Division: Worldwide Development
Information Type: Clinical Study Report
Control: no-treatment

Protocol Title:	Master Protocol to Assess the Safety and Recommended Phase 2 Dose of Next Generations of Autologous Enhanced NY-ESO-1/ LAGE-1a TCR Engineered T cells, Alone or in Combination with Other Agents, in Participants with Advanced Tumors
Substudy 2 Title:	Assessment of Safety and Recommended Phase 2 Dose of Autologous T cells Engineered with an Affinity-enhanced TCR Targeting NY-ESO-1 and LAGE-1a, and co-expressing the dnTGF-βRII (GSK3845097) in Participants with NY-ESO-1 and/or LAGE-1a Positive Previously Treated Advanced (Metastatic or Unresectable) Synovial Sarcoma and Myxoid/Round Cell Liposarcoma
Phase:	1
Compound Number:	GSK3845097
Document Date:	18 August 2023

Subject: Safety, Recommended Phase 2 Dose, Synovial Sarcoma, Myxoid/Round Cell Liposarcoma, NY-ESO-1, LAGE-1a, dnTGF-βRII, Autologous T cells

Indication Studied: Synovial Sarcoma and Myxoid/Round Cell Liposarcoma

Initiation Date (Substudy 2): 05 May 2021

Completion Date: 24 October 2022

Sponsor Signatory: (and Medical Officer)
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This study was performed in compliance with Good Clinical Practices and GSK Standard Operating Procedures for all processes involved, including the archiving of essential documents. This study complies with US 21 CFR 312.120.

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ABBREVIATIONS

Abbreviation	Definition
AE	Adverse event
AESI	Adverse events of special interest
ALT	Alanine aminotransferase
ANC	Absolute neutrophil count
AST	Aspartate aminotransferase
AUC(0-28d)	Area under the persistence–time curve from 1st T cell infusion to 28 days
AUC(0-t)	Area under the persistence–time curve over the dosing interval
AUC(0-tlast)	Area under the persistence–time curve from 1st T cell infusion to last timepoint
BIL	Bilirubin
BOR	Best overall response
bpm	Beats per minute
CFR	Code of Federal Regulations
CI	Confidence interval
Cmax	Maximum observed concentration
CMV	Cytomegalovirus
CNS	Central nervous system
COVID-19	Coronavirus disease 2019
CR	Complete response
CRP	C-reactive protein
CRS	Cytokine release syndrome
CSR	Clinical study report
CT	Computed tomography
CV	Coefficient of variation
DL1	Planned dose level of (1-8) × 10^9 transduced T cells
DL-1	Planned dose level of (0.1-0.8) × 10^9 transduced T cells
DLT	Dose-limiting toxicity
DMSO	Dimethyl sulfoxide
DNA	Deoxyribonucleic acid
dnTGF-βRII	Dominant negative transforming growth factor β receptor type II
DoR	Duration of response
DSC	Dose Selection Committee
EBV	Epstein Barr virus
ECG	Electrocardiogram(s)
ECHO	Echocardiography
ECOG	Eastern Cooperative Oncology Group
EEG	Electroencephalogram
FDA	Food and Drug Administration
FTIH	First-time-in-human
GCP	Good Clinical Practice
G-CSF	Granulocyte colony-stimulating factor
GVHD	Graft versus host disease
HHV6	Human herpesvirus 6

Abbreviation	Definition
HLA	Human leukocyte antigen
ICANS	Immune effector cell-associated neurotoxicity syndrome
ICF	Informed consent form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICU	Intensive care unit
IgG	Immunoglobulin G
IHC	Immunohistochemistry
INR	International normalized ratio
ITT	Intent-to-treat
IV	Intravenous
LDH	Lactate dehydrogenase
LTFU	Long-term follow-up
MedDRA	Medical dictionary for regulatory activities
mITT	Modified Intent-to-treat
MRCLS	Myxoid/round cell liposarcoma
MRI	Magnetic resonance imaging
MTD	Maximum tolerated dose
mTPI-2	Modified Toxicity Probability Interval 2
MUGA	Multigated acquisition scan
NE	Not evaluable
NSAID	Nonsteroidal anti-inflammatory drug
NY-ESO-1	New York esophageal antigen-1
ORR	Overall response rate
OS	Overall survival
PBMC	Peripheral blood mononuclear cell
PCI	Potential clinical importance
PCR	Polymerase chain reaction
PD	Progressive disease
PICC	Peripherally inserted central catheter
PK	Pharmacokinetics
PR	Partial response
PS	Performance status
QTcB	QT duration corrected for heart rate by Bazzetts's formula
RBC	Red blood cell
RCL	Replication competent lentivirus
RECIST	Response Evaluation Criteria in Solid Tumors
RP2D	Recommended Phase 2 dose
SAE	Serious adverse event
SAP	Statistical analysis plan
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SC	Subcutaneous(ly)
SMQ	Standardized MedDRA Query
SS	Synovial sarcoma
TCR	T-cell receptor
TEAE	Treatment-emergent adverse event
TGF	Transforming growth factor

Abbreviation	Definition
Tmax	Time to maximum observed concentration
TME	Tumor microenvironment
ULN	Upper limit of normal
US	United States
UTI	Urinary tract infection
WBC	White blood cell

Trademark Information

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MedDRA

ETHICS AND GOOD CLINICAL PRACTICE

The study protocol, any amendments, the informed consent, and other information that required pre-approval were reviewed and approved by a national, regional, or investigational center ethics committee or institutional review board, in accordance with the ICH GCP and applicable country-specific requirements, including US 21 CFR 312.3(b) for constitution of independent ethics committees. Ethics committee or institutional review board approvals are maintained in the Sponsor's study file.

Investigators were trained to conduct the study in accordance with GCPs and the study protocol, as defined in ICH E3, Section 9.6. Written commitments were obtained from investigators to conduct the study in accordance with ICH GCP and all applicable participant privacy requirements, and the ethical principles that are outlined in the Declaration of Helsinki, and to conduct the study in accordance with the protocol.

The study was monitored in accordance with ICH E6, Section 5.18. No significant findings were identified during monitoring or auditing of a site.

Written informed consent was obtained from each participant prior to the performance of any study-specific procedures. The investigator agreed to provide the participant as much time as necessary to review the document, to inquire about details of the trial, and to decide whether or not to participate in the study. The informed consent was signed and dated by the study participant and by the person who conducted the informed consent discussion. Case report forms were provided for each participant's data to be recorded.

Synopsis

Name of company: GSK Research & Development Limited

Name of finished product: not available at the time of this report

Name of active substance: GSK3845097

Study Number: 209012

Title: Master Protocol to Assess the Safety and Recommended Phase 2 Dose of Next Generations of Autologous Enhanced NY-ESO-1/ LAGE-1a TCR Engineered T cells, Alone or in Combination with Other Agents, in Participants with Advanced Tumors

Substudy 2 Title: Assessment of Safety and Recommended Phase 2 Dose of Autologous T cells Engineered with an Affinity-enhanced TCR Targeting NY-ESO-1 and LAGE-1a, and co-expressing the dnTGF-βRII (GSK3845097) in Participants with NY-ESO-1 and/or LAGE-1a Positive Previously Treated Advanced (Metastatic or Unresectable) Synovial Sarcoma and Myxoid/Round Cell Liposarcoma

Investigators: Multicenter study

Study centers: Substudy 2 was opened to all 21 centers of the master protocol 209012 across 7 countries; 17 centers contributed to screening in 209012 study but only 2 sites in the US, 1 site in Germany, and 1 site in Sweden enrolled participants in Substudy 2.

Publication: None at the time of this report

Study Period: 05 May 2021 to 24 October 2022

Phase of Development: 1

Objectives and endpoints:

Below are the objectives and endpoints for protocol 209012 Substudy 2. The substudy was stopped for further treatment based on the protocol stopping and pausing provisions. Also, further screening and enrolment on master protocol 209012 was closed before further investigation on GSK3845097 could be performed. Therefore, only a subset of the exploratory endpoints was analyzed. The table below lists only those endpoints for which results are reported in this CSR. For the full list of objectives and endpoints, see Substudy 2 SAP Section 1.1.

Objectives	Endpoints
Primary	
To assess the safety, tolerability and determine RP2D of GSK3845097 in HLA-A*02:01, HLA-A*02:05, and/or HLA-A*02:06 positive participants with NY-ESO-1 and/or LAGE-1a positive, previously treated, advanced (metastatic or unresectable) SS and MRCLS	• Frequency of DLTs • Frequency and severity of AEs, SAEs, and AESI; as defined in the core protocol

Objectives	Endpoints
Secondary - Efficacy	
To investigate the antitumor activity of GSK3845097 in HLA-A*02:01, HLA-A*02:05, and/or HLA-A*02:06 positive participants with NY-ESO-1 and/or LAGE-1a positive, previously treated, advanced (metastatic or unresectable) SS and MRCLS	• ORR (investigator assessed according to RECIST v1.1) • DoR
Secondary - Pharmacokinetics	
To characterize in vivo cellular PK profile (levels, expansion, persistence) of GSK3845097 over time	• Cmax • Tmax • AUC(0-t), as data permit
Exploratory	
To further evaluate safety and tolerability of GSK3845097 in HLA-A*02:01, HLA-A*02:05, and/or HLA-A*02:06 positive participants with NY-ESO-1 and/or LAGE-1a positive, previously treated, advanced (metastatic or unresectable) SS and MRCLS	• Changes in laboratory parameters; vital signs; ECOG PS; ECG • RCL • Instances of insertional oncogenesis
To further evaluate the antitumor activity of GSK3845097 in HLA-A*02:01, HLA-A*02:05, and/or HLA-A*02:06 participants with NY-ESO-1 and/or LAGE-1a positive, previously treated, advanced (metastatic or unresectable) SS and MRCLS	• OS

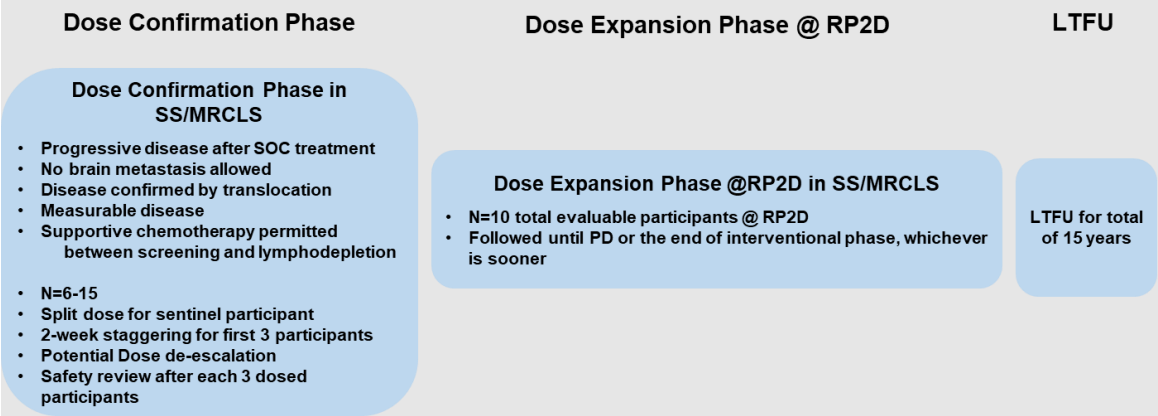
Methodology:

GSK3845097 belongs to the second generation of NY-ESO-1 TCR engineered T cells that incorporate additional sequences on the lentiviral vector construct to encode genes for molecules that would enhance T-cell function within the TME.

GSK3845097 is modified by multicomponent engineering to enable co-expression, alongside the NY-ESO-1^{c259} TCR, of the dnTGF-βRII receptor to decrease the potential inhibition of T-cell function by the TME.

This is an FTIH, single cohort, non-randomized, open-label substudy (part of a Master Protocol) to investigate GSK3845097 in previously treated participants with advanced (metastatic or unresectable) SS and MRCLS, whose tumors express either NY-ESO-1 and/or LAGE-1a and are positive for either HLA-A*02:01, A*02:05, and/or A*02:06. The master protocol 209012 included 2 substudies. The first screening steps for target expression (HLA-typing and NY-ESO-1/Lage-1a tumor antigen expression) were common to all substudies in the core protocol and did not require allocation to a particular substudy until leukapheresis eligibility screening. Substudy allocation was conducted prior to leukapheresis, based on disease indication (NSCLC could only enroll on Substudy 1) and slot availabilities in Substudy 1 or 2 (for SS and MRCLS participants). Consequently, the target expression screening results are being reported for both Substudies 1 and 2 combined. This substudy consists of 2 phases: Dose Confirmation Phase and Dose Expansion Phase (Figure 1).

Figure 1 Substudy 2 Design



LTFU = long-term follow-up; MRCLS = myxoid/round cell liposarcoma; PD = progressive disease; RP2D = recommended Phase 2 dose; SOC = standard of care; SS = synovial sarcoma.

Dose Confirmation Phase

Dose confirmation phase commenced first. Once all participants needed for dose confirmation (n=6-15) had been assigned, participants were to be assigned to dose expansion phase.

The primary objective of the dose confirmation phase was to identify the RP2D of GSK3845097. RP2D was to be determined as the MTD or lower that provides adequate biologic activity with superior tolerability. The MTD was defined as the dose that maximizes the probability of target toxicity of 30% while controlling the probability of excessive or unacceptable toxicity.

Dose Selection Committee review was to occur after the DLT period of 28 days after the last T-cell infusion in every 3 participants to enable dose decision until the final dose selection was achieved (6 to 15 participants).

The starting dose was the RP2D of GSK3377794 (lete-cel); that is, the initial group of 3 participants were to receive a dose in the range of (1 to 8) × 10^9 transduced T cells. DLTs were assessed for each treated participant of the dose confirmation phase as per Core Protocol Section 8.2. If the number of participants with confirmed DLTs in the dosing group required a dose de-escalation according to the mTPI-2 model (see Substudy 2 Protocol Section 5.1.1.2), then a lower dose range of (0.1 to 0.8) × 10^9 transduced T cells was to be explored, with the possibility to re-escalate if the model supports such action.

Dose Expansion Phase

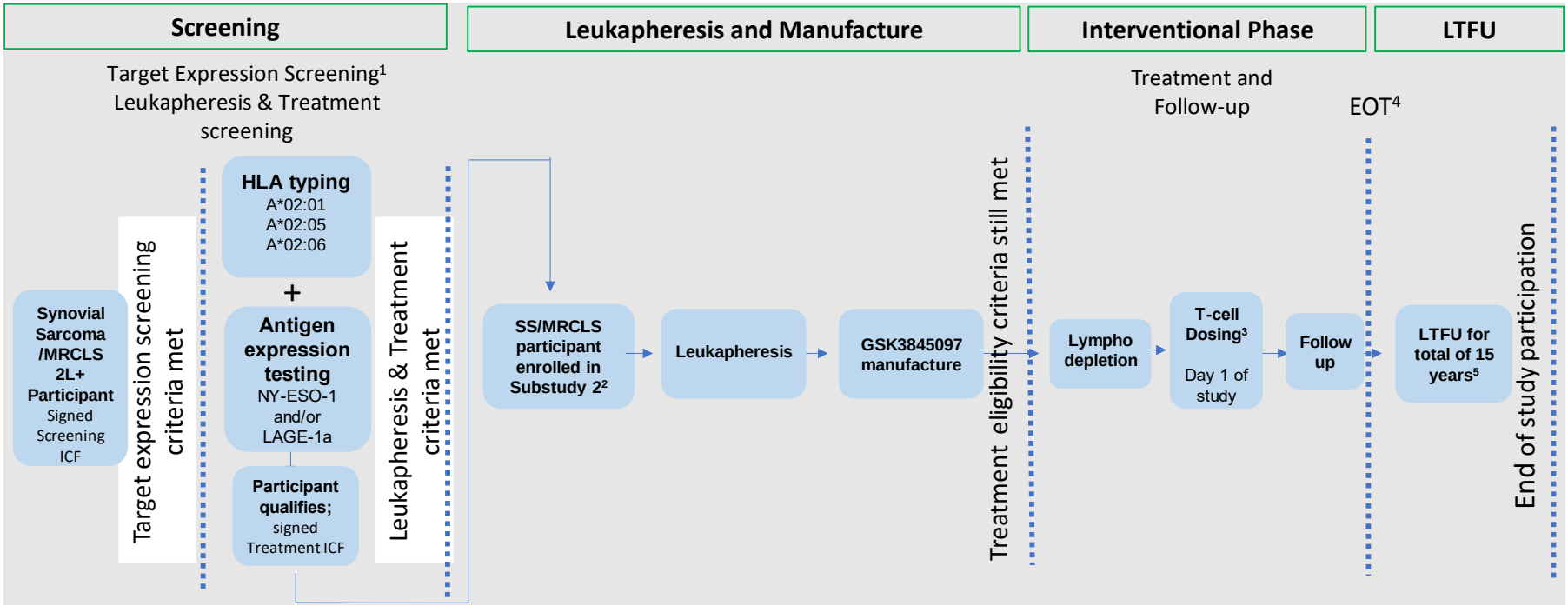
The dose expansion phase was to begin after determination of the RP2D. The cohort was to enroll additional participants to ensure 10 participants become evaluable at the RP2D. Evaluable participants were those who received T-cell infusion and completed at least 2 post-baseline disease assessments since infusion or progressed or died or were withdrawn from the substudy.

Participant Journey

For each individual participant, the study consisted of the following (Figure 2): screening; leukapheresis and manufacture; interventional phase; and LTFU.

For more details, refer to Substudy 2 Protocol Section 5.1.3.

Figure 2 Participant Journey



EOT = end of treatment (i.e., interventional) portion of the trial; HLA = human leukocyte antigen; ICF = informed consent form; LTFU = long-term follow-up; MRCLS = myxoid/round cell liposarcoma; SS = synovial sarcoma.

1. Screening, including HLA typing and antigen testing, could be done in this study or as part of a separate pre-screening protocol.
2. Sponsor was to inform investigators of the participant assignments between substudies and indicate if the participant is a sentinel participant and the number of remaining slots.
3. The first participant to be dosed was to receive the total dose in 2 separate infusions as aliquots of ~30% and ~70% of the total manufactured dose, administered 7 days apart. The second infusion was administered only if no acute toxicities preventing full dosing were observed. If no DLTs were reported for the participants receiving split doses, then all subsequent participants administered the particular product received the full dose as a single, i.e., one-time, infusion.
4. See Substudy 2 Protocol Section 5.3.1 for definition of the end of interventional phase for a participant.
5. The LTFU assessments and procedures could be done in this study or under a separate LTFU protocol.

Number of participants:

- Planned: 6 to 15 participants in the dose confirmation phase, and 10 participants in the dose expansion phase
- Recruited: 5 participants (4 participants were dosed with GSK3845097 in the dose confirmation phase and 1 participant underwent leukapheresis but did not receive lymphodepletion chemotherapy or T-cell infusion)
- Analyzed: 4 participants in the dose confirmation phase

Note: Substudy 2 was closed prior to the completion of the dose confirmation phase. Hence, RP2D was not determined, and the dose expansion phase was not started.

Diagnosis and key eligibility criteria for inclusion:

Eligibility criteria were grouped into 3 parts and eligibility screening took place in the following 3 steps:

- Target expression screening: A set of criteria permitting participants' blood to be screened for HLA-type and an archival or fresh tumor sample to be screened for the expression of NY-ESO-1/LAGE-1a.
- Leukapheresis eligibility screening: To be fulfilled prior to performing leukapheresis procedure.
- Treatment eligibility screening: To be fulfilled prior to starting lymphodepleting chemotherapy and administration of GSK3845097.

Key inclusion criteria:

Refer to Substudy 2 Protocol Section 6.1 for the full list of inclusion criteria.

<u>Target expression screening:</u>

2. Participant was ≥18 years of age and weighed ≥40 kg on the day of signing informed consent form.
4. Participant had a diagnosis of SS or MRCLS as confirmed by local histopathology with evidence of disease-specific translocation. Note: Evidence of a relevant disease-specific translocation was required at latest prior to leukapheresis (Inclusion Criterion 11).
5. Participant had advanced (metastatic or unresectable) SS or MRCLS. Unresectable refers to a tumor lesion in which clear surgical excision margins cannot be obtained without leading to significant functional compromise.

<u>Leukapheresis eligibility screening:</u>

7. Participant was positive for HLA-A*02:01, HLA-A*02:05, and/or HLA-A*02:06 alleles by a validated test in a designated central laboratory prior to leukapheresis.

8. Participant's tumor (either the most recent archival specimen or a fresh biopsy) tested positive for NY-ESO-1 and/or LAGE-1a expression (when LAGE-1a testing was available) by a GSK designated laboratory (and met the threshold criteria defined for the specific tumor type, i.e., ≥2+ in 30% of tumor cells).
9. Participant had measurable disease according to RECIST v1.1.
10. Participant had evidence of radiographic or clinical disease progression.
11. Participant had confirmed evidence of a relevant disease-specific translocation.
    - For SS, presence of a translocation involving chromosome 18 (SYT gene) and/or chromosome X (SSX1, SSX2, or SSX4 genes);
    - For MRCLS, presence of a translocation involving chromosome 12 (DDIT3 gene) and/or chromosome 16 (FUS gene) and/or chromosome 22 (EWSR1 gene).
12. Participant had completed at least one standard of care treatment including anthracycline-containing regimen unless intolerant to or ineligible to receive the therapy.

Treatment eligibility screening:

20. Participant had documented radiographic evidence of disease progression from prior line of therapy.

Treatment fitness (for safety):

Given potential changes in clinical status between screening/enrollment and the start of lymphodepleting chemotherapy, safety assessments done for target expression screening and leukapheresis eligibility screening were reassessed prior to lymphodepletion. If the results of any assessments or procedure were outside of the eligibility criteria, the investigator consulted with the GSK medical monitor prior to proceeding with lymphodepletion.

Key exclusion criteria:

Refer to Substudy 2 Protocol Section 6.2 for the full list of exclusion criteria.

Target expression screening:

3. Previous treatment with genetically engineered NY-ESO-1-specific T cells, NY-ESO-1 vaccine, or NY-ESO-1 targeting antibody.
4. Prior gene therapy using an integrating vector.

Leukapheresis eligibility screening:

6. Participant had CNS metastases.
7. Participant had a history of chronic or recurrent (within the last year prior to leukapheresis) severe autoimmune or immune mediated disease (e.g., Crohn's disease, systemic lupus) requiring steroids or other immunosuppressive treatments.

Treatment eligibility screening:

19. Participant had received systemic corticosteroids or any other immunosuppressive therapy within 2 weeks prior to lymphodepleting chemotherapy.
20. Participant had received ≥50 Gy to a significant volume of the pelvis, long bones or spine, or a cumulative dose of radiation that, in the investigator's opinion would predispose patients to prolonged cytopenia after lymphodepletion.
21. All the participant's target lesions had been irradiated within 3 months prior to lymphodepletion. A lesion with unequivocal progression could be considered a target lesion regardless of time from the last radiotherapy dose.
22. Radiotherapy that involved the lung (V20 exceeding 30% lung volume or mean heart dose >20 Gy) within 3 months OR radiotherapy (including but not limited to palliative radiotherapy) to lung/mediastinum with V20 less than 30% lung volume and with mean heart dose ≤20 Gy within 4 weeks (±3 days).

Treatment Administration:

The study intervention in this study was GSK3845097. Participants underwent leukapheresis to obtain starting material for the manufacture of GSK3845097. Since HLA-typing and NY-ESO-1/Lage-1a expression testing were required prior to leukapheresis, bridging or standard of care systemic chemotherapy, experimental therapy, and/or local therapy (e.g., radiotherapy, cryoablation, surgical resection) may have been administered between target expression screening and leukapheresis. Additionally, systemic chemotherapy may have been administered between leukapheresis and the start of lymphodepletion, if a participant had PD and could not be treatment-free. Prior to administration of study intervention, participants received lymphodepleting chemotherapy consisting of fludarabine 120 mg/m^2 on Days -7 to -4, and cyclophosphamide 3600 mg/m^2 for the first participant on Days -5 and -4 and then 2700 mg/m^2 for other participants on Days -6 to -4 (note: the first participant was dosed per Protocol Amendment 1 and other participants were dosed per Protocol Clarification Letter or Protocol Amendment 3). G-CSF was started on Day -3. The intended dose of GSK3845097 was within the range of (1 to 8) × 10^9 transduced T cells to be administered by IV infusion for the first 3 participants. If a dose de-escalation was decided by the DSC, the target dose range was lowered 10-fold to (0.1 to 0.8) × 10^9 transduced T cells for subsequent participants. The first study participant receiving GSK3845097 was a sentinel participant and was planned to receive the target dose of transduced T cells as 2 separate infusions, of approximately 30% of the target dose on Day 1 and approximately 70% of the target dose on Day 8. If no DLT was reported all subsequent participants were to receive the target T-cell dose as a single infusion.

Batch numbers of the study intervention for the 4 dosed participants are listed in the table below:

Participant ID	Batch number	Manufacturer
110801	G0016	Miltenyi Biotec
110014	G0041	Miltenyi Biotec
110762	G0063	Miltenyi Biotec
110454	G0076	Miltenyi Biotec

Study assessments:

Safety assessments included the rate of AEs, SAEs, AESIs, DLTs, as well as physical exams, ECOG PS, vital signs, cardiac assessments (ECHO, MUGA, ECG), pulmonary assessments, clinical laboratory assessments, T-cell persistence and RCL. All participants were to be followed for survival and for 15 years after GSK3845097 infusion for observation of delayed AEs in accordance with FDA requirements for gene therapy clinical trials.

A DSC was established for making dose recommendations for GSK3845097 based on a review of all relevant data. The committee was tasked to determine whether the same dose can be given to additional participants; or decide to move to a lower dose level. DSC meetings took place after each consecutive group of 3 participants had been dosed in the substudy and followed for the DLT period of 28 days.

Efficacy endpoints relied on tumor assessments for response and progression that were evaluated according to RECIST v1.1 (see Master Protocol Section 12.6). RECIST v1.1 was used in the assessment of disease burden (target and non-target lesions determination) at baseline and as the primary measure of tumor response endpoints.

T-cell vector copies (expansion/persistence) in the peripheral blood were measured in participants by quantitation of transduced cells by PCR of transgene from DNA extracted from PBMC. Persistence was measured to establish the relationships with response to the study intervention as well as a long-term safety measure. For all PK analyses, expansion/persistence of the engineered T cells was applied in lieu of "concentration" to derive PK parameters.

Statistical methods:

Only a subset of the previously planned analyses was performed as the study was closed for further screening and enrolment; and stopped for further treatment based on the protocol stopping and pausing provisions. The following are the key changes to previously planned analyses: 1) since the substudy was closed prior to the establishment of the RP2D, no related analyses were provided (e.g., analyses based on the Evaluable analysis set). 2) The Interim and Primary analyses described in Substudy 2 Protocol Section 10.5 were not conducted; only the Final Analysis was undertaken. 3) Most exploratory endpoints were not analyzed. 4) As appropriate, listings were produced in lieu of tables and figures given the low sample size. 5) No subgroup analyses were undertaken because of recruiting fewer participants than the planned target sample size.

The final analysis was to be performed after the completion of the following sequential steps:

1. Enrolment was complete and all enrolled participants had received T-cell infusion, and
2. All participants had completed the substudy.
    - Completed the substudy was defined as when all enrolled participants had transferred to the separate LTFU protocol, declined consenting to the LTFU

protocol, completed LTFU requirement in the applicable study, had been lost to follow-up, or withdrawn or died.

3. All required database cleaning activities had been completed and database release and database lock had been declared by Data Management.

No inferential statistical hypothesis testing was conducted, i.e., no p-values were calculated. Unless otherwise specified, continuous data were summarized using descriptive statistics: number of subjects (n), mean, standard deviation, median, minimum, and maximum. Categorical data were summarized as the number and percentage of participants in each category. CIs used 95% confidence levels unless otherwise specified.

The primary endpoints were frequency of DLTs, frequency and severity of AEs and SAEs, and frequency and severity of the AESIs. Toxicities meeting the DLT criteria are listed in Core Protocol Section 8.2, and must have been considered to be at least possibly related to transduced T cells, and occurred within the DLT assessment period of 28 days after last dosing of T cells.

The secondary efficacy endpoint was ORR, which was defined as the percentage of participants with a confirmed CR or a confirmed PR as the BOR relative to the total number of participants within the relevant cohort and analysis population per RECIST v1.1 as determined by the local investigators. Participants with either no valid post-baseline assessments, or non-measurable disease at baseline, or experienced death prior to the first disease assessment were treated as non-responders i.e., these participants were included in the denominator when calculating the ORR, and BOR was summarized as NE. The ORR was reported along with the Clopper-Pearson exact 95% CI based on the mITT analysis set. Another secondary efficacy endpoint was DoR, which was defined as the interval of time (in months) from first documented evidence of the confirmed response (PR or CR) to the date of disease progression per RECIST v1.1 criteria or death due to any cause, among participants with a confirmed response of PR or CR as the BOR. DoR was summarized based on the mITT analysis set using the Kaplan-Meier method, or by standard summary statistics if there were no more than 5 confirmed responders within a cohort. See Core SAP Section 4.3.1 for more details on efficacy analyses.

Secondary PK endpoints included Cmax, Tmax, and AUC(0-t) based on the PK analysis set. PK parameters were calculated using standard noncompartmental analyses according to current working practices and using appropriate software. All calculations of noncompartmental parameters were based on actual sampling times. See Core SAP Section 4.3.2 for more details on PK analyses.

Sample size determination

Participants were to be recruited in blocks of 3 in the dose confirmation phase (up to 6-15 participants) until the RP2D could be determined based on the mTPI-2 recommended dose. Once the RP2D was established, the substudy was to expand to up to 10 participants treated at that dose. See Substudy 2 SAP Section 5 for more details.

Analysis sets

Analysis Set	Definition / Criteria	Analyses Evaluated
Screened	All participants who signed an ICF to participate in the study.	• Screen Failures
Enrolled[a]	All participants who started leukapheresis procedure. Note: this analysis set included patients that did not meet the treatment eligibility criteria prior to lymphodepletion or patients that withdrew or died prior to lymphodepletion or T-cell infusion.	• Specific required Study Population displays
ITT	All participants who started leukapheresis procedure. Note: this analysis set included patients that did not meet the treatment eligibility criteria prior to lymphodepletion or patients that withdrew or died prior to lymphodepletion or T-cell infusion.	• Study Population • Safety (where appropriate) • Sensitivity for Secondary Efficacy Endpoint (ORR)[b]
Lymphodepletion	All ITT participants who started lymphodepletion chemotherapy.	• Safety – including AEs and Exposure
Modified ITT (mITT)	All ITT participants who received any dose of NY-ESO-1 specific T cells.	• Safety (where appropriate) • Efficacy
DLT Evaluable	Participants in the mITT analysis set who were part of the dose confirmation phase that either had a DLT (meeting the definition of a DLT as defined in Core Protocol Section 8.2) or had completed the DLT assessment period of 28 days since last T-cell infusion. Note: For participants who received a single dose, the DLT assessment period was up to and including Day 28, and for participants who received split dose, the DLT assessment period was up to and including 28 days after the second split-dose.	• Safety – summary of DLTs for dose confirmation phase
Modified ITT 90 (mITT 90)[c]	Participants in the mITT analysis set who had been followed-up for at least 90 days since the last T-cell infusion.	• Safety – summary of delayed AEs
Evaluable[d]	Participants in the mITT analysis set who received the RP2D and had completed at least 2 disease assessments after infusion or progressed or died or were withdrawn or lost to follow-up from the substudy.	• Interim Analysis (for dose expansion participants and dose confirmation participants who received RP2D)
Pharmacokinetic (PK)	Participants in the mITT analysis set from whom at least one persistence sample was obtained, analyzed, and was measurable.	• PK

AE = adverse event; DLT = dose limiting toxicity; ICF = informed consent form; ITT = intention-to-treat; ORR = overall response rate; PK = pharmacokinetics; RP2D = recommended phase 2 dose.

a. Enrolled and ITT analysis sets are identical. The enrolled analysis set is required for disclosure reporting by EudraCT.
b. Efficacy sensitivity analysis was not performed due to study closure based on protocol stopping provisions.
c. The mITT 90 analysis set was not used since summary of delayed AEs was not produced following closure of substudies based on protocol stopping provisions.
d. Note that all substudies were closed prior to achieving RP2D based on protocol stopping provisions and therefore the Evaluable Analysis Set was not required for analysis purposes.

Changes in conduct of the study or planned analyses

The following analyses were planned and produced after the finalization of the SAP dated 10 May 2023 and post-database lock.

TLF	Title	Reason for change or addition
Table	Summary of Dose-Limiting Toxicities as per Protocol Definition (T-cell Related) by Actual Dose	Post-database lock, an error was found in the reporting of the primary endpoint for the frequency of DLTs. Participant 110014 had an AE of 'Lymphocyte Count Decreased' that was erroneously recorded as DLT in the database. This was confirmed as a transcription error by site. The AE onset was before any study treatment was administered and resolved 1 day following the start of lymphodepletion and prior to T-cell infusion. The AE relationship to study treatment was recorded 'No'. Per the SAP, reported DLTs were to be those collected on the eCRF. Hence an ad hoc analysis was added post-SAP approval to report the number of DLTs as per the protocol definition, which in brief considers a DLT to be: • At least possibly related to transduced T cells; AND • They occur within the DLT-assessment period of 28 days after the initial dosing of T cells. For participants receiving T cells as split dose, DLT assessment period would begin at the start of the first infusion and continue for 28 days after completion of the last infusion. The number of DLTs per the protocol definition also aligned with the DLTs that were agreed by the dose selection committee members.
Table	Summary of Dose-Limiting Toxicities as per Protocol Definition (T-cell Related) by Actual Dose and Planned Dose	

Summary:

Participant disposition:

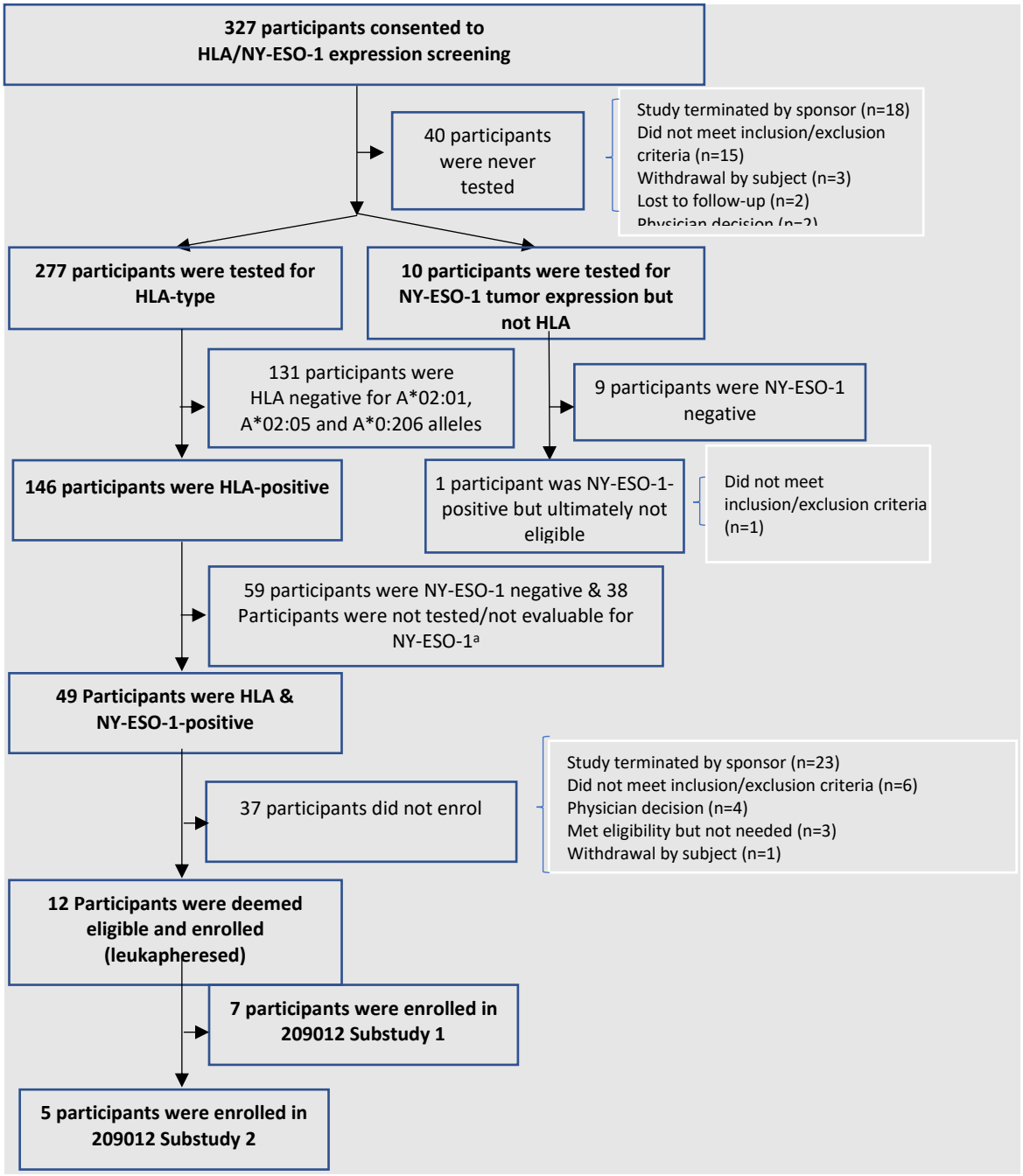
Participants in Substudy 2 were enrolled from 1 center in Germany (N=2), 1 center in Sweden (N=1), and 2 centers in the US (N=2) (Source: Table 1.0180).

A total of 327 participants were screened across all substudies; of whom, 12 participants (4%) were enrolled and 315 (96%) were screen failures. Of the 315 screen failures, 40 participants consented but never initiated HLA/NY-ESO-1 testing, 237 participants were either HLA negative or NY-ESO-1 negative/not evaluable, and 38 participants had other reasons for screen failure (see Figure 3 for details). Of 277 participants tested for HLA type, 146 participants (53%) were found positive for HLA-A*02:01, A*02:05, or A*02:06.

Of 61 participants with SS/MRCLS eligible for NY-ESO-1 tumor expression test, 42 participants (69%) met criterion of 2+ or 3+ in ≥30% of tumor cells. Of 63 participants with NSCLC eligible for NY-ESO-1 tumor expression test, 8 participants (13%) met criterion of 1+, 2+, or 3+ in ≥10% of tumor cells.

Of 12 participants enrolled in the study, 5 participants entered Substudy 2 (Figure 4). Of these 5 participants, 4 participants were treated with GSK3845097 and therefore included in the mITT population; 1 participant underwent leukapheresis but did not initiate treatment because the study was closed based on protocol stopping provisions. Two of the 4 participants treated with GSK3845097 died during the study and the other 2 participants were transferred to the LTFU study 208750 after confirmed disease progression.

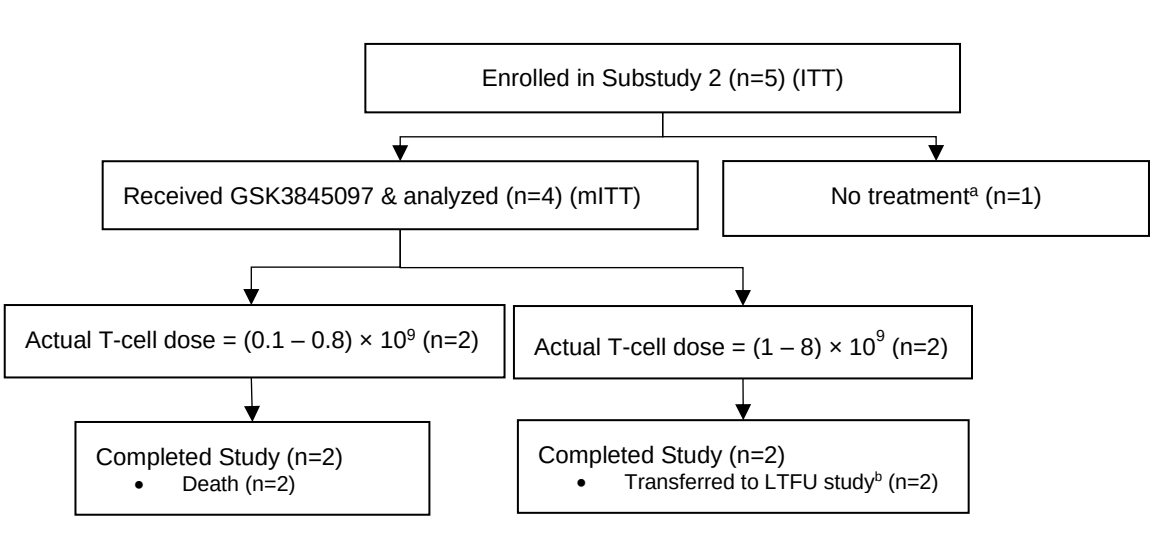
Figure 3 Participant Disposition up to Enrolment



Source: Table 1.0130.

HLA=human leukocyte antigen; NY-ESO-1=New York esophageal antigen-1.
a After the database lock, the NY-ESO-1 expression assay vendor informed the study team that Participant 110017 was erroneously considered NY-ESO-1 negative when the participant's sample should have been reported as not evaluable due to lack of available tumor cells. A new corrected result report was issued. This figure presents the corrected data.
Data as of 12 May 2023.

Figure 4 Participant Disposition Post Enrolment



Source: Table 1.0100, Table 1.0170.
LTFU=long-term follow-up; mITT=Modified Intent-to-Treat.
a One participant underwent leukapheresis but did not initiate treatment because the study was closed based on protocol stopping provisions.
b Two participants had disease progression.
Data as of 12 May 2023.

Protocol deviations:

A listing of important protocol deviations by actual dose for the mITT Population is presented in Table 1. Important protocol deviations were reported for 3 participants ("study treatment not administered per protocol", "incomplete assessment", "missed assessment", and "informed consent/assent not signed and/or dated by the participant or legal representative", each in 1 participant).

Table 1 Important Protocol Deviations by Actual Dose

Participant ID	Protocol Deviation	Impact on Participant Eligibility	Impact on Primary Endpoint
110454[a]	Study treatment not administered per protocol: the site did a renal adjustment of 20 mg/m^2 of fludarabine, instead of 30 mg/m^2.	None	None
110014	Incomplete assessment: vital sign assessment not completed	None	None
	Missed assessment: central lab assessments were not performed at Weeks 3 and 4.	None	None
110762	Informed consent/assent not signed and/or dated by the participant or legal representative: the site did	None	None

Participant ID	Protocol Deviation	Impact on Participant Eligibility	Impact on Primary Endpoint
	not offer the optional genetic ICF to the participant so the participant could not sign the optional genetic ICF.		

Source: Listing 3.
ICF=informed consent form.
Data as of 12 May 2023.

a. Study treatment refers to lymphodepleting chemotherapy component. While fludarabine was administered at 20 mg/m^2 instead of 30 mg/m^2, T-cell dose was administered as intended.

One participant had a non-important protocol deviation of missed assessments due to the COVID-19 pandemic (Source: Listing 4). There was no impact of COVID-19 on the integrity of the study and reliability of the conclusions.

Demographics and baseline characteristics:

A summary of demographics characteristics by actual dose for the mITT Population is presented in Table 2. The age of the 4 participants was 53, 67, 27, and 31 years. All 4 participants were male and Not Hispanic or Latino. Three participants (75%) were White and 1 participant (25%) was Black or African American.

Table 2 Summary of Demographic Characteristics by Actual Dose (mITT Population)

	Dose Confirmation Phase		
	GSK3845097 (1-8) × 10^9 (N=2)	GSK3845097 (0.1-0.8) × 10^9 (N=2)	Total (N=4)
Sex, n (%)			
Female	0	0	0
Male	2 (100%)	2 (100%)	4 (100%)
Age (Years)[a]			
Mean (SD)	29.0 (2.83)	60.0 (9.90)	44.5 (18.86)
Median (Min, Max)	29.0 (27, 31)	60.0 (53, 67)	42.0 (27, 67)
Ethnicity, n (%)			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2 (100%)	2 (100%)	4 (100%)
Race Detail, n (%)			
Black or African American	1 (50%)	0	1 (25%)
White - White/Caucasian/European Heritage	1 (50%)	2 (100%)	3 (75%)
BMI (kg/m^2) at Leukapheresis Eligibility Screening			
Mean (SD)	22.018 (2.1560)	31.021 (1.0205)	26.520 (5.3769)
BSA (m^2) at Leukapheresis Eligibility Screening[b]			

	Dose Confirmation Phase		
	GSK3845097 (1-8) × 10^9 (N=2)	GSK3845097 (0.1-0.8) × 10^9 (N=2)	Total (N=4)
Mean (SD)	1.858 (0.0192)	2.249 (0.1549)	2.054 (0.2433)

Source: Table 1.0220.
BMI=body mass index; BSA=body surface area; Max=maximum; Min=minimum; mITT=Modified Intent-to-Treat; SD=standard deviation.
a. Only year of birth was collected: day and month of birth were imputed to 30 June.
b. BSA was derived using DuBois & Dubois formula.
Note: The reference date for age was GSK3845097 infusion date.
Data as of 12 May 2023.

A summary of disease characteristics at screening by actual dose for the mITT Population is provided in Table 3. Three participants had SS and 1 participant had MRCLS. All 4 participants were positive for at least 1 of 3 of the eligible HLA alleles (A*02:01, A*02:05, A*02:06). Three participants were HLA-A*02:01 positive (heterozygous) and 1 participant was HLA-A*02:01 - A*02:01 positive (homozygous). Three participants had 100% tumor cells positive and 1 participant had 60% tumor cells positive for NY-ESO-1 (2+/3+ per immunohistochemistry). All 4 participants had metastatic Stage IV disease at screening. The median time since diagnosis of metastatic disease to leukapheresis screening was 11.19 (range: 9.1, 14.8) months. One participant (25%) received prior radiotherapy before leukapheresis. Two participants (50%) received radiotherapy between leukapheresis and lymphodepletion. All 4 participants received prior systemic therapy in the advanced (metastatic/unresectable) setting before the start of lymphodepletion (3 participants received 1 prior regimen and 1 participant received 2 prior regimens). Best response to the most recent prior systemic therapy in the metastatic/advanced setting was PD in 1 participant and NE in 1 participant; best response was not recorded for the other 2 participants. One participant received bridging therapy between leukapheresis and lymphodepletion.

Table 3 Summary of Disease Characteristics at Screening by Actual Dose (mITT Population)

	Dose Confirmation Phase		
	GSK3845097 (1-8) × 10^9 (N=2)	GSK3845097 (0.1-0.8) × 10^9 (N=2)	Total (N=4)
Primary Tumor Type, n (%)			
Myxoid/Round Cell Liposarcoma	0	1 (50%)	1 (25%)
Synovial Sarcoma	2 (100%)	1 (50%)	3 (75%)
HLA Status, n (%)			
Positive	2 (100%)	2 (100%)	4 (100%)
One HLA Allele positive			
A*02:01 - other	1 (50%)	2 (100%)	3 (75%)
Two HLA Alleles positive			

	Dose Confirmation Phase		
	GSK3845097 (1-8) × 10^9 (N=2)	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
A*02:01 - A*02:01	1 (50%)	0	1 (25%)
NY-ESO-1 Status, n (%)			
Positive	2 (100%)	2 (100%)	4 (100%)
NY-ESO-1 Expression Score (2+/3+) (%)			
Min.	100	60	60
1st Quartile	100.0	60.0	80.0
Median	100.0	80.0	100.0
3rd Quartile	100.0	100.0	100.0
Max.	100	100	100
Extent of Disease at Screening, n (%)			
Metastatic	2 (100%)	2 (100%)	4 (100%)
Disease Stage at Screening, n (%)			
IV	2 (100%)	2 (100%)	4 (100%)
TNM Staging: Primary Tumor, n (%)			
n	1	2	3
TX	0	1 (50%)	1 (33%)
T3	1 (100%)	1 (50%)	2 (67%)
TNM Staging: Regional Lymph Nodes, n (%)			
n	1	2	3
NX	0	1 (50%)	1 (33%)
N0	1 (100%)	1 (50%)	2 (67%)
TNM Staging: Distant Metastasis, n (%)			
n	1	2	3
M1	1 (100%)	2 (100%)	3 (100%)
Grade at Screening, n (%)			
n	0	1	1
2	0	1 (100%)	1 (100%)
Status of Measurable Disease at Screening, n (%)			
Yes	2 (100%)	2 (100%)	4 (100%)
Non-target Lesions, n (%)			
Yes	1 (50%)	2 (100%)	3 (75%)
No	1 (50%)	0	1 (25%)

	Dose Confirmation Phase		
	GSK3845097 (1-8) × 10^9 (N=2)	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
NY-ESO-1 Tumor Biopsy Site, n (%)			
Primary	1 (50%)	2 (100%)	3 (75%)
Metastatic	1 (50%)	0	1 (25%)
Anatomical Location of Biopsy Site, n (%)			
Bone	1 (50%)	0	1 (25%)
Foot	0	1 (50%)	1 (25%)
Leg	0	1 (50%)	1 (25%)
Other	1 (50%)	0	1 (25%)
Number of Prior Radiotherapy Regimens Before Start of Leukapheresis, n (%)			
0	2 (100%)	1 (50%)	3 (75%)
>1	0	1 (50%)	1 (25%)
Radiotherapy Between Leukapheresis and Lymphodepletion, n (%)			
Yes	0	2 (100%)	2 (50%)
No	2 (100%)	0	2 (50%)
Number of Prior Systemic Therapy Regimens in the Metastatic/Advanced Setting Before Start of Lymphodepletion, n (%)			
1	2 (100%)	1 (50%)	3 (75%)
2	0	1 (50%)	1 (25%)
Best Response to Most Recent Prior Systemic Therapy in the Metastatic/Advanced Setting, n (%)			
n	1	1	2
Complete Response	0	0	0
Partial Response	0	0	0
Stable Disease	0	0	0
Progressive Disease	1 (100%)	0	1 (50%)
Not Evaluable	0	1 (100%)	1 (50%)
Neo-Adjuvant Therapy, n (%)			
Yes	1 (50%)	0	1 (25%)
No	1 (50%)	2 (100%)	3 (75%)
Adjuvant Therapy, n (%)			
No	2 (100%)	2 (100%)	4 (100%)

Source: Table 1.0240.

HLA=human leukocyte antigen; Max=maximum; Min=minimum; mITT=Modified Intent-to-Treat; NY-ESO-1=New York esophageal antigen-1; TNM=tumor, node, and metastasis.

Note: For records with partial dates, "Time since" parameters were not calculated.
Note: For Participants 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For Participant 110014, all "TNM Staging" parameters were unknown.
Note: For Participants 110454 and 110762, the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
Data as of 12 May 2023.

Exposure:

Table 6 shows planned versus actual doses of GSK3845097. Of the 4 treated participants, the first 3 participants were to receive DL1 planned dose of (1 to 8) × 10^9 transduced cells. Per protocol, as 2 (66%) of the first 3 participants treated at DL1 experienced DLTs, the DSC decided to de-escalate the dose for the next set of participants (impacting the fourth participant) to the DL-1 planned dose of (0.1 to 0.8) × 10^9 transduced cells.

A summary of exposure to study treatment by planned dose for the mITT Population is presented in Table 4. All 4 participants received the standard lymphodepletion regimen according to the protocol (including dose reduction provisions):

- Participant 110801 was less than 60 years old and met all criteria to receive the standard lymphodepletion chemotherapy regimen per protocol (Amendment 1) and received:
  - fludarabine 30 mg/m^2 × 4 days and cyclophosphamide 1800 mg/m^2 × 2 days

- Participants 110014 and 110762 were less than 60 years old and met all criteria to receive the updated standard lymphodepletion chemotherapy regimen per protocol (under Protocol Clarification Letter of Protocol Amendment 1 and under Protocol Amendment 3, respectively) and received:
  - fludarabine 30 mg/m^2 × 4 days and cyclophosphamide 900 mg/m^2 × 3 days

- Participant 110454 was more than 60 years old and had intermittent creatinine clearance between 50 and 80 mL/min. Following Protocol Amendment 3 dose reduction guidelines, the participant received:
  - fludarabine 20 mg/m^2 × 3 days and cyclophosphamide 600 mg/m^2 × 3 days.

The median cumulative dose of cyclophosphamide was 2700 mg/m^2 (range: 1800, 3600), and the median cumulative dose of fludarabine was 120 mg/m^2 (range: 60, 120).

Table 4 Summary of Exposure to Study Treatment by Planned Dose (mITT Population)

	Dose Confirmation Phase		
Dose	GSK3845097 DL1 (N=3)	GSK3845097 DL-1 (N=1)	Total (N=4)
Cyclophosphamide Cumulative Dose (mg/m^2)			
Median (Min, Max)	2700.0 (2700, 3600)	1800.0 (1800, 1800)	2700.0 (1800, 3600)
Fludarabine Cumulative Dose (mg/m^2)			
Median (Min, Max)	120.0 (120, 120)	60.0 (60, 60)	120.0 (60, 120)
Actual Transduced Cell Dose Received			
<0.1 (× 10^9 cells)	0	0	0
≥0.1 to ≤0.8 (× 10^9 cells)	1 (33%)	1 (100%)	2 (50%)
>0.8 to <1 (× 10^9 cells)	0	0	0
≥1 to ≤8 (× 10^9 cells)	2 (67%)	0	2 (50%)
>8 (× 10^9 cells)	0	0	0
Median (Min, Max)	1.884 (0.80, 4.90)	0.800 (0.80, 0.80)	1.342 (0.80, 4.90)

Source: Table 3.0340.
Max=maximum; Min=minimum; mITT=Modified Intent-to-Treat.
DL1 planned dose range is (1 to 8) × 10^9 transduced cells;
DL-1 planned dose range is (0.1 to 0.8) × 10^9 transduced cells.
Data as of 12 May 2023.

The first participant (110801) to receive GSK3845097 was a sentinel participant and planned to receive the target GSK3845097 dose at the DL1 dose level to be infused in 2 aliquots (at Day 1 [~30%] and Day 8 [~70%]). However, the participant experienced toxicities that precluded them from receiving the second aliquot. The actual dose received was 0.8×10^9 transduced cells.

Because of the DLT reported for the first sentinel participant, the second participant (110014) was also dosed as a sentinel and received the planned dose of 1.884×10^9 transduced cells in 2 aliquots: 0.746×10^9 transduced cells on Day 1 and 1.138×10^9 transduced cells on Day 8 (Table 5). Because no DLTs were reported for the second sentinel participant, all subsequent participants treated with GSK3845097 received the full planned transduced T cell dose as a single infusion.

Ultimately, 2 participants received GSK3845097 at the dose of (1 to 8) × 10^9 cells and 2 participants at the dose of (0.1 to 0.8) × 10^9 cells. Overall, the median number of transduced T cells was 1.342×10^9 cells (range: 0.80×10^9, 4.90×10^9).

Table 5 Individual Exposure to Study Treatment by Actual Dose (mITT Population)

Participant ID	Transduced T cells (× 10^9)		
	1st Infusion (Day 1)	2nd infusion (Day 8)	Total
110801	0.8	0	0.8
110014[a]	0.746	1.138	1.884
110762	4.9	NA	4.9
110454	0.8	NA	0.8

Source: Listing 15.
mITT=Modified Intent-to-Treat; NA=not applicable.
Note: Participants 110801 and 110014 were sentinel participants to receive split doses.
a This participant received a non-conforming batch.
Data as of 12 May 2023.

Concomitant medications

A summary of concomitant medications by actual dose for the mITT Population is presented in Table 1.0270. All 4 participants received concomitant medications during the study. Overall, the most common concomitant medications (received by >50% of participants) were dexamethasone, fluconazole, G-CSF, magnesium sulfate, ondansetron, paracetamol, and tocilizumab (each reported in 3 participants [75%]).

Safety results:

Dose-limiting toxicities:

DLTs were reported in all 4 participants; however, 1 participant (110014) had a non-serious Grade 3 AE of lymphocyte count decreased prior to treatment (Day -17) indicated as unrelated to study treatment, which was erroneously recorded as a DLT due to a transcription error at site. This AE does not fulfil the DLT definition given in the protocol (Source: Listing 19).

Three out of 4 (75%) participants had reported T-cell related events that met protocol defined DLT criteria and were endorsed by the DSC (Source: Table 3.0101 and Table 6).

The following DLTs were reported: 1 participant (110801) had ALT increased (onset 8 days, duration 72 days, nonserious, Grade 3, related to T-cell infusion, resolved); 1 participant (110762) had ICANS (onset 3 days, duration 5 days, serious, Grade 4, related to T cell infusion, resolved); and 1 participant (110454) had GVHD in skin (onset 18 days, serious, Grade 3, related to T-cell infusion, not resolved), GVHD in gastrointestinal tract (onset 19 days, serious, Grade 3, related to T-cell infusion, not resolved), hemophagocytic lymphohistiocytosis (onset 37 days, serious, Grade 4, related to T-cell infusion, not resolved), and systemic inflammatory response syndrome (onset 39 days, duration 1 day, serious, Grade 5, related to T-cell infusion, fatal) (Source: Listing 19).

Table 6 Summary of Dose-Limiting Toxicities Per Protocol Definition (T-cell Related) by Actual Dose and Planned Dose (DLT Evaluable Population)

GSK3845097		Planned Dose		
	Actual Dose	DL1 (N=3)	DL-1 (N=1)	Total (N=4)
n [No. of Participants with DLT]	(1-8) × 10^9 (N=2)	2[a] [1]	0 [0]	2 [1]
	(0.1-0.8) × 10^9 (N=2)	1[b] [1]	1 [1]	2 [2]

Source: Table 3.0106.
AE=adverse event; DL1=(1-8) × 10^9 T-cells; DL-1=(0.1-0.8) × 10^9 T-cells; DLT=dose-limiting toxicity; eCRF=electronic case report form.
a. One participant (110014) had a non-serious Grade 3 AE of lymphocyte count decreased prior to treatment (Day -17) indicated as unrelated to study treatment, which was erroneously recorded as a DLT due to a transcription error at site. This AE resolved prior to the start of lymphodepletion, does not fulfil the DLT definition given in the protocol and therefore is not counted here.
b. The sentinel participant 110801 in DL1 (planned dose level 1-8 × 10^9) did not receive the second dose of T cells on Day 8; participant 110801 only received total of 0.8 × 10^9 transduced T cells and is consequently summarized under actual dose level (0.1-0.8) × 10^9.
Note: DLTs assigned where "Is this event a DLT" was "Yes" and based on timing and relatedness per the protocol definition.
Data as of 12 May 2023.

Adverse events (pretreatment, before T-cell infusion):

The pre-lymphodepletion phase includes AEs that started before the first day of lymphodepletion chemotherapy. During the pre-lymphodepletion phase (ITT Population), 4 of 5 enrolled participants (80%) had at least 1 AE (Source: Table 3.0120). None of these AEs were considered related to study procedure. Two participants had SAEs and Grade 3 AEs, which were considered not related to study procedure (Source: Listing 20).

The lymphodepletion phase includes AEs that started or worsened on or after the start of lymphodepletion and before T-cell infusion. During the lymphodepletion phase (Lymphodepletion Population), 3 of 4 treated participants (75%) had at least 1 AE (Source: Table 3.0130). Two participants had Grade ≥3 AEs; no SAE was reported (Source: Listing 20).

Treatment-emergent adverse events:

AEs that started or worsened on or after T-cell infusion were classified as TEAEs. A summary of TEAEs by actual dose is presented in Table 7. All 4 participants had TEAEs. Overall, the most common TEAEs occurring in >50% of participants were ALT increased, anemia/RBC count decreased, AST increased, CRS, and thrombocytopenia/platelet count decreased (100% each) and neutropenia/neutrophil count decreased (75%).

Table 7 Summary of TEAEs by Actual Dose (mITT Population)

	Dose Confirmation Phase		
Preferred Term, n (%)	**GSK3845097 (1-8) × 10^9 (N=2)**	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
Any TEAE	**2 (100%)**	**2 (100%)**	**4 (100%)**
Alanine aminotransferase increased	2 (100%)	2 (100%)	4 (100%)
Anaemia/Red blood cell count decreased	2 (100%)	2 (100%)	4 (100%)
Aspartate aminotransferase increased	2 (100%)	2 (100%)	4 (100%)
Cytokine release syndrome	2 (100%)	2 (100%)	4 (100%)
Thrombocytopenia/Platelet count decreased	2 (100%)	2 (100%)	4 (100%)
Neutropenia/Neutrophil count decreased	1 (50%)	2 (100%)	3 (75%)
Febrile neutropenia	1 (50%)	1 (50%)	2 (50%)
Hyponatraemia	2 (100%)	0	2 (50%)
Hypophosphataemia	2 (100%)	0	2 (50%)
Immune effector cell-associated neurotoxicity syndrome	1 (50%)	1 (50%)	2 (50%)
Leukopenia/White blood cell decreased	1 (50%)	1 (50%)	2 (50%)
Pancytopenia	1 (50%)	1 (50%)	2 (50%)
Pyrexia	1 (50%)	1 (50%)	2 (50%)
Unspecified GVHD - gut (liver and intestine)	1 (50%)	1 (50%)	2 (50%)
Unspecified GVHD - skin	1 (50%)	1 (50%)	2 (50%)
Anxiety	1 (50%)	0	1 (25%)
Aplastic anaemia	1 (50%)	0	1 (25%)
Blood alkaline phosphatase increased	1 (50%)	0	1 (25%)
Blood creatinine increased	0	1 (50%)	1 (25%)
Blood glucose increased	0	1 (50%)	1 (25%)
Blood lactate dehydrogenase increased	1 (50%)	0	1 (25%)
Blood sodium increased	0	1 (50%)	1 (25%)
Blood urea increased	0	1 (50%)	1 (25%)
Chest pain	0	1 (50%)	1 (25%)
Cough	1 (50%)	0	1 (25%)
COVID-19 pneumonia	1 (50%)	0	1 (25%)
C-reactive protein increased	0	1 (50%)	1 (25%)
Decreased appetite	1 (50%)	0	1 (25%)
Diarrhoea	1 (50%)	0	1 (25%)
Dyspnoea	0	1 (50%)	1 (25%)

	Dose Confirmation Phase		
Preferred Term, n (%)	**GSK3845097 (1-8) × 10^9 (N=2)**	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
Dysuria	1 (50%)	0	1 (25%)
Fatigue	1 (50%)	0	1 (25%)
Haematocrit decreased	0	1 (50%)	1 (25%)
Haemoglobin decreased	0	1 (50%)	1 (25%)
Haemophagocytic lymphohistiocytosis	0	1 (50%)	1 (25%)
Herpes zoster	1 (50%)	0	1 (25%)
Hyperbilirubinaemia	1 (50%)	0	1 (25%)
Hypoaesthesia	1 (50%)	0	1 (25%)
Hypokalaemia	0	1 (50%)	1 (25%)
Interleukin level increased	0	1 (50%)	1 (25%)
International normalised ratio increased	1 (50%)	0	1 (25%)
Lymphoedema	1 (50%)	0	1 (25%)
Mucosal inflammation	1 (50%)	0	1 (25%)
Muscular weakness	0	1 (50%)	1 (25%)
Pericardial effusion	0	1 (50%)	1 (25%)
Pneumonia	1 (50%)	0	1 (25%)
Procalcitonin increased	0	1 (50%)	1 (25%)
Protein total decreased	0	1 (50%)	1 (25%)
Pulmonary embolism	0	1 (50%)	1 (25%)
Respiratory failure	0	1 (50%)	1 (25%)
Rash/Rash maculo-papular	1 (50%)	0	1 (25%)
Staphylococcal bacteraemia	1 (50%)	0	1 (25%)
Stomatitis	0	1 (50%)	1 (25%)
Supraventricular tachycardia	0	1 (50%)	1 (25%)
Syncope	0	1 (50%)	1 (25%)
Systemic inflammatory response syndrome	0	1 (50%)	1 (25%)
Tachycardia	1 (50%)	0	1 (25%)
Vomiting	0	1 (50%)	1 (25%)

Source: Table 3.0150.
COVID-19=coronavirus disease 2019; GVHD=graft versus host disease; mITT=Modified Intent-to-Treat; TEAE=treatment-emergent adverse event.
Note: Adverse events which started or worsened on or after T-cell infusion were classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
Data as of 12 May 2023.

Grade ≥3 treatment-emergent adverse events:

All 4 participants experienced at least 1 Grade ≥3 TEAE (Table 8). The most common Grade ≥3 TEAEs, occurring in >50% of participants, were anemia/RBC count decreased and thrombocytopenia/platelet count decreased (100% each) and neutropenia/neutrophil count decreased (75%).

The following Grade 4 TEAEs were reported: thrombocytopenia/platelet count decreased (100%); neutropenia/neutrophil count decreased (75%); leukopenia/WBC decreased and pancytopenia (50% each); and anemia/RBC count decreased, ICANS, aplastic anemia, and hemophagocytic lymphohistiocytosis (25% each) (Source: Table 3.0150).

The following Grade 5 TEAEs were reported: respiratory failure and systemic inflammatory response syndrome (25% each) (Source: Table 3.0150).

Table 8 Grade ≥3 TEAEs by Actual Dose (mITT Population)

	Dose Confirmation Phase		
Preferred Term, n (%)	**GSK3845097 (1-8) × 10^9 (N=2)**	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
Any Grade ≥3 TEAE	**2 (100%)**	**2 (100%)**	**4 (100%)**
Anaemia/Red blood cell count decreased	2 (100%)	2 (100%)	4 (100%)
Thrombocytopenia/Platelet count decreased	2 (100%)	2 (100%)	4 (100%)
Neutropenia/Neutrophil count decreased	1 (50%)	2 (100%)	3 (75%)
Alanine aminotransferase increased	1 (50%)	1 (50%)	2 (50%)
Febrile neutropenia	1 (50%)	1 (50%)	2 (50%)
Leukopenia/White blood cell decreased	1 (50%)	1 (50%)	2 (50%)
Pancytopenia	1 (50%)	1 (50%)	2 (50%)
Aspartate aminotransferase increased	0	1 (50%)	1 (25%)
Immune effector cell-associated neurotoxicity syndrome	1 (50%)	0	1 (25%)
Unspecified GVHD - gut (liver and intestine)	0	1 (50%)	1 (25%)
Unspecified GVHD - skin	0	1 (50%)	1 (25%)
Aplastic anaemia	1 (50%)	0	1 (25%)
Blood creatinine increased	0	1 (50%)	1 (25%)
Blood glucose increased	0	1 (50%)	1 (25%)
Blood urea increased	0	1 (50%)	1 (25%)
C-reactive protein increased	0	1 (50%)	1 (25%)
COVID-19 pneumonia	1 (50%)	0	1 (25%)
Dyspnoea	0	1 (50%)	1 (25%)
Haematocrit decreased	0	1 (50%)	1 (25%)

	Dose Confirmation Phase		
Preferred Term, n (%)	**GSK3845097 (1-8) × 10^9 (N=2)**	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
Haemoglobin decreased	0	1 (50%)	1 (25%)
Haemophagocytic lymphohistiocytosis	0	1 (50%)	1 (25%)
Herpes zoster	1 (50%)	0	1 (25%)
Procalcitonin increased	0	1 (50%)	1 (25%)
Protein total decreased	0	1 (50%)	1 (25%)
Pulmonary embolism	0	1 (50%)	1 (25%)
Respiratory failure	0	1 (50%)	1 (25%)
Syncope	0	1 (50%)	1 (25%)
Systemic inflammatory response syndrome	0	1 (50%)	1 (25%)

Source: Table 3.0150.
COVID-19=coronavirus disease 2019; GVHD=graft versus host disease; mITT=Modified Intent-to-Treat; TEAE=treatment-emergent adverse event.
Note: Adverse events which started or worsened on or after T-cell infusion were classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
Data as of 12 May 2023.

Treatment-emergent adverse events related to T-cell infusion:

All 4 participants had at least 1 TEAE related to T-cell infusion (Table 9). The most common T-cell infusion-related TEAE, occurring in >50% of participants, were ALT increased and CRS (100% each) and anemia/RBC count decreased, AST increased, neutropenia/neutrophil count decreased, and thrombocytopenia/platelet count decreased (75% each).

Table 9 Treatment-Emergent T-cell-Related Adverse Events by Actual Dose (mITT Population)

	Dose Confirmation Phase		
Preferred Term, n (%)	**GSK3845097 (1-8) × 10^9 (N=2)**	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
Any T-cell-Related TEAE	**2 (100%)**	**2 (100%)**	**4 (100%)**
Alanine aminotransferase increased	2 (100%)	2 (100%)	4 (100%)
Cytokine release syndrome	2 (100%)	2 (100%)	4 (100%)
Anaemia/Red blood cell count decreased	1 (50%)	2 (100%)	3 (75%)
Aspartate aminotransferase increased	1 (50%)	2 (100%)	3 (75%)
Neutropenia/Neutrophil count decreased	1 (50%)	2 (100%)	3 (75%)
Thrombocytopenia/Platelet count decreased	1 (50%)	2 (100%)	3 (75%)
Febrile neutropenia	1 (50%)	1 (50%)	2 (50%)

	Dose Confirmation Phase		
Preferred Term, n (%)	**GSK3845097 (1-8) × 10^9 (N=2)**	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
Immune effector cell-associated neurotoxicity syndrome	1 (50%)	1 (50%)	2 (50%)
Leukopenia/White blood cell decreased	1 (50%)	1 (50%)	2 (50%)
Pancytopenia	1 (50%)	1 (50%)	2 (50%)
Unspecified GVHD - gut (liver and intestine)	1 (50%)	1 (50%)	2 (50%)
Unspecified GVHD - skin	1 (50%)	1 (50%)	2 (50%)
Anxiety	1 (50%)	0	1 (25%)
Aplastic anaemia	1 (50%)	0	1 (25%)
Blood alkaline phosphatase increased	1 (50%)	0	1 (25%)
Blood creatinine increased	0	1 (50%)	1 (25%)
Blood urea increased	0	1 (50%)	1 (25%)
C-reactive protein increased	0	1 (50%)	1 (25%)
COVID-19 pneumonia	1 (50%)	0	1 (25%)
Cough	1 (50%)	0	1 (25%)
Dyspnoea	0	1 (50%)	1 (25%)
Fatigue	1 (50%)	0	1 (25%)
Haematocrit decreased	0	1 (50%)	1 (25%)
Haemoglobin decreased	0	1 (50%)	1 (25%)
Haemophagocytic lymphohistiocytosis	0	1 (50%)	1 (25%)
Hyperbilirubinaemia	1 (50%)	0	1 (25%)
Interleukin level increased	0	1 (50%)	1 (25%)
Mucosal inflammation	1 (50%)	0	1 (25%)
Muscular weakness	0	1 (50%)	1 (25%)
Pericardial effusion	0	1 (50%)	1 (25%)
Procalcitonin increased	0	1 (50%)	1 (25%)
Protein total decreased	0	1 (50%)	1 (25%)
Pyrexia	0	1 (50%)	1 (25%)
Rash/Rash maculo-papular	1 (50%)	0	1 (25%)
Stomatitis	0	1 (50%)	1 (25%)
Supraventricular tachycardia	0	1 (50%)	1 (25%)
Systemic inflammatory response syndrome	0	1 (50%)	1 (25%)

Source: Table 3.0160.

AE=adverse event; COVID-19=coronavirus disease 2019; GVHD=graft versus host disease; mITT=Modified Intent-to-Treat; TEAE=treatment-emergent adverse event.

Note: Adverse events which started or worsened on or after T-cell infusion were classified as treatment emergent.

Note: T-cell related AEs were defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
Data as of 12 May 2023.

T-cell infusion-related Grade ≥3 TEAEs occurred in 3 participants (75%). The following T-cell infusion-related Grade ≥3 TEAEs were reported: anemia/RBC count decreased and thrombocytopenia/platelet count decreased (75% each); ALT increased, neutropenia/neutrophil count decreased, febrile neutropenia, leukopenia/WBC decreased, and pancytopenia (50% each); and AST increased, ICANS, unspecified GVHD - gut (liver and intestine), unspecified GVHD – skin, aplastic anemia, blood creatinine increased, Blood urea increased, CRP increased, COVID-19 pneumonia, dyspnea, hematocrit decreased, hemoglobin decreased, hemophagocytic lymphohistiocytosis, procalcitonin increased, protein total decreased, and systemic inflammatory response syndrome (25% each). The event of systemic inflammatory response syndrome led to death (Source: Table 3.0160).

Treatment-emergent adverse events related to lymphodepletion:

Listed TEAEs related to lymphodepletion in this section may have also been reported as related to GSK3845097 T-cell infusion in the prior section. Three of 4 participants (75%) had at least 1 TEAE related to lymphodepletion (Source: Table 3.0170). The most common lymphodepletion-related TEAEs, occurring in >50% of participants, were anemia/RBC count decreased and thrombocytopenia/platelet count decreased (75% each).

Lymphodepletion-related Grade ≥3 TEAEs occurred in 3 participants (75%). The following lymphodepletion-related Grade ≥3 TEAEs were reported: anemia/RBC decreased and thrombocytopenia/platelet count decreased (75% each); neutropenia/neutrophil count decreased (50%); and leukopenia/WBC decreased and pancytopenia (25% each). No lymphodepletion-related deaths were reported (Source: Table 3.0170).

Deaths

Of the 4 participants, 2 participants (50%) died and 2 participants (50%) were alive at the last contact in this study and follow-up was ended in this study (Table 10).

The primary cause of death was hemorrhage in the right lung secondary to pulmonary embolism and disease under study in Participant 110801. The participant had developed a Grade 5 SAE of respiratory failure. The time from T-cell infusion to death was 94 days. The SAE of respiratory failure had an onset of 93 days after T-cell infusion. This event was considered not related to GSK3845097 (Source: Listing 39).

The primary cause of death was systemic inflammatory response syndrome (Grade 5 SAE) in Participant 110454. The time from T-cell infusion to death was 39 days. This event was considered related to GSK3845097 (Source: Listing 39).

Table 10 Summary of Deaths by Actual Dose (mITT Population)

	Dose Confirmation Phase		
	GSK3845097 (1-8) × 10^9 (N=2)	GSK3845097 (0.1-0.8) × 10^9 (N=2)	Total (N=4)
Subject Status, n (%)			
Dead	0	2 (100%)	2 (50%)
Alive at last contact, follow-up ended	2 (100%)	0	2 (50%)
Primary Cause of Death, n (%)			
Haemorrhage	0	1 (50%)	1 (25%)
Other Non-Cardiovascular Cause[a]	0	1 (50%)	1 (25%)
Time since T-cell infusion to Death, n (%)			
>30 days	0	2 (100%)	2 (50%)

Source: Table 3.0330.
AE=adverse event; mITT=Modified Intent-to-Treat.
a Participant 110454: primary cause of death was "systemic inflammatory response syndrome".
Data as of 12 May 2023.

Serious adverse events:

No SAEs were reported in the lymphodepletion phase (Source: Table 3.0200).

Treatment-emergent SAEs occurred in 3 participants (75%) (Table 11); Participant 110014 did not experience any treatment-emergent SAE. Treatment-emergent SAEs of febrile neutropenia were reported in 2 participants; all other SAEs occurred in 1 participant.

Table 11 Treatment Emergent Serious Adverse Events by Actual Dose (mITT Population)

	Dose Confirmation Phase		
Preferred Term, n (%)	GSK3845097 (1-8) × 10^9 (N=2)	GSK3845097 (0.1-0.8) × 10^9 (N=2)	Total (N=4)
Any Serious TEAE	**1 (50%)**	**2 (100%)**	**3 (75%)**
Febrile neutropenia	1 (50%)	1 (50%)	2 (50%)
Alanine aminotransferase increased	1 (50%)	0	1 (25%)
Aplastic anaemia	1 (50%)	0	1 (25%)
COVID-19 pneumonia	1 (50%)	0	1 (25%)
Haemophagocytic lymphohistiocytosis	0	1 (50%)	1 (25%)
Herpes zoster	1 (50%)	0	1 (25%)
Hyperbilirubinaemia	1 (50%)	0	1 (25%)

	Dose Confirmation Phase		
Preferred Term, n (%)	**GSK3845097 (1-8) × 10^9 (N=2)**	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
Immune effector cell-associated neurotoxicity syndrome	1 (50%)	0	1 (25%)
International normalised ratio increased	1 (50%)	0	1 (25%)
Pancytopenia	1 (50%)	0	1 (25%)
Pulmonary embolism	0	1 (50%)	1 (25%)
Pyrexia	1 (50%)	0	1 (25%)
Respiratory failure	0	1 (50%)	1 (25%)
Systemic inflammatory response syndrome	0	1 (50%)	1 (25%)
Thrombocytopenia/Platelet count decreased	0	1 (50%)	1 (25%)
Unspecified GVHD - gut (liver and intestine)	0	1 (50%)	1 (25%)
Unspecified GVHD - skin	0	1 (50%)	1 (25%)

Source: Table 3.0220.
COVID-19=coronavirus disease 2019; GVHD=graft versus host disease; mITT=Modified Intent-to-Treat; TEAE=treatment-emergent adverse event.
Note: Adverse events which started or worsened on or after T-cell infusion were classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
Data as of 12 May 2023.

All treatment-emergent SAEs were Grade ≥3, except INR increased and hyperbilirubinemia (Grade 2) and pyrexia (Grade 1). Two SAEs were fatal: respiratory failure and systemic inflammatory response syndrome (Source: Table 3.0220).

The following treatment-emergent SAEs were considered related to T-cell infusion: febrile neutropenia (50%), ALT increased, aplastic anemia, COVID-19 pneumonia, hemophagocytic lymphohistiocytosis, hyperbilirubinemia, ICANS, pancytopenia, systemic inflammatory response syndrome, thrombocytopenia/platelet count decreased, unspecified GVHD - gut (liver and intestine), and unspecified GVHD – skin (25% each) (Source: Table 3.0230).

Adverse events of special interest:

The AESIs included CRS, hematopoietic cytopenias (including pancytopenia and aplastic anemia), GVHD, ICANS, Guillain-Barre syndrome, pneumonitis, treatment-related inflammatory response at tumor site(s), and neutropenia Grade 4 lasting ≥28 days.

A focused list of MedDRA terms based on clinical review was used to identify each type of event. In addition, a focused and comprehensive list of MedDRA terms aligning with MedDRA SMQ list was also used for AESI reporting. Treatment-related inflammatory response at tumor site was not identified using the focused or comprehensive list. Treatment-related inflammatory response was reported as per investigator's assessment.

The following AESIs were reported: CRS (100% of patients), hematopoietic cytopenias (100%), GVHD (50%), and ICANS (50%) (Table 12). These AESIs are described in

detail below. No AESIs were reported for Guillain-Barre syndrome, treatment-related inflammatory response at tumor site(s), pneumonitis, and neutropenia Grade 4 lasting ≥28 days.

Table 12 Summary of Treatment-Emergent Adverse Events of Special Interest by Actual Dose (Focused List; mITT Population)

	Dose Confirmation Phase		
AESI Category Adverse Event, n (%)	**GSK3845097 (1-8) × 10^9 (N=2)**	**GSK3845097 (0.1-0.8) × 10^9 (N=2)**	**Total (N=4)**
Any event	2 (100%)	2 (100%)	4 (100%)
Cytokine release syndrome			
Any Event	2 (100%)	2 (100%)	4 (100%)
Cytokine Release Syndrome (CRS)	2 (100%)	2 (100%)	4 (100%)
Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)			
Any Event	2 (100%)	2 (100%)	4 (100%)
Anaemia/Red blood cell count decreased	2 (100%)	2 (100%)	4 (100%)
Thrombocytopenia/Platelet count decreased	2 (100%)	2 (100%)	4 (100%)
Neutropenia/Neutrophil count decreased	1 (50%)	2 (100%)	3 (75%)
Febrile neutropenia	1 (50%)	1 (50%)	2 (50%)
Leukopenia/White blood cell decreased	1 (50%)	1 (50%)	2 (50%)
Pancytopenia	1 (50%)	1 (50%)	2 (50%)
Aplastic anaemia	1 (50%)	0	1 (25%)
Haematocrit decreased	0	1 (50%)	1 (25%)
Haemoglobin decreased	0	1 (50%)	1 (25%)
Graft versus host disease (GVHD)			
Any Event	1 (50%)	1 (50%)	2 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	1 (50%)	1 (50%)	2 (50%)
Unspecified GVHD - Skin	1 (50%)	1 (50%)	2 (50%)
Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)			
Any Event	1 (50%)	1 (50%)	2 (50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	1 (50%)	1 (50%)	2 (50%)

Source: Table 3.0250.
AESI=adverse event of special interest; mITT=Modified Intent-to-Treat.
Note: Adverse events which started or worsened on or after T-cell infusion were classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
Data as of 12 May 2023.

All 4 treated participants had CRS (total 4 events) after GSK3845097 infusion. All events were considered related to T-cell infusion. No participant had an SAE of CRS.

Three participants had Grade 2 CRS and 1 participant had Grade 1 CRS. CRS resolved in all 4 participants. Three participants required treatment with tocilizumab; 1 of these 3 participants also received steroids (dexamethasone) (Source: Listing 26). The median time to onset of CRS was 1.5 days (range: 1, 2), and the median duration of CRS was 4.5 days (range: 3, 10) (Source: Table 3.0260).

All 4 treated participants had hematopoietic cytopenias after GSK3845097 infusion. The following hematopoietic cytopenias were reported: anemia/RBC count decreased and thrombocytopenia/platelet count decreased (100% each); neutropenia/neutrophil count decreased (75%);, leukopenia/WBC decreased, and pancytopenia (50% each); and aplastic anemia, hematocrit decreased, and hemoglobin decreased (25% each) and febrile neutropenia (50%) (Table 12). All these events were of maximum Grade 3 or 4 (Source: Table 3.0250). All these events resolved except pancytopenia in Participant 110454 and thrombocytopenia in Participant 110454, which did not resolve. The following events were considered related to T cells: pancytopenia and thrombocytopenia (Participant 110454); anemia and neutrophil count decreased (Participant 110801); and pancytopenia, aplastic anemia, and febrile neutropenia (Participant 110762). The following events were considered serious: thrombocytopenia (Participant 110454) and pancytopenia, aplastic anemia, and febrile neutropenia (Participant 110762). Participant 110801 who experienced platelet count decreased, neutrophil count decreased, and anemia required antimicrobial prophylaxis/therapy and high-dose corticosteroids. The time to onset of hematopoietic cytopenias ranged from 2 to 36 days and the duration of hematopoietic cytopenias ranged from 2 to 135 days (Source: Listing 20, Listing 28).

All 4 (100%) participants had a lymphodepletion-emergent or treatment-emergent pancytopenia:

- Participant 110454 had a nonserious pancytopenia that started on Day 18 with a maximum severity of Grade 4 that did not resolve (G-CSF reinitiated, immunosuppressant therapy not given);
- Participant 110762 had a serious pancytopenia that started on Day 11 with a maximum severity of Grade 4 that resolved after 27 days (G-CSF reinitiated, immunosuppressant therapy not given). This participant also had a serious aplastic anemia that started on Day 22 with a maximum severity of Grade 4 that resolved after 16 days and a serious febrile neutropenia that started on Day 25 with a maximum severity of Grade 3 that resolved after 3 days (G-CSF reinitiated, immunosuppressant therapy not given for both events);
- Participant 110014 had a nonserious pancytopenia with started on Day 1 with a maximum severity of Grade 4 that resolved after 23 days (G-CSF or immunosuppressant therapy not given);
- Participant 110801 had a nonserious pancytopenia that started on Day 2 with intermittent neutropenia/neutrophil count decreased of maximum severity of Grade 4 and thrombocytopenia/platelet count decreased of maximum severity of Grade 4 that resolved respectively after 35 and 65 days and intermittent anemia/RBC count decreased of maximum severity of Grade 3 from Day 4 until Day 76 (G-CSF

reinitiated, antimicrobial prophylaxis/therapy and high-dose corticosteroids were given).

Three participants (75%) had persistent cytopenia (neutropenia, thrombocytopenia, anemia) beyond 28 days post T-cell infusion (Week 5) based on the laboratory results. Persistent cytopenias resolved after 1 to 2 months in 2 of these 3 participants and did not resolve in 1 participant as this participant died due to systemic inflammatory response syndrome (see the narrative for Participant 110454 for more details) (Source: Listing 51).

Two participants (50%) had GVHD after GSK3845097 infusion. Participant 110454 had serious, Grade 3, T-cell related GVHD in skin and gastrointestinal tract with an onset of 18 days post-T-cell infusion for skin and 19 days post-T-cell infusion for gastrointestinal tract; the participant received both topical and systemic corticosteroids and ruxolitinib and the events had not resolved at time of death. Participant 110762 had non-serious, Grade 2, T-cell related GVHD in liver and skin with an onset of 20 days post-T-cell infusion; the patient received topical corticosteroids and the events resolved with sequelae 40 days after onset (Source: Listing 29).

Two participants (50%) had ICANS after GSK3845097 infusion. Participant 110454 had non-serious, Grade 1, T-cell related ICANS with an onset of 3 days post-T-cell infusion; the event resolved 2 days after onset. Participant 110762 had serious, Grade 4, T-cell related ICANS with an onset of 3 days post-T-cell infusion; the event was treated with IV dexamethasone from Days 3 to 7 and the event resolved 5 days after onset. Of note, Participant 110762 received levetiracetam from Days -1 to 37 (Source: Listing 27).

Clinical laboratory evaluations:

Listing of all laboratory data by actual dose for the ITT Population is provided in Listing 33. Plots of hemoglobin, neutrophils, and platelets over time for individual participants in the mITT Population are provided in Figure 3.0360. Worst case post-baseline of Grade 3 was observed for the following clinical chemistry parameters: AST increased (2 participants), ALT increased (2 participants), low albumin (1 participant), high magnesium (1 participant), and high sodium (1 participant). Worst-case post-baseline of Grade 3 or 4 was observed for the following hematology parameters: low hemoglobin (4 participants), low leukocytes (4 participants), low lymphocytes (4 participants), low neutrophils (4 participants), and low platelets (4 participants).

Listing of urinalysis data by actual dose for the ITT Population is provided in Listing 34.

Participants meeting hepatobiliary laboratory criteria post-baseline by actual dose for the mITT Population are listed in Listing 35.

Three participants had liver events: 1 participant (110014) met liver monitoring criteria level 1; 1 participant (110762) met liver monitoring criteria level 2, and 1 participant (110801) met liver stopping criteria. None of these 3 participants met Hy's law criteria. Narratives of these participants are provided in the CASE NARRATIVES section. The liver monitoring level 2 profile of Participant 110762 is provided in Listing 36. The liver stopping event profile of Participant 110801 is provided in Listing 37. Liver

monitoring/stopping event reporting details for Participants 110801, 110014, and 110762 are provided in Listing 38.

Vital signs:

Listing of all vital signs by actual dose for the ITT Population is provided in Listing 43. All clinically significant high or low values for blood pressure, temperature, and heart rate are in line with reported AEs or SAEs.

ECOG PS:

All 4 treated participants had ECOG PS of 0 (indicating full activity) or 1 (restricted in strenuous activity) at baseline (pre-lymphodepletion). ECOG PS worsened post-baseline to 2 (restricted in work activity but ambulatory and capable of self-care) in 2 participants (Listing 40).

Electrocardiogram

No clinically significant ECG findings were noted for any participant during the study (Source: Listing 42).

Worst-case post-baseline of QTcB interval ≥450 msec was reported for 2 participants: Participant 110454 had QTcB interval of 456 msec at Day 1 and Participant 110762 had QTcB interval of 455 msec at Day 1. No participant had an increase in QTcB interval >501 msec. QRS was low (<70 msec) for Participant 110454 on Day 1 (Source: Listing 41).

Replication competent lentivirus:

Of 3 participants tested for RCL post-baseline, no participant tested positive for RCL (Source: Table 3.0350).

Insertional oncogenesis:

No integration site analysis was performed as no participant remained in the study 1-year post-treatment.

Efficacy results:

A summary of investigator-assessed best response with confirmation per RECIST 1.1 by actual dose is presented in Table 13. The ORR was 25% (95% CI: 0.6%, 80.6%), with 1 participant achieving confirmed PR. Stable disease was noted in 3 participants (75%).

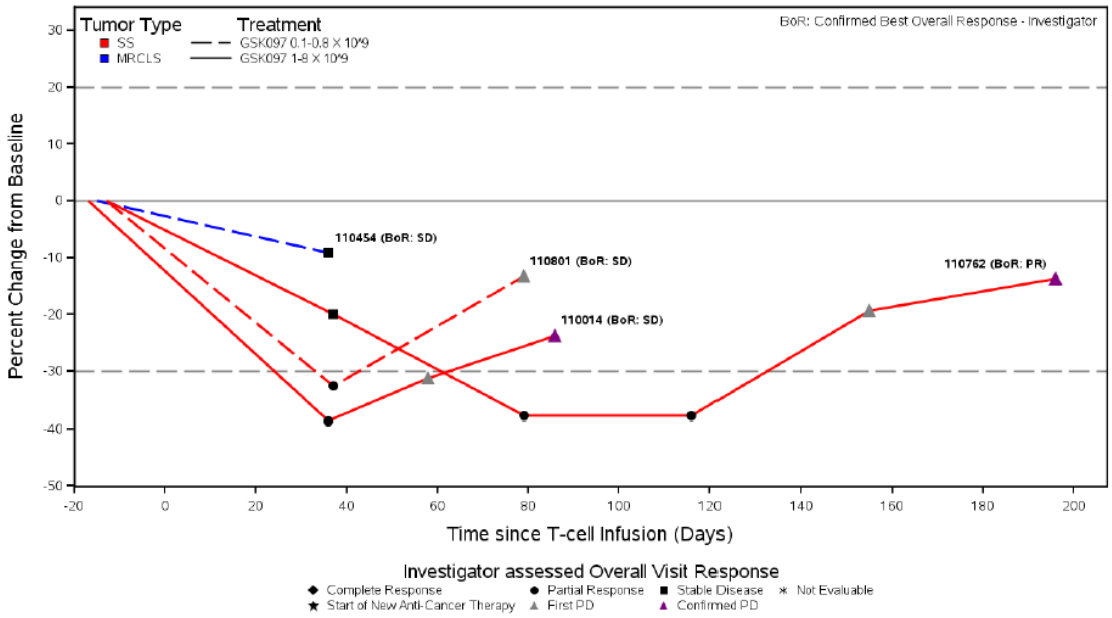
Table 13 Summary of Investigator-Assessed Best Response with Confirmation (RECIST 1.1 Criteria) by Actual Dose (mITT Population)

	Dose Confirmation		
	GSK3845097 $(1\text{-}8) \times 10^9$ (N=2)	GSK3845097 $(0.1\text{-}0.8) \times 10^9$ (N=2)	Total (N=4)
Best Response, n (%)			
Complete Response	0	0	0
Partial Response	1 (50%)	0	1 (25%)
Stable Disease	1 (50%)	2 (100%)	3 (75%)
Progressive Disease	0	0	0
Not Evaluable	0	0	0
Response Rate			
[CR + PR], n (%)	1 (50.0%)	0 (0.0%)	1 (25.0%)
95% Confidence Interval[a]	(1.3%, 98.7%)	(0.0%, 84.2%)	(0.6%, 80.6%)

Source: Table 2.0100.
CI=confidence interval; CR=complete response; PR=partial response; mITT=Modified Intent-to-Treat; RECIST=response evaluation criteria in solid tumors.
a. CIs were calculated using the exact (Clopper-Pearson) method.
Data as of 12 May 2023.

Spider plots of percentage change from baseline in target lesions are shown in Figure 5. Three participants had a decrease in target lesion diameters of ≥30% (at Week 6 for 2 participants and at Weeks 12 and 18 for 1 participant). The initial PR at Week 6 for Participants 110801 and 110014 was followed by PD at the next assessment, hence neither met the criteria of confirmed PR. For Participant 110762, the initial confirmed response of PR occurred at 2.6 months (Day 79) after T-cell infusion with a duration of 2.5 months until confirmed progression. A summary of investigator-assessed DoR per RECIST 1.1 by actual dose is presented in Table 2.0110.

Figure 5 Spider Plot of Investigator-Assessed Percent Change from Baseline in Target Lesion Diameter by Actual Dose (mITT Population)



Source: Figure 2.0120.
BoR=best overall response; mITT=Modified Intent-to-Treat; MRCLS=myxoid/round cell liposarcoma; PD=progressive disease; PR=partial response; RECIST=response evaluation criteria in solid tumors; SD=stable disease; SS=synovial sarcoma.
Note: Participant 110454 had only 1 imaging evaluation as the participant died on Study Day 39.
Note: For Participant 110014, the first PD was due to a non-target lesion progression.
Data as of 12 May 2023.

OS data are not mature. Two participants have died and 2 participants were alive as per the last contact date in the study. The 2 deaths occurred at 1.3 and 3.1 months after T cell infusion (Source: Listing 46). A summary of the deaths is provided in Table 10.

Pharmacokinetic results:

The geometric mean AUC(0-28d) (%CV) was 984,320.98 (82.086) copies per µg gDNA times days; the geometric mean AUC(0-tlast) (%CV) was 1,183,090.87 (96.939) copies per µg gDNA times days, and the geometric mean Cmax (%CV) was 75,882.06 (96.071) copies per µg gDNA (Table 14). The median Tmax was 10.5 days (range: 7, 21) (Source: Table 4.0100).

Table 14 Derived Log-Transformed GSK3845097 Pharmacokinetic Parameters (Pharmacokinetic Population)

Parameter	Treatment	N	n	Geom. Mean	95% CI (Lower, Upper)	SD (logs)	%CV
AUC(0-28) (Copies/ug gDNA times days)	GSK3845097 1-8 × 10^9	2	2	730937.83	(40.61, 13157696626.43)	1.091	151.154
	GSK3845097 0.1-0.8 × 10^9	2	2	1325540.63	(915979.55, 1918228.36)	0.041	4.115
	Total	4	4	984320.98	(314165.86, 3084000.91)	0.718	82.086
AUC(0-tlast) (Copies/ug gDNA times days)	GSK3845097 1-8 × 10^9	2	2	943274.74	(6.02, 147723636698.64)	1.331	221.024
	GSK3845097 0.1-0.8 × 10^9	2	2	1483877.35	(605905.16, 3634053.88)	0.100	9.994
	Total	4	4	1183090.87	(323980.00, 4320340.80)	0.814	96.939
Cmax (Copies/ug gDNA)	GSK3845097 1-8 × 10^9	2	2	54606.56	(4.71, 632476668.59)	1.041	139.944
	GSK3845097 0.1-0.8 × 10^9	2	2	105446.79	(265.02, 41955927.13)	0.666	74.752
	Total	4	4	75882.06	(20957.22, 274754.34)	0.809	96.071

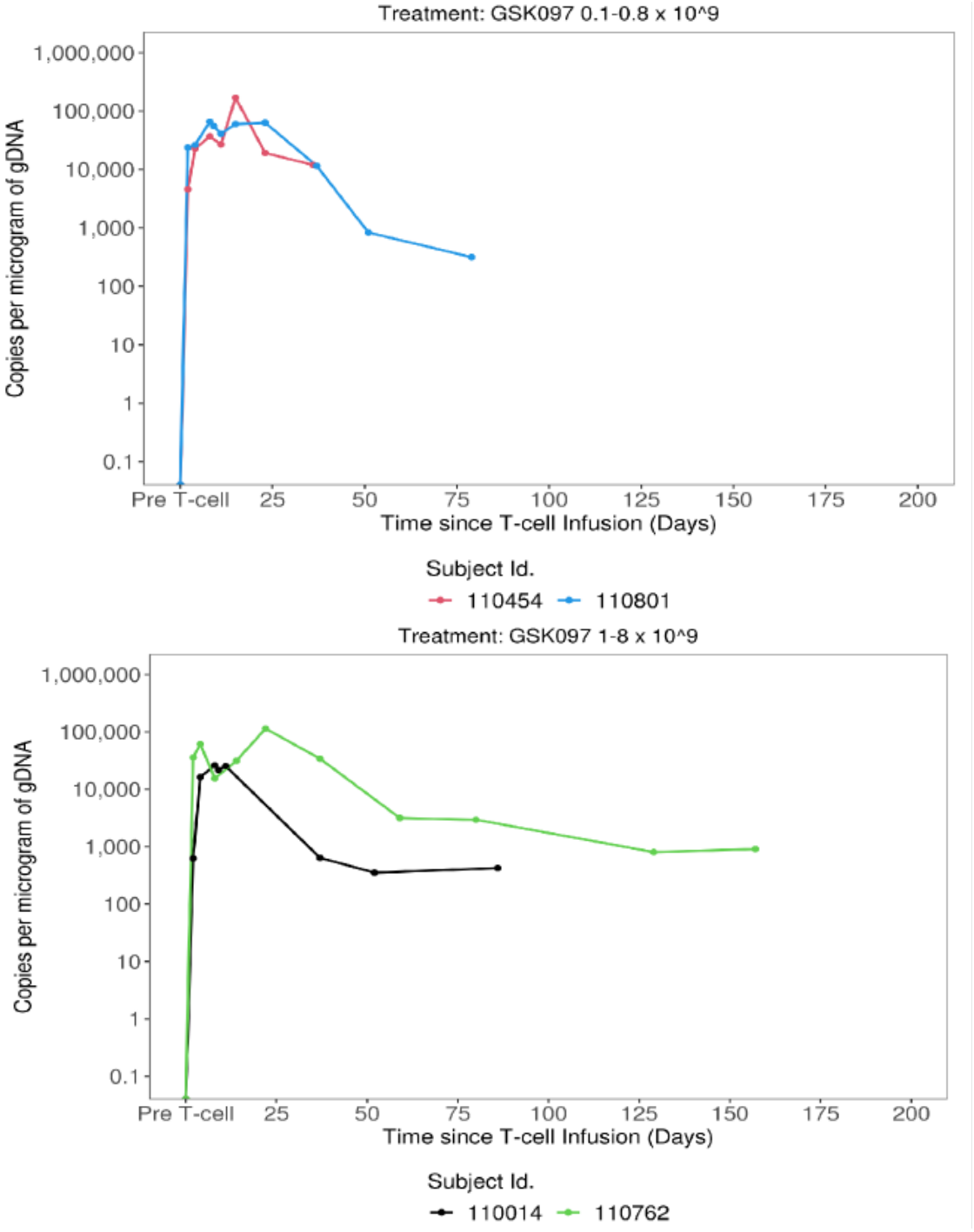
Source: Table 4.0110.

AUC(0-28d)=area under the persistence–time curve from 1st T cell infusion to 28 days; AUC(0-tlast)=area under the persistence–time curve from 1st T cell infusion to last timepoint; CI=confidence interval; Cmax=maximum observed persistence; CV=coefficient of variation; N=number of participants in the population for the treatment and group; n=number of participants in the population for the treatment and group with data; SD=standard deviation.

Data as of 12 May 2023.

GSK3845097 PK concentration-time plot by actual dose for the PK Population is presented in Figure 6. AUC and Cmax were comparable between dosed participants from dose levels of (1-8) $\times 10^9$ or (0.1-0.8) $\times 10^9$transduced T cells. Although 1 participant (110014) followed split dosing regimen and the duration for Participant 110454 (fatal SAE related to T-cell infusion) was shorter, there were no relevant differences in Cmax or AUC when compared to other participants.

Figure 6 GSK3845097 Pharmacokinetic Concentration-Time Plot by Actual Dose (Pharmacokinetic Population)



Source: Figure 4.0120.
Note: Y-axis is log-transformed.
Note: Values reported as "<50" were assigned based on the reported interpretation. If interpretive reported result was "Negative", values were set to 0. If interpretive reported result was "Detectable", values were set to 50.
Note: For each participant, baseline is plotted at zero (pre-T-cell) on the x-axis
Data as of 12 May 2023.

Conclusions:

Five participants entered Substudy 2 and 4 participants were treated with GSK3845097. Two of the 4 participants died during the study and the other 2 participants were transferred to the LTFU study after confirmed disease progression.

Because this substudy was stopped for further treatment based on protocol stopping provisions and because screening and enrollment on master protocol 209012 was closed, the RP2D for GSK3845097 could not be determined due to an insufficient number of dosed participants.

Safety monitoring for the 4 dosed participants revealed that 3 participants (75%) had a DLT, and 2 participants (50%) had a fatal SAE, of which 1 event was T-cell related (systemic inflammatory response syndrome). The AESIs reported on the 4 dosed participants included CRS, hematopoietic cytopenia (including pancytopenia and aplastic anemia), ICANS, and GvHD. All 4 participants had a treatment-emergent T-cell related CRS (3 Grade 1, 1 Grade 2, all nonserious) and a maximum Grade 4 treatment-emergent pancytopenia, 1 of these participants had a serious Grade 4 aplastic anemia.
Two participants had a treatment-emergent GvHD (1 Grade 3 serious; 1 Grade 2 nonserious) involving 2 different organs for each participant. Two participants had a treatment-emergent ICANS (1 Grade 4 serious, 1 Grade 1 nonserious). All participants had treatment-emergent ALT increased (2 Grade 2, 2 Grade 3) and AST increased (2 Grade 1, 1 Grade 2, 1 Grade 3).

There was a signal of clinical activity (confirmed PR) in a participant with locally advanced/metastatic SS; the duration of the response was 2.5 months. The participant with confirmed PR was treated with GSK3845097 at a dose level of (1-8) $\times 10^9$ transduced T cells; this patient completed the interventional phase in Substudy 2 and has been transferred to the LTFU study. Notably, 3 participants (75%) had a decrease in the target lesion diameters of ≥30% (2 of these participants had an initial PR that was not confirmed due to disease progression at subsequent assessment).

The PK profile of GSK3845097 was similar to the PK profile observed in the prior lete-cel studies, including the participant with the T-cell related fatal SAE. No participant was positive for RCL. No integration site analysis was performed as no participant remained in the study 1-year post-treatment.

Based on the fatality in a participant who received GSK3845097 and the decision to place Substudy 2 on voluntary clinical hold, the benefit/risk profile for GSK3845097 is considered unfavourable until further evaluation.

Document Date: 18 August 2023

CASE NARRATIVES

There may be minor discrepancies in the details of the SAEs included in the clinical narratives compared with the safety tabulations. This is because the data comes from 2 different databases (i.e., locked clinical trials database and dynamic SAE database) and has been collected at different points in time. However, all key data points are reconciled. It is considered that these minor discrepancies do not change the overall clinical significance or understanding of the SAE.

Participant 209012-110014

Study ID	Substudy ID	Country Name	City Name	Site ID	Site Name	PI Last Name	Participant ID
209012	2	United States	Houston	243978	MDACC	Araujo	110014

- **Serious Adverse Events:** None
- **Adverse Events of Special Interest:** Pancytopenia (Decreased WBC Count [Grade 4], Neutropenia [Grade 4], Anemia Intermittent [Grade 3], Thrombocytopenia [Grade 4]), Cytokine Release Syndrome (Grade 1), Pneumonia (Grade 1)
- **Date of Leukapheresis:** 21 September 2021
- **Date of Lymphodepletion:** From 22 November 2021 (Day -7) to 25 November 2021 (Day -4)
- **Dates of GSK3845097 Infusion for Sentinel Participant:** 29 November 2021 (Day 1) and 06 December 2021 (Day 8)
- **Clinical Supply:** This was a non-conforming product.
- **Disposition:** The participant completed the interventional phase (confirmed disease progression) on 22 February 2022 (Day 86) and moved to the LTFU study 208750, then unfortunately died from the disease under study on 28 September 2022 (Day 304)

Participant 209012-110014, a 27-year-old male at the time of screening ICF signature, White, Not Hispanic or Latino, was initially diagnosed with SS Stage IV on 18 September 2020, that was positive for SYT-SSX1-specific translocation.

The participant was diagnosed with Stage IV advanced (metastatic/unresectable) disease on 18 September 2020.

Location of tumors:

- Primary site: Extremities
- Metastatic site: Bone, lung, soft tissue (sarcoma right tibia)

Prior anticancer treatments including systemic, radiation, and surgeries: Prior to leukapheresis, the participant received adriamycin and ifosfamide from 05 October 2020 to 18 January 2021; pazopanib from 19 February 2021 to 06 April 2021; underwent a resection of right tibia on 07 April 2021 and a knee arthroplasty on 14 April 2021;

received ifosfamide from 21 June 2021 to 25 June 2021. The participant did not receive radiation therapy.

The participant's last date of diagnosed progression was 20 May 2021.

The participant was screened for target expression:

- HLA-A type was A*02:01/786 - A*02:01/786 (homozygous).
- NY-ESO-1 antigen tumor expression by IHC showed 100% cells [≥2+].

At screening, the participant was found to have an HLA-A type positive for HLA-A*02:01 and to be positive for NY-ESO-1 antigen expression.

The participant was deemed eligible and underwent leukapheresis (enrolled) on 21 September 2021 (Day -69).

Anticancer treatments received between leukapheresis and lymphodepletion: the participant received ifosfamide from 28 September 2021 to 02 October 2021 and from 18 October 2021 to 22 October 2021.

A baseline CT scan on 12 November 2021 (Day -17) revealed 3 target lesions on the following anatomical locations:

- T01) – Paratracheal lymph node - right: short axis = 24 mm
- T02) – Lung – right medial lobe: long diameter = 31 mm
- T03) – Lung – left lower lobe: long diameter = 25 mm

and 2 non-target lesions:

- NT01) – Mediastinal lymph nodes
- NT02) – Bilateral pulmonary nodules

The participant received lymphodepleting chemotherapy from 22 November 2021 (Day -7) until 25 November 2021 (Day -4).

- Fludarabine 30 mg/m^2/day ×4 (Days -7 through -4) and
- Cyclophosphamide 900 mg/m^2/day ×3 (Days -6 through -4).

Mesna was administered on each day of cyclophosphamide at an individual administration dose of 900 mg/m^2.

The manufactured drug product batch was found to be non-conforming due to a slightly higher DMSO concentration (approximately 6%) in the formulation than the maximum per label, which was set at 5%. The 6% DMSO concentration falls within the range assessed during formulation development and has no impact on product quality attributes. The batch also met the safety DMSO limit of ≤1mL/kg/day that can be safely infused to an adult participant. The request to release the batch for infusion as a non-conforming product was approved and the participant was reconsented with documentation of their understanding/acceptance of any associated risks before procedure.

A first dose of 0.746×10^9 transduced cells of GSK3845097 was administered as 2 bags on 29 November 2021 (Day 1), and a second dose of 1.138×10^9 transduced cells was administered as 3 bags on 06 December 2021 (Day 8), for a total dose of 1.884×10^9 transduced cells.

At study entry, the participant had Grade 1 anemia, Grade 2 gait, Grade 1 nausea, Grade 1 tachycardia, and Grade 1 vomiting.

This participant experienced the following AEs:

Serious Adverse Events:

- This participant did not experience any SAEs.

Adverse Events of Special Interest:

- Pancytopenia
  - Decreased WBC count, Grade 4, onset 29 November 2021 and end date 21 December 2021 (Day 1 to Day 23), reported as related to fludarabine and cyclophosphamide.
  - Neutropenia, Grade 4, onset 29 November 2021 and end date 21 December 2021 (Day 1 to Day 23), reported as related to fludarabine and cyclophosphamide.
  - Thrombocytopenia, Grade 4, onset 03 December 2021 and end date 21 December 2021 (Day 5 to Day 23), reported as related to fludarabine and cyclophosphamide.
  - Anemia intermittent, Grade 3, onset 03 December 2021 and end date 06 December 2021 (Day 5 to Day 8), reported as related to fludarabine and cyclophosphamide.
- CRS, Grade 1, onset 29 November 2021 and end date 08 December 2021 (Day 1 to Day 10), reported as related to GSK3845097.
- Pneumonia, Grade 1, onset 01 December 2021 and end date 08 December 2021 (Day 3 to Day 10), reported as related to fludarabine and cyclophosphamide.

Adverse Events Related to Study Treatment (in addition to any AESIs reported above)

- **Related to Fludarabine, Cyclophosphamide, and GSK3845097:**
  - Fatigue, Grade 1, onset 30 November 2021 and end date 21 December 2021 (Day 2 to Day 23)
  - Cough, Grade 1, onset 02 December 2021 and end date 08 December 2021 (Day 4 to Day 10)
  - Rash generalized, Grade 2, onset 05 December 2021 and end date 21 December 2021 (Day 7 to Day 23)
  - Mucositis, Grade 1, onset 21 December 2021 and end date 29 December 2021 (Day 23 to Day 31)

- **Related to Fludarabine and Cyclophosphamide:**
  - Lymphocyte count decreased, Grade 4, onset 24 November 2021 and end date 21 December 2021 (Day -5 to Day 23)
  - Febrile neutropenia, Grade 2, onset 28 November 2021 and end date 07 December 2021 (Day -1 to Day 9)
  - Hyponatremia, Grade 2, onset 29 November 2021 and end date 28 December 2021 (Day 1 to Day 30)
  - Hypophosphatemia, Grade 2, onset 29 November 2021 and end date 08 December 2021 (Day 1 to Day 10)

- **Related to GSK3845097:**
  - Anxiety, Grade 1, onset 30 November 2021 and end date unreported (Day 2 to unreported)
  - ALT increased, Grade 2, onset 09 December 2021 and end date 21 December 2021 (Day 11 to Day 23)

The participant was monitored for delayed AEs per FDA guidance and was confirmed to not have experienced any.

Notable Adverse Events (in addition to any SAEs and AEs reported above):

- All Grade ≥3 AEs not related to treatment: none.
- All maximum Grade ≥2 AEs lasting more than 7 days and not related to treatment:
  - Anorexia, Grade 2, onset 30 November 2021 and end date 21 December 2021 (Day 2 to Day 23)

The participant was in the interventional phase of the study from 29 November 2021 (Day 1) and reached the protocol-defined stopping criteria (confirmed disease progression) on 22 February 2022 (Day 86) and moved to the LTFU study 208750.

The participant died from the disease under study on 28 September 2022 (Day 304), 43 weeks from the first T-cell infusion.

Participant 209012-110258

Study ID	Substudy ID	Country Name	City Name	Site ID	Site Name	PI Last Name	Participant ID
209012	2	Germany	Munich	246852	Munich Clinic	Lindner	110258

- **Serious Adverse Event:** Malignant Neoplasm Progression (Grade 5)
- **Adverse Events of Special Interest:** None
- **Date of Leukapheresis:** The participant did not undergo leukapheresis.
- **Date of Lymphodepletion:** The participant did not receive lymphodepletion.
- **Date of GSK3845097 Infusion:** The participant did not receive GSK3845097 infusion.

- **Disposition:** This participant signed the ICF on 05 July 2022 but did not undergo leukapheresis or receive any study treatment. The participant died on 08 September 2022.

Participant 209012-110258 was a 32-year-old male at the time of screening ICF signature, White, Not Hispanic or Latino. No information on disease characteristics was reported.

The participant was screened for target expression:

- HLA-A type was A*02:05 - A*11:01/295.
- NY-ESO-1 antigen tumor expression by IHC showed 71% cells [≥2+].

At screening, the participant was found to have an HLA-A type positive for HLA-A*02:01 and to be positive for NY-ESO-1 antigen expression.

The participant did not initiate screening for eligibility to leukapheresis and did not undergo the procedure.

The participant did not receive lymphodepleting chemotherapy or transduced cells of GSK3845097.

This participant's medical history was not reported

This participant experienced the following AEs:

Serious Adverse Event:

- SAE of malignant neoplasm progression, Grade 5, onset 08 September 2022 and end date 08 September 2022, reported as not related to study treatment (fludarabine, cyclophosphamide, and GSK3845097) (Case ID: DE2022GSK163830).

Adverse Events of Special Interest:

- This participant did not experience AESIs.

Adverse Events Related to Study Treatment (in addition to any SAEs and or AESIs reported above):

- Not applicable.

Notable Adverse Events (in addition to any SAEs and AEs reported above):

- This participant did not experience any other notable AEs (Grade ≥3 AEs not related to study treatment or maximum Grade ≥2 AEs lasting more than 7 days and not related to treatment).

This participant signed the ICF on 05 July 2022 but did not undergo leukapheresis or receive any study treatments (lymphodepletion chemotherapy or GSK3845097 infusion). The participant died on 08 September 2022.

ARGUS SAE Narratives (Event: Malignant neoplasm progression; Case ID: DE2022GSK163830)

On 08 September 2022, the participant died due to malignant neoplasm progression (Grade 5). Serious criteria included death. The outcome of the SAE of "malignant neoplasm progression" was fatal. The reported cause of death was malignant neoplasm progression.

As per additional information received on 07 November 2022, the investigator considered the SAE of "malignant neoplasm progression" not related to the study treatment since it occurred before the start of GSK3845097. It was unknown whether an autopsy was performed or not.

The participant did not receive GSK3845097, fludarabine phosphate, and cyclophosphamide for neoplasm at the time of event.

The sponsor considered that there was no reasonable possibility that the SAE of "malignant neoplasm progression" may have been caused by the study drugs since the participant did not receive the GSK3845097, fludarabine phosphate, and cyclophosphamide.

Participant 209012-110454

Study ID	Substudy ID	Country Name	City Name	Site ID	Site Name	PI Last Name	Participant ID
209012	2	Germany	Cologne	246666	Cologne Clinic	Ullrich	110454

- **Serious Adverse Events:** Staphylococcus Capis Infection (Grade 3), Peripherally Inserted Central Catheter (PICC) Line Associated Infection (Grade 3), GvHD-Skin (Grade 3), GvHD-GI (Grade 3), Fever in Neutropenia (Grade 3), Thrombocytopenia (Grade 4), Macrophage Activation Syndrome (Grade 4), Systemic Inflammatory Response Syndrome (Grade 5)
- **Adverse Events of Special Interest:** Neutropenia (Grade 4), Cytokine Release Syndrome (Grade 2), Immune Effector Cell-Associated Neurotoxicity Syndrome (Grade 1), Pancytopenia (Grade 4), Graft-Versus-Host Disease (GvHD Skin [Grade 3], GvHD GI [Grade 3])
- **Date of Leukapheresis:** 28 April 2022
- **Date of Lymphodepletion:** From 10 August 2022 (Day -6) to 12 August 2022 (Day -4)
- **Date of GSK3845097 Infusion:** 16 August 2022 (Day 1)
- **Clinical Supply:** This was a conforming product.

- **Disposition:** The participant completed the interventional phase due to the participant's death on 23 September 2022 (Day 39).

Participant 209012-110454, a 67-year-old male at the time of screening ICF signature, White, Not Hispanic or Latino, was initially diagnosed with MRCLS Stage IV in May 2021, which was positive for FUS-DDIT3-tumor specific translocation.

At screening, the disease grade and stage were as follows: Grade 2, TX NX M1, Stage IV.

Location of tumors:

- Primary site: Extremities
- Metastatic site: Bone, lung, left thigh muscle, mesentery

Prior anticancer treatments including systemic, radiation, and surgeries: Prior to leukapheresis, the participant underwent a resection of large myxoid liposarcoma of the left quadriceps compartment on 29 June 2021; received doxorubicin from 03 September 2021 to 21 January2021, then doxorubicin liposomal from 18 February 2022 to 16 March 2022. The participant did not receive radiation therapy prior to leukapheresis.

The participant's last date of diagnosed progression was 06 July 2022.

The participant was screened for target expression:

- HLA-A type was A*02:01/786 - A*30:01.
- NY-ESO-1 antigen tumor expression by IHC showed 100% cells [≥2+].

At screening, the participant was found to have an HLA-A type positive for HLA-A*02:01 and to be positive for NY-ESO-1 antigen expression.

The participant was deemed eligible and underwent leukapheresis (enrolled) on 28 April 2022 (Day -110).

Anticancer treatments received between leukapheresis and lymphodepletion: The participant received trabectedin from 29 April 2022 to 15 June 2022; and eribulin from 12 July 2022 to 19 July 2022 then radiation therapy (12 Gy) to the left femur and local relapse of the left thigh from 04 August 2022 to 09 August 2022 (Day -12 to Day -7).

A baseline CT scan on 01 August 2022 (Day -15) revealed 2 target lesions on the following anatomical locations:

- T01) – Lung – right upper lobe: long diameter = 71 mm
- T02) – Lung – left upper lobe: long diameter = 28 mm

and 4 non-target lesions:

- NT01) – Lung – left, multiple metastases

- NT02) – Upper thigh
- NT03) – Mesenterial tissue
- NT04) – Bone – multiple metastases

The participant received lymphodepleting chemotherapy from 10 August 2022 (Day -6) until 12 August 2022 (Day -4).

- Fludarabine 20 mg/m^2/day ×3 (Days -6 through -4) and
- Cyclophosphamide 600 mg/m^2/day ×3 (Days -6 through -4).

Reasons for dose reductions from standard regimen were:

- ≥60 years old
- The participant with intermittent creatinine clearance between 50 and 80 mL/min was considered renally impaired

A dose of 0.8×10^9 transduced cells of GSK3845097 was administered as 2 bags on 16 August 2022 (Day 1).

This participant had past medical history conditions of hypertension, pulmonary arterial embolism, and thyroidectomy.

This participant experienced the following AEs:

Serious Adverse Events:

- SAE of staphylococcus capis infection, Grade 3, and PICC line associated infection, Grade 3, onset 27 July 2022 and end date 01 August 2022 (Day -20 to Day -15), reported as not related to study treatment (Case ID: DE2022GSK112459)
- SAE of GvHD-Skin, Grade 3, onset 02 September 2022 (Day 18), not resolved, reported as related to GSK3845097 (Case ID: DE2022GSK128355)
- SAE of GvHD-GI, Grade 3, onset 03 September 2022 (Day 19), not resolved, reported as related to GSK3845097 (Case ID: DE2022GSK128355)
- SAE of fever in neutropenia, Grade 3, onset 03 September 2022 and end date 04 September 2022 (Day 19 to Day 20), reported as related to GSK3845097 (Case ID: DE2022GSK128355)
- SAE of thrombocytopenia, Grade 4, onset 12 September 2022 (Day 28), not resolved, reported as related to GSK3845097 (Case ID: DE2022GSK128355)
- SAE of macrophage activation syndrome, Grade 4, onset 21 September 2022 (Day 37), not resolved, reported as related to GSK3845097 (Case ID: DE2022GSK128355)
- SAE of systemic inflammatory response syndrome, Grade 5, onset 23 September 2022 and end date 23 September 2022 (Day 39 to Day 39), reported as related to GSK3845097 (Case ID: DE2022GSK128355)

Adverse Events of Special Interest (in addition to any SAEs reported above):

- CRS, Grade 2, onset 17 August 2022 and end date 20 August 2022 (Day 2 to Day 5), reported as related to GSK3845097.
- ICANS (reduced ICE score), Grade 1, onset 18 August 2022 and end date 19 August 2022 (Day 3 to Day 4), reported as related to GSK3845097.
- Pancytopenia, Grade 4, onset 02 September 2022 (Day 18), not resolved, reported as related to GSK3845097.

Adverse Events Related to Study Treatment (in addition to any SAEs and or AESIs reported above); all reported as related to GSK3845097:

- Leukopenia, Grade 4, onset 17 August 2022 and end date 25 August 2022 (Day 2 to Day 10)
- Fever, Grade 1, onset 18 August 2022 and end date 19 August 2022 (Day 3 to Day 4)
- Neutropenia, Grade 4, onset 17 August 2022 and end date 25 August 2022 (Day 2 to Day 10), reported as related to GSK3845097.
- Elevated CRP, Grade 3, onset 18 August 2022 and end date 24 August 2022 (Day 3 to Day 9)
- Decreased leukocyte count, Grade 3, onset 30 August 2022 (Day 15), not resolved
- Elevated AST, Grade 1, onset 27 August 2022 and end date 03 September 2022 (Day 12 to Day 19)
- Elevated ALT, Grade 2, onset 27 August 2022 and end date 03 September 2022 (Day 12 to Day 19)
- Leukopenia, Grade 4, onset 30 August 2022 (Day 15), not resolved
- Elevated CRP, Grade 3, onset 04 September 2022 and end date 14 September 2022 (Day 20 to Day 30)
- Neutrophil count decreased, Grade 4, onset 04 September 2022 (Day 20), not resolved
- Thrombopenia, Grade 3, onset 09 September 2022 and end date 11 September 2022 (Day 25 to Day 27)
- Increased creatinine, Grade 3, onset 10 September 2022 (Day 26), not resolved
- Increased urea, Grade 3, onset 11 September 2022 (Day 27), not resolved
- Decreased hemoglobin, Grade 3, onset 11 September 2022 and end date 18 September 2022 (Day 27 to Day 34)
- Decreased erythrocytes, Grade 3, onset 11 September 2022 and end date 18 September 2022 (Day 27 to Day 34)
- Decreased hematocrit, Grade 3, onset 11 September 2022 and end date 19 September 2022 (Day 27 to Day 35)
- Mucositis, Grade 2, onset 11 September 2022 (Day 27), not resolved
- Increased procalcitonin, Grade 3, onset 13 September 2022 (Day 29), not resolved
- Supraventricular tachycardia, Grade 1, onset 17 August 2022 and end date 17 August 2022 (Day 2 to Day 2)
- Increased CRP, Grade 3, onset 17 September 2022 (Day 33), not resolved
- Increased interleukin 6, Grade 2, onset 19 September 2022 (Day 35), not resolved
- Decreased hemoglobin, Grade 3, onset 20 September 2022 (Day 36), not resolved

- Decreased erythrocytes, Grade 4, onset 20 September 2022 and end date unreported (Day 36 to unreported)
- Decreased protein, Grade 3, onset 21 September 2022 (Day 37), not resolved

The participant was monitored for delayed AEs per FDA guidance and was confirmed to not have experienced any.

Notable Adverse Events (in addition to any SAEs and AEs reported above):

- not related to study treatment but Grade ≥3:
  - Increased glucose, Grade 3, onset 14 September 2022 and end date 15 September 2022 (Day 30 to Day 31)

- not related to study treatment but with maximum Grade ≥2 lasting more than 7 days:
  - Increased sodium, Grade 2, onset 20 September 2022 (Day 36), not resolved

The participant was in the interventional phase of the study from 16 August 2022 (Day 1) and completed the study due to death on 23 September 2022 (Day 39).

ARGUS SAE Narratives (Events: Staphylococcus capis infection, PICC line associated infection; Case ID: DE2022GSK112459)

On 27 July 2022 (Day -20), the participant developed an SAE 'Staphylococcal infection' (Grade 3) and was hospitalized. Blood culture (performed on 23 July 2022 and 25 July 2022) was positive for staphylococcus capitis. On the same day, a PICC line associated infection (Grade 3) was reported as an SAE of 'Vascular device infection'. Laboratory investigations showed CRP 11.8 mg/L (normal high: 5.00) and neutrophil counts of 170/µL (normal low: 1800).

The participant was treated with amoxicillin + clavulanic acid and flucloxacillin. The outcome of the event of 'Staphylococcal infection' was reported as resolved on 01 August 2022 (Day -15). The outcome of the event of 'Vascular device infection' was unknown.

The sponsor considered that there was no reasonable possibility that the SAEs of staphylococcal infection and vascular device infection may have been caused by GSK3845097, fludarabine phosphate, or cyclophosphamide since the participant did not receive any of the study drugs at the time of the SAEs.

ARGUS SAE Narratives (Event: GvHD-Skin, GvHD-GI, Fever in Neutropenia, Thrombocytopenia, Macrophage Activation Syndrome, Systemic Inflammatory Response Syndrome; Case ID: DE2022GSK128355)

On 02 September 2022 (Day 18), the participant developed an SAE of 'Graft versus host disease in skin' (Grade 3) and was hospitalized.

Prior to the development of the SAE, on 17 August 2022 (Day 2), the participant had a nonserious AE of CRS (Grade 2) (fever and hypotension) and was treated with

tocilizumab ×1 dose; CRS resolved on 20 August 2022 (Day 5). The participant continued with intermittent fever, with blood pressure stabilized, and no hypoxemia. On 19 August 2022 (Day 4), the participant experienced deterioration of the neurological status (ICE score 7). The participant was febrile during that episode. No intervention was required, and the neurological status returned to baseline within 1 day.

On 01 September 2022 (Day 17), the participant returned to clinic for a scheduled visit and was noted to have a new episode of neutropenia and a Grade 1 skin rash, for which G-CSF and topical steroids were started. (participant's ANC count had previously recovered following lymphodepletion and T-cell infusion).

On 02 September 2022 (Day 18), the participant presented to the emergency room due to fever and worsening rash. Rash described as maculopapular exanthema covering 100% body surface area. The participant was started on IV steroids; skin biopsy was compatible with GvHD. This was reported as an SAE of 'Graft versus host disease in skin' (Grade 3). The participant also had changes in the oral mucosa attributed to GvHD. The participant was admitted for management of febrile neutropenia and was treated with G-CSF and meropenem. Blood cultures during this episode were negative.

An SAE of 'Febrile neutropenia' (Grade 3) and 'Graft versus host disease in gastrointestinal tract' (Grade 3) were also reported on 03 September 2022 (Day 19) and the participant was hospitalized. The outcome of 'Febrile neutropenia' was reported as resolved with sequelae on 04 September 2022 (Day 20).

On 10 September 2022 (Day 26) and 11 September 2022 (Day27), the participant developed a new episode of fever with hypotension and tachycardia requiring transfer to the intensive care unit. The participant was managed with fluid resuscitation and meropenem was restarted. Linezolid was added as blood culture was positive for (vancomycin-resistant enterococcus faecium). The participant had persistent neutropenia on G-CSF, and thrombocytopenia (platelet count 9000) which was reported as life-threatening SAE of 'Thrombocytopenia' (Grade 4) on 12 September 2022 (Day 28). Skin rash and oral mucosal changes showing slight improvement; the participant also noted to have nausea and diarrhea related to GvHD.

On 13 September 2022 (Day 29), the participant showed slight improvement of skin rash (Grade 2) and diarrhea (1.5 L/day). Due to slow improvement, the participant was considered to have steroids refractory GvHD and ruxolitinib was started on 14 September 2022 (Day 30). Mild increase in bilirubin was noted with normal AST/ALT; the elevation was considered possibly due to infection or administration of meropenem. Neutropenia and thrombocytopenia persisted despite supportive therapy (G-CSF and platelet transfusions, respectively).

As per follow-up information reported on 19 September 2022 (Day 35), the treating physician assessed the clinical condition of the participant as life-threatening. As per additional information received on 20 September 2022, 22 September 2022 and 23 September 2022, the participant's clinical status was reported as life-threatening. A CT scan of the chest and abdomen was performed on 20 September 2022 (Day 36) that showed a partial remission of the lung metastases.

An SAE of 'Haemophagocytic lymphohistiocytosis' (Grade 4) was reported on 21 September 2022 (Day 37). The participant's medical condition worsened, though the values for macrophage activation syndrome (as ferritin) were improved after treatment with anakinra, participant's clinical situation was critical and life-threatening. The participant suffered from extensive capillary leak syndrome and was transferred to the ICU.

On 23 September 2022 (Day 39), the SAE of 'Systemic inflammatory response syndrome' with outcome of fatal was reported. The SAE was considered the cause of death. No autopsy was performed.

The outcomes of events of 'Graft versus host disease in skin', 'Graft versus host disease in gastrointestinal tract', 'Thrombocytopenia' and 'Haemophagocytic lymphohistiocytosis' were reported as "not resolved".

The investigator considered that there was a reasonable possibility that the events of Graft versus host disease in skin', 'Graft versus host disease in gastrointestinal tract', 'Thrombocytopenia' and 'Haemophagocytic lymphohistiocytosis' may have been caused by GSK3845097.

The investigator considered that there was no reasonable possibility that these events may have been caused by fludarabine phosphate and cyclophosphamide.

The sponsor considered the SAEs of 'Systemic inflammatory response syndrome' and 'Haemophagocytic lymphohistiocytosis' to have a possible relationship to GSK3845097, although this relationship is confounded by recent COVID-19 vaccination and concurrent infection.

Participant 209012-110762

Study ID	Substudy ID	Country Name	City Name	Site ID	Site Name	PI Last Name	Participant ID
209012	2	United States	Atlanta	244818	Emory University/ Winship Cancer Institute	Yushak	110762

- **Serious Adverse Events:** ICANS (Grade 4), Pancytopenia (Grade 4), Pneumonia SARS-CoV-2 (Grade 3), Aplastic Anemia (Grade 4), Febrile Neutropenia (Grade 3), ALT Increased (Grade 3), Hyperbilirubinemia (Grade 2), INR Increased (Grade 2), Fever (Grade 1), Shingles (Grade 3)
- **Adverse Events of Special Interest:** CRS (Grade 2), GvHD-Skin/Liver (Grade 2), Pancytopenia/Aplastic Anemia (Grade 4), Pneumonia (Grade 3), Immune Effector Cell-Associated Neurotoxicity Syndrome (Grade 4)
- **Date of Leukapheresis:** 08 February 2022
- **Date of Lymphodepletion:** From 05 April 2022 (Day -7) to 08 April 2022 (Day -4)
- **Date of GSK3845097 Infusion:** 12 April 2022 (Day 1)

- **Clinical Supply:** This was a conforming product.
- **Disposition:** The participant had confirmed disease progression on 13 September 2022 (Day 155), reached study conclusion on 24 October 2022 (Day 196), and moved to the LTFU trial 208750.

Participant 209012-110762, a 31-year-old male at the time of screening ICF signature, Black or African American, Not Hispanic or Latino, was initially diagnosed with SS Stage IIIb on 27 November 2017, which was positive for SYT-tumor specific translocation (no chromosome x testing done).

The participant was further diagnosed with Stage IV advanced (metastatic/unresectable) disease on 29 March 2021. At screening, the disease grade and stage were as follows: Grade unknown, T3 N0 M1, Stage IV.

Location of tumors:

- Primary site: Extremities
- Metastatic site: Abdominal wall, lung, peritoneum

Prior anticancer treatments including systemic, radiation, and surgeries: Prior to leukapheresis, the participant underwent an excision of mass on the right knee on 02 January 2018; received doxorubicin and ifosfamide from 20 April 2021 to 05 August 2021; underwent a nephroureterectomy on 28 May 2021; and received gemcitabine and docetaxel from 07 October 2021 to 16 November 2021. The participant did not receive radiation therapy prior to leukapheresis.

The participant's last date of diagnosed progression was 01 January 2022 (Day -101).

The participant was screened for target expression:

- HLA-A type was A*02:01/786 - A*74:01.
- NY-ESO-1 antigen tumor expression by IHC showed 295% cells [≥2+].

At screening, the participant was found to have an HLA-A type positive for HLA-A*02:01 and to be positive for NY-ESO-1 antigen expression.

The participant was deemed eligible and underwent leukapheresis (enrolled) on 08 February 2022 (Day -63).

Anticancer treatments received between leukapheresis and lymphodepletion: The participant received trabectedin on 11 March 2022 (Day -22).

A baseline CT scan on 30 March 2022 (Day -13) revealed 3 target lesions on the following anatomical locations:

- T01) – Lung – left lower lobe (pleura left nodule): long diameter = 66 mm
- T02) – Lung – left lower lobe: long diameter = 24 mm
- T03) – Retroperitoneal lymph node: short axis = 85 mm

and 1 non-target lesions:

- NT01) – Pelvis – right groin

The participant received lymphodepleting chemotherapy from 05 April 2022 (Day -7) until 08 April 2022 (Day -4).

- Fludarabine 30 mg/m^2/day ×4 (Days -7 through -4) and
- Cyclophosphamide 900 mg/m^2/day ×3 (Days -6 through -4).

Mesna was administered on each day of cyclophosphamide at an individual administration dose of 98 mg/m^2 twice daily.

A dose of 4.9×10^9 transduced cells of GSK3845097 was administered as 3 bags on 12 April 2022 (Day 1).

This participant had past medical history conditions of former smoking, hydronephrosis, leukocytosis, recurrent UTIs related to nephrostomy tube, small loculated pneumothorax, swelling in legs due to chemotherapy, and ureteral obstruction. At study entry, the participant had Grade 1 anemia, Grade 1 pain abdominal and nephrostomy tube, Grade 1 constipation, gram positive cocci blood (grade not applicable), Grade 3 neutropenia, Grade 1 nausea, and Grade 1 nerve pain.

This participant experienced the following AEs:

Serious Adverse Events:

- SAE of ICANS, Grade 4, onset 14 April 2022 and end date 18 April 2022 (Day 3 to Day 7), reported as related to GSK3845097 (Case ID: US2022GSK065718)
- SAE of Pancytopenia, Grade 4, onset 22 April 2022 and end date 18 May 2022 (Day 11 to Day 37), reported as related to fludarabine, cyclophosphamide, and GSK3845097 (Case ID: US2022GSK075341)
- SAE of Pneumonia SARS-CoV-2, Grade 3, onset 03 May 2022 and end date 20 May 2022 (Day 22 to Day 39), reported as related to GSK3845097 (Case ID: US2022GSK075341)
- SAE of Aplastic Anemia, Grade 4, onset 03 May 2022 and end date 18 May 2022 (Day 22 to Day 37), reported as related to GSK3845097 (Case ID: US2022GSK075341)
- SAE of Febrile Neutropenia, Grade 3, onset 06 May 2022 and end date 08 May 2022 (Day 25 to Day 27), reported as related to GSK3845097 (Case ID: US2022GSK075341)
- SAE of Hyperbilirubinemia, Grade 2, onset 16 May 2022 and end date 20 May 2022 (Day 35 to Day 39), reported as related to GSK3845097 (Case ID: US2022GSK080145)
- SAE of ALT Increased, Grade 3, onset 16 May 2022 and end date 20 May 2022 (Day 35 to Day 39), reported as related to GSK3845097 (Case ID: US2022GSK080145)

- SAE of INR Increased, Grade 2, onset 16 May 2022 and end date 20 May 2022 (Day 35 to Day 39), reported as not related to study treatment (Case ID: US2022GSK080145)
- SAE of Fever, Grade 1, onset 29 August 2022 and end date 01 September 2022 (Day 140 to Day 143), reported as not related to study treatment (Case ID: US2022GSK128369)
- SAE of Shingles, Grade 3, onset 01 September 2022 and resolved end date unknown (Day 143 to unreported), reported as not related to study treatment (Case ID: US2022GSK128369)

Adverse Events of Special Interest (in addition to any SAEs reported above):

- CRS, Grade 2, onset 12 April 2022 and end date 16 April 2022 (Day 1 to Day 5), reported as related to GSK3845097.
- ICANS, Grade 4, onset 14 April 2022 and end date 18 April 2022 (Day 3 to Day 7), reported as related to GSK3845097.
- Pancytopenia/Aplastic Anemia, Grade 4, onset 22 April 2022 and end date 18 May 2022 (Day 11 to Day 37), reported as related to fludarabine, cyclophosphamide, and GSK3845097.
- Pneumonia SARS-CoV-2, Grade 3, onset 03 May 2022 and end date 20 May 2022 (Day 22 to Day 39), reported as related to GSK3845097.
- GvHD Skin/Liver, Grade 2, onset 01 May 2022 and end date 09 June 2022 (Day 20 to Day 59), reported as related to GSK3845097.

Adverse Events Related to Study Treatment (in addition to any SAEs and or AESIs reported above):

- **Related to Fludarabine, Cyclophosphamide, and GSK3845097:**
  - Platelet count decreased, Grade 4, onset 13 April 2022 and end date 09 June 2022 (Day 2 to Day 59)
  - Anemia, Grade 3, onset 17 April 2022 and end date 29 August 2022 (Day 6 to Day 80)
  - WBC count decreased, Grade 4, onset 20 April 2022 and end date 20 May 2022 (Day 9 to Day 39)
  - Neutrophil count decreased, Grade 4, onset 25 April 2022 and end date 16 May 2022 (Day 14 to Day 35)

- **related to GSK3845097:**
  - AST increased, Grade 1, onset 17 April 2022 and end date 02 May 2022 (Day 6 to Day 21)
  - Alkaline phosphatase increased, Grade 1, onset 25 April 2022 and end date 09 June 2022 (Day 14 to Day 59)
  - Bone marrow hypocellular/Aplastic anemia, Grade 4, onset 03 May 2022 and end date 18 May 2022 (Day 22 to Day 37)
  - AST increased, Grade 2, onset 06 May 2022 and end date 20 May 2022 (Day 25 to Day 39)

- **related to Fludarabine and Cyclophosphamide:**
  - Lymphocyte count decreased, Grade 4, onset 06 April 2022 and end date 20 May 2022 (Day -6 to Day 39)
  - WBC count decreased, Grade 4, onset 11 April 2022 and end date 17 April 2022 (Day -1 to Day 6)

The participant was monitored for delayed AEs per FDA guidance and was confirmed to not have experienced any.

Notable Adverse Events (in addition to any SAEs and AEs reported above):

- All Grade ≥3 AEs not related to treatment: None.
- All AEs not related to treatment with maximum Grade ≥2 lasting more than 7 days:
  - INR increased, Grade 2, onset 31 March 2022 and end date 20 May 202 (Day -12 to Day 39)

The participant was in the interventional phase of the study from 12 April 2022 (Day 1) had confirmed disease progression on 13 September 2022 (Day 155), reached study conclusion on 24 October 2022 (Day 196), and moved to the LTFU trial.

ARGUS SAE Narratives (Event: ICANS; Case ID: US2022GSK065718)

On 14 April 2022 (Day 3), the participant developed an SAE of ICANS (Grade 4) that was treated with dexamethasone 10 mg IV every 6 hours with evidence of neurological improvement to ICANS (Grade 3) within less than 1 hour of the initial event. Prior to this event, the participant had also experienced a nonserious AE of CRS (Grade 1) on 12 April 2022 (Day 1) that worsened (Grade 2 severity) on 15 April 2022 (Day 4). The nonserious CRS was treated with tocilizumab (single dose).

Infectious workup included negative blood and urine cultures. EEG showed no seizure activity; both CT and MRI brain scans were unremarkable. On 16 April 2022 (Day 5), the participant's neurological status returned to baseline and the ICANS was reported as resolved. Steroid treatment (dexamethasone) was weaned and subsequently discontinued on 18 April 2022.

The investigator considered that there was a reasonable possibility that the SAE of 'ICANS' may have been caused by GSK3845097. The investigator considered that there was no reasonable possibility that the SAE ICANS may have been caused by fludarabine phosphate and cyclophosphamide.

The sponsor considered that there is a reasonable possibility that the SAE of ICANS may be caused by GSK3845097.

ARGUS SAE Narratives (Events: Pancytopenia, Aplastic Anemia, Febrile Neutropenia, and COVID-19 Pneumonia; Case ID: US2022GSK075341)

Following lymphodepletion (05-08 April 2022, Day -1 to Day -4), the participant experienced initial drop in hemoglobin, platelets, and neutrophils. By 19 April 2022

(Day 8), the participant's neutrophil count was reported to have normalized (ANC 4490/µL) and the platelet count remained above 50,000/µL. On 25 April 2022 (Day 14), during a follow up visit, the participant was noted to be neutropenic and thrombocytopenic. An SAE of 'Pancytopenia' (Grade 4) was reported with initial onset of 22 April 2022 (Day 11).

The participant was initially managed with Tbo-filgrastim 300 µg SC once and a platelet transfusion. Over the following week, the participant required multiple platelet and packed RBC transfusions, received daily filgrastim 300 µg SC (from 27 April to 2 May 2022, Days 16 to 21) and was switched to pegfilgrastim 6 mg SC on 02 May 2022 (Day 21).

Infectious workup was negative for EBV, HHV6, and influenza; CMV PCR identified a low viral load that did not require medical intervention. On 03 May 2022 (Day 22), the participant underwent a bone marrow biopsy for further evaluation of the pancytopenia, which showed a hypocellular marrow suggestive of aplastic anemia (results made available on 10 May 2022), which was reported as a separate SAE (Grade 4).

On 06 May 2022 (Day 25), the participant presented to the clinic reporting night sweats and an episode of low blood pressure. He also reported shortness of breath, cough, congestion, and sore throat since 03 May 2022. Upon evaluation, the participant was febrile with a temperature of 38.4°C, tachycardic with a heart rate of 135 bpm, had a blood pressure of 91/57 mmHg and oxygen saturation of 99%. The participant received 2 liters of IV fluids and 2 grams of cefepime and was admitted to the inpatient unit for further management of fever and neutropenia. An SAE of 'Febrile neutropenia' (Grade 3) was reported on 06 May 2022 (Day 25).

On 07 May 2022 (Day 26), the participant was noted to be hypoxemic (oxygen saturation 84%) requiring oxygen supplementation via nasal canula. An infectious workup was performed including blood culture, urine culture, and upper respiratory panel. Results were positive for Staphylococcus Epidermidis (considered a contaminant) and COVID-19 (the participant reported being unvaccinated). The participant was started on vancomycin, dexamethasone, and remdesivir. A chest X-ray showed reduced lung volumes, but no ground-glass opacity or consolidation. Subsequently the participant was diagnosed with an SAE of 'SARS-CoV-2 pneumonia' (Grade 3). During this admission, the participant had ongoing pancytopenia, requiring intermittent platelet and packed RBC transfusions.

On 08 May 2022 (Day 27), the participant was noted to be afebrile (SAE 'Febrile neutropenia' reported resolved on Day 27) and on 10 May 2022 (Day 29), the participant reported feeling well and had adequate oxygen saturation on room air. The participant continued to be pancytopenic but his WBC counts were slowly rising with WBC 800/µL, ANC 420/µL, and platelets 11,000/µL on 11 May 2022 (Day 30).

The SAEs of 'Aplastic anemia' and 'Pancytopenia' were both reported resolved on 18 May 2022 (Day 37). The SAE of 'COVID-19 pneumonia' was reported resolved on 20 May 2022 (Day 39).

The investigator considered that there was a reasonable possibility that 'Febrile neutropenia', 'Aplastic anemia' and 'COVID-19 pneumonia' may have a possible relationship to GSK3845097 and no reasonable possibility that these events may have been caused by lymphodepleting chemotherapy.

The sponsor considered the events of 'Aplastic anemia' and 'COVID-19 pneumonia' to have a possible relationship to GSK3845097 although, this relationship is confounded by the concomitant administration of lymphodepleting chemotherapy. The sponsor considers the events of 'Aplastic anemia' and 'COVID-19 pneumonia' to have a possible relationship to lymphodepleting chemotherapy.

The sponsor considered that there was a reasonable possibility that the SAE of 'Febrile neutropenia' may have been caused by GSK3845097. The sponsor considered that there was no reasonable possibility that the SAE of 'Febrile neutropenia' may have been caused by fludarabine phosphate and cyclophosphamide.

The investigator considered that there was a reasonable possibility that the SAE 'Pancytopenia' may have a possible relationship to fludarabine, cyclophosphamide, and GSK3845097. The sponsor considered that there was a reasonable possibility that the SAE of 'Pancytopenia' may have been caused by GSK3845097.

ARGUS SAE Narratives (Event: ALT Increased, Hyperbilirubinaemia, INR Increased; Case ID: US2022GSK080145)

On 16 May 2022 (Day 35), during routine follow-up, the participant was noted to have elevated bilirubin, ALT, AST, and INR: ALT = 360 U/L (>5×ULN), AST = 149 U/L (>3×ULN), bilirubin total = 2.0 mg/dL (2×ULN), bilirubin-direct = 11.457 mg/dL, alkaline phosphatase = 244 U/L (>2×ULN), INR = 1.72, LDH = 274 U/L, and creatinine kinase = 43 U/L. The participant reported feeling well and the skin rash diagnosed on 02 May 2022 (Day21) was improving with topical triamcinolone. Due to elevated bilirubin, and history of skin rash, the participant was diagnosed with GvHD of the skin and liver (Grade 2). The elevations in ALT and bilirubin were reported as SAEs of ALT increased (Grade 3), hyperbilirubinemia (Grade 2), and INR increased (Grade 2) per protocol requirements, and the participant was hospitalized.

Infectious workup showed a positive CMV PCR of 155 IU/L (decreasing, and considered not clinically significant), positive EBV nuclear antigen antibody and EBV viral capsid. The participant was not symptomatic with respect to the elevated liver enzymes. On 18 May 2022 (Day 37), repeat laboratory testing showed improvement in liver function tests with ALT = 197 U/L, AST = 53 U/L, bilirubin total = 1.1 mg/dL, bilirubin direct = 7.011 mg/dL, alkaline phosphatase = 219 U/L, and LDH = 279 U/L. A CT scan of the abdomen was performed, which revealed a normal liver. On 20 May 2022 (Day 39), the participant showed continuous improvement with ALT =112 U/L, alkaline phosphatase = 182 U/L and normal AST, total bilirubin, and LDH levels.

The outcome of the SAEs of 'ALT increased', 'Hyperbilirubinemia', and 'INR increased' were reported as resolved on 20 May 2022 (Day 39).

The investigator considered that there was a reasonable possibility that the events of ALT increased and blood bilirubin increased had a relationship to GSK3845097 and no reasonable possibility that the ALT increased and blood bilirubin increased had been caused by lymphodepleting chemotherapy. The sponsor considered the events of ALT increased and blood bilirubin increased had a possible relationship to GSK3845097. The sponsor did not consider the events of ALT increased and blood bilirubin increased to have a possible relationship to lymphodepleting chemotherapy.

ARGUS SAE Narratives (Events: Fever, Shingles; Case ID: US2022GSK128369)

On 29 August 2022 (Day 140), the participant presented to the outpatient clinic for experiencing fever at home and worsening rash that was hot to the touch and painful. Rash was described as "scattered fluid filled vesicles" between 1-3 mm in size. Some lesions appeared to be scabbed and dried. Isolated to the right lower extremity. The participant was given an injection of ketorolac for the pain and a swab of the site was sent to rule out monkeypox infection. The participant was sent home that same day with instructions to continue taking NSAIDS as needed. On 02 September 2022 (Day 144), the participant presented to the hospital emergency room with continued fever and rash. The participant reported that he was currently admitted to the hospital and being treated for cellulitis and possible shingles. Dermatology later (13 September 2022) confirmed the diagnosis as most likely shingles rash. An SAE of 'Pyrexia' (Grade 1) with onset 29 August 2022 (Day 140) and a report of 'Herpes Zoster' (Grade 3) (= CMV reactivation since participant was IgG positive / DNA PCR negative at screening and baseline) with onset date of 01 September 2022 (Day 143) were both reported. The participant completed 4 days of IV vancomycin, cefepime, and metronidazole and was discharged on 05 September 2022 (Day 147). The participant had no known history of exposure to active herpes zoster. The participant was unsure of having had chicken pox as a child but reported he believed he had been vaccinated for chicken pox as a child.

The outcome of the SAE of 'Pyrexia' was reported as resolved on 01 September 2022 (Day 143). The outcome of the SAE of 'Herpes Zoster' was reported as resolving.

The investigator considered that there was no reasonable possibility that the SAE of 'Pyrexia' and 'Herpes Zoster' may have been caused by GSK3845097, fludarabine phosphate, or cyclophosphamide.

The sponsor considered that there was no reasonable possibility that the SAEs of pyrexia and herpes zoster may have been caused by GSK3845097, fludarabine phosphate, or cyclophosphamide. The participant's medical history/risk factors could be considered as confounding factors.

Participant 209012-110801

Study ID	Substudy ID	Country Name	City Name	Site ID	Site Name	PI Last Name	Participant ID
209012	2	Sweden	Stockholm	247463	Karolinska	Yachnin	110801

- **Serious Adverse Events:** Fever (Grade 1), Pulmonary Embolism (Grade 3), Respiratory Insufficiency (Grade 5)
- **Adverse Events of Special Interest:** Cytokine Release Syndrome (Grade 2), Pancytopenia (Platelet Count Decreased [Grade 4], Neutrophil Count Decreased [Grade 4], Anemia [Grade 3], Neutrophil Count Decreased [Grade 1], Neutrophil Count Decreased [Grade 1])
- **Date of Leukapheresis:** 05 May 2021
- **Date of Lymphodepletion:** From 31 August 2021 (Day -7) to 03 September 2021 (Day -4)
- **Date of GSK3845097 Infusion for Sentinel Participant:** 07 September 2021 (Day 1), GSK3845097 infusion not given on Day 8
- **Clinical Supply:** This was a conforming product.
- **Disposition:** The participant continued in the interventional phase until death on 09 December 2021 (Day 94).

Participant 209012-110801, a 53-year-old male at the time of screening ICF signature, White, Not Hispanic or Latino, was initially diagnosed with SS Stage IV on 10 Feb 2020, which was positive for SYT-SSX1-specific translocation and of monophasic histology.

The participant was diagnosed with Stage IV advanced (metastatic/unresectable) disease on 10 February 2020. At screening, the disease grade and stage were as follows: Grade not reported, T3 N0 M1, Stage IV.

Location of tumors:

- Primary site: Extremities (right foot)
- Metastatic site: Lung

Prior anticancer treatments including systemic, radiation, and surgeries: Prior to leukapheresis, the participant received doxorubicin and ifosfamide from 11 March 2020 to 26 June 2020; received radiation therapy (60 Gy) to the right foot from 31 July 2020 to 03 September 2020; received pazopanib from 12 October 2020 to 19 October 2020, received radiation therapy (20 Gy) to the left lower lobe from 15 March 2021 to 18 March 2021.

The participant's last date of diagnosed progression was 25 August 2021.

The participant was screened for target expression:

- HLA-A type was A*02:01/786 - A*24:02/353.
- NY-ESO-1 antigen tumor expression by IHC showed 71% cells [≥2+].

At screening, the participant was found to have an HLA-A type positive for HLA-A*02:01 and to be positive for NY-ESO-1 antigen expression.

The participant was deemed eligible and underwent leukapheresis (enrolled) on 05 May 2021 (Day -125).

Anticancer treatments received between leukapheresis and lymphodepletion: Between leukapheresis and lymphodepletion, the participant received radiation therapy (20 Gy) to the lung on 18 May 2021 (Day -112); radiation therapy (20 Gy) to the left flank from 03 August 2021 to 06 August 2021 (Day -35 to Day -32).

A baseline CT scan on 25 August 2021 (Day-14) revealed 2 target lesions on the following anatomical locations:

- T01) – Infraclavicular lymph node: short axis= 84 mm
- T02) – Lung – right lower lobe: long diameter = 60 mm

and 1 non-target lesion:

- NT01) - Pleura – left

The participant received lymphodepleting chemotherapy from 31 August 2021 (Day -7) until 03 September 2021 (Day -4).

- Fludarabine 30 mg/m^2/day ×4 (Days -7 through -4) and
- Cyclophosphamide 1800 mg/m^2/day ×2 (Days -5 through -4).

Mesna was administered from 02 September 2021 until 04 September 2021 (Days -5 through -3) at an individual administration dose of 1000 mg (×5 on Day -5, ×6 on Day -4, and ×1 on Day -3).

A dose of 0.8×10^9 transduced cells of GSK3845097 was administered as 1 bag on 07 September 2021 (Day 1). The participant was a sentinel participant but did not receive the second aliquot of planned GSK3845097 infusion on 14 September 2021 (Day 8) due to AEs of dyspnea (Grade 3), AST increased (Grade 3), and ALT increased (Grade 3).

This participant had no history of past medical conditions reported. At study entry, the participant had Grade 1 hypercalcemia, Grade 2 hypertension, and Grade 2 hypothyroidism.

This participant experienced the following AEs:

Serious Adverse Events:

- SAE of fever, Grade 1, onset 18 May 2021 and end date 19 May 2021 (Day -112 to Day -111) reported as not related to study treatment (Case ID: SE2021GSK112986).
- SAE of pulmonary embolism, Grade 3, onset 07 December 2021 and end date unreported (Day 92 to unreported), reported as not related to study treatment (Case ID: SE2021GSK252223).
- SAE of respiratory insufficiency, Grade 5, onset 08 December 2021 and end date 09 December 2021 (Day 93 to Day 94), reported as not related to study treatment (Case ID: SE2021GSK252979).

Adverse Events of Special Interest (in addition to any SAEs reported above):

- Pancytopenia
  - Platelet count decreased, Grade 4, onset 08 September 2021 and end date 10 November 2021 (Day 2 to Day 65), reported as related to fludarabine, cyclophosphamide, and GSK3845097.
  - Neutrophil count decreased, Grade 4, onset 08 September 2021 and end date 18 September 2021 (Day 2 to Day 12), reported as related to fludarabine and cyclophosphamide.
  - Anemia, Grade 3, onset 10 September 2021 and end date 24 November 2021 (Day 4 to Day 79), reported as related to fludarabine, cyclophosphamide, and GSK3845097.
  - Neutrophil count decreased, Grade 1, onset 23 September 2021 and end date 26 September 2021 (Day 17 to Day 20), reported as related to GSK3845097.
  - Neutrophil count decreased, Grade 1, onset 07 October 2021 and end date 11 October 2021 (Day 31 to Day 35), reported as related to GSK3845097.
- CRS, Grade 2, onset 08 September 2021 and end date 10 September 2021 (Day 2 to Day 4), reported as related to GSK3845097. The participant received treatment with paracetamol, tocilizumab, piperacillin+tazobactam, and dexavit.

Adverse Events Related to Study Treatment (in addition to any SAEs and or AESIs reported above):

- **Related to Fludarabine, Cyclophosphamide and GSK3845097:**
  - Loss of appetite, Grade 2, onset 02 September 2021 and end date 21 September 2021 (Day -5 to Day 15)
  - Muscle weakness, Grade 1, onset 12 September 2021 (Day 6), not resolved

- **Related to GSK3845097:**
  - Dyspnea, Grade 3, onset 13 September 2021 and end date 16 September 2021 (Day 7 to Day 10)
  - AST increased, Grade 3, 14 September 2021 and end date 26 September 2021 (Day 8 to Day 20)
  - ALT increased, Grade 3, onset 14 September 2021 and end date 24 November 2021 (Day 8 to Day 71)
  - Pericardial effusion, Grade 2, onset 17 September 2021 and end date 21 September 2021 (Day 11 to Day 15)

- **Related to Fludarabine and Cyclophosphamide:**
  - Nausea, Grade 2, onset 02 September 2021 and end date 04 September 2021 (Day -5 to Day -3)

- **Related to Cyclophosphamide:**
  - Dizziness, Grade 1, onset 02 September 2021 and end date 03 September 2021 (Day -5 to Day -4)
  - Sensory neuropathy unspecified, Grade 1, onset 02 September 2021 and end date 02 September 2021 (Day -5 to Day -5)

The participant was monitored for delayed AEs per FDA guidance and was confirmed to not have experienced any.

Notable Adverse Events (in addition to any SAEs and AEs reported above):

- All Grade ≥3 AEs not related to treatment:
  - Syncope, Grade 3, onset 23 September 2021 and end date 23 September 2021 (Day 17 to Day 17)
- All AEs not related to treatment with maximum Grade ≥2 lasting more than 7 days: none

The participant was in the interventional phase of the study from 07 September 2021 (Day 1) and continued until death on 09 December 2021 (Day 94) due to hemorrhage (right lung) secondary to pulmonary embolism and disease under study.

ARGUS SAE Narratives (Event: Fever; Case ID: SE2021GSK112986)

On 18 May 2021 (Day -112), the participant developed a pre-treatment SAE of 'Pyrexia' (Grade 1) of unknown origin and was hospitalized. The participant developed fever while receiving palliative radiotherapy to one of his lung metastases. There was no indication that the participant had an ongoing infection and the outcome of event of 'Pyrexia' was reported as resolved on 19 May 2021 (Day -117). The participant was discharged from the hospital (without any antibiotic prescription). No concomitant medication was given. A CT scan showed no lung emboli. The fever was considered secondary to radiation therapy. The participant did not receive GSK3845097, cyclophosphamide, or fludarabine phosphate at the time of the SAE.

The sponsor considered that there was no reasonable possibility that the SAE of "Pyrexia" may have been caused by GSK3845097, cyclophosphamide, or fludarabine phosphate since the participant did not receive GSK3845097, cyclophosphamide, or fludarabine phosphate.

ARGUS SAE Narratives (Event: Pulmonary Embolism; Case ID: SE2021GSK252223)

On 07 December 2021 (Day 92), the participant developed an SAE of 'Pulmonary embolism' (Grade 3) and was hospitalized. Presenting symptoms included dyspnea and pain in the right side of chest (thorax). A CT showed pulmonary emboli in the right lower lobe (basal). The participant was started on anti-coagulant treatment (dalteparin) and oxygen. Other possible causes were SS with pulmonary metastases. The outcome of the SAE was reported not resolved.

The investigator considered that there was no reasonable possibility that the SAE of 'Pulmonary embolism' may have been caused by GSK3845097, fludarabine phosphate, and cyclophosphamide.

The sponsor considered that there was no reasonable possibility that the SAE of "Pulmonary embolism" may have been caused by GSK3845097, fludarabine phosphate,

and cyclophosphamide. The participant's medical history/risk factors could be considered as confounding factors.

ARGUS SAE Narratives (Event: Respiratory Insufficiency; Case ID: SE2021GSK252979)

On 08 December 2021 (Day 93), the participant developed an SAE of 'Respiratory failure' (Grade 5). Following a recent hospital admission (Day 92) for a pulmonary embolism shown on CT scan (Case SE2021GSK252223), the participant was being treated with anticoagulation and was an inpatient. On the evening of 08 December 2021 (Day 93), while going to the bathroom, the participant experienced an acute event, including a drop in blood pressure and tachypnoea. There was no hemoptysis. An urgent chest CT showed signs suggestive of a bleed, potentially from a pre-existing metastasis in the lung, although this could not be confirmed from the scan. The participant was not thrombocytopenic. Relevant tests indicated Troponin I and NT-pro BNP within normal range and hemoglobin result was 101 g/L (normal low: 134 g/L). Interventions were considered unlikely to be successful. The participant was given oxygen (10-15 L) without improvement, prothrombin complex concentrates (Ocplex), and tranexamic acid (Strataxen).

The lung embolus was in the right lower lobe and the suspected bleeding was from the same area. The radiologist was unable to determine if the bleeding originated from a metastatic lesion. The outcome of 'Respiratory failure' was fatal on 09 December 2021 (Day 94). Results of an autopsy showed evidence of a large bleed in the right lower lobe of the lung, where there was also a known pre-existing metastasis, but it was unclear if the bleeding was from the metastasis. There was blood (at least 1000 mL) in the pleural cavity. The autopsy report determined cause of death was thoracic hemorrhage.

The investigator considered that there was no reasonable possibility that the SAE of 'Respiratory failure' may have been caused by GSK3845097, fludarabine phosphate, or cyclophosphamide.

The sponsor considered that there was no reasonable possibility that the SAE of "Respiratory failure" may have been caused by GSK3845097, fludarabine phosphate, or cyclophosphamide. The participant's medical history/risk factors could be considered as confounding factors.

Signature Page for 209012 TMF-15222522 v2.0

Reason for signing: Approved	Name: Nidale Tarek Role: Approver Date of signature: 18-Aug-2023 14:51:02 GMT+0000

Signature Page for TMF-15222522 v2.0

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0100
Summary of Subject Status and Subject Disposition for the Study Conclusion Record
by Actual Dose

	Dose Confirmation			
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Subject Status				
COMPLETED [1]	2 (100%)	2 (100%)	0	4 (80%)
TRANSFERRED TO LONG-TERM FOLLOW-UP STUDY	0	2 (100%)	0	2 (40%)
DEATH POST LYMPHODEPLETION	2 (100%)	0	0	2 (40%)
WITHDRAWN	0	0	1 (100%)	1 (20%)
Primary Reason for Study Withdrawal				
DID NOT MEET INCLUSION/EXCLUSION CRITERIA	0	0	0	0
LOST TO FOLLOW-UP	0	0	0	0
PHYSICIAN DECISION	0	0	0	0
PROTOCOL DEVIATION	0	0	0	0
SITE TERMINATED BY SPONSOR	0	0	0	0
STUDY TERMINATED BY SPONSOR	0	0	1 (100%)	1 (20%)
SUBJECT REACHED PROTOCOL-DEFINED STOPPING CRITERIA	0	0	0	0
WITHDRAWAL BY SUBJECT	0	0	0	0
DEATH PRIOR TO LYMPHODEPLETION	0	0	0	0

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
[1] Subjects who are transferred to the long-term follow-up protocol or have died are considered to have completed the substudy.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_es8_itt.sas 24MAY2023 18:05

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0110
Summary of Subject Status and Subject Disposition for the Study Conclusion Record
by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Subject Status			
COMPLETED [1]	2 (100%)	2 (100%)	4 (100%)
TRANSFERRED TO LONG-TERM FOLLOW-UP STUDY	0	2 (100%)	2 (50%)
DEATH POST LYMPHODEPLETION	2 (100%)	0	2 (50%)
WITHDRAWN	0	0	0

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
[1] Subjects who are transferred to the long-term follow-up protocol or have died are considered to have completed the substudy.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_es8_mitt.sas 24MAY2023 18:05

Protocol: 209012SS2 Page 1 of 1
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0120
Summary of Subject Status and Subject Disposition for the Study Conclusion Record
by Relationship to COVID-19 Pandemic

No data to report

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: No subjects discontinued or withdrew from the study due to COVID-19 pandemic. For details refer to Table 1.0100
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_es8_relcov.sas 24MAY2023 18:05

Protocol: 209012SS2
Population: Screened Data as of 12MAY2023

Table 1.0130
Summary of Screening Status and Reasons for Screen Failure

	Screened Subjects (N=327)
Target Expression Eligibility Screening Status for 209012 [1]	
ENTERED INTO TARGET EXPRESSION SCREENING VISIT	327 (100%)
COMPLETED TARGET EXPRESSION ELIGIBILITY SCREENING	15 (5%)
MET ELIGIBILITY CRITERIA BUT NOT NEEDED [4]	3 (<1%)
FAILED - HLA/NY-ESO TESTING NOT PERFORMED	40 (12%)
Reason(s) for Failure	
ADVERSE EVENT	0
DID NOT MEET INCLUSION/EXCLUSION CRITERIA	15 (5%)
LOST TO FOLLOW-UP	2 (<1%)
PHYSICIAN DECISION	2 (<1%)
PROTOCOL DEVIATION	0
STUDY TERMINATED BY SPONSOR	18 (6%)
WITHDRAWAL BY SUBJECT	3 (<1%)

[1] Target expression screening status includes all 209012 participants (across substudies) who completed target expression screening or completed the Pre-screen failure CRF page.
[2] Leukapheresis Eligibility Screening Status includes all 209012 participants (across substudies) who completed the leukapheresis eligibility screening status CRF page.
[3] Leukapheresis Screening Status includes Substudy 2 participants who completed the leukapheresis screening status CRF page.
[4] Three participants met the target expression eligibility criteria but did not continue to the leukapheresis eligibility screening. These are treated as screen failures with no reason recorded.
Note: Subjects may have more than one reason for failure, so percentages may sum to more than 100%.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_es6_scr.sas 07JUN2023 11:33

Protocol: 209012SS2
Population: Screened Data as of 12MAY2023

Table 1.0130
Summary of Screening Status and Reasons for Screen Failure

	Screened Subjects (N=327)	
FAILED - HLA/NY-ESO TESTING PERFORMED	269	(82%)
Reason(s) for Failure		
ADVERSE EVENT	0	
DID NOT MEET INCLUSION/EXCLUSION CRITERIA	212	(65%)
LOST TO FOLLOW-UP	2	(<1%)
PHYSICIAN DECISION	5	(2%)
PROTOCOL DEVIATION	0	
STUDY TERMINATED BY SPONSOR	49	(15%)
WITHDRAWAL BY SUBJECT	2	(<1%)

[1] Target expression screening status includes all 209012 participants (across substudies) who completed target expression screening or completed the Pre-screen failure CRF page.
[2] Leukapheresis Eligibility Screening Status includes all 209012 participants (across substudies) who completed the leukapheresis eligibility screening status CRF page.
[3] Leukapheresis Screening Status includes Substudy 2 participants who completed the leukapheresis screening status CRF page.
[4] Three participants met the target expression eligibility criteria but did not continue to the leukapheresis eligibility screening. These are treated as screen failures with no reason recorded.
Note: Subjects may have more than one reason for failure, so percentages may sum to more than 100%.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_es6_scr.sas 07JUN2023 11:33

Protocol: 209012SS2
Population: Screened Data as of 12MAY2023

Table 1.0130
Summary of Screening Status and Reasons for Screen Failure

	Screened Subjects (N=327)	
Leukapheresis Eligibility Screening Status for 209012 [2]		
ENTERED INTO LEUKAPHERESIS ELIGIBILITY SCREENING VISIT	15	(5%)
COMPLETED LEUKAPHERESIS ELIGIBILITY SCREENING	12	(4%)
MET ELIGIBILITY CRITERIA BUT NOT NEEDED	0	
FAILED	3	(<1%)
Reason(s) for Failure		
ADVERSE EVENT	0	
DID NOT MEET INCLUSION/EXCLUSION CRITERIA	3	(<1%)
LOST TO FOLLOW-UP	0	
PHYSICIAN DECISION	0	
PROTOCOL DEVIATION	0	
STUDY TERMINATED BY SPONSOR	0	
WITHDRAWAL BY SUBJECT	0	
Leukapheresis Screening Status for 209012 Substudy 2 [3]		
ENTERED INTO LEUKAPHERESIS VISIT	5	(2%)
ENTERED INTO TRIAL	5	(2%)
MET ELIGIBILITY CRITERIA BUT NOT NEEDED	0	
FAILED	0	

[1] Target expression screening status includes all 209012 participants (across substudies) who completed target expression screening or completed the Pre-screen failure CRF page.
[2] Leukapheresis Eligibility Screening Status includes all 209012 participants (across substudies) who completed the leukapheresis eligibility screening status CRF page.
[3] Leukapheresis Screening Status includes Substudy 2 participants who completed the leukapheresis screening status CRF page.
[4] Three participants met the target expression eligibility criteria but did not continue to the leukapheresis eligibility screening. These are treated as screen failures with no reason recorded.
Note: Subjects may have more than one reason for failure, so percentages may sum to more than 100%.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_es6_scr.sas 07JUN2023 11:33

Protocol: 209012SS2
Population: Screened Data as of 12MAY2023

Table 1.0140
Summary of Screen Failures by HLA and Tumor Antigen Expression Criteria

	Screened Subjects (N=327)
SCREEN FAIL SUBJECTS FOR 209012 [1]	315 (96%)
DID NOT MEET HLA OR TUMOR ANTIGEN EXPRESSION CRITERIA FOR 209012 [1]	278 (88%)
HLA Positive	97 (35%)
NY-ESO-1 Negative	60 (22%)
NY-ESO-1 Not Done	33 (12%)
NY-ESO-1 Not Evaluable	4 (1%)
HLA Negative	131 (47%)
HLA Not Done	50 (18%)
NY-ESO-1 Negative	9 (3%)
NY-ESO-1 Positive	1 (<1%)
NY-ESO-1 Not Done	40 (14%)
MET HLA AND TUMOR ANTIGEN EXPRESSION CRITERIA FOR 209012 [2]	37 (12%)
Reason(s) for Failure	
Did Not Meet Inclusion/Exclusion Criteria	6 (16%)
Met Eligibility Criteria But Not Needed	3 (8%)
Physician Decision	4 (11%)
Study Terminated By Sponsor	23 (62%)
Withdrawal By Subject	1 (3%)

Note: Screened population includes all participants who signed an ICF to participate in the study.
[1] Includes all participants who underwent target expression screening, leukapheresis eligibility screening and leukapheresis screening (all substudies).
[2] Includes participants that were both HLA positive and NY-ESO-1 positive.
Note: Post database lock of Substudy 2, the NY-ESO-1 expression status for screen failure subject 110017 was updated from "Negative" to "Not Evaluable". The data change is not reflected in this table.
mm628244: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_pop_t2.sas 27JUL2023 11:42

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0150
Summary of Subject T-cell Infusion Status and Reason for Failure to Receive T-cell Infusion by Planned Dose

	Dose Confirmation		
	DL-1 (N=2)	DL1 (N=3)	Total (N=5)
T-cell Infusion Status			
Received planned T-cell infusion	1 (50%)	2 (67%)	3 (60%)
Did not receive full planned T-cell infusion, or withdrew	1 (50%)	1 (33%)	2 (40%)
Reason(s) for Failure to Receive Full Planned T-cell Infusion			
ADVERSE EVENT	0	1 (33%)	1 (20%)
PROTOCOL DEVIATION	0	0	0
STUDY CLOSED/TERMINATED	0	0	0
LOST TO FOLLOW-UP	0	0	0
INVESTIGATOR DISCRETION	0	0	0
DECISION BY SUBJECT OR PROXY	0	0	0
INVESTIGATOR SITE CLOSED	0	0	0
PROGRESSIVE DISEASE	0	0	0
Reason(s) for Failure to Start T-cell Infusion			
DEATH PRIOR TO T-CELL INFUSION	0	0	0
WITHDRAWAL PRIOR TO T-CELL INFUSION [1]	1 (50%)	0	1 (20%)

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: Planned doses - DL1 = 1-8 x 10^9 T-cells, DL-1 = 0.1-0.8 x 10^9 T-cells.
Note: The sentinel subject 110801 in dose level 1 (1-8 x 10^9) did not receive the second planned dose of T-cells on Day 8 due to a dose-limiting toxicity.
[1] Includes any subjects who did not receive T-cell infusion for any reason other than death. See Listing 1 for more details.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_es10_itt.sas 05JUN2023 09:57

Protocol: 209012SS2
Population: Lymphodepletion Data as of 12MAY2023

Table 1.0160
Summary of Interventional Phase Status by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Treatment Status			
COMPLETED [1]	2 (100%)	2 (100%)	4 (100%)
DEATH	2 (100%)	0	2 (50%)
CONFIRMED DISEASE PROGRESSION	0	2 (100%)	2 (50%)
WITHDRAWN	0	0	0

Note: Lymphodepletion population includes all ITT participants who started lymphodepletion chemotherapy.
[1] Subjects who have confirmed PD or have died are considered to have completed the interventional phase of the substudy.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_sd1_lymph.sas 24MAY2023 18:05

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0170
Summary of Interventional Phase Status by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Treatment Status			
COMPLETED [1]	2 (100%)	2 (100%)	4 (100%)
DEATH	2 (100%)	0	2 (50%)
CONFIRMED DISEASE PROGRESSION	0	2 (100%)	2 (50%)
WITHDRAWN	0	0	0

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
[1] Subjects who have confirmed PD or have died are considered to have completed the interventional phase of the substudy.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_sd1_mitt.sas 24MAY2023 18:05

Protocol: 209012SS2
Population: Enrolled Data as of 12MAY2023

Table 1.0180
Summary of Number of Subjects by Country and Site ID by Actual Dose

			Dose Confirmation			
Country	Site Id.	Investigator Id.	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Germany	Subtotal		1 (50%)	0	1 (100%)	2 (40%)
	246666	272073	1 (50%)	0	1 (100%)	2 (40%)
Sweden	Subtotal		1 (50%)	0	0	1 (20%)
	247463	212466	1 (50%)	0	0	1 (20%)
United States	Subtotal		0	2 (100%)	0	2 (40%)
	243978	416667	0	1 (50%)	0	1 (20%)
	244818	211108	0	1 (50%)	0	1 (20%)

Note: Enrolled population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_ns1_enrlfl.sas 25MAY2023 06:20

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0190
Summary of Number of Subjects by Country and Site ID by Actual Dose

Country	Site Id.	Investigator Id.	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Germany	Subtotal		1 (50%)	0	1 (25%)
	246666	272073	1 (50%)	0	1 (25%)
Sweden	Subtotal		1 (50%)	0	1 (25%)
	247463	212466	1 (50%)	0	1 (25%)
United States	Subtotal		0	2 (100%)	2 (50%)
	243978	416667	0	1 (50%)	1 (25%)
	244818	211108	0	1 (50%)	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_ns1_mitt.sas 25MAY2023 06:20

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0200
Summary of Study Populations by Actual Dose

Population	Population Definition	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Enrolled	All participants who started leukapheresis procedure.	2 (100%)	2 (100%)	1 (100%)	5 (100%)
Intent-to-Treat	All participants who started leukapheresis procedure.	2 (100%)	2 (100%)	1 (100%)	5 (100%)
Lymphodepletion	All ITT participants who started lymphodepletion chemotherapy.	2 (100%)	2 (100%)	0	4 (80%)
Modified ITT (mITT)	All ITT participants who received any dose of NY-ESO-1 specific T-cells.	2 (100%)	2 (100%)	0	4 (80%)
Modified ITT 90 (mITT90)	Participants in the mITT analysis set who have been followed-up for at least 90 days since the last T-cell infusion.	1 (50%)	1 (50%)	0	2 (40%)
DLT Evaluable Population	Participants in the mITT analysis set who are part of the dose confirmation phase that either had a DLT (meeting the definition of a DLT as defined in Section 8.2 of the Core Protocol) or have completed the DLT assessment period of 28 days since last T-cell infusion.	2 (100%)	2 (100%)	0	4 (80%)

Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy and T-cell infusion.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp1_a.sas 26MAY2023 06:43

Table 1.0200
Summary of Study Populations by Actual Dose

Population	Population Definition	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Pharmacokinetic	Participants in the mITT analysis set from whom at least one persistence sample was obtained, analysed, and was measurable.	2 (100%)	2 (100%)	0	4 (80%)

Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy and T-cell infusion.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp1_a.sas 26MAY2023 06:43

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0205
Summary of Study Populations by Planned Dose

Population	Population Definition	Dose Confirmation DL-1 (N=2)	Dose Confirmation DL1 (N=3)	Total (N=5)
Enrolled	All participants who started leukapheresis procedure.	2 (100%)	3 (100%)	5 (100%)
Intent-to-Treat	All participants who started leukapheresis procedure.	2 (100%)	3 (100%)	5 (100%)
Lymphodepletion	All ITT participants who started lymphodepletion chemotherapy.	1 (50%)	3 (100%)	4 (80%)
Modified ITT (mITT)	All ITT participants who received any dose of NY-ESO-1 specific T-cells.	1 (50%)	3 (100%)	4 (80%)
Modified ITT 90 (mITT90)	Participants in the mITT analysis set who have been followed-up for at least 90 days since the last T-cell infusion.	0	2 (67%)	2 (40%)
DLT Evaluable Population	Participants in the mITT analysis set who are part of the dose confirmation phase that either had a DLT (meeting the definition of a DLT as defined in Section 8.2 of the Core Protocol) or have completed the DLT assessment period of 28 days since last T-cell infusion.	1 (50%)	3 (100%)	4 (80%)
Pharmacokinetic	Participants in the mITT analysis set from whom at least one persistence sample was obtained, analysed, and was measurable.	1 (50%)	3 (100%)	4 (80%)

Note: Planned doses - DL1 = 1-8 x 10^9 T-cells, DL-1 = 0.1-0.8 x 10^9 T-cells.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp1_p.sas 26MAY2023 06:43

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0210
Summary of Demographic Characteristics by Actual Dose

	Dose Confirmation			
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Sex				
n	2	2	1	5
F	0	0	0	0
M	2 (100%)	2 (100%)	1 (100%)	5 (100%)
Age (YEARS) [1]				
n	2	2	1	5
Mean	60.0	29.0	41.0	43.8
SD	9.90	2.83		16.41
Median	60.0	29.0	41.0	41.0
Min.	53	27	41	27
Max.	67	31	41	67
Age Group 1 (YEARS) [1]				
n	2	2	1	5
<=18	0	0	0	0
19-64	1 (50%)	2 (100%)	1 (100%)	4 (80%)
>=65	1 (50%)	0	0	1 (20%)
Age Group 2 (YEARS) [1]				
n	2	2	1	5
<=17	0	0	0	0
18-64	1 (50%)	2 (100%)	1 (100%)	4 (80%)
>=65	1 (50%)	0	0	1 (20%)

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
[2] Body Surface Area (BSA) is derived using DuBois & Dubois formula.
Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: The reference date for age is T-cell infusion date. If the subject did not receive T-cell infusion, then the reference date for age is the date of eligibility for leukapheresis.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm1_itt.sas 25MAY2023 09:22

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0210
Summary of Demographic Characteristics by Actual Dose

	Dose Confirmation			
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Ethnicity				
n	2	2	1	5
HISPANIC OR LATINO	0	0	0	0
NOT HISPANIC OR LATINO	2 (100%)	2 (100%)	1 (100%)	5 (100%)
High Level Race				
n	2	2	1	5
BLACK OR AFRICAN AMERICAN	0	1 (50%)	0	1 (20%)
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0	0
ASIAN	0	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0	0
WHITE	2 (100%)	1 (50%)	1 (100%)	4 (80%)
OTHER	0	0	0	0
MULTIPLE	0	0	0	0

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
[2] Body Surface Area (BSA) is derived using DuBois & Dubois formula.
Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: The reference date for age is T-cell infusion date. If the subject did not receive T-cell infusion, then the reference date for age is the date of eligibility for leukapheresis.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm1_itt.sas 25MAY2023 09:22

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0210
Summary of Demographic Characteristics by Actual Dose

	Dose Confirmation			
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Race Detail				
n	2	2	1	5
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0	0
ASIAN - CENTRAL/SOUTH ASIAN HERITAGE	0	0	0	0
ASIAN - EAST ASIAN HERITAGE	0	0	0	0
ASIAN - JAPANESE HERITAGE	0	0	0	0
ASIAN - SOUTH EAST ASIAN HERITAGE	0	0	0	0
BLACK OR AFRICAN AMERICAN	0	1 (50%)	0	1 (20%)
MIXED ASIAN RACE	0	0	0	0
MIXED RACE	0	0	0	0
MIXED WHITE RACE	0	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0	0
WHITE - ARABIC/NORTH AFRICAN HERITAGE	0	0	0	0
WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE	2 (100%)	1 (50%)	1 (100%)	4 (80%)
Height (cm) at Leukapheresis Elig. Scr.				
n	2	2	1	5
Mean	182.5	177.5	168.0	177.6
SD	6.36	3.54		6.95
Median	182.5	177.5	168.0	178.0
Min.	178	175	168	168
Max.	187	180	168	187

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
[2] Body Surface Area (BSA) is derived using DuBois & Dubois formula.
Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: The reference date for age is T-cell infusion date. If the subject did not receive T-cell infusion, then the reference date for age is the date of eligibility for leukapheresis.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm1_itt.sas 25MAY2023 09:22

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0210
Summary of Demographic Characteristics by Actual Dose

	Dose Confirmation			
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Weight (kg) at Leukapheresis Elig. Scr.				
n	2	2	1	5
Mean	103.50	69.25	100.40	89.18
SD	10.607	4.031		19.100
Median	103.50	69.25	100.40	96.00
Min.	96.0	66.4	100.4	66.4
Max.	111.0	72.1	100.4	111.0
BMI (kg/m^2) at Leukapheresis Elig. Scr.				
n	2	2	1	5
Mean	31.021	22.018	35.573	28.330
SD	1.0205	2.1560		6.1705
Median	31.021	22.018	35.573	30.299
Min.	30.30	20.49	35.57	20.49
Max.	31.74	23.54	35.57	35.57
BSA (m^2) at Leukapheresis Elig. Scr.[2]				
n	2	2	1	5
Mean	2.249	1.858	2.091	2.061
SD	0.1549	0.0192		0.2114
Median	2.249	1.858	2.091	2.091
Min.	2.14	1.84	2.09	1.84
Max.	2.36	1.87	2.09	2.36

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
[2] Body Surface Area (BSA) is derived using DuBois & Dubois formula.
Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: The reference date for age is T-cell infusion date. If the subject did not receive T-cell infusion, then the reference date for age is the date of eligibility for leukapheresis.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm1_itt.sas 25MAY2023 09:22

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0220
Summary of Demographic Characteristics by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Sex			
n	2	2	4
F	0	0	0
M	2 (100%)	2 (100%)	4 (100%)
Age (YEARS) [1]			
n	2	2	4
Mean	60.0	29.0	44.5
SD	9.90	2.83	18.86
Median	60.0	29.0	42.0
Min.	53	27	27
Max.	67	31	67
Age Group 1 (YEARS) [1]			
n	2	2	4
<=18	0	0	0
19-64	1 (50%)	2 (100%)	3 (75%)
>=65	1 (50%)	0	1 (25%)
Age Group 2 (YEARS) [1]			
n	2	2	4
<=17	0	0	0
18-64	1 (50%)	2 (100%)	3 (75%)
>=65	1 (50%)	0	1 (25%)

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
[2] Body Surface Area (BSA) is derived using DuBois & Dubois formula.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: The reference date for age is T-cell infusion date.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm1_mitt.sas 25MAY2023 09:22

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0220
Summary of Demographic Characteristics by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Ethnicity			
n	2	2	4
HISPANIC OR LATINO	0	0	0
NOT HISPANIC OR LATINO	2 (100%)	2 (100%)	4 (100%)
High Level Race			
n	2	2	4
BLACK OR AFRICAN AMERICAN	0	1 (50%)	1 (25%)
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
WHITE	2 (100%)	1 (50%)	3 (75%)
OTHER	0	0	0
MULTIPLE	0	0	0

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
[2] Body Surface Area (BSA) is derived using DuBois & Dubois formula.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: The reference date for age is T-cell infusion date.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm1_mitt.sas 25MAY2023 09:22

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0220
Summary of Demographic Characteristics by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Race Detail			
n	2	2	4
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN - CENTRAL/SOUTH ASIAN HERITAGE	0	0	0
ASIAN - EAST ASIAN HERITAGE	0	0	0
ASIAN - JAPANESE HERITAGE	0	0	0
ASIAN - SOUTH EAST ASIAN HERITAGE	0	0	0
BLACK OR AFRICAN AMERICAN	0	1 (50%)	1 (25%)
MIXED ASIAN RACE	0	0	0
MIXED RACE	0	0	0
MIXED WHITE RACE	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
WHITE - ARABIC/NORTH AFRICAN HERITAGE	0	0	0
WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE	2 (100%)	1 (50%)	3 (75%)
Height (cm) at Leukapheresis Elig. Scr.			
n	2	2	4
Mean	182.5	177.5	180.0
SD	6.36	3.54	5.10
Median	182.5	177.5	179.0
Min.	178	175	175
Max.	187	180	187

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
[2] Body Surface Area (BSA) is derived using DuBois & Dubois formula.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: The reference date for age is T-cell infusion date.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm1_mitt.sas 25MAY2023 09:22

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0220
Summary of Demographic Characteristics by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Weight (kg) at Leukapheresis Elig. Scr.			
n	2	2	4
Mean	103.50	69.25	86.38
SD	10.607	4.031	20.831
Median	103.50	69.25	84.05
Min.	96.0	66.4	66.4
Max.	111.0	72.1	111.0
BMI (kg/m^2) at Leukapheresis Elig. Scr.			
n	2	2	4
Mean	31.021	22.018	26.520
SD	1.0205	2.1560	5.3769
Median	31.021	22.018	26.921
Min.	30.30	20.49	20.49
Max.	31.74	23.54	31.74
BSA (m^2) at Leukapheresis Elig. Scr.[2]			
n	2	2	4
Mean	2.249	1.858	2.054
SD	0.1549	0.0192	0.2433
Median	2.249	1.858	2.006
Min.	2.14	1.84	1.84
Max.	2.36	1.87	2.36

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
[2] Body Surface Area (BSA) is derived using DuBois & Dubois formula.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: The reference date for age is T-cell infusion date.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm1_mitt.sas 25MAY2023 09:22

Protocol: 209012SS2
Population: Enrolled

Data as of 12MAY2023

Table 1.0230
Summary of Age Ranges by Actual Dose

	Dose Confirmation			
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Age Ranges [1]				
Adult (18-64 years)	1 (50%)	2 (100%)	1 (100%)	4 (80%)
>=65-84 years	1 (50%)	0	0	1 (20%)

[1] Only year of birth is collected: day and month of birth are imputed to 30th June.
Note: Enrolled population includes all participants who started leukapheresis procedure.
Note: The reference date for age is T-cell infusion date. If the subject did not receive T-cell infusion, then the reference date for age is the date of eligibility for leukapheresis.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dm11.sas 25MAY2023 06:20

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Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Primary Tumor Type			
n	2	2	4
Myxoid/Round Cell Liposarcoma	1 (50%)	0	1 (25%)
Synovial Sarcoma	1 (50%)	2 (100%)	3 (75%)
HLA Status			
n	2	2	4
Positive	2 (100%)	2 (100%)	4 (100%)
Negative	0	0	0
One HLA Allele positive [1]			
A*02:01 - other	2 (100%)	1 (50%)	3 (75%)
A*02:05 - other	0	0	0
A*02:06 - other	0	0	0
Two HLA Alleles positive [1]			
A*02:01 - A*02:01	0	1 (50%)	1 (25%)
A*02:01 - A*02:05	0	0	0
A*02:01 - A*02:06	0	0	0
A*02:05 - A*02:05	0	0	0
A*02:05 - A*02:06	0	0	0
A*02:06 - A*02:06	0	0	0

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_dc2.sas 07JUL2023 15:25

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
NY-ESO-1 Status			
n	2	2	4
Positive	2 (100%)	2 (100%)	4 (100%)
Negative	0	0	0
Not Evaluable	0	0	0
NY-ESO-1 Expression Score (+1/+2/+3) (%)			
n	2	2	4
Min.	80	100	80
1st Quartile	80.0	100.0	90.0
Median	90.0	100.0	100.0
3rd Quartile	100.0	100.0	100.0
Max.	100	100	100
NY-ESO-1 Expression Score (+2/+3) (%)			
n	2	2	4
Min.	60	100	60
1st Quartile	60.0	100.0	80.0
Median	80.0	100.0	100.0
3rd Quartile	100.0	100.0	100.0
Max.	100	100	100

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_dc2.sas 07JUL2023 15:25

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Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
NY-ESO-1 H Score			
n	2	2	4
Min.	180	295	180
1st Quartile	180.0	295.0	237.5
Median	240.0	297.5	297.5
3rd Quartile	300.0	300.0	300.0
Max.	300	300	300
Extent of Disease at Screening			
n	2	2	4
Local Unresectable	0	0	0
Metastatic	2 (100%)	2 (100%)	4 (100%)
Time since Locally Advanced or Metastatic Disease to Leukapheresis Screening (months)			
n	2	2	4
Min.	9.1	10.3	9.1
1st Quartile	9.07	10.25	9.66
Median	11.93	11.19	11.19
3rd Quartile	14.78	12.12	13.45
Max.	14.8	12.1	14.8

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_dc2.sas 07JUL2023 15:25

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Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Time since Last Recurrence to Leukapheresis Screening (months)			
n	0	2	2
Min.		4.1	4.1
1st Quartile		4.11	4.11
Median		7.18	7.18
3rd Quartile		10.25	10.25
Max.		10.3	10.3
Time since Last Progression to Leukapheresis Screening (months)			
n	2	2	4
Min.	-3.7	1.1	-3.7
1st Quartile	-3.68	1.12	-2.97
Median	-2.97	2.61	-0.57
3rd Quartile	-2.27	4.11	2.61
Max.	-2.3	4.1	4.1

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
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Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Disease Stage at Screening			
n	2	2	4
0	0	0	0
I	0	0	0
IA	0	0	0
IB	0	0	0
IC	0	0	0
II	0	0	0
IIA	0	0	0
IIB	0	0	0
IIC	0	0	0
III	0	0	0
IIIA	0	0	0
IIIB	0	0	0
IIIC	0	0	0
IV	2 (100%)	2 (100%)	4 (100%)
IVA	0	0	0
IVB	0	0	0
IVC	0	0	0
Smoldering	0	0	0

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
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Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
TNM Staging: Primary Tumor			
n	2	1	3
TX	1 (50%)	0	1 (33%)
T0	0	0	0
T1	0	0	0
T1A	0	0	0
T1B	0	0	0
T2	0	0	0
T2A	0	0	0
T2B	0	0	0
T2C	0	0	0
T3	1 (50%)	1 (100%)	2 (67%)
T3B	0	0	0
T4	0	0	0
TNM Staging: Regional Lymph Nodes			
n	2	1	3
NX	1 (50%)	0	1 (33%)
N0	1 (50%)	1 (100%)	2 (67%)
N1	0	0	0
N2	0	0	0
N3	0	0	0

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
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Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
TNM Staging: Distant Metastasis			
n	2	1	3
MX	0	0	0
M0	0	0	0
M1	2 (100%)	1 (100%)	3 (100%)
M1B	0	0	0
M1C	0	0	0
Grade at Screening			
n	1	0	1
1	0	0	0
2	1 (100%)	0	1 (100%)
3	0	0	0
Visceral and/or Non-Visceral Disease			
n	2	2	4
Visceral	1 (50%)	1 (50%)	2 (50%)
Non-Visceral	1 (50%)	1 (50%)	2 (50%)
Visceral And Non-Visceral	0	0	0

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
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Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Status of Measurable Disease at Screening			
n	2	2	4
Yes	2 (100%)	2 (100%)	4 (100%)
No	0	0	0
Non-target Lesions			
n	2	2	4
Yes	2 (100%)	1 (50%)	3 (75%)
No	0	1 (50%)	1 (25%)
NY-ESO-1 Tumor Biopsy Site			
n	2	2	4
Primary	2 (100%)	1 (50%)	3 (75%)
Metastatic	0	1 (50%)	1 (25%)
Anatomical Location of Biopsy Site			
n	2	2	4
Bone	0	1 (50%)	1 (25%)
Foot	1 (50%)	0	1 (25%)
Leg	1 (50%)	0	1 (25%)
Other	0	1 (50%)	1 (25%)

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
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Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Number of Prior Radiotherapy Regimens Before Start of Leukapheresis			
n	2	2	4
0	1 (50%)	2 (100%)	3 (75%)
1	0	0	0
>1	1 (50%)	0	1 (25%)
Radiotherapy Between Leukapheresis and Lymphodepletion			
n	2	2	4
Yes	2 (100%)	0	2 (50%)
No	0	2 (100%)	2 (50%)

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
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Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Number of Prior Systemic Therapy Regimens in the Metastatic/Advanced Setting Before Start of Lymphodepletion			
n	2	2	4
0	0	0	0
1	1 (50%)	2 (100%)	3 (75%)
2	1 (50%)	0	1 (25%)
3	0	0	0
4	0	0	0
>4	0	0	0
Best Response to Most Recent Prior Systemic Therapy in the Metastatic/Advanced Setting			
n	1	1	2
Complete Response	0	0	0
Partial Response	0	0	0
Stable Disease	0	0	0
Progressive Disease	0	1 (100%)	1 (50%)
Not Evaluable	1 (100%)	0	1 (50%)

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
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Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0240
Summary of Disease Characteristics at Screening by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Neo-Adjuvant Therapy			
n	2	2	4
Yes	0	1 (50%)	1 (25%)
No	2 (100%)	1 (50%)	3 (75%)
Adjuvant Therapy			
n	2	2	4
Yes	0	0	0
No	2 (100%)	2 (100%)	4 (100%)

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: For records with partial dates, "Time since" parameters are not calculated.
Note: For subjects 110014, 110762, and 110801, "Grade at Screening" was unknown.
Note: For subject 110014, all "TNM Staging" parameters were unknown.
Note: For subject 110454 and 110762 the best response to the most recent prior systemic therapy in the metastatic/advanced setting was not collected on the CRF when the intent was intermediate standard of care.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_dc2.sas 07JUL2023 15:25

Protocol: 209012SS2
Population: Screened Data as of 12MAY2023

Table 1.0245
Summary of HLA and NY-ESO-1 Results at Screening for 209012

	Screened Subjects (N=327)
HLA Status	
n	277
Positive	146 (53%)
Negative	131 (47%)
One HLA Allele positive [1]	
A*02:01 - other	115 (42%)
A*02:05 - other	10 (4%)
A*02:06 - other	1 (<1%)
Two HLA Alleles positive [1]	
A*02:01 - A*02:01	20 (7%)
A*02:01 - A*02:05	0
A*02:01 - A*02:06	0
A*02:05 - A*02:05	0
A*02:05 - A*02:06	0
A*02:06 - A*02:06	0
NY-ESO-1 Status	
n	124
Positive	50 (40%)
Negative	70 (56%)
Not Evaluable	4 (3%)

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Screened population includes all participants who signed an ICF to participate in the study.
Note: Post database lock of Substudy 2, the NY-ESO-1 expression status for screen failure subject 110017 was updated from "Negative" to "Not Evaluable". The data change is not reflected in this table.
mm628244: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_dc2_scrn.sas 27JUL2023 11:44

Protocol: 209012SS2
Population: Screened Data as of 12MAY2023

Table 1.0245
Summary of HLA and NY-ESO-1 Results at Screening for 209012

	Screened Subjects (N=327)
NY-ESO-1 Expression Score (+1/+2/+3) (%)	
n	50
Min.	10
1st Quartile	90.0
Median	100.0
3rd Quartile	100.0
Max.	100
NY-ESO-1 Expression Score (+2/+3) (%)	
n	50
Min.	0
1st Quartile	75.0
Median	100.0
3rd Quartile	100.0
Max.	100
NY-ESO-1 H Score	
n	50
Min.	10
1st Quartile	195.0
Median	293.5
3rd Quartile	300.0
Max.	300

[1] Percentages calculated based on number of subjects with HLA testing performed.
Note: Screened population includes all participants who signed an ICF to participate in the study.
Note: Post database lock of Substudy 2, the NY-ESO-1 expression status for screen failure subject 110017 was updated from "Negative" to "Not Evaluable". The data change is not reflected in this table.
mm628244: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_dc2_scrn.sas 27JUL2023 11:44

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0250
Summary of Important Protocol Deviations by Actual Dose

Category/Coded Term	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	Dose Confirmation: No Treatment (N=1)	Total (N=5)
Any important protocol deviations	1 (50%)	2 (100%)	0	3 (60%)
ASSESSMENT OR TIME POINT COMPLETION	0	1 (50%)	0	1 (20%)
INCOMPLETE ASSESSMENT	0	1 (50%)	0	1 (20%)
MISSED ASSESSMENT	0	1 (50%)	0	1 (20%)
INFORMED CONSENT	0	1 (50%)	0	1 (20%)
INFORMED CONSENT/ASSENT NOT SIGNED AND/OR DATED BY SUBJECT (PARENT/LEGAL REP)	0	1 (50%)	0	1 (20%)
WRONG STUDY TREATMENT/ ADMINISTRATION/ DOSE	1 (50%)	0	0	1 (20%)
STUDY TREATMENT NOT ADMINISTERED PER PROTOCOL	1 (50%)	0	0	1 (20%)

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dv1_itt.sas 25MAY2023 06:21

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0255
Summary of Important Protocol Deviations by Actual Dose

Category/Coded Term	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Any important protocol deviations	1 (50%)	2 (100%)	3 (75%)
ASSESSMENT OR TIME POINT COMPLETION	0	1 (50%)	1 (25%)
INCOMPLETE ASSESSMENT	0	1 (50%)	1 (25%)
MISSED ASSESSMENT	0	1 (50%)	1 (25%)
INFORMED CONSENT	0	1 (50%)	1 (25%)
INFORMED CONSENT/ASSENT NOT SIGNED AND/OR DATED BY SUBJECT (PARENT/LEGAL REP)	0	1 (50%)	1 (25%)
WRONG STUDY TREATMENT/ ADMINISTRATION/ DOSE	1 (50%)	0	1 (25%)
STUDY TREATMENT NOT ADMINISTERED PER PROTOCOL	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dv1_mitt.sas 25MAY2023 12:13

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 1.0260
Summary of Important COVID-19 Related Protocol Deviations by Actual Dose

No data to report

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_dv1_itt_c19.sas 25MAY2023 06:21

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0270
Summary of Concomitant Medications by Actual Dose

Ingredient	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Any medication	2 (100%)	2 (100%)	4 (100%)
DEXAMETHASONE	2 (100%)	1 (50%)	3 (75%)
FLUCONAZOLE	2 (100%)	1 (50%)	3 (75%)
GRANULOCYTE COLONY STIMULATING FACTOR	2 (100%)	1 (50%)	3 (75%)
MAGNESIUM SULFATE	1 (50%)	2 (100%)	3 (75%)
ONDANSETRON	1 (50%)	2 (100%)	3 (75%)
PARACETAMOL	2 (100%)	1 (50%)	3 (75%)
TOCILIZUMAB	2 (100%)	1 (50%)	3 (75%)
ALLOPURINOL	1 (50%)	1 (50%)	2 (50%)
COLECALCIFEROL	2 (100%)	0	2 (50%)
FUROSEMIDE	2 (100%)	0	2 (50%)
LEVOTHYROXINE	2 (100%)	0	2 (50%)
LIDOCAINE	1 (50%)	1 (50%)	2 (50%)
LINEZOLID	1 (50%)	1 (50%)	2 (50%)
LORAZEPAM	0	2 (100%)	2 (50%)
MEROPENEM	1 (50%)	1 (50%)	2 (50%)
PANTOPRAZOLE	1 (50%)	1 (50%)	2 (50%)
PEGFILGRASTIM	0	2 (100%)	2 (50%)
PIPERACILLIN	2 (100%)	0	2 (50%)
PREDNISOLONE	2 (100%)	0	2 (50%)
PROCHLORPERAZINE	0	2 (100%)	2 (50%)
SODIUM BICARBONATE	1 (50%)	1 (50%)	2 (50%)
SODIUM CHLORIDE	0	2 (100%)	2 (50%)
SULFAMETHOXAZOLE	1 (50%)	1 (50%)	2 (50%)
TAZOBACTAM	2 (100%)	0	2 (50%)
TRIMETHOPRIM	1 (50%)	1 (50%)	2 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: Concomitant medications are medications ongoing or with onset on or after lymphodepletion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_cm8.sas 25MAY2023 06:21

Table 1.0270
Summary of Concomitant Medications by Actual Dose

Ingredient	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	Total (N=4)
VALACICLOVIR	0	2 (100%)	2 (50%)
VANCOMYCIN	0	2 (100%)	2 (50%)
ACYCLOVIR	1 (50%)	0	1 (25%)
ALIZAPRIDE	1 (50%)	0	1 (25%)
AMLODIPINE	1 (50%)	0	1 (25%)
AMPHOTERICIN B	1 (50%)	0	1 (25%)
ANAKINRA	1 (50%)	0	1 (25%)
BENZYDAMINE	1 (50%)	0	1 (25%)
BETAMETHASONE	1 (50%)	0	1 (25%)
BUDESONIDE	1 (50%)	0	1 (25%)
CALCIUM	1 (50%)	0	1 (25%)
CALCIUM CHLORIDE	0	1 (50%)	1 (25%)
CAMPHOR	0	1 (50%)	1 (25%)
CASPOFUNGIN	1 (50%)	0	1 (25%)
CEFEPIME	0	1 (50%)	1 (25%)
CETIRIZINE	1 (50%)	0	1 (25%)
CLEMASTINE	1 (50%)	0	1 (25%)
CLOBETASOL	1 (50%)	0	1 (25%)
DALTEPARIN	1 (50%)	0	1 (25%)
DEFERASIROX	1 (50%)	0	1 (25%)
DEXPANTHENOL	1 (50%)	0	1 (25%)
DIMENHYDRINATE	1 (50%)	0	1 (25%)
DIPHENHYDRAMINE	0	1 (50%)	1 (25%)
EMEND (NOS)	1 (50%)	0	1 (25%)
ENOXAPARIN	0	1 (50%)	1 (25%)
ESOMEPRAZOLE	1 (50%)	0	1 (25%)
FACTOR VIII INHIBITOR BYPASSING FRACTION	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: Concomitant medications are medications ongoing or with onset on or after lymphodepletion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_cm8.sas 25MAY2023 06:21

Protocol: 209012SS2 Page 3 of 4
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0270
Summary of Concomitant Medications by Actual Dose

Ingredient	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	Total (N=4)
FAMOTIDINE	1 (50%)	0	1 (25%)
FOSAPREPITANT	0	1 (50%)	1 (25%)
GRANISETRON	1 (50%)	0	1 (25%)
GUAIFENESIN	0	1 (50%)	1 (25%)
HEPARIN (NOS)	0	1 (50%)	1 (25%)
HYDROMORPHONE	0	1 (50%)	1 (25%)
INSULIN GLARGINE	1 (50%)	0	1 (25%)
INSULIN HUMAN	1 (50%)	0	1 (25%)
INSULIN NOS	1 (50%)	0	1 (25%)
IOHEXOL	0	1 (50%)	1 (25%)
IPRATROPIUM	1 (50%)	0	1 (25%)
IRBESARTAN	1 (50%)	0	1 (25%)
KALINOR (NOS)	1 (50%)	0	1 (25%)
LACTULOSE	1 (50%)	0	1 (25%)
LEVETIRACETAM	0	1 (50%)	1 (25%)
LEVOFLOXACIN	0	1 (50%)	1 (25%)
LEVOMENTHOL	0	1 (50%)	1 (25%)
MAALOX (NOS)	0	1 (50%)	1 (25%)
METHYLPREDNISOLONE	1 (50%)	0	1 (25%)
METOCLOPRAMIDE	1 (50%)	0	1 (25%)
MORPHINE	1 (50%)	0	1 (25%)
NALOXONE	1 (50%)	0	1 (25%)
NOVALGIN NOS	1 (50%)	0	1 (25%)
NYSTATIN	0	1 (50%)	1 (25%)
OLANZAPINE	1 (50%)	0	1 (25%)
OXYCODONE	0	1 (50%)	1 (25%)
OXYGEN	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: Concomitant medications are medications ongoing or with onset on or after lymphodepletion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_cm8.sas 25MAY2023 06:21

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 1.0270
Summary of Concomitant Medications by Actual Dose

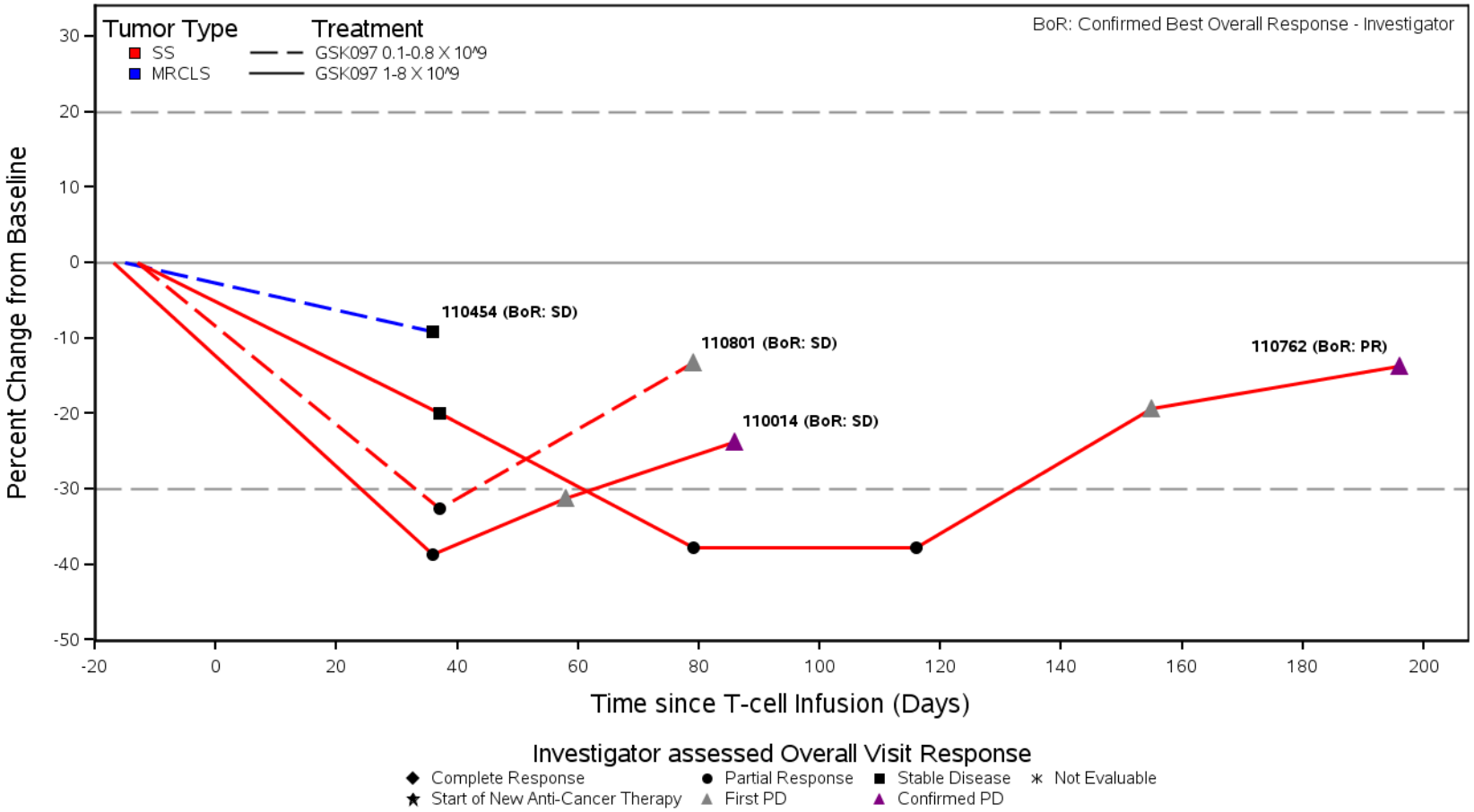
Ingredient	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	Total (N=4)
PETHIDINE	1 (50%)	0	1 (25%)
PHENOL	0	1 (50%)	1 (25%)
PICOSULFATE	1 (50%)	0	1 (25%)
POTASSIUM	0	1 (50%)	1 (25%)
POTASSIUM IODIDE	1 (50%)	0	1 (25%)
POTASSIUM PHOSPHATE DIBASIC	0	1 (50%)	1 (25%)
POVIDONE-IODINE	0	1 (50%)	1 (25%)
PREGABALIN	0	1 (50%)	1 (25%)
REMDESIVIR	0	1 (50%)	1 (25%)
RIVAROXABAN	1 (50%)	0	1 (25%)
RUXOLITINIB	1 (50%)	0	1 (25%)
SALBUTAMOL	1 (50%)	0	1 (25%)
SENNA	0	1 (50%)	1 (25%)
SIMETICONE	1 (50%)	0	1 (25%)
SODIUM LACTATE	0	1 (50%)	1 (25%)
SODIUM PHOSPHATE	0	1 (50%)	1 (25%)
SUCRALFATE	0	1 (50%)	1 (25%)
TILIDINE	1 (50%)	0	1 (25%)
TINZAPARIN	1 (50%)	0	1 (25%)
TRANEXAMIC ACID	1 (50%)	0	1 (25%)
TRIAMCINOLONE	0	1 (50%)	1 (25%)
URAPIDIL	1 (50%)	0	1 (25%)
ZOPICLONE	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: Concomitant medications are medications ongoing or with onset on or after lymphodepletion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_sp_cm8.sas 25MAY2023 06:21

Protocol: 209012SS2
Population: Modified Intent-to-Treat

Data as of 12MAY2023

Figure 2.0120
Spider Plot of Investigator-Assessed Percent Change from Baseline in Target Lesion Diameter by Actual Dose



Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: Patient 110454 had only one imaging evaluation as they died on study day 39.
ak381452: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/f_eff_f1.sas 01JUN2023 04:13

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 2.0100
Summary of Investigator-Assessed Best Response with Confirmation (RECIST 1.1 Criteria)
by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Best Response			
Complete Response	0	0	0
Partial Response	0	1 (50%)	1 (25%)
Stable Disease	2 (100%)	1 (50%)	3 (75%)
Progressive Disease	0	0	0
Not Evaluable	0	0	0
Response Rate			
[CR + PR]	0 (0.0%)	1 (50.0%)	1 (25.0%)
95% Confidence Interval [1]	(0.0%, 84.2%)	(1.3%, 98.7%)	(0.6%, 80.6%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
[1] Confidence intervals were calculated using the exact (Clopper-Pearson) method.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_eff_bestresp.sas 25MAY2023 06:27

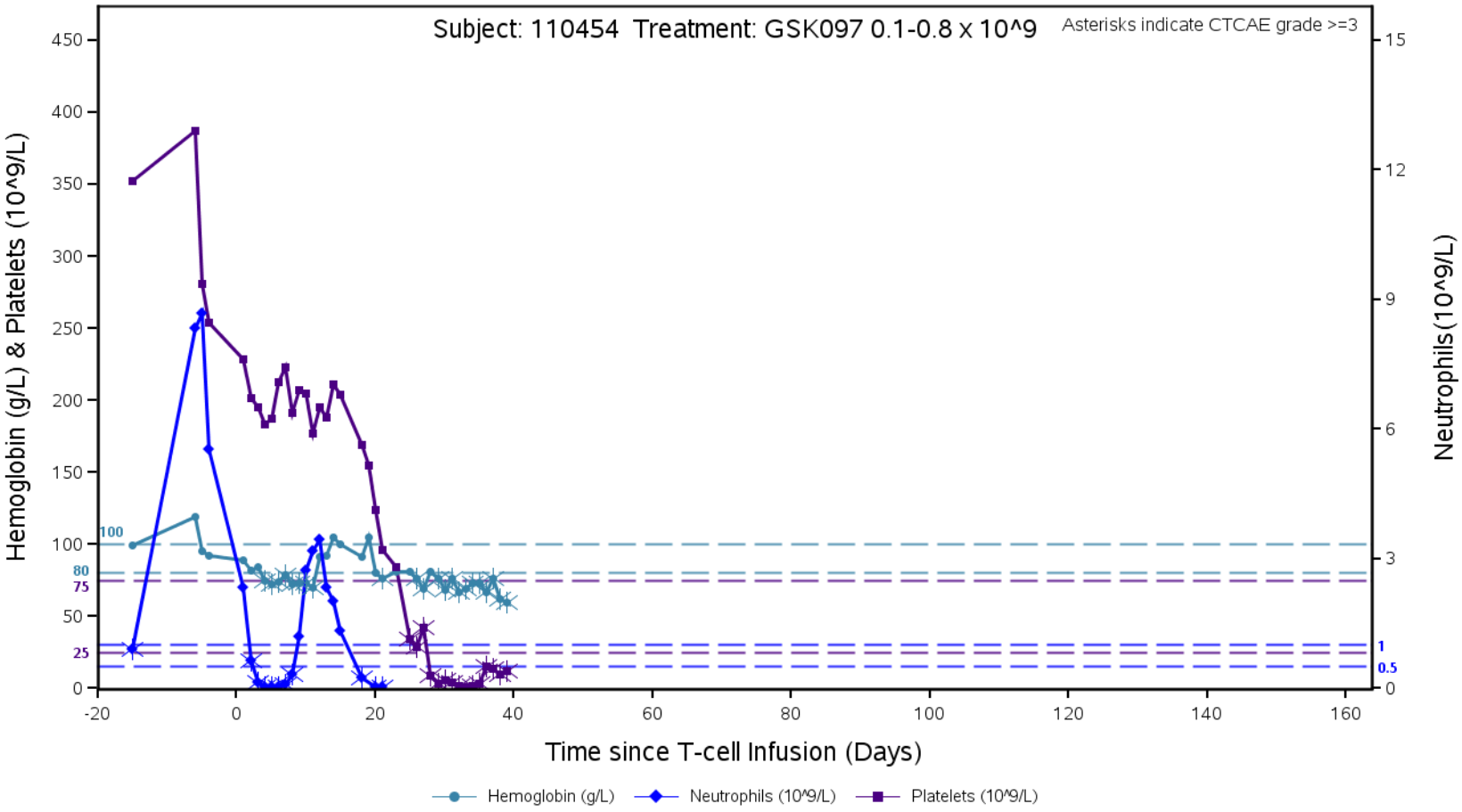
Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 2.0110
Summary of Investigator-Assessed Duration of Response (RECIST 1.1 Criteria)
by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Number of Subjects			
n	0	1	1
Progressed or Died (event)	0	1 (100%)	1 (100%)
Censored, follow-up ended	0	0	0
Censored, follow-up ongoing	0	0	0
Summary Statistics for Duration of Response (Months)			
n	0	1	1
Mean		2.53	2.53
SD			
Median		2.53	2.53
Min.		2.5	2.5
Max.		2.5	2.5

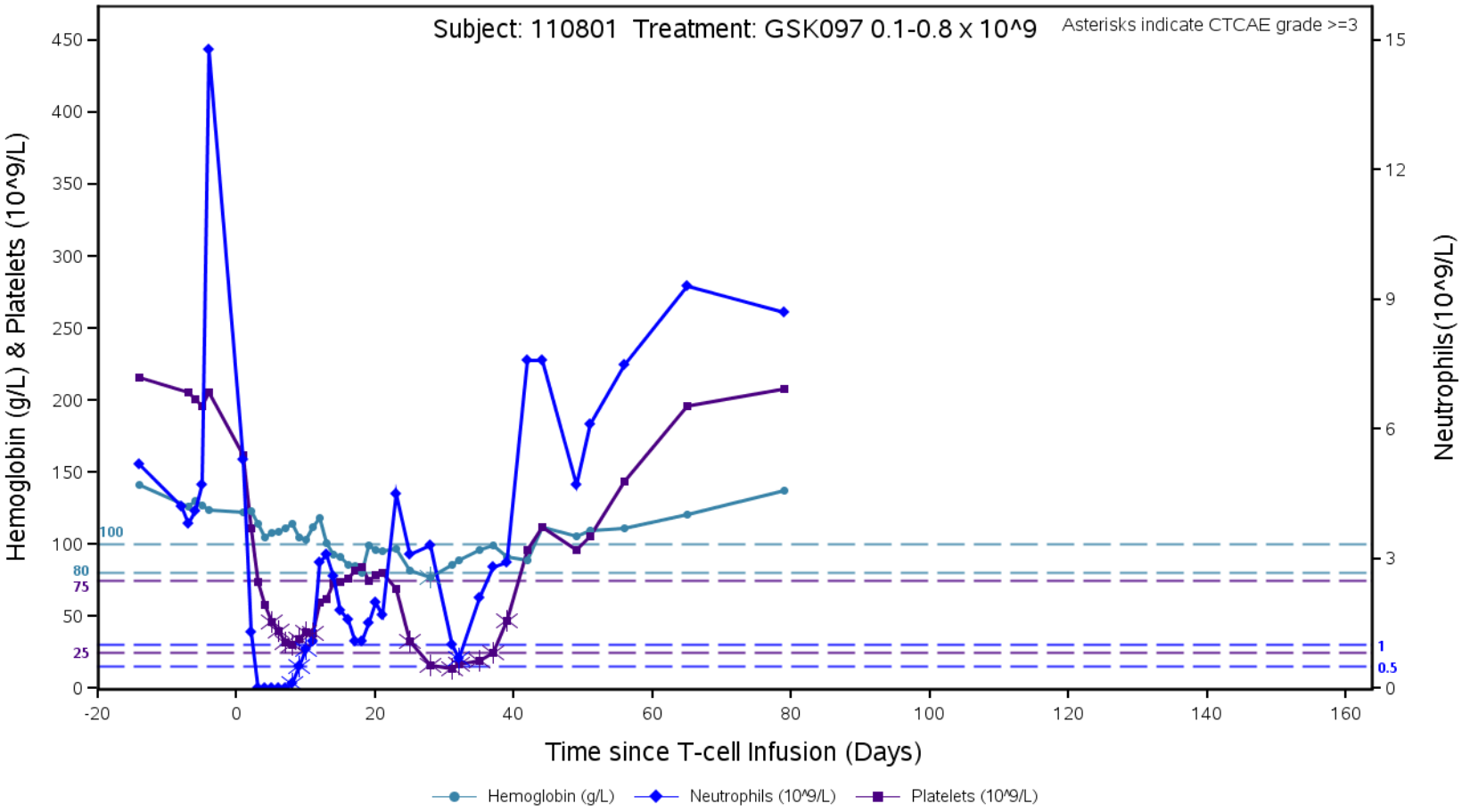
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: Duration of Response is defined as the interval between the initial date of the confirmed response (Partial Response / Complete Response) and the date of progressive disease or death among subjects with a confirmed response per RECIST 1.1.
Note: Minimum criterion of 5 or more confirmed responders for presentation of Kaplan-Meier statistics, has not been met; summary statistics are presented instead.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_eff_dur_resp.sas 30MAY2023 08:42

Figure 3.0360
Plot of Hemoglobin, Neutrophils and Platelets Over Time by Actual Dose



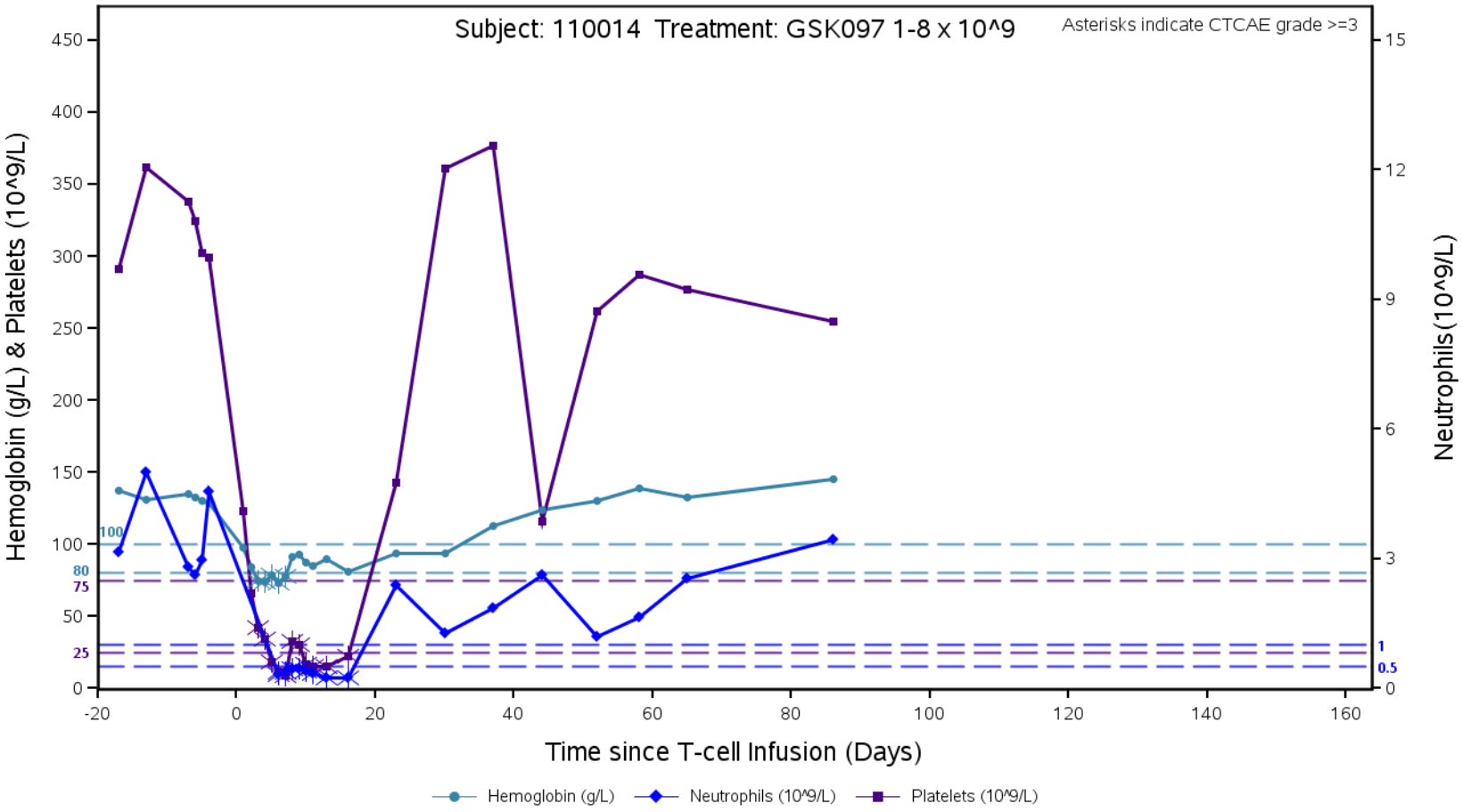
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: The reference lines for Hemoglobin, Neutrophils and Platelets help distinguish the CTCAE grades for Anemia, Neutrophil count decreased and Platelet count decreased, respectively.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/f_saf_safe_f3.sas 25MAY2023 06:27

Figure 3.0360
Plot of Hemoglobin, Neutrophils and Platelets Over Time by Actual Dose



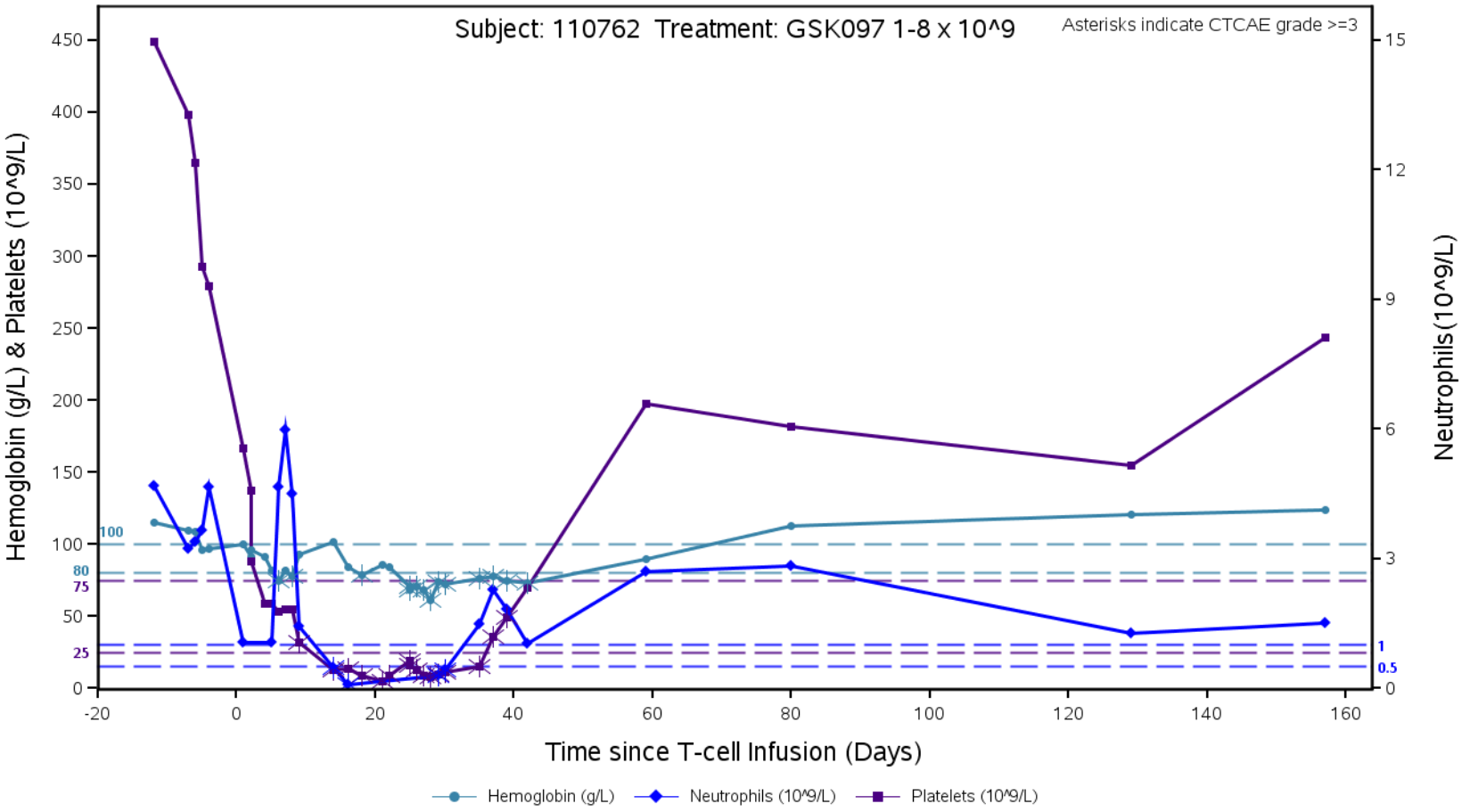
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: The reference lines for Hemoglobin, Neutrophils and Platelets help distinguish the CTCAE grades for Anemia, Neutrophil count decreased and Platelet count decreased, respectively.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/f_saf_safe_f3.sas 25MAY2023 06:27

Figure 3.0360
Plot of Hemoglobin, Neutrophils and Platelets Over Time by Actual Dose



Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: The reference lines for Hemoglobin, Neutrophils and Platelets help distinguish the CTCAE grades for Anemia, Neutrophil count decreased and Platelet count decreased, respectively.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/f_saf_safe_f3.sas 25MAY2023 06:27

Figure 3.0360
Plot of Hemoglobin, Neutrophils and Platelets Over Time by Actual Dose



Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: The reference lines for Hemoglobin, Neutrophils and Platelets help distinguish the CTCAE grades for Anemia, Neutrophil count decreased and Platelet count decreased, respectively.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/f_saf_safe_f3.sas 25MAY2023 06:27

Protocol: 209012SS2
Population: DLT Evaluable Data as of 12MAY2023

Table 3.0100
Summary of Dose-Limiting Toxicities as Reported on CRF by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
No. of Subjects with DLT	2 (100%)	2 (100%)	4 (100%)

Note: DLT Evaluable population includes participants in mITT analysis set who are part of the dose confirmation phase and have completed DLT assessment period of 28 days since last T-cell infusion or withdrawn within 28 days due to an AE meeting the definition of a DLT as defined in Section 8.2 of the Core Protocol.
Note: The sentinel subject 110801 in dose level 1 (1-8 x 10^9) did not receive second dose of T-cells on Day 8, hence is summarised under actual dose level 0.1-0.8 x 10^9.
Note: DLTs assigned where "Is this event a DLT" is "Yes" as per the AE eCRFs. See Table 3.0101 where DLTs have been assigned programmatically based on timing and relatedness from the protocol definition.
mm628244: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_ae19_a.sas 29JUN2023 05:10

Protocol: 209012SS2
Population: DLT Evaluable Data as of 12MAY2023

Table 3.0101
Summary of Dose-Limiting Toxicities as per Protocol Definition (T-cell Related) by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
No. of Subjects with DLT	2 (100%)	1 (50%)	3 (75%)

Note: DLT Evaluable population includes participants in mITT analysis set who are part of the dose confirmation phase and have completed DLT assessment period of 28 days since last T-cell infusion or withdrawn within 28 days due to an AE meeting the definition of a DLT as defined in Section 8.2 of the Core Protocol.
Note: The sentinel subject 110801 in dose level 1 (1-8 x 10^9) did not receive second dose of T-cells on Day 8, hence is summarised under actual dose level 0.1-0.8 x 10^9.
Note: DLTs assigned where "Is this event a DLT" is "Yes" as per the AE eCRFs, and the AE occurred on or after, and was related to, T-cell infusion.
mm628244: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_ae19_b.sas 29JUN2023 05:11

Protocol: 209012SS2
Population: DLT Evaluable Data as of 12MAY2023

Table 3.0105
Summary of Dose-Limiting Toxicities as Reported on CRF by Actual Dose and Planned Dose

	Planned Dose		
Actual Dose	DL-1 (N=1)	DL1 (N=3)	Total (N=4)
GSK097 0.1-0.8 x 10^9 (N=2)			
n	1	1	2
Number of Subjects with DLT	1	1*	2
GSK097 1-8 x 10^9 (N=2)			
n	0	2	2
Number of Subjects with DLT	0	2	2

* The sentinel subject 110801 in dose level 1 (1-8 x 10^9) did not receive second dose of T-cells on Day 8, hence is summarised under actual dose level 0.1-0.8 x 10^9.
Note: DLT Evaluable population includes participants in mITT analysis set who are part of the dose confirmation phase and have completed DLT assessment period of 28 days since last T-cell infusion or withdrawn within 28 days due to an AE meeting the definition of a DLT as defined in Section 8.2 of the Core Protocol.
Note: Planned doses - DL1 = 1-8 x 10^9 T-cells, DL-1 = 0.1-0.8 x 10^9 T-cells.
Note: DLTs assigned where "Is this event a DLT" is "Yes" as per the AE eCRFs. See Table 3.0106 where DLTs have been assigned programmatically based on timing and relatedness from the protocol definition.
mm628244: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_safe_t8.sas 29JUN2023 05:12

Protocol: 209012SS2
Population: DLT Evaluable Data as of 12MAY2023

Table 3.0106
Summary of Dose-Limiting Toxicities as per Protocol Definition (T-cell Related) by Actual Dose and Planned Dose

	Planned Dose		
Actual Dose	DL-1 (N=1)	DL1 (N=3)	Total (N=4)
GSK097 0.1-0.8 x 10^9 (N=2)			
n	1	1	2
Number of Subjects with DLT	1	1*	2
GSK097 1-8 x 10^9 (N=2)			
n	0	2	2
Number of Subjects with DLT	0	1	1

* The sentinel subject 110801 in dose level 1 (1-8 x 10^9) did not receive second dose of T-cells on Day 8, hence is summarised under actual dose level 0.1-0.8 x 10^9.
Note: DLT Evaluable population includes participants in mITT analysis set who are part of the dose confirmation phase and have completed DLT assessment period of 28 days since last T-cell infusion or withdrawn within 28 days due to an AE meeting the definition of a DLT as defined in Section 8.2 of the Core Protocol.
Note: Planned doses - DL1 = 1-8 x 10^9 T-cells, DL-1 = 0.1-0.8 x 10^9 T-cells.
Note: DLTs assigned where "Is this event a DLT" is "Yes" as per the AE eCRFs, and the AE occurred on or after, and was related to, T-cell infusion.
mm628244: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_safe_t8b.sas 29JUN2023 05:11

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0110
Summary of Adverse Events Grouped by Similarity of Preferred Terms and by Actual Dose

Synoymn/ Preferred Term	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Acute GVHD - Other (Lung, Bone Marrow, not specified)				
Acute graft versus host disease	0	0	0	0
Acute graft versus host disease oral	0	0	0	0
Acute GVHD - Gut (Liver and Intestine)				
Acute graft versus host disease in intestine	0	0	0	0
Acute graft versus host disease in liver	0	0	0	0
Acute GVHD - Skin				
Acute graft versus host disease in skin	0	0	0	0
Anaemia/Red blood cell count decreased				
Anaemia	1 (50%)	2 (100%)	0	3 (60%)
Red blood cell count decreased	1 (50%)	0	0	1 (20%)
Chronic GVHD - Skin				
Chronic graft versus host disease in skin	0	0	0	0
Chronic GVHD - Gut (Liver and Intestine)				
Chronic graft versus host disease in intestine	0	0	0	0
Chronic graft versus host disease in liver	0	0	0	0

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_ae1_similar.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0110
Summary of Adverse Events Grouped by Similarity of Preferred Terms and by Actual Dose

Synoymn/ Preferred Term	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Chronic GVHD Other - (Lung, Bone Marrow, not specified)				
Chronic graft versus host disease	0	0	0	0
Chronic graft versus host disease in eye	0	0	0	0
Chronic graft versus host disease in lung	0	0	0	0
Chronic graft versus host disease oral	0	0	0	0
Cytokine Release Syndrome (CRS)				
Cytokine release syndrome	2 (100%)	2 (100%)	0	4 (80%)
Cytokine storm	0	0	0	0
Immune effector cell-associated neurotoxicity syndrome (ICANS)				
Encephalopathy	0	0	0	0
Immune effector cell-associated neurotoxicity syndrome	1 (50%)	1 (50%)	0	2 (40%)
Leukopenia/White blood cell decreased				
Leukopenia	1 (50%)	0	0	1 (20%)
White blood cell count decreased	1 (50%)	2 (100%)	0	3 (60%)
Lymphopenia/Lymphocyte count decreased				
CD4 lymphocytes decreased	0	0	0	0
CD8 lymphocytes decreased	0	0	0	0
Lymphocyte count decreased	0	2 (100%)	0	2 (40%)
Lymphopenia	0	0	0	0

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_ae1_similar.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0110
Summary of Adverse Events Grouped by Similarity of Preferred Terms and by Actual Dose

Synoymn/ Preferred Term	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Neutropenia/Neutrophil count decreased				
Neutropenia	1 (50%)	1 (50%)	0	2 (40%)
Neutrophil count decreased	2 (100%)	1 (50%)	0	3 (60%)
Rash/Rash maculo-papular				
Rash	0	1 (50%)	0	1 (20%)
Rash erythematous	0	0	0	0
Rash maculo-papular	0	0	0	0
Tachycardia				
Sinus tachycardia	0	1 (50%)	0	1 (20%)
Tachycardia	0	0	0	0
Thrombocytopenia/Platelet count decreased				
Platelet count decreased	1 (50%)	1 (50%)	0	2 (40%)
Thrombocytopenia	1 (50%)	1 (50%)	0	2 (40%)
Unspecified GVHD - Gut (Liver and Intestine)				
Graft versus host disease in gastrointestinal tract	1 (50%)	0	0	1 (20%)
Graft versus host disease in liver	0	1 (50%)	0	1 (20%)

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_ae1_similar.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0110
Summary of Adverse Events Grouped by Similarity of Preferred Terms and by Actual Dose

Synoymn/ Preferred Term	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Unspecified GVHD - Other (Lung, Bone Marrow, not specified)				
Engraftment syndrome	0	0	0	0
Graft versus host disease	0	0	0	0
Graft versus host disease in eye	0	0	0	0
Graft versus host disease in lung	0	0	0	0
Prophylaxis against graft versus host disease	0	0	0	0
Transfusion associated graft versus host disease	0	0	0	0
Unspecified GVHD - Skin				
Graft versus host disease in skin	1 (50%)	1 (50%)	0	2 (40%)

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_ae1_similar.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0120
Summary of Adverse Events in the Pre-Lymphodepletion Phase by Maximum Grade and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	1 (50%)	0	1 (50%)	0	0	1 (50%)	2 (100%)
Pyrexia	1 (50%)	0	0	0	0	0	1 (50%)
Staphylococcal infection	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Vascular device infection	0	0	1 (50%)	0	0	1 (50%)	1 (50%)

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: The pre-Lymphodepletion phase includes AEs which start before the first day of lymphodepletion chemotherapy.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_plym.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0120
Summary of Adverse Events in the Pre-Lymphodepletion Phase by Maximum Grade and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	1 (50%)	1 (50%)	0	0	1 (50%)	2 (100%)
Hyperbilirubinaemia	0	1 (50%)	0	0	0	0	1 (50%)
International normalised ratio increased	1 (50%)	0	0	0	0	0	1 (50%)
Leukopenia/White blood cell decreased	1 (50%)	0	0	0	0	0	1 (50%)
Lymphopenia/Lymphocyte count decreased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: The pre-Lymphodepletion phase includes AEs which start before the first day of lymphodepletion chemotherapy.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_plym.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0120
Summary of Adverse Events in the Pre-Lymphodepletion Phase by Maximum Grade and by Actual Dose

Treatment: Total (N=5)

	Maximum Grade									
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4	Grade 5	Grade 3+4+5		Total	
ANY EVENT	1	(20%)	1	(20%)	2	(40%)	0	0	2	(40%)	4	(80%)
Hyperbilirubinaemia	0		1	(20%)	0		0	0	0		1	(20%)
International normalised ratio increased	1	(20%)	0		0		0	0	0		1	(20%)
Leukopenia/White blood cell decreased	1	(20%)	0		0		0	0	0		1	(20%)
Lymphopenia/Lymphocyte count decreased	0		0		1	(20%)	0	0	1	(20%)	1	(20%)
Pyrexia	1	(20%)	0		0		0	0	0		1	(20%)
Staphylococcal infection	0		0		1	(20%)	0	0	1	(20%)	1	(20%)
Vascular device infection	0		0		1	(20%)	0	0	1	(20%)	1	(20%)

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: The pre-Lymphodepletion phase includes AEs which start before the first day of lymphodepletion chemotherapy.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_plym.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Lymphodepletion Data as of 12MAY2023

Table 3.0130
Summary of Adverse Events in the Lymphodepletion Phase by Maximum Grade
and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	1 (50%)	0	0	0	0	1 (50%)
Decreased appetite	0	1 (50%)	0	0	0	0	1 (50%)
Dizziness	1 (50%)	0	0	0	0	0	1 (50%)
Nausea	0	1 (50%)	0	0	0	0	1 (50%)
Peripheral sensory neuropathy	1 (50%)	0	0	0	0	0	1 (50%)

Note: Lymphodepletion population includes all ITT participants who started lymphodepletion chemotherapy.
Note: The lymphodepletion phase includes AEs which start or worsen on or after lymphodepletion and before T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_lym.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Lymphodepletion Data as of 12MAY2023

Table 3.0130
Summary of Adverse Events in the Lymphodepletion Phase by Maximum Grade and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Leukopenia/White blood cell decreased	0	0	1 (50%)	1 (50%)	0	2 (100%)	2 (100%)
Lymphopenia/Lymphocyte count decreased	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Back pain	1 (50%)	0	0	0	0	0	1 (50%)
Febrile neutropenia	0	1 (50%)	0	0	0	0	1 (50%)
Hypomagnesaemia	1 (50%)	0	0	0	0	0	1 (50%)
Neutropenia/Neutrophil count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)

Note: Lymphodepletion population includes all ITT participants who started lymphodepletion chemotherapy.
Note: The lymphodepletion phase includes AEs which start or worsen on or after lymphodepletion and before T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_lym.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Lymphodepletion Data as of 12MAY2023

Table 3.0130
Summary of Adverse Events in the Lymphodepletion Phase by Maximum Grade and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade											
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
ANY EVENT	0		1	(25%)	0		2	(50%)	0		2	(50%)	3	(75%)
Leukopenia/White blood cell decreased	0		0		1	(25%)	1	(25%)	0		2	(50%)	2	(50%)
Lymphopenia/Lymphocyte count decreased	0		0		0		2	(50%)	0		2	(50%)	2	(50%)
Back pain	1	(25%)	0		0		0		0		0		1	(25%)
Decreased appetite	0		1	(25%)	0		0		0		0		1	(25%)
Dizziness	1	(25%)	0		0		0		0		0		1	(25%)
Febrile neutropenia	0		1	(25%)	0		0		0		0		1	(25%)
Hypomagnesaemia	1	(25%)	0		0		0		0		0		1	(25%)
Nausea	0		1	(25%)	0		0		0		0		1	(25%)
Neutropenia/Neutrophil count decreased	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
Peripheral sensory neuropathy	1	(25%)	0		0		0		0		0		1	(25%)

Note: Lymphodepletion population includes all ITT participants who started lymphodepletion chemotherapy.
Note: The lymphodepletion phase includes AEs which start or worsen on or after lymphodepletion and before T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_lym.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0140
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and by Actual Dose

System Organ Class Preferred Term	Dose Confirmation GSK097 0.1-0.8 x 10^9 (N=2)	 GSK097 1-8 x 10^9 (N=2)	 Total (N=4)
ANY EVENT	2 (100%)	2 (100%)	4 (100%)
Blood and lymphatic system disorders			
Any event	2 (100%)	2 (100%)	4 (100%)
Anaemia	1 (50%)	2 (100%)	3 (75%)
Febrile neutropenia	1 (50%)	1 (50%)	2 (50%)
Pancytopenia	1 (50%)	1 (50%)	2 (50%)
Thrombocytopenia	1 (50%)	1 (50%)	2 (50%)
Aplastic anaemia	0	1 (50%)	1 (25%)
Leukopenia	1 (50%)	0	1 (25%)
Neutropenia	1 (50%)	0	1 (25%)
General disorders and administration site conditions			
Any event	2 (100%)	2 (100%)	4 (100%)
Pyrexia	1 (50%)	1 (50%)	2 (50%)
Chest pain	1 (50%)	0	1 (25%)
Fatigue	0	1 (50%)	1 (25%)
Mucosal inflammation	0	1 (50%)	1 (25%)
Systemic inflammatory response syndrome	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae_soc.sas 06JUN2023 06:10

Table 3.0140
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and by Actual Dose

System Organ Class Preferred Term	Dose Confirmation GSK097 0.1-0.8 x 10^9 (N=2)	 GSK097 1-8 x 10^9 (N=2)	 Total (N=4)
Immune system disorders			
Any event	2 (100%)	2 (100%)	4 (100%)
Cytokine release syndrome	2 (100%)	2 (100%)	4 (100%)
Graft versus host disease in skin	1 (50%)	1 (50%)	2 (50%)
Graft versus host disease in liver	0	1 (50%)	1 (25%)
Graft versus host disease in gastrointestinal tract	1 (50%)	0	1 (25%)
Haemophagocytic lymphohistiocytosis	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae_soc.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0140
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and by Actual Dose

System Organ Class Preferred Term	Dose Confirmation GSK097 0.1-0.8 x 10^9 (N=2)	 GSK097 1-8 x 10^9 (N=2)	 Total (N=4)
Investigations			
Any event	2 (100%)	2 (100%)	4 (100%)
Alanine aminotransferase increased	2 (100%)	2 (100%)	4 (100%)
Aspartate aminotransferase increased	2 (100%)	2 (100%)	4 (100%)
Neutrophil count decreased	2 (100%)	1 (50%)	3 (75%)
Platelet count decreased	1 (50%)	1 (50%)	2 (50%)
White blood cell count decreased	1 (50%)	1 (50%)	2 (50%)
Blood alkaline phosphatase increased	0	1 (50%)	1 (25%)
Blood creatinine increased	1 (50%)	0	1 (25%)
Blood glucose increased	1 (50%)	0	1 (25%)
Blood lactate dehydrogenase increased	0	1 (50%)	1 (25%)
Blood sodium increased	1 (50%)	0	1 (25%)
Blood urea increased	1 (50%)	0	1 (25%)
C-reactive protein increased	1 (50%)	0	1 (25%)
Haematocrit decreased	1 (50%)	0	1 (25%)
Haemoglobin decreased	1 (50%)	0	1 (25%)
Interleukin level increased	1 (50%)	0	1 (25%)
International normalised ratio increased	0	1 (50%)	1 (25%)
Procalcitonin increased	1 (50%)	0	1 (25%)
Protein total decreased	1 (50%)	0	1 (25%)
Red blood cell count decreased	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae_soc.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0140
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and by Actual Dose

System Organ Class Preferred Term	Dose Confirmation GSK097 0.1-0.8 x 10^9 (N=2)	 GSK097 1-8 x 10^9 (N=2)	 Total (N=4)
Nervous system disorders			
Any event	2 (100%)	2 (100%)	4 (100%)
Immune effector cell-associated neurotoxicity syndrome	1 (50%)	1 (50%)	2 (50%)
Hypoaesthesia	0	1 (50%)	1 (25%)
Syncope	1 (50%)	0	1 (25%)
Cardiac disorders			
Any event	2 (100%)	1 (50%)	3 (75%)
Pericardial effusion	1 (50%)	0	1 (25%)
Sinus tachycardia	0	1 (50%)	1 (25%)
Supraventricular tachycardia	1 (50%)	0	1 (25%)
Gastrointestinal disorders			
Any event	2 (100%)	1 (50%)	3 (75%)
Diarrhoea	0	1 (50%)	1 (25%)
Stomatitis	1 (50%)	0	1 (25%)
Vomiting	1 (50%)	0	1 (25%)
Metabolism and nutrition disorders			
Any event	1 (50%)	2 (100%)	3 (75%)
Hyponatraemia	0	2 (100%)	2 (50%)
Hypophosphataemia	0	2 (100%)	2 (50%)
Decreased appetite	0	1 (50%)	1 (25%)
Hypokalaemia	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae_soc.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0140
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and by Actual Dose

System Organ Class Preferred Term	Dose Confirmation GSK097 0.1-0.8 x 10^9 (N=2)		Dose Confirmation GSK097 1-8 x 10^9 (N=2)		Total (N=4)	
Infections and infestations						
Any event	0		2	(100%)	2	(50%)
COVID-19 pneumonia	0		1	(50%)	1	(25%)
Herpes zoster	0		1	(50%)	1	(25%)
Pneumonia	0		1	(50%)	1	(25%)
Staphylococcal bacteraemia	0		1	(50%)	1	(25%)
Respiratory, thoracic and mediastinal disorders						
Any event	1	(50%)	1	(50%)	2	(50%)
Cough	0		1	(50%)	1	(25%)
Dyspnoea	1	(50%)	0		1	(25%)
Pulmonary embolism	1	(50%)	0		1	(25%)
Respiratory failure	1	(50%)	0		1	(25%)
Hepatobiliary disorders						
Any event	0		1	(50%)	1	(25%)
Hyperbilirubinaemia	0		1	(50%)	1	(25%)
Musculoskeletal and connective tissue disorders						
Any event	1	(50%)	0		1	(25%)
Muscular weakness	1	(50%)	0		1	(25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae_soc.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0140
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and by Actual Dose

System Organ Class Preferred Term	Dose Confirmation GSK097 0.1-0.8 x 10^9 (N=2)	 GSK097 1-8 x 10^9 (N=2)	 Total (N=4)
Psychiatric disorders			
Any event	0	1 (50%)	1 (25%)
Anxiety	0	1 (50%)	1 (25%)
Renal and urinary disorders			
Any event	0	1 (50%)	1 (25%)
Dysuria	0	1 (50%)	1 (25%)
Skin and subcutaneous tissue disorders			
Any event	0	1 (50%)	1 (25%)
Rash	0	1 (50%)	1 (25%)
Vascular disorders			
Any event	0	1 (50%)	1 (25%)
Lymphoedema	0	1 (50%)	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae_soc.sas 06JUN2023 06:10

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0150
Summary of Treatment Emergent Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	0	2 (100%)	2 (100%)	2 (100%)
Alanine aminotransferase increased	0	1 (50%)	1 (50%)	0	0	1 (50%)	2 (100%)
Anaemia/Red blood cell count decreased	0	0	1 (50%)	1 (50%)	0	2 (100%)	2 (100%)
Aspartate aminotransferase increased	1 (50%)	0	1 (50%)	0	0	1 (50%)	2 (100%)
Cytokine Release Syndrome (CRS)	0	2 (100%)	0	0	0	0	2 (100%)
Neutropenia/Neutrophil count decreased	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Thrombocytopenia/Platelet count decreased	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Blood creatinine increased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Blood glucose increased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Blood sodium increased	0	1 (50%)	0	0	0	0	1 (50%)
Blood urea increased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
C-reactive protein increased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Chest pain	1 (50%)	0	0	0	0	0	1 (50%)
Dyspnoea	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Haematocrit decreased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Haemoglobin decreased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Haemophagocytic lymphohistiocytosis	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Hypokalaemia	0	1 (50%)	0	0	0	0	1 (50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	1 (50%)	0	0	0	0	0	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0150
Summary of Treatment Emergent Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade											
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
Interleukin level increased	0		1	(50%)	0		0		0		0		1	(50%)
Leukopenia/White blood cell decreased	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Muscular weakness	1	(50%)	0		0		0		0		0		1	(50%)
Pancytopenia	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Pericardial effusion	0		1	(50%)	0		0		0		0		1	(50%)
Procalcitonin increased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Protein total decreased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Pulmonary embolism	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Pyrexia	1	(50%)	0		0		0		0		0		1	(50%)
Respiratory failure	0		0		0		0		1	(50%)	1	(50%)	1	(50%)
Stomatitis	0		1	(50%)	0		0		0		0		1	(50%)
Supraventricular tachycardia	1	(50%)	0		0		0		0		0		1	(50%)
Syncope	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Systemic inflammatory response syndrome	0		0		0		0		1	(50%)	1	(50%)	1	(50%)
Unspecified GVHD - Gut (Liver and Intestine)	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Unspecified GVHD - Skin	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Vomiting	1	(50%)	0		0		0		0		0		1	(50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0150
Summary of Treatment Emergent Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Alanine aminotransferase increased	0	1 (50%)	1 (50%)	0	0	1 (50%)	2 (100%)
Anaemia/Red blood cell count decreased	0	0	2 (100%)	0	0	2 (100%)	2 (100%)
Aspartate aminotransferase increased	1 (50%)	1 (50%)	0	0	0	0	2 (100%)
Cytokine Release Syndrome (CRS)	1 (50%)	1 (50%)	0	0	0	0	2 (100%)
Hyponatraemia	0	2 (100%)	0	0	0	0	2 (100%)
Hypophosphataemia	0	2 (100%)	0	0	0	0	2 (100%)
Thrombocytopenia/Platelet count decreased	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Anxiety	1 (50%)	0	0	0	0	0	1 (50%)
Aplastic anaemia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Blood alkaline phosphatase increased	1 (50%)	0	0	0	0	0	1 (50%)
Blood lactate dehydrogenase increased	1 (50%)	0	0	0	0	0	1 (50%)
COVID-19 pneumonia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Cough	1 (50%)	0	0	0	0	0	1 (50%)
Decreased appetite	0	1 (50%)	0	0	0	0	1 (50%)
Diarrhoea	1 (50%)	0	0	0	0	0	1 (50%)
Dysuria	1 (50%)	0	0	0	0	0	1 (50%)
Fatigue	1 (50%)	0	0	0	0	0	1 (50%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Herpes zoster	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Hyperbilirubinaemia	0	1 (50%)	0	0	0	0	1 (50%)
Hypoaesthesia	1 (50%)	0	0	0	0	0	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b.sas 06JUN2023 06:11

Protocol: 209012SS2 Page 4 of 7
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0150
Summary of Treatment Emergent Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
International normalised ratio increased	0	1 (50%)	0	0	0	0	1 (50%)
Leukopenia/White blood cell decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Lymphoedema	1 (50%)	0	0	0	0	0	1 (50%)
Mucosal inflammation	1 (50%)	0	0	0	0	0	1 (50%)
Neutropenia/Neutrophil count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Pancytopenia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Pneumonia	1 (50%)	0	0	0	0	0	1 (50%)
Pyrexia	1 (50%)	0	0	0	0	0	1 (50%)
Rash/Rash maculo-papular	0	1 (50%)	0	0	0	0	1 (50%)
Staphylococcal bacteraemia	0	1 (50%)	0	0	0	0	1 (50%)
Tachycardia	0	1 (50%)	0	0	0	0	1 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	0	1 (50%)	0	0	0	0	1 (50%)
Unspecified GVHD - Skin	0	1 (50%)	0	0	0	0	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0150
Summary of Treatment Emergent Adverse Events by Maximum Grade and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade														
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total		
ANY EVENT	0		0		0		2	(50%)	2	(50%)	4	(100%)	4	(100%)	
Alanine aminotransferase increased	0		2	(50%)	2	(50%)	0		0		2	(50%)	4	(100%)	
Anaemia/Red blood cell count decreased	0		0		3	(75%)	1	(25%)	0		4	(100%)	4	(100%)	
Aspartate aminotransferase increased	2	(50%)	1	(25%)	1	(25%)	0		0		1	(25%)	4	(100%)	
Cytokine Release Syndrome (CRS)	1	(25%)	3	(75%)	0		0		0		0		4	(100%)	
Thrombocytopenia/Platelet count decreased	0		0		0		4	(100%)	0		4	(100%)	4	(100%)	
Neutropenia/Neutrophil count decreased	0		0		0		3	(75%)	0		3	(75%)	3	(75%)	
Febrile neutropenia	0		0		2	(50%)	0		0		2	(50%)	2	(50%)	
Hyponatraemia	0		2	(50%)	0		0		0		0		2	(50%)	
Hypophosphataemia	0		2	(50%)	0		0		0		0		2	(50%)	
Immune effector cell-associated neurotoxicity syndrome (ICANS)	1	(25%)	0		0		1	(25%)	0		1	(25%)	2	(50%)	
Leukopenia/White blood cell decreased	0		0		0		2	(50%)	0		2	(50%)	2	(50%)	
Pancytopenia	0		0		0		2	(50%)	0		2	(50%)	2	(50%)	
Pyrexia	2	(50%)	0		0		0		0		0		2	(50%)	
Unspecified GVHD - Gut (Liver and Intestine)	0		1	(25%)	1	(25%)	0		0		1	(25%)	2	(50%)	
Unspecified GVHD - Skin	0		1	(25%)	1	(25%)	0		0		1	(25%)	2	(50%)	
Anxiety	1	(25%)	0		0		0		0		0		1	(25%)	
Aplastic anaemia	0		0		0		1	(25%)	0		1	(25%)	1	(25%)	
Blood alkaline phosphatase increased	1	(25%)	0		0		0		0		0		1	(25%)	

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0150
Summary of Treatment Emergent Adverse Events by Maximum Grade and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
Blood creatinine increased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Blood glucose increased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Blood lactate dehydrogenase increased	1 (25%)	0	0	0	0	0	1 (25%)
Blood sodium increased	0	1 (25%)	0	0	0	0	1 (25%)
Blood urea increased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
C-reactive protein increased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
COVID-19 pneumonia	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Chest pain	1 (25%)	0	0	0	0	0	1 (25%)
Cough	1 (25%)	0	0	0	0	0	1 (25%)
Decreased appetite	0	1 (25%)	0	0	0	0	1 (25%)
Diarrhoea	1 (25%)	0	0	0	0	0	1 (25%)
Dyspnoea	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Dysuria	1 (25%)	0	0	0	0	0	1 (25%)
Fatigue	1 (25%)	0	0	0	0	0	1 (25%)
Haematocrit decreased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Haemoglobin decreased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Haemophagocytic lymphohistiocytosis	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Herpes zoster	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Hyperbilirubinaemia	0	1 (25%)	0	0	0	0	1 (25%)
Hypoaesthesia	1 (25%)	0	0	0	0	0	1 (25%)
Hypokalaemia	0	1 (25%)	0	0	0	0	1 (25%)
Interleukin level increased	0	1 (25%)	0	0	0	0	1 (25%)
International normalised ratio increased	0	1 (25%)	0	0	0	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0150
Summary of Treatment Emergent Adverse Events by Maximum Grade and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade											
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
Lymphoedema	1	(25%)	0		0		0		0		0		1	(25%)
Mucosal inflammation	1	(25%)	0		0		0		0		0		1	(25%)
Muscular weakness	1	(25%)	0		0		0		0		0		1	(25%)
Pericardial effusion	0		1	(25%)	0		0		0		0		1	(25%)
Pneumonia	1	(25%)	0		0		0		0		0		1	(25%)
Procalcitonin increased	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Protein total decreased	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Pulmonary embolism	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Rash/Rash maculo-papular	0		1	(25%)	0		0		0		0		1	(25%)
Respiratory failure	0		0		0		0		1	(25%)	1	(25%)	1	(25%)
Staphylococcal bacteraemia	0		1	(25%)	0		0		0		0		1	(25%)
Stomatitis	0		1	(25%)	0		0		0		0		1	(25%)
Supraventricular tachycardia	1	(25%)	0		0		0		0		0		1	(25%)
Syncope	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Systemic inflammatory response syndrome	0		0		0		0		1	(25%)	1	(25%)	1	(25%)
Tachycardia	0		1	(25%)	0		0		0		0		1	(25%)
Vomiting	1	(25%)	0		0		0		0		0		1	(25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0160
Summary of Treatment Emergent T-cell Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade											
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
ANY EVENT	0		0		0		1	(50%)	1	(50%)	2	(100%)	2	(100%)
Alanine aminotransferase increased	0		1	(50%)	1	(50%)	0		0		1	(50%)	2	(100%)
Anaemia/Red blood cell count decreased	0		0		1	(50%)	1	(50%)	0		2	(100%)	2	(100%)
Aspartate aminotransferase increased	1	(50%)	0		1	(50%)	0		0		1	(50%)	2	(100%)
Cytokine Release Syndrome (CRS)	0		2	(100%)	0		0		0		0		2	(100%)
Neutropenia/Neutrophil count decreased	1	(50%)	0		0		1	(50%)	0		1	(50%)	2	(100%)
Thrombocytopenia/Platelet count decreased	0		0		0		2	(100%)	0		2	(100%)	2	(100%)
Blood creatinine increased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Blood urea increased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
C-reactive protein increased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Dyspnoea	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Febrile neutropenia	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Haematocrit decreased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Haemoglobin decreased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Haemophagocytic lymphohistiocytosis	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	1	(50%)	0		0		0		0		0		1	(50%)
Interleukin level increased	0		1	(50%)	0		0		0		0		1	(50%)
Leukopenia/White blood cell decreased	0		0		0		1	(50%)	0		1	(50%)	1	(50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_trel.sas 06JUN2023 06:11

Table 3.0160
Summary of Treatment Emergent T-cell Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade											
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
Muscular weakness	1	(50%)	0		0		0		0		0		1	(50%)
Pancytopenia	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Pericardial effusion	0		1	(50%)	0		0		0		0		1	(50%)
Procalcitonin increased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Protein total decreased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Pyrexia	1	(50%)	0		0		0		0		0		1	(50%)
Stomatitis	0		1	(50%)	0		0		0		0		1	(50%)
Supraventricular tachycardia	1	(50%)	0		0		0		0		0		1	(50%)
Systemic inflammatory response syndrome	0		0		0		0		1	(50%)	1	(50%)	1	(50%)
Unspecified GVHD - Gut (Liver and Intestine)	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Unspecified GVHD - Skin	0		0		1	(50%)	0		0		1	(50%)	1	(50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_trel.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0160
Summary of Treatment Emergent T-cell Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade											
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
ANY EVENT	0		1	(50%)	0		1	(50%)	0		1	(50%)	2	(100%)
Alanine aminotransferase increased	0		1	(50%)	1	(50%)	0		0		1	(50%)	2	(100%)
Cytokine Release Syndrome (CRS)	1	(50%)	1	(50%)	0		0		0		0		2	(100%)
Anaemia/Red blood cell count decreased	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Anxiety	1	(50%)	0		0		0		0		0		1	(50%)
Aplastic anaemia	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Aspartate aminotransferase increased	0		1	(50%)	0		0		0		0		1	(50%)
Blood alkaline phosphatase increased	1	(50%)	0		0		0		0		0		1	(50%)
COVID-19 pneumonia	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Cough	1	(50%)	0		0		0		0		0		1	(50%)
Fatigue	1	(50%)	0		0		0		0		0		1	(50%)
Febrile neutropenia	0		0		1	(50%)	0		0		1	(50%)	1	(50%)
Hyperbilirubinaemia	0		1	(50%)	0		0		0		0		1	(50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Leukopenia/White blood cell decreased	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Mucosal inflammation	1	(50%)	0		0		0		0		0		1	(50%)
Neutropenia/Neutrophil count decreased	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Pancytopenia	0		0		0		1	(50%)	0		1	(50%)	1	(50%)
Rash/Rash maculo-papular	0		1	(50%)	0		0		0		0		1	(50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
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Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0160
Summary of Treatment Emergent T-cell Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
Thrombocytopenia/Platelet count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	0	1 (50%)	0	0	0	0	1 (50%)
Unspecified GVHD - Skin	0	1 (50%)	0	0	0	0	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
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Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0160
Summary of Treatment Emergent T-cell Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade															
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
ANY EVENT	0		1	(25%)	0		2	(50%)	1	(25%)	3	(75%)	4	(100%)
Alanine aminotransferase increased	0		2	(50%)	2	(50%)	0		0		2	(50%)	4	(100%)
Cytokine Release Syndrome (CRS)	1	(25%)	3	(75%)	0		0		0		0		4	(100%)
Anaemia/Red blood cell count decreased	0		0		2	(50%)	1	(25%)	0		3	(75%)	3	(75%)
Aspartate aminotransferase increased	1	(25%)	1	(25%)	1	(25%)	0		0		1	(25%)	3	(75%)
Neutropenia/Neutrophil count decreased	1	(25%)	0		0		2	(50%)	0		2	(50%)	3	(75%)
Thrombocytopenia/Platelet count decreased	0		0		0		3	(75%)	0		3	(75%)	3	(75%)
Febrile neutropenia	0		0		2	(50%)	0		0		2	(50%)	2	(50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	1	(25%)	0		0		1	(25%)	0		1	(25%)	2	(50%)
Leukopenia/White blood cell decreased	0		0		0		2	(50%)	0		2	(50%)	2	(50%)
Pancytopenia	0		0		0		2	(50%)	0		2	(50%)	2	(50%)
Unspecified GVHD - Gut (Liver and Intestine)	0		1	(25%)	1	(25%)	0		0		1	(25%)	2	(50%)
Unspecified GVHD - Skin	0		1	(25%)	1	(25%)	0		0		1	(25%)	2	(50%)
Anxiety	1	(25%)	0		0		0		0		0		1	(25%)
Aplastic anaemia	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
Blood alkaline phosphatase increased	1	(25%)	0		0		0		0		0		1	(25%)
Blood creatinine increased	0		0		1	(25%)	0		0		1	(25%)	1	(25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
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Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0160
Summary of Treatment Emergent T-cell Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade														
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5			Total	
Blood urea increased	0		0		1	(25%)	0		0		1	(25%)		1	(25%)
C-reactive protein increased	0		0		1	(25%)	0		0		1	(25%)		1	(25%)
COVID-19 pneumonia	0		0		1	(25%)	0		0		1	(25%)		1	(25%)
Cough	1	(25%)	0		0		0		0		0			1	(25%)
Dyspnoea	0		0		1	(25%)	0		0		1	(25%)		1	(25%)
Fatigue	1	(25%)	0		0		0		0		0			1	(25%)
Haematocrit decreased	0		0		1	(25%)	0		0		1	(25%)		1	(25%)
Haemoglobin decreased	0		0		1	(25%)	0		0		1	(25%)		1	(25%)
Haemophagocytic lymphohistiocytosis	0		0		0		1	(25%)	0		1	(25%)		1	(25%)
Hyperbilirubinaemia	0		1	(25%)	0		0		0		0			1	(25%)
Interleukin level increased	0		1	(25%)	0		0		0		0			1	(25%)
Mucosal inflammation	1	(25%)	0		0		0		0		0			1	(25%)
Muscular weakness	1	(25%)	0		0		0		0		0			1	(25%)
Pericardial effusion	0		1	(25%)	0		0		0		0			1	(25%)
Procalcitonin increased	0		0		1	(25%)	0		0		1	(25%)		1	(25%)
Protein total decreased	0		0		1	(25%)	0		0		1	(25%)		1	(25%)
Pyrexia	1	(25%)	0		0		0		0		0			1	(25%)
Rash/Rash maculo-papular	0		1	(25%)	0		0		0		0			1	(25%)
Stomatitis	0		1	(25%)	0		0		0		0			1	(25%)
Supraventricular tachycardia	1	(25%)	0		0		0		0		0			1	(25%)
Systemic inflammatory response syndrome	0		0		0		0		1	(25%)	1	(25%)		1	(25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
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Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0170
Summary of Treatment Emergent Lymphodepletion Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Anaemia/Red blood cell count decreased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Muscular weakness	1 (50%)	0	0	0	0	0	1 (50%)
Neutropenia/Neutrophil count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Thrombocytopenia/Platelet count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Lymphodepletion related AEs are defined as AEs identified by the investigator as related to fludarabine or cyclophosphamide.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_lymrel.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0170
Summary of Treatment Emergent Lymphodepletion Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Anaemia/Red blood cell count decreased	0	0	2 (100%)	0	0	2 (100%)	2 (100%)
Thrombocytopenia/Platelet count decreased	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Cough	1 (50%)	0	0	0	0	0	1 (50%)
Fatigue	1 (50%)	0	0	0	0	0	1 (50%)
Hyponatraemia	0	1 (50%)	0	0	0	0	1 (50%)
Hypophosphataemia	0	1 (50%)	0	0	0	0	1 (50%)
Leukopenia/White blood cell decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Mucosal inflammation	1 (50%)	0	0	0	0	0	1 (50%)
Neutropenia/Neutrophil count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Pancytopenia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Pneumonia	1 (50%)	0	0	0	0	0	1 (50%)
Rash/Rash maculo-papular	0	1 (50%)	0	0	0	0	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Lymphodepletion related AEs are defined as AEs identified by the investigator as related to fludarabine or cyclophosphamide.
Note: Preferred terms are combined as shown in Table 3.0110.
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Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0170
Summary of Treatment Emergent Lymphodepletion Related Adverse Events by Maximum Grade and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade											
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
ANY EVENT	0		0		0		3	(75%)	0		3	(75%)	3	(75%)
Anaemia/Red blood cell count decreased	0		0		3	(75%)	0		0		3	(75%)	3	(75%)
Thrombocytopenia/Platelet count decreased	0		0		0		3	(75%)	0		3	(75%)	3	(75%)
Neutropenia/Neutrophil count decreased	0		0		0		2	(50%)	0		2	(50%)	2	(50%)
Cough	1	(25%)	0		0		0		0		0		1	(25%)
Fatigue	1	(25%)	0		0		0		0		0		1	(25%)
Hyponatraemia	0		1	(25%)	0		0		0		0		1	(25%)
Hypophosphataemia	0		1	(25%)	0		0		0		0		1	(25%)
Leukopenia/White blood cell decreased	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
Mucosal inflammation	1	(25%)	0		0		0		0		0		1	(25%)
Muscular weakness	1	(25%)	0		0		0		0		0		1	(25%)
Pancytopenia	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
Pneumonia	1	(25%)	0		0		0		0		0		1	(25%)
Rash/Rash maculo-papular	0		1	(25%)	0		0		0		0		1	(25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Lymphodepletion related AEs are defined as AEs identified by the investigator as related to fludarabine or cyclophosphamide.
Note: Preferred terms are combined as shown in Table 3.0110.
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Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0180
Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
ANY EVENT	Number of Subjects with AEs	2 (100%)	2 (100%)	0	4 (80%)
	Number of AEs	49	49	0	98
Blood and lymphatic system disorders					
Anaemia	Number of Subjects with AEs	1 (50%)	2 (100%)	0	3 (60%)
	Number of AEs	1	2	0	3
Neutropenia	Number of Subjects with AEs	1 (50%)	1 (50%)	0	2 (40%)
	Number of AEs	1	1	0	2
Thrombocytopenia	Number of Subjects with AEs	1 (50%)	1 (50%)	0	2 (40%)
	Number of AEs	1	1	0	2
Febrile neutropenia	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Leukopenia	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	2	0	0	2
Pancytopenia	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Immune system disorders					
Cytokine release syndrome	Number of Subjects with AEs	2 (100%)	2 (100%)	0	4 (80%)
	Number of AEs	2	2	0	4
Graft versus host disease in liver	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
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Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0180
Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Graft versus host disease in skin	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Investigations					
Aspartate aminotransferase increased	Number of Subjects with AEs	2 (100%)	2 (100%)	0	4 (80%)
	Number of AEs	2	3	0	5
Alanine aminotransferase increased	Number of Subjects with AEs	2 (100%)	1 (50%)	0	3 (60%)
	Number of AEs	2	1	0	3
Neutrophil count decreased	Number of Subjects with AEs	2 (100%)	1 (50%)	0	3 (60%)
	Number of AEs	4	1	0	5
White blood cell count decreased	Number of Subjects with AEs	1 (50%)	2 (100%)	0	3 (60%)
	Number of AEs	1	5	0	6
Lymphocyte count decreased	Number of Subjects with AEs	0	2 (100%)	0	2 (40%)
	Number of AEs	0	3	0	3
Platelet count decreased	Number of Subjects with AEs	1 (50%)	1 (50%)	0	2 (40%)
	Number of AEs	1	1	0	2
Blood alkaline phosphatase increased	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Blood creatinine increased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
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Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0180
Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Blood glucose increased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Blood lactate dehydrogenase increased	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Blood sodium increased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Blood urea increased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
C-reactive protein increased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	3	0	0	3
Haematocrit decreased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Haemoglobin decreased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	2	0	0	2
Interleukin level increased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
International normalised ratio increased	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Procalcitonin increased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Protein total decreased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Red blood cell count decreased	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	2	0	0	2

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
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Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0180
Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Metabolism and nutrition disorders					
Decreased appetite	Number of Subjects with AEs	1 (50%)	1 (50%)	0	2 (40%)
	Number of AEs	1	1	0	2
Hyponatraemia	Number of Subjects with AEs	0	2 (100%)	0	2 (40%)
	Number of AEs	0	2	0	2
Hypophosphataemia	Number of Subjects with AEs	0	2 (100%)	0	2 (40%)
	Number of AEs	0	2	0	2
Hypokalaemia	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	2	0	0	2
Hypomagnesaemia	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Cardiac disorders					
Pericardial effusion	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Sinus tachycardia	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Supraventricular tachycardia	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Gastrointestinal disorders					
Diarrhoea	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
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Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0180
Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Nausea	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Stomatitis	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Vomiting	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
General disorders and administration site conditions					
Chest pain	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Fatigue	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Mucosal inflammation	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Pyrexia	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Nervous system disorders					
Dizziness	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Hypoaesthesia	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Immune effector cell-associated neurotoxicity syndrome	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
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Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0180
Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Peripheral sensory neuropathy	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Syncope	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Infections and infestations					
Pneumonia	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Staphylococcal bacteraemia	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Musculoskeletal and connective tissue disorders					
Back pain	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Muscular weakness	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1
Respiratory, thoracic and mediastinal disorders					
Cough	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Dyspnoea	Number of Subjects with AEs	1 (50%)	0	0	1 (20%)
	Number of AEs	1	0	0	1

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae15_nsae_soc.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0180
Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Hepatobiliary disorders					
Hyperbilirubinaemia	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	4	0	4
Psychiatric disorders					
Anxiety	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Renal and urinary disorders					
Dysuria	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Skin and subcutaneous tissue disorders					
Rash	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1
Vascular disorders					
Lymphoedema	Number of Subjects with AEs	0	1 (50%)	0	1 (20%)
	Number of AEs	0	1	0	1

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae15_nsae_soc.sas 06JUN2023 06:11

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0190
Summary of Treatment Emergent T-cell Related Non-Serious Adverse Events by Overall Frequency and by Actual Dose

	Dose Confirmation		
Preferred Term	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Any event	2 (100%)	2 (100%)	4 (100%)
Cytokine release syndrome	2 (100%)	2 (100%)	4 (100%)
Alanine aminotransferase increased	2 (100%)	1 (50%)	3 (75%)
Aspartate aminotransferase increased	2 (100%)	1 (50%)	3 (75%)
Neutrophil count decreased	2 (100%)	1 (50%)	3 (75%)
Anaemia	1 (50%)	1 (50%)	2 (50%)
Platelet count decreased	1 (50%)	1 (50%)	2 (50%)
White blood cell count decreased	1 (50%)	1 (50%)	2 (50%)
Anxiety	0	1 (50%)	1 (25%)
Blood alkaline phosphatase increased	0	1 (50%)	1 (25%)
Blood creatinine increased	1 (50%)	0	1 (25%)
Blood urea increased	1 (50%)	0	1 (25%)
C-reactive protein increased	1 (50%)	0	1 (25%)
Cough	0	1 (50%)	1 (25%)
Dyspnoea	1 (50%)	0	1 (25%)
Fatigue	0	1 (50%)	1 (25%)
Graft versus host disease in liver	0	1 (50%)	1 (25%)
Graft versus host disease in skin	0	1 (50%)	1 (25%)
Haematocrit decreased	1 (50%)	0	1 (25%)
Haemoglobin decreased	1 (50%)	0	1 (25%)
Immune effector cell-associated neurotoxicity syndrome	1 (50%)	0	1 (25%)
Interleukin level increased	1 (50%)	0	1 (25%)
Leukopenia	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae3.sas 06JUN2023 06:12

Table 3.0190
Summary of Treatment Emergent T-cell Related Non-Serious Adverse Events by Overall Frequency and by Actual Dose

Preferred Term	Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Mucosal inflammation	0	1 (50%)	1 (25%)
Muscular weakness	1 (50%)	0	1 (25%)
Neutropenia	1 (50%)	0	1 (25%)
Pancytopenia	1 (50%)	0	1 (25%)
Pericardial effusion	1 (50%)	0	1 (25%)
Procalcitonin increased	1 (50%)	0	1 (25%)
Protein total decreased	1 (50%)	0	1 (25%)
Pyrexia	1 (50%)	0	1 (25%)
Rash	0	1 (50%)	1 (25%)
Red blood cell count decreased	1 (50%)	0	1 (25%)
Stomatitis	1 (50%)	0	1 (25%)
Supraventricular tachycardia	1 (50%)	0	1 (25%)
Thrombocytopenia	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae3.sas 06JUN2023 06:12

Protocol: 209012SS2
Population: Lymphodepletion Data as of 12MAY2023

Table 3.0200
Summary of Serious Adverse Events in the Lymphodepletion Phase by Maximum Grade and by Actual Dose

No data to report

Note: Lymphodepletion population includes all ITT participants who started lymphodepletion chemotherapy.
Note: The lymphodepletion phase includes AEs which start or worsen on or after lymphodepletion and before T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_lym_s.sas 06JUN2023 06:12

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0210
Summary of Serious Adverse Events by System Organ Class and Preferred Term
and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
ANY EVENT	Number of Subjects with SAEs	2 (100%)	1 (50%)	0	3 (60%)
	Number of SAEs	11	10	0	21
	Number of Drug-related SAEs	6	7	0	13
	Number of Fatal SAEs	2	0	0	2
	Number of Drug-related Fatal SAEs	1	0	0	1
General disorders and administration site conditions					
Pyrexia	Number of Subjects with SAEs	1 (50%)	1 (50%)	0	2 (40%)
	Number of SAEs	1	1	0	2
	Number of Drug-related SAEs	0	0	0	0
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Systemic inflammatory response syndrome	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	1	0	0	1
	Number of Fatal SAEs	1	0	0	1
	Number of Drug-related Fatal SAEs	1	0	0	1

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
Note: Drug-related SAEs are defined as SAEs identified by the investigator as related to T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae16_sae_soc.sas 06JUN2023 06:27

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0210
Summary of Serious Adverse Events by System Organ Class and Preferred Term
and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Blood and lymphatic system disorders					
Febrile neutropenia	Number of Subjects with SAEs	1 (50%)	1 (50%)	0	2 (40%)
	Number of SAEs	1	1	0	2
	Number of Drug-related SAEs	1	1	0	2
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Aplastic anaemia	Number of Subjects with SAEs	0	1 (50%)	0	1 (20%)
	Number of SAEs	0	1	0	1
	Number of Drug-related SAEs	0	1	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Pancytopenia	Number of Subjects with SAEs	0	1 (50%)	0	1 (20%)
	Number of SAEs	0	1	0	1
	Number of Drug-related SAEs	0	1	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Thrombocytopenia	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	1	0	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
Note: Drug-related SAEs are defined as SAEs identified by the investigator as related to T-cell infusion.
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Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0210
Summary of Serious Adverse Events by System Organ Class and Preferred Term
and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Infections and infestations					
COVID-19 pneumonia	Number of Subjects with SAEs	0	1 (50%)	0	1 (20%)
	Number of SAEs	0	1	0	1
	Number of Drug-related SAEs	0	1	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Herpes zoster	Number of Subjects with SAEs	0	1 (50%)	0	1 (20%)
	Number of SAEs	0	1	0	1
	Number of Drug-related SAEs	0	0	0	0
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Staphylococcal infection	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	0	0	0	0
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Vascular device infection	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	0	0	0	0
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
Note: Drug-related SAEs are defined as SAEs identified by the investigator as related to T-cell infusion.
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Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0210
Summary of Serious Adverse Events by System Organ Class and Preferred Term
and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Hepatobiliary disorders					
Hyperbilirubinaemia	Number of Subjects with SAEs	0	1 (50%)	0	1 (20%)
	Number of SAEs	0	1	0	1
	Number of Drug-related SAEs	0	1	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Immune system disorders					
Graft versus host disease in skin	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	1	0	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Graft versus host disease in gastrointestinal tract	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	1	0	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
Note: Drug-related SAEs are defined as SAEs identified by the investigator as related to T-cell infusion.
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Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0210
Summary of Serious Adverse Events by System Organ Class and Preferred Term
and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Haemophagocytic lymphohistiocytosis	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	1	0	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Investigations					
Alanine aminotransferase increased	Number of Subjects with SAEs	0	1 (50%)	0	1 (20%)
	Number of SAEs	0	1	0	1
	Number of Drug-related SAEs	0	1	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
International normalised ratio increased	Number of Subjects with SAEs	0	1 (50%)	0	1 (20%)
	Number of SAEs	0	1	0	1
	Number of Drug-related SAEs	0	0	0	0
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
Note: Drug-related SAEs are defined as SAEs identified by the investigator as related to T-cell infusion.
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Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0210
Summary of Serious Adverse Events by System Organ Class and Preferred Term
and by Actual Dose (Number of Subjects and Occurrences)

System Organ Class / Preferred Term		Dose Confirmation: GSK097 0.1-0.8 x 10^9 (N=2)	Dose Confirmation: GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Nervous system disorders					
Immune effector cell-associated neurotoxicity syndrome	Number of Subjects with SAEs	0	1 (50%)	0	1 (20%)
	Number of SAEs	0	1	0	1
	Number of Drug-related SAEs	0	1	0	1
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Respiratory, thoracic and mediastinal disorders					
Pulmonary embolism	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	0	0	0	0
	Number of Fatal SAEs	0	0	0	0
	Number of Drug-related Fatal SAEs	0	0	0	0
Respiratory failure	Number of Subjects with SAEs	1 (50%)	0	0	1 (20%)
	Number of SAEs	1	0	0	1
	Number of Drug-related SAEs	0	0	0	0
	Number of Fatal SAEs	1	0	0	1
	Number of Drug-related Fatal SAEs	0	0	0	0

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
Note: Drug-related SAEs are defined as SAEs identified by the investigator as related to T-cell infusion.
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Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0220
Summary of Treatment Emergent Serious Adverse Events by Maximum Grade
and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	0	2 (100%)	2 (100%)	2 (100%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Haemophagocytic lymphohistiocytosis	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Pulmonary embolism	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Respiratory failure	0	0	0	0	1 (50%)	1 (50%)	1 (50%)
Systemic inflammatory response syndrome	0	0	0	0	1 (50%)	1 (50%)	1 (50%)
Thrombocytopenia/Platelet count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Unspecified GVHD - Skin	0	0	1 (50%)	0	0	1 (50%)	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
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Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0220
Summary of Treatment Emergent Serious Adverse Events by Maximum Grade
and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade											
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5	Grade 3+4+5		Total	
ANY EVENT	0		0		0		1	(50%)	0	1	(50%)	1	(50%)
Alanine aminotransferase increased	0		0		1	(50%)	0		0	1	(50%)	1	(50%)
Aplastic anaemia	0		0		0		1	(50%)	0	1	(50%)	1	(50%)
COVID-19 pneumonia	0		0		1	(50%)	0		0	1	(50%)	1	(50%)
Febrile neutropenia	0		0		1	(50%)	0		0	1	(50%)	1	(50%)
Herpes zoster	0		0		1	(50%)	0		0	1	(50%)	1	(50%)
Hyperbilirubinaemia	0		1	(50%)	0		0		0	0		1	(50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0		0		0		1	(50%)	0	1	(50%)	1	(50%)
International normalised ratio increased	0		1	(50%)	0		0		0	0		1	(50%)
Pancytopenia	0		0		0		1	(50%)	0	1	(50%)	1	(50%)
Pyrexia	1	(50%)	0		0		0		0	0		1	(50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
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Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0220
Summary of Treatment Emergent Serious Adverse Events by Maximum Grade
and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade															
Adverse Event	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Grade 3+4+5		Total	
ANY EVENT	0		0		0		1	(25%)	2	(50%)	3	(75%)	3	(75%)
Febrile neutropenia	0		0		2	(50%)	0		0		2	(50%)	2	(50%)
Alanine aminotransferase increased	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Aplastic anaemia	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
COVID-19 pneumonia	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Haemophagocytic lymphohistiocytosis	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
Herpes zoster	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Hyperbilirubinaemia	0		1	(25%)	0		0		0		0		1	(25%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
International normalised ratio increased	0		1	(25%)	0		0		0		0		1	(25%)
Pancytopenia	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
Pulmonary embolism	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Pyrexia	1	(25%)	0		0		0		0		0		1	(25%)
Respiratory failure	0		0		0		0		1	(25%)	1	(25%)	1	(25%)
Systemic inflammatory response syndrome	0		0		0		0		1	(25%)	1	(25%)	1	(25%)
Thrombocytopenia/Platelet count decreased	0		0		0		1	(25%)	0		1	(25%)	1	(25%)
Unspecified GVHD - Gut (Liver and Intestine)	0		0		1	(25%)	0		0		1	(25%)	1	(25%)
Unspecified GVHD - Skin	0		0		1	(25%)	0		0		1	(25%)	1	(25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_s.sas 06JUN2023 06:12

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0230
Summary of Treatment Emergent T-cell Related Serious Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	0	1 (50%)	1 (50%)	1 (50%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Haemophagocytic lymphohistiocytosis	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Systemic inflammatory response syndrome	0	0	0	0	1 (50%)	1 (50%)	1 (50%)
Thrombocytopenia/Platelet count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Unspecified GVHD - Skin	0	0	1 (50%)	0	0	1 (50%)	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_trel_s.sas 06JUN2023 06:12

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0230
Summary of Treatment Emergent T-cell Related Serious Adverse Events by Maximum Grade and by Actual Dose

Treatment: GSK097 1-8 x 10^9 (N=2)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Alanine aminotransferase increased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Aplastic anaemia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
COVID-19 pneumonia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Hyperbilirubinaemia	0	1 (50%)	0	0	0	0	1 (50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Pancytopenia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_trel_s.sas 06JUN2023 06:12

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0230
Summary of Treatment Emergent T-cell Related Serious Adverse Events by Maximum Grade and by Actual Dose

Treatment: Total (N=4)

	Maximum Grade						
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	1 (25%)	1 (25%)	2 (50%)	2 (50%)
Febrile neutropenia	0	0	2 (50%)	0	0	2 (50%)	2 (50%)
Alanine aminotransferase increased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Aplastic anaemia	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
COVID-19 pneumonia	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Haemophagocytic lymphohistiocytosis	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Hyperbilirubinaemia	0	1 (25%)	0	0	0	0	1 (25%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Pancytopenia	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Systemic inflammatory response syndrome	0	0	0	0	1 (25%)	1 (25%)	1 (25%)
Thrombocytopenia/Platelet count decreased	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Unspecified GVHD - Gut (Liver and Intestine)	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Unspecified GVHD - Skin	0	0	1 (25%)	0	0	1 (25%)	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_trel_s.sas 06JUN2023 06:12

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0240
Summary of Treatment Emergent T-cell Related Serious Fatal and Non-Fatal AEs by Overall Frequency and by Actual Dose

Outcome: Fatal

Adverse Event	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Any event	1 (50%)	0	1 (25%)
Systemic inflammatory response syndrome	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae20.sas 06JUN2023 06:12

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0240
Summary of Treatment Emergent T-cell Related Serious Fatal and Non-Fatal AEs by Overall Frequency and by Actual Dose

Outcome: Non-Fatal

Adverse Event	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Any event	1 (50%)	1 (50%)	2 (50%)
Febrile neutropenia	1 (50%)	1 (50%)	2 (50%)
Alanine aminotransferase increased	0	1 (50%)	1 (25%)
Aplastic anaemia	0	1 (50%)	1 (25%)
COVID-19 pneumonia	0	1 (50%)	1 (25%)
Graft versus host disease in gastrointestinal tract	1 (50%)	0	1 (25%)
Graft versus host disease in skin	1 (50%)	0	1 (25%)
Haemophagocytic lymphohistiocytosis	1 (50%)	0	1 (25%)
Hyperbilirubinaemia	0	1 (50%)	1 (25%)
Immune effector cell-associated neurotoxicity syndrome	0	1 (50%)	1 (25%)
Pancytopenia	0	1 (50%)	1 (25%)
Thrombocytopenia	1 (50%)	0	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: T-cell related AEs are defined as AEs identified by the investigator as related to T-cell infusion.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae20.sas 06JUN2023 06:12

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0250
Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade and by Actual Dose (Focused List)

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

AESI Category Adverse Event	Maximum Grade Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Cytokine release syndrome							
Any Event	0	2 (100%)	0	0	0	0	2 (100%)
Cytokine Release Syndrome (CRS)	0	2 (100%)	0	0	0	0	2 (100%)
Graft versus host disease							
Any Event	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Unspecified GVHD - Skin	0	0	1 (50%)	0	0	1 (50%)	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_si.sas 06JUN2023 06:13

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0250
Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade and by Actual Dose (Focused List)

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

AESI Category Adverse Event	Maximum Grade Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)							
Any Event	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Anaemia/Red blood cell count decreased	0	0	1 (50%)	1 (50%)	0	2 (100%)	2 (100%)
Neutropenia/Neutrophil count decreased	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Thrombocytopenia/Platelet count decreased	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Haematocrit decreased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Haemoglobin decreased	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Leukopenia/White blood cell decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Pancytopenia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Aplastic anaemia	0	0	0	0	0	0	0
Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)							
Any Event	1 (50%)	0	0	0	0	0	1 (50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	1 (50%)	0	0	0	0	0	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_si.sas 06JUN2023 06:13

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0250
Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade and by Actual Dose (Focused List)

Treatment: GSK097 1-8 x 10^9 (N=2)

AESI Category Adverse Event	Maximum Grade Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Cytokine release syndrome							
Any Event	1 (50%)	1 (50%)	0	0	0	0	2 (100%)
Cytokine Release Syndrome (CRS)	1 (50%)	1 (50%)	0	0	0	0	2 (100%)
Graft versus host disease							
Any Event	0	1 (50%)	0	0	0	0	1 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	0	1 (50%)	0	0	0	0	1 (50%)
Unspecified GVHD - Skin	0	1 (50%)	0	0	0	0	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_si.sas 06JUN2023 06:13

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0250
Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade and by Actual Dose (Focused List)

Treatment: GSK097 1-8 x 10^9 (N=2)

AESI Category / Adverse Event	Maximum Grade: Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)							
Any Event	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Anaemia/Red blood cell count decreased	0	0	2 (100%)	0	0	2 (100%)	2 (100%)
Thrombocytopenia/Platelet count decreased	0	0	0	2 (100%)	0	2 (100%)	2 (100%)
Aplastic anaemia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Leukopenia/White blood cell decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Neutropenia/Neutrophil count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Pancytopenia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Haematocrit decreased	0	0	0	0	0	0	0
Haemoglobin decreased	0	0	0	0	0	0	0
Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)							
Any Event	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0	0	0	1 (50%)	0	1 (50%)	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_si.sas 06JUN2023 06:13

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0250
Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade and by Actual Dose (Focused List)

Treatment: Total (N=4)

AESI Category Adverse Event	Maximum Grade Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	4 (100%)	0	4 (100%)	4 (100%)
Cytokine release syndrome							
Any Event	1 (25%)	3 (75%)	0	0	0	0	4 (100%)
Cytokine Release Syndrome (CRS)	1 (25%)	3 (75%)	0	0	0	0	4 (100%)
Graft versus host disease							
Any Event	0	1 (25%)	1 (25%)	0	0	1 (25%)	2 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	0	1 (25%)	1 (25%)	0	0	1 (25%)	2 (50%)
Unspecified GVHD - Skin	0	1 (25%)	1 (25%)	0	0	1 (25%)	2 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_si.sas 06JUN2023 06:13

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0250
Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade and by Actual Dose (Focused List)

Treatment: Total (N=4)

AESI Category Adverse Event	Maximum Grade Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)							
Any Event	0	0	0	4 (100%)	0	4 (100%)	4 (100%)
Anaemia/Red blood cell count decreased	0	0	3 (75%)	1 (25%)	0	4 (100%)	4 (100%)
Thrombocytopenia/Platelet count decreased	0	0	0	4 (100%)	0	4 (100%)	4 (100%)
Neutropenia/Neutrophil count decreased	0	0	0	3 (75%)	0	3 (75%)	3 (75%)
Febrile neutropenia	0	0	2 (50%)	0	0	2 (50%)	2 (50%)
Leukopenia/White blood cell decreased	0	0	0	2 (50%)	0	2 (50%)	2 (50%)
Pancytopenia	0	0	0	2 (50%)	0	2 (50%)	2 (50%)
Aplastic anaemia	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Haematocrit decreased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Haemoglobin decreased	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)							
Any Event	1 (25%)	0	0	1 (25%)	0	1 (25%)	2 (50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	1 (25%)	0	0	1 (25%)	0	1 (25%)	2 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_si.sas 06JUN2023 06:13

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0260
Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Cytokine Release Syndrome (CRS) by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Number of Subjects Experiencing Cytokine release syndrome	2 (100%)	2 (100%)	4 (100%)
Time to onset from T-cell infusion (days)			
n	2	2	4
< -8	0	0	0
-8 - -1	0	0	0
1 - 14	2 (100%)	2 (100%)	4 (100%)
15 - 30	0	0	0
31 - 60	0	0	0
> 60	0	0	0
Mean	2.0	1.0	1.5
SD	0.00	0.00	0.58
Median	2.0	1.0	1.5
Min.	2	1	1
Max.	2	1	2

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Adverse events with partial or missing dates are not used in the duration derivation.
Note: Preferred terms identified in the focused list are summarized.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_esi2b_crs.sas 06JUN2023 18:57

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0260
Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Cytokine Release Syndrome (CRS) by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Duration (days)			
n	2	2	4
1 - 30	2 (100%)	2 (100%)	4 (100%)
31 - 60	0	0	0
61 - 90	0	0	0
> 90	0	0	0
Mean	3.5	7.5	5.5
SD	0.71	3.54	3.11
Median	3.5	7.5	4.5
Min.	3	5	3
Max.	4	10	10

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Adverse events with partial or missing dates are not used in the duration derivation.
Note: Preferred terms identified in the focused list are summarized.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_esi2b_crs.sas 06JUN2023 18:57

Protocol: 209012SS2
Population: Modified Intent-To-Treat Data as of 12MAY2023

Table 3.0270
Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Febrile Neutropenia by Actual Dose

No data to report

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Adverse events with partial or missing dates are not used in the duration derivation.
Note: Preferred terms identified in the focused list are summarized.
Note: Data not reported in table as condition of >=3 subjects is not met. Please refer to Listing 20.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_esi2b_neut.sas 06JUN2023 18:58

Protocol: 209012SS2 Page 1 of 1
Population: Modified Intent-To-Treat Data as of 12MAY2023

Table 3.0280
Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Graft vs Host Disease (GvHD) by Actual treatment

No data to report

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Adverse events with partial or missing dates are not used in the duration derivation.
Note: Preferred terms identified in the focused list are summarized.
Note: Data not reported in table as condition of >=3 subjects is not met. Please refer to Listing 29.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_esi2b_ghd.sas 06JUN2023 18:58

Protocol: 209012SS2
Population: Modified Intent-To-Treat Data as of 12MAY2023

Table 3.0290
Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Immune Effector Cell-Associated Neurotoxicity syndrome (ICANS) by Actual Dose

No data to report

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Adverse events with partial or missing dates are not used in the duration derivation.
Note: Preferred terms identified in the focused list are summarized.
Note: Data not reported in table as condition of >=3 subjects is not met. Please refer to Listing 27.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_esi2b_icans.sas 06JUN2023 18:58

Protocol: 209012SS2
Population: Modified Intent-To-Treat Data as of 12MAY2023

Table 3.0300
Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Pneumonitis
by Actual Dose

No data to report

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Adverse events with partial or missing dates are not used in the duration derivation.
Note: Preferred terms identified in the focused list are summarized.
Note: Data not reported in table as condition of >=3 subjects is not met. Please refer to Listing 32.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_esi2b_pnmtis.sas 06JUN2023 18:58

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0310
Summary of All Serious Treatment Emergent Adverse Events of Special Interest
by Maximum Grade and by Actual Dose (Focused List)

Treatment: GSK097 0.1-0.8 x 10^9 (N=2)

AESI Category Adverse Event	Maximum Grade						
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Graft versus host disease							
Any Event	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Unspecified GVHD - Gut (Liver and Intestine)	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Unspecified GVHD - Skin	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)							
Any Event	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Thrombocytopenia/Platelet count decreased	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Aplastic anaemia	0	0	0	0	0	0	0
Pancytopenia	0	0	0	0	0	0	0
Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)							
Any Event	0	0	0	0	0	0	0
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0	0	0	0	0	0	0

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_s_si.sas 06JUN2023 18:58

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0310
Summary of All Serious Treatment Emergent Adverse Events of Special Interest
by Maximum Grade and by Actual Dose (Focused List)

Treatment: GSK097 1-8 x 10^9 (N=2)

AESI Category Adverse Event	Maximum Grade Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Graft versus host disease							
Any Event	0	0	0	0	0	0	0
Unspecified GVHD - Gut (Liver and Intestine)	0	0	0	0	0	0	0
Unspecified GVHD - Skin	0	0	0	0	0	0	0
Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)							
Any Event	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Aplastic anaemia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Febrile neutropenia	0	0	1 (50%)	0	0	1 (50%)	1 (50%)
Pancytopenia	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Thrombocytopenia/Platelet count decreased	0	0	0	0	0	0	0
Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)							
Any Event	0	0	0	1 (50%)	0	1 (50%)	1 (50%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0	0	0	1 (50%)	0	1 (50%)	1 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_s_si.sas 06JUN2023 18:58

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0310
Summary of All Serious Treatment Emergent Adverse Events of Special Interest
by Maximum Grade and by Actual Dose (Focused List)

Treatment: Total (N=4)

AESI Category Adverse Event	Maximum Grade Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+4+5	Total
ANY EVENT	0	0	0	2 (50%)	0	2 (50%)	2 (50%)
Graft versus host disease							
Any Event	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Unspecified GVHD - Gut (Liver and Intestine)	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Unspecified GVHD - Skin	0	0	1 (25%)	0	0	1 (25%)	1 (25%)
Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)							
Any Event	0	0	0	2 (50%)	0	2 (50%)	2 (50%)
Febrile neutropenia	0	0	2 (50%)	0	0	2 (50%)	2 (50%)
Aplastic anaemia	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Pancytopenia	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Thrombocytopenia/Platelet count decreased	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)							
Any Event	0	0	0	1 (25%)	0	1 (25%)	1 (25%)
Immune effector cell-associated neurotoxicity syndrome (ICANS)	0	0	0	1 (25%)	0	1 (25%)	1 (25%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: AEs which start or worsen on or after T-cell infusion are classified as treatment emergent.
Note: Preferred terms are combined as shown in Table 3.0110.
sxt29322: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_ae5b_s_si.sas 06JUN2023 18:58

Protocol: 209012SS2
Population: Intent-to-Treat Data as of 12MAY2023

Table 3.0320
Summary of Deaths by Actual Dose

	Dose Confirmation			
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	No Treatment (N=1)	Total (N=5)
Subject Status				
Dead	2 (100%)	0	0	2 (40%)
Alive at last contact, follow-up ended	0	2 (100%)	1 (100%)	3 (60%)
Alive at last contact, follow-up ongoing	0	0	0	0
Primary Cause of Death				
Cardiac Arrhythmia	0	0	0	0
Haemorrhage	1 (50%)	0	0	1 (20%)
Heart Failure	0	0	0	0
Myocardial Infarction	0	0	0	0
Other Cardiovascular Cause	0	0	0	0
Cancer	0	0	0	0
Disease under study	0	0	0	0
Other cancer	0	0	0	0
Pulmonary Embolism (PE)	0	0	0	0
Sepsis	0	0	0	0
Stroke	0	0	0	0
Suicide	0	0	0	0
Trauma	0	0	0	0
Other Non-Cardiovascular Cause	1 (50%)	0	0	1 (20%)

Note: Intent-to-Treat population includes all participants who started leukapheresis procedure.
Note: "No Treatment" column consists of patients who underwent leukapheresis but did not go on to receive lymphodepletion chemotherapy or T-cell infusion.
Note: Participant 110454: primary cause of death is "systemic inflammatory response syndrome".
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_dd1_itt.sas 31MAY2023 06:06

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0330
Summary of Deaths by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
Subject Status			
Dead	2 (100%)	0	2 (50%)
Alive at last contact, follow-up ended	0	2 (100%)	2 (50%)
Alive at last contact, follow-up ongoing	0	0	0
Primary Cause of Death			
Cardiac Arrhythmia	0	0	0
Haemorrhage	1 (50%)	0	1 (25%)
Heart Failure	0	0	0
Myocardial Infarction	0	0	0
Other Cardiovascular Cause	0	0	0
Cancer	0	0	0
Disease under study	0	0	0
Other cancer	0	0	0
Pulmonary Embolism (PE)	0	0	0
Sepsis	0	0	0
Stroke	0	0	0
Suicide	0	0	0
Trauma	0	0	0
Other Non-Cardiovascular Cause	1 (50%)	0	1 (25%)
Time since T-cell infusion to Death			
<=30 days	0	0	0
>30 days	2 (100%)	0	2 (50%)

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: Participant 110454: primary cause of death is "systemic inflammatory response syndrome".
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_dd1_mitt.sas 31MAY2023 06:04

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

Table 3.0340
Summary of Exposure to Study Treatment by Planned Dose

Dose	Dose Confirmation DL-1 (N=1)	DL1 (N=3)	Total (N=4)
Cyclophosphamide Cumulative Dose (mg/m^2)			
n	1	3	4
Mean	1800.0	3000.0	2700.0
SD		519.62	734.85
Median	1800.0	2700.0	2700.0
Min.	1800	2700	1800
Max.	1800	3600	3600
Fludarabine Cumulative Dose (mg/m^2)			
n	1	3	4
Mean	60.0	120.0	105.0
SD		0.00	30.00
Median	60.0	120.0	120.0
Min.	60	120	60
Max.	60	120	120
Actual Transduced Cell Dose Received			
<0.1 (x 10^9 cells)	0	0	0
>=0.1 to <=0.8 (x 10^9 cells)	1 (100%)	1 (33%)	2 (50%)
>0.8 to <1 (x 10^9 cells)	0	0	0
>=1 to <=8 (x 10^9 cells)	0	2 (67%)	2 (50%)
>8 (x 10^9 cells)	0	0	0
n	1	3	4
Mean	0.800	2.528	2.096
SD		2.1245	1.9379
Median	0.800	1.884	1.342
Min.	0.80	0.80	0.80
Max.	0.80	4.90	4.90

Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
Note: Planned doses - DL1 = 1-8 x 10^9 T-cells, DL-1 = 0.1-0.8 x 10^9 T-cells.
jg700320: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_ex1.sas 26MAY2023 06:43

Protocol: 209012SS2
Population: Modified Intent-to-Treat Data as of 12MAY2023

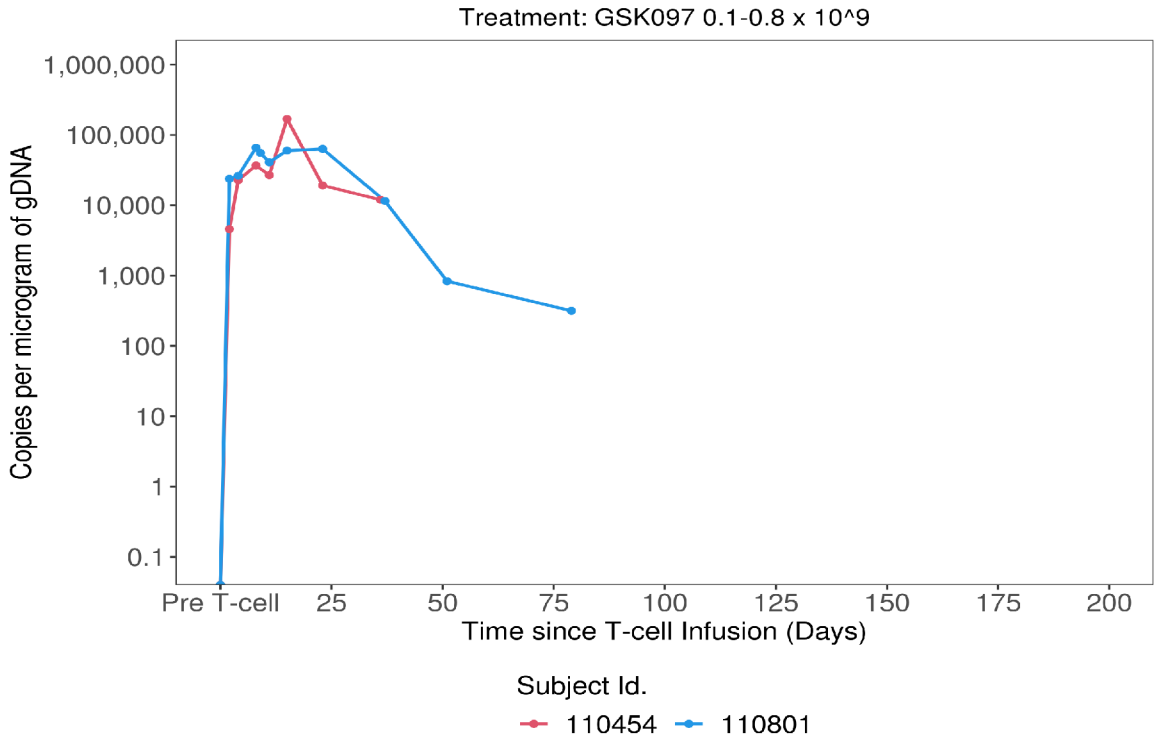
Table 3.0350
Summary of Replication Competent Lentivirus Positive by Actual Dose

	Dose Confirmation		
	GSK097 0.1-0.8 x 10^9 (N=2)	GSK097 1-8 x 10^9 (N=2)	Total (N=4)
n [1]	1 (50%)	2 (100%)	3 (75%)
Subjects with Replication Competent Lentivirus Positive	0	0	0

[1] n reflects the number of subjects with RCL assessed post T-cell infusion.
Note: Modified Intent-to-treat population includes all ITT participants who received any dose of NY-ESO-1 specific T-cells.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_saf_rcl.sas 31MAY2023 06:09

Protocol: 209012SS2
Population: Pharmacokinetic

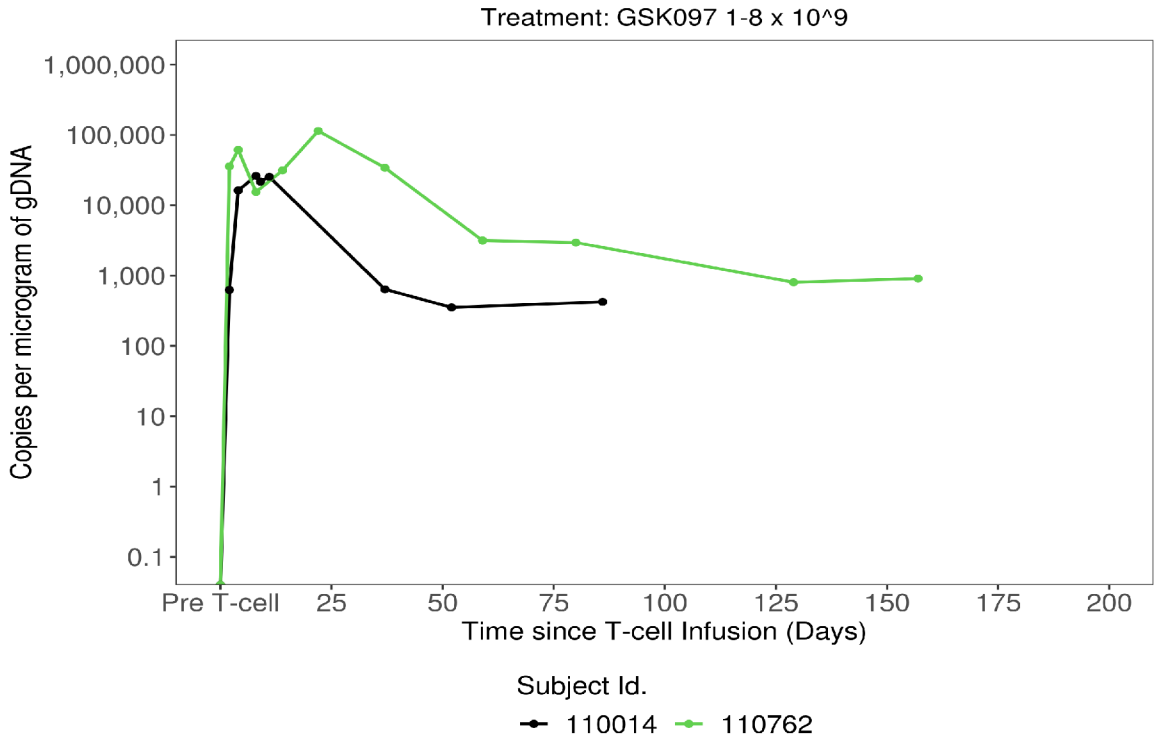
Figure 4.0120
GSK3845097 Pharmacokinetic Concentration-Time Plot by Actual Dose



Note: PK population includes all participants in the mITT analysis set from whom at least one persistence sample was obtained, analysed, and was measurable.
Note: Y-axis is log transformed.
Note: Values reported as "<50" are assigned based on the reported interpretation. If interpretive reported result is "Negative", values are set to 0. If interpretive reported result is "Detectable", values are set to 50.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/f_pk1.sas 25MAY2023 05:46

Protocol: 209012SS2
Population: Pharmacokinetic

Figure 4.0120
GSK3845097 Pharmacokinetic Concentration-Time Plot by Actual Dose



Note: PK population includes all participants in the mITT analysis set from whom at least one persistence sample was obtained, analysed, and was measurable.
Note: Y-axis is log transformed.
Note: Values reported as "<50" are assigned based on the reported interpretation. If interpretive reported result is "Negative", values are set to 0. If interpretive reported result is "Detectable", values are set to 50.
haj12129: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/f_pk1.sas 25MAY2023 05:46

Protocol: 209012SS2
Population: Pharmacokinetic Data as of 12MAY2023

Table 4.0100
Summary of Derived GSK3845097 Pharmacokinetic Parameters

Parameter	Treatment	N	n	Mean	95% CI (Lower,Upper)	SD	Median	Min.	Max.
AUC(0-28) (Copies/ug gDNA times days)	GSK097 0.1-0.8 x 10^9	2	2	1326101.39	(836136.84, 1816065.95)	54533.555	1326101.39	1287540.3	1364662.4
	GSK097 1-8 x 10^9	2	2	959248.26	(-6933822.31, 8852318.83)	878506.815	959248.26	338050.1	1580446.4
	Total	4	4	1142674.83	(266620.44, 2018729.21)	550554.071	1326101.39	338050.1	1580446.4
AUC(0-tlast) (Copies/ug gDNA times days)	GSK097 0.1-0.8 x 10^9	2	2	1487565.70	(157370.12, 2817761.28)	148052.126	1487565.70	1382877.0	1592254.4
	GSK097 1-8 x 10^9	2	2	1393041.27	(-11631883.15, 14417965.70)	1449687.389	1393041.27	367957.5	2418125.1
	Total	4	4	1440303.49	(98744.82, 2781862.15)	843099.011	1487565.70	367957.5	2418125.1
Cmax (Copies/ug gDNA)	GSK097 0.1-0.8 x 10^9	2	2	117367.10	(-537466.22, 772200.42)	72883.617	117367.10	65830.6	168903.6
	GSK097 1-8 x 10^9	2	2	70095.40	(-488325.78, 628516.58)	62152.848	70095.40	26146.7	114044.1
	Total	4	4	93731.25	(-4399.68, 191862.18)	61670.122	89937.35	26146.7	168903.6
Tmax (Days)	GSK097 0.1-0.8 x 10^9	2	2	10.5	(-34.0, 55.0)	4.95	10.5	7	14
	GSK097 1-8 x 10^9	2	2	14.0	(-74.9, 102.9)	9.90	14.0	7	21
	Total	4	4	12.3	(1.6, 22.9)	6.70	10.5	7	21

'N' is the number of subjects in the population for the treatment and group.
'n' is the number of subjects in the population for the treatment and group with data.
Note: The Pharmacokinetic population includes all participants in the mITT population from whom at least one PK sample was obtained, analyzed, and was measurable.
ak381452: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_pk03_pp_40100.sas 25MAY2023 05:41

Protocol: 209012SS2
Population: Pharmacokinetic Data as of 12MAY2023

Table 4.0110
Summary of Derived Log-Transformed GSK3845097 Pharmacokinetic Parameters

Parameter	Treatment	N	n	Geom. Mean	95% CI (Lower,Upper)	SD (logs)	%CVb
AUC(0-28) (Copies/ug gDNA times days)	GSK097 0.1-0.8 x 10^9	2	2	1325540.63	(915979.55, 1918228.36)	0.041	4.115
	GSK097 1-8 x 10^9	2	2	730937.83	(40.61, 13157696626.43)	1.091	151.154
	Total	4	4	984320.98	(314165.86, 3084000.91)	0.718	82.086
AUC(0-tlast) (Copies/ug gDNA times days)	GSK097 0.1-0.8 x 10^9	2	2	1483877.35	(605905.16, 3634053.88)	0.100	9.994
	GSK097 1-8 x 10^9	2	2	943274.74	(6.02, 147723636698.64)	1.331	221.024
	Total	4	4	1183090.87	(323980.00, 4320340.80)	0.814	96.939
Cmax (Copies/ug gDNA)	GSK097 0.1-0.8 x 10^9	2	2	105446.79	(265.02, 41955927.13)	0.666	74.752
	GSK097 1-8 x 10^9	2	2	54606.56	(4.71, 632476668.59)	1.041	139.944
	Total	4	4	75882.06	(20957.22, 274754.34)	0.809	96.071

'N' is the number of subjects in the population for the treatment and group.
'n' is the number of subjects in the population for the treatment and group with data.
Note: The Pharmacokinetic population includes all participants in the mITT population from whom at least one PK sample was obtained, analyzed, and was measurable.
ak381452: /arenv/arprod/gsk3845097/mid209012ss2/final_01/drivers/t_pk05_pp_40110.sas 25MAY2023 05:41