. 3. Participants must be HLA-A*02:01, HLA-A*02:05, and/or HLA-A*02:06 positive and have NY-ESO-1/LAGE-1a positive tumor prior to conducting leukapheresis eligibility screening procedures. 4. Participants must meet all eligibility requirements prior to leukapheresis, as specified in Protocol Section 5. 5. If an archival tumor specimen is not available, then a fresh tumor tissue biopsy may be considered at the discretion of the investigator. See Protocol Section 8.9.2. 6. Only collect this sample if optional Liquid Biopsy Consent has been signed by the participant as part of the Informed Consent for Screening. Sample may be collected any time from signature of optional consent until leukapheresis. 7. Medical history will be recorded in the eCRF at Target Expression Screening and at Lymphodepletion Screening/Baseline visits; however, any changes in medical history must be recorded in source documents throughout the conduct of the study.
Informed Consent for Leukapheresis and Treatment		X		
Inclusion/Exclusion for Screening	X			
Inclusion/Exclusion for Leukapheresis		X		
Demographics	X			
HLA -A*02:01, A*02:05 and A*02:06 genotyping[1]	X			
Tumor expression of NY-ESO-1/ LAGE-1a[5]	X			
Liquid Biopsy (blood)[6]	X			
Medical History[7]	X	X		
Prior/Concomitant Medications[8]	X	X	X	
ECOG	X	X		
Physical Exam[10]		X		
Vital Signs / Height / Weight[15]		X		
12-lead ECG[9]		X		
ECHO/MUGA[11]		X		
CT / MRI[11,12]		X		

	Screening Phase[1]		Leuka-pheresis[4]	Notes
Day (D) / Week (W)	**Target Expression Screening[2]**	**Leukapheresis Eligibility Screening (Within 42 days prior to Leukapheresis)[3]**		
Brain MRI[11]		X		8. Includes all prescriptions, over-the-counter medications, and herbal remedies. Any use of mutagenic agents or investigational agents must also be reported. 9. Collect a single ECG. If QTc is >480 msec, collect 2 more ECGs 5 minutes apart and use the average of those QT values to determine eligibility. If the average QTc is >480 msec, obtain a manual overread of the triplicate. 10. All clinical assessments required at Leukapheresis Eligibility Screening must be performed within 42 days prior to leukapheresis, except for vital signs, weight, lymphocyte subset (CD3/CD4/CD8), hematology, clinical chemistry, coagulation tests, physical exam and urinalysis which must be done within 7 days prior to leukapheresis. 11. ECHO/MUGA, CT/MRI scan, brain MRI and laboratory assessments performed as standard of care prior to study consent will be acceptable as long as assessment is done within required time period before leukapheresis. 12. Any FDG PET/CT performed as part of clinical routine within the required time period before leukapheresis will also be collected centrally but will not replace CT scans. 13. CD3 count prior to leukapheresis should be preferably performed within 24 hours from leukapheresis procedure. 14. WOCBP must have a negative urine or serum pregnancy test at Screening and again prior to leukapheresis. 15. Includes temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturation. Height will be collected at the Screening visit only. FEV1, FVC, TLC, and DLCO will be measured to determine eligibility as described in Protocol Section 5. 16. Includes HIV, HBV, HCV, HTLV, EBV, CMV, and syphilis (spirochete bacterium). Must be completed within 28 days prior to leukapheresis. Testing is required at Screening and needs to be repeated at Baseline (see Table 7) to satisfy eligibility criteria.
Lymphocyte Subset (CD3/CD4/CD8)[10,11,13]		X		
Hematology[10,11]		X		
Clinical Chemistry[10,11]		X		
Coagulation Tests[10,11]		X		
Pregnancy Test[14]		X[14]	X[14]	
Urinalysis[10,11]		X		
PFTs[15]		X		
Infectious Disease Markers[11,16]		X		
Creatinine clearance by GFR or 24-h Urine Collection		X		
Adverse Events[17]	X	X	X	
Leukapheresis[18]			X	

	Screening Phase[1]		Leuka-pheresis[4]	Notes
Day (D) / Week (W)	**Target Expression Screening[2]**	**Leukapheresis Eligibility Screening (Within 42 days prior to Leukapheresis)[3]**		
				17. Adverse events (AEs) should be collected and reported as noted in Protocol Section 8.4. 18. Arm assignment should occur before leukapheresis.

Abbreviations: CMV = cytomegalovirus; CT = computed tomography; DLCO = pulmonary diffusing capacity for carbon monoxide; EBV = Epstein-Barr virus; ECG = electrocardiogram; ECHO = echocardiogram; ECOG = Eastern Cooperative Oncology Group; eCRF = electronic case report form; FDG PET = fluorodeoxyglucose positron emission tomography; FEV1 = forced expiratory volume in 1 second; FVC = forced vital capacity; GFR = glomerular filtration rate; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HLA = human leukocyte antigen; HTLV = human T lymphotropic virus; LAGE-1a = cancer testis antigen 2; MRI = magnetic resonance imaging; MUGA = multigated acquisition; NY-ESO-1 = New York esophageal squamous cell carcinoma 1; PFT = pulmonary function test; SoC = standard of care; TLC = total lung capacity; WOCBP = women of child-bearing potential.

Table 7 Schedule of Activities - Lymphodepletion/Treatment (Interventional Phase) (Part 3)

	Base-line	Lymphodepletion				Lete-cel Infusion[1]	Post-T-cell Infusion											
Day (D) / Week (W)	**Day -17 to -9**	**Day**									**Week[2]**							
		-8	**-7**	**-6**	**-5**	**1**	**2**	**3**	**4**	**5**	**2**	**3**	**4**	**5**	**6**	**7**	**10 to 25 Q3W**	**Arm A: 34-106 Q12W Arms B & C: 28-106 Q3W**
Visit Window	**n/a**					**n/a**	**±1 day**				**±3 days**						**±3 days**	
Treatment Fitness and Lymphodepletion Eligibility Screening[3]	X																	
Med. History[4]	X																	
Physical Exam	X					X	X	X	X	X	X	X	X	X	X	X	X	X
Neurological assessments[5]	X					X	X	X	X	X	X	X	X	X	X	X	X	X
ICE[5]						X	X	X	X	X	X							
Prior/Concomitant Medications[6]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ECOG	X					X					X	X	X	X	X	X	X	X
Vital Signs[7,8]	X					X[8]	X	X	X	X	X	X	X	X	X	X	X	X
ECHO/MUGA[9]	X																	
12-lead ECG[10]	X					X			X		X							
Body CT/MRI[11,12]	X[11,12]					See footnotes 11 and 12												
RECIST evaluation	X[11]					See footnote 11												
Brain MRI[13]	X[13]					See footnote 13												
Chest X-Ray	X																	
Hematology[15]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Chemistry[15]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Ferritin[15]	X																	
Troponin and NT-proBNP/BNP[15]	X																	
Coagulation Tests[14,15]	X					X	X	X	X	X	X	X						

	Base-line	Lymphodepletion				Lete-cel Infusion[1]	Post-T-cell Infusion											
Day (D) / Week (W)	**Day -17 to -9**	**Day**									**Week[2]**							
		-8	**-7**	**-6**	**-5**	**1**	**2**	**3**	**4**	**5**	**2**	**3**	**4**	**5**	**6**	**7**	**10 to 25 Q3W**	**Arm A: 34-106 Q12W Arms B & C: 28-106 Q3W**
Visit Window	n/a					n/a	±1 day				±3 days						±3 days	
Pregnancy Test[16]	X[16]					X[16]							X			X	X	X
Urinalysis	X																	
Infectious Disease Markers (HIV, HBV, HCV, HTLV, EBV, and syphilis)	X																	
CMV IgG and PCR[17]	X					X					X		X		X	X		
TSH with Free T4[18]	X	See footnote 18																
CRP[15]	X					X			X		X	X	X	X	X	X	X	X
Uric Acid	X					X												
GFR or 24-h urine collection[19]	X																	
Adverse Events[20]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Vector Copies (Persistence) for Safety (blood)[21]	X						For collection, see footnote 21											
VSV-G DNA (RCL) for Safety (blood)[22]	X						For collection, see footnote 22											
Lymphodepletion																		
Fludarabine		X	X	X	X													
Cyclophosphamide			X	X	X													
Investigational Product Administration																		
Lete-cel						X[23]												
Pembrolizumab	See footnote 24																	
See Table 10 **for PK, Immunogenicity, and Biomarkers Samples**																		
Genetic sample	X[25]																	
CCI [redacted]																		

	Base-line	Lymphodepletion				Lete-cel Infusion[1]	Post-T-cell Infusion											
Day (D) / Week (W)	Day -17 to -9	Day									Week[2]							
		-8	-7	-6	-5	1	2	3	4	5	2	3	4	5	6	7	10 to 25 Q3W	Arm A: 34-106 Q12W Arms B & C: 28-106 Q3W
Visit Window	n/a					n/a	±1 day				±3 days						±3 days	
CCI																		

Abbreviations:
AE = adverse event; BNP = B-type natriuretic peptide; CMV = cytomegalovirus; CRP = C-reactive protein; CRS = cytokine release syndrome; CT = computed tomography; CTCAE = Common Technical Criteria for Adverse Events; DNA = deoxyribonucleic acid; EBV = Epstein-Barr virus; ECG = electrocardiogram; ECHO = echocardiogram; ECOG = Eastern Co-operative Oncology Group; eCRF = electronic case report form; EoT = end of treatment; FDG PET = fluorodeoxyglucose positron emission tomography; GFR = glomerular filtration rate; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; CCI ; HTLV = human T lymphotropic virus; ICANS=Immune Effector Cell-Associated Neurotoxicity Syndrome; ICE = Immune Effector Cell-Associated Encephalopathy; IgG = immunoglobulin G; MRI = magnetic resonance imaging; MUGA = multigated acquisition; NT-proBNP = N-terminal pro B-type natriuretic peptide; PCR = polymerase chain reaction; PD = progressive disease; PK = pharmacokinetic; PMBC = peripheral blood mononuclear cell; Q3W = once every 3 weeks; Q6W = once every six weeks; Q9W = once every 9 weeks; Q12W = once every 12 weeks; RCL = replication competent lentivirus; RECIST = Response Evaluation Criteria In Solid Tumors; T4 = thyroxine; TSH = thyroid stimulating hormone; VSV-G = vesicular stomatitis virus G.

1. On Day 1, all samples will be collected and assessments performed prior to Lete-cel infusion (within 24 h), unless otherwise specified.
2. Week N visit for N>1 is scheduled on 1st day of the week; Day = 7N-6
3. Treatment fitness will be evaluated according to Protocol Section 5 and determined in consultation with Medical Monitor.
4. Medical history, including history of tobacco use, will be recorded in the eCRF at Screening and Baseline visits; however, any changes in medical history must be recorded in source documents throughout the conduct of the study
5. Neurological assessments are to be performed for patients with brain metastases and patients with neurological adverse events up to 12 weeks post resolution of the event. ICE should be measured on the day of Lete-cel infusion prior to treatment. Following infusion, ICE should be measured according to instructions in Protocol Section 10.9.8.2.
6. Includes all prescriptions, over-the-counter medications and herbal remedies. Any use of mutagenic agents or investigational agents must also be reported. It also includes use of antibiotics and probiotics taken 60 days prior to lymphodepletion and up to Week 7 visit.
7. Includes temperature, blood pressure, pulse rate, respiratory rate, oxygen saturation and weight. Height will be collected at the Screening visit only.
8. Vital signs on day of Lete-cel infusion should be taken pre-infusion, and at 5, 15, and 30 minutes, and 1, 1.5, 2, and 4 hours after the infusion has started. On pembrolizumab infusion days, vital signs should be taken pre- and post-infusion.
9. If participant's ECHO/MUGA at leukapheresis eligibility screening met eligibility for left ventricular ejection fraction ≥45% as specified in Protocol Section 5.1.2, and if prior ECHO/MUGA was obtained within 90 days prior to the first day of lymphodepletion, then a repeat ECHO/MUGA will not be required. Repeat ECHO/MUGA at baseline should be obtained as clinically indicated. If suspected CRS Grade ≥2, an ECHO/MUGA is required at onset of Grade ≥2 CRS. Additional monitoring must be conducted (including inpatient continuous cardiac telemetry monitoring) for a minimum of 3 days post onset and as long as deemed necessary by the Investigator (refer to Protocol Section 10.9.5)

10. Collect a single ECG at baseline. If QTc is >480 msec, collect 2 more ECGs 5 minutes apart and use the average of those QT values to determine eligibility. If the average QTc is >480 msec, obtain a manual overread of the triplicate. Single ECGs will be collected at all other time points that require ECGs. ECG can also be performed at other time points if medically indicated. Participants with clinically significant cardiovascular risk factors (per Protocol Section 8.2.3) will undergo evaluation by a cardiologist prior to lymphodepletion.
11. Diagnostic quality CT scan of chest/abdomen/pelvis with contrast is required at Baseline (within 2 weeks prior to lymphodepletion), Week 7 (±7 days), Week 13 (±7 days), Week 19 (±7 days), Week 25 (±7 days), Week 34 (±7 days), and Q12W (±7 days) thereafter, until EoT. If a participant is found to have a tumor response by imaging, a follow-up confirmatory scan must be done no earlier than 4 weeks and no later than the next scheduled imaging time point after the initial scan showing response. If a participant is found to have progressive disease by imaging, a follow-up confirmatory scan must be done no earlier than 4 weeks and no later than 8 weeks after the initial scan showing PD. Investigator assessed RECIST v1.1 [redacted] evaluation must be done following instructions in Appendix 11.
12. Any FDG PET/CT performed as part of clinical routine will be collected centrally but will not replace CT scans.
13. Brain MRI (or CT Scan if MRI not feasible) should be performed at Baseline (within 4 weeks prior to lymphodepletion) if more than 4 months have elapsed from last brain MRI. A repeat brain MRI prior to lymphodepletion would need to show stability or reduction of CNS metastases if any radiotherapy was administered after the MRI performed for leukopheresis eligibility screening. Brain MRI should be performed as clinically indicated thereafter (see Protocol Section 10.9.8).
14. Coagulation tests include INR, PTT or aPTT and fibrinogen. Coagulation tests should be taken at baseline, Day 1, 2, 3, 4, 5, 8 and 15.
15. If CRS and/or ICANS is suspected, chemistry, hematology, ferritin, coagulation and CRP tests should be performed locally every day for the first week and every other day thereafter until symptoms are improving or an alternative diagnosis is confirmed. In addition, if CRS is suspected, cytokine samples will be collected for central analysis following same schedule, as detailed in Table 8. Troponin and NT-proBNP / BNP tests should be monitored for participants with CRS Grade ≥2 as clinically indicated.
16. WOCBP must have a negative urine or serum pregnancy test (highly sensitive) at Baseline (within 24 hours prior to lymphodepletion), prior to Lete-cel infusion, and thereafter will need to have pregnancy tests performed at all visits indicated in the table for the duration of the contraception period (see Protocol Section 5.3.3.2 and Protocol Section 8.4.7).
17. Only participants who are CMV IgG seropositive at Baseline will continue to be monitored for CMV viremia by CMV DNA PCR post Baseline. CMV will also be assessed if GBS is suspected.
18. Thyroid tests must be performed Q6W during pembrolizumab administration. See footnote 24 for first pembrolizumab administration.
19. See Protocol Table 11 for specifics on renal assessment.
20. Adverse events should be collected and reported as noted in Protocol Section 8.4.
21. PBMCs for Persistence will be collected at Baseline (Day -17 to Day - 9) and at Week 13, Week 25, and every 6 months thereafter (e.g., 12 months, 18 months, 24 months, etc.) until 5 years post Lete-cel infusion, then once a year for up to 15 years. After Week 22, the visit window for this assessment will be ±3 months. Some of these samples may be taken after the participant enters the LTFU protocol (GSK Study 208750) or study Part 5 (Table 12). PBMCs for Persistence may be collected in additional time points as clinically indicated. If vector persistence is undetected for two consecutive visit assessments and the participant is ≥2 years post-infusion, samples for persistence of gene modified cells will be discontinued.
22. PBMCs for RCL will be collected at Baseline (Day -17 to Day - 9) and at Week 13, Week 25, and every 6 months thereafter (e.g., 12 months, 18 months, 24 months, etc.) until 5 years post Lete-cel infusion, then once a year for up to 15 years. After Week 22, the visit window for this assessment will be ± 3 months. Some of these samples may be taken after the participant enters the LTFU protocol (GSK Study 208750). If vector persistence is undetected for two consecutive visit assessments and the participant is ≥2 years post-infusion, samples for RCL will be discontinued.
23. Participants will be hospitalized on the day of T-cell infusion (Day 1) and may be in the hospital for follow-up care until Day 3 as clinically indicated. Participants will be in close proximity to the hospital for at least 7 days post infusion. Additional hospitalization may be warranted based upon clinical need.
24. Arms B and C only. First pembrolizumab administration on Day 22 (Week 4 Day 1), then Q3W for up to 35 cycles. If toxicities that preclude pembrolizumab treatment, such as CRS Grade ≥2, are present at Day 22, the first infusion of pembrolizumab will be on Week 7 Day 1, in which case, Cycle 35 will occur on Week 109 Day 1. If AEs do not resolve by Week 7

Day 1 to ≤ Grade 1, pembrolizumab will not be administered, and the participant will be evaluated until disease progression or EoT. Pembrolizumab may be administered up to 3 days before or after the scheduled Day 1 of each cycle due to administrative reasons.

25. For biomarker analysis, if genetic sample collection is not done at Baseline, it may be done at any other subsequent visit in the Interventional Phase. Collection of a genetic sample is optional and all participants must provide consent for sample collection and analysis prior to sampling.

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[redacted]

Table 8 Schedule of Activities - Pharmacokinetics, Immunogenicity, and Biomarkers (Interventional Phase) (Part 3 cont.)

		Visit											
Assessment	**Sample Type**	**Day -17 to -9 (Baseline)**	**D1 (Lete-cel infusion)**	**D2**	**D3**	**D4**	**D5**	**W2**	**W3**	**W4**	**W7**	**W10 to 25 Q3W**	**Arm A: W34-W106 Q12W Arms B & C: W28-W106 Q3W**
Visit Window[1]				**±1 day**				**±3 days**				**±3 days**	
CCI													
Vector Copies (pharmacokinetics)[9]	PBMC	X	X	X		X		X	X	X	X	X	X[2]
Cell Phenotype and Functional Assays[9]	PBMC	X				X		X		X	X	X	X[2]
Cytokine Analyses[3,9]	Serum	X	X	X	X	X	X	X	X	X	X	X	X[2]
CCI													
Pembrolizumab pharmacokinetics[6]	Serum									X[6]	X[6]	X[6]	X[6]
Liquid biopsy (blood)[7]	Plasma	X								X[7]		X[7]	X[7]
Tumor Biopsy[8]	Biopsy	X								X			

Abbreviations: cfDNA = cell-free DNA; CRS = cytokine release syndrome; CT = computed tomography; ctDNA = circulating tumor DNA; D = Day; MRI = magnetic resonance imaging; PBMC = peripheral blood mononuclear cells; PK = pharmacokinetics; Q3W = once every 3 weeks; Q12W = once every 12 weeks; CCI ; W = Week.

1. Week N visit for N>1 is scheduled on 1st day of the week; Day = 7N-6
2. Sample collection to match imaging (Body CT/MRI) visits as indicated in Table 7
3. If CRS is suspected, cytokine levels should be measured every day for the first week and approximately every other day thereafter until symptoms are improving or an alternative diagnosis is confirmed. Chemistry, hematology, ferritin, coagulation and CRP tests should also be performed locally following same schedule, as detailed in Table 7. Troponin and NT-proBNP / BNP tests should be monitored for participants with CRS Grade ≥2 as clinically indicated.

CCI

6. Arms B & C only. Collect blood for pharmacokinetics analysis at visits Week 4 Day 1 (before and after the first pembrolizumab infusion), W7, W10, W13, W22, W34, W46, W58, W82, and W106. First pembrolizumab administration should be on Day 22 (Week 4 Day 1). If toxicities that preclude pembrolizumab treatment, such as CRS Grade ≥2, are present at Day 22, infusion of pembrolizumab will start on Week 7 Day 1. For participants who start pembrolizumab on Week 7 Day 1, collect blood for pharmacokinetics analysis at visit Week 7 Day 1 (before and after the first pembrolizumab infusion), W10, W13, W16, W25, W37, W49, W61, W85, and W109. Collect blood before (within 24 hrs) and after (within 30 mins) the first pembrolizumab infusion and before (within 24 hrs) the pembrolizumab infusion at all other visits that include pharmacokinetics sample collection.

7. Blood sample from which cell-free DNA (cfDNA), circulating tumor DNA (ctDNA), and exosomes may be extracted and should match tumor biopsy visits and imaging (Body CT/MRI) visits (Table 7), except for Week 7 where no liquid biopsy sample is needed. An additional biopsy may be taken at disease progression unless clinically unsafe to do so.
8. Biopsies for research are taken at Baseline) and Week 4 (with flexibility until Week 6), with the exception of participants for whom there is no safely accessible tumor tissue. In addition to the indicated collection times, tumor biopsies can be obtained at any time during the study if clinically indicated. The baseline biopsy should be collected anytime within 28 days prior to the start of lymphodepleting chemotherapy, with preference for closer to the time of Lete-cel infusion. An archived FFPE block from a biopsy taken preferably after completion of the participant's last line of therapy and within 90 days prior to initiating lymphodepleting chemotherapy, may be accepted at the discretion of the Medical Monitor (or designee).An additional biopsy will be taken at disease progression unless clinically unsafe to do so.
9. For participants who receive pembrolizumab (Arms B and C), collect samples for these assessments before pembrolizumab infusion.

Table 9 Schedule of Activities - Pembrolizumab Therapy Following Disease Progression after Lete-cel Infusion (Part 4 - Arm A only)

Pembrolizumab (P) Week (W)	PBL	PW1	PW2	PW4	PW7	PW10 to PW103 (Q3W)
Visit Window[1]	-28 days[2]	±1 day	±3 days			±3 days
Pembrolizumab Eligibility[3]	X					
Physical Exam	X	X	X	X	X	X
Neurological Exam[4] and ICE	X	See note 4				
Prior/Concomitant Medications	X	X	X	X	X	X
ECOG	X	X	X	X	X	X
Vital Signs	X	X	X	X	X	X
ECG[5]	X	X		X		
CT/MRI[6]	X				X[6]	X
RECIST Evaluation[6]	X				X	X
Hematology[9]	X	X	X	X	X	X
Chemistry[9]	X	X	X	X	X	X
Pregnancy Test[7]	X	See note 7				
CMV IgG and PCR[8]	See note 8					
TSH with Free T4[9]	See note 9					
CRP[10]		X	X	X	X	X
Ferritin[10]	See note 10					
Coagulation Tests[10]	See note 10					
Troponin and NT-proBNP/BNP[10]	See note 10					
Adverse Events		X	X	X	X	X
Vector Copies (Persistence for Safety) [blood]	See notes 11 and 12					
VSV-G DNA (RCL) [blood]	See notes 11 and 12					
Pembrolizumab administration		X		X	X	X

Notes

1. Week N visit for N>1 is scheduled on 1st day of the week; Day = 7N-6.
2. Baseline assessments required only if the assessments have not been performed within 28 days prior to first pembrolizumab administration.
3. See Protocol Section 5.1.4.
4. Neurological assessment for participants with brain metastases and those with neurological adverse events up to 12 weeks post resolution of the event.
5. Single ECG on the days of pembrolizumab administration, prior to infusion.
6. Pembrolizumab Baseline CT/MRI prior to pembrolizumab therapy must be obtained within 4 weeks prior to first pembrolizumab administration. If the CT/MRI has been obtained at PD within 4 weeks prior to pembrolizumab therapy initiation, this can be considered as baseline measurement. Diagnostic quality CT scan of chest/abdomen/pelvis with contrast is required every 6 weeks (±7 days) until PW25, at PW34, and then every 12 weeks (±7 days) thereafter, until EoT for pembrolizumab. If a participant is found to have a tumor response by imaging, a follow-up confirmatory scan must be done no earlier than 4 weeks and no later than the next scheduled imaging timepoint after the initial scan showing response. If a participant is found to have progressive disease by imaging, a follow-up confirmatory scan must be done no earlier than 4 weeks and no later than 8 weeks after the initial scan showing PD. Investigator assessed RECIST v1.1/CCI [redacted] must be done following instructions in Appendix 11. Any FDG PET/CT performed as per clinical routine will be collected centrally but will not replace CT scans.
7. WOCBP will need to have pregnancy tests (highly sensitive) performed at all visits indicated in the table for the duration of the contraception period (see Protocol Section 5.3.3.2 and Protocol Section 8.4.7).
8. Only participants who are CMV IgG seropositive at PBL will continue to be monitored for CMV viremia by CMV DNA PCR post PBL.
9. Thyroid tests must be performed Q6W during pembrolizumab administration.
10. If CRS and/or ICANS is suspected, chemistry, hematology, ferritin, coagulation and CRP tests should be performed locally every day for the first week and every other day thereafter until symptoms are improving or an alternative diagnosis is confirmed. In addition, if CRS is suspected, cytokine samples will be collected for central analysis following same schedule, as detailed in Table 10. Troponin and NT-proBNP / BNP tests should be monitored for participants with CRS Grade ≥2 as clinically indicated.
11. PBMCs for Persistence and RCL testing will be collected at PW13, PW25, and every 6 months until EoT for pembrolizumab or disease progression, whichever comes first. Data collected at Baseline (Day -14 to Day - 9) prior to lete-cel will be used as baseline.
12. If vector persistence is undetected for two consecutive visit assessments and the participant is ≥2 years post-infusion, samples for RCL and persistence of gene modified cells will be discontinued.

							However, if VSV-G DNA copies are detected at any time point during year 1, refer to the safety monitoring procedures in Protocol Section 8.3.5.
See Table 10 **for PK, Immunogenicity, and Biomarker Samples**							

EoT = end of treatment; FDG PET = fluorodeoxyglucose positron emission tomography; IgG = immunoglobulin G; MRI = magnetic resonance imaging; PBL = Pembrolizumab Baseline; PCR = polymerase chain reaction; PD = progressive disease; PK = pharmacokinetics; PW = Pembrolizumab Week; Q3W = once every 3 weeks; RCL = replication competent lentivirus; RECIST = Response Evaluation Criteria In Solid Tumors; VSV-G = vascular stomatitis virus G.
Note: Pembrolizumab therapy is only allowed in case of disease progression within the first 25 weeks after lete-cel infusion. Pembrolizumab therapy will not be allowed if disease progression occurs after the Week 25 scan. Pembrolizumab treatment will be administered for up to 35 cycles Q3W at 200 mg or until subsequent disease progression.

Table 10 Schedule of Activities (PK, Immunogenicity, and Biomarkers) – Pembrolizumab Therapy Following Disease Progression after Lete-cel Infusion (Part 4-Arm A only)

Pembrolizumab (P) Week (W)	Sample Type	PW1	PW2	PW4	PW7D1	PW10 to PW103 Q3W
Visit Window[1]		±1 day	±3 days			
Vector Copies (pharmacokinetics)[2]	PBMC	X	X	X	X	X[4]
Cell Phenotype and Functional Assays[2]	PBMC	X	X	X	X	X[5]
Cytokine Analyses[2,3]	Serum	X	X	X	X	X[5]
CCI [redacted]						
Pembrolizumab pharmacokinetics[6]	Serum	X		X	X	X
Liquid biopsy (blood)[7]	Plasma	X			X	X[7]
Tumor Biopsy[8]	Biopsy	X[9]			X	

Abbreviations: cfDNA = cell-free DNA; CT = computed tomography; ctDNA = circulating tumor DNA; D = Day; MRI = magnetic resonance imaging; PBMC = peripheral blood mononuclear cells; PK = pharmacokinetics; Q3W = once every 3 weeks; PW = Pembrolizumab Week.

1. Week N visit for N>1 is scheduled on 1st day of the week; Day = 7N-6
2. Collect samples for these assessments before pembrolizumab infusion.
3. If CRS is suspected, cytokine levels should be measured every day for the first week and approximately every other day thereafter until symptoms are improving or an alternative diagnosis is confirmed. Chemistry, hematology, ferritin, coagulation and CRP tests should also be performed locally following same schedule, as detailed in Table 9. Troponin and NT-proBNP / BNP tests should be monitored for participants with CRS Grade ≥2 as clinically indicated.

CCI [redacted]

5. Sample collection to match imaging (Body CT/MRI) visits as indicated in Table 9.

CCI [redacted]

7. Blood sample from which cell-free DNA (cfDNA), circulating tumor DNA (ctDNA), and exosomes may be extracted should match tumor biopsy visits and imaging (Body CT/MRI) visits. See Table 9 for tumor biopsy before first pembrolizumab administration.
8. In addition to the indicated collection times, tumor biopsies can be obtained at any time during the study execution if clinically appropriate.
9. Tumor biopsy to be collected within 14 days before first pembrolizumab administration.

Table 11 Schedule of Activities – End of Treatment/End of Interventional Phase

Day (D) / Week (W)	Completion/ Withdrawal[1]	Notes
Clinical Assessments and Procedures[2]		1. Participants will complete the EoT visit after completing interventional portion of the study (Parts 3 or 4; see Protocol Section 4.4.1), discontinuation of pembrolizumab (if relevant) or early withdrawal from the interventional phase. EoT visit is to be completed only once for each participant. All procedures and assessments, as indicated, should be performed preferably 4 weeks and no later than 60 days from last pembrolizumab treatment or visit, as relevant. If performed sooner, only complete assessments not already performed as part of last pembrolizumab treatment or visit. EoT visit must be completed prior to initiating non-protocol anti-cancer therapy, if relevant (See Protocol Section 6.9.1). 2. See Protocol Section 8 for details. 3. Includes all prescriptions, over-the-counter medications, and herbal remedies. Any use of mutagenic agents or investigational agents must also be reported. 4. Includes temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturation. 5. If clinically needed. 6. If a participant is found to have a tumor response or progressive disease by imaging via RECIST v1.1, a follow-up confirmation scan must be done no earlier than 4 weeks and no later than 8 weeks following the scan when response or disease progression was first seen. A participant is not considered to have a response or progression until a follow-up scan confirms the finding. Any FDG PET/CT performed as per clinical routine will be collected centrally but will not replace CT scans. 7. If a CT / MRI assessment has been completed within the last 4 weeks, additional CT / MRI assessments are not required as part of EoT visit, unless it is confirmatory scan (within the schedule in Note #6, above). 8. If disease progression has been confirmed prior to EoT visit, additional CT / MRI assessments are not required as part of EoT visit. 9. Adverse events should be reported as noted in Protocol Section 8.4.
Prior/Concomitant Medications[3]	X	
Physical Exam	X	
ECOG	X	
Vital Signs / Height / Weight[4]	X	
ECG	X[5]	
CT / MRI[6,7,8]	X	
Hematology	X	
Chemistry	X	
Adverse Events[9]	X	
CCI		
Correlative Studies and Research Assessments		11. Biopsies for research are taken at Baseline, Week 7, and at confirmation of PD, with the exception of participants for whom there is no safely accessible tumor tissue. 12. Liquid Biopsy samples should match tumor biopsy and/or CT/MRI assessment time points. See footnote 6 for CT/MRI assessment.
Tumor biopsy[11]	X	
Liquid Biopsy (blood)[12]	X	
Blood for Cell Phenotype and Functional Assays	X	
Cytokine Analyses	X	

Abbreviations: cfDNA = cell-free DNA; CT = computed tomography; CTCAE = Common Technical Criteria for Adverse Events; D = Day; DNA = deoxyribonucleic acid; ECG = electrocardiogram; ECOG = Eastern Co-operative Oncology Group; EoT = end of treatment; FDG PET = fluorodeoxyglucose positron emission tomography; MRI = magnetic resonance imaging; PD = Progressive Disease; W = Week.

Table 12 Schedule of Activities – Long Term Follow-up after Disease Progression or Completion of Interventional Phase (Part 5 or Study 208750)

Time post-infusion[1]													
	Year 1			**Year 2**		**Year 3**		**Year 4**		**Year 5**		**Year 6-15[9]**	
Months	**3**	**6**	**12**	**18**	**24**	**30**	**36**	**42**	**48**	**54**	**60**	**Annually**	**Unscheduled Visit[7]**
Visit Window	**±2 weeks**		**±3 months**									**±6 months**	
Medical History[2]	X	X	X	X	X	X	X	X	X	X	X	X	
Physical Exam	X	X	X	X	X	X	X	X	X	X	X		
Subsequent anti-cancer therapies or allogeneic stem cell transplant (allo-SCT)[2,3]	X	X	X	X	X	X	X	X	X	X	X	X	
Delayed Adverse Events[4]	X	X	X	X	X	X	X	X	X	X	X	X[5]	
CBC with differential and Serum Chemistry[6]	X	X	X	X	X	X	X	X	X	X	X		
VSV-G DNA (RCL) and vector copies (Persistence) for safety (blood)[6,7]	X	X	X	X	X	X	X	X	X	X	X	X	
Survival Status[8]	X	X	X	X	X	X	X	X	X	X	X	X	X

Allo-SCT = allogeneic stem cell transplant; CBC = complete blood cell (count); RCL = replication competent lentivirus; VSV-G = vesicular stomatitis virus G

1. If a site visit is not feasible, then medical evaluation of participants may take place via telemedicine (e.g., phone call or video conferences) where country and/or local regulations allow. Where applicable country and local regulations; and infrastructure for home healthcare allow, upon approval by the sponsor home healthcare may take place at a location other than the clinical trial site to perform study assessments, which may include medical history, physical exam, collection of blood samples, measurement of height and weight. Remote visits may be performed upon approval by the sponsor at the participant's home by qualified study personnel or at a local medical facility, unless the Investigator deems that a site visit is necessary.
2. Collect new medical history/medications and chemotherapies and/or radiotherapy.

3. All participants who received pembrolizumab will be followed for 24 months after their last dose to ascertain if they are candidates to receive an allogeneic- stem cell transplant (allo-SCT). Participants who receive an allo-SCT within the 24-month follow-up period will be monitored for 18 months for post allo-SCT complications as described in Protocol Section 8.4.5.
4. Delayed adverse event collection is limited to:

- New malignancies
- New incidence or exacerbation of pre-existing neurologic disorder
- New incidence or exacerbation of a prior rheumatologic or other autoimmune disorder
- New incidence of a hematologic disorder
- New incidence of infection (potentially related to gene modified cell therapy)
- Unanticipated illness and/or hospitalization deemed related to gene modified cell therapy
- Specific events outlined in Protocol Section 8.3 for participants who received pembrolizumab and had allo-SCT

5. During years 6-15 of annual follow-up period, AEs and SAEs will be entered in the CRF if reported by the patient or investigator.
6. If a visit for medical evaluation is conducted via telemedicine, a site visit to collect a blood samples should be performed as soon as practicable.
7. If vector persistence is undetected for two consecutive visit assessments and the participant is ≥2 years post-infusion, samples for RCL and persistence of gene modified cells will be discontinued.
8. If a participant is contacted between the scheduled visits, the date of last contact should be recorded as an unscheduled visit.
9. Subjects who do not have persistence of gene modified cells may be followed remotely during years 6-15.

13.3. Appendix 3: Assessment Windows

No assessment windows will be applied.

13.4. Appendix 4: Study Phases and Treatment Emergent

13.4.1. Study Phases

Disposition data will be summarized by the treatment phases defined below. The table should also be used to identify any assessments that are part of the Pembrolizumab Following Disease Progression Phase, so these data can be removed from the main tables as specified in the sections above. Data falling into the Pembrolizumab Following Disease Progression after lete-cel Infusion Phase will be flagged in all listings.

Study Phase	Definition
Pre-lymphodepletion Phase	From the date of treatment informed consent signed (Screening) to the date prior to initiating lymphodepletion [First leukapheresis ≤ Date < First day of lymphodepletion]
Interventional Phase – Lymphodepletion	First day of Lymphodepletion ≤ Date < T-cell Infusion
Interventional Phase – Post T-cell Infusion	T-cell infusion ≤ Date ≤ Start of Follow-up Phase (Date of confirmed PD / Withdrawal from Interventional Phase)
Follow-up Phase	Start of follow-up phase (Date of confirmed PD / Withdrawal from Interventional Phase) < Date
Pembrolizumab Following Disease Progression Phase (Arm A only)	From the date of initiating pembrolizumab treatment (first dose of pembrolizumab) to end of study for participants that received pembrolizumab treatment following disease progression in treatment Arm A only

13.4.1.1. Study Phases for Concomitant Medication and Blood Products

Study Phase	Definition
Prior	End Date of medication or blood product is not missing and End Date < Lymphodepletion Start Date or lymphodepletion start date is missing
Concomitant	Any medication or blood product that is not Prior

NOTES:

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

13.4.1.2. 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 mesures 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

13.4.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent (T-cell Phase)	• If the participant is in Arm C or if the participant is in Arm A but has not received Pembrolizumab post disease progression: o If AE onset date is on or after T-cell infusion start date (T-cell Infusion Start Date ≤ AE Start Date) OR if AE onset date is before T-cell infusion start date, but the AE increases in grade after T-cell infusion (with respect to the maximum grade of the AE before T-cell infusion) • If the participant is in Arm A and has received Pembrolizumab post disease progression: o If AE onset date is on or after T-cell infusion start date (T-cell Infusion Start Date ≤ AE Start Date < Pembrolizumab Start Date) OR if AE onset date is before T-cell infusion start date, but the AE increases in grade after T-cell infusion and before Pembrolizumab start date (with respect to the maximum grade of the AE before T-cell infusion) • If AE onset date is missing and AE end date is before the T-cell start date, then the AE *will not* be classified as Treatment-Emergent. If AE onset date is missing and AE end date is either missing or on or after T-cell start date, then the AE will be classified as treatment-emergent. o If T-cell infusion date is missing, AE will not classified as Treatment Emergent
Lymphodepletion Emergent (Lymphodepletion Phase)	• If AE onset date is on or after Lymphodepletion start date and before T-cell infusion start date ([Lymphodepletion Start Date ≤ AE Start Date < T-cell Infusion Start Date] or [Lymphodepletion Start Date ≤ AE Start Date and T-cell Infusion Start Date is missing]) OR if AE onset date is before lymphodepletion start date, but the AE increases in grade in the lymphodepletion phase (with respect to the maximum grade of the AE before lymphodepletion) • If AE onset date is missing and AE end date is before the lymphodepletion start date, then the AE *will not* be classified as Lymphodepletion-Emergent. If AE onset date is missing and AE end date is either missing or after lymphodepletion start date, then the AE will be classified as lymphodepletion-emergent o If lymphodepletion date is missing, AE cannot be classified as Lymphodepletion-Emergent
Pre-Lymphodepletion Emergent (Pre-Lymphodepletion Phase)	• If AE onset date is before the Lymphodepletion start date (AE Start Date ≤ Lymphodepletion Start Date or Lymphodepletion Start Date is missing). • If AE onset date is missing the AE will be classified as Pre-Lymphodepletion -Emergent.

Pembrolizumab Therapy Following Disease Progression Emergent (Pembrolizumab Following Disease Progression Phase)	• If AE onset date is on or after the first dose of pembrolizumab therapy following disease progression after lete-cel infusion (AE start date ≥ pembrolizumab start date) OR if AE onset date is before the first dose of pembrolizumab, but the AE increases in grade after the first dose of pembrolizumab (with respect to the maximum grade of the AE before start of pembrolizumab) in Arm A

NOTES:

- Time of study treatment dosing and start[/stop] time of AEs should be considered, if collected.

13.5. Appendix 5: Data Display Standards & Handling Conventions

13.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: US1SALX00259
HARP Compound	: arprod\GSK3377794\mid208471
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.2 & ADaM IG Version 1.1].	
Generation of RTF Files	
• RTF files will be generated for SAC upon request.	

13.5.2. Reporting Standards

General

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

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

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

Unscheduled Visits	
• Unscheduled visits will not be included in summary tables and/or figures, except in cases where worst-case and/or best-case post-baseline or last assessment is calculated. • All unscheduled visits will be included in listings.	
Descriptive Summary Statistics	
Continuous Data	Refer to GSK Standard Statistical Display Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to GSK Standard Statistical Display Principals 7.01 to 7.13.	

13.5.3. 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 00000314000: Non-Compartmental 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. Graphical displays: Refer to Combined Statistical Displays Principles section 7. Listings: Refer to Combined Statistical Displays Principles section 5. Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.
NONMEM/Pop PK File	Not applicable.
NONMEM/PK/PD File	Not applicable.
Pharmacokinetic Parameter Derivation	
PK Parameter to be Derived by Programmer	None
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.

13.6. Appendix 6: Derived and Transformed Data

13.6.1. 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. • For character variables, if multiple assessments on different days are reported for the same scheduled assessment, then the worst-case assessment for that scheduled assessment will be analysed. • 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 Lete-cel Infusion Date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < Lete-cel Infusion Date → Study Day = Ref Date – Lete-cel Infusion Date
  • Ref Data ≥ Lete-cel Infusion Date → Study Day = Ref Date – (Lete-cel Infusion 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 CR) is assigned to the latest date of disease assessments; for other response categories (SD [or Non-CR/Non-PD], NE, PD), the date of response is assigned to the earliest date of disease assessments based on scan date.
Date of New Anti-Cancer Therapy
• Derived as the earliest date of new on-study anti-cancer therapy, non-palliative radiotherapy (where applicable) or cancer-related surgical procedure (where applicable). • Missing or partial dates will be imputed for derivation of new anti-cancer therapy following rules specified in Section 13.7.2.1.

13.6.2. Study Population

Age
• For participants with a Lete-cel Infusion Date, age is derived using Lete-cel Infusion Date as the reference date. For ITT participants without a Lete-cel Infusion Date, date of eligibility for leukapheresis is used as the reference date.
BMI
• (Weight in kg) / (Height in meters)^2
Body Surface Area (BSA) (m^2) DuBois & DuBois Formula
• 0.007184 x Height(cm)$^{0.725}$ x Weight(kg)$^{0.425}$
Time Since Initial Diagnosis
• Calculated as the number of Months from the Date of Initial Diagnosis: o Leukapheresis Eligibility Screening Visit Date = Missing → Elapse Time = Missing o Date of Initial Diagnosis = Completely/partially Missing → Elapse Time = Missing • Otherwise → Elapse Time = (Leukapheresis Eligibility Screening Visit Date– Date of Initial Diagnosis + 1) / 30.4375
Time Since Metastatic Disease to Screening
• Time (in months) since metastatic disease to screening will be calculated as: (Leukapheresis Eligibility Screening Visit Date - Date of Diagnosis of Metastatic Disease +1) / 30.4375
Time Since Last Progression
• Time (in months) since last progression to screening will be calculated (if applicable) as: (Leukapheresis Eligibility Screening Visit Date – Date of Last Progression +1) / 30.4375
Time Since Last Recurrence
• Time (in months) since last progression to screening will be calculated (if applicable) as: (Leukapheresis Eligibility Screening Visit Date – Date of Last Recurrence +1) / 30.4375
Extent of Exposure
• Extent of exposure will only be calculated for participants assigned to combination treatment for pembrolizumab exposure. • Number of days of exposure to Pembrolizumab will be calculated based on the formula: **Duration of Exposure in Days = Treatment Stop Date – (Treatment Start Date) + 21** • The cumulative dose will be based on the formula: **Cumulative Dose = Sum of Dose at Each Visit**

13.6.3. Efficacy

CCI

[redacted]

13.6.4. Safety

Adverse Events

AEs of Special Interest evaluated in this RAP

- Cytokine release syndrome (CRS)
- Pneumonitis/pneumonia
- Graft vs host disease (GvHD)
- Guillain Barre syndrome (GBS) or acute inflammatory demyelinating polyneuropathy (AIDP)
- Pancytopenia/Aplastic anemia (including analysis of all hematopoietic cytopenias)
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
- Treatment-related inflammatory response at tumor site(s)

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

Imputed dates will not be used to calculate AE duration.

QTcF Formula (Fridericia Corrected QT Interval)

- $QT / RR^{1/3}$

List of PTs to Be Combined (this list will be reviewed at the time of reporting and may be updated with additional terms)

The following synonyms will be combined under the PT as shown below. The combined term will be used when reporting AE data in tables by PT. Synonymous terms will be combined regardless of body system.

Synonym (Combined Term)	MedDRA Preferred Term Version 23.1
Anemia/Red blood cell count decreased	Anemia Red blood cell count decreased
Cytokine Release Syndrome (CRS)	Cytokine release syndrome Cytokine storm
Acute GVHD – Skin	Acute graft versus host disease in skin
Acute GVHD – Gut (Liver and Intestine)	Acute graft versus host disease in liver Acute graft versus host disease in intestine
Acute GVHD - Other (Lung, Bone Marrow, not specified)	Acute graft versus host disease
Chronic GVHD - Skin	Chronic graft versus host disease in skin
Chronic GVHD - Gut (Liver and Intestine)	Chronic graft versus host disease in liver Chronic graft versus host disease in intestine
Chronic GVHD Other - (Lung, Bone Marrow, not specified)	Chronic graft versus host disease
Unspecified GVHD - Skin%	Graft versus host disease in skin
Unspecified GVHD - Gut (Liver and Intestine)%	Graft versus host disease in liver Graft versus host disease in gastrointestinal tract
Unspecified GVHD - Other (Lung, Bone Marrow, not specified)%	Graft versus host disease Graft versus host disease in eye Graft versus host disease in lung Prophylaxis against graft versus host disease Transfusion associated graft versus host disease

Adverse Events	
	Engraftment syndrome
Leukopenia/White blood cell decreased	White blood cell count decreased Leukopenia
Lymphopenia/Lymphocyte count decreased	Lymphocyte count decreased CD4 lymphocytes decreased CD8 lymphocytes decreased Lymphopenia
Neutropenia/Neutrophil count decreased	Neutrophil count decreased Neutropenia
Rash/Rash maculo-papular	Rash maculo-papular Rash Rash erythematous
Thrombocytopenia/Platelet count decreased	Platelet count decreased Thrombocytopenia
Immune effector cell-associated neurotoxicity syndrome (ICANS)	Immune effector cell-associated neurotoxicity syndrome Encephalopathy

FOCUSED LIST

(this list will be reviewed at the time of reporting and may be updated with additional terms)

Guillain-Barre syndrome	
	Demyelinating polyneuropathy Guillain-Barre syndrome Peripheral sensorimotor neuropathy Subacute inflammatory demyelinating polyneuropathy Zika virus associated Guillain Barre syndrome
Graft versus host disease	
	Acute graft versus host disease in skin Acute graft versus host disease in liver Acute graft versus host disease in intestine Acute graft versus host disease Acute graft versus host disease oral Chronic graft versus host disease in skin Chronic graft versus host disease Chronic graft versus host disease in liver Chronic graft versus host disease in intestine Chronic graft versus host disease Chronic graft versus host disease in eye Chronic graft versus host disease oral Graft versus host disease in skin Graft versus host disease in liver Graft versus host disease in gastrointestinal tract Graft versus host disease

	Graft versus host disease in eye Graft versus host disease in lung Prophylaxis against graft versus host disease Transfusion associated graft versus host disease Engraftment syndrome
Cytokine release syndrome	
	Cytokine release syndrome Cytokine storm
Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)	
	Febrile bone marrow aplasia Autoimmune aplastic anaemia Aplastic anaemia Pancytopenia Bone marrow failure
	Aplastic anaemia Full blood count abnormal Full blood count decreased Cytopenia Haemoglobin abnormal Hypoplastic anaemia Red blood cell count abnormal Haematocrit decreased Normochromic anaemia Normochromic normocytic anaemia Normocytic anaemia Reticulocyte count decreased Reticulocytopenia Haematocrit abnormal Haemoglobin decreased Anaemia macrocytic Erythropoiesis abnormal Anaemia Erythropenia Microcytic anaemia Red blood cell count decreased Neutropenic sepsis Band neutrophil percentage decreased Febrile neutropenia Granulocytopenia Neutropenia Neutrophil count abnormal

	Neutrophil percentage decreased Neutrophil count decreased Plateletcrit abnormal Plateletcrit decreased Acquired amegakaryocytic thrombocytopenia Megakaryocytes decreased Platelet production decreased Platelet count abnormal Platelet count decreased Platelet disorder Thrombocytopenia White blood cell count decreased Leukopenia Lymphocyte count decreased Lymphopenia CD4 lymphocytes decreased CD8 lymphocytes decreased
Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)	Encephalopathy Immune effector cell-associated neurotoxicity syndrome

13.7. Appendix 7: Reporting Standards for Missing Data

13.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Participants who do not receive pembrolizumab will be considered to have ended the interventional phase of the study after being on study until Week 106 post lete-cel infusion (approximately 2 years), CCI [redacted] CCI [redacted] CCI [redacted], or death (whichever occurs first) in order to allow for the primary analysis to occur. Participants who receive pembrolizumab in Arms B or C, or in Arm A following disease progression after lete-cel infusion (Part 4), will be considered on the interventional phase of the study until completion of 35 cycles of pembrolizumab, progressive disease (Arms B and C), further progressive disease (Arm A Part 4), or death (whichever occurs first).Participant study completion (i.e. as specified in the protocol) was defined as when he/she has PD or has died prior to PD, or 70% of total treated participants in this study have progressed, died or have been lost to follow-up. • Withdrawn participants will not be replaced in the study. • 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.

13.7.2. 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: o These data will be indicated by the use of a "blank" in participant listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o 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.

13.7.2.1. Handling of Missing and Partial Dates

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.

The partial date imputation will follow ADaM conventions. The ADaM approach is to populate the numeric date variables with the imputed date and add a flag variable to the dataset that indicates the level of imputation.

The flag variable can contain the values: blank, 'D', 'M', 'Y'.

Blank: indicates that no imputation was done
D='Day': indicates that the day portion of the date is imputed
M='Month': indicates that the month and day portions of the date are imputed
Y='Year': indicates that the entire date (year, month, day) is imputed

Example of date variables:

XYZD_- Character date variable
XYZDT – numeric date variable
XYZDTFL – flag variable

Details on imputing partial dates for specific datasets are outlined below.

<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.
Where necessary, display macros may impute dates as temporary variables for sorting data in listings only. In addition, partial dates may be imputed for ‘slotting’ data to study phases (see Section 13.4.1) or for specific analysis purposes as outlined below.
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.
With the exception of new anti-cancer therapy start date in the time to event analysis dataset and exposure end date in the exposure analysis dataset, imputed dates will not be stored in datasets.

</td></tr>
<tr><td>Concomitant Medications/ Blood Products</td><td>

These imputation rules will be used for classifying a medication as prior or concomitant.
Completely missing start dates will not be imputed.
Partial start dates for any concomitant medications recorded in the CRF will be imputed using the following convention:

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

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

If month and year of start date = month and year of lymphodepletion start date then

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

Else set start date = 1st of month.

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

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

If year of start date = year of lymphodepletion start date then

If stop date contains a full date and stop date is earlier than lymphodepletion start date then set start date = January 1.
Else set start date = lymphodepletion 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>Earliest of (Dec 31st and date of last contact) will be used.</td></tr>
<tr><td>Completely missing start/end date</td><td>No imputation</td></tr>
</table>

The recorded partial date will be displayed in listings.

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

Element	Reporting Detail
Surgical Procedures/ Radiotherapy	• No imputation for completely missing dates. • If partial date contains a year only, set to January 1st. • If partial date contains a month and a year set to the 1st of the month.

New Anti-Cancer Therapy/Radiotherapy/Surical Procedures for Efficacy Evaluation	Start dates for follow-up on-study anti-cancer therapy, non-palliative radiotherapy (where applicable), and surgical procedures (where applicable) will be imputed in order to define event and censoring rules for progression-free survival, response rate, or duration of response (i.e. start date for new anti-cancer therapy). Dates will only be imputed when a month and year are available but the day is missing. The following rules will be used to impute the date when partial start dates are present on anti-cancer therapy, non-palliative radiotherapy, and/or surgical procedures dataset[s]:
	• 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:
	  ○ If the month of partial date is the same as the month of T-cell infusion, minimum of (T-cell infusion date + 1, last day of the month) will be used for the day;
	  ○ 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;
	  ○ If both conditions above are met, the later date will be used for the day;
	  ○ Otherwise, a '01' will be used for the day;
	Completely or partial missing end dates will remain missing, with no imputation applied;

Treatment End Date for Pembrolizumab	• If there is more than one study treatment (e.g. for Pembrolizumab population), imputation of missing treatment end date will be applied to all applicable treatments following rules below and treatment end date is the latest treatment end date across all study treatments.If treatment end date is missing for a cycle, treatment start date for the cycle will be used.

13.8. Appendix 8: Values of Potential Clinical Importance

13.8.1. Laboratory Data

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 laboratory parameters including clinical chemistry, hematology, liver function tests, thyroid function tests, pancreatic enzyme tests, QTc (Bazett's or Fridericia's) values, and vital signs (heart rate, blood pressure, temperature).

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.

Laboratory Values

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

To identify laboratory values of potential clinical importance, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE v4.03) will be used to assign grades to the 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.

For lab test values that can be graded, values of grade 1 or above are defined as values of potential clinical concern. For lab test values that cannot be graded, values out of the normal range are defined as values of potential clinical concern. For lab tests reported descriptively as 'Normal', 'Abnormal, not clinically significant', or 'Abnormal, clinically significant' (such as urinalysis), responses of 'Abnormal, clinically significant' will be considered as of potential clinical concern.

13.8.2. ECG Parameters

To identify QTc (Bazett's or Fridericia's) values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign grades (see adverse event 'Electrocardiogram QT corrected interval prolonged'). The eCRF collects either QTcB or QTcF. Note that there is a slight inconsistency between NCI-CTCAE v4.03 and ICH E14 (Absolute QTc

interval prolongation). The clinical concern range for QRS duration is approximately based on the limits determined by Ramirez et al. (Ramirez, 2011).

By default, the definition of PCI is defined based on QTc value (e.g., QTcF Interval, Aggregate) where a participant has a QTc value >=450 or a QTc increase of >30msec.

PCI Flag	Potential Clinical Importance (PCI) Range
High (H)	Grade 1 or Higher (QTc>=450 ms) or QTc increase from baseline of >30ms or QRS duration >105 msec
Low (L)	QRS duration < 70 msec

13.8.3. Vital Signs

To identify heart rate values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Hypothermia', 'Fever', 'Sinus bradycardia', 'Sinus tachycardia', 'Supraventricular tachycardia', and 'Ventricular tachycardia'.

The following criteria will be used to flag vital sign values that are values of potential clinical importance:

Vital Sign Parameter (Absolute)	Units	Potential Clinical Importance (PCI) Range	
		Lower	Upper
Heart Rate	bpm	Decrease to <60	Increase to >100
Temperature	Degrees C	Decrease to ≤35	Increase to ≥38
Pulse Oximetry	%	Decrease to <88	N/A

To identify blood pressure values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Hypertension'. Change from baseline to grade 1, 2 or 3 will be presented. Systolic and diastolic blood pressure ≥ Grade 1 is flagged as High (H) in the listing.

Vital Sign Parameter	Potential Clinical Importance (PCI) Range	Unit
Increase from baseline Systolic Blood Pressure	≥120 to <140 (Grade 1) ≥140 to <160 (Grade 2) ≥160 (Grade 3)	mmHg
Increase from baseline Diastolic Blood Pressure	≥80 to <90 (Grade 1) ≥90 to <100 (Grade 2) ≥100 (Grade 3)	mmHg

Values of potential clinical importance for hypotension will be presented as defined below

Vital Sign Parameter (Absolute)	Units	Potential Clinical Importance (PCI) Range
Decrease from baseline Systolic Blood Pressure	mmHg	≥80 to <100 (Low) <80 (Very low)
Decrease from baseline Diastolic Blood Pressure	mmHg	≥60 to <70 (Low) <60 (Very low)

13.9. Appendix 11: Abbreviations & Trade Marks

13.9.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
AIC	Akaike's Information Criteria
A&R	Analysis and Reporting
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBL	Database Lock
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
eCRF	Electronic Case Record Form
EMA	European Medicines Agency
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
GSK	GlaxoSmithKline
IA	Interim Analysis
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library (GSK Standards Library)
IMMS	International Modules Management System
IP	Investigational Product
IMT	Issue Management Team
ITT	Intent-To-Treat
MMRM	Mixed Model Repeated Measures
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
PP	Per Protocol
PopPK	Population PK
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAP	Reporting & Analysis Plan
RAMOS	Randomization & Medication Ordering System
SAC	Statistical Analysis Complete

Abbreviation	Description
SDSP	Study Data Standardization Plan
SDTM	Study Data Tabulation Model
SMQ	Standardised MedDRA Query
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings

13.9.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
none

Trademarks not owned by the GlaxoSmithKline Group of Companies
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SAS
NONMEM

13.10. Appendix 12: List of Data Displays

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

13.10.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.41	1.1 to 1.1
Efficacy	2.1 to 2.13	2.1 to 2.8
Safety	3.1 to 3.73	3.1 to 3.6
Pharmacokinetic	4.1 to 4.2	4.1 to 4.1
gSection	**Listings**	
ICH Listings	1 to 34	
Other Listings	35 to 71	

13.10.2. Mock Example Shell Referencing

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

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln

NOTES:

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

13.10.3. Deliverables

Delivery	Description
IA	Interim Futility Analysis
SAC	Final Statistical Analysis Complete

13.10.4. Study Population Tables

Study Population Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	ITT	ES8	Summary of Subject Status and Subject Disposition for the Study Conclusion Record	ICH E3, FDAAA, EudraCT Participant status will be displayed with the categories Completed (Death, Transferred to LTFU), Ongoing (LEUKAPHERESIS PHASE, INTERVENTIONAL PHASE (LYMPHODEPLETION), INTERNEVTIONAL PHASE (POST T-CELL INF.), FOLLOW-UP PHASE), and Withdrawn (Primary reasons as captured in the CRF – add "Death before T-cell Infusion" as a sub-category under Withdrawn). Add sub-bullet under FOLLOW-UP PHASE: Ongoing on Pembrolizumab Therapy Following Disease Progression after Lete-cel Infusion Death after T-cell infusion is considered "Completed". Death before T-cell infusion is considered "withdrawn" At the end of study reporting, there should be no subjects in interventional phase.	IA, SAC

Study Population Tables					
				Display as: Arm A, Arm C, Overall Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
1.2.	mITT	ES8	Summary of Subject Status and Subject Disposition for the Study Conclusion Record	ICH E3, FDAAA, EudraCT Participant status will be displayed with the categories Completed (death, transferred to LTFU), Ongoing (in Interventional Phase, in Follow-up Phase), Withdrawn (Reasons from CRF– add “Death before T-cell Infusion” as a sub-category under Withdrawn) Death after T-cell infusion is considered “completed”. Death before t-cell infusion is considered "withdrawn" Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Display as: Arm A, Arm C, Overall	IA, SAC
1.3.	ITT	ES8	Summary of Subject Status and Subject Disposition for the Study Conclusion Record by Relationship to COVID-19 Pandemic	Display as: Arm A, Arm C, Overall	SAC
1.4.	Lymphodepletion	SD1	Summary of Interventional Phase Status	ICH E3 Footnote: Lymphodepletion population includes all participants who received any dose of lymphodepletion chemotherapy. Display as: Arm A, Arm C, Overall	SAC

Study Population Tables					
1.5.	Pembrolizumab	SD1	Summary of Treatment Status and Reasons for Discontinuation of Pembrolizumab	ICH E3 Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. Only needed for Arm C	IA, SAC
1.6.	Screened	ES6	Summary of Screen Status and Reasons for Screen Failures	Journal Requirements Show all categories collected in the eCRF. Footnote: Screened population includes all participants who signed an ICF to participate in the study. Display as: Arm A, Arm C, Overall	SAC
1.7.	ITT	ES10	Summary of Subject Lete-cel Infusion Status and Reason for Failure to Receive Lete-cel Infusion	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.. Lete-cel Infusion Status categories: Completed, Failed (based on CRF) Be sure “death prior to lete-cel infusion” is a category for reasons for failure Display as: Arm A, Arm C, Overall	IA, SAC
1.8.	Enrolled	NS1	Summary of Number of Participantss by Country and Site ID (Enrolled Population)	EudraCT/Clinical Operations	SAC

Study Population Tables					
				Footnote: Enrolled population includes all participants who started the leukapheresis procedure. Display as: Arm A, Arm C, Overall	
1.9.	mITT	NS1	Summary of Number of Participants by Country and Site ID (mITT Population)	Plain Language Summaries (PLS) Display as: Arm A, Arm C, Overall Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
Protocol Deviation					
1.10.	ITT	DV1	Summary of Important Protocol Deviations	ICH E3 Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure. Display as: Arm A, Arm C, Overall	IA, SAC
1.11.	ITT	DV1	Summary of Important COVID-19 Related Protocol Deviations	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure. Display as: Arm A, Arm C, Overall	SAC
1.12.	ITT	DV1	Summary of Important Non COVID-19 Related Protocol Deviations	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure. Display as: Arm A, Arm C, Overall	SAC
Population Analysed					
1.13.	Enrolled	SP1	Summary of Study Populations	GSK Statistical Display Standard Summarize all populations (except Screened) from Section 4	IA, SAC

Study Population Tables					
				Display as: Arm A, Arm C, Overall Footnote: Enrolled population includes all participants who started the leukapheresis procedure.	
Demographic and Baseline Characteristics					
1.14.	ITT	DM1	Summary of Demographic Characteristics (ITT Population)	ICH E3, FDAAA, EudraCT Report sex, age [years] summary, age [years] categories [<=18, 19-64, >=65], ethnicity, race, baseline height [cm], baseline weight [kg], BMI, and body surface area (BSA). Display as: Arm A, Arm C, Overall Footnote: [1] Intent-to-Treat population includes all participants who started the leukapheresis procedure. [2] The reference date for age is lete-cel infusion date. If the subject did not receive lete-cel infusion, the reference date for age is the date of leukapheresis eligibility. Age is imputed when full date of birth is not provided.	IA, SAC
1.15.	mITT	DM1	Summary of Demographic Characteristics (mITT Population)	ICH E3, FDAAA, EudraCT Report sex, age [years] summary, age [years] categories [>=18, 19-64, <=65], ethnicity, race, baseline height [cm], baseline weight [kg], BMI, and body surface area (BSA). Display as: Arm A, Arm C, Overall	IA, SAC

Study Population Tables					
				Footnote: [1] Modified Intent-to-Treat population includes all participants who received lete-cel infusion.. [2] The reference date for age is lete-cel infusion date. If the subject did not receive lete-cel infusion, the reference date for age is the date of leukapheresis eligibility. Age is imputed when full date of birth is not provided.	
1.16.	Enrolled	DM11	Summary of Age Ranges	EudraCT Display as: Arm A, Arm C, Overall Footnote: Enrolled population includes all participants who started the leukapheresis procedure. [1] Age is imputed when full date of birth is not provided. Note: The reference date for age is lete-cel infusion date. If the subject did not receive lete-cel infusion, the reference date for age is the date of leukapheresis eligibility.	SAC
Prior and Concomitant Medications					
1.17.	ITT	MH1	Summary of Past Medical Conditions (ITT Population)	ICH E3, GSK DS-NPD-101 Display as: Arm A, Arm C, Overall	SAC

Study Population Tables					
				Footnote: [1] Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
1.18.	mITT	MH1	Summary of Past Medical Conditions (mITT Population)	ICH E3, GSK DS-NPD-101 Display as: Arm A, Arm C, Overall Footnote: [1] Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
1.19.	ITT	MH1	Summary of Current Medical Conditions (ITT Population)	ICH E3, GSK DS-NPD-101 Display as: Arm A, Arm C, Overall Footnote: [1] Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
1.20.	mITT	MH1	Summary of Current Medical Conditions (mITT Population)	ICH E3, GSK DS-NPD-101 Display as: Arm A, Arm C, Overall Footnote: [1] Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
1.21.	mITT	CM8	Summary of Concomitant Medications by Ingredient	ICH E3 Display as: Arm A, Arm C, Overall	IA, SAC

Study Population Tables					
				Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Note: Concomitant medications are those initiated after or ongoing at lymphodepletion.	
Exposure and Treatment Compliance					
1.22.	Lymphodepletion	EX1	Summary of Exposure to Study Treatment	n, Mean, SD, Median, Min, Max for each: vein to vein time, Cumulative Dose of Cyclophosphamide, Cumulative Dose of Fludarabine, and total number of Transduced T-cells Cumulative dose of Cyclophosphamide (<=1800, >1800 to <=2400, and >2400 to <=2700 mg/m^2) Cumulative Dose of Fludarabine (<=60, >60 to <=80, >80 to <=90, >90 to <=120, and >120 mg/m^2) Report total number of transduced T-cells in 10^9 cells and categorize it into <1, >=1 to <=8, and >8 to <=15 and >15 (10^9 cells) Display as: Arm A, Arm C, Overall Footnote: Lymphodepletion population includes all participants who received any dose of lymphodepletion chemotherapy.	IA, SAC

Study Population Tables					
1.23.	Pembrolizumab	OEX5	Summary of Exposure to Pembrolizumab (Pembrolizumab Population)	ICH E3 This display will be created for Arms A and C with separate tables for each. The Arm A table should only contain those patients who received pembro following PD after lete-cel dosing Display number of doses and [mean, median, SD, min, max] and cumulative dose	IA, SAC
1.24.	Pembrolizumab	ODMOD3	Summary of Dose Delays (Pembrolizumab)	ICH E3 This display will be created for Arms A and C with separate tables for each. The Arm A table should only contain those patients who received pembro following PD after lete-cel dosing For this summary, no need to include delay duration, please do include the dose delays by planned time (can use visit, i.e. week 3 day 1, rather than cycle) Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab.	SAC
1.25.	Pembrolizumab	ODMOD9	Summary of Incomplete Infusions (Pembrolizumab)	ICH E3 This display will be created for Arms A and C with separate tables for each. The Arm A table should only contain those patients who received pembro following PD after lete-cel dosing	SAC

Study Population Tables					
				Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab.	
1.26.	Pembrolizumab	ODMOD16	Summary of Infusion Interruptions (Pembrolizumab)	ICH E3 (interruption of infusion, but was subsequently completed) This display will be created for Arms A and C with separate tables for each. The Arm A table should only contain those patients who received pembro following PD after lete-cel dosing Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab.	SAC
Disease Characteristics					
1.27.	ITT	DC1	Summary of Disease Characteristics at Initial Diagnosis (ITT Population)	ICH E3 Display as: Arm A, Arm C, Overall Stage of Lung Cancer at Initial Diagnosis Disease Stage at Time of Enrolment Time from Initial Diagnosis to Leukapheresis Eligibility Screening (months) TNM Staging Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
1.28.	mITT	DC1	Summary of Disease Characteristics at Initial Diagnosis (mITT Population)	ICH E3 Display as: Arm A, Arm C, Overall	IA, SAC

Study Population Tables					
				Stage of Lung Cancer at Initial Diagnosis Disease Stage at Time of Enrolment TNM Staging Time from Initial Diagnosis to Leukapheresis Eligibility Screening (months) Histology and Histology Grade at Initial Diagnosis Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	
1.29.	ITT	DC2	Summary of Disease Characteristics at Screening (ITT Population)	ICH E3 Display as: Arm A, Arm C, Overall Stage at Screening Number of Prior Systemic Therapy Regimens Number of Prior Radiotherapy Regimens LAGE1 status HLA status NY-ESO-1 status Status of visceral/nonvisceral disease Measurable Disease at Screening? Non-target Lesions? Time from last progression to leukapheresis eligibility screening (months) Time from last recurrence to leukapheresis eligibility screening (months)	IA, SAC

Study Population Tables					
				Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
1.30.	mITT	DC2	Summary of Disease Characteristics at Screening (mITT Population)	ICH E3 Display as: Arm A, Arm C, Overall Stage at Screening Number of Prior Radiotherapy Regimens LAGE1 status HLA status NY-ESO-1 status Status of visceral/nonvisceral disease Measurable Disease at Screening Non-target Lesions Time from last progression to leukapheresis eligibility screening (months) Time from last recurrence to leukapheresis eligibility screening (months) Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	IA, SAC
1.31.	mITT	MD1	Summary of Metastatic Disease at Screening (mITT Population)	Only include sites present in data (i.e. where “yes” on metastatic sites CRF) Display as: Arm A, Arm C, Overall Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	IA, SAC
1.32.	mITT	LA1	Summary of Disease Burden at Baseline (mITT Population)	ICH E3 Display as: Arm A, Arm C, Overall	IA, SAC

Study Population Tables					
				Include target and non-target lesions at baseline Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	

Study Population Tables					
Anti-Cancer Therapy					
1.33.	ITT	AC1	Summary of Prior Anti-Cancer Therapy (ITT Population)	ICH E3 Display as: Arm A, Arm C, Overall Note: Therapies and procedures prior to leukapheresis or full lines of therapy given between leukaphersis and lymphodepletion are defined as prior. Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
1.34.	mITT	AC1	Summary of Prior Anti-Cancer Therapy (mITT Population)	ICH E3 Display as: Arm A, Arm C, Overall Note: Therapies and procedures prior to leukapheresis or full lines of therapy given between leukaphersis and lymphodepletion are defined as prior. Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	IA, SAC
1.35.	ITT	CM8	Summary of Prior Dictionary-Coded Anti-Cancer Therapy (ITT Population)	IDSL Display as: Arm A, Arm C, Overall Note: Therapies and procedures prior to leukapheresis or full lines of therapy given between leukaphersis and lymphodepletion are defined as prior. Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
1.36.	mITT	CM8	Summary of Prior Dictionary-Coded Anti-Cancer Therapy (mITT Population)	IDSL Display as: Arm A, Arm C, Overall Note: Therapies and procedures prior to leukapheresis or full lines of therapy	SAC

Study Population Tables					
				given between leukaphersis and lymphodepletion are defined as prior. Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	
1.37.	ITT	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens in the Advanced/Metastatic Setting (ITT Population)	IDSL Display as: Arm A, Arm C, Overall Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure. Note: Therapies and procedures that begin prior to leukapheresis are defined as prior.	SAC
1.38.	mITT	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens in the Advanced/Metastatic Setting (mITT Population)	IDSL Display as: Arm A, Arm C, Overall Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Note: Therapies and procedures that begin prior to leukapheresis are defined as prior.	SAC
1.39.	mITT	CM8	Summary of Dictionary Coded Bridging Anti-Cancer Therapy	IDSL Display as: Arm A, Arm C, Overall Footnote: [1] Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Note: Bridging therapy is defined as supportive systemic therapy given between leukapheresis and	IA, SAC

Study Population Tables					
				lymphodepletion to maintain disease control.	
1.40.	mITT	FAC1	Summary of On-Study Anti-Cancer Therapy (mITT Population)	IDSL Display as: Arm A, Arm C, Overall Include time from T-cell infusion to first post-treatment anti-cancer therapy Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. On-study and follow-up therapies are defined as systemic therapy, radiotherapy, or cancer related surgery given on or after the start of lymphodepletion chemotherapy. [1] Time from Study Treatment Discontinuation to Start of Subsequent Anti-Cancer Therapy align with censoring rules for PFS	SAC
1.41.	mITT	FAC1	Summary of On-Study Dictionary Coded Anti-Cancer Therapy (mITT Population)	IDSL Display as: Arm A, Arm C, Overall Include time from T-cell infusion to first post-treatment anti-cancer therapy Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. On-study and follow-up therapies are defined as systemic therapy, radiotherapy, or cancer related surgery given on or after the start of lymphodepletion chemotherapy.	SAC

Study Population Tables					
				[1] Time from Study Treatment Discontinuation to Start of Subsequent Anti-Cancer Therapy align with censoring rules for PFS	

13.10.5. Study Population Figures

Study Population Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	ITT	PAN6	Recruitment over time by Country Relative to COVID-19 Pandemic Measures	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

13.10.6. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
2.1.	mITT	RE1a	Summary of Investigator-Assessed Best Response with Confirmation (RECIST 1.1 Criteria)(mITT Population)	95% CI is based on Clopper-Pearson exact confidence interval Display as: Arm A, Arm C as two columns in the same table Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	IA, SAC
2.2.	ITT	RE1a	Summary of Investigator-Assessed Best Response with Confirmation (RECIST 1.1 Criteria)(ITT Population)	95% CI is based on Clopper-Pearson exact confidence interval Note: p value not to be reported Display as: Arm A, Arm C as two columns in the same table Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
2.3.	mITT	RE1c	Summary of Investigator-Assessed Disease Control Rate with Confirmation (RECIST 1.1 Criteria) (mITT Population)	95% CI is based on Clopper-Pearson exact confidence interval Note: p value not to be reported Display as: Arm A, Arm C as two columns in the same table Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Efficacy: Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.4.	ITT	RE1c	Summary of Investigator-Assessed Disease Control Rate with Confirmation (RECIST 1.1 Criteria) (ITT Population)	95% CI is based on Clopper-Pearson exact confidence interval Note: p value not to be reported Display as: Arm A, Arm C as two columns in the same table Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
CCI [redacted]					
Time-to-Event Endpoints					
2.6.	mITT	EFF_T1	Summary of Time to Response Based on Investigator Assessment (RECIST 1.1 Criteria)	Display as: Arm A, Arm C as two columns in the same table Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Efficacy: Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.7.	mITT	EFF_T2	Summary of Progression-Free Survival Based on Investigator Assessment (RECIST 1.1 Criteria)	Summarize probability of event at timepoints every 3 months Display as: Arm A, Arm C as two columns in the same table Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
CCI					
2.9.	mITT	EFF_T3	Summary of Reverse Kaplan-Meier Estimates for Progression Free Survival Follow-up	Display as: Arm A, Arm C as two columns in the same table Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
2.10.	mITT	EFF_T2	Summary of Duration of Response Based on Investigator Assessment (RECIST 1.1 Criteria)	Summarize probability of event at timepoints every 3 months Display as: Arm A, Arm C as two columns in the same table Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Efficacy: Tables					
No.	Population	GSK Standard / Example Shell	Title	Programming Notes	Deliverable [Priority]
CCI [redacted]					
2.12.	mITT	TTE1	Summary of Overall Survival	Display as: Arm A, Arm C as two columns in the same table Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
2.13.	mITT	EFF_T3	Summary of Reverse Kaplan-Meier Estimates for Overall Survival Follow-up	Display as: Arm A, Arm C as two columns in the same table Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

13.10.7. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
2.1.	mITT	EFF_F3	Plot of Duration on Study	For Arm C, include marker for pembro and final pembro dose (after discontinuation) Include arrow for ongoing subjects Separate figures for Arm A and Arm C Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	IA, SAC
2.2.	mITT	RE8b	Investigator-Assessed Maximum Percent Reduction from Baseline in Tumour Measurement (RECIST 1.1 Criteria)	Label with subject ID Separate figures for Arm A and Arm C Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	IA, SAC
2.3.	mITT	EFF_F1	Spider Plot of Percent Change from Baseline in Target Lesion Diameter	Label with subject ID Add symbol to mark new lesions Separate figures for Arm A and Arm C Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	IA, SAC
Time-to-Event Endpoints					
2.4.	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Progression-Free Survival with 95% Confidence Bands (RECIST 1.1 Criteria)	Separate figures for Arm A and Arm C Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Efficacy: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.5.	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Duration of Response with 95% Confidence Bands (RECIST 1.1 Criteria)	Separate figures for Arm A and Arm C Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
2.6.	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Overall Survival with 95% Confidence Bands	Separate figures for Arm A and Arm C Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

CCI

[redacted]

13.10.8. Safety Tables

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.1.	ITT	AE1	Summary of Adverse Events in the Pre-Lymphodepletion Phase by System Organ Class and Preferred Term	ICH E3 Display as: Arm A, Arm C, Overall The pre-Lymphodepletion phase includes AEs which start before the first day of lymphodepletion chemotherapy. Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
3.2.	ITT	AE5B	Summary of Adverse Events in the Pre-Lymphodepletion Phase by Maximum Grade	ICH E3 Display as: Arm A, Arm C, Overall Include Combined PT Term AEs Remove SYSTEM ORGAN CLASS row. Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
3.3.	ITT	AE1	Summary of All Adverse Events Grouped by Similarity of Preferred Terms	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure. Only include Combined PT Term AEs Remove “Any event”	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				SOC should be Combined PT Term Label Column "Synonym/Preferred Term" If combined AE does not appear, Show 0 counts Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.4.	Lymphodepletion	AE1	Summary of Adverse Events in the Lymphodepletion Phase by System Organ Class and Preferred Term	ICH E3 Use Combined PT list Lymphodepletion population includes all participants who received any dose of lymphodepletion chemotherapy. The lymphodepletion phase includes AEs which start or worsen on or after lymphodepletion and before T-cell infusion. Display as: Arm A, Arm C, Overall	IA, SAC
3.5.	Lymphodepletion	AE5B	Summary of Adverse Events in the Lymphodepletion Phase by Maximum Grade	Lymphodepletion population includes all participants who received any dose of lymphodepletion chemotherapy. The lymphodepletion phase includes AEs which start or worsen on or after	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				lymphodepletion and before T-cell infusion. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms) Display as: Arm A, Arm C, Overall	
3.6.	Lymphodepletion	AE5B	Summary of Lymphodepletion Related Adverse Events in the Lymphodepletion Phase by Maximum Grade	ICH E3 Use combined PT list Lymphodepletion population includes all participants who received any dose of lymphodepletion chemotherapy. Lymphodepletion related AEs are defined as AEs identified by the investigator as related to fludarabine or cyclophosphamide. The lymphodepletion phase includes AEs which start or worsen on or after lymphodepletion and before T-cell infusion. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms) Display as: Arm A, Arm C, Overall	IA, SAC
3.7.	mITT	AE1	Summary of All Treatment Emergent Adverse Events by System Organ Class and Preferred Term	ICH E3 Do not use combined PT terms	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.8.	mITT	AE5B	Summary of Treatment-Emergent Adverse Events by Maximum Grade	Use combined PT list Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.9.	mITT	AE1	Summary of All Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Overall)	Do not use combined PT terms Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. For this table, columns should be: Monotherapy, Combination Therapy, Overall (i.e. do not summarize by treatment arm) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.10.	mITT	AE5B	Summary of All Treatment-Emergent Adverse Events by Maximum Grade (Overall)	Use combined PT list Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms)	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				For this table, columns should be: Monotherapy, Combination Therapy, Overall (i.e. do not summarize by treatment arm) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.11.	mITT	AE5B	Summary of Treatment-Emergent Lymphodepletion-Related Adverse Events by Maximum Grade	ICH E3 Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Lymphodepletion related AEs are defined as AEs identified by the investigator as related to fludarabine or cyclophosphamide. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.12.	mITT	AE1	Summary of All Treatment-Emergent T-cell-Related Adverse Events by System Organ Class and Preferred Term	ICH E3 Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion. Do not use combined PT terms Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	IA, SAC
3.13.	mITT	AE5B	Summary of Treatment-Emergent T-cell-Related Adverse Events by Maximum Grade	ICH E3 Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after lete-cel infusion are classified as treatment emergent. T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms). Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.14.	Pembrolizumab	AE1	Summary of All Treatment-Emergent Pembrolizumab-Related Adverse Events by System Organ Class and Preferred Term	ICH E3 Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. AEs which start or worsen on or after lete-cel infusion are classified as treatment emergent. Pembrolizumab related AEs are defined as AEs identified by the investigator as related to Pembrolizumab. Do not use combined PT terms This display will be created for Arm C only	IA, SAC
3.15.	Pembrolizumab	AE5B	Summary of Treatment-Emergent Pembrolizumab-Related Adverse Events by Maximum Grade	Use combined PT list	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. AEs which start or worsen on or after lete-cel infusion are classified as treatment emergent. Pembrolizumab related AEs are defined as AEs identified by the investigator as related to Pembrolizumab. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms). This display will be created for Arm C only	
3.16.	Pembrolizumab	AE1	Summary of All Adverse Events in the Pembrolizumab Following Disease Progression Phase by System Organ Class and Preferred Term	Arm A only Footnotes: [1] Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. [2] The Pembrolizumab Following Disease Progression Phase includes AEs which start or worsen on or after the first dose of pembrolizumab for participants in Arm A who receive Pembrolizumab following disease progression after Lete-cel infusion.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.17.	Pembrolizumab	AE5b	Summary of Adverse Events in the Pembrolizumab Following Disease Progression Phase by Maximum Grade	Arm A only Footnotes: [1] Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. [2] The Pembrolizumab Following Disease Progression Phase includes AEs which start or worsen on or after the first dose of pembrolizumab for participants in Arm A who receive Pembrolizumab following disease progression after Lete-cel infusion.	SAC
3.18.	mITT	AE15	Summary of Common (>=5%) Treatment-Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	FDAAA, EudraCT Do not combine PT terms Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.19.	mITT	AE3	Summary of Treatment-Emergent T-cell Related Non-Serious Adverse Events by Overall Frequency	PLS Do not combine PT terms Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.20.	Pembrolizumab	AE3	Summary of Treatment-Emergent Pembrolizumab-Related Non-Serious Adverse Events by Overall Frequency	Plain Language Summary requirements (PLS). Do not combine PT Terms Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. AEs which start or worsen on or after lete-cel infusion are classified as treatment emergent.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Pembrolizumab related AEs are defined as AEs identified by the investigator as related to Pembrolizumab. Arm C only	
Serious and Other Significant Adverse Events					
3.21.	ITT	AE5B	Summary of Serious Adverse Events in the Pre-Lymphodepletion Phase by Maximum Grade	ICH E3 The pre-Lymphodepletion phase includes AEs which start before the first day of lymphodepletion chemotherapy. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms). Display as: Arm A, Arm C, OverallFootnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
3.22.	Lymphodepletion	AE5B	Summary of Serious Adverse Events in the Lymphodepletion Phase by Maximum Grade	ICH E3 Lymphodepletion population includes all participants who received any dose of lymphodepletion chemotherapy. The lymphodepletion phase includes AEs which start or worsen on or after lymphodepletion and before T-cell infusion. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms).	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Display as: Arm A, Arm C, Overall	
3.23.	mITT	AE1	Summary of Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term	ICH E3 Do not use combined PT terms Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	IA, SAC
3.24.	mITT	AE1	Summary of Treatment Emergent Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences)	ICH E3 Do not use combined PT terms Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.25.	mITT	AE5B	Summary of Treatment-Emergent Serious Adverse Events by Maximum Grade	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms). Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	IA, SAC
3.26.	mITT	AE1	Summary of Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Overall)	Do not use combined PT terms Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. For this table, columns should be: Monotherapy, Combination Therapy, Overall (i.e. do not summarize by treatment arm) Use Actual Treatment received	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.27.	mITT	AE5B	Summary of Treatment-Emergent Serious Adverse Events by Maximum Grade (Overall)	Use combined PT list Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms) For this table, columns should be: Monotherapy, Combination Therapy, Overall (i.e. do not summarize by treatment arm) Use Actual Treatment received	SAC
3.28.	Pembrolizumab	AE1	Summary of Serious Adverse Events in the Pembrolizumab Following Disease Progression Phase by System Organ Class and Preferred Term	Arm A only Footnotes: [1] Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. [2] The Pembrolizumab Following Disease Progression Phase includes AEs which start or worsen on or after the first dose of pembrolizumab for participants in Arm A who receive Pembrolizumab following disease progression after Lete-cel infusion. Only create if at least 5 subjects receive Pembro in Arm A.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.29.	Pembrolizumab	AE5b	Summary of Serious Adverse Events in the Pembrolizumab Following Disease Progression Phase by Maximum Grade	Arm A only Footnotes: [1] Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. [2] The Pembrolizumab Following Disease Progression Phase includes AEs which start or worsen on or after the first dose of pembrolizumab for participants in Arm A who receive Pembrolizumab following disease progression after Lete-cel infusion. Only create if at least 5 subjects receive Pembro in Arm A.	SAC
3.30.	mITT	AE5B	Summary of Treatment-Emergent Lymphodepletion-Related Serious Adverse Events by Maximum Grade	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Lymphodepletion related AEs are defined as AEs identified by the investigator as related to fludarabine or cyclophosphamide. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms). Display as Arm A, Arm C, Overall	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.31.	mITT	AE5B	Summary of Treatment-Emergent T-cell-Related Serious Adverse Events by Maximum Grade	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion. Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms). Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	IA, SAC
3.32.	Pembrolizumab	AE5B	Summary of Treatment-Emergent Pembrolizumab-Related Serious Adverse Events by Maximum Grade	Use combined PT list Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. AEs which start or worsen on or after lete-cel infusion are classified as treatment emergent. Pembrolizumab related AEs are defined as AEs identified by the investigator as related to Pembrolizumab.	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms). Arm C only	
3.33.	mITT	AE20	Summary of T-cell Related Serious Fatal and Non-Fatal AEs by Overall Frequency	Plain Language Summary requirements (PLS). Do not combine PT Terms Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.34.	Pembrolizumab	AE20	Summary of Pembrolizumab Related Serious Fatal and Non-Fatal AEs by Overall Frequency	Plain Language Summary requirements (PLS). Do not combine PT Terms	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab. AEs which start or worsen on or after lete-cel infusion are classified as treatment emergent. Pembrolizumab related AEs are defined as AEs identified by the investigator as related to Pembrolizumab. Arm C only	

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events of Special Interest					
3.35.	mITT	AE5B	Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade (Comprehensive List)	Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.36.	mITT	AE5B	Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade (Focused List)	Preferred terms are combined as shown in table 3.3 (Summary of All Adverse Events Grouped by Similarity of Preferred Terms). Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.37.	mITT	AE5B	Summary of AEs Linked to AESIs Identified by the Investigator by Maximum Grade	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Based on new AESI CRF forms (AEs marked as related to AESI)	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.38.	mITT	CM8	Summary of the Concomitant Medications Linked to AESIs	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Based on new AESI CRF forms (AEs marked as related to AESI) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.39.	mITT	ESI1	Summary of Characteristics of Treatment Emergent Cytokine Release Syndrome (CRS)	Report # of subjects with event & # of events Report Even charateristics, # of occurrences, outcome, and max grade based on all subjects and for all subjects with event. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				[1] Subjects may be included in more than one category for 'Event Characteristics'. [2] Outcome worst case hierarchy: FATAL > NOT RECOVERED/NOT RESOLVED > RECOVERED/RESOVLED WITH SEQUELAE > RECOVERING/RESOLVING > RECOVERED/RESOLVED Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.40.	mITT	ESI2b	Summary of Onset and Duration of the First Occurrence of Treatment Emergent Cytokine Release Syndrome (CRS)	Time to onset from T-cell infuion (days) (<-8, -8-1,1-14,15-30,31-60,>60) Duration (days) (1-30, 31-60,61-90,>90, Missing) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Only create if >= 5 subjects	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.41.	mITT	ESI2b	Summary of Onset and Duration of the First Occurrence of Treatment Emergent Grade 3 and Above Cytokine Release Syndrome (CRS)	Time to onset from T-cell infuion (days) (<-8, -8-1,1-14,15-30,31-60,>60) Duration (days) (1-30, 31-60,61-90,>90, Missing) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Only create if >= 5 subjects	SAC
3.42.	mITT	EX1	Summary of Number of Doses per Patient that Received Tocilizumab for CRS	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Only create if at least 5 events	SAC
3.43.	mITT	PR1	Summary of Procedures Associated with Cytokine Release Syndrome (CRS)	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Include percentage of subjects who received both corticosteroids and Tocilizumab.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Only create if at least 5 events	
3.44.	mITT	ESI2b	Summary of Onset and Duration of ICU Admission for Subjects with Cytokine Release Syndrome (CRS)	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Only create if at least 5 events	SAC
3.45.	mITT	ESI1	Summary of Characteristics of Treatment Emergent Haematopoietic Cytopenias	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Preferred terms identified in the focused list are summarized. [1] Subjects may be included in more than one category for 'Event Characteristics'. [2] Outcome worst case hierarchy: FATAL > NOT RECOVERED/NOT	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				RESOLVED > RECOVERED/RESOVLED WITH SEQUELAE > RECOVERING/RESOLVING > RECOVERED/RESOLVED Report # of subjects with event & # of events Report Event charateristics, # of occurrences, outcome, and max grade based on all subjects and for all subjects with event. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.46.	mITT	ESI2b	Summary of Onset and Duration of the First Occurrence of Treatment Emergent Febrile Neutropenia	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Study Day is relative to the day of first T-cell Infusion, which is Study Day 1 Adverse events with partial or missing dates are not used in time of onset and duration derivations Time to onset from T-cell infuion (days) (<-8, -8-1,1-14,15-30,31-60,>60)	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Duration (days) (1-30, 31-60,61-90,>90, Missing) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Create only if >=5 subjects	
3.47.	mITT	ESI1	Summary of Characteristics of Pneumonitis/Pneumonia	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Preferred terms identified in the focused list are summarized. [1] Subjects may be included in more than one category for 'Event Characteristics'. [2] Outcome worst case hierarchy: FATAL > NOT RECOVERED/NOT RESOLVED > RECOVERED/RESOVLED WITH SEQUELAE > RECOVERING/RESOLVING > RECOVERED/RESOLVED	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Report Event characteristics, # of occurrences, outcome, and max grade based on all subjects and for all subjects with event. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.48.	mITT	ESI2b	Summary of Onset and Duration of the First Occurrence of Treatment Emergent Pneumonitis/Pneumonia	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Study Day is relative to the day of first T-cell Infusion, which is Study Day 1 Adverse events with partial or missing dates are not used in time of onset and duration derivations Time to onset from T-cell infuion (days) (<-8, -8-1,1-14,15-30,31-60,>60) Duration (days) (1-30, 31-60,61-90,>90, Missing) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Create only if >=5 subjects	
3.49.	mITT	ESI1	Summary of Characteristics of Treatment Emergent Graft vs Host Disease (GvHD)	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Preferred terms identified in the focused list are summarized. [1] Subjects may be included in more than one category for 'Event Characteristics'. [2] Outcome worst case hierarchy: FATAL > NOT RECOVERED/NOT RESOLVED > RECOVERED/RESOVLED WITH SEQUELAE > RECOVERING/RESOLVING > RECOVERED/RESOLVED Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.50.	mITT	ESI2b	Summary of Onset and Duration of the First Occurrence of Treatment Emergent Graft vs Host Disease (GvHD)	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Study Day is relative to the day of first T-cell Infusion, which is Study Day 1 Adverse events with partial or missing dates are not used in time of onset and duration derivations Time to onset from T-cell infuion (days) (<-8, -8-1,1-14,15-30,31-60,>60) Duration (days) (1-30, 31-60,61-90,>90, Missing) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Create only if >=5 subjects	SAC
3.51.	mITT	ESI1	Summary of Characteristics of Treatment Emergent Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Preferred terms identified in the focused list are summarized. [1] Subjects may be included in more than one category for 'Event Characteristics'. [2] Outcome worst case hierarchy: FATAL > NOT RECOVERED/NOT RESOLVED > RECOVERED/RESOVLED WITH SEQUELAE > RECOVERING/RESOLVING > RECOVERED/RESOLVED Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.52.	mITT	ESI2b	Summary of Onset and Duration of the First Occurrence of Treatment-Emergent Cytokine Release Syndrome (CRS)	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. AEs which start or worsen on or after T-cell infusion are classified as treatment emergent. Study Day is relative to the day of first T-cell Infusion, which is Study Day 1	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Adverse events with partial or missing dates are not used in time of onset and duration derivations Time to onset from T-cell infuion (days) (<-8, -8-1,1-14,15-30,31-60,>60) Duration (days) (1-30, 31-60,61-90,>90, Missing) Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Create only if at least 5 subjects	
COVID-related					
3.53.	ITT	AE1	Summary of COVID-19-Related Adverse Events by System Organ Class and Preferred Term	Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Create only if at least 5 subjects Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.54.	ITT	PAN1	Summary of COVID-19 Assessments for Subjects with COVID-19 Adverse Events	Sections 1 & 2 of Impact of COVID-19 on Assessment of Safety in Clinical Trials – Points to Consider Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total) Create only if at least 5 subjects Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
Deaths					
3.55.	mITT	DD1	Summary of Deaths	IDSL Time to death from t-cell infusion is reported in days. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
Laboratory: Chemistry					
3.56.	mITT	LB1	Summary of Post-Baseline Change of Chemistry Values by Visit	ICH E3 Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				N = Number of subjects per treatment group. Calculate n, min, mean, max, median, SD by test and visit Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.57.	mITT	LB16A	Summary of Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3 Includes all labs which are graded by CTCAE Include worst case post-baseline, and at all planned timepoints Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.58.	mITT	LB15A	Summary of Worst Case Chemistry Results Relative to Normal Range Post-Baseline Relative to Baseline	ICH E3 This table will include all labs which are NOT graded by CTCAE Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	IA, SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
Laboratory: Hematology					
3.59.	mITT	LB1	Summary of Post-Baseline Change of Hematology Values by Visit	ICH E3 Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. N = Number of subjects per treatment group. Calculate n, min, mean, max, median, SD by test and visit Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.60.	mITT	LB16A	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3 Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. For labs that are gradeable by CTCAE Include worst case post-baseline, and at all planned timepoints	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
3.61.	mITT	LB15A	Summary of Worst Case Hematology Results Relative to Normal Range Post-Baseline Relative to Baseline	ICH E3 Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. This table will include all labs which are NOT graded by CTCAE Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	IA, SAC
Laboratory: Urinalysis					
3.62.	mITT	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline	ICH E3 Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Little n does not include Not done or No results.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
Laboratory: Hepatobiliary (Liver)					
3.63.	mITT	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting	GSK Statistical Display Standard Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Only required if liver stopping event form is filled and minimum of 5 subjects with event. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.64.	mITT	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities	GSK Statistical Display Standard If >=10 events then create both the summary table and the listing LIVER13. If <10 events, only create listing LIVER13. Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
ECG					
3.65.	mITT	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category	GSK Statistical Display Standard Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Only QTcF will be reported. If missing, then calculate based on derivation provided in the RAP. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.66.	mITT	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category	GSK Statistical Display Standard Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Only QTcF will be reported. If missing, then calculate based on derivation provided in the RAP. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
Vital Signs					
3.67.	mITT	VS7	Summary of Worst Case Change in Vital Sign Results Relative to Potential Clinical Importance (PCI) Criteria Post-Baseline Relative to Baseline	ICH E3 Heart rate, pulse oximetry, temperature, SBP, DBP Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
Cardiovascular Risk Factors					
3.68.	mITT	SU1	Summary of Substance Use	GSK Statistical Display Standard Smoking History Smokeless Tobacco Use Betel quid-areca nut use Alcohol use	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Nicotene oral/topical use Include Baseline visit only Required by GCSP Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
Performance Status					
3.69.	mITT	PS1A	Summary of ECOG Performance Status	ICH E3 All planned assessments (Only includeing baseline and last assessment post-infusion) (not by visit) Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.70.	mITT	PS3A	Summary of Change in ECOG Performance Status from Baseline	ICH E3	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Include all planned visits, best and worst case post-baseline, don't include baseline visit Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
Biomarker					
3.71.	mITT	Custom: SAFE_T4	Summary of Subjects Showing >1% Gene Marked PBMCs 1 Year Post-Treatment	Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion. Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	SAC
3.72.	mITT	Custom: SAFE_T4	Summary of Replication Competent Lentivirus Positive	n reflects the number of subjects with RCL assessed post T-cell infusion. Note: for Arm A patients treated with pembrolizumab, do not exclude data after the first dose of pembrolizumab Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Use actual treatment, separate table for each arm. Arm C table has three columns: Arm C (lete-cel monotherapy), Arm C (lete-cel + Pembrolizumab) and Arm C (Total)	
CCI					

13.10.9. Safety Figures

Safety: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Hematology					
3.1.	mITT	Custom: SAFE_F3	Hematology Values Over Time (Neutrophils)	Show each treatment including the total on a separate page (actual treatment) Include Total Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
3.2.	mITT	Custom: SAFE_F3	Hematology Values Over Time (Hemoglobin)	Show each treatment including the total on a separate page (actual treatment) Include Total Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
3.3.	mITT	Custom: SAFE_F3	Hematology Values Over Time (Platelets)	Show each treatment including the total on a separate page (actual treatment) Include Total Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Safety: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.4.	mITT	Custom: SAFE_F3	Hematology Values Over Time (Lymphocytes)	Show each treatment including the total on a separate page (actual treatment) Include Total Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
Laboratory: Hepatobiliary (Liver)					
3.5.	mITT	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT	GSK Statistical Display Standard Show each treatment including the total on a separate page (actual treatment) Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
3.6.	mITT	LIVER9	Scatter Plot of Maximum Total Bilirubin vs Maximum ALT – eDISH Plot	GSK Statistical Display Standard Show each treatment including the total on a separate page (actual treatment) Footnote: Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

13.10.10. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Pharmacokinetic Parameters					
4.1.	PK	PK03	Summary of Derived GSK3377794 Pharmacokinetic Parameters	GSK Statistical Display Standard The Pharmacokinetic population includes all participants in the mITT population from whom at least one PK sample was obtained, analyzed, and was measurable. Include Cmax, AUC and Tmax parameters. Calculate n, min, arithmetic mean, 95% CI, max, median and SD Display as Arm A, Arm C, Overall	IA, SAC
4.2.	PK	PK05	Summary of Derived Log-Transformed GSK3377794 Pharmacokinetic Parameters	The Pharmacokinetic population includes all participants in the mITT population from whom at least one PK sample was obtained, analyzed, and was measurable. Include Cmax and AUC, Exclude Tmax parameter. Calculate n, geometric mean , 95% CI, %CVb and SD (Logs) Display as Arm A, Arm C, Overall	IA, SAC

13.10.11. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.3	PK	Custom: PK_F1	GSK3377794 Pharmacokinetic Concentration-Time Plot	GSK Statistical Display Standard The Pharmacokinetic population includes all participants in the mITT population from whom at least one PK sample was obtained, analyzed, and was measurable. Label x-axis=0 as "Pre T-cell". Plot each subject using a different coloured line and list all subjects in x-axis legend. Y-axis is log transformed (not the values). Values <1 are set to 1. Display as Arm A, Arm C, Overall	IA, SAC

13.10.12. ICH Listings

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	ITT	ES2	Listing of Reasons for Study Withdrawal	ICH E3 Identify all analysis population for each subject in the first column under analysis population. Add a flag variable to indicate withdrawal due to COVID Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
2.	Pembrolizumab	SD2	Listing of Reasons for Study Treatment Discontinuation (Pembrolizumab)	ICH E3 Only include study treatment discontinuation of pembro This display will be created for Arms A and C. The Arm A listing should only contain those patients who received pembro following PD after lete-cel dosing Flag study treatment that is discontinued due to COVID-19 Footnote:	IA, SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab.	
Protocol Deviation					
3.	ITT	DV2	Listing of Important Protocol Deviations	ICH E3 Flag which PDs are COVID-related Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
4.	ITT	DV2	Listing of Non-Important Protocol Deviations due to COVID-19 Pandemic	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
5.	ITT	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	ICH E3 Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
Populations Analysed					
6.	Screened	SP3	Listing of Subjects Excluded from Any Population	ICH E3 Enrolled, ITT, mITT, PK	SAC
Demographic and Baseline Characteristics					
7.	ITT	DM2	Listing of Demographic Characteristics	ICH E3 Add BMI, BSA	SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
8.	ITT	DM9	Listing of Race	ICH E3 Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
Exposure and Treatment Compliance					
9.	ITT	Custom: POP_L1	Listing of Exposure to T-cell Infusion	ICH E3 Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
10.	ITT	EX3	Listing of Exposure Data	Be sure to add Pembro as a treatment where applicable Cumulative dose column should list total number of transduced cell dose. Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
11.	ITT	LA5	Listing of Investigator-Assessed Lesion Assessments (RECIST 1.1 Criteria)	ICH E3 For Arm A, please add a flag for all response assessments post-PD Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
12.	ITT	RE5	Listing of Investigator-Assessed Responses at Each Visit with Confirmation (RECIST 1.1 Criteria)	ICH E3 For Arm A, please add a flag for all response assessments post-PD Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
CCI					

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
Time to Response					
15.	mITT	TTE9	Listing of Time to Response	Use T-cell infusion date Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
16.	mITT	TTE9	Listing of Progression-Free Survival	Use T-cell infusion date Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
17.	mITT	TTE9	Listing of Duration of Response Based on Investigator-Assessed Response	Use T-cell infusion date Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
18.	mITT	TTE9	Listing of Overall Survival	Use T-cell Infusion date Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
Adverse Events					
19.	ITT	Custom: SAFE_L9	Listing of All Adverse Events	ICH E3 List overall record on 1st line (ANL01FL='Y') followed by a row for each event segment order by start date, segments are linked by AEREFID	IA, SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Overall record line will contain all phases where event started or worsend in phase(LEUKEMFL/LYMEMFL/TRTEMFL) concatenated in the Overall Phase(s) column An event can have multiple phases and will be determined whether the AE started or worsened in a given phase. For example, an AE started in Leukapheresis phase, continued into but did not worsen in the lymphodepletion phase and continued in and worsened in the T-cell infusion, will have two phases assigned: Leukapheresis (LEUKEMFL=1) & T-cell Infusion (TRTEMFL=Y). This listing shall include outcome of AE as well (i.e. dose reduced, etc) Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
20.	ITT	AE7	Listing of Subject Numbers for Individual Adverse Events	ICH E3 All AEs Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious and Other Significant Adverse Events					
21.	ITT	AE14	Listing of Reasons for Considering as a Serious Adverse Event	ICH E3 Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
22.	ITT	Custom: SAFE_L11	Listing of Non-Fatal Serious Adverse Events	ICH E3 List overall record on 1st line (ANL01FL='Y') followed by a row for each event segment order by start date, segments are linked by AEREFID Overall record line will contain all phases where event started or worsend in phase(LEUKEMFL/LYMEMFL/TRTEMFL) concatenated in the Overall Phase(s) column An event can have multiple phases and will be determined whether the AE started or worsened in a given phase. For example, an AE started in Leukapheresis phase, continued into but did not worsen in the lymphodepletion phase and continued in and worsened in the T-cell infusion, will have two phases assigned: Leukapheresis (LEUKEMFL=1) & T-cell Infusion (TRTEMFL=Y).	IA, SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
23.	ITT	Custom: SAFE_L11	Listing of Delayed Adverse Events by Delayed Category (GSK Adjudicated)	ICH E3 Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure. Use "Time Since T-cell Infusion" instead of Time Since First Dose/Time Since Last Dose. Report Site ID/unique subject ID/subject ID	SAC
24.	ITT	AE8	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study	ICH E3 Specify if due to T-cell or pembro Flag if COVID-19 AE Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	IA, SAC
Adverse Events of Special Interest					
25.	ITT	Custom: SAFE_L10	Cytokine Release Syndrome (CRS) Subject Profile	See CGT mock up for details	SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
26.	ITT	Custom: SAFE_L11	Pancytopenia/Aplastic Anemia Subject Profile	See CGT mock up for details Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
27.	ITT	Custom: SAFE_L12	Pneumonia Subject Profile	See CGT mock up for details Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
28.	ITT	Custom: SAFE_L13	Pneumonitis Subject Profile	See CGT mock up for details Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
29.	ITT	Custom: SAFE_L14	Graft vs Host Disease (GvHD) Subject Profile	See CGT mock up for details Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
30.	ITT	Custom: SAFE_L15	Immune Effector Cell-Associated Neurotoxicity syndrome (ICANS) Subject Profile	See CGT mock up for details	SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	
31.	ITT	Custom: SAFE_L16	Guillain-Barre Syndrome (GBS) Subject Profile	See CGT mock up for details Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
All Laboratory					
32.	ITT	LB5A	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance	ICH E3 May want to include PCI flag (as seen in LB5)	SAC]
33.	ITT	UR2	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance	ICH E3 Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
34.	ITT	EG3	Listing of All ECG Values	ICH E3 Show all values and indicate potential clinical importance QTc, QTcB, and QTcF values. Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**

13.10.13. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
35.	Screened	ES7	Listing of Reasons for Screen Failure	Footnote: Screened population includes all participants who signed an ICF to participate in the study.	SAC
Protocol Deviation					
36.	ITT	PAN5	Country Level Listing of Start Dates of COVID-19 Pandemic Measures	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
37.	ITT	PAN7	Listing of Visits impacted by COVID-19 Pandemic	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Disease Characteristics					
38.	ITT	DC3	Listing of Disease Characteristics at Initial Diagnosis	Stage of Lung Cancer at Initial Diagnosis Disease Stage at Time of Enrolment Time from Initial Diagnosis to Leukapheresis Eligibility Screening (months) Histology and Histology Grade at Initial Diagnosis Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
39.	ITT	DC4	Listing of Disease Characteristics at Screening	Stage at Screening Number of Prior Systemic Therapy Regimens Number of Prior Radiotherapy Regimens LAGE1 status HLA status NY-ESO-1 status Status of visceral/nonvisceral disease Measurable Disease at Screening? Non-target Lesions? TNM Staging at Baseline Time from last progression to leukapheresis eligibility screening (months) Time from last recurrence to leukapheresis eligibility screening (months) Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
40.	ITT	MD2	Listing of Metastatic Disease at Screening	IDSL Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
Anti-Cancer Therapy					
41.	ITT	AC6	Listing of Systemic Anti-Cancer Therapy	Add a column for Phase [Prior, Prior: Bridging, On-study]. Footnote: Therapies and procedures prior to leukapheresis or full lines of therapy given between leukaphersis and lymphodepletion are defined as prior. Bridging therapy is defined as supportive systemic therapy given between leukapheresis and lymphodepletion to maintain disease control. Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
42.	ITT	AC7	Listing of Anti-Cancer Radiotherapy	Add a column for Phase [Prior, On-study]. Footnote: Therapies and procedures prior to leukapheresis or full lines of therapy given between leukaphersis and lymphodepletion are defined as prior. Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
Prior and Concomitant Medications					
43.	ITT	CM3	Listing of Concomitant Medications by Ingredient	Should include blood products/blood supportive care products Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
44.	ITT	MH2	Listing of Past and Current Medical Conditions	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Dose Modifications					
45.	ITT	ODMOD12A	Listing of Lymphodepletion Chemotherapy Dose Delays	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
46.	ITT	ODMOD10A	Listing of Lymphodepletion Chemotherapy Dose Reductions	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
47.	Pembrolizumab	ODMOD12A	Listing of Dose Delays (Pembrolizumab)	This listing will be created for Arms A and C. The Arm A listing should only contain those patients who received pembro following PD after lete-cel dosing Do not include Duration of Delay column Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
48.	Pembrolizumab	ODMOD14A	Listing of Incomplete Infusions (Pembrolizumab)	This listing will be created for Arms A and C. The Arm A listing should only contain those patients who received pembro following PD after lete-cel dosing Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab.	SAC
49.	Pembrolizumab	ODMOD17A	Listing of Infusion Interruptions (Pembrolizumab)	This listing will be created for Arms A and C. The Arm A listing should only contain those patients who received pembro following PD after lete-cel dosing Footnote: Pembrolizumab population includes all participants in the mITT population who received at least one infusion of pembrolizumab.	SAC
Hepatobiliary (Liver)					
50.	ITT	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting	GSK Hepatic Safety Panel Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
51.	ITT	LIVER15	Liver Stopping Event Profile	GSK Hepatic Safety Panel Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
52.	ITT	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline	Listing used instead of table if <10 events Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
Other Safety					
53.	ITT	PREG1	Listing of Subjects or Partners of Subjects Who Became Pregnant During the Study	GSK Statistical Display Standard Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
54.	ITT	LVEF2	Listing of Left Ventricular Ejection Fraction Results	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
55.	ITT	PAN12	Listing of COVID-19 Assessments and Symptom Assessments for Subjects with COVID-19 Adverse Events	Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
56.	ITT	ARR1	Patient Profile for Arrythmias	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
57.	ITT	CHF1	Patient Profile for Congestive Heart Failure	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
58.	ITT	CVATIA1	Patient Profile for Cerebrovascular Events, Stroke and Transient Ischemic Attack	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
59.	ITT	DVT1	Patient Profile for Deep Vein Thrombosis/Pulmonary Embolism	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
60.	ITT	MI1	Patient Profile for Myocardial Infarction	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
61.	ITT	PATE1	Patient Profile for Peripheral Arterial Thromboembolism	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
62.	ITT	PUL1	Patient Profile for Pulmonary Hypertension	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
63.	ITT	REV1	Patient Profile for Revascularisation	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
64.	ITT	VAL1	Patient Profile for Valvulopathy	GSK Statistical Display Standard Only produce if a subject experiences this CV event Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
65.	ITT	DD3	Subject Profile for Death	ICH E3 Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Substance Use					
66.	ITT	SU2	Listing of Substance Use	List smoking history, smokeless tobacco use, betel quid/areca nut use, cigarettes per day, years smoked, and current nicotine use Replace Study day with ”Time from lete-cel infusion” Footnote: Intent-to-Treat population includes all participants who started the leukapheresis procedure.	SAC
Biomarker					
67.	mITT	Custom: SAFE_L7	Listing of Subjects with Integration Site Analysis Data	Produce a null report if there is no data to report Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC
68.	mITT	Custom: SAFE_L8	Listing of Replication Competent Lentivirus Data	For “Analysis Pop” in first column, include only the non-default populations (i.e. Evaluable, Pembro, PK) Modified Intent-to-Treat population includes all participants who received lete-cel infusion.	SAC

Non-ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
CCI [redacted]					
PK Endpoints					
70.	PK	PK07	Listing of GSK3377794 Pharmacokinetic Concentration-Time Data		SAC
71.	PK	PK13	Listing of Derived GSK3377794 Pharmacokinetic Parameters		SAC

13.11. Appendix 13: Custom Mock-ups

13.11.1. Study Population

13.11.1.1. Tables

N/A

13.11.1.2. Figures

N/A

13.11.2. Efficacy

13.11.2.1. Tables

13.11.2.1.1. EFF_T1: Summary of Time to Response Based on Investigator Assessment (RECIST 1.1 Criteria)

Protocol: ABC123456		Page 1 of x
Population: study specific		(Data as of: DDMMMYYYY)
Table X.XX		
	Arm A	Arm C
	(N=xxx)	(N=xxx)
Number of responders	xx (yy%)	xx (yy%)
Time to Response (months)		
Min	x	x
1st Quartile	x.x	x.x
Median	x.x	x.x
3rd Quartile	x.xx	x.xx
Max.	x	x
/Directory/program.sas DDMMMYYYY HH:MM		

13.11.2.1.2. EFF_T2: Summary of [Time-to-Event Endpoint]

Protocol: ABC123456			**Page 1 of 1**
Population: Intent-to-Treat/Safety/Other study specific			**(Data as of: 30MAY2011)**
	Table X		
	Summary of [Time-to-Event Endpoint]		
	Arm A	**Arm C**	
	(N = 300)	**(N = 100)**	
Number of Subjects			
n	**200**	**150**	
Endpoint (*event*)	**255 (85%)**	**175 (88%)**	
Event sub-category		**100 (50%)**	
Event sub-category		**75 (38%)**	
Censored	**45 (15%)**	**25 (13%)**	

Follow-up ended	**25 (8%)**	**10 (5%)**	
Follow-up ongoing	**20 (7%)**	**15 (8%)**	
Estimates for Time Variable (TimeUnit)[1]			
1st Quartile	**12.3**	**13.2**	
95% CI	**(10.1,14.5)**	**(10.8,15.1)**	
Median	**12.3**	**13.2**	
95% CI	**(10.1,14.5)**	**(10.8,15.1)**	
3rd Quartile	**12.3**	**13.2**	
95% CI	**(10.1,14.5)**	**(10.8,15.1)**	
Probability of [Time-to-Event] at [timepoint 1] [1]			
Number of subjects at Risk	**xx**	**xx**	
Estimate	**12.3**	**12.3**	
95% CI	**(10.1,14.5)**	**(10.1,14.5)**	

Probability of [Time-to-Event] at [timepoint 2] [1]			
Number of subjects at Risk	**xx**	**xx**	
Estimate	**13.2**	**13.2**	
95% CI	**(10.8,15.1)**	**(10.8,15.1)**	
Probability of [Time-to-Event] at [timepoint 2] [1]			
Number of subjects at Risk	**xx**	**xx**	
Estimate	**13.2**	**13.2**	
95% CI	**(10.8,15.1)**	**(10.8,15.1)**	

[1] Confidence Intervals estimated using the Brookmeyer Crowley method

13.11.2.1.3. EFF_T3: Summary of Reverse Kaplan-Meier Estimates for [Progression Free/Overall] Survival Follow-up (RECIST 1.1 Criteria)

Protocol: ABC123456
Population: Intent-to-Treat/Safety/Other study specific

(Data as of: 30MAY2011)

Table X

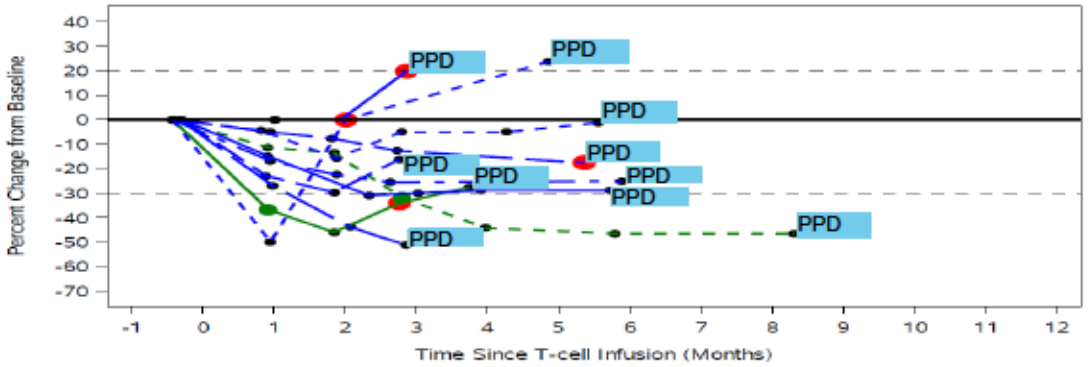
Summary of Reverse Kaplan-Meier Estimates for Progression Free Survival Follow-up

	Arm A (N = 300)	Arm C (N = 200)
Number of Subjects		
Progressed or Died	xx	xx
Follow-up ongoing	xx	xx
Follow-up ended	xx	xx
Estimates for PFS Follow-up (Months)[1][2]		
1st Quartile	12.3	13.2
95% CI	(10.1,14.5)	(10.8,15.1)
Median	12.3	13.2
95% CI	(10.1,14.5)	(10.8,15.1)
3rd Quartile	12.3	13.2
95% CI	(10.1,14.5)	(10.8,15.1)

[1] Estimated using the reverse Kaplan-Meier method from investigator-assessed progression free survival values.
[2] Confidence Intervals estimated using the Brookmeyer Crowley method.

13.11.2.2. Figures

13.11.2.2.1. EFF_F1: Spider Plot of <Investigator-Assessed><Independent-Reviewer Assessed> Percent Change from Baseline in Target Lesion Diameter

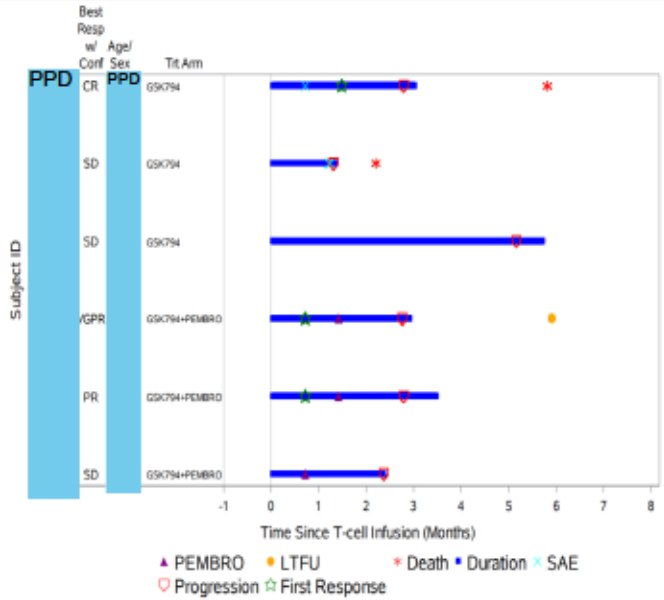


<footnotes as defined in the programming document>
/Directory/program.sas DDMMMYYYY HH:MM

The image is used as the mock example for this figure. All content must be updated based on 208471.

13.11.2.2.2. EFF_F3: Plot of Duration on Interventional Phase

Protocol: 208471				Page 1 of x
Population: Study Specific				(Data as of: DDMMMYYYY)
Figure X				
Plot of Duration on Interventional Phase				
Treatment: Arm A / Arm C				



<footnotes as defined in the programming document>
/Directory/program.sas DDMMMYYYY HH:MM

The image is used as the mock example for this figure. All content must be updated based on 208471 needs

13.11.3. Safety

13.11.3.1. Tables

13.11.3.1.1. SAFE_T1: Summary of Time to Resolution of Persistent Clinically Significant <AESI>

Protocol: ABC123456

Population: Intent-to-Treat/ Study specified

(Data as of: DDMMMYY)

Table x

Summary of Time to Resolution of Persistent Clinically Significant <AESI>

Parameter	Arm C – Lete-cel Monotherapy (N=10)	Arm C – Lete-cel + Pembrolizumab (N=10)	Arm C -- Total (N=20)
Subjects with Grade 3 or 4 [1]	8 (80%)	8 (80%)	16 (80%)
Subjects with Persistent Grade 3 or 4 at Month 1 [2]			
n	4	4	4
Recovered [3]	2 (50%)	2 (50%)	2 (50%)
Not recovered	2 (50%)	2 (50%)	2 (50%)
Death	1 (25%)	1 (25%)	1 (25%)
Ongoing	0	0	0
Lost to follow-up	1 (25%)	1 (25%)	1 (25%)
Estimates of Time to Recovery (Days) [4]			
1st Quartile	12.3	12.3	12.3
95% CI	(10.1,14.5)	(10.1,14.5)	(10.1,14.5)
Median	12.3	12.3	12.3

95% CI	(10.1,14.5)	(10.1,14.5)	(10.1,14.5)
3rd Quartile	12.3	12.3	12.3
95% CI	(10.1,14.5)	(10.1,14.5)	(10.1,14.5)
Recovery Probability			
Recovery at Study Day 90	0.82	0.82	0.82
95% CI	(0.70,0.95)	(0.70,0.95)	(0.70,0.95)

<analysis population definition as provided in the RAP/SAP.>
NA = Not applicable.
[1] Events occurring within 31 days post T-cell infusion
[2] Events at last value within 31 days of T-cell infusion
[3] Recovery defined as first time resolve to Grade 2 or below
[4] Confidence Intervals estimated using the Brookmeyer Crowley method
/Directory/program.sas 01JAN2002 12:01

Note: this mock shell shows the column layout for Arm C, please refer to programming notes for details of how to display different arms in different treatment phases.

13.11.3.1.2. SAFE_T4: Multiple titles as defined in section 13.10.5

Protocol: ABC123456			Page 1 of 1
Population: Intent-to-Treat/ Study specified			(Data as of: 24APR2018)
Table x.xx			
Multiple titles as defined in section 13.10.5			
	Arm A	Arm C	Overall
	(N=10)	(N=10)	(N=20)
<Replication Competent Lentivirus Positive> <>1% Gene Marked PBMCs 1 Year Post-treatment>			
n	xx	xx	xx
Count	xx (yy%)	xx (yy%)	xx (yy%)
<footnotes as defined in the programming document> /Directory/program.sas 01JAN2002 12:01			

This is a mock example for this display. All content must be updated based on 208471 needs (please refer to Section 8 and programming notes for more details)


CCI

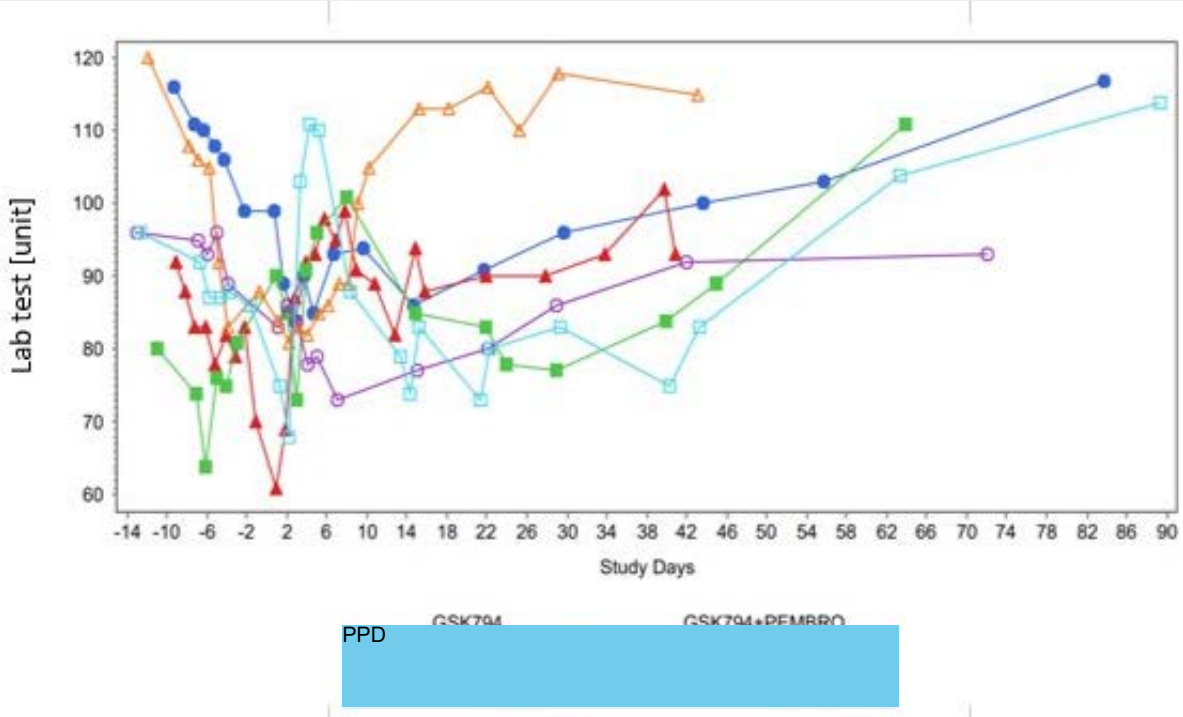
CCI

[redacted]

13.11.3.2. Figures

13.11.3.2.1. SAFE_F3: <Lab Category> Values Over Time <Among Subjects With <Condition> on or After <Timepoint>> - <Lab Parameter>

Protocol: ABC123456			Page 1 of 1
Population: Intent-to-Treat/Safety/Other study specific			(Data as of: 30MAY2011)
Figure x.xx			
Multiple titles as defined in section 13.12.9			



<footnotes as defined in the programming document>

/Directory/program.sas 01JAN2002 12:01

The image is used as the mock example for this figure. All content must be updated based on 208471 needs.

13.11.4. Pharmacokinetics (PK)

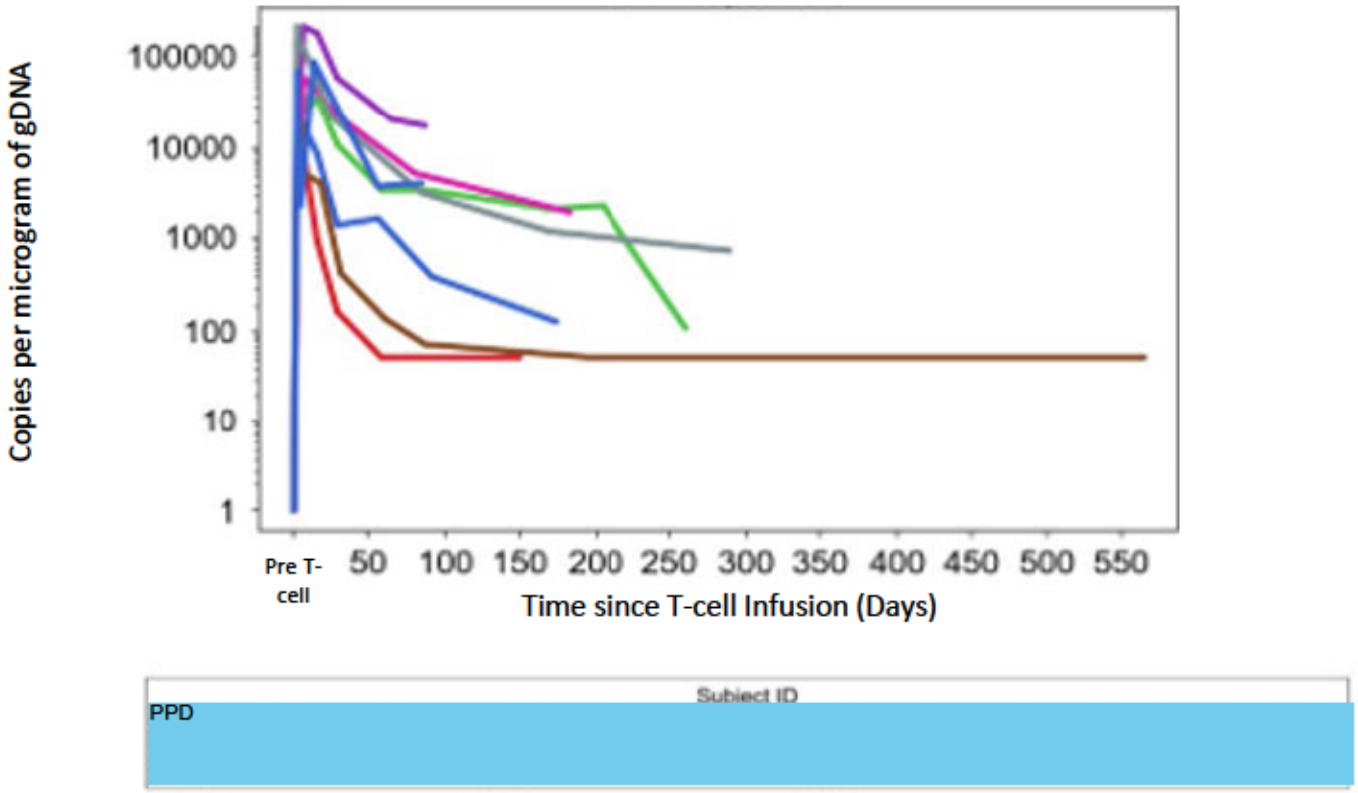
13.11.4.1. Tables

N/A

13.11.4.2. Figures

13.11.4.2.1. PK_F1: GSK3377794 Pharmacokinetic Concentration-Time Plot

Protocol: ABC123456			Page 1 of 1
Population: As defined in the RAP			(Data as of: 30MAY2011)
Figure x.xx			
GSK3377794 Pharmacokinetic Concentration-Time Plot			
Treatment: Arm A / Arm C			



<footnotes as defined in the programming document>
/Directory/program.sas 01JAN2002 12:01

The image is used as the mock example for this figure. All content must be updated based on 208471 needs.

13.11.5. ICH Listings

13.11.5.1. POP_L1: Listing of Exposure to T-cell Infusion

Protocol: ABC123456 Page 1 of x
Population: <analysis population> (Data as of: DDMMMYYYY)

Listing X
Listing of Exposure to T-cell Infusion

Treatment: Arm A

Site Id./ Unique Subject Id./ Subject Id. / Analysis Pop.	Start Date/ Start Time/ Start Day	End Date/ End Time/ End Day	Total Cell Dose (unit)	Total Number of Transduced Cells Infused (unit)	Percentage of Manufactured Cells Transduced (%)	Average Vector Copy	Lot Number 1	Lot Number 2
PPD SCR, ENRL, ITT, SAF, mITT	PPD 008/ 14:30/ 1	PPD 008/ 14:30/ 1	xx.xx	xx.xx	xx.xx	xx.xx	AD03-17-P2-043	AD03-17-P2-044
PPD SCR, ENRL, ITT,	PPD 2008/ 14:30/ 1	PPD 2008/ 14:30/ 1	xx.xx	xx.xx	xx.xx	xx.xx	AD03-17-P2-043	AD03-17-P2-044

13.11.6. Non-ICH Listings

CCI

[redacted]

CCI

[redacted]

13.11.6.2. SAFE_L7: Listing of Integration Site Analysis Results

Protocol: ABC123456						
Population: Intent-to-Treat/Safety/Other study specific						
Listing X						
Listing of Integration Site Analysis Results						
[ADxx.TRTA]						
Treatment: Arm A/ Arm C						
[ADxx.SITEID]						
Site Id.: PPD						
ADxx.USUBJID/ ADxx.SUBJID/ ADxx.ANALPOP	ADxx.AGE/ ADxx.SEX/ ADxx.RACE	ADxx.AVISIT	AD??.??DTC/ AD??.??DY	???	???	???
Unique Subject Id./ Subject Id./ Analysis Pop.	Age (YEARS)/ Sex/ Race Detail	[Visit] or [Planned Time]	Date/ Study Day	Shannon Index (Normal Range)	Gini Index	DNA Amount (ng)
/Directory/program.sas 01JAN2002 12:01						

13.11.6.3. SAFE_L8: Listing of Replication Competent Lentivirus Data

Protocol: ABC123456				Page 1 of 1
Population: Study specific				(Data as of: DDMMMYYYY)
Listing X				
Listing of Replication Competent Lentivirus Data				
Treatment: Arm A / Arm C				
Site Id./ Unique Subject Id./ Subject Id./ Analysis Pop.	Age (YEARS)/ Sex/ Race Detail	Visit	Date/ Study Day	RCL Interpretive Result
PPD SCR, ENRL, ITT	PPD	Baseline_Pre_Lympho	YYYY-MM-DD/ 15	NEGATIVE
		DAY x	YYYY-MM-DD/ 15	NEGATIVE
		WEEK x	YYYY-MM-DD/ 44	NEGATIVE
		MONTH x	YYYY-MM-DD/ 180	NEGATIVE
		COMPLETION / WITHDRAWN	YYYY-MM-DD/ 180	NEGATIVE
/Directory/program.sas 01JAN2002 12:01				

13.11.6.4. SAFE_L9: Listing of All Adverse Events; Listing of Non-Fatal Serious Adverse Events; Listing of Delayed Adverse Events by Delayed Category (GSK Adjudicated)

Protocol: ABC123456 Page 1 of x

Population: study specific (Data as of: DDMMMYYYY)

Listing X

<Title>

<By Delayed AE Category (only for GSK adjudicated listing)>

Site Id.: PPD

Treatment: Arm A / Arm C

Unique Subject Id./ Subject Id./ Analysis Pop.	Age (YEARS)/ Sex/ Race Detail/ Weight (kg)	Preferred Term/ Verbatim Text	Onset Date/ Date of Resolution/ Duration (DAYS)	Time Since T-Cell Infusion	Maximum Grade/ Overall Phase(s)/ Serious/	Segment Grade/ Segment Phase	Action(s) Taken/ Outcome/ Relation to Study Treatment	Investigator Assessed Delayed AE [1]
PPD SCR, ITT, mITT	PPD	Nasal congestion and blockage/ PPD	YYYY-MM-DD/ YYYY-MM-DD/ xx	19d	1/ T-cell/ Y		DOSE REDUCED/ RECOVERED/RESOLVED/ N	Yes: <Delayed AE Category>
PPD SCR, ITT, mITT, EVAL	PPD	Candidiasis mouth PPD	1999-05-04/ /	36d	4/ Leuk, Lymph, T-cell/ Y		DRUG WITHDRAWN, DOSE REDUCED/ NOT RECOVERED/NOT RESOLVED/ N/ Y: TRT A, TRT B, TRT C	No
			YYYY-MM-DD/ YYYY-MM-DD/ xx			2/ Leuk		
			YYYY-MM-DD/ YYYY-MM-DD/ xx			3/ Lymph		
			YYYY-MM-DD/ YYYY-MM-DD/ xx			3/ T-cell		

```
                                        YYYY-MM-DD/                     4/
                                        YYYY-MM-DD/                     T-cell
                                        xx                              Infusion


/Directory/program.sas  01JAN2002 12:01
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13.11.6.5. SAFE_L10: Cytokine Release Syndrome (CRS) Subject Profile

Protocol: ABC123456

Population: <study specified>

Listing X
Cytokine Release Syndrome (CRS) Subject Profile

Treatment: GSK Treatment
Site Id.: PPD
Unique Subject Id: PPD

Subject Id: PPD
Analysis Population: SCR, ITT, SAF, mITT
Start Date/[Time] of Treatment: YYYY-MM-DD
End Date/[Time] of Treatment: YYYY-MM-DD

Age (YEARS): PPD
Sex: PPD
Race Details: PPD
Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>

Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y

Seriousness Criteria	Y: Results in Death, Is Life Threatening
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Signs and symptoms experienced by the subject	Rash; Decreased Cardiac Output; Dyspnea
Tests performed	C-reactive Protein; Aspartate Amino Transferase

Indication of Procedure/ Start Date/ Stop Date	Supplemental Oxygen/ YYYY-MM-DD/ YYYY-MM-DD
Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	NOT APPLICABLE
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	DOSE NOT CHANGED
Related to study treatment(s)	No
Signs and symptoms experienced by the subject	Rash, Decreased Cardiac Output, Dyspnea
Tests performed	C-reactive Protein, Aspartate Amino Transferase

Indication of Procedure/ Onset Date/ Date Of Resolution	Mechanical Ventilation Assisstance (e.g. C-PAP, Ventilator)/ 2020-11-10/ 2020-11-17

All Adverse Events Suspected to be Linked to CRS

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	No

Concomitant Medication Information

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL
Indication of Medication	Vasopression; Intravenous fluids; Other Medication

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL
Indication of Medication	Vasopression; Intravenous fluids; Other Medication

For definition of analysis populations refer to table x.xxx: Summary of Study Populations.
AESI specific details.

/Directory/program.sas 01JAN2002 12:01

13.11.6.6. SAFE_L11: Pancytopenia/Aplastic Anemia Subject Profile

Protocol: ABC123456

Population: <study specified>

(Data as of: DDMMMYYYY)

Listing X

Pancytopenia / Aplastic Anemia Subject Profile

Treatment: GSK Treatment

Site Id.: PPD

Unique Subject Id: PPD

Subject Id: PPD

Analysis Population: SCR, ITT, SAF, mITT

Start Date/[Time] of Treatment: YYYY-MM-DD

End Date/[Time] of Treatment: YYYY-MM-DD

Age (YEARS): PPD

Sex: PPD

Race Details: PPD

Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	Confusional state
Verbatim term	PPD
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx

Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Was treatment with G-CSF initiated?	Yes or No
Was immunosuppresive agent given?	Yes or No
Other Immunosuppression methods provided	aggressive regimens
Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD

Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	NOT APPLICABLE
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	DOSE NOT CHANGED
Related to study treatment(s)	No
Was treatment with G-CSF initiated?	Yes or No
Was immunosuppresive agent given?	Yes or No
Other Immunosuppression methods provided	aggressive regimens

All Adverse Events Suspected to be Linked to P-AA

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED

Related to study treatment(s)	No

Concomitant Medication Information

Ingredient	<text>
Verbatim text	<text>
Start date[time]/ Study day	YYYY-MM-DD/ xxx
End date [time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

Ingredient	<text>
Verbatim text	<text>
Start date[time]/ Study day	YYYY-MM-DD/ xxx
End date[time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

For definition of analysis populations refer to table x.xxx: Summary of Study Populations.
AESI specific details.

/Directory/program.sas 01JAN2002 12:01

13.11.6.7. SAFE_L12: Pneumonia Subject Profile

Protocol: ABC123456 Page 1 of x
Population: <study specified> (Data as of: DDMMMYYYY)

Listing X
Pneumonia Subject Profile

Treatment: GSK Treatment
Site Id.: PPD
Unique Subject Id: PPD

Subject Id: PPD
Analysis Population: SCR, ITT, SAF, mITT
Start Date/[Time] of Treatment: YYYY-MM-DD
End Date/[Time] of Treatment: YYYY-MM-DD

Age (YEARS): PPD
Sex: PPD
Race Details: PPD
Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (Days)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Level of cough	Usual level of cough Increased cough

Increased sputum purulence	Yes No Unknown
Did the chest auscultation show evidence of crackles/rales and/or bronchial or bronchovesicular breath sounds?	Yes No Unknown
Worsening dyspnea?	Yes <Grade 1 or 2 or 3 or 4> No
Temperature	xxx
Respiration rate	xxx
Was an x-ray performed?	Yes No
Was a culture/swab taken?	Yes No Unknown
Does subject have pleural effusion?	Yes <specify location> No Unknown
Does subject have hypoxemia?	Yes No Unknown
Does subject have WBC count performed at time of event?	Yes <High WBC, Normal WBC, Low WBC> No Unknown
Was BUN >19mg/dL (7mmol/L)?	Yes No Unknown
Was there evidence that the subject was confused?	Yes No Unknown

Was this subject in a health care setting (inpatient) when the pneumonia developed?	Yes No Unknown
Bacteria Culture	
Observation date	YYYY-MM-DD
Sample source for bacteria culture	Blood Respiratory secretion Other
Pathogen from pneumonia culture	<list all pathogens>

<Footnote 1>
<Footnote …>
<Footnote 9>
/Directory/program.sas DDMMMYYYY HH:MM

13.11.6.8. SAFE_L13: Pneumonitis Subject Profile

Protocol: ABC123456 Page 1 of x
Population: <study specified> (Data as of: DDMMMYYYY)

Listing X
Pneumonitis Subject Profile

Treatment: GSK Treatment
Site Id.: PPD
Unique Subject Id: PPD

Subject Id: PPD
Analysis Population: SCR, ITT, SAF, mITT
Start Date/[Time] of Treatment: YYYY-MM-DD
End Date/[Time] of Treatment: YYYY-MM-DD

Age (YEARS): PPD
Sex: PPD
Race Details: PPD
Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (Days)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Cough?	Yes: <mild, moderate, severe> No

Increased sputum purulence	Yes: <is there blood in cough or sputum? Yes/no> No
Did the chest auscultation show evidence of crackles/rales and/or bronchial or bronchovesicular breath sounds?	Yes No Unknown
Worsening dyspnea?	Yes <Grade 1 or 2 or 3 or 4> No
Temperature	xxx
Respiration rate	xxx
Was an x-ray performed?	Yes No
Was a blood test taken to check for other infections?	Yes No Unknown
Does subject have pleural effusion?	Yes <specify location> No Unknown
Does subject have hypoxemia?	Yes No Unknown
Does subject have WBC count performed at time of event?	Yes <High WBC, Normal WBC, Low WBC> No Unknown
Was this subject in a health care setting (inpatient) when the pneumonitis developed?	Yes No Unknown

Bacteria Culture

Observation date	YYYY-MM-DD
Sample source for bacteria culture	Blood Respiratory secretion Other <text>

<Footnote 1>
<Footnote …>
<Footnote 9>
/Directory/program.sas DDMMMYYYY HH:MM

13.11.6.9. SAFE_L14: Graft vs Host Disease (GvHD) Subject Profile

Protocol: ABC123456

Population: <study specified>

Listing X
Graft-Versus-Host Disease (GVHD) Subject Profile

Treatment: GSK Treatment
Site Id.: PPD
Unique Subject Id: PPD

Subject Id: PPD
Analysis Population: SCR, ITT, SAF, mITT
Start Date/[Time] of Treatment: YYYY-MM-DD
End Date/[Time] of Treatment: YYYY-MM-DD

Age (YEARS): PPD
Sex: PPD
Race Details: PPD
Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	Confusional state
Verbatim term	PPD
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)	4/ Leuk, Lymph, T-cell

Serious[: Criteria for determining seriousness]	Y: Results in Death, Is life threatening, …
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Symptoms Experienced	Fever, Rash, Nausea, …
Tests Performed	Alanine Amino Transferase, Bilirubin, …
Biopsy Site	<site>
Medication Administered	Corticosteroids - Prophylactic, Sirolimus, …
Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)	1/ T-cell
Serious[: Criteria for determining seriousness]	Y: Results in Death, Is life threatening, …
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	NOT APPLICABLE
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	DOSE NOT CHANGED
Related to study treatment(s)	No
Symptoms Experienced	Fever, Rash, Nausea, …

Tests Performed	Alanine Amino Transferase, Bilirubin, …
Biopsy Site	<site>
Medication Administered	Corticosteroids - Prophylactic, Sirolimus, …

All Adverse Events Suspected to be Linked to GVHD

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)	1/ T-cell
Serious[: Criteria for determining seriousness]	Y: Results in Death, Is life threatening, …
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)	1/ T-cell
Serious[: Criteria for determining seriousness]	N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	No

Concomitant Medication Information

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

For definition of analysis populations refer to table x.xxx: Summary of Study Populations.
AESI specific details.

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13.11.6.10. SAFE_L15: Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS) Subject Profile

Protocol: ABC123456

Population: <study specified>

(Data as of: DDMMMYYYY)

Listing X

Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS) Subject Profile

Treatment: GSK Treatment

Site Id.: PPD

Unique Subject Id: PPD

Subject Id: PPD

Analysis Population: SCR, ITT, SAF, mITT

Start Date/[Time] of Treatment: YYYY-MM-DD

End Date/[Time] of Treatment: YYYY-MM-DD

Age (YEARS) PPD

Sex: PPD

Race Details: PPD

Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	Confusional state
Verbatim term	PPD
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx

Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Participant received anti-seizure prophylaxis	Yes: <treatment name> No
ICANS panel completed for the participant	Yes: <value from predefined drop down options> No: <reason>
Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	NOT APPLICABLE
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	DOSE NOT CHANGED

Related to study treatment(s)	No
Participant received anti-seizure prophylaxis	Yes: <treatment name> No
ICANS panel completed for the participant	Yes: <value from predefined drop down options> No: <reason>

All Adverse Events Suspected to be Linked to ICANS

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	No

Concomitant Medication Information

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

For definition of analysis populations refer to table x.xxx: Summary of Study Populations.
AESI specific details.

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13.11.6.11. SAFE_L16: Guillain-Barre Syndrome (GBS) Subject Profile

Protocol: ABC123456

Population: <study specified>

Listing X

Guillian-Barre Syndrome (GBS) Subject Profile

Treatment: GSK Treatment

Site Id.: PPD

Unique Subject Id: PPD

Subject Id: PPD

Age (YEARS): PPD

Analysis Population: SCR, ITT, SAF, mITT

Sex: PPD

Start Date/[Time] of Treatment: YYYY-MM-DD

Race Details: PPD

End Date/[Time] of Treatment: YYYY-MM-DD

Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (Days)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE

Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Any vaccination received within 4 weeks prior to onset of symptoms	Yes: <treatment name> No
Was Brighton Criteria Assessed at hospital admission?	Yes: <treatment name> No
Brighton Criteria Score at GBS hospital admission	Grade 1 or 2 or 3 or 4
Brighton Criteria Score 7 days after GBS hospital admission	Grade 1 or 2 or 3 or 4
Symptoms Experienced	Preceding symptoms of respiratory or gastrointestinal tract, Pain, Cranial Nerve….
Did the patient experience Hypokalaemia, Phosphataemia, Magnesaemia, Hypoglycaemia?	Yes: Magnesaemia, Hypoglycaemia
Was Patient Diabetic?	Yes No
Did Patient develop CNS metastasis?	Yes No
Early initiation of intravenous or plasma exchange	Yes No
Did Patient receive Supplemental Oxygen or Mechanical Ventilation assisitance?	Supplemental Oxygen (Start Date/End Date) Mechanical Ventilation assisitance (Start Date/End Date)
Was Patient admitted to ICU?	Yes No
MRC score at hospital admission	31-40
MRC score at 7 days from hospital admission	51-60
EGRS score at hospital admission	High Risk (EGRIS 5-7)
EGRS score at 7 days from hospital admission	Low Risk (EGRIS 0-2)
mEGOS score at hospital admission	Value from drop down menu
mEGOS score at 7 days from hospital admission	Value from drop down menu
Test performed	CSF , Electropysiological & pathologicval studies or Other (Specify)

Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	NOT APPLICABLE
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	DOSE NOT CHANGED
Related to study treatment(s)	No
Brighton Criteria Score at GBS hospital admission	Grade 1 or 2 or 3 or 4
Brighton Criteria Score 7 days after GBS hospital admission	Grade 1 or 2 or 3 or 4
Symptoms Experienced	Preceding symptoms of respiratory or gastrointestinal tract, Pain, Cranial Nerve….
Was Brighton Criteria Assessed at hospital admission?	Yes: <treatment name> No
Any vaccination received within 4 weeks prior to onset of symptoms	Yes: <treatment name> No
Did Patient Experience any?	Hypokalaemia, Phosphataemia, Magnesaemia, Hypoglycaemia
Was Patient Diabetic?	Yes No
Did Patient develop CNS metastasis?	Yes No
Early initiation of intravenous or plasma exchnage	Yes No
Did Patient receive Supplemental Oxygen or Mechanical Ventilation assisitance?	Supplemental Oxygen (Start Date/End Date) Mechanical Ventilation assisitance (Start Date/End Date)

Was Patient admitted to ICU?	Yes No
MRC score at hospital admission	31-40
MRC score at 7 days from hospital admission	51-60
EGRS score at hospital admission	High Risk (EGRIS 5-7)
EGRS score at 7 days from hospital admission	Low Risk (EGRIS 0-2)
mEGOS score at hospital admission	Value from drop down menu
mEGOS score at 7 days from hospital admission	Value from drop down menu
Test performed	CSF , Electropysiological & pathologicval studies or Other (Specify)

All Adverse Events Suspected to be Linked to GBS

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED

Related to study treatment(s)	No

Concomitant Medication Information

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

For definition of analysis populations refer to table x.xxx: Summary of Study Populations.
AESI specific details.

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