Clinical trial results:
A Phase 1/2 Multicenter Study Evaluating the Safety and Efficacy of KTE-C19 in Adults with Refractory Aggressive Non-Hodgkin Lymphoma

Summary

EudraCT number	2015-005007-86
Trial protocol	NL DE FR
Global end of trial date	27 July 2023

Results information

Result version number	v1 (current)
This version publication date	23 June 2024
First version publication date	23 June 2024

Trial information

Trial identification

Sponsor protocol code	KTE-C19-101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02348216
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com
Scientific contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 July 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 July 2023
Global end of trial reached?	Yes
Global end of trial date	27 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was separated into 3 distinct phases designated as the Phase 1 study, Phase 2 pivotal study (Cohort 1 and Cohort 2), and Phase 2 safety management study (Cohort 3 and Cohort 4, Cohort 5 and Cohort 6).
The primary objectives of this study were:
- Phase 1 Study: Evaluate the safety of axicabtagene ciloleucel regimens
- Phase 2 Pivotal Study; Evaluate the efficacy of axicabtagene ciloleucel
- Phase 2 Safety Management Study: Assess the impact of prophylactic regimens or earlier interventions on the rate and severity of cytokine release syndrome (CRS) and neurologic toxicities

Subjects who received an infusion of KTE-C19 completed the remainder of the 15 year follow-up assessments in a separate long-term follow-up study, KT-US-982-5968.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements. This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 April 2015
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	Canada: 25
Country: Number of subjects enrolled	France: 32
Country: Number of subjects enrolled	Germany: 24
Country: Number of subjects enrolled	Israel: 6
Country: Number of subjects enrolled	Netherlands: 42
Country: Number of subjects enrolled	United States: 178
Worldwide total number of subjects	307
EEA total number of subjects	98

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)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	215
From 65 to 84 years	91
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Canada, France, Germany, Israel, Netherlands, and the United States.

Pre-assignment

Screening details:

390 participants were screened. Participants who initially responded and subsequently relapsed, became eligible for second course of conditioning chemotherapy and axicabtagene ciloleucel. Participants received the same axicabtagene ciloleucel regimen as the original target dose.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot

Arm description:

Participants with diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL), or transformed follicular lymphoma (TFL) received conditioning chemotherapy (fludarabine 30 mg/m^2 intravenously [IV] over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel chimeric antigen receptor (CAR) transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of body weight (BW) on Day 0.

Arm type	Experimental
Investigational medicinal product name	Axicabtagene Ciloleucel
Investigational medicinal product code	
Other name	Yescarta®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single infusion of chimeric antigen receptor (CAR)-transduced autologous T cells administered intravenously at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Arm title	Phase 2 (Pivotal Study): Cohort 1

Arm description:

Participants with refractory DLBCL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.

Arm type	Experimental
Investigational medicinal product name	Axicabtagene Ciloleucel
Investigational medicinal product code	
Other name	Yescarta®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single infusion of chimeric antigen receptor (CAR)-transduced autologous T cells administered intravenously at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Arm title	Phase 2 (Pivotal Study): Cohort 2

Arm description:

Participants with refractory PMBCL or TFL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.

Arm type	Experimental
Investigational medicinal product name	Axicabtagene Ciloleucel
Investigational medicinal product code	
Other name	Yescarta®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single infusion of chimeric antigen receptor (CAR)-transduced autologous T cells administered intravenously at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg.

Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion

Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Arm title	Phase 2 (Safety Management Study): Cohort 3

Arm description:

Participants with relapsed or refractory transplant ineligible DLBCL, PMBCL, or TFL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0. Participants also received a prophylactic regimen of levetiracetam (750 mg orally or IV twice daily (BID) starting on Day 0) and tocilizumab (8 mg/kg IV over 1 hour (not to exceed 800 mg)) on Day 2).

Arm type	Experimental
Investigational medicinal product name	Axicabtagene Ciloleucel
Investigational medicinal product code	
Other name	Yescarta®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single infusion of chimeric antigen receptor (CAR)-transduced autologous T cells administered intravenously at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg.

Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Tocilizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Levetiracetam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Arm title	Phase 2 (Safety Management Study): Cohort 4

Arm description:

Participants with r/r DLBCL,PMBCL,TFL,or high-grade B-cell lymphoma(HGBCL)after 2 systemic lines of therapy will receive optional bridging therapy(dexamethasone 20mg to 40mg,eitherorally or IV daily for 1 to 4 days or 1g/m^2 of high-dose methylprednisolone(HDMP)for 3 days with rituximab at 375mg/m^2 weekly for 3 weeks or bendamustine 90 mg/m^2 on Days 1 and 2 and rituximab 375mg/m^2 on Day 1),conditioning chemotherapy(fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3;followed by single infusion of axicabtagene ciloleucel CAR transduced autologous T cells IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW. Participants will receive a prophylactic regimen of levetiracetam(750 mg orally or IV twice daily(BID)starting on Day 0).Participants received tocilizumab(initiated on persistent Grade 1 cytokine release syndrome(CRS)for over 24 hours)and dexamethasone(persistent Grade 1 CRS for over 72 hours and at onset of Grade 1 neurologic toxicity).

Arm type	Experimental
Investigational medicinal product name	Levetiracetam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Axicabtagene Ciloleucel
Investigational medicinal product code	
Other name	Yescarta®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single infusion of chimeric antigen receptor (CAR)-transduced autologous T cells administered intravenously at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details: Administered according to package insert	
Investigational medicinal product name	High-dose methylprednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered according to package insert	
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered according to package insert	
Investigational medicinal product name	Tocilizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered according to package insert	
Arm title	Phase 2 (Safety Management Study): Cohort 5

Arm description:

Participants with r/r DLBCL, PMBCL ,TFL, or HGBCL after 2 systemic lines of therapy received debulking therapy (R-CHOP:rituximab 375mg/m^2 D1,doxorubicin 50mg/m^2 D1,prednisone 100mg D1 to D5,cyclophosphamide 750mg/m^2 D1,vincristine 1.4 mg/m^2 D1 or R-ICE:rituximab 375mg/ m^2 D1,ifosfamide 5g/m^2 24h-CI D2,carboplatin AUC5 D2 maximum dose 800mg,etoposide 100 mg/m^2/day D1 to D3 or R-GEMOX:rituximab 375mg/m^2 D1,gemcitabine 1000mg/m^2 D2,oxaliplatin 100mg/m^2 D2 or R-GDP:rituximab 375mg/m^2 D1 or D8,gemcitabine 1g/m^2 D1 & D8,dexamethasone 40mg D1 to D4,cisplatin 75mg/m^2 D1(or carboplatin AUC5 D1) or radiotherapy:20 to 30 Gy), conditioning chemotherapy (fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3; followed by single infusion of axicabtagene ciloleucel at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0. Participants also received a prophylactic regimen of levetiracetam (750 mg orally or IV BID starting on D0).D=Day.

Arm type	Experimental
Investigational medicinal product name	Axicabtagene Ciloleucel
Investigational medicinal product code	
Other name	Yescarta®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single infusion of chimeric antigen receptor (CAR)-transduced autologous T cells administered intravenously at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg.

Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
Administered according to package insert

Investigational medicinal product name	Levetiracetam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
Administered according to package insert

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
Administered according to package insert

Investigational medicinal product name	Doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
Administered according to package insert

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Administered according to package insert

Investigational medicinal product name	Vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
Administered according to package insert

Investigational medicinal product name	Ifosfamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
Administered according to package insert

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Etoposide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Oxaliplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Arm title	Phase 2 (Safety Management Study): Cohort 6

Arm description:

Participants with r/r DLBCL,PMBCL,TFL orHGBCL after 2 systemic lines of therapy may receive bridging therapy(dexamethasone 20mg to 40mg,orally or IV daily for 1 to 4 days or 1g/m^2 HDMP for 3 days with rituximab at 375mg/m^2 weekly for 3 weeks or bendamustine 90 mg/m^2 on Days 1 and 2 and rituximab 375mg/m^2 on Day 1),conditioning chemotherapy(fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3; followed by single infusion of axicabtagene ciloleucel CAR transduced autologous T cells IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.Participants will also receive a prophylactic regimen of levetiracetam 750 mg orally or IV twice daily(BID)starting on Day 0)and corticosteroids(dexamethasone, 10 mg once daily on Days 0, 1, and 2).Participants received tocilizumab(initiated on persistent Grade 1 CRS for over 24 hours)and dexamethasone(persistent Grade 1 CRS for over 72 hours and at onset of Grade 1 neurologic toxicity).

Arm type	Experimental
Investigational medicinal product name	Levetiracetam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Axicabtagene Ciloleucel
Investigational medicinal product code	
Other name	Yescarta®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single infusion of chimeric antigen receptor (CAR)-transduced autologous T cells administered intravenously at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg.

Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Methylprednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	High-dose methylprednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Investigational medicinal product name	Tocilizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered according to package insert

Number of subjects in period 1	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2
Started	8	81	30
Completed	0	0	0
Not completed	8	81	30
Enrolled but did not take axicabtagene ciloleucel	1	4	6
Death	5	53	11
Full consent withdrawal	-	-	-
Reason not specified	2	19	11
Lost to follow-up	-	5	2

Number of subjects in period 1	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5
Started	42	46	58
Completed	0	0	0
Not completed	42	46	58
Enrolled but did not take axicabtagene ciloleucel	4	5	8
Death	20	16	32
Full consent withdrawal	1	3	-
Reason not specified	17	21	17
Lost to follow-up	-	1	1

Number of subjects in period 1	Phase 2 (Safety Management Study): Cohort 6
Started	42
Completed	0
Not completed	42

Enrolled but did not take axicabtagene ciloleucel	2
Death	17
Full consent withdrawal	3
Reason not specified	19
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL), or transformed follicular lymphoma (TFL) received conditioning chemotherapy (fludarabine 30 mg/m^2 intravenously [IV] over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel chimeric antigen receptor (CAR) transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of body weight (BW) on Day 0.

Reporting group title	Phase 2 (Pivotal Study): Cohort 1

Reporting group description:

Participants with refractory DLBCL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.

Reporting group title	Phase 2 (Pivotal Study): Cohort 2

Reporting group description:

Participants with refractory PMBCL or TFL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.

Reporting group title	Phase 2 (Safety Management Study): Cohort 3

Reporting group description:

Participants with relapsed or refractory transplant ineligible DLBCL, PMBCL, or TFL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0. Participants also received a prophylactic regimen of levetiracetam (750 mg orally or IV twice daily (BID) starting on Day 0) and tocilizumab (8 mg/kg IV over 1 hour (not to exceed 800 mg)) on Day 2).

Reporting group title	Phase 2 (Safety Management Study): Cohort 4

Reporting group description:

Participants with r/r DLBCL,PMBCL,TFL,or high-grade B-cell lymphoma(HGBCL)after 2 systemic lines of therapy will receive optional bridging therapy(dexamethasone 20mg to 40mg,eitherorally or IV daily for 1 to 4 days or 1g/m^2 of high-dose methylprednisolone(HDMP)for 3 days with rituximab at 375mg/m^2 weekly for 3 weeks or bendamustine 90 mg/m^2 on Days 1 and 2 and rituximab 375mg/m^2 on Day 1),conditioning chemotherapy(fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3;followed by single infusion of axicabtagene ciloleucel CAR transduced autologous T cells IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW. Participants will receive a prophylactic regimen of levetiracetam(750 mg orally or IV twice daily(BID)starting on Day 0).Participants received tocilizumab(initiated on persistent Grade 1 cytokine release syndrome(CRS)for over 24 hours)and dexamethasone(persistent Grade 1 CRS for over 72 hours and at onset of Grade 1 neurologic toxicity).

Reporting group title	Phase 2 (Safety Management Study): Cohort 5

Reporting group description:

Participants with r/r DLBCL, PMBCL ,TFL, or HGBCL after 2 systemic lines of therapy received debulking therapy (R-CHOP:rituximab 375mg/m^2 D1,doxorubicin 50mg/m^2 D1,prednisone 100mg D1 to D5,cyclophosphamide 750mg/m^2 D1,vincristine 1.4 mg/m^2 D1 or R-ICE:rituximab 375mg/ m^2 D1,ifosfamide 5g/m^2 24h-CI D2,carboplatin AUC5 D2 maximum dose 800mg,etoposide 100 mg/m^2/day D1 to D3 or R-GEMOX:rituximab 375mg/m^2 D1,gemcitabine 1000mg/m^2 D2,oxaliplatin 100mg/m^2 D2 or R-GDP:rituximab 375mg/m^2 D1 or D8,gemcitabine 1g/m^2 D1 & D8,dexamethasone 40mg D1 to D4,cisplatin 75mg/m^2 D1(or carboplatin AUC5 D1) or radiotherapy:20 to 30 Gy), conditioning chemotherapy (fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3; followed by single infusion of axicabtagene ciloleucel at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0. Participants also received a prophylactic regimen of levetiracetam (750 mg orally or IV BID starting on D0).D=Day.

Reporting group title	Phase 2 (Safety Management Study): Cohort 6

Reporting group description:

Participants with r/r DLBCL,PMBCL,TFL orHGBCL after 2 systemic lines of therapy may receive bridging therapy(dexamethasone 20mg to 40mg,orally or IV daily for 1 to 4 days or 1g/m^2 HDMP for 3 days with rituximab at 375mg/m^2 weekly for 3 weeks or bendamustine 90 mg/m^2 on Days 1 and 2 and rituximab 375mg/m^2 on Day 1),conditioning chemotherapy(fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3; followed by single infusion of axicabtagene ciloleucel CAR transduced autologous T cells IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.Participants will also receive a prophylactic regimen of levetiracetam 750 mg orally or IV twice daily(BID)starting on Day 0)and corticosteroids(dexamethasone, 10 mg once daily on Days 0, 1, and 2).Participants received tocilizumab(initiated on persistent Grade 1 CRS for over 24 hours)and dexamethasone(persistent Grade 1 CRS for over 72 hours and at onset of Grade 1 neurologic toxicity).

Reporting group values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2
Number of subjects	8	81	30
Age categorical Units: Subjects			
18 – 64 Years	5	64	21
65 – 84 Years	3	17	9
85 Years and Over	0	0	0
Gender categorical Units: Subjects			
Female	2	27	7
Male	6	54	23
Race Units: Subjects			
White	6	71	23
Other or More Than One Race	1	6	3
Black or African American	1	3	1
Asian	0	1	3
Ethnicity Units: Subjects			
Hispanic or Latino	1	18	2
Not Hispanic or Latino	7	63	28
Unknown or Not Reported	0	0	0

Reporting group values	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5
Number of subjects	42	46	58
Age categorical Units: Subjects			
18 – 64 Years	33	32	39
65 – 84 Years	9	14	19
85 Years and Over	0	0	0
Gender categorical Units: Subjects			
Female	18	13	15
Male	24	33	43
Race Units: Subjects			
White	34	37	39

Other or More Than One Race	3	9	12
Black or African American	4	0	2
Asian	1	0	5
Ethnicity Units: Subjects			
Hispanic or Latino	6	0	1
Not Hispanic or Latino	36	45	57
Unknown or Not Reported	0	1	0

Reporting group values	Phase 2 (Safety Management Study): Cohort 6	Total	
Number of subjects	42	307	
Age categorical Units: Subjects			
18 – 64 Years	21	215	
65 – 84 Years	20	91	
85 Years and Over	1	1	
Gender categorical Units: Subjects			
Female	18	100	
Male	24	207	
Race Units: Subjects			
White	36	246	
Other or More Than One Race	5	39	
Black or African American	1	12	
Asian	0	10	
Ethnicity Units: Subjects			
Hispanic or Latino	3	31	
Not Hispanic or Latino	39	275	
Unknown or Not Reported	0	1	

End points

End points reporting groups

Reporting group title	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL), or transformed follicular lymphoma (TFL) received conditioning chemotherapy (fludarabine 30 mg/m^2 intravenously [IV] over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel chimeric antigen receptor (CAR) transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of body weight (BW) on Day 0.

Reporting group title	Phase 2 (Pivotal Study): Cohort 1

Reporting group description:

Participants with refractory DLBCL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.

Reporting group title	Phase 2 (Pivotal Study): Cohort 2

Reporting group description:

Participants with refractory PMBCL or TFL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.

Reporting group title	Phase 2 (Safety Management Study): Cohort 3

Reporting group description:

Participants with relapsed or refractory transplant ineligible DLBCL, PMBCL, or TFL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0. Participants also received a prophylactic regimen of levetiracetam (750 mg orally or IV twice daily (BID) starting on Day 0) and tocilizumab (8 mg/kg IV over 1 hour (not to exceed 800 mg)) on Day 2).

Reporting group title	Phase 2 (Safety Management Study): Cohort 4

Reporting group description:

Participants with r/r DLBCL,PMBCL,TFL,or high-grade B-cell lymphoma(HGBCL)after 2 systemic lines of therapy will receive optional bridging therapy(dexamethasone 20mg to 40mg,eitherorally or IV daily for 1 to 4 days or 1g/m^2 of high-dose methylprednisolone(HDMP)for 3 days with rituximab at 375mg/m^2 weekly for 3 weeks or bendamustine 90 mg/m^2 on Days 1 and 2 and rituximab 375mg/m^2 on Day 1),conditioning chemotherapy(fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3;followed by single infusion of axicabtagene ciloleucel CAR transduced autologous T cells IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW. Participants will receive a prophylactic regimen of levetiracetam(750 mg orally or IV twice daily(BID)starting on Day 0).Participants received tocilizumab(initiated on persistent Grade 1 cytokine release syndrome(CRS)for over 24 hours)and dexamethasone(persistent Grade 1 CRS for over 72 hours and at onset of Grade 1 neurologic toxicity).

Reporting group title	Phase 2 (Safety Management Study): Cohort 5

Reporting group description:

Participants with r/r DLBCL, PMBCL ,TFL, or HGBCL after 2 systemic lines of therapy received debulking therapy (R-CHOP:rituximab 375mg/m^2 D1,doxorubicin 50mg/m^2 D1,prednisone 100mg D1 to D5,cyclophosphamide 750mg/m^2 D1,vincristine 1.4 mg/m^2 D1 or R-ICE:rituximab 375mg/ m^2 D1,ifosfamide 5g/m^2 24h-CI D2,carboplatin AUC5 D2 maximum dose 800mg,etoposide 100 mg/m^2/day D1 to D3 or R-GEMOX:rituximab 375mg/m^2 D1,gemcitabine 1000mg/m^2 D2,oxaliplatin 100mg/m^2 D2 or R-GDP:rituximab 375mg/m^2 D1 or D8,gemcitabine 1g/m^2 D1 & D8,dexamethasone 40mg D1 to D4,cisplatin 75mg/m^2 D1(or carboplatin AUC5 D1) or radiotherapy:20 to 30 Gy), conditioning chemotherapy (fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3; followed by single infusion of axicabtagene ciloleucel at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0. Participants also received a prophylactic regimen of levetiracetam (750 mg orally or IV BID starting on D0).D=Day.

Reporting group title	Phase 2 (Safety Management Study): Cohort 6

Reporting group description:

Participants with r/r DLBCL,PMBCL,TFL orHGBCL after 2 systemic lines of therapy may receive bridging therapy(dexamethasone 20mg to 40mg,orally or IV daily for 1 to 4 days or 1g/m^2 HDMP for 3 days with rituximab at 375mg/m^2 weekly for 3 weeks or bendamustine 90 mg/m^2 on Days 1 and 2 and rituximab 375mg/m^2 on Day 1),conditioning chemotherapy(fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3; followed by single infusion of axicabtagene ciloleucel CAR transduced autologous T cells IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.Participants will also receive a prophylactic regimen of levetiracetam 750 mg orally or IV twice daily(BID)starting on Day 0)and corticosteroids(dexamethasone, 10 mg once daily on Days 0, 1, and 2).Participants received tocilizumab(initiated on persistent Grade 1 CRS for over 24 hours)and dexamethasone(persistent Grade 1 CRS for over 72 hours and at onset of Grade 1 neurologic toxicity).

Primary: Phase 2 Pivotal Study (Cohorts 1 and 2): Overall Response Rate (ORR) as Assessed by Investigator per Revised International Working Group (IWG) Response Criteria for Malignant Lymphoma

End point title	Phase 2 Pivotal Study (Cohorts 1 and 2): Overall Response Rate (ORR) as Assessed by Investigator per Revised International Working Group (IWG) Response Criteria for Malignant Lymphoma[1][2]

End point description:

ORR was defined either a complete response (CR) or partial response (PR),assessed by the study investigators by revised IWG Response Criteria for Malignant Lymphoma (Cheson et al, 2007).CR: complete disappearance of all detectable clinical evidence of disease and symptoms; all lymph nodes and nodal masses must have regressed to normal size; spleen and/or liver must be normal size,not be palpable,and no nodules;bone marrow aspirate and biopsy must show no evidence of disease.PR: a ≥ 50% decrease in sum of product of diameters (SPD) of up to 6 of the largest dominant nodes or nodal masses;no increase in size of nodes, liver or spleen and no new sites; multiple splenic and hepatic nodules regress by ≥ 50% in the SPD; > 50% decrease in the greatest transverse diameter for single nodules. 95% confidence interval (CI) was calculated by Clopper-Pearson method. The Modified Intent-to-Treat (mITT) analysis set included all participants treated with at least 1.0 x 10^6 anti-CD19 CAR T cells/kg.

End point type	Primary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to last follow-up visit (maximum duration: 7.7 years)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 2 (Cohorts 1 and 2) of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	24		
Units: percentage of participants				
number (confidence interval 95%)	83 (73 to 91)	83 (63 to 95)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1 Study: Number of Participants Experiencing Adverse Events (AEs) defined as Dose Limiting Toxicities (DLTs)

End point title	Phase 1 Study: Number of Participants Experiencing Adverse Events (AEs) defined as Dose Limiting Toxicities (DLTs)[3][4]

End point description:

DLT was defined as axicabtagene ciloleucel-related events with onset within first 30 days following infusion:Grade (GR) 4 neutropenia lasting > 21 days and GR 4 thrombocytopenia lasting > 35 days from day of cell transfer;Any axicabtagene ciloleucel-related AE requiring intubation;
All other GR 3 toxicities lasting > 3 days and all GR 4 toxicities, exception conditions: aphasia/dysphasia or confusion/cognitive disturbance which resolved to GR ≤ 1 ; fever GR 3; myelosuppression, decreased hemoglobin, neutropenia and thrombocytopenia ; immediate hypersensitivity reactions occurring within 2 hours of cell infusion that were reversible to a ≤ GR 2 within 24 hours of cell administration; hypogammaglobulinemia GR 3 or 4. DLT-Evaluable Analysis Set included participants treated in Phase 1 dosing cohort who received the target dose and were followed for at least 30 days after the axicabtagene ciloleucel infusion.

End point type	Primary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to 30 days

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 1 of the study, all the arms in the baseline period were not included.

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: participants	1			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2 Safety Management Study (Cohort 3): Percentage of Participants With Treatment-Emergent Cytokine Release Syndrome (CRS) and Neurologic Toxicities by Severity Grades

End point title	Phase 2 Safety Management Study (Cohort 3): Percentage of Participants With Treatment-Emergent Cytokine Release Syndrome (CRS) and Neurologic Toxicities by Severity Grades[5][6]

End point description:

TEAE was defined as any AE with onset on or after the start of treatment. CRS events were graded by Lee et al 2014. Grade 1:No life threatening symptoms and require symptomatic treatment only;Grade2:Symptoms require and respond to moderate intervention; Grade 3: Symptoms require and respond to aggressive intervention; Grade 4: Life-threatening symptoms, requirements for ventilator support or continuous venovenous hemodialysis (CVVHD),and Grade 5: Death. Neurologic toxicities were graded by Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.Grade 1:Mild, asymptomatic or mild symptoms; Grade 2:Moderate and minimal, local or noninvasive intervention;Grade 3: Severe or medically significant but not life-threatening,hospitalization;Grade 4: Life-threatening and urgent intervention indicated;Grade 5: Death related to AE. The Safety Analysis Set included all participants treated with any dose of axicabtagene ciloleucel.

End point type	Primary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to last follow-up visit (maximum duration: 6.8 years)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 2 (Cohort 3) of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Safety Management Study): Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: percentage of participants				
number (not applicable)				
Worst Grade 1 CRS	34			
Worst Grade 2 CRS	55			
Worst Grade 3 CRS	0			
Worst Grade 4 CRS	3			
Worst Grade 5 CRS	0			
Worst Grade ≥ 3 CRS	3			
Worst Grade 1 Neurologic Toxicities	24			
Worst Grade 2 Neurologic Toxicities	21			
Worst Grade 3 Neurologic Toxicities	37			
Worst Grade 4 Neurologic Toxicities	3			
Worst Grade 5 Neurologic Toxicities	3			
Worst Grade ≥ 3 Neurologic Toxicities	42			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2 Safety Management Study (Cohort 4): Percentage of Participants With Treatment-Emergent CRS and Neurologic Toxicities by Severity Grades

End point title	Phase 2 Safety Management Study (Cohort 4): Percentage of Participants With Treatment-Emergent CRS and Neurologic Toxicities by Severity Grades[7][8]

End point description:

TEAE was defined as any AE with onset on or after the start of treatment. CRS events were graded by Lee et al 2014. Grade 1 : No life threatening symptoms and require symptomatic treatment only; Grade 2: Symptoms require and respond to moderate intervention; Grade 3: Symptoms require and respond to aggressive intervention; Grade 4: Life-threatening symptoms and requirements for ventilator support or CVVHD, and Grade 5: Death. Neurologic toxicities were graded by CTCAE version 4.03. Grade 1: Mild, asymptomatic or mild symptoms and intervention not indicated; Grade 2: Moderate and minimal, local or noninvasive intervention indicated; Grade 3: Severe or medically significant but not immediately life-threatening, hospitalization or prolongation of hospitalization indicated; Grade 4: Life-threatening and urgent intervention indicated; Grade 5: Death related to AE. The Safety Analysis Set included all participants treated with any dose of axicabtagene ciloleucel.

End point type	Primary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to last follow-up visit (maximum duration: 5.4 years)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical comparison was planned or performed.

End point values	Phase 2 (Safety Management Study): Cohort 4			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: percentage of participants				
number (not applicable)				
Worst Grade 1 CRS	32			
Worst Grade 2 CRS	59			
Worst Grade 3 CRS	2			
Worst Grade 4 CRS	0			
Worst Grade 5 CRS	0			
Worst Grade ≥ 3 CRS	2			
Worst Grade 1 Neurologic Toxicities	34			
Worst Grade 2 Neurologic Toxicities	10			
Worst Grade 3 Neurologic Toxicities	17			
Worst Grade 4 Neurologic Toxicities	0			
Worst Grade 5 Neurologic Toxicities	0			
Worst Grade ≥ 3 Neurologic Toxicities	17			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2 Safety Management Study (Cohort 5): Percentage of Participants With Treatment-Emergent CRS and Neurologic Toxicities by Severity Grades

End point title	Phase 2 Safety Management Study (Cohort 5): Percentage of Participants With Treatment-Emergent CRS and Neurologic Toxicities by Severity Grades[9][10]

End point description:

TEAE was defined as any AE with onset on or after the start of treatment. CRS events were graded by Lee et al 2014. Grade 1 : No life threatening symptoms and require symptomatic treatment only; Grade 2: Symptoms require and respond to moderate intervention; Grade 3: Symptoms require and respond to aggressive intervention; Grade 4: Life-threatening symptoms and requirements for ventilator support or CVVHD, and Grade 5: Death. Neurologic toxicities were graded by CTCAE version 4.03. Grade 1: Mild, asymptomatic or mild symptoms and intervention not indicated; Grade 2: Moderate and minimal, local or noninvasive intervention indicated; Grade 3: Severe or medically significant but not immediately life-threatening, hospitalization or prolongation of hospitalization indicated; Grade 4: Life-threatening and urgent intervention indicated; Grade 5: Death related to AE. The Safety Analysis Set included all participants treated with any dose of axicabtagene ciloleucel.

End point type	Primary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to last follow-up visit (maximum duration: 4.4 years)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data has been reported only for the specified arms for which participants were available and data was evaluable for the specified outcome measure.

End point values	Phase 2 (Safety Management Study): Cohort 5			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: percentage of participants				
number (not applicable)				
Worst Grade 1 CRS	38			
Worst Grade 2 CRS	46			
Worst Grade 3 CRS	0			
Worst Grade 4 CRS	2			
Worst Grade 5 CRS	0			
Worst Grade ≥ 3 CRS	2			
Worst Grade 1 Neurologic Toxicities	26			
Worst Grade 2 Neurologic Toxicities	18			
Worst Grade 3 Neurologic Toxicities	10			
Worst Grade 4 Neurologic Toxicities	2			
Worst Grade 5 Neurologic Toxicities	0			
Worst Grade ≥ 3 Neurologic Toxicities	12			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2 Safety Management Study (Cohort 6): Percentage of Participants With Treatment-Emergent CRS and Neurologic Toxicities by Severity Grades

End point title	Phase 2 Safety Management Study (Cohort 6): Percentage of Participants With Treatment-Emergent CRS and Neurologic Toxicities by Severity Grades[11][12]

End point description:

TEAE was defined as any AE with onset on or after the start of treatment. CRS events were graded by Lee et al 2014. Grade 1 : No life threatening symptoms and require symptomatic treatment only; Grade 2: Symptoms require and respond to moderate intervention; Grade 3: Symptoms require and respond to aggressive intervention; Grade 4: Life-threatening symptoms and requirements for ventilator support or CVVHD, and Grade 5: Death. Neurologic toxicities were graded by CTCAE version 4.03. Grade 1: Mild, asymptomatic or mild symptoms and intervention not indicated; Grade 2: Moderate and minimal, local or noninvasive intervention indicated; Grade 3: Severe or medically significant but not immediately life-threatening, hospitalization or prolongation of hospitalization indicated; Grade 4: Life-threatening and urgent intervention indicated; Grade 5: Death related to AE. The Safety Analysis Set included all participants treated with any dose of axicabtagene ciloleucel.

End point type	Primary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to last follow-up visit (maximum duration: 4.1 years)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data has been reported only for the specified arms for which participants were available and data was evaluable for the specified outcome measure.

End point values	Phase 2 (Safety Management Study): Cohort 6			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: percentage of participants				
number (not applicable)				
Worst Grade 1 CRS	35			
Worst Grade 2 CRS	45			
Worst Grade 3 CRS	0			
Worst Grade 4 CRS	0			
Worst Grade 5 CRS	0			
Worst Grade ≥ 3 CRS	0			
Worst Grade 1 Neurologic Toxicities	23			
Worst Grade 2 Neurologic Toxicities	18			
Worst Grade 3 Neurologic Toxicities	8			
Worst Grade 4 Neurologic Toxicities	5			
Worst Grade 5 Neurologic Toxicities	5			
Worst Grade ≥ 3 Neurologic Toxicities	18			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Duration of Response (DOR) as Assessed by Investigator per Revised IWG Response Criteria for Malignant Lymphoma

End point title	Phase 2: Duration of Response (DOR) as Assessed by Investigator per Revised IWG Response Criteria for Malignant Lymphoma[13]

End point description:

Among participants who experience an objective response (OR), DOR was defined as the date of their first objective response (CR or PR which was subsequently confirmed) to disease progression per the revised IWG Response Criteria for Malignant Lymphoma or death regardless of cause. CR and PR as defined in outcome measure 1. Participants in the mITT Analysis Set with objective response were analyzed. 99.99=median was not estimable because almost 50% of participants were censored;99= lower limit of 95% CI was not estimable because almost 50% of participants were censored; 99999= upper limit of 95% CI was not estimable because almost 50% of participants were censored.

End point type	Secondary

End point timeframe:

First OR to last follow-up visit (maximum duration: 7.7, 6.8, 5.4, 4.4, 4.1 years for Cohorts 1, 2, 3, 4, 5, and 6 respectively)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 2 of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	20	24	31
Units: months				
median (confidence interval 95%)	5.0 (2.1 to 34.7)	75.4 (11.1 to 9999)	99.99 (5.0 to 99999)	99.99 (99 to 99999)

End point values	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	38		
Units: months				
median (confidence interval 95%)	27.5 (2.2 to 99999)	99.99 (7.8 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Pivotal Study (Cohorts 1 and 2): ORR per Independent Radiological Review Committee (IRRC)

End point title	Phase 2 Pivotal Study (Cohorts 1 and 2): ORR per Independent Radiological Review Committee (IRRC)[14]

End point description:

ORR was defined as the percentage of participants achieving either a CR or a PR, as assessed by the IRRC using revised IWG Response Criteria for Malignant Lymphoma. CR: complete disappearance of all detectable clinical evidence of disease and disease-related symptoms; all lymph nodes and nodal masses must have regressed to normal size; spleen and/or liver must be normal size, not be palpable, and no nodules; bone marrow aspirate and biopsy must show no evidence of disease. PR: a ≥ 50% decrease in SPD of up to 6 of the largest dominant nodes or nodal masses; no increase in size of nodes, liver or spleen and no new sites of disease; multiple splenic and hepatic nodules (if present) must regress by ≥ 50% in the SPD; > 50% decrease in the greatest transverse diameter for single nodules. 95% CI was calculated by Clopper-Pearson method. Participants in the mITT Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel to the data cutoff date of 11 August 2018 (maximum: 2.7 years)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on the arms under Phase 2 (Cohorts 1 and 2) of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	24		
Units: percentage of participants				
number (confidence interval 95%)	70 (59 to 80)	88 (68 to 97)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 Study: ORR as Assessed by Investigator per Revised IWG Response Criteria for Malignant Lymphoma

End point title	Phase 1 Study: ORR as Assessed by Investigator per Revised IWG Response Criteria for Malignant Lymphoma[15]

End point description:

ORR was defined as the percentage of participants achieving either a CR or a PR, as assessed by the study investigators using revised IWG Response Criteria for Malignant Lymphoma (Cheson et al, 2007). CR: complete disappearance of all detectable clinical evidence of disease and disease-related symptoms; all lymph nodes and nodal masses must have regressed to normal size; spleen and/or liver must be normal size, not be palpable, and no nodules; bone marrow aspirate and biopsy must show no evidence of disease. PR: a ≥ 50% decrease in SPD of up to 6 of the largest dominant nodes or nodal masses; no increase in size of nodes, liver or spleen and no new sites of disease; multiple splenic and hepatic nodules (if present) must regress by ≥ 50% in the SPD; > 50% decrease in the greatest transverse diameter for single nodules. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel to the data cutoff date of 27 January 2017 (maximum: 20 months)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 1 of the study, all the arms in the baseline period were not included.

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: percentage of participants				
number (not applicable)	71			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Progression-Free Survival (PFS) as Assessed by Investigator per Revised IWG Response Criteria for Malignant Lymphoma

End point title	Phase 2: Progression-Free Survival (PFS) as Assessed by Investigator per Revised IWG Response Criteria for Malignant Lymphoma[16]

End point description:

PFS was defined as the time from the axicabtagene ciloleucel infusion date to the date of disease progression per the revised IWG Response Criteria for Malignant Lymphoma (Cheson et al, 2007) or death from any cause. Participants not meeting the criteria for progression by the analysis data cutoff date were censored. Disease progression was defined by at least one of ≥ 50% increase from nadir in the sum of the products of at least 2 lymph nodes, a 50% increase in the product of the diameters of a single lymph node; appearance of a new lesion > 1.5 cm in any axis; ≥ 50% increase in size of splenic or hepatic nodules; ≥ 50% increase in the longest diameter node > 1 cm in its short axis. KM estimates was used for analyses. Participants in the mITT Analysis Set were analyzed. 99.99=median was not estimable because almost 50% of participants were censored;99999= upper limit of 95% 99.99=median was not estimable because almost 50% of participants were censored.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel to disease progression or death regardless of cause (maximum duration: 7.7, 6.8, 5.4, 4.4, 4.1 years for Cohorts 1, 2, 3, 4, 5, and 6 respectively)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 2 of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	24	38	41
Units: months				
median (confidence interval 95%)	5.1 (3.0 to 8.8)	49.1 (3.7 to 99999)	6.2 (2.4 to 99999)	99.99 (3.0 to 99999)

End point values	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	40		
Units: months				

median (confidence interval 95%)	3.1 (2.9 to 29.1)	99.99 (8.7 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Safety Management Study (Cohorts 3, 4, 5, and 6): ORR as Assessed by Investigator per the Revised IWG Response Criteria for Malignant Lymphoma

End point title	Phase 2 Safety Management Study (Cohorts 3, 4, 5, and 6): ORR as Assessed by Investigator per the Revised IWG Response Criteria for Malignant Lymphoma[17]

End point description:

ORR was defined as the percentage of participants achieving either a CR or a PR, as assessed by the study investigators using revised IWG Response Criteria for Malignant Lymphoma (Cheson et al, 2007). CR: complete disappearance of all detectable clinical evidence of disease and disease-related symptoms; all lymph nodes and nodal masses must have regressed to normal size; spleen and/or liver must be normal size, not be palpable, and no nodules; bone marrow aspirate and biopsy must show no evidence of disease. PR: a ≥ 50% decrease in SPD of up to 6 of the largest dominant nodes or nodal masses; no increase in size of nodes, liver or spleen and no new sites of disease; multiple splenic and hepatic nodules (if present) must regress by ≥ 50% in the SPD; > 50% decrease in the greatest transverse diameter for single nodules. 95% CI was calculated by Clopper-Pearson method. Participants in the mITT Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel to last follow-up visit (maximum duration: 6.8, 5.4, 4.4, 4.1 years for Cohorts 3, 4, 5, and 6 respectively)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under the Phase 2 safety Management Study (Cohorts 3, 4, 5, and 6) of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	41	50	40
Units: percentage of participants				
number (confidence interval 95%)	63 (46 to 78)	76 (60 to 88)	72 (58 to 84)	95 (83 to 99)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Overall Survival (OS)

End point title	Phase 2: Overall Survival (OS)[18]

End point description:

OS was defined as the time from axicabtagene ciloleucel infusion to the date of death. Participants who did not die by the analysis data cutoff date were censored at their last contact date. KM estimates was used for analyses. Participants in the mITT Analysis Set were analyzed. 99.99=median was not estimable because almost 50% of participants were censored;99999= upper limit of 95% 99.99=median was not estimable because almost 50% of participants were censored.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel to the date of death regardless of cause (maximum duration: 7.7, 6.8, 5.4, 4.4, 4.1 years for Cohorts 1, 2, 3, 4, 5, and 6 respectively)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 2 of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	24	38	41
Units: months				
median (confidence interval 95%)	15.4 (10.4 to 45.7)	99.99 (15.0 to 99999)	34.8 (5.4 to 99999)	99.99 (14.6 to 99999)

End point values	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	40		
Units: months				
median (confidence interval 95%)	20.6 (12.6 to 43.1)	99.99 (18.9 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Pivotal Study (Cohorts 1 and 2): Best Overall Response Using IRRC per Cheson 2007

End point title	Phase 2 Pivotal Study (Cohorts 1 and 2): Best Overall Response Using IRRC per Cheson 2007[19]

End point description:

The best overall response for each participant was based on the assessments of response (CR, PR, stable disease [SD], PD, and not done [ND]) made by the the IRRC using IWG 2007 criteria (Cheson et al, 2007). CR and PR as defined in outcome measure 1. PD defined by at least one of the following: ≥ 50% increase from nadir in the sum of the products of at least 2 lymph nodes, or at least a 50% increase in the product of the diameters of a single lymph node; appearance of a new lesion > 1.5 cm in any axis; ≥ 50% increase in size of splenic or hepatic nodules; ≥ 50% increase in the longest diameter

of any single previously identified node > 1 cm in its short axis. SD: Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD. Percentage of participants with best overall response of CR, PR, SD, PD, and ND was reported. Participants in the mITT Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel to the data cutoff date of 11 August 2018 (maximum: 2.7 years)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on the arms under Phase 2 (Cohorts 1 and 2) of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	24		
Units: percentage of participants				
number (not applicable)				
CR	51	67		
PR	19	21		
SD	21	4		
PD	8	4		
ND	1	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Pivotal Study (Cohorts 1 and 2): Duration of Response (DOR) Using IRRC per Cheson 2007

End point title	Phase 2 Pivotal Study (Cohorts 1 and 2): Duration of Response (DOR) Using IRRC per Cheson 2007[20]

End point description:

Among participants who experience an objective response, DOR was defined as the date of their first objective response (CR or PR which was subsequently confirmed) to PD, as assessed by the IRRC using revised IWG Response Criteria for Malignant Lymphoma (Cheson et al, 2007) or death regardless of cause. CR and PR as defined in outcome measure 1. PD was defined by at least one:≥ 50% increase from nadir in the sum of the products of at least 2 lymph nodes,or at least a 50% increase in the product of the diameters of a single node;appearance of a new lesion > 1.5 cm in any axis; ≥ 50% increase in size of snodules;≥ 50% increase in the longest diameter of anode > 1 cm in its short axis. Kaplan-Meier (KM) estimates. Participants in the mITT Analysis Set with objective response were analyzed. 99.99=median was not estimable because almost 50% of participants were censored;99999= upper limit of CI was not estimable because almost 50% of participants were censored.

End point type	Secondary

End point timeframe:

First objective response up to the data cutoff date of 11 August 2018 (maximum: 2.7 years)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on the arms under Phase 2 (Cohorts 1 and 2) of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	21		
Units: months				
median (confidence interval 95%)	99.99 (5.4 to 99999)	99.99 (11.1 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Pivotal Study (Cohorts 1 and 2): PFS Using IRRC per Cheson 2007

End point title	Phase 2 Pivotal Study (Cohorts 1 and 2): PFS Using IRRC per Cheson 2007[21]

End point description:

PFS was defined as the time from the axicabtagene ciloleucel infusion date to the date of disease progression as assessed by the IRRC using revised IWG Response Criteria for Malignant Lymphoma (Cheson et al, 2007) or death from any cause. Participants not meeting the criteria for progression by the analysis data cutoff date were censored at their last evaluable disease assessment date. PD defined by at least: ≥ 50% increase from nadir in the sum of the products of at least 2 lymph nodes,or at least a 50% increase in the product of the diameters of a single node; appearance of a new lesion > 1.5 cm; ≥ 50% increase in size of nodules; ≥ 50% increase in the longest diameter of any node > 1 cm in its short axis. KM estimates were used for analyses. Participants in the mITT Analysis Set were analyzed. 99.99=median was not estimable because almost 50% of participants were censored;99999= upper limit of 95% of CI was not estimable because almost 50% of participants were censored.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel to the data cutoff date of 11 August 2018 (maximum: 2.7 years)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 2 (Cohorts 1 and 2) of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	24		
Units: months				
median (confidence interval 95%)	6.9 (4.5 to 15.0)	99.99 (9.0 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Treatment-Emergent Adverse Events (TEAEs)

End point title	Percentage of Participants Experiencing Treatment-Emergent Adverse Events (TEAEs)

End point description:

An adverse event was defined as any untoward medical occurrence in a clinical trial participants. The event did not necessarily have a relationship with study treatment. Adverse events included worsening of a pre-existing medical condition. Worsening indicated that the pre-existing medical condition had increased in severity, frequency, and/or duration or had an association with a worse outcome. A pre-existing condition that had not worsened during the study or involved an intervention such as elective cosmetic surgery or a medical procedure while on study, was not considered an adverse event. TEAE was defined as any AE with onset on or after the start of treatment. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to last follow up visit (maximum duration: 7.7 years)

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	77	24	38
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	50	40	
Units: percentage of participants				
number (not applicable)	100	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Clinically Significant Changes in Laboratory Values Reported as Grade 3 or Higher TEAEs

End point title	Percentage of Participants With Clinically Significant Changes in Laboratory Values Reported as Grade 3 or Higher TEAEs

End point description:

Grading categories were determined by Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. Grade 1: mild, Grade 2: moderate, Grade 3: severe or medically significant, Grade 4: life-threatening. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to last follow up visit (maximum duration: 7.7 years)

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	77	24	38
Units: percentage of participants				
number (not applicable)	100	96	96	97

End point values	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	50	40	
Units: percentage of participants				
number (not applicable)	98	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics: Peak Level of Anti-CD19 CAR T Cells in Blood

End point title	Pharmacokinetics: Peak Level of Anti-CD19 CAR T Cells in Blood

End point description:

Peak was defined as the maximum number of CAR T cells measured post-infusion. Participants in the Safety Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline up to Month 60 (for Phase 1 and Phase 2 Cohorts 1, 2, and 3); Baseline up to Month 24 (for Phase 2 Cohorts 4, 5, and 6)

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	76	22	36
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	58.512 (18.028 to 147.732)	31.512 (12.445 to 74.746)	58.633 (27.884 to 103.190)	53.670 (22.813 to 146.075)

End point values	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	39	49	40	
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	52.91 (27.25 to 92.78)	26.63 (12.52 to 117.53)	64.38 (6.27 to 131.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Anti-Axicabtagene Ciloleucel Antibodies

End point title	Percentage of Participants with Anti-Axicabtagene Ciloleucel Antibodies

End point description:

Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

First infusion date of axicabtagene ciloleucel up to last follow-up visit (maximum duration: 7.7, 6.8, 5.4, 4.4, 4.1 years for Phase 1 and Phase 2 Cohorts 1, 2, 3, 4, 5, and 6 respectively)

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	77	24	38
Units: percentage of participants				
number (not applicable)	29	5	8	11

End point values	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	50	40	
Units: percentage of participants				
number (not applicable)	0	8	8	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamics: Peak Level of Cytokines in Serum (Phase 1 and Phase 2 Cohorts 1, 2, and 3)

End point title	Pharmacodynamics: Peak Level of Cytokines in Serum (Phase 1 and Phase 2 Cohorts 1, 2, and 3)[22]

End point description:

Peak was defined as the maximum post-baseline level of the cytokine. Following key cytokines were measured: interferon-gamma induced protein 10 (IP-10), ferritin, granzyme B, intercellular adhesion molecule (ICAM-1), interferon-gamma (IFN-gamma), interleukin-1 receptor antagonist (IL-1RA), IL-2, interleukin-2 receptor alpha (IL-2 R alpha), IL-6, IL-7, IL-8, IL-10, IL-15, perforin, tumor necrosis factor alpha (TNF alpha), and vascular cell adhesion molecule- 1 (VCAM-1). Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Baseline up to Month 3

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data has been reported only for the specified arms for which participants were available and data was evaluable for the specified outcome measure.

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	77	24	38
Units: pg/mL				
median (full range (min-max))				
IP-10	2000.0 (147.0 to 2000.0)	2000.0 (628.1 to 2000.0)	2000.0 (434.2 to 2000.0)	2000.0 (541.0 to 2000.0)
Granzyme B	33.1 (0.6 to 463.8)	31.1 (1.0 to 3306.0)	17.3 (1.0 to 406.8)	44.1 (1.0 to 534.6)
ICAM-1	792754.3 (537796.8 to 2424877.7)	1322829.3 (557025.0 to 7495123.2)	989188.4 (544589.3 to 4588974.8)	1009966.4 (256768.6 to 4879749.7)

IFN-gamma	792.0 (81.1 to 1876.0)	493.8 (32.4 to 1876.0)	364.9 (7.5 to 1876.0)	1857.2 (65.0 to 1876.0)
IL-1 RA	2173.3 (544.3 to 4000.0)	2371.2 (510.8 to 4000.0)	1999.9 (649.9 to 4000.0)	2160.5 (653.7 to 4000.0)
IL-2	18.4 (3.1 to 91.0)	25.0 (0.9 to 123.1)	13.4 (0.9 to 63.7)	20.0 (0.9 to 189.4)
IL-2 R alpha	16872.7 (2189.0 to 34044.5)	14383.7 (78.0 to 100000.0)	7817.3 (78.0 to 66024.6)	12386.4 (3002.6 to 100000.0)
IL-6	305.3 (2.4 to 976.0)	89.4 (3.5 to 976.0)	44.6 (3.6 to 976.0)	921.8 (13.3 to 976.0)
IL-7	51.5 (31.2 to 71.5)	38.9 (13.8 to 153.5)	44.1 (27.9 to 98.8)	38.8 (19.1 to 83.8)
IL-8	86.4 (17.1 to 750.0)	118.4 (14.2 to 750.0)	77.2 (9.8 to 750.0)	120.9 (10.3 to 750.0)
IL-10	52.5 (3.8 to 614.0)	43.9 (0.7 to 466.0)	18.8 (0.7 to 263.6)	48.2 (1.8 to 466.0)
IL-15	57.1 (18.7 to 271.3)	56.5 (13.1 to 226.6)	47.6 (11.3 to 195.2)	50.3 (21.9 to 537.3)
Perforin	5389.0 (2582.7 to 20724.3)	11309.5 (2282.3 to 39818.9)	8278.7 (2332.6 to 31857.7)	15411.9 (4327.4 to 30575.9)
TNF alpha	10.5 (1.8 to 443.1)	8.6 (2.6 to 166.9)	6.8 (2.2 to 44.9)	10.9 (3.3 to 52.1)
VCAM-1	1387033.6 (609223.2 to 8424222.9)	1478356.8 (642372.6 to 3859375.8)	1058453.9 (634769.7 to 2864040.2)	1367940.7 (721050.0 to 5184238.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamics: Peak Level of Cytokines (IP-10, Granzyme B, IFN-gamma, IL-1 RA, IL-10, IL-15, IL-2, IL-6, IL-7, IL-8, TNF alpha, and GM-CSF) in Serum (Phase 2 Cohorts 4, 5, and 6)

End point title	Pharmacodynamics: Peak Level of Cytokines (IP-10, Granzyme B, IFN-gamma, IL-1 RA, IL-10, IL-15, IL-2, IL-6, IL-7, IL-8, TNF alpha, and GM-CSF) in Serum (Phase 2 Cohorts 4, 5, and 6)[23]

End point description:

Peak was defined as the maximum post-baseline level of the cytokine. Following key cytokines were measured: IP-10, granzyme B, IFN-gamma, IL-1 RA, IL-2, IL-6, IL-7, IL-8, IL-10, IL-15, TNF alpha, and granulocyte-macrophage colony-stimulating factor (GM-CSF). Participants in the Safety Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline up to Month 3

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data has been reported only for the specified arms for which participants were available and data was evaluable for the specified outcome measure.

End point values	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	50	40	
Units: pg/mL				
median (full range (min-max))				
IP-10	1549.70 (469.20 to 2000.00)	1746.15 (349.80 to 2000.00)	1560.03 (347.00 to 2000.000)	
Granzyme B	23.10 (1.00 to 322.60)	27.90 (1.00 to 375.76)	18.40 (1.00 to 162.30)	
IFN-gamma	334.50 (24.90 to 1876.00)	314.90 (7.50 to 1876.00)	207.95 (18.80 to 1876.00)	
IL-1 RA (N=31, 50, 40)	1093.70 (193.30 to 4493.10)	908.00 (229.00 to 9000.00)	1279.50 (227.00 to 9000.00)	
IL-2	11.20 (0.90 to 79.40)	11.85 (0.90 to 142.70)	8.40 (0.90 to 277.60)	
IL-6	136.70 (1.60 to 976.00)	97.95 (1.60 to 976.00)	47.25 (1.60 to 976.00)	
IL-7	33.10 (18.00 to 67.50)	29.80 (1.40 to 65.20)	28.25 (13.20 to 74.30)	
IL-8	67.40 (8.50 to 750.00)	75.10 (5.80 to 750.00)	52.55 (10.00 to 750.00)	
IL-10	19.60 (1.40 to 466.00)	14.45 (0.70 to 300.90)	13.30 (0.70 to 171.20)	
IL-15	45.80 (22.30 to 272.70)	34.15 (1.40 to 140.00)	37.20 (9.50 to 86.30)	
TNF alpha	5.70 (2.00 to 54.60)	5.25 (1.40 to 33.30)	4.80 (2.10 to 20.20)	
GM-CSF	4.40 (1.90 to 47.00)	2.90 (1.90 to 35.60)	1.90 (1.90 to 47.40)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamics: Peak Level of Cytokines (Ferritin, ICAM-1, IL-2 R, Perforin, and VCAM-1) in Serum (Phase 2 Cohorts 4, 5, and 6)

End point title	Pharmacodynamics: Peak Level of Cytokines (Ferritin, ICAM-1, IL-2 R, Perforin, and VCAM-1) in Serum (Phase 2 Cohorts 4, 5, and 6)[24]

End point description:

Peak was defined as the maximum post-baseline level of the cytokine. Following key cytokines were measured: Ferritin, ICAM-1, IL-2 R, Perforin, and VCAM-1. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Baseline up to Month 3

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data has been reported only for the specified arms for which participants were

available and data was evaluable for the specified outcome measure.

End point values	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	50	40	
Units: ng/mL				
median (full range (min-max))				
Ferritin	1086.36 (95.55 to 23900)	1516.11 (89.29 to 31600)	903.50 (171.61 to 6555.10)	
ICAM-1	907.97 (359.51 to 5141.64)	636.74 (361.38 to 4835.93)	654.81 (355.15 to 4419.09)	
IL-2 R	10.78 (2.81 to 94.59)	7.82 (1.36 to 83.60)	6.43 (1.70 to 33.31)	
Perforin	17.22 (3.88 to 44.42)	10.85 (2.53 to 100.00)	10.12 (1.97 to 39.62)	
VCAM-1	1255.32 (594.51 to 3932.61)	854.63 (476.60 to 6501.14)	836.04 (411.93 to 5079.25)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamics: Peak Level of Cytokine (Ferritin) in Serum (Phase 1 and Phase 2 Cohorts 1 and 2)

End point title	Pharmacodynamics: Peak Level of Cytokine (Ferritin) in Serum (Phase 1 and Phase 2 Cohorts 1 and 2)[25]

End point description:

Peak was defined as the maximum post-baseline level of the cytokine. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Baseline up to Month 3

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data has been reported only for the specified arms for which participants were available and data was evaluable for the specified outcome measure.

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	77	24	
Units: pg/mL				

median (full range (min-max))	1973400.0 (1201900.0 to 32984400.0)	3681400.0 (780.0 to 25000000.0)	1979360.0 (780.0 to 25000000.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamics: Peak Level of Cytokine (CRP) in Serum

End point title	Pharmacodynamics: Peak Level of Cytokine (CRP) in Serum

End point description:

Peak was defined as the maximum post-baseline level of the cytokine. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Baseline up to Month 3

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	77	24	38
Units: mg/mL				
median (full range (min-max))	112.6 (14.6 to 655.0)	215.7 (31.0 to 496.0)	186.6 (18.5 to 496.0)	137.8 (2.1 to 496.0)

End point values	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	50	40	
Units: mg/mL				
median (full range (min-max))	126.53 (18.19 to 496.00)	74.84 (1.81 to 496.00)	76.11 (7.31 to 496.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamics: Peak Level of Cytokine (Ferritin) in Serum (Phase 2

Cohort 3)

End point title	Pharmacodynamics: Peak Level of Cytokine (Ferritin) in Serum (Phase 2 Cohort 3)[26]

End point description:

Peak was defined as the maximum post-baseline level of the cytokine. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Baseline up to Month 3

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data has been reported only for the specified arms for which participants were available and data was evaluable for the specified outcome measure.

End point values	Phase 2 (Safety Management Study): Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: ng/mL				
median (full range (min-max))	2440.2 (0.8 to 25000.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Safety Management Study: Number of Participants With the European Quality of Life Five Dimension Five Level Scale (EQ-5D) Score

End point title	Phase 2 Safety Management Study: Number of Participants With the European Quality of Life Five Dimension Five Level Scale (EQ-5D) Score[27]

End point description:

EQ-5D is a self-reported questionnaire used for assessing the overall health status of a participant scoring 5 dimensions of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension was divided into 5 levels of severity: "No problem", "Slight problems", "Moderate problems", "Severe problems", and "Extreme problems (unable to perform)". EQ-5D health states, defined by the EQ-5D descriptive system, are converted into a single summary index by applying a formula that attaches values (also called QOL weights or QOL utilities) to each of the levels in each dimension. EQ-5D Summary Index values range from -0.11 (worst health state) to 1.00 (perfect health state). Participants in Safety Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 4, Month 3, and Month 6

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data has been reported only for the specified arms for which participants were available and data was evaluable for the specified outcome measure.

End point values	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	47	34
Units: participants				
Baseline: Mobility : No problem	30	25	33	26
Baseline: Mobility : Slight problem	7	9	5	4
Baseline: Mobility : Moderate problem	1	5	7	3
Baseline: Mobility : Severe problem	0	0	1	1
Baseline: Mobility : Unable to perform	0	0	1	0
Wk 4: Mobility : No problem N=32,37,38,29	16	21	23	20
Wk 4: Mobility : Slight problem N=32,37,38,29	11	7	9	5
Wk 4: Mobility : Moderate problem N=32,37,38,29	4	5	4	4
Wk 4: Mobility : Severe problem N=32,37,38,29	0	3	1	0
Wk 4: Mobility : Unable to perform N=32,37,38,29	1	1	1	0
Month 3: Mobility : No problem N=23,31,33,29	14	20	21	22
Month 3: Mobility : Slight problem N=23,31,33,29	6	8	6	3
Month 3: Mobility : Moderate problem N=23,31,33,29	2	2	6	3
Month 3: Mobility : Severe problem N=23,31,33,29	1	1	0	1
Mon 3: Mobility : Unable to perform N=23,31,33,29	0	0	0	0
Month 6: Mobility : No problem N=18,25,17,27	10	19	11	15
Month 6: Mobility : Slight problem N=18,25,17,27	6	4	2	8
Month 6: Mobility : Moderate problem N=18,25,17,27	2	2	4	3
Month 6: Mobility : Severe problem N=18,25,17,27	0	0	0	1
Mon 6: Mobility : Unable to perform N=18,25,17,27	0	0	0	0
Baseline: Self-care : No problem	37	38	44	32
Baseline: Self-care : Slight problem	1	1	3	1
Baseline: Self-care : Moderate problem	0	0	0	1
Baseline: Self-care : Severe problem	0	0	0	0
Baseline: Self-care : Unable to perform	0	0	0	0
Wk 4: Self-care : No problem N=32,37,38,29	25	33	31	24
Wk 4: Self-care : Slight problem N=32,37,38,29	5	3	6	3
Wk 4: Self-care : Moderate problem N=32,37,38,29	1	0	1	1
Wk 4: Self-care : Severe problem N=32,37,38,29	0	1	0	1
Wk 4: Self-care : Unable to perform N=32,37,38,29	1	0	0	0
Month 3: Self-care : No problem N=23,31,33,29	19	29	32	25

Month 3: Self-care : Slight problem N=23,31,33,29	4	2	1	4
Mon 3: Self-care : Moderate problem N=23,31,33,29	0	0	0	0
Month 3: Self-care : Severe problem N=23,31,33,29	0	0	0	0
Mon 3: Self-care : Unable to perform N=23,31,33,29	0	0	0	0
Month 6: Self-care : No problem N=18,25,17,27	17	25	16	20
Month 6: Self-care : Slight problem N=18,25,17,27	1	0	1	7
Mon 6: Self-care : Moderate problem N=18,25,17,27	0	0	0	0
Month 6: Self-care : Severe problem N=18,25,17,27	0	0	0	0
Mon 6: Self-care : Unable to perform N=18,25,17,27	0	0	0	0
Baseline: Usual activities : No problem	22	22	24	16
Baseline: Usual activities : Slight problem	10	6	13	14
Baseline: Usual activities : Moderate problem	4	8	8	2
Baseline: Usual activities : Severe problem	2	1	1	2
Baseline: Usual activities : Unable to perform	0	2	1	0
Wk 4: Usual activities : No problem N=32,37,37,29	6	12	12	12
Wk 4: Usu act : Slight problem N=32,37,37,29	13	11	13	11
Wk 4: Usu act : Moderate problem N=32,37,37,29	11	8	8	4
Wk 4: Usu act : Severe problem N=32,37,37,29	0	3	2	1
Wk 4: Usu act : Unable to perform N=32,37,37,29	2	3	2	1
Mon 3: Usual activities : No problem N=23,31,33,29	8	16	19	12
Mon 3: Usu act : Slight problem N=23,31,33,29	9	9	10	14
Mon 3: Usu act : Moderate problem N=23,31,33,29	5	5	2	2
Mon 3: Usu act : Severe problem N=23,31,33,29	1	1	1	1
Mon 3: Usu act : Unable to perform N=23,31,33,29	0	0	1	0
Mon 6: Usual activities : No problem N=18,25,17,27	9	15	10	11
Mon 6: Usu act : Slight problem N=18,25,17,27	5	7	4	12
Mon 6: Usu act : Moderate problem N=18,25,17,27	3	3	2	3
Mon 6: Usu act : Severe problem N=18,25,17,27	1	0	1	0
Mon 6: Usu act : Unable to perform N=18,25,17,27	0	0	0	1
Baseline: Pain/Discomfort : No problem	18	17	16	15
Baseline: Pain/Discomfort : Slight problem	9	17	18	14
Baseline: Pain/Discomfort : Moderate problem	8	5	7	4

Baseline: Pain/Discomfort : Severe problem	1	0	5	1
Baseline: Pain/Discomfort : Unable to perform	2	0	1	0
Wk 4: Pain/Discomfort : No problem N=32,37,37,29	12	19	20	17
Wk 4: Pai : Slight problem N=32,37,37,29	12	13	10	9
Wk 4: Pai : Moderate problem N=32,37,37,29	7	2	5	3
Wk 4: Pai : Severe problem N=32,37,37,29	1	3	2	0
Wk 4: Pai : Unable to perform N=32,37,37,29	0	0	0	0
Mon 3: Pain/Discomfort : No problem N=23,31,33,29	9	10	18	16
Mon 3: Pai : Slight problem N=23,31,33,29	5	14	9	5
Mon 3: Pai : Moderate problem N=23,31,33,29	9	6	6	5
Mon 3: Pai : Severe problem N=23,31,33,29	0	1	0	3
Mon 3: Pai : Unable to perform N=23,31,33,29	0	0	0	0
Mon 6: Pain/Discomfort : No problem N=17,25,17,27	8	9	6	12
Mon 6: Pai : Slight problem N=17,25,17,27	4	14	8	8
Mon 6: Pai : Moderate problem N=17,25,17,27	5	1	3	4
Mon 6: Pai : Severe problem N=17,25,17,27	0	1	0	3
Mon 6: Pai : Unable to perform N=17,25,17,27	0	0	0	0
Baseline: Anxiety/Depression : No problem	16	23	18	21
Baseline: Anxiety/Depression : Slight problem	16	13	17	9
Baseline: Anxiety/Depression : Moderate problem	3	3	10	3
Baseline: Anxiety/Depression : Severe problem	1	0	1	1
Baseline: Anxiety/Depression : Unable to perform	2	0	1	0
Wk 4: Anx : No problem N=32,37,38,29	9	25	21	23
Wk 4: Anx : Slight problem N=32,37,38,29	15	8	12	3
Wk 4: Anx : Moderate problem N=32,37,38,29	7	3	5	3
Wk 4: Anx : Severe problem N=32,37,38,29	1	1	0	0
Wk 4: Anx : Unable to perform N=32,37,38,29	0	0	0	0
Mon 3: Anx : No problem N=23,31,33,29	11	19	16	19
Mon 3: Anx : Slight problem N=23,31,33,29	5	8	12	7
Mon 3: Anx : Moderate problem N=23,31,33,29	6	4	4	2
Mon 3: Anx : Severe problem N=23,31,33,29	1	0	1	1

Mon 3: Anx : Unable to perform N=23,31,33,29	0	0	0	0
Mon 6: Anx : No problem N=18,25,17,26	9	14	7	18
Mon 6: Anx : Slight problem N=18,25,17,26	5	10	8	5
Mon 6: Anx : Moderate problem N=18,25,17,26	3	0	1	3
Mon 6: Anx : Severe problem N=18,25,17,26	0	1	1	0
Mon 6: Anx : Unable to perform N=18,25,17,26	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Positive Replication Competent Retrovirus (RCR)

End point title	Percentage of Participants With Positive Replication Competent Retrovirus (RCR)

End point description:

RCR was analyzed in blood samples by central laboratory. Because axicabtagene ciloleucel comprised retroviral vector transduced T cells, the presence of RCR in the blood of treated participants was reported. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Day 0 (pre-infusion) up to last follow-up visit (maximum duration: 7.7, 6.8, 5.4, 4.4, 4.1 years for Phase 1 and Phase 2 Cohorts 1, 2, 3, 4, 5, and 6 respectively)

End point values	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2	Phase 2 (Safety Management Study): Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	77	24	38
Units: percentage of participants				
number (not applicable)	0	0	0	0

End point values	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	50	40	
Units: percentage of participants				
number (not applicable)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Safety Management Study: EQ-5D Visual Analogue Scale (VAS) Score

End point title	Phase 2 Safety Management Study: EQ-5D Visual Analogue Scale (VAS) Score[28]

End point description:

EQ-5D is a self-reported questionnaire used for assessing the overall health status of a participant. The EQ-5D-VAS records the participant's self-rated health on a vertical visual analogue scale and is asked to make a global assessment of their current state of health with 0 indicating the worst health they can imagine and 100 indicating the best health they can imagine. Participants in Safety Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 4, Month 3, and Month 6

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As the endpoint was focused on only the arms under Phase 2 of the study, all the arms in the baseline period were not included.

End point values	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5	Phase 2 (Safety Management Study): Cohort 6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	47	34
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline	71.2 (± 21.3)	69.5 (± 18.8)	66.7 (± 20.7)	70.9 (± 17.0)
Wk 4 N=32,36,38,29	67.8 (± 15.6)	67.2 (± 20.9)	70.8 (± 14.8)	76.1 (± 13.2)
Month 3 N=23,31,33,29	74.9 (± 16.6)	78.8 (± 14.7)	73.3 (± 19.9)	76.5 (± 15.0)
Month 6 N=18,25,17,27	77.1 (± 21.4)	85.1 (± 12.1)	77.1 (± 14.7)	79.8 (± 14.0)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Adverse event:Up to 7.7years;All-cause Death:Enrollment upto last followup visit(maximum:7.7 years);Death for Participant Flow of Phase 2 Cohort 1(53) is more than deaths(49) reported here because deaths are separately given for main and retreatment arms.

Adverse event reporting additional description:

Adverse events:The Safety Analysis Set included participants treated with any dose of axicabtageneciloleucel;Retreatment groups:The Safety-Retreatment Analysis Set included participants re-treated of axicabtageneciloleucel.All-cause mortality:All Enrolled Analysis Set included enrolled participants,Retreatment group:Safety-Retreatment Analysis Set.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL), or transformed follicular lymphoma (TFL) received conditioning chemotherapy (fludarabine 30 mg/m^2 intravenously [IV] over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel chimeric antigen receptor (CAR) transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of body weight (BW) on Day 0.

Reporting group title	Phase 2 (Pivotal Study): Cohort 1

Reporting group description:

Participants with refractory DLBCL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.

Reporting group title	Phase 2 (Pivotal Study): Cohort 2

Reporting group description:

Participants with refractory PMBCL or TFL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.

Reporting group title	Phase 2 (Safety Management Study): Cohort 3

Reporting group description:

Participants with relapsed or refractory transplant ineligible DLBCL, PMBCL, or TFL received conditioning chemotherapy (fludarabine 30 mg/m^2 IV over 30 minutes and cyclophosphamide 500 mg/m^2 IV over 60 minutes) on Days -5, -4, and -3; followed by a single infusion of axicabtagene ciloleucel CAR transduced autologous T cells administered IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0. Participants also received a prophylactic regimen of levetiracetam (750 mg orally or IV twice daily (BID) starting on Day 0) and tocilizumab (8 mg/kg IV over 1 hour (not to exceed 800 mg)) on Day 2).

Reporting group title	Phase 2 (Safety Management Study): Cohort 4

Reporting group description:

Participants with r/r DLBCL,PMBCL,TFL,or high-grade B-cell lymphoma(HGBCL)after 2 systemic lines of therapy will receive optional bridging therapy(dexamethasone 20mg to 40mg,eitherorally or IV daily for 1 to 4 days or 1g/m^2 of high-dose methylprednisolone(HDMP)for 3 days with rituximab at 375mg/m^2 weekly for 3 weeks or bendamustine 90 mg/m^2 on Days 1 and 2 and rituximab 375mg/m^2 on Day 1),conditioning chemotherapy(fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3;followed by single infusion of axicabtagene ciloleucel CAR transduced autologous T cells IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW. Participants will receive a prophylactic regimen of levetiracetam(750 mg orally or IV twice daily(BID)starting on Day 0).Participants received tocilizumab(initiated on persistent Grade 1 cytokine release syndrome(CRS)for over 24 hours)and dexamethasone(persistent Grade 1 CRS for over 72 hours and at

onset of Grade 1 neurologic toxicity).

Reporting group title	Phase 2 (Safety Management Study): Cohort 5

Reporting group description:

Participants with r/r DLBCL, PMBCL ,TFL, or HGBCL after 2 systemic lines of therapy received debulking therapy (R-CHOP:rituximab 375mg/m^2 D1,doxorubicin 50mg/m^2 D1,prednisone 100mg D1 to D5,cyclophosphamide 750mg/m^2 D1,vincristine 1.4 mg/m^2 D1 or R-ICE:rituximab 375mg/ m^2 D1,ifosfamide 5g/m^2 24h-CI D2,carboplatin AUC5 D2 maximum dose 800mg,etoposide 100 mg/m^2/day D1 to D3 or R-GEMOX:rituximab 375mg/m^2 D1,gemcitabine 1000mg/m^2 D2,oxaliplatin 100mg/m^2 D2 or R-GDP:rituximab 375mg/m^2 D1 or D8,gemcitabine 1g/m^2 D1 & D8,dexamethasone 40mg D1 to D4,cisplatin 75mg/m^2 D1(or carboplatin AUC5 D1) or radiotherapy:20 to 30 Gy), conditioning chemotherapy (fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3; followed by single infusion of axicabtagene ciloleucel at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0. Participants also received a prophylactic regimen of levetiracetam (750 mg orally or IV BID starting on D0).D=Day.

Reporting group title	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 5

Reporting group description:

Participants who initially responded and subsequently relapsed, became eligible for second course of conditioning chemotherapy and axicabtagene ciloleucel. Participants received the same axicabtagene ciloleucel regimen as the original target dose.

Reporting group title	Retreatment Axicabtagene Ciloleucel: Phase 1

Reporting group description:

Participants who initially responded and subsequently relapsed, became eligible for second course of conditioning chemotherapy and axicabtagene ciloleucel. Participants received the axicabtagene ciloleucel regimen selected for Phase 2.

Reporting group title	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 1

Reporting group description:

Participants who initially responded and subsequently relapsed, became eligible for second course of conditioning chemotherapy and axicabtagene ciloleucel. Participants received the same axicabtagene ciloleucel regimen as the original target dose.

Reporting group title	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 2

Reporting group description:

Participants who initially responded and subsequently relapsed, became eligible for second course of conditioning chemotherapy and axicabtagene ciloleucel. Participants received the same axicabtagene ciloleucel regimen as the original target dose.

Reporting group title	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 3

Reporting group description:

Participants who initially responded and subsequently relapsed, became eligible for second course of conditioning chemotherapy and axicabtagene ciloleucel. Participants received the same axicabtagene ciloleucel regimen as the original target dose.

Reporting group title	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 4

Reporting group description:

Participants who initially responded and subsequently relapsed, became eligible for second course of conditioning chemotherapy and axicabtagene ciloleucel. Participants received the same axicabtagene ciloleucel regimen as the original target dose.

Reporting group title	Phase 2 (Safety Management Study): Cohort 6

Reporting group description:

Participants with r/r DLBCL,PMBCL,TFL orHGBCL after 2 systemic lines of therapy may receive bridging therapy(dexamethasone 20mg to 40mg,orally or IV daily for 1 to 4 days or 1g/m^2 HDMP for 3 days with rituximab at 375mg/m^2 weekly for 3 weeks or bendamustine 90 mg/m^2 on Days 1 and 2 and rituximab 375mg/m^2 on Day 1),conditioning chemotherapy(fludarabine 30mg/m^2 IV and cyclophosphamide 500mg/m^2 IV)on Days -5,-4, and -3; followed by single infusion of axicabtagene ciloleucel CAR transduced autologous T cells IV at a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg of BW on Day 0.Participants will also receive a prophylactic regimen of levetiracetam 750 mg orally or IV twice daily(BID)starting on Day 0)and corticosteroids(dexamethasone, 10 mg once daily on Days 0, 1, and 2).Participants received tocilizumab(initiated on persistent Grade 1 CRS for over 24 hours)and dexamethasone(persistent Grade 1 CRS for over 72 hours and at onset of Grade 1 neurologic toxicity).

Serious adverse events	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	40 / 77 (51.95%)	14 / 24 (58.33%)
number of deaths (all causes)	5	49	13
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			
subjects affected / exposed	1 / 7 (14.29%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lymphoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			

subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Gait disturbance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	1 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health ~ deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary ~ disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reexpansion pulmonary oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	3 / 3	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase			

increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 7 (14.29%)	16 / 77 (20.78%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	1 / 1	17 / 17	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated ~ neurotoxicity syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgraphia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Leukoencephalopathy			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	1 / 7 (14.29%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apraxia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Cerebral venous sinus thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disturbance in attention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspraxia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine with aura			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure like phenomena			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriplegia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			

subjects affected / exposed	1 / 7 (14.29%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Visual impairment			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue ulceration			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Toxic skin eruption			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bone pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 7 (28.57%)	7 / 77 (9.09%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	1 / 2	1 / 9	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			

subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19 pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus enteritis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human herpesvirus 6 encephalitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial ~ viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract ~ infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 38 (68.42%)	24 / 41 (58.54%)	27 / 50 (54.00%)
number of deaths (all causes)	23	20	37
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			
subjects affected / exposed	3 / 38 (7.89%)	3 / 41 (7.32%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Squamous cell carcinoma			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Carcinoma in situ			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Central nervous system lymphoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	3 / 50 (6.00%)
occurrences causally related to treatment / all	3 / 4	2 / 2	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Gait disturbance			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 38 (7.89%)	2 / 41 (4.88%)	5 / 50 (10.00%)
occurrences causally related to treatment / all	1 / 4	2 / 2	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health ~ deterioration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			

subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 38 (0.00%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary ~ disease			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reexpansion pulmonary oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	3 / 38 (7.89%)	1 / 41 (2.44%)	5 / 50 (10.00%)
occurrences causally related to treatment / all	3 / 3	1 / 1	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			

subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			

subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Somnolence			
subjects affected / exposed	2 / 38 (5.26%)	3 / 41 (7.32%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	2 / 2	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	9 / 38 (23.68%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	10 / 10	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	3 / 50 (6.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	4 / 50 (8.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated ~ neurotoxicity syndrome			
subjects affected / exposed	1 / 38 (2.63%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgraphia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoencephalopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apraxia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous sinus thrombosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disturbance in attention			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspraxia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine with aura			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure like phenomena			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriplegia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	1 / 38 (2.63%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Visual impairment			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Vomiting			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue ulceration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Toxic skin eruption			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Anuria			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cystitis haemorrhagic			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 38 (2.63%)	3 / 41 (7.32%)	3 / 50 (6.00%)
occurrences causally related to treatment / all	1 / 1	2 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	3 / 50 (6.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	3 / 3
Bacteraemia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19 pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus enteritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human herpesvirus 6 encephalitis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia respiratory syncytial ~ viral			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract ~ infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acidosis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 5	Retreatment Axicabtagene Ciloleucel: Phase 1	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 1
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	5 / 9 (55.56%)
number of deaths (all causes)	2	1	8
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lymphoma			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health ~ deterioration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary ~ disease			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reexpansion pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated ~ neurotoxicity syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgraphia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoencephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apraxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous sinus thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspraxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine with aura			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure like phenomena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriplegia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Visual impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue ulceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Toxic skin eruption			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cystitis haemorrhagic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19 pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human herpesvirus 6 encephalitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial ~ viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract ~ infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acidosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 2	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 3	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 4
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	2 / 2 (100.00%)	0 / 2 (0.00%)
number of deaths (all causes)	2	1	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lymphoma			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health ~ deterioration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary ~ disease			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reexpansion pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated ~ neurotoxicity syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgraphia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoencephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apraxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous sinus thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspraxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine with aura			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure like phenomena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriplegia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Visual impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue ulceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Toxic skin eruption			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cystitis haemorrhagic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19 pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human herpesvirus 6 encephalitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial ~ viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract ~ infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acidosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2 (Safety Management Study): Cohort 6		
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 40 (62.50%)		
number of deaths (all causes)	20		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			

subjects affected / exposed	2 / 40 (5.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			
Myelodysplastic syndrome				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute myeloid leukaemia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diffuse large B-cell lymphoma				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carcinoma in situ				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cancer pain				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Basal cell carcinoma				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Central nervous system lymphoma				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Hypotension				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Shock				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Gait disturbance				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Fatigue				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthenia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	4 / 40 (10.00%)			
occurrences causally related to treatment / all	2 / 4			
deaths causally related to treatment / all	0 / 0			
General physical health ~ deterioration				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Haemophagocytic lymphohistiocytosis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Hypoxia				

subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Acute respiratory failure				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspiration				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary ~ disease				

subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reexpansion pulmonary oedema				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Confusional state				
subjects affected / exposed	5 / 40 (12.50%)			
occurrences causally related to treatment / all	5 / 5			
deaths causally related to treatment / all	0 / 0			
Agitation				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disorientation				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Hallucination				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Restlessness				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Alanine aminotransferase increased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ejection fraction decreased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Platelet count decreased				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutrophil count decreased				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Troponin T increased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Hip fracture				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brain herniation				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seroma				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Cardiac arrest				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Atrial fibrillation				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute left ventricular failure				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomyopathy				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus tachycardia				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Somnolence				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aphasia				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Tremor				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune effector cell-associated ~ neurotoxicity syndrome				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysgraphia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Headache				

subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Depressed level of consciousness				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysarthria				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukoencephalopathy				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Presyncope				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Apraxia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Ataxia				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain injury				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral venous sinus thrombosis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebellar infarction				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain oedema				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Disturbance in attention				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspraxia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hemiparesis				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lethargy				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Memory impairment				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine with aura				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxic encephalopathy				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Seizure like phenomena				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Quadriplegia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Febrile neutropenia				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Neutropenia				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone marrow failure				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Febrile bone marrow aplasia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukopenia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Visual impairment				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				

Vomiting				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tongue ulceration				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				

subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Toxic skin eruption			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anuria			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Cystitis haemorrhagic				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back pain				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amyotrophy				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Arthralgia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Musculoskeletal pain				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Pneumonia				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences causally related to treatment / all	3 / 3			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Covid-19				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Urinary tract infection				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Covid-19 pneumonia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus colitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenovirus infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atypical pneumonia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus enteritis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Human herpesvirus 6 encephalitis				

subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myelitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral herpes				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumococcal sepsis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia necrotising				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia influenzal				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial ~ viral				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia staphylococcal				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinitis				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotavirus infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Upper respiratory tract infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract ~ infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acidosis				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Decreased appetite				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lactic acidosis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Phase 1 Study: Axicabtagene Ciloleucel and Conditioning Chemot	Phase 2 (Pivotal Study): Cohort 1	Phase 2 (Pivotal Study): Cohort 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	77 / 77 (100.00%)	23 / 24 (95.83%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Cancer pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	3 / 7 (42.86%)	44 / 77 (57.14%)	14 / 24 (58.33%)
occurrences (all)	3	49	22
Hypertension			
subjects affected / exposed	1 / 7 (14.29%)	9 / 77 (11.69%)	4 / 24 (16.67%)
occurrences (all)	1	14	8
Capillary leak syndrome			
subjects affected / exposed	1 / 7 (14.29%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 7 (14.29%)	32 / 77 (41.56%)	7 / 24 (29.17%)
occurrences (all)	1	34	7
Fatigue			

subjects affected / exposed	2 / 7 (28.57%)	34 / 77 (44.16%)	12 / 24 (50.00%)
occurrences (all)	3	41	15
Pyrexia			
subjects affected / exposed	7 / 7 (100.00%)	66 / 77 (85.71%)	21 / 24 (87.50%)
occurrences (all)	9	81	32
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	2 / 24 (8.33%)
occurrences (all)	0	5	2
Pain			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	1 / 24 (4.17%)
occurrences (all)	0	5	1
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	0	4	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	2 / 24 (8.33%)
occurrences (all)	0	5	2
Gait disturbance			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Influenza like illness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 7 (14.29%)	12 / 77 (15.58%)	2 / 24 (8.33%)
occurrences (all)	1	14	2
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Swelling			

subjects affected / exposed	1 / 7 (14.29%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
Puncture site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Hernia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	3 / 7 (42.86%)	10 / 77 (12.99%)	3 / 24 (12.50%)
occurrences (all)	3	10	3
Graft versus host disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Scrotal oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Perineal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	4 / 7 (57.14%)	24 / 77 (31.17%)	5 / 24 (20.83%)
occurrences (all)	5	27	5
Cough			
subjects affected / exposed	2 / 7 (28.57%)	18 / 77 (23.38%)	6 / 24 (25.00%)
occurrences (all)	4	20	12
Nasal congestion			
subjects affected / exposed	1 / 7 (14.29%)	4 / 77 (5.19%)	1 / 24 (4.17%)
occurrences (all)	2	4	1
Oropharyngeal pain			

subjects affected / exposed	1 / 7 (14.29%)	4 / 77 (5.19%)	2 / 24 (8.33%)
occurrences (all)	1	5	2
Pleural effusion			
subjects affected / exposed	3 / 7 (42.86%)	9 / 77 (11.69%)	1 / 24 (4.17%)
occurrences (all)	3	9	1
Dyspnoea			
subjects affected / exposed	3 / 7 (42.86%)	11 / 77 (14.29%)	4 / 24 (16.67%)
occurrences (all)	4	11	5
Wheezing			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	0	4	0
Pulmonary oedema			
subjects affected / exposed	2 / 7 (28.57%)	5 / 77 (6.49%)	0 / 24 (0.00%)
occurrences (all)	2	6	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 7 (14.29%)	4 / 77 (5.19%)	1 / 24 (4.17%)
occurrences (all)	1	4	1
Tachypnoea			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences (all)	0	3	1
Laryngeal haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Atelectasis			
subjects affected / exposed	1 / 7 (14.29%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Paranasal cyst			

subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	9 / 77 (11.69%)	3 / 24 (12.50%)
occurrences (all)	0	9	3
Insomnia			
subjects affected / exposed	1 / 7 (14.29%)	7 / 77 (9.09%)	2 / 24 (8.33%)
occurrences (all)	1	7	4
Confusional state			
subjects affected / exposed	1 / 7 (14.29%)	19 / 77 (24.68%)	8 / 24 (33.33%)
occurrences (all)	1	20	10
Agitation			
subjects affected / exposed	1 / 7 (14.29%)	5 / 77 (6.49%)	3 / 24 (12.50%)
occurrences (all)	1	6	3
Hallucination			
subjects affected / exposed	1 / 7 (14.29%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	1	4	0
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	1 / 24 (4.17%)
occurrences (all)	0	4	1
Delirium			
subjects affected / exposed	1 / 7 (14.29%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Bradyphrenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Disorientation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Depression			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Restlessness			
subjects affected / exposed	1 / 7 (14.29%)	2 / 77 (2.60%)	1 / 24 (4.17%)
occurrences (all)	1	2	1

Mood altered			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Investigations			
White blood cell count decreased			
subjects affected / exposed	2 / 7 (28.57%)	23 / 77 (29.87%)	8 / 24 (33.33%)
occurrences (all)	7	63	15
Platelet count decreased			
subjects affected / exposed	2 / 7 (28.57%)	25 / 77 (32.47%)	5 / 24 (20.83%)
occurrences (all)	6	46	10
Neutrophil count decreased			
subjects affected / exposed	2 / 7 (28.57%)	27 / 77 (35.06%)	7 / 24 (29.17%)
occurrences (all)	9	63	16
Lymphocyte count decreased			
subjects affected / exposed	2 / 7 (28.57%)	12 / 77 (15.58%)	6 / 24 (25.00%)
occurrences (all)	2	24	9
C-reactive protein increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 7 (28.57%)	11 / 77 (14.29%)	4 / 24 (16.67%)
occurrences (all)	3	18	9
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 7 (28.57%)	11 / 77 (14.29%)	5 / 24 (20.83%)
occurrences (all)	2	14	7
Alanine aminotransferase increased			
subjects affected / exposed	3 / 7 (42.86%)	13 / 77 (16.88%)	5 / 24 (20.83%)
occurrences (all)	3	14	8
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	2 / 24 (8.33%)
occurrences (all)	0	5	2
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 7 (14.29%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences (all)	1	3	3
Serum ferritin increased			

subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Weight increased			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	0	6	0
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences (all)	0	4	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood immunoglobulin G decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	3	0
Blood potassium decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Immunoglobulins decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Blood albumin decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Blood magnesium decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0

Injury, poisoning and procedural complications			
Skin abrasion			
subjects affected / exposed	1 / 7 (14.29%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Infusion related reaction			
subjects affected / exposed	2 / 7 (28.57%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	2	1	1
Fall			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	2 / 24 (8.33%)
occurrences (all)	0	5	2
Head injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 7 (14.29%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	1 / 24 (4.17%)
occurrences (all)	0	5	1
Sinus bradycardia			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	2 / 24 (8.33%)
occurrences (all)	0	5	8
Ventricular arrhythmia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 77 (3.90%)	2 / 24 (8.33%)
occurrences (all)	1	3	2
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	19 / 77 (24.68%)	2 / 24 (8.33%)
occurrences (all)	0	25	11
Tachycardia			
subjects affected / exposed	3 / 7 (42.86%)	29 / 77 (37.66%)	8 / 24 (33.33%)
occurrences (all)	3	35	9
Bradycardia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	4	0
Acute left ventricular failure			

subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	0 / 24 (0.00%)
occurrences (all)	0	4	0
Nervous system disorders			
Tremor			
subjects affected / exposed	4 / 7 (57.14%)	23 / 77 (29.87%)	6 / 24 (25.00%)
occurrences (all)	4	23	7
Headache			
subjects affected / exposed	3 / 7 (42.86%)	34 / 77 (44.16%)	12 / 24 (50.00%)
occurrences (all)	4	39	14
Encephalopathy			
subjects affected / exposed	4 / 7 (57.14%)	20 / 77 (25.97%)	6 / 24 (25.00%)
occurrences (all)	5	22	7
Dysarthria			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences (all)	0	3	1
Somnolence			
subjects affected / exposed	3 / 7 (42.86%)	10 / 77 (12.99%)	4 / 24 (16.67%)
occurrences (all)	3	12	5
Aphasia			
subjects affected / exposed	1 / 7 (14.29%)	13 / 77 (16.88%)	4 / 24 (16.67%)
occurrences (all)	1	14	5
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)	12 / 77 (15.58%)	9 / 24 (37.50%)
occurrences (all)	1	13	10
Memory impairment			
subjects affected / exposed	0 / 7 (0.00%)	6 / 77 (7.79%)	2 / 24 (8.33%)
occurrences (all)	0	6	2
Paraesthesia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	2 / 24 (8.33%)
occurrences (all)	0	5	2

Dyskinesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Dysgraphia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	3 / 77 (3.90%)	0 / 24 (0.00%)
occurrences (all)	0	6	0
Disturbance in attention			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	2 / 24 (8.33%)
occurrences (all)	0	1	3
Post herpetic neuralgia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Head discomfort			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Dementia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Apraxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Poor sucking reflex			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Presyncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Sensory loss			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 7 (57.14%)	47 / 77 (61.04%)	13 / 24 (54.17%)
occurrences (all)	7	75	20
Neutropenia			
subjects affected / exposed	3 / 7 (42.86%)	26 / 77 (33.77%)	12 / 24 (50.00%)
occurrences (all)	5	41	20
Thrombocytopenia			
subjects affected / exposed	2 / 7 (28.57%)	24 / 77 (31.17%)	6 / 24 (25.00%)
occurrences (all)	2	30	7
Febrile neutropenia			
subjects affected / exposed	4 / 7 (57.14%)	21 / 77 (27.27%)	8 / 24 (33.33%)
occurrences (all)	4	22	9
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	13 / 77 (16.88%)	3 / 24 (12.50%)
occurrences (all)	0	19	7
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	0 / 24 (0.00%)
occurrences (all)	0	6	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hypoacusis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	1 / 7 (14.29%)	2 / 77 (2.60%)	2 / 24 (8.33%)
occurrences (all)	1	2	2
Vitreous floaters			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Eyelid function disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 7 (14.29%)	17 / 77 (22.08%)	11 / 24 (45.83%)
occurrences (all)	1	18	12
Constipation			
subjects affected / exposed	2 / 7 (28.57%)	15 / 77 (19.48%)	5 / 24 (20.83%)
occurrences (all)	3	17	9
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	22 / 77 (28.57%)	12 / 24 (50.00%)
occurrences (all)	1	27	13
Diarrhoea			
subjects affected / exposed	5 / 7 (71.43%)	29 / 77 (37.66%)	8 / 24 (33.33%)
occurrences (all)	5	32	9
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	8 / 77 (10.39%)	3 / 24 (12.50%)
occurrences (all)	1	8	3
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 7 (14.29%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Anal incontinence			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Stomatitis			

subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	2 / 7 (28.57%)	7 / 77 (9.09%)	3 / 24 (12.50%)
occurrences (all)	2	7	3
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	2 / 24 (8.33%)
occurrences (all)	0	6	2
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	0	4	0
Toothache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Flatulence			
subjects affected / exposed	1 / 7 (14.29%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences (all)	1	3	1
Ascites			
subjects affected / exposed	1 / 7 (14.29%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Odynophagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0

Rash			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	6 / 77 (7.79%)	2 / 24 (8.33%)
occurrences (all)	0	6	2
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	2 / 24 (8.33%)
occurrences (all)	0	2	2
Pollakiuria			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Acute kidney injury			
subjects affected / exposed	1 / 7 (14.29%)	6 / 77 (7.79%)	0 / 24 (0.00%)
occurrences (all)	1	7	0
Urinary incontinence			
subjects affected / exposed	0 / 7 (0.00%)	7 / 77 (9.09%)	1 / 24 (4.17%)
occurrences (all)	0	7	1
Urinary retention			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	0	4	0
Haematuria			

subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	0	4	0
Urinary tract obstruction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Bladder spasm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	2 / 7 (28.57%)	10 / 77 (12.99%)	3 / 24 (12.50%)
occurrences (all)	2	10	3
Pain in extremity			
subjects affected / exposed	1 / 7 (14.29%)	7 / 77 (9.09%)	4 / 24 (16.67%)
occurrences (all)	1	7	4
Muscular weakness			
subjects affected / exposed	3 / 7 (42.86%)	11 / 77 (14.29%)	2 / 24 (8.33%)
occurrences (all)	4	11	2
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	12 / 77 (15.58%)	2 / 24 (8.33%)
occurrences (all)	0	13	2
Back pain			
subjects affected / exposed	1 / 7 (14.29%)	13 / 77 (16.88%)	2 / 24 (8.33%)
occurrences (all)	1	14	2
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Flank pain			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Bone pain			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Neck pain			

subjects affected / exposed	2 / 7 (28.57%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences (all)	2	3	1
Tenosynovitis stenosans			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	2 / 7 (28.57%)	5 / 77 (6.49%)	4 / 24 (16.67%)
occurrences (all)	3	5	4
Herpes zoster			
subjects affected / exposed	2 / 7 (28.57%)	3 / 77 (3.90%)	3 / 24 (12.50%)
occurrences (all)	2	3	3
Sinusitis			
subjects affected / exposed	2 / 7 (28.57%)	3 / 77 (3.90%)	2 / 24 (8.33%)
occurrences (all)	2	3	3
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)	3 / 77 (3.90%)	1 / 24 (4.17%)
occurrences (all)	1	3	1
Pneumonia			
subjects affected / exposed	1 / 7 (14.29%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	1	4	0
Candida infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Oral candidiasis			
subjects affected / exposed	1 / 7 (14.29%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Clostridium difficile infection			
subjects affected / exposed	0 / 7 (0.00%)	5 / 77 (6.49%)	0 / 24 (0.00%)
occurrences (all)	0	5	0
Covid-19			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	3
Clostridium difficile colitis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 7 (14.29%)	1 / 77 (1.30%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Folliculitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 77 (2.60%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Ear infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Wound infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	2 / 7 (28.57%)	23 / 77 (29.87%)	8 / 24 (33.33%)
occurrences (all)	2	28	11
Decreased appetite			
subjects affected / exposed	3 / 7 (42.86%)	31 / 77 (40.26%)	12 / 24 (50.00%)
occurrences (all)	3	33	14
Hypophosphataemia			
subjects affected / exposed	3 / 7 (42.86%)	19 / 77 (24.68%)	6 / 24 (25.00%)
occurrences (all)	5	29	10
Hyponatraemia			
subjects affected / exposed	4 / 7 (57.14%)	20 / 77 (25.97%)	10 / 24 (41.67%)
occurrences (all)	4	26	11
Hypoalbuminaemia			
subjects affected / exposed	2 / 7 (28.57%)	22 / 77 (28.57%)	9 / 24 (37.50%)
occurrences (all)	2	24	16
Hypocalcaemia			
subjects affected / exposed	2 / 7 (28.57%)	23 / 77 (29.87%)	11 / 24 (45.83%)
occurrences (all)	2	25	11
Hypernatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 77 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	2
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	12 / 77 (15.58%)	6 / 24 (25.00%)
occurrences (all)	0	23	26
Hypomagnesaemia			
subjects affected / exposed	2 / 7 (28.57%)	5 / 77 (6.49%)	4 / 24 (16.67%)
occurrences (all)	3	5	4
Dehydration			
subjects affected / exposed	2 / 7 (28.57%)	5 / 77 (6.49%)	4 / 24 (16.67%)
occurrences (all)	2	6	4
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	6 / 77 (7.79%)	1 / 24 (4.17%)
occurrences (all)	0	10	3
Hypermagnesaemia			

subjects affected / exposed	0 / 7 (0.00%)	1 / 77 (1.30%)	2 / 24 (8.33%)
occurrences (all)	0	1	2
Malnutrition			
subjects affected / exposed	0 / 7 (0.00%)	4 / 77 (5.19%)	0 / 24 (0.00%)
occurrences (all)	0	4	0
Metabolic acidosis			
subjects affected / exposed	1 / 7 (14.29%)	3 / 77 (3.90%)	0 / 24 (0.00%)
occurrences (all)	1	3	0

Non-serious adverse events	Phase 2 (Safety Management Study): Cohort 3	Phase 2 (Safety Management Study): Cohort 4	Phase 2 (Safety Management Study): Cohort 5
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 38 (100.00%)	41 / 41 (100.00%)	50 / 50 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	0	1	2
Cancer pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypotension			
subjects affected / exposed	22 / 38 (57.89%)	24 / 41 (58.54%)	25 / 50 (50.00%)
occurrences (all)	30	30	28
Hypertension			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	3 / 50 (6.00%)
occurrences (all)	2	2	3
Capillary leak syndrome			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Deep vein thrombosis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Hot flush			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	11 / 38 (28.95%)	11 / 41 (26.83%)	14 / 50 (28.00%)
occurrences (all)	16	13	15
Fatigue			
subjects affected / exposed	18 / 38 (47.37%)	19 / 41 (46.34%)	12 / 50 (24.00%)
occurrences (all)	21	20	13
Pyrexia			
subjects affected / exposed	35 / 38 (92.11%)	39 / 41 (95.12%)	40 / 50 (80.00%)
occurrences (all)	48	49	60
Asthenia			
subjects affected / exposed	3 / 38 (7.89%)	2 / 41 (4.88%)	4 / 50 (8.00%)
occurrences (all)	3	2	5
Pain			
subjects affected / exposed	5 / 38 (13.16%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	5	0	0
Malaise			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	1	1	2
Non-cardiac chest pain			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Gait disturbance			
subjects affected / exposed	4 / 38 (10.53%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences (all)	4	0	2
Influenza like illness			

subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	3	2	0
Oedema			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	0	1	2
Oedema peripheral			
subjects affected / exposed	6 / 38 (15.79%)	2 / 41 (4.88%)	3 / 50 (6.00%)
occurrences (all)	7	2	3
Chest pain			
subjects affected / exposed	1 / 38 (2.63%)	3 / 41 (7.32%)	0 / 50 (0.00%)
occurrences (all)	1	3	0
Peripheral swelling			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Swelling			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Puncture site pain			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	0 / 50 (0.00%)
occurrences (all)	0	3	0
Catheter site pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	2 / 38 (5.26%)	6 / 41 (14.63%)	1 / 50 (2.00%)
occurrences (all)	2	6	1
Graft versus host disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

Scrotal oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	9 / 38 (23.68%)	6 / 41 (14.63%)	5 / 50 (10.00%)
occurrences (all)	10	6	5
Cough			
subjects affected / exposed	9 / 38 (23.68%)	11 / 41 (26.83%)	6 / 50 (12.00%)
occurrences (all)	11	12	6
Nasal congestion			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	2	1	0
Oropharyngeal pain			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	2	1	2
Pleural effusion			
subjects affected / exposed	5 / 38 (13.16%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	5	3	0
Dyspnoea			
subjects affected / exposed	5 / 38 (13.16%)	3 / 41 (7.32%)	4 / 50 (8.00%)
occurrences (all)	5	3	5
Wheezing			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Tachypnoea			

subjects affected / exposed	3 / 38 (7.89%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	3	0	0
Hiccups			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Laryngeal haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Atelectasis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Paranasal cyst			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 38 (10.53%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences (all)	4	0	2
Insomnia			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	4	2	0
Confusional state			
subjects affected / exposed	16 / 38 (42.11%)	4 / 41 (9.76%)	6 / 50 (12.00%)
occurrences (all)	19	6	8
Agitation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	1 / 38 (2.63%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	1	2	0

Mental status changes			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Delirium			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences (all)	2	0	2
Bradyphrenia			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Disorientation			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Depression			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Mood altered			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Investigations			
White blood cell count decreased			
subjects affected / exposed	10 / 38 (26.32%)	6 / 41 (14.63%)	14 / 50 (28.00%)
occurrences (all)	13	13	24
Platelet count decreased			
subjects affected / exposed	9 / 38 (23.68%)	10 / 41 (24.39%)	17 / 50 (34.00%)
occurrences (all)	16	17	20
Neutrophil count decreased			
subjects affected / exposed	11 / 38 (28.95%)	13 / 41 (31.71%)	25 / 50 (50.00%)
occurrences (all)	18	29	49
Lymphocyte count decreased			
subjects affected / exposed	4 / 38 (10.53%)	4 / 41 (9.76%)	8 / 50 (16.00%)
occurrences (all)	4	4	12
C-reactive protein increased			

subjects affected / exposed	2 / 38 (5.26%)	5 / 41 (12.20%)	7 / 50 (14.00%)
occurrences (all)	2	6	7
Weight decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	4 / 50 (8.00%)
occurrences (all)	1	0	4
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 38 (18.42%)	4 / 41 (9.76%)	7 / 50 (14.00%)
occurrences (all)	10	4	9
Alanine aminotransferase increased			
subjects affected / exposed	8 / 38 (21.05%)	5 / 41 (12.20%)	7 / 50 (14.00%)
occurrences (all)	12	6	8
Blood creatinine increased			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	1 / 50 (2.00%)
occurrences (all)	0	3	1
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 38 (10.53%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences (all)	4	1	1
Serum ferritin increased			
subjects affected / exposed	2 / 38 (5.26%)	3 / 41 (7.32%)	5 / 50 (10.00%)
occurrences (all)	2	3	5
Weight increased			
subjects affected / exposed	1 / 38 (2.63%)	4 / 41 (9.76%)	4 / 50 (8.00%)
occurrences (all)	1	4	4
Blood bilirubin increased			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	5	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	4 / 50 (8.00%)
occurrences (all)	0	5	6
Blood immunoglobulin G decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	3 / 50 (6.00%)
occurrences (all)	1	0	3
Blood potassium decreased			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	4 / 50 (8.00%)
occurrences (all)	0	0	6
Urine output decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Immunoglobulins decreased			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	0 / 50 (0.00%)
occurrences (all)	0	3	0
Blood fibrinogen decreased			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	5	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	3 / 50 (6.00%)
occurrences (all)	0	0	3
Blood albumin decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin abrasion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Head injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	1	1	2
Sinus bradycardia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	3 / 50 (6.00%)
occurrences (all)	5	2	3
Tachycardia			
subjects affected / exposed	6 / 38 (15.79%)	7 / 41 (17.07%)	7 / 50 (14.00%)
occurrences (all)	7	8	8
Bradycardia			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Acute left ventricular failure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Tremor			
subjects affected / exposed	16 / 38 (42.11%)	5 / 41 (12.20%)	11 / 50 (22.00%)
occurrences (all)	16	5	12
Headache			
subjects affected / exposed	19 / 38 (50.00%)	16 / 41 (39.02%)	17 / 50 (34.00%)
occurrences (all)	21	20	20
Encephalopathy			

subjects affected / exposed	9 / 38 (23.68%)	5 / 41 (12.20%)	5 / 50 (10.00%)
occurrences (all)	10	6	5
Dysarthria			
subjects affected / exposed	3 / 38 (7.89%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences (all)	3	4	1
Somnolence			
subjects affected / exposed	3 / 38 (7.89%)	5 / 41 (12.20%)	5 / 50 (10.00%)
occurrences (all)	6	5	5
Aphasia			
subjects affected / exposed	8 / 38 (21.05%)	4 / 41 (9.76%)	9 / 50 (18.00%)
occurrences (all)	10	4	9
Dizziness			
subjects affected / exposed	5 / 38 (13.16%)	7 / 41 (17.07%)	8 / 50 (16.00%)
occurrences (all)	6	8	9
Memory impairment			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences (all)	5	3	1
Dysgeusia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Dysgraphia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	3 / 50 (6.00%)
occurrences (all)	0	0	3
Seizure			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Disturbance in attention			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Post herpetic neuralgia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Head discomfort			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Dementia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Apraxia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Muscle contractions involuntary			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Poor sucking reflex			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Sensory loss			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	22 / 38 (57.89%)	19 / 41 (46.34%)	19 / 50 (38.00%)
occurrences (all)	34	27	47
Neutropenia			
subjects affected / exposed	18 / 38 (47.37%)	16 / 41 (39.02%)	16 / 50 (32.00%)
occurrences (all)	30	24	25

Thrombocytopenia			
subjects affected / exposed	12 / 38 (31.58%)	7 / 41 (17.07%)	9 / 50 (18.00%)
occurrences (all)	21	9	10
Febrile neutropenia			
subjects affected / exposed	10 / 38 (26.32%)	3 / 41 (7.32%)	2 / 50 (4.00%)
occurrences (all)	10	3	2
Pancytopenia			
subjects affected / exposed	0 / 38 (0.00%)	4 / 41 (9.76%)	2 / 50 (4.00%)
occurrences (all)	0	4	3
Leukopenia			
subjects affected / exposed	4 / 38 (10.53%)	7 / 41 (17.07%)	8 / 50 (16.00%)
occurrences (all)	4	14	11
Lymphopenia			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	0 / 50 (0.00%)
occurrences (all)	0	7	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Ear pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences (all)	2	1	1
Vitreous floaters			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Eyelid function disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Vomiting			
subjects affected / exposed	9 / 38 (23.68%)	6 / 41 (14.63%)	7 / 50 (14.00%)
occurrences (all)	10	8	7
Constipation			
subjects affected / exposed	7 / 38 (18.42%)	6 / 41 (14.63%)	8 / 50 (16.00%)
occurrences (all)	7	6	8
Nausea			
subjects affected / exposed	15 / 38 (39.47%)	12 / 41 (29.27%)	12 / 50 (24.00%)
occurrences (all)	18	17	14
Diarrhoea			
subjects affected / exposed	16 / 38 (42.11%)	25 / 41 (60.98%)	11 / 50 (22.00%)
occurrences (all)	25	29	11
Abdominal pain			
subjects affected / exposed	3 / 38 (7.89%)	2 / 41 (4.88%)	5 / 50 (10.00%)
occurrences (all)	3	2	5
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Anal incontinence			
subjects affected / exposed	0 / 38 (0.00%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences (all)	0	2	1
Stomatitis			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	4 / 50 (8.00%)
occurrences (all)	2	1	4
Dry mouth			
subjects affected / exposed	3 / 38 (7.89%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	3	5	0
Dyspepsia			
subjects affected / exposed	0 / 38 (0.00%)	2 / 41 (4.88%)	3 / 50 (6.00%)
occurrences (all)	0	2	3
Abdominal distension			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Abdominal pain upper			
subjects affected / exposed	3 / 38 (7.89%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	3	1	2

Dysphagia			
subjects affected / exposed	5 / 38 (13.16%)	3 / 41 (7.32%)	2 / 50 (4.00%)
occurrences (all)	5	3	2
Toothache			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Odynophagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	2	2	0
Rash			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	2	1	2
Pruritus			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	3 / 50 (6.00%)
occurrences (all)	1	1	3
Hyperhidrosis			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	2 / 50 (4.00%)
occurrences (all)	2	2	2
Alopecia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Erythema			

subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	3 / 38 (7.89%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	3	1	0
Pollakiuria			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences (all)	2	2	1
Acute kidney injury			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences (all)	2	2	1
Urinary incontinence			
subjects affected / exposed	4 / 38 (10.53%)	1 / 41 (2.44%)	3 / 50 (6.00%)
occurrences (all)	4	1	3
Urinary retention			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Urinary tract obstruction			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Bladder spasm			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	5 / 38 (13.16%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences (all)	6	4	1
Pain in extremity			

subjects affected / exposed	1 / 38 (2.63%)	4 / 41 (9.76%)	1 / 50 (2.00%)
occurrences (all)	1	4	1
Muscular weakness			
subjects affected / exposed	4 / 38 (10.53%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	4	1	2
Arthralgia			
subjects affected / exposed	1 / 38 (2.63%)	4 / 41 (9.76%)	4 / 50 (8.00%)
occurrences (all)	1	4	4
Back pain			
subjects affected / exposed	1 / 38 (2.63%)	5 / 41 (12.20%)	4 / 50 (8.00%)
occurrences (all)	1	5	4
Muscle spasms			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences (all)	3	1	1
Flank pain			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Bone pain			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	3	1	0
Neck pain			
subjects affected / exposed	1 / 38 (2.63%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	1	2	0
Tenosynovitis stenosans			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	7 / 38 (18.42%)	3 / 41 (7.32%)	1 / 50 (2.00%)
occurrences (all)	7	3	1
Herpes zoster			
subjects affected / exposed	1 / 38 (2.63%)	4 / 41 (9.76%)	1 / 50 (2.00%)
occurrences (all)	1	5	1

Sinusitis			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	2	2	0
Urinary tract infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	2 / 50 (4.00%)
occurrences (all)	0	1	3
Pneumonia			
subjects affected / exposed	1 / 38 (2.63%)	6 / 41 (14.63%)	4 / 50 (8.00%)
occurrences (all)	1	7	4
Candida infection			
subjects affected / exposed	4 / 38 (10.53%)	0 / 41 (0.00%)	2 / 50 (4.00%)
occurrences (all)	4	0	2
Oral candidiasis			
subjects affected / exposed	1 / 38 (2.63%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	1	2	0
Clostridium difficile infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Covid-19			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	0 / 50 (0.00%)
occurrences (all)	0	3	0
Conjunctivitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Clostridium difficile colitis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Tooth infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0

Oral herpes			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	6 / 38 (15.79%)	6 / 41 (14.63%)	10 / 50 (20.00%)
occurrences (all)	9	7	13
Decreased appetite			
subjects affected / exposed	10 / 38 (26.32%)	3 / 41 (7.32%)	6 / 50 (12.00%)
occurrences (all)	10	4	6
Hypophosphataemia			
subjects affected / exposed	5 / 38 (13.16%)	6 / 41 (14.63%)	5 / 50 (10.00%)
occurrences (all)	5	7	7
Hyponatraemia			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	1 / 50 (2.00%)
occurrences (all)	3	3	1
Hypoalbuminaemia			

subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	0 / 50 (0.00%)
occurrences (all)	4	2	0
Hypocalcaemia			
subjects affected / exposed	4 / 38 (10.53%)	1 / 41 (2.44%)	1 / 50 (2.00%)
occurrences (all)	4	1	2
Hypernatraemia			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 50 (0.00%)
occurrences (all)	3	2	0
Hypomagnesaemia			
subjects affected / exposed	6 / 38 (15.79%)	2 / 41 (4.88%)	5 / 50 (10.00%)
occurrences (all)	7	3	9
Dehydration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 5	Retreatment Axicabtagene Ciloleucel: Phase 1	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	1 / 1 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Squamous cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	1 / 9 (11.11%)
occurrences (all)	1	3	1
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Capillary leak syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Subclavian vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
Fatigue			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Pyrexia			
subjects affected / exposed	2 / 2 (100.00%)	1 / 1 (100.00%)	9 / 9 (100.00%)
occurrences (all)	2	1	13
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Swelling			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Puncture site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Graft versus host disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Scrotal oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Perineal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	5 / 9 (55.56%)
occurrences (all)	0	0	5
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paranasal cyst			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	3 / 9 (33.33%)
occurrences (all)	0	1	3
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bradyphrenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Mood altered			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
White blood cell count decreased			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	3 / 9 (33.33%)
occurrences (all)	1	1	9
Platelet count decreased			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	3 / 9 (33.33%)
occurrences (all)	1	1	8
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	4 / 9 (44.44%)
occurrences (all)	0	0	11
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	3 / 9 (33.33%)
occurrences (all)	0	3	8
C-reactive protein increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	6
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Serum ferritin increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood immunoglobulin G decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immunoglobulins decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	4 / 9 (44.44%)
occurrences (all)	0	0	11
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Acute left ventricular failure			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	4 / 9 (44.44%)
occurrences (all)	0	0	5
Headache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	2	0	4
Encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Aphasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Dyskinesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysgraphia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dementia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Apraxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Poor sucking reflex			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Presyncope			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Sensory loss			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	3 / 9 (33.33%)
occurrences (all)	0	1	9
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	4
Pancytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	3 / 9 (33.33%)
occurrences (all)	1	1	3
Nausea			
subjects affected / exposed	2 / 2 (100.00%)	1 / 1 (100.00%)	4 / 9 (44.44%)
occurrences (all)	2	1	4
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Anal incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	1	0	3
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Neck pain			

subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Tenosynovitis stenosans			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	5
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	4 / 9 (44.44%)
occurrences (all)	0	0	5
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	3
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	3 / 9 (33.33%)
occurrences (all)	0	1	4
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	7
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	9
Hypomagnesaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	2 / 9 (22.22%)
occurrences (all)	0	1	5
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypermagnesaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Malnutrition			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 2	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 3	Retreatment Axicabtagene Ciloleucel: Phase 2 Cohort 4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	2 / 2 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Hypertension			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Capillary leak syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	2 / 2 (100.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	2 / 2 (100.00%)	1 / 2 (50.00%)	2 / 2 (100.00%)
occurrences (all)	3	1	2
Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Puncture site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Hernia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Graft versus host disease			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			

Scrotal oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	1
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Atelectasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paranasal cyst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Confusional state			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bradyphrenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Mood altered			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Investigations			
White blood cell count decreased			
subjects affected / exposed	2 / 2 (100.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	6	0	2
Platelet count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	1
Neutrophil count decreased			
subjects affected / exposed	2 / 2 (100.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	2
Lymphocyte count decreased			
subjects affected / exposed	2 / 2 (100.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	1
C-reactive protein increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood immunoglobulin G decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Immunoglobulins decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Acute left ventricular failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Tremor			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	2 / 2 (100.00%)
occurrences (all)	2	0	4
Encephalopathy			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Aphasia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Dizziness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Dyskinesia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dysgraphia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dementia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Apraxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Poor sucking reflex			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sensory loss			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Neutropenia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pancytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 2 (100.00%)
occurrences (all)	0	0	2
Constipation			
subjects affected / exposed	2 / 2 (100.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	2 / 2 (100.00%)
occurrences (all)	0	1	2
Diarrhoea			
subjects affected / exposed	2 / 2 (100.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	3	0	1
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			

subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis stenosans			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Clostridium difficile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Hyponatraemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
Hypoalbuminaemia			

subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 2 (Safety Management Study): Cohort 6		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 40 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Squamous cell carcinoma subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2		
Myelodysplastic syndrome subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Cancer pain subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Vascular disorders Hypotension subjects affected / exposed occurrences (all)	21 / 40 (52.50%) 30		
Hypertension subjects affected / exposed occurrences (all)	4 / 40 (10.00%) 8		
Capillary leak syndrome subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Deep vein thrombosis subjects affected / exposed occurrences (all)	3 / 40 (7.50%) 3		
Hot flush subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Embolism subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2		
Subclavian vein thrombosis subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
General disorders and administration site conditions Chills subjects affected / exposed occurrences (all)	8 / 40 (20.00%) 8		
Fatigue			

subjects affected / exposed	18 / 40 (45.00%)			
occurrences (all)	25			
Pyrexia				
subjects affected / exposed	33 / 40 (82.50%)			
occurrences (all)	41			
Asthenia				
subjects affected / exposed	5 / 40 (12.50%)			
occurrences (all)	5			
Pain				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Malaise				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	2			
Non-cardiac chest pain				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Gait disturbance				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Influenza like illness				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	3			
Oedema				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	2			
Oedema peripheral				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences (all)	3			
Chest pain				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Peripheral swelling				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	2			
Swelling				

subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Puncture site pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Catheter site pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Hernia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	8 / 40 (20.00%)		
occurrences (all)	11		
Graft versus host disease			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Scrotal oedema			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Perineal pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	7 / 40 (17.50%)		
occurrences (all)	8		
Cough			
subjects affected / exposed	6 / 40 (15.00%)		
occurrences (all)	8		
Nasal congestion			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	4		
Oropharyngeal pain			

subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	2			
Pleural effusion				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Dyspnoea				
subjects affected / exposed	8 / 40 (20.00%)			
occurrences (all)	12			
Wheezing				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Pulmonary oedema				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Upper-airway cough syndrome				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Tachypnoea				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Hiccups				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences (all)	5			
Laryngeal haemorrhage				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Rhinitis allergic				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Rhinorrhoea				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Atelectasis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Paranasal cyst				

subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	5		
Insomnia			
subjects affected / exposed	6 / 40 (15.00%)		
occurrences (all)	6		
Confusional state			
subjects affected / exposed	12 / 40 (30.00%)		
occurrences (all)	14		
Agitation			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	4		
Hallucination			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Mental status changes			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Delirium			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Bradyphrenia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Restlessness			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		

Mood altered			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Investigations			
White blood cell count decreased			
subjects affected / exposed	10 / 40 (25.00%)		
occurrences (all)	24		
Platelet count decreased			
subjects affected / exposed	6 / 40 (15.00%)		
occurrences (all)	6		
Neutrophil count decreased			
subjects affected / exposed	14 / 40 (35.00%)		
occurrences (all)	25		
Lymphocyte count decreased			
subjects affected / exposed	7 / 40 (17.50%)		
occurrences (all)	11		
C-reactive protein increased			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Serum ferritin increased			

subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Weight increased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Blood bilirubin increased				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Blood immunoglobulin G decreased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Blood potassium decreased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Urine output decreased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Immunoglobulins decreased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Blood fibrinogen decreased				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Oxygen saturation decreased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Blood albumin decreased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Blood magnesium decreased				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			

Injury, poisoning and procedural complications			
Skin abrasion			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Infusion related reaction			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	4		
Head injury			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Procedural pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Sinus bradycardia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Ventricular arrhythmia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	6		
Tachycardia			
subjects affected / exposed	6 / 40 (15.00%)		
occurrences (all)	8		
Bradycardia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Acute left ventricular failure			

subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Ventricular tachycardia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Tremor			
subjects affected / exposed	9 / 40 (22.50%)		
occurrences (all)	12		
Headache			
subjects affected / exposed	13 / 40 (32.50%)		
occurrences (all)	16		
Encephalopathy			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	4		
Dysarthria			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Somnolence			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	5		
Aphasia			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	4		
Dizziness			
subjects affected / exposed	6 / 40 (15.00%)		
occurrences (all)	7		
Memory impairment			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Paraesthesia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Dysgeusia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		

Dyskinesia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Dysgraphia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Seizure				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Disturbance in attention				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Post herpetic neuralgia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Head discomfort				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Dementia				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	2			
Peripheral sensory neuropathy				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Apraxia				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	2			
Muscle contractions involuntary				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Poor sucking reflex				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Peripheral motor neuropathy				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			

Presyncope			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Sensory loss			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	13 / 40 (32.50%)		
occurrences (all)	16		
Neutropenia			
subjects affected / exposed	20 / 40 (50.00%)		
occurrences (all)	43		
Thrombocytopenia			
subjects affected / exposed	10 / 40 (25.00%)		
occurrences (all)	18		
Febrile neutropenia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Pancytopenia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	7 / 40 (17.50%)		
occurrences (all)	15		
Lymphopenia			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	6		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Hypoacusis			

subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Eye disorders			
Vision blurred			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Vitreous floaters			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Eyelid function disorder			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	8 / 40 (20.00%)		
occurrences (all)	9		
Constipation			
subjects affected / exposed	15 / 40 (37.50%)		
occurrences (all)	19		
Nausea			
subjects affected / exposed	14 / 40 (35.00%)		
occurrences (all)	20		
Diarrhoea			
subjects affected / exposed	11 / 40 (27.50%)		
occurrences (all)	14		
Abdominal pain			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	5		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Anal incontinence			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Stomatitis			

subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Dry mouth			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Dyspepsia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Abdominal distension			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	5		
Dysphagia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Rectal haemorrhage			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Flatulence			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Odynophagia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		

Rash subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1			
Pruritus subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2			
Hyperhidrosis subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1			
Alopecia subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2			
Erythema subjects affected / exposed occurrences (all)	3 / 40 (7.50%) 4			
Night sweats subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1			
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1			
Pollakiuria subjects affected / exposed occurrences (all)	4 / 40 (10.00%) 4			
Acute kidney injury subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1			
Urinary incontinence subjects affected / exposed occurrences (all)	3 / 40 (7.50%) 3			
Urinary retention subjects affected / exposed occurrences (all)	3 / 40 (7.50%) 3			
Haematuria				

subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	2		
Urinary tract obstruction			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Bladder spasm			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Muscular weakness			
subjects affected / exposed	6 / 40 (15.00%)		
occurrences (all)	6		
Arthralgia			
subjects affected / exposed	9 / 40 (22.50%)		
occurrences (all)	12		
Back pain			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Muscle spasms			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Neck pain			

subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Tenosynovitis stenosans			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	4		
Herpes zoster			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Pneumonia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Candida infection			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Clostridium difficile infection			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Covid-19			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	4		

Nasopharyngitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Conjunctivitis				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences (all)	1			
Clostridium difficile colitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus infection				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	2			
Tooth infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	2			
Ear infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Tinea versicolour				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Viral upper respiratory tract infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			
Wound infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences (all)	0			

Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	11 / 40 (27.50%)		
occurrences (all)	14		
Decreased appetite			
subjects affected / exposed	8 / 40 (20.00%)		
occurrences (all)	13		
Hypophosphataemia			
subjects affected / exposed	11 / 40 (27.50%)		
occurrences (all)	12		
Hyponatraemia			
subjects affected / exposed	6 / 40 (15.00%)		
occurrences (all)	8		
Hypoalbuminaemia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Hypocalcaemia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Hypernatraemia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	3		
Hyperglycaemia			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	6		
Hypomagnesaemia			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	6		
Dehydration			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Hyperkalaemia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Hypermagnesaemia			

subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Malnutrition			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Metabolic acidosis			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 January 2015	• Visit windows for screening, leukapheresis, and Month 1 imaging were expanded to provide greater logistical flexibility for the subjects and study sites. • Additional toxicity assessments prior to the infusion of axicabtagene ciloleucel were added. • Recovery criteria for discharge of subject from hospital after Day 7 were expanded. • Grade 3 or higher CRS was designated for expedited safety reporting.
27 February 2015	• Total sample size of the study was increased from approximately 118–124 to 118– 136 subjects based upon the contingency for additional cohort assessment in Phase 1. • Exclusion criterion was added for subjects with a history of aminoglycoside hypersensitivity. • Cyclophosphamide dose for the initial A1 cohort in Phase 1 was increased from 300 to 500 mg/m2/day. • Contingency for an additional cohort (B1) added in the event that a more intensive lymphodepletion therapy is deemed warranted. Subjects would receive 30 mg/kg cyclophosphamide Days –7 and -6 and 25 mg/m2 fludarabine Days –5 through –1. • Objective response rate, the primary endpoint of Phase 2, was specified to be based on investigator assessment; response rate according to the central reviewer was designated as a secondary endpoint.
27 October 2015	• Enrollment was aligned with the day of leukapheresis. • Eligibility criteria governing renal, hepatic, cardiac, pulmonary function were revised (adding oxygen saturation of > 92%, adding cardiac and pleural effusion criteria). • Deep vein thrombosis and pulmonary embolism were added as exclusion criteria. • Clarification that indwelling line or drain were exclusion criteria but Ommaya reservoir and dedicated central venous access catheters were permitted. • Clarifications were made for the concomitant use of corticosteroids and other agents with immunosuppressive potential for the management of CRS and neurologic events. • Expanded instructions were given for management of possible hypotension and renal insufficiency arising from CRS; specifically, use of IV saline was detailed. • Blood samples were added for measurement of cytokine levels, CRP, and antibodies to axicabtagene ciloleucel or bovine serum albumin. • Expanded instructions were given about subject requirements prior to initiating leukapheresis; namely, no significant infection before proceeding with leukapheresis. • Instructions were added for subjects eligible to receive a second treatment with axicabtagene ciloleucel.

18 April 2016	• IND and EudraCT numbers added to title page. • Several eligibility criteria in Section 5 were clarified as related to prior radiation or systemic therapy, history of hepatitis B or C, history of CNS lymphoma, and history of autoimmune disease. • Section 6 was updated with additional toxicity management guidance to include specific treatments for CRS, management of cardiac toxicity, management of neurologic events, deep vein thrombosis prophylaxis. • Description of histiocytosis haematophagic/hemophagocytic lymphohistiocytosis (HLH) was added. • Lumbar puncture when expect expansion, infiltration of the CAR T cells, and neurologic events were added. • Confirmation of eligibility with PET-CT. • Recommendation that CRP, ferritin, and LDH (if elevated at baseline) be monitored daily starting at Day 0 through hospitalization.
05 January 2022	• A Long-term Follow-up (LTFU) protocol, KT-US-982-5968 has been developed to allow for rollover of subjects to complete the 15-year follow-up after infusion of KTE-C19 on the KTE-C19-101/ZUMA-1 study. Subjects will be provided the opportunity to rollover to the LTFU protocol after a minimum of 24-months follow-up for safety follow-up and reduced burden of study-specific assessments.
22 June 2022	• References to availability of retreatment with axicabtagene ciloleucel in the KT-US-982-5968 long-term follow-up (LTFU) have been removed following a separate amendment to the LTFU protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported