



## 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 <sup>[1]</sup> |
| 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                                 |
| <b>Arm title</b>             | Cohort 1 (25x10 <sup>6</sup> 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<sup>6</sup> 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.

|  |  |
|--|--|
| <b>Arm title</b>   | Cohort 2 (75x10 <sup>6</sup> cells)          |
| Arm description:<br>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 <sup>6</sup> 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:<br>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. |  |
| <b>Arm title</b>   | Cohort 3 (225x10 <sup>6</sup> cells)         |
| Arm description:<br>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 <sup>6</sup> 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:<br>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. |  |
| <b>Arm title</b>   | Cohort 4 (450x10 <sup>6</sup> cells)         |
| Arm description:<br>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 <sup>6</sup> 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:<br>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. |  |
| <b>Arm title</b>   | Cohort 3B (225x10 <sup>6</sup> cells)        |
| Arm description:<br>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 <sup>6</sup> 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.

|                  |                                       |
|------------------|---------------------------------------|
| <b>Arm title</b> | Cohort 4B (450x10 <sup>6</sup> 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<sup>6</sup> 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.

|                  |                                       |
|------------------|---------------------------------------|
| <b>Arm title</b> | Cohort 5B (900x10 <sup>6</sup> 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<sup>6</sup> 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.

| <b>Number of subjects in period 1<sup>[2]</sup></b> | Cohort 1 (25x10 <sup>6</sup> cells) | Cohort 2 (75x10 <sup>6</sup> cells) | Cohort 3 (225x10 <sup>6</sup> 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   | -                                   | -                                   | -                                    |

| <b>Number of subjects in period 1<sup>[2]</sup></b> | Cohort 4 (450x10 <sup>6</sup> cells) | Cohort 3B (225x10 <sup>6</sup> cells) | Cohort 4B (450x10 <sup>6</sup> 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                                     |

| <b>Number of subjects in period 1<sup>[2]</sup></b> | Cohort 5B (900x10 <sup>6</sup> 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 <sup>6</sup> 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 <sup>6</sup> CAR T cells using the original manufacturing process.   |                                       |
| Reporting group title  | Cohort 2 (75x10 <sup>6</sup> 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 <sup>6</sup> CAR T cells using the original manufacturing process.   |                                       |
| Reporting group title  | Cohort 3 (225x10 <sup>6</sup> 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 <sup>6</sup> CAR T cells using the original manufacturing process.  |                                       |
| Reporting group title  | Cohort 4 (450x10 <sup>6</sup> 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 <sup>6</sup> CAR T cells using the original manufacturing process.  |                                       |
| Reporting group title  | Cohort 3B (225x10 <sup>6</sup> 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 <sup>6</sup> CAR T cells using the modified manufacturing process. |                                       |
| Reporting group title  | Cohort 4B (450x10 <sup>6</sup> 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 <sup>6</sup> CAR T cells using the modified manufacturing process. |                                       |
| Reporting group title  | Cohort 5B (900x10 <sup>6</sup> 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 <sup>6</sup> CAR T cells using the modified manufacturing process. |                                       |

| Reporting group values                             | Cohort 1 (25x10 <sup>6</sup> cells) | Cohort 2 (75x10 <sup>6</sup> cells) | Cohort 3 (225x10 <sup>6</sup> 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<br>Units: years<br>arithmetic mean<br>standard deviation | 50.7<br>± 14.57 | 44.0<br>± 12.73 | 47.0<br>± 0 |
| Gender categorical<br>Units: Subjects                                   |                 |                 |             |
| Female  | 2               | 1               | 0           |
| Male  | 1               | 1               | 1           |
| Stage of Lymphoma at screening<br>Units: Subjects                       |                 |                 |             |
| One   | 0               | 0               | 0           |
| Two   | 0               | 2               | 0           |
| Three   | 1               | 0               | 1           |
| Four  | 2               | 0               | 0           |
| ECOG Score<br>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           |

| <b>Reporting group values</b>   | Cohort 4 (450x10 <sup>6</sup> cells) | Cohort 3B (225x10 <sup>6</sup> cells) | Cohort 4B (450x10 <sup>6</sup> cells) |
|---|--------------------------------------|---------------------------------------|---------------------------------------|
| Number of subjects  | 4                                    | 1                                     | 3                                     |
| Age categorical<br>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<br>Units: years<br>arithmetic mean<br>standard deviation | 56.5<br>± 8.58                       | 72.0<br>± 0                           | 58.7<br>± 3.51                        |
| Gender categorical<br>Units: Subjects                                   |                                      |                                       |                                       |
| Female  | 0                                    | 0                                     | 0                                     |
| Male  | 4                                    | 1                                     | 3                                     |

|   |   |   |   |
|---|---|---|---|
| Stage of Lymphoma at screening<br>Units: Subjects |   |   |   |
| One   | 0 | 0 | 0 |
| Two   | 0 | 0 | 0 |
| Three   | 3 | 0 | 1 |
| Four  | 1 | 1 | 2 |
| ECOG Score<br>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<br>(900x10 <sup>6</sup> cells) | Total |  |
|---|--|-------|--|
| Number of subjects                                    | 1  | 15    |  |
| Age categorical<br>Units: Subjects                    |  |       |  |
| In utero  | 0  | 0     |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0  | 0     |  |
| Newborns (0-27 days)                                  | 0  | 0     |  |
| Infants and toddlers (28 days-23<br>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<br>Units: years                        |  |       |  |
| arithmetic mean                                       | 70.0                                     |       |  |
| standard deviation                                    | ± 0                                      | -     |  |
| Gender categorical<br>Units: Subjects                 |  |       |  |
| Female  | 0  | 3     |  |
| Male  | 1  | 12    |  |
| Stage of Lymphoma at screening<br>Units: Subjects     |  |       |  |
| One   | 0  | 0     |  |
| Two   | 0  | 2     |  |
| Three   | 0  | 6     |  |
| Four  | 1  | 7     |  |
| ECOG Score<br>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 <sup>6</sup> cells)   |
| Reporting group description:<br>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.<br>Cohort 1 dosed with 25x10 <sup>6</sup> CAR T cells using the original manufacturing process. |                                       |
| Reporting group title   | Cohort 2 (75x10 <sup>6</sup> cells)   |
| Reporting group description:<br>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.<br>Cohort 2 dosed with 75x10 <sup>6</sup> CAR T cells using the original manufacturing process. |                                       |
| Reporting group title   | Cohort 3 (225x10 <sup>6</sup> cells)  |
| Reporting group description:<br>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 <sup>6</sup> CAR T cells using the original manufacturing process.   |                                       |
| Reporting group title   | Cohort 4 (450x10 <sup>6</sup> cells)  |
| Reporting group description:<br>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 <sup>6</sup> CAR T cells using the original manufacturing process.   |                                       |
| Reporting group title   | Cohort 3B (225x10 <sup>6</sup> cells) |
| Reporting group description:<br>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 <sup>6</sup> CAR T cells using the modified manufacturing process.  |                                       |
| Reporting group title   | Cohort 4B (450x10 <sup>6</sup> cells) |
| Reporting group description:<br>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 <sup>6</sup> CAR T cells using the modified manufacturing process.  |                                       |
| Reporting group title   | Cohort 5B (900x10 <sup>6</sup> cells) |
| Reporting group description:<br>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 <sup>6</sup> 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:<br>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. <sup>[1]</sup> |
| End point description:<br>To assess the safety and tolerability of AUTO4 administration. The incidence of Grade 3-5 toxicities occurring within 60 days of AUTO4 infusion.<br>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:<br>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<br>(25x10 <sup>6</sup><br>cells) | Cohort 2<br>(75x10 <sup>6</sup><br>cells) | Cohort 3<br>(225x10 <sup>6</sup><br>cells) | Cohort 4<br>(450x10 <sup>6</sup><br>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<br>(225x10 <sup>6</sup><br>cells) | Cohort 4B<br>(450x10 <sup>6</sup><br>cells) | Cohort 5B<br>(900x10 <sup>6</sup><br>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<br>(25x10 <sup>6</sup><br>cells) | Cohort 2<br>(75x10 <sup>6</sup><br>cells) | Cohort 3<br>(225x10 <sup>6</sup><br>cells) | Cohort 4<br>(450x10 <sup>6</sup><br>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<br>(225x10 <sup>6</sup><br>cells) | Cohort 4B<br>(450x10 <sup>6</sup><br>cells) | Cohort 5B<br>(900x10 <sup>6</sup><br>cells) |  |
|------------------|---|---|---|--|
|------------------|---|---|---|--|

|                             | 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<br>(25x10 <sup>6</sup><br>cells) | Cohort 2<br>(75x10 <sup>6</sup><br>cells) | Cohort 3<br>(225x10 <sup>6</sup><br>cells) | Cohort 4<br>(450x10 <sup>6</sup><br>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<br>(225x10 <sup>6</sup><br>cells) | Cohort 4B<br>(450x10 <sup>6</sup><br>cells) | Cohort 5B<br>(900x10 <sup>6</sup><br>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<br>(25x10 <sup>6</sup> cells) | Cohort 2<br>(75x10 <sup>6</sup> cells) | Cohort 3<br>(225x10 <sup>6</sup> cells) | Cohort 4<br>(450x10 <sup>6</sup> 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<br>(225x10 <sup>6</sup> cells) | Cohort 4B<br>(450x10 <sup>6</sup> cells) | Cohort 5B<br>(900x10 <sup>6</sup> 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

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**Secondary: Complete response (CR) rate**

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|                 |                             |
|-----------------|-----------------------------|
| 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<br>(25x10 <sup>6</sup><br>cells) | Cohort 2<br>(75x10 <sup>6</sup><br>cells) | Cohort 3<br>(225x10 <sup>6</sup><br>cells) | Cohort 4<br>(450x10 <sup>6</sup><br>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<br>(225x10 <sup>6</sup><br>cells) | Cohort 4B<br>(450x10 <sup>6</sup><br>cells) | Cohort 5B<br>(900x10 <sup>6</sup><br>cells) | Infused Set -<br>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                        |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Progression-free survival**

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|                 |                           |
|-----------------|---------------------------|
| 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

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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      |           |

|                                  |                       |  |  |  |
|----------------------------------|-----------------------|--|--|--|
| <b>End point values</b>          | 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  |                  |

|                             |                       |  |  |  |
|-----------------------------|-----------------------|--|--|--|
| <b>End point values</b>     | 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<br>( $25 \times 10^6$ cells) | Cohort 2<br>( $75 \times 10^6$ cells) | Cohort 3<br>( $225 \times 10^6$ cells) | Cohort 4<br>( $450 \times 10^6$ 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<br>( $225 \times 10^6$ cells) | Cohort 4B<br>( $450 \times 10^6$ cells) | Cohort 5B<br>( $900 \times 10^6$ 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<br>(25x10 <sup>6</sup><br>cells) | Cohort 2<br>(75x10 <sup>6</sup><br>cells) | Cohort 3<br>(225x10 <sup>6</sup><br>cells) | Cohort 4<br>(450x10 <sup>6</sup><br>cells) |
|-------------------------------|---|---|--|--|
| Subject group type            | Reporting group                           | Reporting group                           | Reporting group                            | Reporting group                            |
| Number of subjects analysed   | 0 <sup>[3]</sup>                          | 1 <sup>[4]</sup>                          | 0 <sup>[5]</sup>                           | 2 <sup>[6]</sup>                           |
| 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<br>(225x10 <sup>6</sup><br>cells) | Cohort 4B<br>(450x10 <sup>6</sup><br>cells) | Cohort 5B<br>(900x10 <sup>6</sup><br>cells) |  |
|-------------------------------|---|---|---|--|
| Subject group type            | Reporting group                             | Reporting group                             | Reporting group                             |  |
| Number of subjects analysed   | 0 <sup>[7]</sup>                            | 0 <sup>[8]</sup>                            | 0 <sup>[9]</sup>                            |  |
| 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<br>(25x10 <sup>6</sup><br>cells) | Cohort 2<br>(75x10 <sup>6</sup><br>cells) | Cohort 3<br>(225x10 <sup>6</sup><br>cells) | Cohort 4<br>(450x10 <sup>6</sup><br>cells) |
|-------------------------------|---|---|--|--|
| Subject group type            | Reporting group                           | Reporting group                           | Reporting group                            | Reporting group                            |
| Number of subjects analysed   | 0 <sup>[10]</sup>                         | 1 <sup>[11]</sup>                         | 0 <sup>[12]</sup>                          | 0 <sup>[13]</sup>                          |
| 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<br>(225x10 <sup>6</sup><br>cells) | Cohort 4B<br>(450x10 <sup>6</sup><br>cells) | Cohort 5B<br>(900x10 <sup>6</sup><br>cells) |  |
|-------------------------------|---|---|---|--|
| Subject group type            | Reporting group                             | Reporting group                             | Reporting group                             |  |
| Number of subjects analysed   | 0 <sup>[14]</sup>                           | 0 <sup>[15]</sup>                           | 0 <sup>[16]</sup>                           |  |
| 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

|                                   |   |
|-----------------------------------|---|
| <b>Attachments (see zip file)</b> | 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:<br>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:<br>Up to 27 months   |                      |

|                                  |                       |  |  |  |
|----------------------------------|-----------------------|--|--|--|
| <b>End point values</b>          | 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 <sup>6</sup> 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<sup>6</sup> CAR T cells using the original manufacturing process.

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | Cohort 2 (75x10 <sup>6</sup> 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<sup>6</sup> CAR T cells using the original manufacturing process.

|                       |                                      |
|-----------------------|--------------------------------------|
| Reporting group title | Cohort 3 (225x10 <sup>6</sup> 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<sup>6</sup> CAR T cells using the original manufacturing process.

|                       |                                      |
|-----------------------|--------------------------------------|
| Reporting group title | Cohort 4 (450x10 <sup>6</sup> 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<sup>6</sup> CAR T cells using the original manufacturing process.

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Cohort 3B (225x10 <sup>6</sup> 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<sup>6</sup> CAR T cells using the modified manufacturing process.

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Cohort 4B (450x10 <sup>6</sup> 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<sup>6</sup> CAR T cells using the modified manufacturing process.

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Cohort 5B (900x10 <sup>6</sup> 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<sup>6</sup> CAR T cells using the modified manufacturing process.

|                       |       |
|-----------------------|-------|
| Reporting group title | Total |
|-----------------------|-------|

Reporting group description:

All patients infused.

| <b>Serious adverse events</b>                                       | Cohort 1 (25x10 <sup>6</sup> cells) | Cohort 2 (75x10 <sup>6</sup> cells) | Cohort 3 (225x10 <sup>6</sup> 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         |

| <b>Serious adverse events</b>                                       | Cohort 4 (450x10 <sup>6</sup> cells) | Cohort 3B (225x10 <sup>6</sup> cells) | Cohort 4B (450x10 <sup>6</sup> 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         |

| <b>Serious adverse events</b>                                       | Cohort 5B<br>(900x10 <sup>6</sup> 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 %

| <b>Non-serious adverse events</b>                                   | Cohort 1 (25x10 <sup>6</sup> cells) | Cohort 2 (75x10 <sup>6</sup> cells) | Cohort 3 (225x10 <sup>6</sup> 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<br>occurrences (all)  | 0 / 3 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Chills<br>subjects affected / exposed<br>occurrences (all)  | 0 / 3 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Gait disturbance<br>subjects affected / exposed<br>occurrences (all)  | 0 / 3 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Non-cardiac chest pain<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 3 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Immune system disorders<br>Cytokine release syndrome<br>subjects affected / exposed<br>occurrences (all)        | 0 / 3 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Reproductive system and breast disorders<br>Vulval disorder<br>subjects affected / exposed<br>occurrences (all) | 1 / 3 (33.33%)<br>1 | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)    | 1 / 3 (33.33%)<br>1 | 1 / 2 (50.00%)<br>1 | 0 / 1 (0.00%)<br>0 |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)  | 0 / 3 (0.00%)<br>0  | 1 / 2 (50.00%)<br>1 | 0 / 1 (0.00%)<br>0 |
| Epistaxis<br>subjects affected / exposed<br>occurrences (all)   | 1 / 3 (33.33%)<br>1 | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Nasal congestion<br>subjects affected / exposed<br>occurrences (all)  | 1 / 3 (33.33%)<br>1 | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)  | 0 / 3 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 |
| Psychiatric disorders   |                     |                     |                    |

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

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

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

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

| <b>Non-serious adverse events</b>                                   | Cohort 4 (450x10 <sup>6</sup> cells) | Cohort 3B (225x10 <sup>6</sup> cells) | Cohort 4B (450x10 <sup>6</sup> 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<br>occurrences (all)  | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 3 (0.00%)<br>0  |
| Chills<br>subjects affected / exposed<br>occurrences (all)  | 1 / 4 (25.00%)<br>1 | 0 / 1 (0.00%)<br>0   | 0 / 3 (0.00%)<br>0  |
| Gait disturbance<br>subjects affected / exposed<br>occurrences (all)  | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 3 (0.00%)<br>0  |
| Non-cardiac chest pain<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 1 / 3 (33.33%)<br>1 |
| Immune system disorders<br>Cytokine release syndrome<br>subjects affected / exposed<br>occurrences (all)        | 3 / 4 (75.00%)<br>3 | 1 / 1 (100.00%)<br>2 | 1 / 3 (33.33%)<br>1 |
| Reproductive system and breast disorders<br>Vulval disorder<br>subjects affected / exposed<br>occurrences (all) | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 3 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)    | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 3 (0.00%)<br>0  |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)  | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 1 / 3 (33.33%)<br>1 |
| Epistaxis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 3 (0.00%)<br>0  |
| Nasal congestion<br>subjects affected / exposed<br>occurrences (all)  | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 3 (0.00%)<br>0  |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)  | 0 / 4 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 1 / 3 (33.33%)<br>1 |
| Psychiatric disorders   |                     |                      |                     |



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

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

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

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

| <b>Non-serious adverse events</b>                                   | Cohort 5B<br>(900x10 <sup>6</sup> 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<br>occurrences (all)  | 1 / 1 (100.00%)<br>1 | 1 / 15 (6.67%)<br>1  |  |
| Chills<br>subjects affected / exposed<br>occurrences (all)  | 0 / 1 (0.00%)<br>0   | 1 / 15 (6.67%)<br>1  |  |
| Gait disturbance<br>subjects affected / exposed<br>occurrences (all)  | 1 / 1 (100.00%)<br>1 | 1 / 15 (6.67%)<br>1  |  |
| Non-cardiac chest pain<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 1 (0.00%)<br>0   | 1 / 15 (6.67%)<br>1  |  |
| Immune system disorders<br>Cytokine release syndrome<br>subjects affected / exposed<br>occurrences (all)        | 0 / 1 (0.00%)<br>0   | 5 / 15 (33.33%)<br>6 |  |
| Reproductive system and breast disorders<br>Vulval disorder<br>subjects affected / exposed<br>occurrences (all) | 0 / 1 (0.00%)<br>0   | 1 / 15 (6.67%)<br>1  |  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)    | 0 / 1 (0.00%)<br>0   | 2 / 15 (13.33%)<br>2 |  |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)  | 0 / 1 (0.00%)<br>0   | 2 / 15 (13.33%)<br>2 |  |
| Epistaxis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 1 (0.00%)<br>0   | 1 / 15 (6.67%)<br>1  |  |
| Nasal congestion<br>subjects affected / exposed<br>occurrences (all)  | 0 / 1 (0.00%)<br>0   | 1 / 15 (6.67%)<br>1  |  |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)  | 0 / 1 (0.00%)<br>0   | 1 / 15 (6.67%)<br>1  |  |
| Psychiatric disorders   |                      |                      |  |

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



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

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

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

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### 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:

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### Online references

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