# Clinical trial results:
# Phase 2/3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Posoleucel (ALVR105, Viralym-M) Compared to Placebo for the Prevention of AdV, BKV, CMV, EBV, HHV-6, and JCV Infection and/or Disease, in High-Risk Patients After Allogeneic Hematopoietic Cell Transplant

## Summary

| | |
|---|---|
| EudraCT number | 2021-005105-27 |
| Trial protocol | IT FR ES BE |
| Global end of trial date | 30 January 2024 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 05 May 2024 |
| First version publication date | 05 May 2024 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | P-105-202 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05305040 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | AlloVir, Inc |
| Sponsor organisation address | 1100 Winter Street, Waltham, United States, MA 02451 |
| Public contact | Clinical Trials Information Line, AlloVir, Inc., +1 833 409-2281, clinicaltrials@allovir.com |
| Scientific contact | Clinical Trials Information Line, AlloVir, Inc., +1 833 409-2281, clinicaltrials@allovir.com |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMEA-002908-PIP01-20 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 30 January 2024 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 30 January 2024 |
| Was the trial ended prematurely? | Yes |

Notes:

## General information about the trial

Main objective of the trial:

To compare the efficacy of posoleucel (ALVR105) to placebo by the number of clinically significant infections or episodes of end-organ disease per patient due to Adenovirus (AdV), BK virus (BKV), Cytomegalovirus (CMV), Epstein-Barr virus (EBV), Human herpes virus 6 (HHV-6), or JC virus (JCV) as determined by an independent, blinded Clinical Adjudication Committee (CAC) through Week 14.

Protection of trial subjects:

This study was performed in accordance with Good Clinical Practice, including the archiving of essential documents.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 24 March 2022 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Spain: 17 |
| Country: Number of subjects enrolled | Belgium: 23 |
| Country: Number of subjects enrolled | France: 44 |
| Country: Number of subjects enrolled | Italy: 27 |
| Country: Number of subjects enrolled | Australia: 6 |
| Country: Number of subjects enrolled | Korea, Democratic People's Republic of: 34 |
| Country: Number of subjects enrolled | Türkiye: 47 |
| Country: Number of subjects enrolled | United States: 233 |
| Country: Number of subjects enrolled | United Kingdom: 11 |
| Country: Number of subjects enrolled | Canada: 9 |
| Worldwide total number of subjects | 451 |
| EEA total number of subjects | 111 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |

| | |
|---|---|
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 4 |
| Children (2-11 years) | 45 |
| Adolescents (12-17 years) | 22 |
| Adults (18-64 years) | 271 |
| From 65 to 84 years | 109 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Participants at high risk for viral infection after allogeneic Hematopoietic Cell Transplant were enrolled in the Phase 3 portion of study P-105-202 between Mar 2022 and Jan 2024. The Phase 3 study was discontinued in Dec 2023 after futility analysis of the Primary Outcome Measure. No safety concerns were identified.

### Pre-assignment

Screening details:

A total of 451 participants were enrolled in this Phase 3 study. Due to the early termination of this study, 74 were not dosed. The 377 randomized participants that were dosed comprise the Safety Population and are presented in the participant flow.

### Pre-assignment period milestones

| | |
|---|---|
| Number of subjects started | 451 |
| Number of subjects completed | 377 |

### Pre-assignment subject non-completion reasons

| | |
|---|---|
| Reason: Number of subjects | Randomized but not dosed: 74 |

### Period 1

| | |
|---|---|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Data analyst |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Posoleucel (ALVR105) |

Arm description:

Participants received posoleucel administered as 2-4 mL intravenous (IV) infusion once every 14 days for 7 doses.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Posoleucel |
| Investigational medicinal product code | ALVR105 |
| Other name | Viralym-M |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

2×10^7 cells or 4 × 10^7cells administered as a 2-4 mL IV infusion once every 14 days for 7 doses.

| | |
|---|---|
| **Arm title** | Placebo |

Arm description:

Participants received placebo administered as 2-4 mL IV infusion once every 14 days for 7 doses.

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Placebo was administered as a 2-4 mL IV infusion once every 14 days for 7 doses.

| **Number of subjects in period 1[1]** | Posoleucel (ALVR105) | Placebo |
|---|---|---|
| Started | 188 | 189 |
| Completed | 100 | 101 |
| Not completed | 88 | 88 |
| Adverse event, serious fatal | 14 | 13 |
| Consent withdrawn by subject | 15 | 10 |
| Investigator's Decision | 1 | 1 |
| Adverse event, non-fatal | 3 | 3 |
| Study Closure | 34 | 46 |
| Not Specified | 13 | 10 |
| Graft versus host disease | 2 | - |
| Lost to follow-up | 2 | 1 |
| Primary Malignancy Relapse | 3 | 4 |
| COVID-19 Reasons | 1 | - |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Of the participants that were randomized, 74 were not dosed and are not included in the baseline population. The baseline period represents the safety population which included all participants who received at least one dose of posoleucel or placebo.

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Posoleucel (ALVR105) |
| Reporting group description: | |
| Participants received posoleucel administered as 2-4 mL intravenous (IV) infusion once every 14 days for 7 doses. | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Participants received placebo administered as 2-4 mL IV infusion once every 14 days for 7 doses. | |

| Reporting group values | Posoleucel (ALVR105) | Placebo | Total |
|---|---|---|---|
| Number of subjects | 188 | 189 | 377 |
| Age categorical<br>Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 0 |
| Newborns (0-27 days) | | | 0 |
| Infants and toddlers (28 days-23 months) | | | 0 |
| Children (2-11 years) | | | 0 |
| Adolescents (12-17 years) | | | 0 |
| Adults (18-64 years) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous<br>Units: years | | | |
| median | 55.0 | 53.0 | |
| full range (min-max) | 1 to 77 | 0 to 75 | - |
| Gender categorical<br>Units: Subjects | | | |
| Female | 78 | 66 | 144 |
| Male | 110 | 123 | 233 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic or Latino | 13 | 24 | 37 |
| Not Hispanic or Latino | 143 | 144 | 287 |
| Unknown or Not Reported | 32 | 21 | 53 |
| Race<br>Units: Subjects | | | |
| American Indian or Alaskan Native | 1 | 1 | 2 |
| Asian | 25 | 21 | 46 |
| Black or African American | 7 | 5 | 12 |
| Native Hawaiian or Other Pacific Islander | 1 | 1 | 2 |
| White | 118 | 131 | 249 |
| Other | 9 | 8 | 17 |
| Unknown | 27 | 22 | 49 |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Posoleucel (ALVR105) |
| Reporting group description: Participants received posoleucel administered as 2-4 mL intravenous (IV) infusion once every 14 days for 7 doses. | |
| Reporting group title | Placebo |
| Reporting group description: Participants received placebo administered as 2-4 mL IV infusion once every 14 days for 7 doses. | |

### Primary: Average Number of Clinically Significant Infections or Episodes of End-Organ Disease Through Week 14

| | |
|---|---|
| End point title | Average Number of Clinically Significant Infections or Episodes of End-Organ Disease Through Week 14 |
| End point description: The number of clinically significant infections or episodes of end-organ disease per participant due to AdV, BKV, CMV, EBV, HHV-6, or JCV.<br>Analysis Population Description: Includes modified Intent-to-Treat (mITT) Population comprised of all randomized participants who received study drug and completed through Week 14 visit. | |
| End point type | Primary |
| End point timeframe: Through Week 14 | |

| End point values | Posoleucel (ALVR105) | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 159 | 155 | | |
| Units: Infections/Episodes per participant | | | | |
| arithmetic mean (standard deviation) | 0.2 (± 0.44) | 0.2 (± 0.42) | | |

### Statistical analyses

| Statistical analysis title | ANCOVA Analysis |
|---|---|
| Comparison groups | Placebo v Posoleucel (ALVR105) |
| Number of subjects included in analysis | 314 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5603 [1] |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.01 |

| | |
|---|---|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.09 |
| upper limit | 0.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.049 |

Notes:

[1] - 1-sided p-value

## Secondary: Average Number of Clinically Significant Infections or Episodes of End-Organ Disease Through Week 26

| | |
|---|---|
| End point title | Average Number of Clinically Significant Infections or Episodes of End-Organ Disease Through Week 26 |

End point description:

The number of clinically significant infections or episodes of end-organ disease per participant due to AdV, BKV, CMV, EBV, HHV-6, or JCV.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Through Week 26

| End point values | Posoleucel (ALVR105) | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0[2] | 0[3] | | |
| Units: Infections/Episodes per participant | | | | |
| arithmetic mean (standard deviation) | () | () | | |

Notes:

[2] - Data not collected due to early termination of the study.

[3] - Data not collected due to early termination of the study.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Clinically Significant Infections or Episodes of End-Organ Disease Due to Each Virus

| | |
|---|---|
| End point title | Number of Participants With Clinically Significant Infections or Episodes of End-Organ Disease Due to Each Virus |

End point description:

The number of participants with clinically significant infections or episodes of end-organ disease due to each of the following viruses: AdV, BKV, CMV, EBV, HHV-6, or JCV.
Analysis Population Description: Includes mITT Population comprised of all randomized participants who received study drug and completed through Week 14 visit.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Through Week 14

| End point values | Posoleucel (ALVR105) | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 159 | 155 | | |
| Units: participants | | | | |
| AdV | 3 | 2 | | |
| BKV | 2 | 2 | | |
| CMV | 16 | 19 | | |
| EBV | 10 | 6 | | |
| HHV-6 | 0 | 0 | | |
| JCV | 0 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Day 1 through Week 26

Adverse event reporting additional description:

Adverse events are reported for the Safety Population which included all participants who received at least one dose of posoleucel or placebo. Non-serious AEs can be calculated by subtracting the number of events from the serious AE table from the corresponding events in the combined table.

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 25.1 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Posoleucel (ALVR105) |

Reporting group description:

Participants received posoleucel (2×10^7 cells [if <40 kg body weight at screening] or 4 × 10^7cells [if ≥40 kg body weight at screening]), administered as a 2-4 mL intravenous (IV) infusion once every 14 days for 7 doses.

| | |
|---|---|
| Reporting group title | Placebo |

Reporting group description:

Participants received placebo administered as a 2-4 mL IV infusion once every 14 days for 7 doses.

| Serious adverse events | Posoleucel (ALVR105) | Placebo | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 88 / 188 (46.81%) | 86 / 189 (45.50%) | |
| number of deaths (all causes) | 18 | 19 | |
| number of deaths resulting from adverse events | 18 | 19 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute lymphocytic leukaemia recurrent | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Acute myeloid leukaemia recurrent | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 188 (0.53%) | 6 / 189 (3.17%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Chronic lymphocytic leukaemia recurrent | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Leukaemia recurrent | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Myelofibrosis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-Hodgkin's lymphoma | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Post transplant lymphoproliferative disorder | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Precursor T-lymphoblastic lymphoma/leukaemia recurrent | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |

| | | | |
|---|---|---|---|
| Hypertensive crisis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemic shock | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chills | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disease progression | | | |
| subjects affected / exposed | 3 / 188 (1.60%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 1 | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Fever and rigors | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Positive cultures from indwelling CVAD | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 4 / 188 (2.13%) | 12 / 189 (6.35%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic inflammatory response syndrome | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Acute graft versus host disease | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Acute graft versus host disease in intestine | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 3 / 189 (1.59%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute graft versus host disease in liver | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute graft versus host disease in skin | | | |
| subjects affected / exposed | 4 / 188 (2.13%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 1 / 4 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune disorder | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic graft versus host disease | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic graft versus host disease in liver | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic graft versus host disease in skin | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft versus host disease | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Graft versus host disease in gastrointestinal tract | | | |
| subjects affected / exposed | 7 / 188 (3.72%) | 7 / 189 (3.70%) | |
| occurrences causally related to treatment / all | 1 / 7 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Graft versus host disease in liver | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft versus host disease in skin | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemophagocytic lymphohistiocytosis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 3 / 189 (1.59%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 4 / 188 (2.13%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Enterobacter test positive | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Epstein-Barr virus antigen positive | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epstein-Barr virus test positive | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes simplex test positive | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Human rhinovirus test positive | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza A virus test positive | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test abnormal | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test increased | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus test positive | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transplant failure | | | |
| subjects affected / exposed | 3 / 188 (1.60%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Aplasia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|---|---|---|
| Cardiac disorders | | | |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 3 / 189 (1.59%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Cardiac failure | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cardio-respiratory arrest with sepsis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Central nervous system lesion | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar haematoma | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |

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|---|---|---|---|
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Headache | | | |
| subjects affected / exposed | 3 / 188 (1.60%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status epilepticus | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient aphasia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytopenia | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile bone marrow aplasia | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 4 / 188 (2.13%) | 6 / 189 (3.17%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombotic microangiopathy | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Warm autoimmune haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strabismus | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |

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|---|---|---|---|
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 6 / 188 (3.19%) | 4 / 189 (2.12%) | |
| occurrences causally related to treatment / all | 1 / 6 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hospitalization for nausea and vomiting | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 3 / 189 (1.59%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Bile duct stone | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic necrosis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 4 / 188 (2.13%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis haemorrhagic | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Chondrocalcinosis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Adenoviral haemorrhagic cystitis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenovirus infection | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 3 / 189 (1.59%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenovirus reactivation | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anorectal infection | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspergillus infection | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 4 / 189 (2.12%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |

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|---|---|---|---|
| Bacterial sepsis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchopulmonary aspergillosis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COVID-19 | | | |
| subjects affected / exposed | 5 / 188 (2.66%) | 4 / 189 (2.12%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheter site infection | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridial sepsis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 3 / 188 (1.60%) | 4 / 189 (2.12%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cytomegalovirus infection reactivation | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 4 / 189 (2.12%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytomegalovirus viraemia | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related bacteraemia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterobacter bacteraemia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epstein-Barr viraemia | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epstein-Barr virus infection | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epstein-Barr virus infection reactivation | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 188 (1.06%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes simplex | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Human bocavirus infection | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Human herpesvirus 6 infection reactivation | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella sepsis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis aseptic | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Norovirus infection | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paronychia | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumococcal sepsis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 4 / 188 (2.13%) | 4 / 189 (2.12%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotavirus infection | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 5 / 188 (2.66%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Sepsis with fever and rigor | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis with multiple organ failure | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Sinusitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic candida | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxoplasmosis | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 2 / 189 (1.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheobronchitis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular device infection | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral haemorrhagic cystitis | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 188 (0.53%) | 0 / 189 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 188 (0.00%) | 1 / 189 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| **Non-serious adverse events** | Posoleucel (ALVR105) | Placebo | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 180 / 188 (95.74%) | 184 / 189 (97.35%) | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 16 / 188 (8.51%) | 7 / 189 (3.70%) | |
| occurrences (all) | 16 | 7 | |
| General disorders and administration | | | |

| | | | |
|---|---|---|---|
| site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 11 / 188 (5.85%) | 8 / 189 (4.23%) | |
| occurrences (all) | 11 | 8 | |
| Fatigue | | | |
| subjects affected / exposed | 22 / 188 (11.70%) | 17 / 189 (8.99%) | |
| occurrences (all) | 22 | 17 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 17 / 188 (9.04%) | 20 / 189 (10.58%) | |
| occurrences (all) | 17 | 20 | |
| Pyrexia | | | |
| subjects affected / exposed | 33 / 188 (17.55%) | 36 / 189 (19.05%) | |
| occurrences (all) | 33 | 36 | |
| Immune system disorders | | | |
| Acute graft versus host disease | | | |
| subjects affected / exposed | 11 / 188 (5.85%) | 7 / 189 (3.70%) | |
| occurrences (all) | 11 | 7 | |
| Acute graft versus host disease in skin | | | |
| subjects affected / exposed | 36 / 188 (19.15%) | 27 / 189 (14.29%) | |
| occurrences (all) | 36 | 27 | |
| Graft versus host disease in gastrointestinal tract | | | |
| subjects affected / exposed | 24 / 188 (12.77%) | 16 / 189 (8.47%) | |
| occurrences (all) | 24 | 16 | |
| Graft versus host disease in skin | | | |
| subjects affected / exposed | 15 / 188 (7.98%) | 15 / 189 (7.94%) | |
| occurrences (all) | 15 | 15 | |
| Hypogammaglobulinaemia | | | |
| subjects affected / exposed | 6 / 188 (3.19%) | 12 / 189 (6.35%) | |
| occurrences (all) | 6 | 12 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 30 / 188 (15.96%) | 20 / 189 (10.58%) | |
| occurrences (all) | 30 | 20 | |
| Dyspnoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 14 / 188 (7.45%) | 22 / 189 (11.64%) | |
| occurrences (all) | 14 | 22 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 9 / 188 (4.79%) | 14 / 189 (7.41%) | |
| occurrences (all) | 9 | 14 | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 10 / 188 (5.32%) | 5 / 189 (2.65%) | |
| occurrences (all) | 10 | 5 | |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 11 / 188 (5.85%) | 7 / 189 (3.70%) | |
| occurrences (all) | 11 | 7 | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 14 / 188 (7.45%) | 16 / 189 (8.47%) | |
| occurrences (all) | 14 | 16 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 9 / 188 (4.79%) | 11 / 189 (5.82%) | |
| occurrences (all) | 9 | 11 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 30 / 188 (15.96%) | 22 / 189 (11.64%) | |
| occurrences (all) | 30 | 22 | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 10 / 188 (5.32%) | 8 / 189 (4.23%) | |
| occurrences (all) | 10 | 8 | |
| Platelet count decreased | | | |
| subjects affected / exposed | 22 / 188 (11.70%) | 15 / 189 (7.94%) | |
| occurrences (all) | 22 | 15 | |
| White blood cell count decreased | | | |
| subjects affected / exposed | 12 / 188 (6.38%) | 8 / 189 (4.23%) | |
| occurrences (all) | 12 | 8 | |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 8 / 188 (4.26%) | 10 / 189 (5.29%) | |
| occurrences (all) | 8 | 10 | |
| Nervous system disorders | | | |

| | | | |
|---|---|---|---|
| Dizziness | | | |
| subjects affected / exposed | 10 / 188 (5.32%) | 12 / 189 (6.35%) | |
| occurrences (all) | 10 | 12 | |
| Headache | | | |
| subjects affected / exposed | 22 / 188 (11.70%) | 22 / 189 (11.64%) | |
| occurrences (all) | 22 | 22 | |
| Tremor | | | |
| subjects affected / exposed | 14 / 188 (7.45%) | 11 / 189 (5.82%) | |
| occurrences (all) | 14 | 11 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 26 / 188 (13.83%) | 24 / 189 (12.70%) | |
| occurrences (all) | 26 | 24 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 10 / 188 (5.32%) | 9 / 189 (4.76%) | |
| occurrences (all) | 10 | 9 | |
| Neutropenia | | | |
| subjects affected / exposed | 12 / 188 (6.38%) | 7 / 189 (3.70%) | |
| occurrences (all) | 12 | 7 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 6 / 188 (3.19%) | 14 / 189 (7.41%) | |
| occurrences (all) | 6 | 14 | |
| Eye disorders | | | |
| Dry eye | | | |
| subjects affected / exposed | 5 / 188 (2.66%) | 13 / 189 (6.88%) | |
| occurrences (all) | 5 | 13 | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 25 / 188 (13.30%) | 16 / 189 (8.47%) | |
| occurrences (all) | 25 | 16 | |
| Constipation | | | |
| subjects affected / exposed | 12 / 188 (6.38%) | 10 / 189 (5.29%) | |
| occurrences (all) | 12 | 10 | |
| Diarrhoea | | | |
| subjects affected / exposed | 46 / 188 (24.47%) | 37 / 189 (19.58%) | |
| occurrences (all) | 46 | 37 | |
| Nausea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 36 / 188 (19.15%) | 22 / 189 (11.64%) | |
| occurrences (all) | 36 | 22 | |
| Vomiting | | | |
| subjects affected / exposed | 29 / 188 (15.43%) | 21 / 189 (11.11%) | |
| occurrences (all) | 29 | 21 | |
| Skin and subcutaneous tissue disorders | | | |
| Dry skin | | | |
| subjects affected / exposed | 10 / 188 (5.32%) | 9 / 189 (4.76%) | |
| occurrences (all) | 10 | 9 | |
| Erythema | | | |
| subjects affected / exposed | 11 / 188 (5.85%) | 9 / 189 (4.76%) | |
| occurrences (all) | 11 | 9 | |
| Pruritus | | | |
| subjects affected / exposed | 17 / 188 (9.04%) | 14 / 189 (7.41%) | |
| occurrences (all) | 17 | 14 | |
| Rash | | | |
| subjects affected / exposed | 16 / 188 (8.51%) | 14 / 189 (7.41%) | |
| occurrences (all) | 16 | 14 | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 17 / 188 (9.04%) | 12 / 189 (6.35%) | |
| occurrences (all) | 17 | 12 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 14 / 188 (7.45%) | 6 / 189 (3.17%) | |
| occurrences (all) | 14 | 6 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 8 / 188 (4.26%) | 11 / 189 (5.82%) | |
| occurrences (all) | 8 | 11 | |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 13 / 188 (6.91%) | 11 / 189 (5.82%) | |
| occurrences (all) | 13 | 11 | |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 13 / 188 (6.91%) | 18 / 189 (9.52%) | |
| occurrences (all) | 13 | 18 | |

| | | | |
|---|---|---|---|
| Cytomegalovirus infection reactivation | | | |
| subjects affected / exposed | 10 / 188 (5.32%) | 11 / 189 (5.82%) | |
| occurrences (all) | 10 | 11 | |
| Pneumonia | | | |
| subjects affected / exposed | 11 / 188 (5.85%) | 14 / 189 (7.41%) | |
| occurrences (all) | 11 | 14 | |
| Sepsis | | | |
| subjects affected / exposed | 10 / 188 (5.32%) | 3 / 189 (1.59%) | |
| occurrences (all) | 10 | 3 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 5 / 188 (2.66%) | 14 / 189 (7.41%) | |
| occurrences (all) | 5 | 14 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 18 / 188 (9.57%) | 22 / 189 (11.64%) | |
| occurrences (all) | 18 | 22 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 18 / 188 (9.57%) | 11 / 189 (5.82%) | |
| occurrences (all) | 18 | 11 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 23 / 188 (12.23%) | 12 / 189 (6.35%) | |
| occurrences (all) | 23 | 12 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 19 / 188 (10.11%) | 13 / 189 (6.88%) | |
| occurrences (all) | 19 | 13 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 10 / 188 (5.32%) | 7 / 189 (3.70%) | |
| occurrences (all) | 10 | 7 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 27 October 2020 | Major revisions include:<br>• Clarification on cell line change language<br>• Clarification on retreatment option<br>• Update to blood volume table<br>• Update to Open Label Cohort Inclusion criteria<br>• Clarification to unblinding section direction |
| 07 April 2021 | Major revisions include:<br>• Extended the window for dosing post-HCT<br>• Increased cap on percentage of patients receiving letermovir prophylaxis<br>• Changes to inclusion/exclusion criteria<br>• Assessment of viremia prior to randomization<br>• Reduction in plasma samples collected in pediatric patients < 12 years of age<br>• Updates to Schedule of Activities<br>• Updated language regarding adverse events assessments<br>• Treatment of Overdose<br>• Updated Concomitant Therapy and Excluded Medications Sections<br>• Definitions of clinical viremia, disease, and resolution<br>• Infection Assessments<br>• Updated Statistical Analysis Section<br>• Updated Laboratory Tests<br>• Updated Cytokine Release Syndrome Information<br>• Changed references to the study drug from Viralym-M to posoleucel to conform to other company protocols. |
| 28 July 2021 | Major revisions include:<br>• Randomized patients are now in one cohort, the Phase 3 study cohort. The open label cohort remains the same. Cohorts A and B were removed.<br>• The study schema was updated to identify the Phase 3 study cohort and to be clearer on the timing of the Open Label cohort. Cohorts A and B were removed.<br>• The inclusion criterion indicates that patients should have no known or suspected clinically significant disease from any of the 6 viruses. Inclusion criteria for viremia levels for Cohorts A and B were removed.<br>• Exclusion criterion #2 regarding having evidence for more than 3 viruses was removed.<br>• Removed optional pre-screening period to assess viral load because it is no longer necessary since patients are not assigned to cohort based on viral load.<br>• A targeted percentage of patients not receiving letermovir is described. |
| 19 October 2021 | Major revisions include:<br>• to add stratification factors<br>• revise power and sample size<br>• revise endpoints<br>• remove visits and laboratories at odd numbered weeks for patients <12 years of age to reduce patient burden. |
| 11 January 2023 | Major revisions include:<br>• ALVR105 was changed to posoleucel throughout<br>• Clarifications made to language throughout protocol |
| 01 May 2023 | Major revisions include:<br>• changes made to inclusion/exclusion criteria to capture the highest risk patients without compromising safety<br>• removed requirement for engraftment for randomization.<br>• engraftment now required prior to dosing with no change to criterion for confirming engraftment. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The Phase 3 study was discontinued in Dec 2023 after futility analysis of the Primary Outcome Measure. No safety concerns were identified. The Phase 2 portion of study P-105-202 was not carried out within the EU.

Notes: