**ClinicalTrials.gov PRS**
Last Update: 09/12/2023 00:38

**ClinicalTrials.gov ID: NCT05993299**

# Study Results

## Participant Flow

| | |
|---|---|
| Pre-assignment Details | This study is a sub study of the master protocol (NCT03967223). The results presented are until the primary completion date. Data collection is still ongoing and additional results will be provided after study completion. |

Reporting Groups

| | Description |
|---|---|
| Letetresgene Autoleucel (Lete-cel) | Eligible participants were leukapheresed to manufacture autologous lete-cel. Participants underwent lymphodepleting chemotherapy which generally consisted of fludarabine 30 mg/m^2/day on day -7 through day -4 and cyclophosphamide 900 milligrams per meter square per day (mg/m^2/day) on day -6 through day -4. followed by a single infusion of lete-cel on Day 1. The dose of lete-cel was within the range of 1×10^9 to 15×10^9 transduced T cells. |

Overall Study

| | Letetresgene Autoleucel (Lete-cel) |
|---|---|
| Started | 7 |
| Received T Cell Infusion | 5 |
| Completed | 1 |
| Not Completed | 6 |
| Did not meet treatment eligibility criteria | 2 |
| Ongoing | 4 |

# Baseline Characteristics

Reporting Groups

| | Description |
|---|---|
| Letetresgene Autoleucel (Lete-cel) | Eligible participants were leukapheresed to manufacture autologous lete-cel. Participants underwent lymphodepleting chemotherapy which generally consisted of fludarabine 30 mg/m^2/day on day -7 through day -4 and cyclophosphamide 900 milligrams per meter square per day (mg/m^2/day) on day -6 through day -4. followed by a single infusion of lete-cel on Day 1. The dose of lete-cel was within the range of 1×10^9 to 15×10^9 transduced T cells. |

Baseline Measures

| | | Letetresgene Autoleucel (Lete-cel) |
|---|---|---|
| Overall Number of Participants | | 7 |
| **Age, Continuous** | Mean (Standard Deviation)<br>Unit of measure: years<br>Number Analyzed | 7 participants |
| | | 49.4 (16.70) |
| **Age, Customized** | Measure Type: Count of Participants<br>Unit of measure: participants<br>Number Analyzed | 7 participants |
| <=18 years | | 1 14.29% |
| 19-64 years | | 6 85.71% |
| **Sex: Female, Male** | Measure Type: Count of Participants<br>Unit of measure: participants<br>Number Analyzed | 7 participants |
| | Female | 5 71.43% |
| | Male | 2 28.57% |
| **Ethnicity** | Measure Count of | 7 participants |

| | | Letetresgene Autoleucel (Lete-cel) |
|---|---|---|
| **(NIH/OMB)** | Type: Participants<br>Unit of measure: participants<br>Number Analyzed | |
| | Hispanic or Latino | 3 42.86% |
| | Not Hispanic or Latino | 4 57.14% |
| | Unknown or Not Reported | 0 0% |
| **Race (NIH/OMB)** | Measure Type: Count of Participants<br>Unit of measure: participants<br>Number Analyzed | 7 participants |
| | American Indian or Alaska Native | 0 0% |
| | Asian | 0 0% |
| | Native Hawaiian or Other Pacific Islander | 0 0% |
| | Black or African American | 0 0% |
| | White | 7 100% |
| | More than one race | 0 0% |
| | Unknown or Not Reported | 0 0% |
| **Region of Enrollment** | Measure Type: Number<br>Unit of measure: participants<br>Number Analyzed | 7 participants |
| Canada | | 1 |
| Netherlands | | 2 |

| | | Letetresgene Autoleucel (Lete-cel) |
|---|---|---|
| | | |
| United Kingdom | | 1 |
| United States | | 3 |

# Outcome Measures

**1. Primary Outcome Measure:**

| | |
|---|---|
| Measure Title | Overall Response Rate (ORR) |
| Measure Description | ORR is defined as the percentage of participants with a confirmed complete response (CR) or confirmed partial response (PR) via investigator assessment per Response Evaluation Criteria in Solid Tumors Criteria (RECIST) version 1.1 relative to the total number of participants in the analysis population. CR is defined as disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<)10 millimeters (mm). PR is defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g., percent change from baseline). 95% CI is based on Clopper-Pearson exact confidence interval. |
| Time Frame | Up to approximately 36 months |

Analysis Population Description

Modified intent-to-treat (mITT) population included all participants who received any dose of Lete-cel.

Reporting Groups

| | Description |
|---|---|
| Letetresgene Autoleucel (Lete-cel) | Eligible participants were leukapheresed to manufacture autologous lete-cel. Participants underwent lymphodepleting chemotherapy which generally consisted of fludarabine 30 mg/m^2/day on day -7 through day -4 and cyclophosphamide 900 milligrams per meter square per day (mg/m^2/day) on day -6 through day -4. followed by a single infusion of lete-cel on Day 1. The dose of lete-cel was within the range of 1×10^9 to 15×10^9 transduced T cells. |

Measured Values

| | Letetresgene Autoleucel (Lete-cel) |
|---|---|
| Overall Number of Participants Analyzed | 5 |
| Overall Response Rate (ORR) | Number (95% Confidence Interval)<br>Unit of measure: percentage of participants<br>80 (28.4 to 99.5) |

**2. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Time to Response (TTR) |
| Measure Description | Time to response was defined as the interval of time between the date of T-cell infusion and the first documented evidence of the confirmed response (PR or CR), in the subset of participants with a confirmed PR or CR as their best confirmed overall response. CR is defined as disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<)10 millimeters (mm). PR is defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g., percent change from baseline). |
| Time Frame | Up to approximately 54 months |
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**3. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Duration of Response (DOR) |
| Measure Description | Duration of response was defined as the interval between the initial date of confirmed response (PR/CR) and the date of progressive disease as assessed by local investigators, or death among participants with a confirmed response per RECIST 1.1. CR is defined as disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<)10 millimeters (mm). PR is defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g., percent change from baseline). |
| Time Frame | Up to approximately 54 months |
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**4. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Disease Control Rate (DCR) |
| Measure Description | DCR is defined as the percentage of participants with a confirmed CR, PR, or stable disease (SD) with a minimal 12 weeks (84 days ± 7 day window) duration relative to the total number of participants within the analysis population at the time of primary analysis as determined by local investigators per RECIST v1.1. CR is defined as disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<)10 millimeters (mm). PR is defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g., percent change from baseline). SD is defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease. The disease progression (PD) is defined as the date of radiological disease progression based on imaging data per RECIST v1.1. 95% CI is based on Clopper-Pearson exact confidence interval. |
| Time Frame | Up to approximately 36 months |

Analysis Population Description

Modified intent-to-treat (mITT) population included all participants who received any dose of Lete-cel.

Reporting Groups

| | Description |
|---|---|
| Letetresgene Autoleucel (Lete-cel) | Eligible participants were leukapheresed to manufacture autologous lete-cel. Participants underwent lymphodepleting chemotherapy which generally consisted of fludarabine 30 mg/m^2/day on day -7 through day -4 and cyclophosphamide 900 milligrams per meter square per day (mg/m^2/day) on day -6 through day -4. followed by a single infusion of lete-cel on Day 1. The dose of lete-cel was within the range of 1×10^9 to 15×10^9 transduced T cells. |

Measured Values

| | Letetresgene Autoleucel (Lete-cel) |
|---|---|
| Overall Number of Participants Analyzed | 5 |
| Disease Control Rate (DCR) | Number (95% Confidence Interval)<br>Unit of measure: Percentage of Participants<br>80.0 (28.4 to 99.5) |

**5. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Progression Free Survival (PFS) |
| Measure Description | PFS is defined as the interval of time between from the date of T-cell infusion to the earliest date of radiological progression of disease (PD) as assessed by local investigator per RECIST v1.1, or death due to any cause. The PD is defined as the date of radiological disease progression based on imaging data per RECIST v1.1. |
| Time Frame | Up to approximately 54 months |
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**6. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Treatment Emergent Serious Adverse Events (TESAEs) |
| Measure Description | An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations which involve medical or scientific judgment or is associated with liver injury and impaired liver function. |

| | |
|---|---|
| Time Frame | Up to approximately 54 months |
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**7. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Number of Participants With AEs of Special Interest (AESIs) |
| Measure Description | An AESI may be of scientific and medical concern related to the treatment, monitored, and rapidly communicated by investigator to sponsor. AESIs included cytokine release syndrome (CRS), hematopoietic cytopenias (including pancytopenia and aplastic anemia), graft vs host disease (GVHD), ICANS, Guillain-Barre syndrome, treatment-related inflammatory response at tumor site(s), and neutropenia Grade 4 lasting ≥28 days. |
| Time Frame | Up to approximately 54 months |
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**8. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Number of Participants With TEAEs and TESAEs by Severity |
| Measure Description | An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations which involve medical or scientific judgment or is associated with liver injury and impaired liver function. AEs and SAEs were graded according to National Cancer Institute-Common Toxicity Criteria for Adverse Events (NCI-CTCAE) version 5.0. Grade 1-Mild; Grade 2- Moderate; Grade 3- Severe or medically significant but not immediately life-threatening; Grade 4- Life-threatening consequences; Grade 5- Death related to AE. |
| Time Frame | Up to approximately 54 months |
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**9. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Number of Participants With AESIs by Severity |
| Measure Description | An AESI may be of scientific and medical concern related to the treatment, monitored, and rapidly communicated by investigator to sponsor. AESIs included cytokine release syndrome (CRS), hematopoietic cytopenias (including pancytopenia and aplastic anemia), graft vs host disease (GVHD), ICANS, Guillain-Barre syndrome, treatment-related inflammatory response at tumor site(s), and neutropenia Grade 4 lasting ≥28 days. |
| Time Frame | Up to approximately 54 months |

| | |
|---|---|
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**10. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Percentage of Participants With Replication Competent Lentivirus (RCL) Positive |
| Measure Description | RCL was monitored using a polymerase chain reaction (PCR)-based assay that detects and measures copies of the gene coding for the vector's envelope protein, namely vesicular stomatitis virus G protein (VSV-G). |
| Time Frame | Up to approximately 54 months |
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**11. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Instances of Insertional Oncogenesis (IO) |
| Measure Description | Instances of Insertional Oncogenesis (IO) was summarized descriptively. |
| Time Frame | Up to approximately 54 months |
| Anticipated Reporting Date | July 2025 |

Outcome Measure Data Not Reported

**12. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Maximum Transgene Expansion (Cmax) |
| Measure Description | Cmax was defined as maximum observed persistence, determined directly from the persistence–time data. Blood samples were collected for PK analysis. |
| Time Frame | Up to approximately 14 days |

Analysis Population Description

Pharmacokinetic (PK) population included participants in the safety population from whom at least one persistence sample was obtained, analyzed and was measurable.

Reporting Groups

| | Description |
|---|---|
| Letetresgene Autoleucel (Lete-cel) | Eligible participants were leukapheresed to manufacture autologous lete-cel. Participants underwent lymphodepleting chemotherapy which generally consisted of fludarabine 30 mg/m^2/day on day -7 through day -4 and cyclophosphamide 900 milligrams per meter square per day (mg/m^2/day) on day -6 through day -4. followed by a single infusion of lete-cel on Day 1. The dose of lete-cel was within the range of 1×10^9 to 15×10^9 transduced T cells. |

Measured Values

| | Letetresgene Autoleucel (Lete-cel) |
|---|---|
| Overall Number of Participants Analyzed | 5 |
| Maximum Transgene Expansion (Cmax) | Geometric Mean (Geometric Coefficient of Variation)<br>Unit of measure: Copies per microgram DNA<br>119701.64 (68.267%) |

**13. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Time to Cmax (Tmax) |
| Measure Description | Tmax was defined as time to reach Cmax, determined directly from the persistence–time data. Blood samples were collected for PK analysis. |
| Time Frame | Up to approximately 14 days |

Analysis Population Description
Pharmacokinetic (PK) population

Reporting Groups

| | Description |
|---|---|
| Letetresgene Autoleucel (Lete-cel) | Eligible participants were leukapheresed to manufacture autologous lete-cel. Participants underwent lymphodepleting chemotherapy which generally consisted of fludarabine 30 mg/m^2/day on day -7 through day -4 and cyclophosphamide 900 milligrams per meter square per day (mg/m^2/day) on day -6 through day -4. followed by a single infusion of lete-cel on Day 1. The dose of lete-cel was within the range of 1×10^9 to 15×10^9 transduced T cells. |

Measured Values

| | Letetresgene Autoleucel (Lete-cel) |
|---|---|
| Overall Number of Participants Analyzed | 5 |
| Time to Cmax (Tmax) | Median (Full Range)<br>Unit of measure: Days<br>6.90 (1.9 to 13.6) |

**14. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Area Under the Time Curve From Zero to Time 28 Days (AUC[0-28]) |
| Measure Description | Area under the persistence–time curve from time zero to Day 28. Blood samples were collected for PK analysis. |
| Time Frame | Up to 28 days |

Analysis Population Description
Pharmacokinetic (PK) population

Reporting Groups

| | Description |
|---|---|
| Letetresgene Autoleucel (Lete-cel) | Eligible participants were leukapheresed to manufacture autologous lete-cel. Participants underwent lymphodepleting chemotherapy which generally consisted of fludarabine 30 mg/m^2/day on day -7 through day -4 and cyclophosphamide 900 milligrams per meter square per day (mg/m^2/day) on day -6 through day -4. followed by a single infusion of lete-cel on Day 1. The dose of lete-cel was within the range of 1×10^9 to 15×10^9 transduced T cells. |

Measured Values

| | Letetresgene Autoleucel (Lete-cel) |
|---|---|
| Overall Number of Participants Analyzed | 5 |
| Area Under the Time Curve From Zero to Time 28 Days (AUC[0-28]) | Geometric Mean (Geometric Coefficient of Variation)<br>Unit of measure: Copies per microgram gDNA times days<br>1911782.96 (53.709%) |

## Reported Adverse Events

| | |
|---|---|
| Time Frame | All cause mortality, non-serious adverse events (Non-SAEs) and serious adverse events (SAEs) were collected maximum up to approximately 36 months. Data collection is still ongoing and additional results will be provided after study completion. |
| Adverse Event Reporting Description | All-Cause mortality, Non-SAEs and SAEs were collected for intent-to-treat population that included all participants who started leukapheresis procedure. |

Reporting Groups

| | Description |
|---|---|
| Letetresgene Autoleucel (Lete-cel) | Eligible participants were leukapheresed to manufacture autologous lete-cel. Participants underwent lymphodepleting chemotherapy which generally consisted of fludarabine 30 mg/m^2/day on day -7 through day -4 and cyclophosphamide 900 milligrams per meter square per day (mg/m^2/day) on day -6 through day -4. followed by a single infusion of lete-cel on Day 1. The dose of lete-cel was within the range of 1×10^9 to 15×10^9 transduced T cells. |

**All-Cause Mortality**

| | Letetresgene Autoleucel (Lete-cel) | |
|---|---|---|
| | Affected/At Risk (%) | # Events |
| Total All-Cause Mortality | 1/7 (14.29%) | |

**Serious Adverse Events**

| | Letetresgene Autoleucel (Lete-cel) | |
|---|---|---|
| | Affected/At Risk (%) | # Events |
| Total | 4/7 (57.14%) | |
| Blood and lymphatic system disorders | | |
| Anaemia [A] † | 1/7 (14.29%) | 1 |
| Gastrointestinal disorders | | |
| Gastrointestinal haemorrhage [A] † | 1/7 (14.29%) | 1 |
| Nausea [A] † | 1/7 (14.29%) | 2 |
| Small intestinal obstruction [A] † | 1/7 (14.29%) | 1 |
| Vomiting [A] † | 1/7 (14.29%) | 2 |
| Immune system disorders | | |
| Cytokine release syndrome [A] † | 1/7 (14.29%) | 1 |
| Graft versus host disease [A] † | 1/7 (14.29%) | 1 |
| Injury, poisoning and procedural complications | | |
| Radiation pneumonitis [A] † | 1/7 (14.29%) | 1 |
| Investigations | | |
| Weight decreased [A] † | 1/7 (14.29%) | 1 |
| Metabolism and nutrition disorders | | |

| | Letetresgene Autoleucel (Lete-cel) | |
|---|---|---|
| | Affected/At Risk (%) | # Events |
| Dehydration [A] † | 1/7 (14.29%) | 2 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | |
| Tumour haemorrhage [A] † | 1/7 (14.29%) | 1 |
| Respiratory, thoracic and mediastinal disorders | | |
| Haemoptysis [A] † | 1/7 (14.29%) | 1 |

†Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 25.1

**Other Adverse Events**

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

| | Letetresgene Autoleucel (Lete-cel) | |
|---|---|---|
| | Affected/At Risk (%) | # Events |
| Total | 5/7 (71.43%) | |
| Blood and lymphatic system disorders | | |
| Anaemia [A] † | 2/7 (28.57%) | 2 |
| Eosinophilia [A] † | 1/7 (14.29%) | 1 |
| Neutropenia [A] † | 1/7 (14.29%) | 1 |
| Cardiac disorders | | |
| Sinus tachycardia [A] † | 1/7 (14.29%) | 2 |
| Gastrointestinal disorders | | |
| Abdominal discomfort [A] † | 1/7 (14.29%) | 1 |
| Abdominal pain [A] † | 2/7 (28.57%) | 2 |
| Constipation [A] † | 3/7 (42.86%) | 4 |
| Diarrhoea [A] † | 1/7 (14.29%) | 1 |
| Dysphagia [A] † | 1/7 (14.29%) | 2 |
| Frequent bowel movements [A] † | 1/7 (14.29%) | 1 |
| Gastrooesophageal reflux disease [A] † | 3/7 (42.86%) | 3 |
| Nausea [A] † | 3/7 (42.86%) | 6 |

| | Letetresgene Autoleucel (Lete-cel) | |
|---|---|---|
| | Affected/At Risk (%) | # Events |
| Vomiting [A] † | 1/7 (14.29%) | 5 |
| General disorders | | |
| Axillary pain [A] † | 1/7 (14.29%) | 1 |
| Catheter site phlebitis [A] † | 1/7 (14.29%) | 1 |
| Fatigue [A] † | 4/7 (57.14%) | 6 |
| Non-cardiac chest pain [A] † | 1/7 (14.29%) | 1 |
| Oedema peripheral [A] † | 2/7 (28.57%) | 2 |
| Pyrexia [A] † | 1/7 (14.29%) | 2 |
| Hepatobiliary disorders | | |
| Hyperbilirubinaemia [A] † | 1/7 (14.29%) | 1 |
| Immune system disorders | | |
| Cytokine release syndrome [A] † | 4/7 (57.14%) | 4 |
| Graft versus host disease [A] † | 1/7 (14.29%) | 2 |
| Infections and infestations | | |
| COVID-19 [A] † | 3/7 (42.86%) | 3 |
| Cytomegalovirus infection reactivation [A] † | 1/7 (14.29%) | 1 |
| Enterocolitis infectious [A] † | 1/7 (14.29%) | 1 |
| Pneumonia [A] † | 1/7 (14.29%) | 1 |
| Rhinitis [A] † | 1/7 (14.29%) | 2 |
| Injury, poisoning and procedural complications | | |
| Infusion related reaction [A] † | 1/7 (14.29%) | 1 |
| Investigations | | |
| Alanine aminotransferase increased [A] † | 3/7 (42.86%) | 3 |
| Aspartate aminotransferase increased [A] † | 2/7 (28.57%) | 2 |
| Blood alkaline phosphatase increased [A] † | 1/7 (14.29%) | 1 |
| Blood fibrinogen decreased [A] † | 2/7 (28.57%) | 3 |
| Blood lactate dehydrogenase increased [A] † | 1/7 (14.29%) | 1 |

| | Letetresgene Autoleucel (Lete-cel) | |
|---|---|---|
| | Affected/At Risk (%) | # Events |
| Lymphocyte count decreased [A] † | 1/7 (14.29%) | 1 |
| Neutrophil count decreased [A] † | 2/7 (28.57%) | 5 |
| Platelet count decreased [A] † | 2/7 (28.57%) | 2 |
| Weight decreased [A] † | 1/7 (14.29%) | 1 |
| White blood cell count decreased [A] † | 2/7 (28.57%) | 2 |
| Metabolism and nutrition disorders | | |
| Hypervolaemia [A] † | 1/7 (14.29%) | 1 |
| Hypoalbuminaemia [A] † | 1/7 (14.29%) | 1 |
| Hypocalcaemia [A] † | 1/7 (14.29%) | 1 |
| Hypokalaemia [A] † | 2/7 (28.57%) | 4 |
| Hyponatraemia [A] † | 1/7 (14.29%) | 1 |
| Hypophosphataemia [A] † | 1/7 (14.29%) | 1 |
| Musculoskeletal and connective tissue disorders | | |
| Arthralgia [A] † | 2/7 (28.57%) | 2 |
| Back pain [A] † | 1/7 (14.29%) | 1 |
| Bone pain [A] † | 1/7 (14.29%) | 1 |
| Myalgia [A] † | 1/7 (14.29%) | 1 |
| Nervous system disorders | | |
| Dysgeusia [A] † | 1/7 (14.29%) | 1 |
| Headache [A] † | 1/7 (14.29%) | 1 |
| Paraesthesia [A] † | 1/7 (14.29%) | 1 |
| Psychiatric disorders | | |
| Anxiety [A] † | 1/7 (14.29%) | 3 |
| Depression [A] † | 1/7 (14.29%) | 1 |
| Insomnia [A] † | 1/7 (14.29%) | 2 |
| Reproductive system and breast disorders | | |
| Menstruation irregular [A] † | 1/7 (14.29%) | 1 |

| | Letetresgene Autoleucel (Lete-cel) | |
|---|---|---|
| | Affected/At Risk (%) | # Events |
| Respiratory, thoracic and mediastinal disorders | | |
| Cough [A] † | 2/7 (28.57%) | 2 |
| Dysphonia [A] † | 1/7 (14.29%) | 1 |
| Dyspnoea [A] † | 3/7 (42.86%) | 5 |
| Productive cough [A] † | 1/7 (14.29%) | 1 |
| Pulmonary embolism [A] † | 1/7 (14.29%) | 1 |
| Rhinitis allergic [A] † | 1/7 (14.29%) | 1 |
| Sleep apnoea syndrome [A] † | 1/7 (14.29%) | 1 |
| Skin and subcutaneous tissue disorders | | |
| Alopecia [A] † | 1/7 (14.29%) | 1 |
| Dry skin [A] † | 1/7 (14.29%) | 1 |
| Onychomadesis [A] † | 1/7 (14.29%) | 1 |
| Pruritus [A] † | 1/7 (14.29%) | 1 |
| Rash maculo-papular [A] † | 2/7 (28.57%) | 2 |
| Vascular disorders | | |
| Hot flush [A] † | 1/7 (14.29%) | 1 |

†Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 25.1

## Limitations and Caveats

[Not specified]

## More Information

**Certain Agreements:**

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

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

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results

from all centers of a multi-center trial but requests that reports based on single site data not precede the primary publication of the entire clinical trial.

**Results Point of Contact:**

Name/Official Title: GSK Response Center
Organization: GlaxoSmithKline
Phone: 866-435-7343
Email: GSKClinicalSupportHD@gsk.com