Clinical trial results:
A SINGLE ARM, OPEN-LABEL, MULTI-CENTRE, PHASE I/II STUDY EVALUATING THE SAFETY AND CLINICAL ACTIVITY OF AUTO4, A CAR T CELL TREATMENT TARGETING TRBC1, IN PATIENTS WITH RELAPSED OR REFRACTORY TRBC1 POSITIVE SELECTED T CELL NON-HODGKIN LYMPHOMA

Summary

EudraCT number	2017-001965-26
Trial protocol	GB ES
Global end of trial date	12 December 2024

Results information

Result version number	v1 (current)
This version publication date	20 December 2025
First version publication date	20 December 2025

Trial information

Trial identification

Sponsor protocol code	AUTO4-TL1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03590574
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Autolus Limited
Sponsor organisation address	191 Wood Lane, London, United Kingdom,
Public contact	Clinical Project manager, Autolus Ltd, 44 02038296230, clinicaltrials@autolus.com
Scientific contact	Clinical Project manager, Autolus Ltd, 44 02038296230, clinicaltrials@autolus.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	03 March 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 December 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Phase I:
To assess the safety and tolerability of AUTO4 administration.
To identify the recommended phase II dose (RP2D) and maximum tolerated dose (MTD), if an MTD exists.

Phase II:
To assess the safety and clinical activity of AUTO4 when administered at the RP2D

Protection of trial subjects:

Standard drugs and palliative radiotherapy required by the participant could be administered alongside the trial protocol. Participants could receive bridging therapy, between leukapheresis and admission for pre-conditioning therapy, prior to AUTO4 infusion.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 September 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	15 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	United Kingdom: 15
Worldwide total number of subjects	20
EEA total number of subjects	5

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	16
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

First participant enrolled: 22-Sep-2018
Last participant enrolled: 10-Oct-2023

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	125[1]
Number of subjects completed	15

Pre-assignment subject non-completion reasons

Reason: Number of subjects	No TRBC1 status: 7
Reason: Number of subjects	TRBC1 negative: 68
Reason: Number of subjects	TRBC1 not evaluable: 10
Reason: Number of subjects	TRBC1 positive but not enrolled: 20
Reason: Number of subjects	enrolled - died prior to infusion: 2
Reason: Number of subjects	enrolled - withdrew due to "other" before infusion: 3

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: The pre-assignment period includes all screened subjects. Of these 20 enrolled (the worldwide number enrolled), but 5 withdrew prior to receiving AUTO4 infusion, such that 15 patients are analysed (baseline period).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1 (25x10^6 cells)

Arm description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma.
Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3.
Cohort 1 dosed with 25x10^6 CAR T cells using the original manufacturing process.

Arm type	Experimental
Investigational medicinal product name	AUTO4 (RQR8/ANTI-TRBC1 CAR Positive T Cells)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Following pre-conditioning with chemotherapy (fludarabine and cyclophosphamide) over Days -6 to -3, patients were treated with a single infusion of RQR8/aTRBC1-CAR positive T cells on Day 0. Provided that all criteria were satisfied, patients could receive re-treatment (second cycle) of AUTO4.

Arm title	Cohort 2 (75x10^6 cells)

Arm description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3.
Cohort 2 dosed with 75x10^6 CAR T cells using the original manufacturing process.

Arm type	Experimental
Investigational medicinal product name	AUTO4 (RQR8/ANTI-TRBC1 CAR Positive T Cells)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Following pre-conditioning with chemotherapy (fludarabine and cyclophosphamide) over Days -6 to -3, patients were treated with a single infusion of RQR8/aTRBC1-CAR positive T cells on Day 0. Provided that all criteria were satisfied, patients could receive re-treatment (second cycle) of AUTO4.

Arm title	Cohort 3 (225x10^6 cells)

Arm description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 3 dosed with 225x10^6 CAR T cells using the original manufacturing process.

Arm type	Experimental
Investigational medicinal product name	AUTO4 (RQR8/ANTI-TRBC1 CAR Positive T Cells)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Following pre-conditioning with chemotherapy (fludarabine and cyclophosphamide) over Days -6 to -3, patients were treated with a single infusion of RQR8/aTRBC1-CAR positive T cells on Day 0. Provided that all criteria were satisfied, patients could receive re-treatment (second cycle) of AUTO4.

Arm title	Cohort 4 (450x10^6 cells)

Arm description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 4 dosed with 450x10^6 CAR T cells using the original manufacturing process.

Arm type	Experimental
Investigational medicinal product name	AUTO4 (RQR8/ANTI-TRBC1 CAR Positive T Cells)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Following pre-conditioning with chemotherapy (fludarabine and cyclophosphamide) over Days -6 to -3, patients were treated with a single infusion of RQR8/aTRBC1-CAR positive T cells on Day 0. Provided that all criteria were satisfied, patients could receive re-treatment (second cycle) of AUTO4.

Arm title	Cohort 3B (225x10^6 cells)

Arm description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 3B dosed with 225x10^6 CAR T cells using the modified manufacturing process.

Arm type	Experimental

Investigational medicinal product name	AUTO4 (RQR8/ANTI-TRBC1 CAR Positive T Cells)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Following pre-conditioning with chemotherapy (fludarabine and cyclophosphamide) over Days -6 to -3, patients were treated with a single infusion of RQR8/aTRBC1-CAR positive T cells on Day 0. Provided that all criteria were satisfied, patients could receive re-treatment (second cycle) of AUTO4.

Arm title	Cohort 4B (450x10^6 cells)

Arm description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 4B dosed with 450x10^6 CAR T cells using the modified manufacturing process.

Arm type	Experimental
Investigational medicinal product name	AUTO4 (RQR8/ANTI-TRBC1 CAR Positive T Cells)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Following pre-conditioning with chemotherapy (fludarabine and cyclophosphamide) over Days -6 to -3, patients were treated with a single infusion of RQR8/aTRBC1-CAR positive T cells on Day 0. Provided that all criteria were satisfied, patients could receive re-treatment (second cycle) of AUTO4.

Arm title	Cohort 5B (900x10^6 cells)

Arm description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 5B dosed with 900x10^6 CAR T cells using the modified manufacturing process.

Arm type	Experimental
Investigational medicinal product name	AUTO4 (RQR8/ANTI-TRBC1 CAR Positive T Cells)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Following pre-conditioning with chemotherapy (fludarabine and cyclophosphamide) over Days -6 to -3, patients were treated with a single infusion of RQR8/aTRBC1-CAR positive T cells on Day 0. Provided that all criteria were satisfied, patients could receive re-treatment (second cycle) of AUTO4.

Number of subjects in period 1[2]	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)
Started	3	2	1
Completed	1	1	0
Not completed	2	1	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Other	2	1	1
Death	-	-	-

Number of subjects in period 1[2]	Cohort 4 (450x10^6 cells)	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)
Started	4	1	3
Completed	2	0	0
Not completed	2	1	3
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	1	1	2
Other	-	-	-
Death	-	-	1

Number of subjects in period 1[2]	Cohort 5B (900x10^6 cells)
Started	1
Completed	0
Not completed	1
Adverse event, serious fatal	1
Consent withdrawn by subject	-
Other	-
Death	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Five participants enrolled did not receive AUTO4 infusion (2 died, 3 withdrew due to 'other' reasons). These participants are not included in the analyses.

Baseline characteristics

Reporting groups	
Reporting group title	Cohort 1 (25x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 1 dosed with 25x10^6 CAR T cells using the original manufacturing process.	
Reporting group title	Cohort 2 (75x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 2 dosed with 75x10^6 CAR T cells using the original manufacturing process.	
Reporting group title	Cohort 3 (225x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 3 dosed with 225x10^6 CAR T cells using the original manufacturing process.	
Reporting group title	Cohort 4 (450x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 4 dosed with 450x10^6 CAR T cells using the original manufacturing process.	
Reporting group title	Cohort 3B (225x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 3B dosed with 225x10^6 CAR T cells using the modified manufacturing process.	
Reporting group title	Cohort 4B (450x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 4B dosed with 450x10^6 CAR T cells using the modified manufacturing process.	
Reporting group title	Cohort 5B (900x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 5B dosed with 900x10^6 CAR T cells using the modified manufacturing process.	

Reporting group values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)
Number of subjects	3	2	1
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	2	1
From 65-84 years	0	0	0

85 years and over	0	0	0

Age continuous			
Units: years			
arithmetic mean	50.7	44.0	47.0
standard deviation	± 14.57	± 12.73	± 0
Gender categorical			
Units: Subjects			
Female	2	1	0
Male	1	1	1
Stage of Lymphoma at screening			
Units: Subjects			
One	0	0	0
Two	0	2	0
Three	1	0	1
Four	2	0	0
ECOG Score			
Units: Subjects			
0 - Fully Active	1	1	0
1 - Restricted	2	1	1
2 - Ambulatory	0	0	0
3 - Limited Self-care	0	0	0
4 - Completely Disabled	0	0	0
5 - Death	0	0	0

Reporting group values	Cohort 4 (450x10^6 cells)	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)
Number of subjects	4	1	3
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	0	3
From 65-84 years	0	1	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	56.5	72.0	58.7
standard deviation	± 8.58	± 0	± 3.51
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	4	1	3

Stage of Lymphoma at screening Units: Subjects			
One	0	0	0
Two	0	0	0
Three	3	0	1
Four	1	1	2
ECOG Score Units: Subjects			
0 - Fully Active	1	0	1
1 - Restricted	3	1	2
2 - Ambulatory	0	0	0
3 - Limited Self-care	0	0	0
4 - Completely Disabled	0	0	0
5 - Death	0	0	0

Reporting group values	Cohort 5B (900x10^6 cells)	Total	
Number of subjects	1	15	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	13	
From 65-84 years	1	2	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	70.0		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	0	3	
Male	1	12	
Stage of Lymphoma at screening Units: Subjects			
One	0	0	
Two	0	2	
Three	0	6	
Four	1	7	
ECOG Score Units: Subjects			
0 - Fully Active	1	5	
1 - Restricted	0	10	
2 - Ambulatory	0	0	
3 - Limited Self-care	0	0	
4 - Completely Disabled	0	0	
5 - Death	0	0	

End points

End points reporting groups

Reporting group title	Cohort 1 (25x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 1 dosed with 25x10^6 CAR T cells using the original manufacturing process.	
Reporting group title	Cohort 2 (75x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 2 dosed with 75x10^6 CAR T cells using the original manufacturing process.	
Reporting group title	Cohort 3 (225x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 3 dosed with 225x10^6 CAR T cells using the original manufacturing process.	
Reporting group title	Cohort 4 (450x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 4 dosed with 450x10^6 CAR T cells using the original manufacturing process.	
Reporting group title	Cohort 3B (225x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 3B dosed with 225x10^6 CAR T cells using the modified manufacturing process.	
Reporting group title	Cohort 4B (450x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 4B dosed with 450x10^6 CAR T cells using the modified manufacturing process.	
Reporting group title	Cohort 5B (900x10^6 cells)
Reporting group description:	
Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 5B dosed with 900x10^6 CAR T cells using the modified manufacturing process.	
Subject analysis set title	Infused Set - Phase I
Subject analysis set type	Full analysis
Subject analysis set description:	
The Infused Set comprises all patients who have received at least one infusion of AUTO4 treatment.	

Primary: Incidence of Grade 3 to Grade 5 toxicity occurring within 60 days of AUTO4 infusion.

End point title	Incidence of Grade 3 to Grade 5 toxicity occurring within 60 days of AUTO4 infusion.[1]
End point description:	
To assess the safety and tolerability of AUTO4 administration. The incidence of Grade 3-5 toxicities occurring within 60 days of AUTO4 infusion. The analysis was conducted on the safety set which included all 15 participants enrolled and treated in the Phase 1 dose escalation.	
End point type	Primary
End point timeframe:	
Within 60 days of AUTO4 infusion.	

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: This is a Phase 1 study and evaluation of toxicity is not associated with a statistical analyses

End point values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)	Cohort 4 (450x10^6 cells)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	1	4
Units: Participants	3	2	1	4

End point values	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)	Cohort 5B (900x10^6 cells)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	1	
Units: Participants	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Frequency of DLT of AUTO4 within 28 days of AUTO4 infusion.

End point title	Frequency of DLT of AUTO4 within 28 days of AUTO4

End point description:

To identify the RP2D and MTD, if an MTD exists, of AUTO4 by monitoring the frequency of DLT of AUTO4 within 28 days of AUTO4 infusion.
The analysis was conducted on the safety set which included all 15 participants enrolled and treated in the Phase 1 dose escalation.

End point type	Primary

End point timeframe:

28 days of AUTO4 infusion

Notes:

[2] - 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: This is a Phase 1 study and reporting of DLTs is not associated with a statistical analyses

End point values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)	Cohort 4 (450x10^6 cells)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	1	4
Units: Participants	0	0	0	0

End point values	Cohort 3B (225x10^6	Cohort 4B (450x10^6	Cohort 5B (900x10^6	

	cells)	cells)	cells)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	1	
Units: Participants	0	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency and severity of all adverse events and serious adverse events.

End point title	Frequency and severity of all adverse events and serious adverse events.

End point description:

All adverse events (AEs)/serious adverse events (SAEs) were recorded from admission for pre-conditioning chemotherapy (Day -6 relative to AUTO4). Due to the long period between consent and AUTO4 treatment, any AEs/SAEs related to bridging chemotherapy not associated with study procedures did not require reporting as study AEs/SAEs. Any significant events were added to the patient's medical history. All AEs/SAEs related to study procedures (leukapheresis, bone marrow assessments) were reported.
The analysis was conducted on the safety set which included all 15 participants enrolled and treated in the Phase 1 dose escalation.

End point type	Secondary

End point timeframe:

24 months post-treatment

End point values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)	Cohort 4 (450x10^6 cells)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	1	4
Units: Participants				
Patients with any AE	3	2	1	4
Patients with any AE of Grade 3 or higher	3	2	1	4
Patients with any SAE	2	1	0	2
Patients with any SAE of Grade 3 or higher	2	0	0	1

End point values	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)	Cohort 5B (900x10^6 cells)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	1	
Units: Participants				
Patients with any AE	1	2	1	
Patients with any AE of Grade 3 or higher	1	1	1	

Patients with any SAE	0	2	1	
Patients with any SAE of Grade 3 or higher	0	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence and severity of opportunistic infections following AUTO4 infusion.

End point title	Incidence and severity of opportunistic infections following AUTO4 infusion.

End point description:

Incidence and severity of opportunistic infections following AUTO4 infusion.
The analysis was conducted on the safety set which included all 15 participants enrolled and treated in the Phase 1 dose escalation.

End point type	Secondary

End point timeframe:

24 months post-treatment

End point values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)	Cohort 4 (450x10^6 cells)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	1	4
Units: Participants				
Any infection or infestation post-infusion	3	1	1	1
Any infection or infestation ≥Grade3 post-infusion	1	0	0	0

End point values	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)	Cohort 5B (900x10^6 cells)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	1	
Units: Participants				
Any infection or infestation post-infusion	1	1	1	
Any infection or infestation ≥Grade3 post-infusion	0	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Complete response (CR) rate

End point title	Complete response (CR) rate

End point description:

Participants achieving objective response per Lugano criteria based on independent central radiology review.
The Lugano classification of response by FDG PET-CT:
1. no uptake or no residual uptake (when used interim)
2. slight uptake, but below blood pool (mediastinum)
3. uptake above mediastinal, but below or equal to uptake in the liver
4. uptake slightly to moderately higher than liver
5. markedly increased uptake or any new lesion (on response evaluation)
Non-progressive disease:
- Complete metabolic response – score of 1, 2, or 3 in nodal or extranodal sites with or without a residual mass
- Partial metabolic response – score of 4 or 5 with reduced uptake compared with baseline and residual mass(es) of any size
- Stable disease or no metabolic response – score of 4 or 5 with no obvious change in FDG uptake

Progressive disease score of 4 or 5 in any lesion with an increase in intensity of FDG uptake from baseline.

End point type	Secondary

End point timeframe:

Up to end of study

End point values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)	Cohort 4 (450x10^6 cells)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	1	4
Units: Participants	1	0	1	3

End point values	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)	Cohort 5B (900x10^6 cells)	Infused Set - Phase I
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	3	1	15
Units: Participants	0	0	0	5

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival

End point title	Progression-free survival

End point description:

PFS was defined as the time from the first treatment of AUTO4 to documented disease progression/relapse or death due to any cause.
If a patient did not have relapse or death due to any reason prior to data cut-off, PFS was censored at the date of the last adequate assessment by default.
Patients who proceeded to SCT after AUTO4 infusion were censored at the time of SCT (including the

conditioning regimen for SCT).
Patients who received new non-protocol anti-cancer therapies other than SCT were censored as the date of last adequate assessment prior to new therapy.
Patients who experienced event after missing two or more scheduled disease assessments were censored at the date of last adequate assessment prior to the event.
The analysis was conducted on the infused set which included all 15 participants enrolled and treated in the Phase 1 dose escalation.

End point type	Secondary

End point timeframe:

Up to 30 months

End point values	Infused Set - Phase I			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: months				
median (confidence interval 95%)	2.89 (0.95 to 6.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival

End point description:

Number of participants alive at end of study following treatment with AUTO4. No median overall survival was evaluable.

End point type	Secondary

End point timeframe:

Up to 30 months

End point values	Infused Set - Phase I			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Participants	9			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response (PR and CR).

End point title	Time to response (PR and CR).

End point description:

To evaluate the overall clinical efficacy of AUTO4.
The analysis was conducted on the infused set which included all 15 participants enrolled and treated in the Phase 1 dose escalation.

End point type	Secondary

End point timeframe:

24 months post-treatment

End point values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)	Cohort 4 (450x10^6 cells)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	1	4
Units: Participants				
By Month 1	1	0	1	3
By Month 3	0	1	0	0
By Month 6	0	0	0	0
By Month 9	0	0	0	1
By Month 12	0	0	0	0
By Month 18	0	0	0	0
By Month 24	0	0	0	0

End point values	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)	Cohort 5B (900x10^6 cells)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	1	
Units: Participants				
By Month 1	0	0	1	
By Month 3	0	0	0	
By Month 6	0	0	0	
By Month 9	0	0	0	
By Month 12	0	0	0	
By Month 18	0	0	0	
By Month 24	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: RQR8/aTRBC1-CAR positive T cells as determined by polymerase chain reaction and/or flow cytometry at a range of time points in the peripheral blood.

End point title	RQR8/aTRBC1-CAR positive T cells as determined by polymerase chain reaction and/or flow cytometry at a range of time points in the peripheral blood.

End point description:

To determine the expansion and persistence of AUTO4 following infusion.
The analysis was conducted on the infused set which included all 15 participants enrolled and treated in the Phase 1 dose escalation.

End point type	Secondary

End point timeframe:

At 24 months

End point values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)	Cohort 4 (450x10^6 cells)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[3]	1[4]	0[5]	2[6]
Units: copies/microgram DNA				
median (full range (min-max))	(to)	0 (0 to 0)	(to)	0 (0 to 0)

Notes:

[3] - Participants with available data at Month 24

[4] - Participants with available data at Month 24

[5] - Participants with available data at Month 24

[6] - Participants with available data at Month 24

End point values	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)	Cohort 5B (900x10^6 cells)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[7]	0[8]	0[9]	
Units: copies/microgram DNA				
median (full range (min-max))	(to)	(to)	(to)	

Notes:

[7] - Participants with available data at Month 24

[8] - Participants with available data at Month 24

[9] - Participants with available data at Month 24

Attachments (see zip file)	Individual Concentration-time Profiles (PCR)/F14_1_1_1.jpg

Statistical analyses

No statistical analyses for this end point

Secondary: Enumeration of circulating TRBC1 positive T cells assessed by flow cytometry at a range of time points in the peripheral blood.

End point title	Enumeration of circulating TRBC1 positive T cells assessed by flow cytometry at a range of time points in the peripheral blood.

End point description:

Duration of TRBC1 positive T cell aplasia.
The analysis was conducted on the infused set which included all 15 participants enrolled and treated in the Phase 1 dose escalation.

End point type	Secondary

End point timeframe:

At 24 months

End point values	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)	Cohort 4 (450x10^6 cells)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[10]	1[11]	0[12]	0[13]
Units: cells/microlitre				
median (full range (min-max))	(to)	61.0 (61.0 to 61.0)	(to)	(to)

Notes:

[10] - Data only analysed for participants with available data at the timepoint

[11] - Data only analysed for participants with available data at the timepoint

[12] - Data only analysed for participants with available data at the timepoint

[13] - Data only analysed for participants with available data at the timepoint

End point values	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)	Cohort 5B (900x10^6 cells)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[14]	0[15]	0[16]	
Units: cells/microlitre				
median (full range (min-max))	(to)	(to)	(to)	

Notes:

[14] - Data only analysed for participants with available data at the timepoint

[15] - Data only analysed for participants with available data at the timepoint

[16] - Data only analysed for participants with available data at the timepoint

Attachments (see zip file)	Individual Concentration-time Profiles (FC)/F14_4_2_2.jpg

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response

End point title	Duration of response

End point description:

DOR is defined as the time from the first observed CR or PR to documented disease progression or death due to any cause, for patients who are considered as responders.

End point type	Secondary

End point timeframe:

Up to 27 months

End point values	Infused Set - Phase I			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Months				
median (confidence interval 95%)	4.27 (0.99 to 25.07)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Day -6 up to 24 months.
After Day 60, only the following were collected:
SAEs and treatment-related non-serious AEs; AEs of special interest; AEs related to a study procedure.

Adverse event reporting additional description:

Only AEs/SAEs related to study procedures were collected until admission for lymphodeletion chemotherapy. AEs related to intervening/bridging non-study related anti-cancer therapy administered prior to pre-conditioning or AEs associated with disease progression were not reported as AEs but were recorded as an update to the patients medical history.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Cohort 1 (25x10^6 cells)

Reporting group description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 1 dosed with 25x10^6 CAR T cells using the original manufacturing process.

Reporting group title	Cohort 2 (75x10^6 cells)

Reporting group description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 2 dosed with 75x10^6 CAR T cells using the original manufacturing process.

Reporting group title	Cohort 3 (225x10^6 cells)

Reporting group description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 3 dosed with 225x10^6 CAR T cells using the original manufacturing process.

Reporting group title	Cohort 4 (450x10^6 cells)

Reporting group description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 4 dosed with 450x10^6 CAR T cells using the original manufacturing process.

Reporting group title	Cohort 3B (225x10^6 cells)

Reporting group description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 3B dosed with 225x10^6 CAR T cells using the modified manufacturing process.

Reporting group title	Cohort 4B (450x10^6 cells)

Reporting group description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 4B dosed with 450x10^6 CAR T cells using the modified manufacturing process.

Reporting group title	Cohort 5B (900x10^6 cells)

Reporting group description:

Adult patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma. Pre-conditioning with Flu & CY; Days -6, -5, -4 and -3. Cohort 5B dosed with 900x10^6 CAR T cells using the modified manufacturing process.

Reporting group title	Total

Reporting group description:

All patients infused.

Serious adverse events	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	0 / 1 (0.00%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	11 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	4 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasmocytoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Transfusion reaction			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	4 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (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
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (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
Infections and infestations			
Epstein-Barr virus infection reactivation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (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
Infection			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (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	Cohort 4 (450x10^6 cells)	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	0 / 1 (0.00%)	2 / 3 (66.67%)
number of deaths (all causes)	1	0	2
number of deaths resulting from adverse events	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasmocytoma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (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
Injury, poisoning and procedural complications			
Transfusion reaction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 4 (50.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (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
Gastric haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (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
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 5B (900x10^6 cells)	Total	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	8 / 15 (53.33%)	
number of deaths (all causes)	1	6	
number of deaths resulting from adverse events	1	2	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	11 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	4 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasmocytoma			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Transfusion reaction			

subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	1 / 1	
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	4 / 4	4 / 4	
deaths causally related to treatment / all	1 / 1	1 / 1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences causally related to treatment / all	0 / 0	4 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymph node pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 15 (20.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 1 (0.00%)	3 / 15 (20.00%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			

subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Cohort 1 (25x10^6 cells)	Cohort 2 (75x10^6 cells)	Cohort 3 (225x10^6 cells)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	2 / 2 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	1 / 1 (100.00%)
occurrences (all)	3	2	1
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Chest pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulval disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Investigations			
Neutrophil count decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	6	3	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	1 / 1 (100.00%)
occurrences (all)	9	4	3
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epstein-Barr virus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Palpitations			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 3 (100.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	13	6	0
Neutropenia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	4	10	0
Thrombocytopenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	8	0

Febrile neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Immune thrombocytopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	1 / 1 (100.00%)
occurrences (all)	2	1	2
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			

Rash maculo-papular			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	1 / 1 (100.00%)
occurrences (all)	0	1	1
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Livedo reticularis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Epstein-Barr virus infection reactivation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Candida infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Cytomegalovirus infection reactivation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Onychomycosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Peritonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Toxoplasmosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Wound infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypoproteinaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Cohort 4 (450x10^6 cells)	Cohort 3B (225x10^6 cells)	Cohort 4B (450x10^6 cells)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	1 / 1 (100.00%)	2 / 3 (66.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Flushing			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 1 (100.00%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	2
Asthenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chest pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	3 / 4 (75.00%)	1 / 1 (100.00%)	1 / 3 (33.33%)
occurrences (all)	3	2	1
Reproductive system and breast disorders			
Vulval disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Psychiatric disorders			

Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Neutrophil count decreased			
subjects affected / exposed	3 / 4 (75.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	8	7	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	4	2	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Clostridium test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epstein-Barr virus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 4 (50.00%)	1 / 1 (100.00%)	1 / 3 (33.33%)
occurrences (all)	5	2	1
Neutropenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Lymphopenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0

Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 1 (100.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Rash maculo-papular			
subjects affected / exposed	2 / 4 (50.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Livedo reticularis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Candida infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toxoplasmosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoproteinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 5B (900x10^6 cells)	Total	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	15 / 15 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	4 / 15 (26.67%)	
occurrences (all)	0	5	
Flushing			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Raynaud's phenomenon			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	7 / 15 (46.67%)	
occurrences (all)	0	10	
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	5 / 15 (33.33%)	
occurrences (all)	0	5	
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	4	
Chest pain			

subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)	
occurrences (all)	1	1	
Chills			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Gait disturbance			
subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)	
occurrences (all)	1	1	
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 1 (0.00%)	5 / 15 (33.33%)	
occurrences (all)	0	6	
Reproductive system and breast disorders			
Vulval disorder			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Psychiatric disorders			

Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	6 / 15 (40.00%)	
occurrences (all)	0	24	
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	5 / 15 (33.33%)	
occurrences (all)	0	22	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)	3 / 15 (20.00%)	
occurrences (all)	1	3	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)	2 / 15 (13.33%)	
occurrences (all)	1	2	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 1 (100.00%)	2 / 15 (13.33%)	
occurrences (all)	1	3	
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Clostridium test positive			
subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)	
occurrences (all)	1	1	
Epstein-Barr virus test positive			
subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)	
occurrences (all)	1	1	
Platelet count decreased			

subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	2	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	2	
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
Headache			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)	
occurrences (all)	1	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	8 / 15 (53.33%)	
occurrences (all)	0	27	
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 15 (26.67%)	
occurrences (all)	0	18	
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 15 (20.00%)	
occurrences (all)	0	5	
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	11	

Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 15 (6.67%) 1	
Immune thrombocytopenia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 15 (6.67%) 6	
Eye disorders Dry eye subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 15 (6.67%) 1	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	5 / 15 (33.33%) 8	
Nausea subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	3 / 15 (20.00%) 3	
Vomiting subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	2 / 15 (13.33%) 3	
Abdominal pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 15 (6.67%) 1	
Ascites subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 15 (6.67%) 1	
Constipation subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 15 (6.67%) 1	
Dyspepsia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 15 (6.67%) 1	
Toothache subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 15 (6.67%) 2	
Skin and subcutaneous tissue disorders			

Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	3 / 15 (20.00%)	
occurrences (all)	0	3	
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
Skin lesion			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Livedo reticularis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Infections and infestations			
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 1 (0.00%)	2 / 15 (13.33%)	
occurrences (all)	0	2	
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Candida infection			

subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		
Cytomegalovirus infection reactivation				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	2		
Device related infection				
subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)		
occurrences (all)	1	1		
Gingivitis				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		
Onychomycosis				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		
Peritonitis				
subjects affected / exposed	1 / 1 (100.00%)	1 / 15 (6.67%)		
occurrences (all)	1	1		
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		
Staphylococcal infection				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		
Toxoplasmosis				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		
Upper respiratory tract infection				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		
Vulvovaginal candidiasis				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		
Wound infection				
subjects affected / exposed	0 / 1 (0.00%)	1 / 15 (6.67%)		
occurrences (all)	0	1		

Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all) Hypoproteinaemia subjects affected / exposed occurrences (all)	 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	 1 / 15 (6.67%) 1 1 / 15 (6.67%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 June 2022	Version 6 (the final amended version) was a substantial amendment to version 5 (dated 07 July 2021) to introduce new dose escalation cohorts using the modified manufacturing process.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
07 March 2024	Study terminated. Only Phase I of the study was conducted.	-

Notes:

Limitations and caveats

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

Phase 2 was not started and therefore no planned Phase 2 endpoints were available for analysis.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/39528665