Clinical trial results:
A global randomized multicenter Phase 3 trial to compare the efficacy and safety of JCAR017 to standard of care in adult subjects with high-risk, transplant-eligible relapsed or refractory aggressive B-cell non-Hodgkin lymphomas (TRANSFORM).

Summary

EudraCT number	2018-000929-32
Trial protocol	FR BE ES GB SE NL IT
Global end of trial date	23 October 2023

Results information

Result version number	v1 (current)
This version publication date	08 November 2024
First version publication date	08 November 2024

Trial information

Trial identification

Sponsor protocol code	JCAR017-BCM-003

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussee de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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	13 December 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

compare the efficacy in subjects treated with JCAR017 versus subjects treated according to standard of care (SOC) defined as event-free survival (EFS)

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 October 2018
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	United States: 115
Country: Number of subjects enrolled	France: 14
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Japan: 9
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Switzerland: 4
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Italy: 2
Worldwide total number of subjects	184
EEA total number of subjects	50

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	123
From 65 to 84 years	61
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

184 subjects randomized

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Standard of Care Arm

Arm description:

3 cycles of standard of care (SOC) salvage therapy (rituximab, dexamethasone, cytarabine and cisplatin [R-DHAP], rituximab, ifosfamide, carboplatin and etoposide [R-ICE], rituximab, gemcitabine, dexamethasone, and cisplatin [R-GDP]) per physician's choice. Participants responding to SOC are expected to undergo high dose chemotherapy (HDCT) and hematopoietic stem cell transplant (HSCT). If requested by the investigator, participants may be allowed to receive JCAR017 upon meeting progression, relapse, or suboptimal response. 1 cycle = 3 weeks

Arm type	Active comparator
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:

Etoposide 200 mg/m² - Days 2 to 5

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:

375 mg/m² - Day 1

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:

Dexamethasone 40 mg – Days 1 to 4

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

Dosage and administration details: Cytarabine 2 x 2000 mg/m² - Day 2	
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: Cisplatin 100 mg/m² - Day 1	
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: Ifosfamide 5000 mg/m² - Day 2	
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: Etoposide 100 mg/m² - Days 1 to 3	
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: Carboplatin area under the curve (AUC) 5 (maximum dose 800 mg) – Day 2	
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: Gemcitabine 1000 mg/m² - Days 1 and 8	
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: Cisplatin 75 mg/m² - Day 1	
Investigational medicinal product name	Carmustine
Investigational medicinal product code	
Other name	BCNU
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Carmustine (BCNU) 300 mg/m² - Day 1	

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

Dosage and administration details:

Cytarabine 200 mg/m² - Days 2 to 5

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

Dosage and administration details:

Melphalan 140 mg/m² - Day 6

Arm title	Liso-cel Arm

Arm description:

[Lymphodepleting chemotherapy (LDC)] Fludarabine IV (30 mg/m^2/day for 3 days) and cyclophosphamide IV (300 mg/m^2/day for 3 days) followed by JCAR017 IV infusion at a dose of 100 x 10^6 JCAR017-positive viable transduced T cells (CAR+ T cells) on Day 29 (2 to 7 days after completion of LD chemotherapy)

Arm type	Experimental
Investigational medicinal product name	JCAR017
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

dose of 100 x 106 JCAR017-positive viable transduced T cells (CAR+ T cells) on Day 29

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:

Cyclophosphamide IV (300 mg/m2/day for 3 days)

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:

Fludarabine IV (30 mg/m2/day for 3 days)

Number of subjects in period 1	Standard of Care Arm	Liso-cel Arm
Started	92	92
Treated	91	90
Crossover	61	0 [1]
JCAR017 conforming cell product	57	89
JCAR017 nonconforming cell product	1 [2]	1 [3]
Completed	37	81
Not completed	55	11
Adverse event, serious fatal	2	2
Consent withdrawn by subject	1	1
Physician decision	3	-
other reasons	5	-
Adverse event, non-fatal	1	-
Study drug manufacturing failure	-	1
Disease relapse	15	6
Death due to the COVID-19 pandemic	-	1
Lack of efficacy	28	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of subjects at this milestone only

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of subjects at this milestone only

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of subjects at this milestone only

Baseline characteristics

Reporting groups	
Reporting group title	Standard of Care Arm
Reporting group description:	
3 cycles of standard of care (SOC) salvage therapy (rituximab, dexamethasone, cytarabine and cisplatin [R-DHAP], rituximab, ifosfamide, carboplatin and etoposide [R-ICE], rituximab, gemcitabine, dexamethasone, and cisplatin [R-GDP]) per physician's choice. Participants responding to SOC are expected to undergo high dose chemotherapy (HDCT) and hematopoietic stem cell transplant (HSCT). If requested by the investigator, participants may be allowed to receive JCAR017 upon meeting progression, relapse, or suboptimal response. 1 cycle = 3 weeks	
Reporting group title	Liso-cel Arm
Reporting group description:	
[Lymphodepleting chemotherapy (LDC)] Fludarabine IV (30 mg/m^2/day for 3 days) and cyclophosphamide IV (300 mg/m^2/day for 3 days) followed by JCAR017 IV infusion at a dose of 100 x 10^6 JCAR017-positive viable transduced T cells (CAR+ T cells) on Day 29 (2 to 7 days after completion of LD chemotherapy)	

Reporting group values	Standard of Care Arm	Liso-cel Arm	Total
Number of subjects	92	92	184
Age categorical Units:			
Age Continuous Units: years			
arithmetic mean	54.2	58.3	
standard deviation	± 13.94	± 12.61	-
Sex: Female, Male Units: Participants			
Female	31	48	79
Male	61	44	105
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	8	10	18
Black or African American	3	4	7
Native Hawaiian or Other Pacific Islander	0	0	0
White	55	54	109
Not Collected or Reported	25	22	47
Other	1	2	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	3	6
Not Hispanic or Latino	62	65	127
Unknown or Not Reported	27	24	51

End points

End points reporting groups

Reporting group title	Standard of Care Arm

Reporting group description:

3 cycles of standard of care (SOC) salvage therapy (rituximab, dexamethasone, cytarabine and cisplatin [R-DHAP], rituximab, ifosfamide, carboplatin and etoposide [R-ICE], rituximab, gemcitabine, dexamethasone, and cisplatin [R-GDP]) per physician's choice. Participants responding to SOC are expected to undergo high dose chemotherapy (HDCT) and hematopoietic stem cell transplant (HSCT). If requested by the investigator, participants may be allowed to receive JCAR017 upon meeting progression, relapse, or suboptimal response. 1 cycle = 3 weeks

Reporting group title	Liso-cel Arm

Reporting group description:

[Lymphodepleting chemotherapy (LDC)] Fludarabine IV (30 mg/m^2/day for 3 days) and cyclophosphamide IV (300 mg/m^2/day for 3 days) followed by JCAR017 IV infusion at a dose of 100 x 10^6 JCAR017-positive viable transduced T cells (CAR+ T cells) on Day 29 (2 to 7 days after completion of LD chemotherapy)

Primary: Event-free Survival (EFS) Per Independent Review Committee (IRC)

End point title	Event-free Survival (EFS) Per Independent Review Committee (IRC)[1]

End point description:

Time from randomization to death, progressive disease (PD), failure to achieve complete response (CR) or partial response (PR) by 9 weeks or start of new antineoplastic therapy, whichever occurs first. CR: Target nodes masses must regress to ≤ 1.5cm in LDi, no extralymphatic sites, no new lesions. PR: ≥ 50% decrease in sum of diameters of up to 6 target nodes and extranodal sites, no new lesions, spleen must have regressed > 50% in length. PD: LDi > 1.5cm, increase by ≥ 50% from PPD nadir, an increase in LDi or SDi from nadir, 0.5 cm for lesions ≤ 2cm, 1.0cm for lesions > 2cm. Complete metabolic response: Lymph nodes score 1, 2, 3 with/without residual mass on 5-point scale, no new lesions, no FDG-avid disease. Partial metabolic response: Lymph nodes score 4 or 5, reduced uptake from baseline, no new lesions, residual uptake higher than normal, reduced from baseline. Progressive metabolic disease: Score 4 or 5 with an increase in uptake intensity from baseline and/or new FDG-avid.

End point type	Primary

End point timeframe:

From randomization to death from any cause, PD, failure to achieve CR or PR by 9 weeks post randomization, or start of new antineoplastic therapy due to efficacy concerns, whichever occurs first (Up to 36 months)

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: Only summary statistics planned for this endpoint

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Months				
median (confidence interval 95%)	2.4 (2.2 to 4.9)	29.5 (9.5 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS)

End point title	Progression-free Survival (PFS)

End point description:

Progression-free survival is defined as the time from randomization to progressive disease (PD) or death from any cause, whichever occurs first. Estimates of time to event are from Kaplan-Meier product-limit estimates. PD: LDi > 1.5 cm, increase by ≥ 50% from PPD nadir, an increase in LDi or SDi from nadir, 0.5 cm for lesions ≤ 2 cm, 1.0 cm for lesions > 2 cm. Progressive metabolic disease: Score 4 or 5 with an increase in the intensity of uptake from baseline and/or new FDG-avid. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to progression, or death from any cause, whichever occurs first (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Months				
median (confidence interval 95%)	6.2 (4.3 to 8.6)	99999 (12.6 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response Rate (CRR)

End point title	Complete Response Rate (CRR)

End point description:

Complete response rate (CRR) is defined as the percentage of participants achieving a best overall response of complete response (CR). Participants with unknown or missing response will be counted as non-evaluable in the analysis. CR: Target nodes/nodal masses must regress to ≤ 1.5 cm in LDi, no extralymphatic sites, no new lesions. Complete metabolic response: Lymph nodes/extralymphatic sites score 1, 2, 3 with/without residual mass on 5-point scale, no new lesions, no FDG-avid disease.

End point type	Secondary

End point timeframe:

From randomization up to 3 years post randomization (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Percentage of participants				
number (confidence interval 95%)	43.5 (33.2 to 54.2)	73.9 (63.7 to 82.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Complete Response (CR)

End point title	Number of Participants with Complete Response (CR)

End point description:

The number of participants achieving a best overall response of complete response (CR). Participants with unknown or missing response will be counted as non-evaluable in the analysis. CR: Target nodes/nodal masses must regress to ≤ 1.5 cm in LDi, no extralymphatic sites, no new lesions. Complete metabolic response: Lymph nodes/extralymphatic sites score 1, 2, 3 with/without residual mass on 5-point scale, no new lesions, no FDG-avid disease.

End point type	Secondary

End point timeframe:

From randomization up to 3 years post randomization (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Participants	40	68		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

Overall Survival (OS) is defined as the time from randomization to death due to any cause. Estimates of time to event are from Kaplan-Meier product-limit estimates. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to time of death due to any cause (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Months				
median (confidence interval 95%)	99999 (18.2 to 99999)	99999 (42.8 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR)

End point title	Overall Response Rate (ORR)

End point description:

ORR is defined as the percentage of participants achieving a best overall response of partial response (PR) or complete response (CR). CR: Target nodes masses must regress to ≤ 1.5cm in LDi, no extralymphatic sites, no new lesions. PR: ≥ 50% decrease in sum of diameters of up to 6 target nodes and extranodal sites, no new lesions, spleen must have regressed > 50% in length. Complete metabolic response: Lymph nodes score 1, 2, 3 with/without residual mass on 5-point scale, no new lesions, no FDG-avid disease. Partial metabolic response: Lymph nodes score 4 or 5, reduced uptake from baseline, no new lesions, residual uptake higher than normal, reduced from baseline.

End point type	Secondary

End point timeframe:

From randomization to PR or CR (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Percentage of participants				
number (confidence interval 95%)	48.9 (38.3 to 59.6)	87.0 (78.3 to 93.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR) Per Independent Review Committee (IRC)

End point title	Duration of Response (DoR) Per Independent Review Committee (IRC)

End point description:

The time from first partial or complete response (CR or PR) to disease progression, start of new antineoplastic therapy due to efficacy concerns or death, whichever occurs first. CR: Target nodes masses must regress to ≤ 1.5cm in LDi, no extralymphatic sites, no new lesions. PR: ≥ 50% decrease in sum of diameters of up to 6 target nodes and extranodal sites, no new lesions, spleen must have regressed > 50% in length. PD: LDi > 1.5cm, increase by ≥ 50% from PPD nadir, an increase in LDi or SDi from nadir, 0.5 cm for lesions ≤ 2cm, 1.0cm for lesions > 2cm. Complete metabolic response: Lymph nodes score 1, 2, 3 with/without residual mass on 5-point scale, no new lesions, no FDG-avid

disease. Partial metabolic response: Lymph nodes score 4 or 5, reduced uptake from baseline, no new lesions, residual uptake higher than normal, reduced from baseline. Progressive metabolic disease: Score 4 or 5 with an increase in uptake intensity from baseline and/or new FDG-avid. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to to disease progression, start of new antineoplastic therapy due to efficacy concerns or death, whichever occurs first (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	80		
Units: Months				
median (confidence interval 95%)	9.1 (5.1 to 999999)	99999 (16.9 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival on Next Line of Treatment (PFS-2)

End point title	Progression-free Survival on Next Line of Treatment (PFS-2)

End point description:

Progression-free Survival (PFS)-2 based on investigator's assessment is defined as time from randomization to second objective progressive disease (PD) or death from any cause, whichever occurs first. Estimates of time to event are from Kaplan-Meier product-limit estimates. PD: LDi > 1.5 cm, increase by ≥ 50% from PPD nadir, an increase in LDi or SDi from nadir, 0.5 cm for lesions ≤ 2 cm, 1.0 cm for lesions > 2 cm. Progressive metabolic disease: Score 4 or 5 with an increase in the intensity of uptake from baseline and/or new FDG-avid.

End point type	Secondary

End point timeframe:

From randomization to second objective progression, or death from any cause, whichever occurs first (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Participants				
Number of patients who died	15	10		
Number of patients with first progression	60	40		
Number of patients with second progression	8	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Event-free Survival (EFS) Rate

End point title	Event-free Survival (EFS) Rate

End point description:

EFS rate is defined as the percentage of participants free of any EFS event at fixed timepoints. Complete response: Target nodes masses must regress to ≤ 1.5cm in LDi, no extralymphatic sites, no new lesions. Partial response: ≥ 50% decrease in sum of diameters of up to 6 target nodes and extranodal sites, no new lesions, spleen must have regressed > 50% in length. Progression: LDi > 1.5cm, increase by ≥ 50% from PPD nadir, an increase in LDi or SDi from nadir, 0.5 cm for lesions ≤ 2cm, 1.0cm for lesions > 2cm. Complete metabolic response: Lymph nodes score 1, 2, 3 with/without residual mass on 5-point scale, no new lesions, no FDG-avid disease. Partial metabolic response: Lymph nodes score 4 or 5, reduced uptake from baseline, no new lesions, residual uptake higher than normal, reduced from baseline. Metabolic progression: Score 4 or 5 with an increase in uptake intensity from baseline and/or new FDG-avid.

End point type	Secondary

End point timeframe:

Months 6, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Percentage of participants				
number (confidence interval 95%)				
EFS Rate at 6 months	36.2 (26.3 to 46.1)	68.1 (58.6 to 77.7)		
EFS Rate at 12 months	22.6 (13.9 to 31.3)	57.0 (46.8 to 67.2)		
EFS Rate at 18 months	22.6 (13.9 to 31.3)	52.6 (42.3 to 62.8)		
EFS Rate at 24 months	21.5 (13.0 to 30.0)	51.4 (41.1 to 61.7)		
EFS Rate at 36 months	19.1 (11.0 to 27.3)	45.8 (35.2 to 56.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) Rate

End point title	Overall Survival (OS) Rate

End point description:

Overall Survival (OS) rate is defined as the percentage of participants alive at fixed timepoints. OS is defined as the time from randomization to death due to any cause.

End point type	Secondary

End point timeframe:

Months 6, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Percentage of participants				
number (confidence interval 95%)				
OS Rate at 6 months	88.9 (82.4 to 95.4)	93.4 (88.4 to 98.5)		
OS Rate at 12 months	72.0 (62.7 to 81.3)	83.5 (75.8 to 91.1)		
OS Rate at 18 months	61.7 (51.5 to 71.8)	73.3 (64.2 to 82.5)		
OS Rate at 24 months	58.2 (47.9 to 68.5)	67.5 (57.8 to 77.2)		
OS Rate at 36 months	51.8 (41.2 to 62.4)	62.8 (52.7 to 72.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) Rate

End point title	Progression-free Survival (PFS) Rate

End point description:

Progression-free Survival (PFS) rate is defined as the percentage of participants free of any PFS event at fixed timepoints. Progression-free survival is defined as the time from randomization to progressive disease (PD) or death from any cause, whichever occurs first. Estimates of time to event are from Kaplan-Meier product-limit estimates. PD: LDi > 1.5 cm, increase by ≥ 50% from PPD nadir, an increase in LDi or SDi from nadir, 0.5 cm for lesions ≤ 2 cm, 1.0 cm for lesions > 2 cm. Progressive metabolic disease: Score 4 or 5 with an increase in the intensity of uptake from baseline and/or new FDG-avid.

End point type	Secondary

End point timeframe:

Months 6, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Percentage of participants				
number (confidence interval 95%)				
PFS Rate at 6 months	51.7 (40.2 to 63.1)	73.7 (64.5 to 83.0)		
PFS Rate at 12 months	31.3 (20.3 to 42.4)	63.0 (52.8 to 73.2)		
PFS Rate at 18 months	31.3 (20.3 to 42.4)	58.2 (47.7 to 68.7)		

PFS Rate at 24 months	29.7 (18.8 to 40.7)	57.0 (46.4 to 67.5)		
PFS Rate at 36 months	26.5 (15.9 to 37.1)	50.9 (39.9 to 62.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Serious Treatment-Emergent Adverse Events (TEAEs)

End point title	Number of Participants with Serious Treatment-Emergent Adverse Events (TEAEs)

End point description:

A serious adverse event is defined as any adverse event occurring at any dose that results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; or constitutes an important medical event. Treatment emergent adverse events are adverse events occurring or worsening on or after the date of randomization and within 90 days after last dose of chemotherapy (Arm A), or within 90 days after the infusion of JCAR017 (Arm B) or start of new antineoplastic therapy, whichever occurs first as well as those AEs made known to the investigator at any time thereafter that are suspected of being related to study treatment. Graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to 90 days after last dose or start of new antineoplastic therapy, whichever occurs first (Up to 39 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	92		
Units: Participants				
Overall	45	43		
NHL: Diffuse Large B-cell Lymphoma (DLBCL)	29	23		
NIH: Follicular Lymphoma Grade 3B	99999	0		
NIH: HGBCL with DLBCL Histology	9	17		
NIH: PMLBCL	4	2		
NIH: T Cell/Histiocyte-Rich Large B-Cell Lymphoma	3	1		
DLBCL: DLBCL NOS de novo	25	20		
DLBCL: DLBCL from Transformed Indolent NHL	4	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Participants with Treatment Emergent Adverse Events (TEAEs)

End point description:

Treatment emergent adverse events are adverse events occurring or worsening on or after the date of randomization and within 90 days after last dose of chemotherapy (Arm A), or within 90 days after the infusion of JCAR017 (Arm B) or start of new antineoplastic therapy, whichever occurs first as well as those AEs made known to the investigator at any time thereafter that are suspected of being related to study treatment. Graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to 90 days after last dose or start of new antineoplastic therapy, whichever occurs first (Up to 39 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	92		
Units: Participants				
Overall	90	92		
(NHL): Diffuse Large B-cell Lymphoma (DLBCL)	57	60		
NIH: Follicular Lymphoma Grade 3B	99999	1		
NIH: HGBCL with DLBCL Histology	20	22		
NIH: PMLBL	9	8		
NIH: T Cell/Histiocyte-Rich Large B-Cell Lymphoma	4	1		
DLBCL: DLBCL NOS de novo	49	53		
DLBCL: DLBCL from Transformed Indolent NHL	8	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hematology Parameters 1: Hemoglobin

End point title	Change from Baseline in Hematology Parameters 1: Hemoglobin

End point description:

Change from baseline in hemoglobin. Baseline value will be defined as the last value on the randomization date (+3 days) or before the date/time of randomization (date if date/time not collected). 99999=NA

End point type	Secondary

End point timeframe:

baseline, months 1, 2, 3, 4, 6, 9, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	84		
Units: g/L				
arithmetic mean (standard deviation)				
Hemoglobin Month 1	-16.98 (± 13.408)	-14.94 (± 14.628)		
Hemoglobin Month 2	-25.00 (± 99999)	99999 (± 99999)		
Hemoglobin Month 3	-30.83 (± 19.013)	-15.78 (± 19.410)		
Hemoglobin Month 4	-22.00 (± 99999)	99999 (± 99999)		
Hemoglobin Month 6	-6.80 (± 14.935)	-3.16 (± 19.755)		
Hemoglobin Month 9	0.36 (± 19.242)	-0.52 (± 15.632)		
Hemoglobin Month 12	6.17 (± 14.598)	3.32 (± 15.417)		
Hemoglobin Month 18	11.37 (± 14.592)	7.38 (± 12.854)		
Hemoglobin Month 24	13.88 (± 18.996)	7.38 (± 16.986)		
Hemoglobin Month 36	14.41 (± 16.978)	13.63 (± 12.417)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Hematology Parameters 2

End point title	Change from Baseline in Selected Hematology Parameters 2

End point description:

Change from baseline in selected hematology parameters such as leukocytes, lymphocytes, neutrophils, and platelets. Baseline value will be defined as the last value on the randomization date (+3 days) or before the date/time of randomization (date if date/time not collected). 99999=NA

End point type	Secondary

End point timeframe:

baseline, months 1, 2, 3, 4, 6, 9, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	84		
Units: 10^9/L				
arithmetic mean (standard deviation)				
Month 1 leukocytes	0.815 (± 6.9413)	-3.219 (± 2.4688)		
Month 2 leukocytes	-0.870 (± 99999)	99999 (± 99999)		

Month 3 leukocytes	-3.445 (± 5.8845)	-2.234 (± 2.3520)		
Month 4 leukocytes	-1.180 (± 99999)	99999 (± 99999)		
Month 6 leukocytes	-1.699 (± 1.9099)	-1.853 (± 2.5876)		
Month 9 leukocytes	-0.710 (± 3.0670)	-1.156 (± 3.3604)		
Month 12 leukocytes	-0.427 (± 1.4093)	-1.138 (± 2.3772)		
Month 18 leukocytes	-0.598 (± 1.6136)	-1.088 (± 2.8028)		
Month 24 leukocytes	0.694 (± 3.0465)	-0.806 (± 2.5709)		
Month 36 leukocytes	0.761 (± 2.3637)	-0.970 (± 3.0158)		
Month 1 lymphocytes	-0.2824 (± 0.43519)	-0.7380 (± 0.43499)		
Month 2 lymphocytes	-0.2100 (± 99999)	99999 (± 99999)		
Month 3 lymphocytes	-0.4216 (± 0.55872)	-0.1318 (± 0.43385)		
Month 4 lymphocytes	-0.1700 (± 99999)	99999 (± 99999)		
Month 6 lymphocytes	0.1343 (± 0.38219)	-0.0845 (± 0.48047)		
Month 9 lymphocytes	0.3264 (± 0.66121)	-0.0442 (± 0.39684)		
Month 12 lymphocytes	0.5089 (± 0.71831)	0.0097 (± 0.37252)		
Month 18 lymphocytes	0.6942 (± 0.98993)	0.2283 (± 0.55421)		
Month 24 lymphocytes	0.8688 (± 1.12695)	0.3298 (± 0.51386)		
Month 36 lymphocytes	1.2253 (± 1.20268)	0.3550 (± 0.55387)		
Month 1 neutrophils	1.368 (± 6.5393)	-2.065 (± 2.3479)		
Month 2 neutrophils	-0.590 (± 99999)	99999 (± 99999)		
Month 3 neutrophils	-0.621 (± 6.8377)	-1.909 (± 2.1727)		
Month 4 neutrophils	-1.160 (± 99999)	99999 (± 99999)		
Month 6 neutrophils	-1.648 (± 1.7635)	-1.584 (± 2.4539)		
Month 9 neutrophils	-0.879 (± 2.9777)	-1.001 (± 3.1318)		
Month 12 neutrophils	-0.822 (± 1.5780)	-1.035 (± 2.2898)		
Month 18 neutrophils	-1.167 (± 1.3772)	-1.189 (± 2.6342)		
Month 24 neutrophils	-0.124 (± 2.5434)	-0.998 (± 2.5506)		
Month 36 neutrophils	-0.404 (± 1.8392)	-0.998 (± 2.5222)		
Month 1 platelets	13.9 (± 140.94)	29.4 (± 115.53)		
Month 2 platelets	13.0 (± 99999)	99999 (± 99999)		
Month 3 platelets	-189.5 (± 132.93)	-65.7 (± 100.52)		

Month 4 platelets	-74.0 (± 99999)	99999 (± 99999)		
Month 6 platelets	-45.5 (± 94.13)	-48.2 (± 89.04)		
Month 9 platelets	-57.0 (± 110.48)	-48.9 (± 89.29)		
Month 12 platelets	-66.5 (± 85.82)	-42.4 (± 92.65)		
Month 18 platelets	-68.0 (± 84.69)	-32.6 (± 81.68)		
Month 24 platelets	-29.4 (± 103.87)	-28.7 (± 79.70)		
Month 36 platelets	-45.2 (± 123.28)	-10.5 (± 72.79)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Chemistry Parameters 1

End point title	Change from Baseline in Selected Chemistry Parameters 1

End point description:

Change from baseline in selected chemistry parameters such as alanine aminotransferase, aspartate aminotransferase, and lactate dehydrogenase. Baseline value will be defined as the last value on the randomization date (+3 days) or before the date/time of randomization (date if date/time not collected). 99999=NA

End point type	Secondary

End point timeframe:

baseline, months 1, 2, 3, 4, 6, 9, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	76	88		
Units: U/L				
arithmetic mean (standard deviation)				
Month 1 Alanine Aminotransferase	17.22 (± 25.997)	-0.52 (± 18.337)		
Month 2 Alanine Aminotransferase	4.00 (± 99999)	99999 (± 99999)		
Month 3 Alanine Aminotransferase	-3.40 (± 22.295)	2.53 (± 13.246)		
Month 4 Alanine Aminotransferase	-3.00 (± 99999)	99999 (± 99999)		
Month 6 Alanine Aminotransferase	2.81 (± 21.067)	3.08 (± 14.813)		
Month 9 Alanine Aminotransferase	2.43 (± 20.165)	5.23 (± 16.660)		
Month 12 Alanine Aminotransferase	0.72 (± 23.542)	4.19 (± 19.653)		
Month 18 Alanine Aminotransferase	10.40 (± 15.892)	-0.45 (± 10.943)		

Month 24 Alanine Aminotransferase	7.69 (± 15.134)	1.88 (± 13.211)		
Month 36 Alanine Aminotransferase	12.41 (± 17.429)	13.98 (± 104.054)		
Month 1 Aspartate Aminotransferase	3.38 (± 16.624)	2.03 (± 17.526)		
Month 2 Aspartate Aminotransferase	5.00 (± 99999)	99999 (± 99999)		
Month 3 Aspartate Aminotransferase	-6.47 (± 17.248)	-1.24 (± 8.800)		
Month 4 Aspartate Aminotransferase	3.00 (± 99999)	99999 (± 99999)		
Month 6 Aspartate Aminotransferase	1.23 (± 15.911)	1.78 (± 8.550)		
Month 9 Aspartate Aminotransferase	3.68 (± 12.549)	2.12 (± 10.355)		
Month 12 Aspartate Aminotransferase	-1.44 (± 16.180)	1.88 (± 13.200)		
Month 18 Aspartate Aminotransferase	4.90 (± 7.663)	-1.22 (± 7.452)		
Month 24 Aspartate Aminotransferase	4.63 (± 9.172)	0.90 (± 10.757)		
Month 36 Aspartate Aminotransferase	9.06 (± 15.117)	14.95 (± 94.651)		
Month 1 Lactate Dehydrogenase	-66.7 (± 222.79)	-14.0 (± 203.18)		
Month 2 Lactate Dehydrogenase	27.0 (± 99999)	99999 (± 99999)		
Month 3 Lactate Dehydrogenase	-57.2 (± 377.22)	-84.1 (± 183.29)		
Month 4 Lactate Dehydrogenase	117.0 (± 99999)	99999 (± 99999)		
Month 6 Lactate Dehydrogenase	-85.5 (± 310.71)	-53.7 (± 183.53)		
Month 9 Lactate Dehydrogenase	-85.0 (± 362.52)	-62.0 (± 186.25)		
Month 12 Lactate Dehydrogenase	-52.9 (± 74.56)	-41.9 (± 207.30)		
Month 18 Lactate Dehydrogenase	-44.1 (± 71.19)	-50.8 (± 133.31)		
Month 24 Lactate Dehydrogenase	-45.6 (± 75.04)	-63.3 (± 148.25)		
Month 36 Lactate Dehydrogenase	-46.0 (± 85.14)	-59.9 (± 124.62)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Chemistry Parameters 2

End point title	Change from Baseline in Selected Chemistry Parameters 2

End point description:

Change from baseline in selected chemistry parameters such as magnesium, phosphate, potassium, and sodium. Baseline value will be defined as the last value on the randomization date (+3 days) or before the date/time of randomization (date if date/time not collected). 99999=NA

End point type	Secondary

End point timeframe:
baseline, months 1, 2, 3, 4, 6, 9, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	76	88		
Units: mmol/L				
arithmetic mean (standard deviation)				
Month 1 magnesium	-0.023 (± 0.1145)	0.009 (± 0.0933)		
Month 2 magnesium	-0.080 (± 99999)	99999 (± 99999)		
Month 3 magnesium	-0.063 (± 0.1210)	0.007 (± 0.1010)		
Month 4 magnesium	-0.200 (± 99999)	99999 (± 99999)		
Month 6 magnesium	-0.041 (± 0.1452)	0.015 (± 0.1090)		
Month 9 magnesium	-0.027 (± 0.1459)	0.025 (± 0.1079)		
Month 12 magnesium	0.012 (± 0.1047)	0.031 (± 0.1054)		
Month 18 magnesium	0.033 (± 0.0639)	0.032 (± 0.1065)		
Month 24 magnesium	0.040 (± 0.1145)	0.015 (± 0.1027)		
Month 36 magnesium	0.039 (± 0.0920)	0.011 (± 0.0751)		
Month 1 phosphate	-0.061 (± 0.2643)	-0.038 (± 0.2498)		
Month 2 phosphate	0.030 (± 99999)	99999 (± 99999)		
Month 3 phosphate	-0.128 (± 0.3299)	0.039 (± 0.2316)		
Month 4 phosphate	0.130 (± 99999)	99999 (± 99999)		
Month 6 phosphate	0.140 (± 0.2166)	-0.020 (± 0.2276)		
Month 9 phosphate	0.025 (± 0.2020)	-0.028 (± 0.2098)		
Month 12 phosphate	-0.021 (± 0.1578)	-0.090 (± 0.2051)		
Month 18 phosphate	-0.025 (± 0.2666)	-0.059 (± 0.2224)		
Month 24 phosphate	-0.064 (± 0.2469)	-0.061 (± 0.2549)		
Month 36 phosphate	-0.044 (± 0.2464)	-0.061 (± 0.2053)		
Month 1 potassium	-0.08 (± 0.400)	-0.05 (± 0.460)		
Month 2 potassium	0.30 (± 99999)	99999 (± 99999)		
Month 3 potassium	-0.33 (± 0.604)	0.00 (± 0.428)		
Month 4 potassium	0.80 (± 99999)	99999 (± 99999)		

Month 6 potassium	0.11 (± 0.337)	0.08 (± 0.359)		
Month 9 potassium	-0.06 (± 0.447)	0.12 (± 0.391)		
Month 12 potassium	0.01 (± 0.445)	0.06 (± 0.491)		
Month 18 potassium	0.06 (± 0.380)	0.15 (± 0.411)		
Month 24 potassium	0.09 (± 0.516)	0.09 (± 0.435)		
Month 36 potassium	0.07 (± 0.549)	0.11 (± 0.430)		
month 1 sodium	-2.75 (± 3.493)	-1.09 (± 2.875)		
month 2 sodium	-1.00 (± 99999)	99999 (± 99999)		
month 3 sodium	-1.86 (± 4.496)	0.59 (± 3.054)		
month 4 sodium	-2.00 (± 99999)	99999 (± 99999)		
month 6 sodium	-0.42 (± 2.514)	0.33 (± 3.222)		
month 9 sodium	0.52 (± 2.108)	-0.08 (± 3.111)		
month 12 sodium	0.33 (± 2.114)	-0.34 (± 4.046)		
month 18 sodium	0.45 (± 2.964)	0.74 (± 3.572)		
month 24 sodium	-1.00 (± 3.246)	1.02 (± 3.795)		
month 36 sodium	-0.44 (± 2.229)	0.25 (± 3.432)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) by Subgroups

End point title	Overall Response Rate (ORR) by Subgroups

End point description:

ORR is defined as the percentage of participants achieving a best overall response of partial response (PR) or complete response (CR). CR: Target nodes masses must regress to ≤ 1.5cm in LDi, no extralymphatic sites, no new lesions. PR: ≥ 50% decrease in sum of diameters of up to 6 target nodes and extranodal sites, no new lesions, spleen must have regressed > 50% in length. Complete metabolic response: Lymph nodes score 1, 2, 3 with/without residual mass on 5-point scale, no new lesions, no FDG-avid disease. Partial metabolic response: Lymph nodes score 4 or 5, reduced uptake from baseline, no new lesions, residual uptake higher than normal, reduced from baseline. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to PR or CR (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Percentage of participants				
number (confidence interval 95%)				

NHL: Diffuse Large B-cell Lymphoma (DLBCL)	51.7 (38.2 to 65.0)	86.7 (75.4 to 94.1)		
NIH: Follicular Lymphoma Grade 3B	99999 (99999 to 99999)	100 (2.5 to 100.0)		
NIH: HGBCL with DLBCL Histology	42.9 (21.8 to 66.0)	81.8 (59.7 to 94.8)		
NIH: PMLBCL	33.3 (7.5 to 70.1)	100 (63.1 to 100.0)		
NIH: T Cell/Histiocyte-Rich Large B-Cell Lymphoma	75.0 (19.4 to 99.4)	100 (2.5 to 100.0)		
DLBCL: DLBCL NOS de novo	54.0 (39.3 to 68.2)	86.8 (74.7 to 94.5)		
DLBCL: DLBCL from Transformed Indolent NHL	37.5 (8.5 to 75.5)	85.7 (42.1 to 99.6)		
DLBCL: Germinal Center B-cell like (GCB)	50.0 (33.8 to 66.2)	91.1 (78.8 to 97.5)		
DLBCL: Activated B-cell-like, non-GCB	44.8 (26.4 to 64.3)	85.7 (63.7 to 97.0)		
NHL: DBL/THL	40.0 (19.1 to 63.9)	81.8 (59.7 to 94.8)		
NHL: Non-DHL/THL	51.4 (39.3 to 63.3)	88.6 (78.7 to 94.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Event-free Survival (EFS) by Subgroups

End point title	Event-free Survival (EFS) by Subgroups

End point description:

Time from randomization to death, progressive disease (PD), failure to achieve complete response (CR) or partial response (PR) by 9 weeks or start of new antineoplastic therapy, whichever occurs first. CR: Target nodes masses must regress to ≤ 1.5cm in LDi, no extralymphatic sites, no new lesions. PR: ≥ 50% decrease in sum of diameters of up to 6 target nodes and extranodal sites, no new lesions, spleen must have regressed > 50% in length. PD: LDi > 1.5cm, increase by ≥ 50% from PPD nadir, an increase in LDi or SDi from nadir, 0.5cm for lesions ≤ 2cm, 1.0cm for lesions > 2cm. Complete metabolic response: Lymph nodes score 1, 2, 3 with/without residual mass on 5-point scale, no new lesions, no FDG-avid disease. Partial metabolic response: Lymph nodes score 4 or 5, reduced uptake, no new lesions, residual uptake higher than normal, reduced from baseline. Progressive metabolic disease: Score 4 or 5 with an increase in uptake intensity from baseline and/or new FDG-avid. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to death from any cause, PD, failure to achieve CR or PR by 9 weeks post randomization, or start of new antineoplastic therapy due to efficacy concerns, whichever occurs first (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Months				
median (confidence interval 95%)				
NHL: Diffuse Large B-cell Lymphoma (DLBCL)	3.0 (2.2 to 6.4)	99999 (9.5 to 99999)		

NIH: Follicular Lymphoma Grade 3B	99999 (99999 to 99999)	99999 (99999 to 99999)		
NIH: HGBCL with DLBCL Histology	2.2 (0.9 to 3.9)	4.6 (4.1 to 12.6)		
NIH: PMLBCL	2.2 (1.0 to 99999)	99999 (11.0 to 99999)		
NIH: T Cell/Histiocyte-Rich Large B-Cell Lymphoma	99999 (2.3 to 99999)	99999 (99999 to 99999)		
DLBCL: DLBCL NOS de novo	4.4 (2.2 to 7.5)	33.2 (9.4 to 99999)		
DLBCL: DLBCL from Transformed Indolent NHL	2.1 (1.2 to 11.2)	99999 (1.9 to 99999)		
DLBCL: Germinal Center B-cell like (GCB)	2.1 (1.6 to 4.9)	11.7 (6.0 to 99999)		
DLBCL: Activated B-cell-like, non-GCB	2.3 (2.1 to 7.5)	33.2 (4.9 to 99999)		
NHL: DBL/THL	2.1 (0.9 to 3.9)	4.6 (4.1 to 12.6)		
NHL: Non-DHL/THL	2.8 (2.2 to 6.4)	99999 (15.6 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) by Subgroups

End point title	Progression-free Survival (PFS) by Subgroups

End point description:

Progression-free survival is defined as the time from randomization to progressive disease (PD) or death from any cause, whichever occurs first. Estimates of time to event are from Kaplan-Meier product-limit estimates. PD: LDi > 1.5 cm, increase by ≥ 50% from PPD nadir, an increase in LDi or SDi from nadir, 0.5 cm for lesions ≤ 2 cm, 1.0 cm for lesions > 2 cm. Progressive metabolic disease: Score 4 or 5 with an increase in the intensity of uptake from baseline and/or new FDG-avid. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to progression, or death from any cause, whichever occurs first (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Months				
median (confidence interval 95%)				
NHL: Diffuse Large B-cell Lymphoma (DLBCL)	6.0 (2.9 to 8.6)	99999 (30.9 to 99999)		
NIH: Follicular Lymphoma Grade 3B	99999 (99999 to 99999)	99999 (99999 to 99999)		
NIH: HGBCL with DLBCL Histology	4.3 (1.4 to 6.5)	5.8 (4.3 to 14.8)		
NIH: PMLBCL	99999 (1.0 to 99999)	99999 (11.0 to 99999)		
NIH: T Cell/Histiocyte-Rich Large B-Cell Lymphoma	99999 (28.2 to 99999)	99999 (99999 to 99999)		

DLBCL: DLBCL NOS de novo	6.4 (3.1 to 8.6)	99999 (12.2 to 99999)		
DLBCL: DLBCL from Transformed Indolent NHL	3.4 (1.2 to 99999)	99999 (2.3 to 99999)		
DLBCL: Germinal Center B-cell like (GCB)	4.6 (2.0 to 6.4)	14.8 (6.2 to 99999)		
DLBCL: Activated B-cell-like, non-GCB	7.5 (2.3 to 9.4)	33.2 (6.6 to 99999)		
NHL: DBL/THL	4.3 (1.4 to 6.5)	5.8 (4.3 to 14.8)		
NHL: Non-DHL/THL	6.4 (4.6 to 9.4)	99999 (33.2 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) by Subgroups

End point title	Overall Survival (OS) by Subgroups

End point description:

Overall Survival (OS) is defined as the time from randomization to death due to any cause. Estimates of time to event are from Kaplan-Meier product-limit estimates. 99999=NA

End point type	Secondary

End point timeframe:

From randomization to time of death due to any cause (Up to 36 months)

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	92		
Units: Months				
median (confidence interval 95%)				
NHL: Diffuse Large B-cell Lymphoma (DLBCL)	99999 (17.0 to 99999)	99999 (42.8 to 99999)		
NIH: Follicular Lymphoma Grade 3B	99999 (99999 to 99999)	99999 (99999 to 99999)		
NIH: HGBCL with DLBCL Histology	16.3 (5.3 to 99999)	13.3 (7.9 to 99999)		
NIH: PMLBCL	99999 (17.9 to 99999)	99999 (11.0 to 99999)		
NIH: T Cell/Histiocyte-Rich Large B-Cell Lymphoma	99999 (8.9 to 99999)	99999 (99999 to 99999)		
DLBCL: DLBCL NOS de novo	99999 (16.7 to 99999)	99999 (42.8 to 99999)		
DLBCL: DLBCL from Transformed Indolent NHL	28.2 (2.0 to 99999)	99999 (14.2 to 99999)		
DLBCL: Germinal Center B-cell like (GCB)	99999 (18.2 to 99999)	99999 (15.8 to 99999)		
DLBCL: Activated B-cell-like, non-GCB	16.3 (9.7 to 99999)	99999 (32.4 to 99999)		
NHL: DBL/THL	16.3 (5.3 to 30.7)	13.3 (7.9 to 99999)		

NHL: Non-DHL/THL	99999 (27.5 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the European Organization for Research and Treatment of Cancer – Quality of Life C30 Questionnaire (EORTC QLQ-C30)

End point title	Change from Baseline in the European Organization for Research and Treatment of Cancer – Quality of Life C30 Questionnaire (EORTC QLQ-C30)

End point description:

Change from baseline in EORTC QLQ-C30 specified parameters including global health/quality of life, cognitive functioning, physical functioning, and fatigue. It is composed of both multi-item scales and single item measures. All of the scales and single-item measures range in score from 0 to 100. A 10-point change in the scoring is considered to be a meaningful change in HRQoL. Functional scale and global health status/HRQoL higher scale score represents a higher level of well-being and better ability of daily functioning. Symptom scale/item higher score represents a high level of symptomatic problem. Baseline value will be defined as the last value on the randomization date (+3 days) or before the date/time of randomization (date if date/time not collected).

End point type	Secondary

End point timeframe:

baseline, months 1, 6, 9, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	43		
Units: score on a scale				
arithmetic mean (standard deviation)				
Global Health/Quality of Life Month 1	-9.55 (± 25.655)	-5.23 (± 18.004)		
Global Health/Quality of Life Month 6	-2.78 (± 24.734)	12.36 (± 23.635)		
Global Health/Quality of Life Month 9	5.30 (± 24.516)	12.50 (± 22.252)		
Global Health/Quality of Life Month 12	15.63 (± 32.865)	8.93 (± 24.525)		
Global Health/Quality of Life Month 18	14.81 (± 29.397)	8.33 (± 23.442)		
Global Health/Quality of Life Month 24	12.50 (± 28.934)	7.29 (± 23.093)		
Global Health/Quality of Life Month 36	15.00 (± 21.802)	2.67 (± 21.071)		
Physical Functioning Month 1	-8.94 (± 19.867)	-4.03 (± 16.339)		
Physical Functioning Month 6	-2.08 (± 11.081)	2.24 (± 17.470)		
Physical Functioning Month 9	0.61 (± 9.167)	5.00 (± 21.825)		

Physical Functioning Month 12	10.00 (± 17.817)	4.52 (± 17.875)		
Physical Functioning Month 18	13.33 (± 22.608)	1.73 (± 17.027)		
Physical Functioning Month 24	10.67 (± 18.645)	2.78 (± 22.147)		
Physical Functioning Month 36	7.33 (± 15.540)	-1.87 (± 16.613)		
Cognitive Functioning Month 1	-8.54 (± 19.047)	-0.39 (± 16.462)		
Cognitive Functioning Month 6	-3.33 (± 14.365)	3.45 (± 20.596)		
Cognitive Functioning Month 9	-3.03 (± 16.361)	9.72 (± 23.008)		
Cognitive Functioning Month 12	-4.17 (± 7.715)	4.17 (± 27.074)		
Cognitive Functioning Month 18	0.00 (± 18.634)	4.17 (± 26.580)		
Cognitive Functioning Month 24	0.00 (± 13.608)	0.00 (± 26.919)		
Cognitive Functioning Month 36	-1.67 (± 9.461)	2.67 (± 17.795)		
Fatigue Month 1	19.24 (± 24.848)	0.26 (± 20.501)		
Fatigue Month 6	0.69 (± 27.657)	-12.84 (± 29.811)		
Fatigue Month 9	-4.04 (± 29.090)	-10.65 (± 36.702)		
Fatigue Month 12	-6.94 (± 8.267)	-9.52 (± 33.363)		
Fatigue Month 18	-6.17 (± 22.299)	-10.22 (± 30.919)		
Fatigue Month 24	-6.67 (± 19.030)	-8.80 (± 30.557)		
Fatigue Month 36	-3.33 (± 16.605)	-5.33 (± 25.884)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Functional Assessment of Cancer Therapy-Lymphoma Subscale (FACT-Lym)

End point title	Change from Baseline in the Functional Assessment of Cancer Therapy-Lymphoma Subscale (FACT-Lym)

End point description:

Change from Baseline in the Functional Assessment of Cancer Therapy-Lymphoma 15-item lymphoma-specific “Additional concerns” subscale (FACT-Lym). The LYM items are scored on a 0 (“Not at all”) to 4 (“Very much”) response scale. Items are aggregated to a single score on a 0-60 scale. Baseline value will be defined as the last value on the randomization date (+3 days) or before the date/time of randomization (date if date/time not collected). A meaningful change from baseline in the FACT-Lym score, often referred to as the minimally important difference (MID), typically ranges between 6.5 and 11.2 points for the total score. This range indicates a clinically significant improvement or deterioration in a patient’s health-related quality of life.

End point type	Secondary

End point timeframe:

baseline, months 1, 6, 9, 12, 18, 24, 36

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	40		
Units: score on a scale				
arithmetic mean (standard deviation)				
Month 1	-0.76 (± 5.558)	0.35 (± 7.329)		
Month 6	2.19 (± 9.474)	3.52 (± 10.805)		
Month 9	0.11 (± 9.597)	5.48 (± 14.330)		
Month 12	5.43 (± 3.645)	3.93 (± 13.485)		
Month 18	3.50 (± 5.632)	2.56 (± 12.149)		
Month 24	5.20 (± 5.789)	2.18 (± 12.374)		
Month 36	4.90 (± 5.152)	0.50 (± 9.478)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Completing High Dose Chemotherapy (HDCT)

End point title	Percentage of Participants Completing High Dose Chemotherapy (HDCT)

End point description:

Percentage of Participants Completing High Dose Chemotherapy (HDCT).

End point type	Secondary

End point timeframe:

Up to 5 months after first dose

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	0[2]		
Units: Percentage of participants				
number (not applicable)	47.3			

Notes:

[2] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Hospital Resource Utilization (HRU) Results

End point title	Hospital Resource Utilization (HRU) Results

End point description:

Hospital resource utilization (HRU) results including hospitalized, reasons for hospitalizations, and admitted to intensive care unit (ICU)

End point type	Secondary

End point timeframe:

Up to 36 months

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	92		
Units: Number of participants				
Hospitalized	74	87		
Hospitalized due to Adverse Event (AE)	42	44		
Hospitalized due to Progression of Disease	2	6		
Hospitalized per protocol	11	22		
Hospitalized due to other reasons	56	71		
Admitted to Intensive Care Unit (ICU)	4	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Completing Hematopoietic Stem Cell Transplant (HSCT)

End point title	Percentage of Participants Completing Hematopoietic Stem Cell Transplant (HSCT)

End point description:

Percentage of Participants Completing Hematopoietic Stem Cell Transplant (HSCT).

End point type	Secondary

End point timeframe:

Up to 5 months after first dose

End point values	Standard of Care Arm	Liso-cel Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	0[3]		
Units: Percentage of participants				
number (not applicable)	47.3			

Notes:
[3] - 0 subject analyzed

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for All-Cause Mortality from first dose until study completion (assessed up to approximately 60 months). SAEs and non-serious AEs were assessed from first dose to 90 days after last dose of study therapy (Up to 39 months).

Adverse event reporting additional description:

The number at Risk for All-Cause Mortality=All randomized participants.
The number at Risk for SAEs and non-serious AEs=All treated participants.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	SOC Arm only

Reporting group description:

3 cycles of standard of care (SOC) salvage therapy (R-DHAP, R-ICE and R-GDP) per physician's choice. Participants responding to SOC are expected to undergo high dose chemotherapy (HDCT) and hematopoietic stem cell transplant (HSCT). 1 cycle = 3 weeks

Reporting group title	SOC-JCAR017 Arm Post-Crossover (All Crossed)

Reporting group description:

Participants who crossed over to JCAR017 regardless of if they received CAR T therapy or not. 3 cycles of standard of care (SOC) salvage therapy (R-DHAP, R-ICE and R-GDP) per physician's choice. Participants responding to SOC are expected to undergo high dose chemotherapy (HDCT) and hematopoietic stem cell transplant (HSCT)

Reporting group title	SOC-JCAR017 Arm Post-Crossover (All Treated)

Reporting group description:

Participants who crossed over to JCAR017 and received CAR T therapy. 3 cycles of standard of care (SOC) salvage therapy (R-DHAP, R-ICE and R-GDP) per physician's choice. Participants responding to SOC are expected to undergo high dose chemotherapy (HDCT) and hematopoietic stem cell transplant (HSCT). As requested by the investigator, participants were allowed to receive JCAR017 upon meeting progression, relapse, or suboptimal response. 1 cycle = 3 weeks

Reporting group title	Liso-cel Arm only

Reporting group description:

[Lymphodepleting chemotherapy (LDC)] Fludarabine IV (30 mg/m^2/day for 3 days) and cyclophosphamide IV (300 mg/m^2/day for 3 days) followed by JCAR017 IV infusion at a dose of 100 x 10^6 JCAR017-positive viable transduced T cells (CAR+ T cells) on Day 29 (2 to 7 days after completion of LD chemotherapy)

Serious adverse events	SOC Arm only	SOC-JCAR017 Arm Post-Crossover (All Crossed)	SOC-JCAR017 Arm Post-Crossover (All Treated)
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 30 (70.00%)	19 / 61 (31.15%)	24 / 58 (41.38%)
number of deaths (all causes)	9	33	0
number of deaths resulting from adverse events	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Myelodysplastic syndrome			

subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Bowen's disease			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Basal cell carcinoma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer metastatic			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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			
Hypertension			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Hypertensive emergency			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Vasculitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
General disorders and administration site conditions			
Peripheral swelling			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Mucosal inflammation			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
General physical health deterioration			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fatigue			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Face oedema			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Chills			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Pyrexia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 61 (0.00%)	5 / 58 (8.62%)
occurrences causally related to treatment / all	1 / 2	0 / 0	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Engraftment syndrome			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Cytokine release syndrome			
subjects affected / exposed	0 / 30 (0.00%)	5 / 61 (8.20%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	6 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 distress syndrome			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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

Pulmonary embolism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Oropharyngeal pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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 failure			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Mental status changes			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

White blood cell count decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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			
Infusion related reaction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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			
Myocardial infarction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postural orthostatic tachycardia syndrome			

subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Sinus tachycardia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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			
Aphasia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Cognitive disorder			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 30 (0.00%)	2 / 61 (3.28%)	0 / 58 (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
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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	1 / 30 (3.33%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytopenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 neutropenia			

subjects affected / exposed	4 / 30 (13.33%)	3 / 61 (4.92%)	5 / 58 (8.62%)
occurrences causally related to treatment / all	4 / 4	3 / 3	6 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	3 / 30 (10.00%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	3 / 3	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Photophobia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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			
Ileus			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Gastrointestinal toxicity			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Gastritis			

subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Constipation			
subjects affected / exposed	0 / 30 (0.00%)	2 / 61 (3.28%)	0 / 58 (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
Colitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Abdominal pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Nausea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Vomiting			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 30 (13.33%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	3 / 5	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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			

Pain in extremity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Catheter site infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
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 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Bacterial sepsis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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	1 / 30 (3.33%)	1 / 61 (1.64%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Clostridium difficile infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Device related bacteraemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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	1 / 30 (3.33%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Klebsiella sepsis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pseudomonal			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Urinary tract infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
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 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Sepsis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Pseudomonal sepsis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Hypokalaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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
Hypercalcaemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	0 / 58 (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
Electrolyte imbalance			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	0 / 58 (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

Serious adverse events	Liso-cel Arm only		
Total subjects affected by serious adverse events			
subjects affected / exposed	43 / 92 (46.74%)		
number of deaths (all causes)	34		
number of deaths resulting from adverse events	1		

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Myelodysplastic syndrome			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Bowen's disease			
subjects affected / exposed	0 / 92 (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 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid cancer metastatic			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive emergency			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vasculitis			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Peripheral swelling			

subjects affected / exposed	2 / 92 (2.17%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucosal inflammation				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Face oedema				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chills				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				

subjects affected / exposed	6 / 92 (6.52%)		
occurrences causally related to treatment / all	4 / 7		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Engraftment syndrome			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytokine release syndrome			
subjects affected / exposed	12 / 92 (13.04%)		
occurrences causally related to treatment / all	13 / 13		
deaths causally related to treatment / all	0 / 0		
Anaphylactic reaction			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epistaxis			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Acute respiratory distress syndrome				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	2 / 92 (2.17%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oropharyngeal pain				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Depression				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes				

subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
White blood cell count decreased			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Platelet count decreased			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
C-reactive protein increased			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Postural orthostatic tachycardia syndrome				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus tachycardia				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Aphasia				
subjects affected / exposed	2 / 92 (2.17%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tremor				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

Somnolence				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	2 / 92 (2.17%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Lymphopenia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	2 / 92 (2.17%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Cytopenia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				

subjects affected / exposed	7 / 92 (7.61%)			
occurrences causally related to treatment / all	7 / 8			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	7 / 92 (7.61%)			
occurrences causally related to treatment / all	7 / 7			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	4 / 92 (4.35%)			
occurrences causally related to treatment / all	4 / 4			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Diplopia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Photophobia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Ileus				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal toxicity				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				

subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal stenosis				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				

subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stomatitis			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			

Pain in extremity				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Catheter site infection				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	2 / 92 (2.17%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchopulmonary aspergillosis				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				

subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 92 (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 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related bacteraemia				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal bacteraemia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterocolitis infectious				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				

subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fungal infection				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infectious pleural effusion				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella sepsis				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia pseudomonal				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Septic shock				

subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	2 / 92 (2.17%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				
subjects affected / exposed	0 / 92 (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 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				
subjects affected / exposed	0 / 92 (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	SOC Arm only	SOC-JCAR017 Arm Post-Crossover (All Crossed)	SOC-JCAR017 Arm Post-Crossover (All Treated)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 30 (100.00%)	57 / 61 (93.44%)	55 / 58 (94.83%)
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 30 (10.00%)	4 / 61 (6.56%)	5 / 58 (8.62%)
occurrences (all)	6	7	10
Deep vein thrombosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	4 / 58 (6.90%)
occurrences (all)	1	0	4
Orthostatic hypotension			
subjects affected / exposed	0 / 30 (0.00%)	2 / 61 (3.28%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Jugular vein thrombosis			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences (all)	2	1	1
Hypotension			
subjects affected / exposed	2 / 30 (6.67%)	10 / 61 (16.39%)	4 / 58 (6.90%)
occurrences (all)	6	18	5
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 30 (10.00%)	3 / 61 (4.92%)	5 / 58 (8.62%)
occurrences (all)	5	3	6
Chills			
subjects affected / exposed	0 / 30 (0.00%)	4 / 61 (6.56%)	3 / 58 (5.17%)
occurrences (all)	0	6	4
Pyrexia			
subjects affected / exposed	6 / 30 (20.00%)	6 / 61 (9.84%)	11 / 58 (18.97%)
occurrences (all)	9	9	12
Pain			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	5 / 58 (8.62%)
occurrences (all)	1	1	5
Oedema peripheral			
subjects affected / exposed	4 / 30 (13.33%)	7 / 61 (11.48%)	13 / 58 (22.41%)
occurrences (all)	7	11	15
Non-cardiac chest pain			

subjects affected / exposed	1 / 30 (3.33%)	2 / 61 (3.28%)	1 / 58 (1.72%)
occurrences (all)	1	2	1
Mucosal inflammation			
subjects affected / exposed	5 / 30 (16.67%)	0 / 61 (0.00%)	8 / 58 (13.79%)
occurrences (all)	5	0	11
Malaise			
subjects affected / exposed	0 / 30 (0.00%)	2 / 61 (3.28%)	4 / 58 (6.90%)
occurrences (all)	0	2	4
Fatigue			
subjects affected / exposed	10 / 30 (33.33%)	12 / 61 (19.67%)	28 / 58 (48.28%)
occurrences (all)	19	15	36
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 61 (3.28%)	2 / 58 (3.45%)
occurrences (all)	0	2	3
Cytokine release syndrome			
subjects affected / exposed	0 / 30 (0.00%)	24 / 61 (39.34%)	0 / 58 (0.00%)
occurrences (all)	0	26	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	4 / 58 (6.90%)
occurrences (all)	1	1	4
Cough			
subjects affected / exposed	3 / 30 (10.00%)	3 / 61 (4.92%)	7 / 58 (12.07%)
occurrences (all)	6	3	7
Dyspnoea			
subjects affected / exposed	4 / 30 (13.33%)	5 / 61 (8.20%)	6 / 58 (10.34%)
occurrences (all)	4	9	9
Rhinorrhoea			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	4 / 58 (6.90%)
occurrences (all)	2	2	5
Pulmonary embolism			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	3 / 58 (5.17%)
occurrences (all)	1	0	3
Pleural effusion			

subjects affected / exposed	3 / 30 (10.00%)	3 / 61 (4.92%)	3 / 58 (5.17%)
occurrences (all)	3	3	3
Oropharyngeal pain			
subjects affected / exposed	0 / 30 (0.00%)	3 / 61 (4.92%)	8 / 58 (13.79%)
occurrences (all)	0	4	8
Nasal congestion			
subjects affected / exposed	2 / 30 (6.67%)	3 / 61 (4.92%)	0 / 58 (0.00%)
occurrences (all)	2	3	0
Epistaxis			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	3 / 58 (5.17%)
occurrences (all)	2	6	3
Hiccups			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	5 / 58 (8.62%)
occurrences (all)	2	1	8
Psychiatric disorders			
Depression			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	2 / 58 (3.45%)
occurrences (all)	2	2	3
Anxiety			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	4 / 58 (6.90%)
occurrences (all)	1	1	5
Confusional state			
subjects affected / exposed	0 / 30 (0.00%)	6 / 61 (9.84%)	0 / 58 (0.00%)
occurrences (all)	0	7	0
Insomnia			
subjects affected / exposed	5 / 30 (16.67%)	4 / 61 (6.56%)	5 / 58 (8.62%)
occurrences (all)	7	5	6
Hallucination			
subjects affected / exposed	1 / 30 (3.33%)	3 / 61 (4.92%)	1 / 58 (1.72%)
occurrences (all)	1	3	1
Investigations			
Weight increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	5 / 58 (8.62%)
occurrences (all)	0	1	10
Weight decreased			

subjects affected / exposed	1 / 30 (3.33%)	3 / 61 (4.92%)	2 / 58 (3.45%)
occurrences (all)	1	4	2
Platelet count decreased			
subjects affected / exposed	1 / 30 (3.33%)	2 / 61 (3.28%)	1 / 58 (1.72%)
occurrences (all)	1	3	3
Neutrophil count decreased			
subjects affected / exposed	0 / 30 (0.00%)	3 / 61 (4.92%)	0 / 58 (0.00%)
occurrences (all)	0	10	0
International normalised ratio increased			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences (all)	3	2	1
C-reactive protein increased			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	0 / 58 (0.00%)
occurrences (all)	2	1	0
Blood creatinine increased			
subjects affected / exposed	2 / 30 (6.67%)	3 / 61 (4.92%)	2 / 58 (3.45%)
occurrences (all)	4	3	3
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 30 (3.33%)	4 / 61 (6.56%)	5 / 58 (8.62%)
occurrences (all)	3	4	9
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 30 (10.00%)	2 / 61 (3.28%)	3 / 58 (5.17%)
occurrences (all)	3	3	4
Alanine aminotransferase increased			
subjects affected / exposed	3 / 30 (10.00%)	2 / 61 (3.28%)	5 / 58 (8.62%)
occurrences (all)	3	4	8
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	3 / 58 (5.17%)
occurrences (all)	0	2	3
Fall			
subjects affected / exposed	2 / 30 (6.67%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences (all)	2	0	1
Vascular access site pain			

subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	4 / 58 (6.90%)
occurrences (all)	0	1	5
Allergic transfusion reaction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	3 / 58 (5.17%)
occurrences (all)	0	0	3
Cardiac disorders			
Tachycardia			
subjects affected / exposed	5 / 30 (16.67%)	4 / 61 (6.56%)	6 / 58 (10.34%)
occurrences (all)	7	9	7
Sinus tachycardia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	3 / 58 (5.17%)
occurrences (all)	5	2	4
Palpitations			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	3 / 58 (5.17%)
occurrences (all)	0	1	3
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 30 (0.00%)	3 / 61 (4.92%)	0 / 58 (0.00%)
occurrences (all)	0	4	0
Dizziness			
subjects affected / exposed	1 / 30 (3.33%)	10 / 61 (16.39%)	12 / 58 (20.69%)
occurrences (all)	1	11	15
Dysgeusia			
subjects affected / exposed	3 / 30 (10.00%)	0 / 61 (0.00%)	8 / 58 (13.79%)
occurrences (all)	3	0	8
Headache			
subjects affected / exposed	8 / 30 (26.67%)	16 / 61 (26.23%)	12 / 58 (20.69%)
occurrences (all)	9	20	17
Paraesthesia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	0 / 58 (0.00%)
occurrences (all)	2	1	0
Peripheral sensory neuropathy			

subjects affected / exposed	3 / 30 (10.00%)	2 / 61 (3.28%)	7 / 58 (12.07%)
occurrences (all)	5	2	7
Tremor			
subjects affected / exposed	0 / 30 (0.00%)	10 / 61 (16.39%)	1 / 58 (1.72%)
occurrences (all)	0	10	1
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	8 / 30 (26.67%)	1 / 61 (1.64%)	8 / 58 (13.79%)
occurrences (all)	10	1	8
Thrombocytopenia			
subjects affected / exposed	25 / 30 (83.33%)	21 / 61 (34.43%)	40 / 58 (68.97%)
occurrences (all)	45	26	89
Neutropenia			
subjects affected / exposed	14 / 30 (46.67%)	31 / 61 (50.82%)	36 / 58 (62.07%)
occurrences (all)	33	65	85
Lymphopenia			
subjects affected / exposed	4 / 30 (13.33%)	9 / 61 (14.75%)	7 / 58 (12.07%)
occurrences (all)	10	13	18
Leukopenia			
subjects affected / exposed	7 / 30 (23.33%)	5 / 61 (8.20%)	6 / 58 (10.34%)
occurrences (all)	13	8	9
Anaemia			
subjects affected / exposed	20 / 30 (66.67%)	24 / 61 (39.34%)	41 / 58 (70.69%)
occurrences (all)	33	46	73
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	5 / 58 (8.62%)
occurrences (all)	1	0	5
Ear pain			
subjects affected / exposed	0 / 30 (0.00%)	2 / 61 (3.28%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Vision blurred			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	3 / 58 (5.17%)
occurrences (all)	1	1	4
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	4 / 58 (6.90%)
occurrences (all)	4	3	5
Oral pain			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	6 / 58 (10.34%)
occurrences (all)	2	1	6
Oesophagitis			
subjects affected / exposed	2 / 30 (6.67%)	0 / 61 (0.00%)	2 / 58 (3.45%)
occurrences (all)	2	0	2
Nausea			
subjects affected / exposed	17 / 30 (56.67%)	14 / 61 (22.95%)	36 / 58 (62.07%)
occurrences (all)	31	15	60
Haemorrhoids			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	4 / 58 (6.90%)
occurrences (all)	2	1	4
Haematochezia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	5 / 58 (8.62%)
occurrences (all)	2	1	5
Dyspepsia			
subjects affected / exposed	3 / 30 (10.00%)	3 / 61 (4.92%)	8 / 58 (13.79%)
occurrences (all)	3	3	9
Dry mouth			
subjects affected / exposed	3 / 30 (10.00%)	2 / 61 (3.28%)	5 / 58 (8.62%)
occurrences (all)	3	2	6
Diarrhoea			
subjects affected / exposed	14 / 30 (46.67%)	9 / 61 (14.75%)	24 / 58 (41.38%)
occurrences (all)	20	10	34
Constipation			
subjects affected / exposed	5 / 30 (16.67%)	10 / 61 (16.39%)	19 / 58 (32.76%)
occurrences (all)	5	10	23
Abdominal pain upper			
subjects affected / exposed	2 / 30 (6.67%)	0 / 61 (0.00%)	3 / 58 (5.17%)
occurrences (all)	2	0	3

Abdominal pain lower			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	3 / 58 (5.17%)
occurrences (all)	0	0	3
Stomatitis			
subjects affected / exposed	4 / 30 (13.33%)	1 / 61 (1.64%)	5 / 58 (8.62%)
occurrences (all)	4	1	6
Abdominal pain			
subjects affected / exposed	5 / 30 (16.67%)	4 / 61 (6.56%)	8 / 58 (13.79%)
occurrences (all)	6	4	9
Vomiting			
subjects affected / exposed	10 / 30 (33.33%)	6 / 61 (9.84%)	16 / 58 (27.59%)
occurrences (all)	11	6	21
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	4 / 58 (6.90%)
occurrences (all)	1	1	5
Hyperhidrosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	3 / 58 (5.17%)
occurrences (all)	0	0	3
Erythema			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	3 / 58 (5.17%)
occurrences (all)	0	1	3
Dry skin			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	3 / 58 (5.17%)
occurrences (all)	1	0	3
Alopecia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 61 (0.00%)	4 / 58 (6.90%)
occurrences (all)	1	0	4
Skin mass			
subjects affected / exposed	2 / 30 (6.67%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences (all)	2	0	1
Skin lesion			
subjects affected / exposed	0 / 30 (0.00%)	3 / 61 (4.92%)	0 / 58 (0.00%)
occurrences (all)	0	3	0
Rash maculo-papular			

subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences (all)	3	1	1
Pruritus			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Petechiae			
subjects affected / exposed	0 / 30 (0.00%)	0 / 61 (0.00%)	3 / 58 (5.17%)
occurrences (all)	0	0	3
Rash			
subjects affected / exposed	1 / 30 (3.33%)	5 / 61 (8.20%)	0 / 58 (0.00%)
occurrences (all)	1	5	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	4 / 58 (6.90%)
occurrences (all)	3	5	7
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 30 (10.00%)	7 / 61 (11.48%)	8 / 58 (13.79%)
occurrences (all)	4	10	9
Back pain			
subjects affected / exposed	3 / 30 (10.00%)	3 / 61 (4.92%)	12 / 58 (20.69%)
occurrences (all)	3	3	13
Musculoskeletal chest pain			
subjects affected / exposed	2 / 30 (6.67%)	4 / 61 (6.56%)	0 / 58 (0.00%)
occurrences (all)	2	4	0
Muscle spasms			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	1 / 58 (1.72%)
occurrences (all)	2	2	2
Flank pain			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	3 / 58 (5.17%)
occurrences (all)	3	2	3
Bone pain			
subjects affected / exposed	3 / 30 (10.00%)	3 / 61 (4.92%)	6 / 58 (10.34%)
occurrences (all)	3	3	6
Myalgia			

subjects affected / exposed	2 / 30 (6.67%)	5 / 61 (8.20%)	3 / 58 (5.17%)
occurrences (all)	2	5	3
Neck pain			
subjects affected / exposed	0 / 30 (0.00%)	2 / 61 (3.28%)	3 / 58 (5.17%)
occurrences (all)	0	2	3
Pain in extremity			
subjects affected / exposed	2 / 30 (6.67%)	4 / 61 (6.56%)	6 / 58 (10.34%)
occurrences (all)	4	4	7
Muscular weakness			
subjects affected / exposed	0 / 30 (0.00%)	2 / 61 (3.28%)	3 / 58 (5.17%)
occurrences (all)	0	2	4
Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	1 / 58 (1.72%)
occurrences (all)	2	2	1
Oral candidiasis			
subjects affected / exposed	3 / 30 (10.00%)	0 / 61 (0.00%)	1 / 58 (1.72%)
occurrences (all)	3	0	1
COVID-19			
subjects affected / exposed	2 / 30 (6.67%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	1 / 30 (3.33%)	1 / 61 (1.64%)	3 / 58 (5.17%)
occurrences (all)	1	1	3
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	12 / 30 (40.00%)	8 / 61 (13.11%)	20 / 58 (34.48%)
occurrences (all)	16	11	25
Dehydration			
subjects affected / exposed	1 / 30 (3.33%)	2 / 61 (3.28%)	3 / 58 (5.17%)
occurrences (all)	1	2	3
Hypercalcaemia			
subjects affected / exposed	3 / 30 (10.00%)	1 / 61 (1.64%)	2 / 58 (3.45%)
occurrences (all)	3	3	2
Hyperglycaemia			

subjects affected / exposed	4 / 30 (13.33%)	4 / 61 (6.56%)	5 / 58 (8.62%)
occurrences (all)	8	14	8
Hyperkalaemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 61 (1.64%)	4 / 58 (6.90%)
occurrences (all)	0	1	4
Hypernatraemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	1 / 58 (1.72%)
occurrences (all)	2	1	1
Hyperphosphataemia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 61 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Hypertriglyceridaemia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	4 / 58 (6.90%)
occurrences (all)	3	4	6
Hyperuricaemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	3 / 58 (5.17%)
occurrences (all)	2	1	4
Hypoalbuminaemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 61 (1.64%)	2 / 58 (3.45%)
occurrences (all)	3	4	2
Hypocalcaemia			
subjects affected / exposed	1 / 30 (3.33%)	6 / 61 (9.84%)	5 / 58 (8.62%)
occurrences (all)	3	12	5
Hypokalaemia			
subjects affected / exposed	8 / 30 (26.67%)	10 / 61 (16.39%)	14 / 58 (24.14%)
occurrences (all)	13	13	28
Hypomagnesaemia			
subjects affected / exposed	8 / 30 (26.67%)	5 / 61 (8.20%)	13 / 58 (22.41%)
occurrences (all)	21	9	27
Hyponatraemia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 61 (3.28%)	5 / 58 (8.62%)
occurrences (all)	6	6	7
Hypophosphataemia			
subjects affected / exposed	7 / 30 (23.33%)	5 / 61 (8.20%)	10 / 58 (17.24%)
occurrences (all)	11	6	14
Malnutrition			

subjects affected / exposed	4 / 30 (13.33%)	2 / 61 (3.28%)	0 / 58 (0.00%)
occurrences (all)	5	2	0

Non-serious adverse events	Liso-cel Arm only		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	92 / 92 (100.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	8 / 92 (8.70%)		
occurrences (all)	10		
Deep vein thrombosis			
subjects affected / exposed	4 / 92 (4.35%)		
occurrences (all)	4		
Orthostatic hypotension			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	6		
Jugular vein thrombosis			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Hypotension			
subjects affected / exposed	19 / 92 (20.65%)		
occurrences (all)	37		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	11 / 92 (11.96%)		
occurrences (all)	11		
Chills			
subjects affected / exposed	8 / 92 (8.70%)		
occurrences (all)	8		
Pyrexia			
subjects affected / exposed	22 / 92 (23.91%)		
occurrences (all)	24		
Pain			
subjects affected / exposed	4 / 92 (4.35%)		
occurrences (all)	5		
Oedema peripheral			

subjects affected / exposed	15 / 92 (16.30%)		
occurrences (all)	19		
Non-cardiac chest pain			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	5		
Mucosal inflammation			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	5		
Malaise			
subjects affected / exposed	3 / 92 (3.26%)		
occurrences (all)	3		
Fatigue			
subjects affected / exposed	37 / 92 (40.22%)		
occurrences (all)	45		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	9 / 92 (9.78%)		
occurrences (all)	11		
Cytokine release syndrome			
subjects affected / exposed	33 / 92 (35.87%)		
occurrences (all)	34		
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	13 / 92 (14.13%)		
occurrences (all)	14		
Dyspnoea			
subjects affected / exposed	13 / 92 (14.13%)		
occurrences (all)	13		
Rhinorrhoea			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			

subjects affected / exposed	0 / 92 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	3 / 92 (3.26%)		
occurrences (all)	3		
Oropharyngeal pain			
subjects affected / exposed	2 / 92 (2.17%)		
occurrences (all)	3		
Nasal congestion			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	5		
Epistaxis			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	9		
Hiccups			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	6		
Psychiatric disorders			
Depression			
subjects affected / exposed	4 / 92 (4.35%)		
occurrences (all)	4		
Anxiety			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	5		
Confusional state			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	5		
Insomnia			
subjects affected / exposed	19 / 92 (20.65%)		
occurrences (all)	22		
Hallucination			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Investigations			
Weight increased			

subjects affected / exposed	2 / 92 (2.17%)		
occurrences (all)	4		
Weight decreased			
subjects affected / exposed	3 / 92 (3.26%)		
occurrences (all)	3		
Platelet count decreased			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	11		
Neutrophil count decreased			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	13		
International normalised ratio increased			
subjects affected / exposed	4 / 92 (4.35%)		
occurrences (all)	8		
C-reactive protein increased			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	10		
Blood alkaline phosphatase increased			
subjects affected / exposed	8 / 92 (8.70%)		
occurrences (all)	10		
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	12		
Alanine aminotransferase increased			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	7		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Fall			

subjects affected / exposed occurrences (all)	4 / 92 (4.35%) 5		
Vascular access site pain subjects affected / exposed occurrences (all)	6 / 92 (6.52%) 6		
Infusion related reaction subjects affected / exposed occurrences (all)	8 / 92 (8.70%) 8		
Allergic transfusion reaction subjects affected / exposed occurrences (all)	1 / 92 (1.09%) 1		
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	9 / 92 (9.78%) 12		
Sinus tachycardia subjects affected / exposed occurrences (all)	7 / 92 (7.61%) 27		
Palpitations subjects affected / exposed occurrences (all)	3 / 92 (3.26%) 3		
Nervous system disorders			
Aphasia subjects affected / exposed occurrences (all)	4 / 92 (4.35%) 4		
Dizziness subjects affected / exposed occurrences (all)	22 / 92 (23.91%) 29		
Dysgeusia subjects affected / exposed occurrences (all)	3 / 92 (3.26%) 3		
Headache subjects affected / exposed occurrences (all)	40 / 92 (43.48%) 61		
Paraesthesia			

subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Peripheral sensory neuropathy			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	8		
Tremor			
subjects affected / exposed	11 / 92 (11.96%)		
occurrences (all)	12		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	10 / 92 (10.87%)		
occurrences (all)	14		
Thrombocytopenia			
subjects affected / exposed	54 / 92 (58.70%)		
occurrences (all)	125		
Neutropenia			
subjects affected / exposed	75 / 92 (81.52%)		
occurrences (all)	196		
Lymphopenia			
subjects affected / exposed	25 / 92 (27.17%)		
occurrences (all)	41		
Leukopenia			
subjects affected / exposed	17 / 92 (18.48%)		
occurrences (all)	39		
Anaemia			
subjects affected / exposed	62 / 92 (67.39%)		
occurrences (all)	133		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	4 / 92 (4.35%)		
occurrences (all)	4		
Ear pain			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	7		
Eye disorders			

Vision blurred			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	7		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	6		
Oral pain			
subjects affected / exposed	3 / 92 (3.26%)		
occurrences (all)	3		
Oesophagitis			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	49 / 92 (53.26%)		
occurrences (all)	80		
Haemorrhoids			
subjects affected / exposed	2 / 92 (2.17%)		
occurrences (all)	2		
Haematochezia			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 92 (3.26%)		
occurrences (all)	3		
Dyspepsia			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	5		
Dry mouth			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	7		
Diarrhoea			
subjects affected / exposed	23 / 92 (25.00%)		
occurrences (all)	33		
Constipation			

subjects affected / exposed	30 / 92 (32.61%)		
occurrences (all)	43		
Abdominal pain upper			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Abdominal pain lower			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	3		
Stomatitis			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	6		
Abdominal pain			
subjects affected / exposed	13 / 92 (14.13%)		
occurrences (all)	15		
Vomiting			
subjects affected / exposed	18 / 92 (19.57%)		
occurrences (all)	30		
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	2 / 92 (2.17%)		
occurrences (all)	2		
Hyperhidrosis			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	2 / 92 (2.17%)		
occurrences (all)	2		
Dry skin			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	5		
Alopecia			
subjects affected / exposed	2 / 92 (2.17%)		
occurrences (all)	2		
Skin mass			
subjects affected / exposed	0 / 92 (0.00%)		
occurrences (all)	0		

Skin lesion			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Rash maculo-papular			
subjects affected / exposed	2 / 92 (2.17%)		
occurrences (all)	3		
Pruritus			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	9		
Petechiae			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	9 / 92 (9.78%)		
occurrences (all)	9		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 92 (4.35%)		
occurrences (all)	4		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	17 / 92 (18.48%)		
occurrences (all)	17		
Back pain			
subjects affected / exposed	14 / 92 (15.22%)		
occurrences (all)	16		
Musculoskeletal chest pain			
subjects affected / exposed	3 / 92 (3.26%)		
occurrences (all)	3		
Muscle spasms			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	6		
Flank pain			
subjects affected / exposed	3 / 92 (3.26%)		
occurrences (all)	4		
Bone pain			

subjects affected / exposed occurrences (all)	12 / 92 (13.04%) 15		
Myalgia subjects affected / exposed occurrences (all)	11 / 92 (11.96%) 13		
Neck pain subjects affected / exposed occurrences (all)	7 / 92 (7.61%) 8		
Pain in extremity subjects affected / exposed occurrences (all)	8 / 92 (8.70%) 8		
Muscular weakness subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 6		
Infections and infestations			
Pneumonia subjects affected / exposed occurrences (all)	2 / 92 (2.17%) 2		
Oral candidiasis subjects affected / exposed occurrences (all)	2 / 92 (2.17%) 2		
COVID-19 subjects affected / exposed occurrences (all)	0 / 92 (0.00%) 0		
Urinary tract infection subjects affected / exposed occurrences (all)	6 / 92 (6.52%) 7		
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	21 / 92 (22.83%) 29		
Dehydration subjects affected / exposed occurrences (all)	2 / 92 (2.17%) 3		
Hypercalcaemia			

subjects affected / exposed	2 / 92 (2.17%)			
occurrences (all)	3			
Hyperglycaemia				
subjects affected / exposed	6 / 92 (6.52%)			
occurrences (all)	13			
Hyperkalaemia				
subjects affected / exposed	0 / 92 (0.00%)			
occurrences (all)	0			
Hypernatraemia				
subjects affected / exposed	1 / 92 (1.09%)			
occurrences (all)	2			
Hyperphosphataemia				
subjects affected / exposed	2 / 92 (2.17%)			
occurrences (all)	4			
Hypertriglyceridaemia				
subjects affected / exposed	6 / 92 (6.52%)			
occurrences (all)	8			
Hyperuricaemia				
subjects affected / exposed	3 / 92 (3.26%)			
occurrences (all)	4			
Hypoalbuminaemia				
subjects affected / exposed	4 / 92 (4.35%)			
occurrences (all)	9			
Hypocalcaemia				
subjects affected / exposed	7 / 92 (7.61%)			
occurrences (all)	12			
Hypokalaemia				
subjects affected / exposed	21 / 92 (22.83%)			
occurrences (all)	28			
Hypomagnesaemia				
subjects affected / exposed	15 / 92 (16.30%)			
occurrences (all)	26			
Hyponatraemia				
subjects affected / exposed	9 / 92 (9.78%)			
occurrences (all)	14			
Hypophosphataemia				

subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	11		
Malnutrition			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 February 2019	Eligibility criteria, study design, endpoints, concomitant medication and procedures, prohibited concomitant medication and procedures updated.
09 December 2019	Toxicity management guidelines update for MAS/HLH

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
13 March 2020	Temporary suspension of screening, enrollment, and apheresis due to COVID-19 pandemic	27 April 2020

Notes:

Limitations and caveats

None reported