



## Clinical trial results:

### OPEN LABEL, MULTICENTER PHASE II STUDY OF THE C5A-ANTIBODY IFX-1 ALONE OR IFX-1 + PEMBROLIZUMAB IN PATIENTS WITH PD-1- OR PD-L1-RESISTANT/REFRACTORY LOCALLY ADVANCED OR METASTATIC CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC)

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2020-000864-42 |
| Trial protocol           | DE FR BE       |
| Global end of trial date | 04 June 2024   |

#### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 25 January 2025 |
| First version publication date | 25 January 2025 |

#### Trial information

##### Trial identification

|                       |            |
|-----------------------|------------|
| Sponsor protocol code | IFX-1-P2.8 |
|-----------------------|------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04812535 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |                                                                             |
|------------------------------|-----------------------------------------------------------------------------|
| Sponsor organisation name    | InflaRx GmbH                                                                |
| Sponsor organisation address | Winzerlaer Strasse 2 , Jena, Germany, 07745                                 |
| Public contact               | Chief Medical Officer (CMO), InflaRx GmbH, +49 3641508 180, info@inflarx.de |
| Scientific contact           | Chief Medical Officer (CMO), InflaRx GmbH, +49 3641508 180, info@inflarx.de |

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                       | 17 September 2024 |
| Is this the analysis of the primary completion data? | Yes               |
| Primary completion date                              | 04 June 2024      |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 04 June 2024      |
| Was the trial ended prematurely?                     | Yes               |

Notes:

## General information about the trial

Main objective of the trial:

Arm A:

- To assess the antitumor activity of IFX-1

Arm B:

- To determine the maximum tolerated dose (MTD) or recommended Phase II dose (RP2D)
- To assess the antitumor activity of IFX-1 + pembrolizumab
- To assess the safety profile of IFX-1 + pembrolizumab

Protection of trial subjects:

A steering committee was constituted to support the patient enrollment in both treatment arms and monitor patient safety throughout the study. The steering committee included the clinical study monitor and  $\geq 3$  cSCC experts (principal investigators included).

Background therapy: -

Evidence for comparator: -

|                                                           |               |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment                          | 31 March 2021 |
| Long term follow-up planned                               | No            |
| Independent data monitoring committee (IDMC) involvement? | No            |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                  |
|--------------------------------------|------------------|
| Country: Number of subjects enrolled | Belgium: 3       |
| Country: Number of subjects enrolled | France: 6        |
| Country: Number of subjects enrolled | Germany: 12      |
| Country: Number of subjects enrolled | Spain: 5         |
| Country: Number of subjects enrolled | United States: 4 |
| Worldwide total number of subjects   | 30               |
| EEA total number of subjects         | 26               |

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)      | 6  |
| From 65 to 84 years       | 16 |
| 85 years and over         | 8  |

## Subject disposition

### Recruitment

Recruitment details:

Participants were enrolled at study sites in Belgium, France, Germany, Spain and United States of America. The first participant was screened on 31-Mar-2021. The last study visit occurred on 04-Jun-2024.

### Pre-assignment

Screening details:

30 participants were screened.

### Period 1

|                              |                               |
|------------------------------|-------------------------------|
| Period 1 title               | Study period (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>             | Arm A |

Arm description:

Vilobelimab monotherapy was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until end of treatment (EOT).

|                                        |                       |
|----------------------------------------|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Vilobelimab           |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Infusion              |

Dosage and administration details:

administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until EOT

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | Arm B: Regimen 1: |
|------------------|-------------------|

Arm description:

Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 400 mg on Days 1, 4, 8, and 15, followed by 800 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

|                                        |                       |
|----------------------------------------|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Pembrolizumab         |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Infusion              |

Dosage and administration details:

administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

|                                        |                       |
|----------------------------------------|-----------------------|
| Investigational medicinal product name | Vilobelimab           |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |

|                          |          |
|--------------------------|----------|
| Routes of administration | Infusion |
|--------------------------|----------|

Dosage and administration details:

administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 400 mg on Days 1, 4, 8, and 15, followed by 800 mg Q2W starting on Day 22 of Cycle 1 until EOT

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | Arm B: Regimen 2: |
|------------------|-------------------|

Arm description:

Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 600 mg on Days 1, 4, 8, and 15, followed by 1200 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

|                                        |                       |
|----------------------------------------|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Pembrolizumab         |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Infusion              |

Dosage and administration details:

administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

|                                        |                       |
|----------------------------------------|-----------------------|
| Investigational medicinal product name | Vilobelimab           |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Infusion              |

Dosage and administration details:

administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 600 mg on Days 1, 4, 8, and 15, followed by 1200 mg Q2W starting on Day 22 of Cycle 1 until EOT

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | Arm B: Regimen 3: |
|------------------|-------------------|

Arm description:

Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

|                                        |                       |
|----------------------------------------|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Pembrolizumab         |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Infusion              |

Dosage and administration details:

administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

|                                        |                       |
|----------------------------------------|-----------------------|
| Investigational medicinal product name | Vilobelimab           |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Infusion              |

Dosage and administration details:

administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until EOT

| <b>Number of subjects in period 1</b> <sup>[1]</sup> | Arm A | Arm B: Regimen 1: | Arm B: Regimen 2: |
|------------------------------------------------------|-------|-------------------|-------------------|
| Started                                              | 10    | 3                 | 6                 |
| Completed                                            | 1     | 1                 | 1                 |
| Not completed                                        | 9     | 2                 | 5                 |
| Consent withdrawn by subject                         | -     | -                 | -                 |
| Death                                                | 7     | 2                 | 4                 |
| Due to premature study termination by sponsor        | 2     | -                 | 1                 |

| <b>Number of subjects in period 1</b> <sup>[1]</sup> | Arm B: Regimen 3: |
|------------------------------------------------------|-------------------|
| Started                                              | 6                 |
| Completed                                            | 1                 |
| Not completed                                        | 5                 |
| Consent withdrawn by subject                         | 1                 |
| Death                                                | 1                 |
| Due to premature study termination by sponsor        | 3                 |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 5 participants were enrolled but were screen failures and did therefore not receive the study drug.

## Baseline characteristics

### Reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Arm A             |
| Reporting group description:<br>Vilobelimab monotherapy was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until end of treatment (EOT).                                                                                                                                                                                                                                           |                   |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Arm B: Regimen 1: |
| Reporting group description:<br>Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 400 mg on Days 1, 4, 8, and 15, followed by 800 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle  |                   |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Arm B: Regimen 2: |
| Reporting group description:<br>Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 600 mg on Days 1, 4, 8, and 15, followed by 1200 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle |                   |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Arm B: Regimen 3: |
| Reporting group description:<br>Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle |                   |

| Reporting group values                | Arm A  | Arm B: Regimen 1: | Arm B: Regimen 2: |
|---------------------------------------|--------|-------------------|-------------------|
| Number of subjects                    | 10     | 3                 | 6                 |
| Age categorical<br>Units: Subjects    |        |                   |                   |
| Adults (18-65 years)                  | 3      | 0                 | 2                 |
| From 66-85 years                      | 5      | 1                 | 3                 |
| 86 years and over                     | 2      | 2                 | 1                 |
| Age continuous<br>Units: years        |        |                   |                   |
| arithmetic mean                       | 74.0   | 81.3              | 72.8              |
| standard deviation                    | ± 13.4 | ± 13.3            | ± 10.6            |
| Gender categorical<br>Units: Subjects |        |                   |                   |
| Female                                | 5      | 1                 | 2                 |
| Male                                  | 5      | 2                 | 4                 |

| Reporting group values             | Arm B: Regimen 3: | Total |  |
|------------------------------------|-------------------|-------|--|
| Number of subjects                 | 6                 | 25    |  |
| Age categorical<br>Units: Subjects |                   |       |  |
| Adults (18-65 years)               | 2                 | 7     |  |
| From 66-85 years                   | 3                 | 12    |  |
| 86 years and over                  | 1                 | 6     |  |

|                                                                         |               |    |  |
|-------------------------------------------------------------------------|---------------|----|--|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 70.8<br>± 9.6 | -  |  |
| Gender categorical<br>Units: Subjects                                   |               |    |  |
| Female                                                                  | 1             | 9  |  |
| Male                                                                    | 5             | 16 |  |

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### Subject analysis sets

|                            |               |
|----------------------------|---------------|
| Subject analysis set title | FAS           |
| Subject analysis set type  | Full analysis |

Subject analysis set description:

The Full Analysis Set (FAS) contains all patients assigned to study treatment.

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|                                                                         |                |  |  |
|-------------------------------------------------------------------------|----------------|--|--|
| <b>Reporting group values</b>                                           | FAS            |  |  |
| Number of subjects                                                      | 25             |  |  |
| Age categorical<br>Units: Subjects                                      |                |  |  |
| Adults (18-65 years)                                                    | 7              |  |  |
| From 66-85 years                                                        | 12             |  |  |
| 86 years and over                                                       | 6              |  |  |
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 73.8<br>± 11.6 |  |  |
| Gender categorical<br>Units: Subjects                                   |                |  |  |
| Female                                                                  | 9              |  |  |
| Male                                                                    | 16             |  |  |

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## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Arm A             |
| Reporting group description:<br>Vilobelimab monotherapy was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until end of treatment (EOT).                                                                                                                                                                                                                                           |                   |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Arm B: Regimen 1: |
| Reporting group description:<br>Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 400 mg on Days 1, 4, 8, and 15, followed by 800 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle  |                   |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Arm B: Regimen 2: |
| Reporting group description:<br>Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 600 mg on Days 1, 4, 8, and 15, followed by 1200 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle |                   |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Arm B: Regimen 3: |
| Reporting group description:<br>Vilobelimab + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle |                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | FAS               |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Full analysis     |
| Subject analysis set description:<br>The Full Analysis Set (FAS) contains all patients assigned to study treatment.                                                                                                                                                                                                                                                                                                                                                                                     |                   |

### Primary: Frequency of dose-limiting toxicities (DLTs) by dose cohort

|                                                                                                                                                                                                                                        |                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                        | Frequency of dose-limiting toxicities (DLTs) by dose cohort <sup>[1]</sup> |
| End point description:                                                                                                                                                                                                                 |                                                                            |
| End point type                                                                                                                                                                                                                         | Primary                                                                    |
| End point timeframe:<br>Cycle 1 Day 1 - Cycle 1 Day 36                                                                                                                                                                                 |                                                                            |
| Notes:<br>[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.<br>Justification: DLTs were only analyzed descriptively. |                                                                            |

| End point values            | Arm A           | Arm B: Regimen 1: | Arm B: Regimen 2: | Arm B: Regimen 3: |
|-----------------------------|-----------------|-------------------|-------------------|-------------------|
| Subject group type          | Reporting group | Reporting group   | Reporting group   | Reporting group   |
| Number of subjects analysed | 10              | 3                 | 6                 | 6                 |
| Units: participants         |                 |                   |                   |                   |
| Number of patients with DLT | 0               | 0                 | 0                 | 0                 |

## Statistical analyses

No statistical analyses for this end point

### Primary: Best overall response rate

|                 |                                           |
|-----------------|-------------------------------------------|
| End point title | Best overall response rate <sup>[2]</sup> |
|-----------------|-------------------------------------------|

End point description:

Investigator assessed best overall response rate (best ORR) for Vilobelimab (Arm A) and Vilobelimab + pembrolizumab (Arms B), with response being defined as best response of complete response (CR)/confirmed CR (iCR) or PR/confirmed partial response (PR) (iPR) per modified RECIST v1.1/iRECIST

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to 36 months

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: Best overall response rate was only analyzed descriptively.

| End point values                 | Arm A               | Arm B: Regimen 1:   | Arm B: Regimen 2:   | Arm B: Regimen 3:   |
|----------------------------------|---------------------|---------------------|---------------------|---------------------|
| Subject group type               | Reporting group     | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed      | 10                  | 3                   | 6                   | 6                   |
| Units: percent                   |                     |                     |                     |                     |
| number (confidence interval 95%) |                     |                     |                     |                     |
| Responder                        | 10.0 (0.3 to 44.5)  | 0.0 (0.0 to 70.8)   | 16.7 (0.4 to 64.1)  | 33.3 (4.3 to 77.7)  |
| CR/iCR                           | 10.0 (0.3 to 44.5)  | 0.0 (0.0 to 70.8)   | 0.0 (0.0 to 45.9)   | 0.0 (0.0 to 45.9)   |
| PR/iPR                           | 0.0 (0.0 to 30.8)   | 0.0 (0.0 to 70.8)   | 16.7 (0.4 to 64.1)  | 33.3 (4.3 to 77.7)  |
| Non-responder                    | 90.0 (55.5 to 99.7) | 100 (29.2 to 100.0) | 66.7 (22.3 to 95.7) | 66.7 (22.3 to 95.7) |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to 36 months

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

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 27.0 |
|--------------------|------|

### Reporting groups

|                       |       |
|-----------------------|-------|
| Reporting group title | Arm A |
|-----------------------|-------|

Reporting group description:

Vilobelimab monotherapy was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until EOT.

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Arm B: Regimen 1: |
|-----------------------|-------------------|

Reporting group description:

IFX-1 + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 400 mg on Days 1, 4, 8, and 15, followed by 800 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Arm B: Regimen 2: |
|-----------------------|-------------------|

Reporting group description:

IFX-1 + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 600 mg on Days 1, 4, 8, and 15, followed by 1200 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Arm B: Regimen 3: |
|-----------------------|-------------------|

Reporting group description:

IFX-1 + pembrolizumab combination therapy; Vilobelimab was administered as a 30-minute (-5/+10 minutes) intravenous infusion as follows: 800 mg on Days 1, 4, 8, and 15, followed by 1600 mg Q2W starting on Day 22 of Cycle 1 until EOT. Vilobelimab treatment was combined with pembrolizumab, administered as a 30-minute (-5/+10 minutes) intravenous infusion at a dose of 400 mg starting at Day 8 of Cycle 1 and then Q6W on Day 1 of each treatment cycle

| Serious adverse events                                              | Arm A           | Arm B: Regimen 1: | Arm B: Regimen 2: |
|---------------------------------------------------------------------|-----------------|-------------------|-------------------|
| Total subjects affected by serious adverse events                   |                 |                   |                   |
| subjects affected / exposed                                         | 7 / 10 (70.00%) | 2 / 3 (66.67%)    | 2 / 6 (33.33%)    |
| number of deaths (all causes)                                       | 7               | 2                 | 4                 |
| number of deaths resulting from adverse events                      | 3               | 2                 | 2                 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                 |                   |                   |
| Metastases to meninges                                              |                 |                   |                   |
| subjects affected / exposed                                         | 1 / 10 (10.00%) | 0 / 3 (0.00%)     | 0 / 6 (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             |

|                                                      |                 |                |               |
|------------------------------------------------------|-----------------|----------------|---------------|
| Tumour haemorrhage                                   |                 |                |               |
| subjects affected / exposed                          | 0 / 10 (0.00%)  | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0           | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0          | 0 / 0         |
| Injury, poisoning and procedural complications       |                 |                |               |
| Fall                                                 |                 |                |               |
| subjects affected / exposed                          | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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                                    |                 |                |               |
| Cardiac failure                                      |                 |                |               |
| subjects affected / exposed                          | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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         |
| Cardiac-respiratory arrest                           |                 |                |               |
| subjects affected / exposed                          | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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         |
| Nervous system disorders                             |                 |                |               |
| Haemorrhage intracranial                             |                 |                |               |
| subjects affected / exposed                          | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0          | 0 / 0         |
| Metabolic encephalopathy                             |                 |                |               |
| subjects affected / exposed                          | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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         |
| Presyncope                                           |                 |                |               |
| subjects affected / exposed                          | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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         |
| General disorders and administration site conditions |                 |                |               |
| General physical health deterioration                |                 |                |               |

|                                                 |                 |                |                |
|-------------------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed                     | 1 / 10 (10.00%) | 2 / 3 (66.67%) | 2 / 6 (33.33%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 2          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 2          | 0 / 1          |
| <b>Blood and lymphatic system disorders</b>     |                 |                |                |
| Anaemia                                         |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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          |
| Anaemia of chronic disease                      |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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>Immune system disorders</b>                  |                 |                |                |
| Amyloidosis                                     |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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>Renal and urinary disorders</b>              |                 |                |                |
| Acute kidney injury                             |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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>Infections and infestations</b>              |                 |                |                |
| COVID-19                                        |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (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          |
| COVID-19 pneumonia                              |                 |                |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Clostridium difficile infection                 |                 |                |                |

|                                                 |                 |               |                |
|-------------------------------------------------|-----------------|---------------|----------------|
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0         | 0 / 0          |
| Pneumonia staphylococcal                        |                 |               |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0         | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0         | 0 / 1          |

|                                                                     |                   |  |  |
|---------------------------------------------------------------------|-------------------|--|--|
| <b>Serious adverse events</b>                                       | Arm B: Regimen 3: |  |  |
| Total subjects affected by serious adverse events                   |                   |  |  |
| subjects affected / exposed                                         | 1 / 6 (16.67%)    |  |  |
| number of deaths (all causes)                                       | 1                 |  |  |
| number of deaths resulting from adverse events                      | 1                 |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                   |  |  |
| Metastases to meninges                                              |                   |  |  |
| subjects affected / exposed                                         | 0 / 6 (0.00%)     |  |  |
| occurrences causally related to treatment / all                     | 0 / 0             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Tumour haemorrhage                                                  |                   |  |  |
| subjects affected / exposed                                         | 0 / 6 (0.00%)     |  |  |
| occurrences causally related to treatment / all                     | 0 / 0             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Injury, poisoning and procedural complications                      |                   |  |  |
| Fall                                                                |                   |  |  |
| subjects affected / exposed                                         | 0 / 6 (0.00%)     |  |  |
| occurrences causally related to treatment / all                     | 0 / 0             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Cardiac disorders                                                   |                   |  |  |
| Cardiac failure                                                     |                   |  |  |
| subjects affected / exposed                                         | 0 / 6 (0.00%)     |  |  |
| occurrences causally related to treatment / all                     | 0 / 0             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Cardiac-respiratory arrest                                          |                   |  |  |

|                                                      |                |  |  |
|------------------------------------------------------|----------------|--|--|
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Nervous system disorders                             |                |  |  |
| Haemorrhage intracranial                             |                |  |  |
| subjects affected / exposed                          | 1 / 6 (16.67%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1          |  |  |
| deaths causally related to treatment / all           | 0 / 1          |  |  |
| Metabolic encephalopathy                             |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Presyncope                                           |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| General disorders and administration site conditions |                |  |  |
| General physical health deterioration                |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Blood and lymphatic system disorders                 |                |  |  |
| Anaemia                                              |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Anaemia of chronic disease                           |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Immune system disorders                              |                |  |  |
| Amyloidosis                                          |                |  |  |

|                                                 |               |  |  |
|-------------------------------------------------|---------------|--|--|
| subjects affected / exposed                     | 0 / 6 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Renal and urinary disorders                     |               |  |  |
| Acute kidney injury                             |               |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Infections and infestations                     |               |  |  |
| COVID-19                                        |               |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| COVID-19 pneumonia                              |               |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Clostridium difficile infection                 |               |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Pneumonia staphylococcal                        |               |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |

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

| <b>Non-serious adverse events</b>                                   | Arm A           | Arm B: Regimen 1: | Arm B: Regimen 2: |
|---------------------------------------------------------------------|-----------------|-------------------|-------------------|
| Total subjects affected by non-serious adverse events               |                 |                   |                   |
| subjects affected / exposed                                         | 9 / 10 (90.00%) | 3 / 3 (100.00%)   | 5 / 6 (83.33%)    |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                 |                   |                   |
| Tumour pain                                                         |                 |                   |                   |

|                                                                                                                        |                      |                     |                     |
|------------------------------------------------------------------------------------------------------------------------|----------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                                                       | 2 / 10 (20.00%)<br>2 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Skin neoplasm bleeding<br>subjects affected / exposed<br>occurrences (all)                                             | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Tumour haemorrhage<br>subjects affected / exposed<br>occurrences (all)                                                 | 0 / 10 (0.00%)<br>0  | 1 / 3 (33.33%)<br>1 | 0 / 6 (0.00%)<br>0  |
| Tumour ulceration<br>subjects affected / exposed<br>occurrences (all)                                                  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Vascular disorders<br>Hypertension<br>subjects affected / exposed<br>occurrences (all)                                 | 0 / 10 (0.00%)<br>0  | 1 / 3 (33.33%)<br>1 | 0 / 6 (0.00%)<br>0  |
| Lymphoedema<br>subjects affected / exposed<br>occurrences (all)                                                        | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Lymphorrhoea<br>subjects affected / exposed<br>occurrences (all)                                                       | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Scalp haematoma<br>subjects affected / exposed<br>occurrences (all)                                                    | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| General disorders and administration<br>site conditions<br>Fatigue<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>1 | 1 / 3 (33.33%)<br>1 | 0 / 6 (0.00%)<br>0  |
| Asthenia<br>subjects affected / exposed<br>occurrences (all)                                                           | 2 / 10 (20.00%)<br>2 | 0 / 3 (0.00%)<br>0  | 1 / 6 (16.67%)<br>2 |
| Pain<br>subjects affected / exposed<br>occurrences (all)                                                               | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  | 2 / 6 (33.33%)<br>2 |
| Chest pain                                                                                                             |                      |                     |                     |

|                                                 |                 |                |                |
|-------------------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 1 / 3 (33.33%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 0               | 1              | 0              |
| Extravasation                                   |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0              | 0              |
| General physical health deterioration           |                 |                |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)                               | 0               | 0              | 1              |
| Influenza like illness                          |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                               | 2               | 0              | 0              |
| Infusion site paraesthesia                      |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0              | 0              |
| Oedema peripheral                               |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0              | 0              |
| Respiratory, thoracic and mediastinal disorders |                 |                |                |
| Dry throat                                      |                 |                |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 1 / 3 (33.33%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 0               | 1              | 0              |
| Dyspnoea                                        |                 |                |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0              |
| Pulmonary hypertension                          |                 |                |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0              |
| Rhinorrhoea                                     |                 |                |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)                               | 0               | 0              | 1              |
| Psychiatric disorders                           |                 |                |                |
| Anxiety                                         |                 |                |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0              | 0              |
| Depressed mood                                  |                 |                |                |

|                                                |                 |                |                |
|------------------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0              |
| Depression                                     |                 |                |                |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0              |
| Panic attack                                   |                 |                |                |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)                              | 0               | 0              | 1              |
| Sleep disorder                                 |                 |                |                |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0              |
| Investigations                                 |                 |                |                |
| Weight decreased                               |                 |                |                |
| subjects affected / exposed                    | 2 / 10 (20.00%) | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                              | 2               | 0              | 0              |
| Blood creatinine increased                     |                 |                |                |
| subjects affected / exposed                    | 1 / 10 (10.00%) | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                              | 1               | 0              | 0              |
| Intraocular pressure increased                 |                 |                |                |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0              |
| Lipase increased                               |                 |                |                |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 1 / 3 (33.33%) | 0 / 6 (0.00%)  |
| occurrences (all)                              | 0               | 1              | 0              |
| Lymphocyte count decreased                     |                 |                |                |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)                              | 0               | 0              | 3              |
| SARS-CoV-2 test positive                       |                 |                |                |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 1 / 3 (33.33%) | 0 / 6 (0.00%)  |
| occurrences (all)                              | 0               | 1              | 0              |
| Thyroxine free increased                       |                 |                |                |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0              |
| Injury, poisoning and procedural complications |                 |                |                |

|                             |                 |               |                |
|-----------------------------|-----------------|---------------|----------------|
| Fall                        |                 |               |                |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 3               | 0             | 0              |
| Contusion                   |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |
| Osteoradionecrosis          |                 |               |                |
| subjects affected / exposed | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 0               | 0             | 0              |
| Traumatic haematoma         |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |
| Wound complication          |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |
| Wound haemorrhage           |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |
| Cardiac disorders           |                 |               |                |
| Cardiac failure             |                 |               |                |
| subjects affected / exposed | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)           | 0               | 0             | 1              |
| Palpitations                |                 |               |                |
| subjects affected / exposed | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)           | 0               | 0             | 1              |
| Nervous system disorders    |                 |               |                |
| Dizziness                   |                 |               |                |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)           | 2               | 0             | 1              |
| Dementia                    |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |
| Headache                    |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |
| Neuropathy peripheral       |                 |               |                |

|                                                  |                     |                    |                     |
|--------------------------------------------------|---------------------|--------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | 0 / 3 (0.00%)<br>0 | 1 / 6 (16.67%)<br>1 |
| Blood and lymphatic system disorders             |                     |                    |                     |
| Anaemia                                          |                     |                    |                     |
| subjects affected / exposed                      | 1 / 10 (10.00%)     | 0 / 3 (0.00%)      | 1 / 6 (16.67%)      |
| occurrences (all)                                | 1                   | 0                  | 1                   |
| Anaemia of chronic disease                       |                     |                    |                     |
| subjects affected / exposed                      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      | 1 / 6 (16.67%)      |
| occurrences (all)                                | 0                   | 0                  | 1                   |
| Eosinophilia                                     |                     |                    |                     |
| subjects affected / exposed                      | 1 / 10 (10.00%)     | 0 / 3 (0.00%)      | 0 / 6 (0.00%)       |
| occurrences (all)                                | 1                   | 0                  | 0                   |
| Eye disorders                                    |                     |                    |                     |
| Vitreous floaters                                |                     |                    |                     |
| subjects affected / exposed                      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      | 0 / 6 (0.00%)       |
| occurrences (all)                                | 0                   | 0                  | 0                   |
| Gastrointestinal disorders                       |                     |                    |                     |
| Diarrhoea                                        |                     |                    |                     |
| subjects affected / exposed                      | 1 / 10 (10.00%)     | 0 / 3 (0.00%)      | 0 / 6 (0.00%)       |
| occurrences (all)                                | 1                   | 0                  | 0                   |
| Constipation                                     |                     |                    |                     |
| subjects affected / exposed                      | 0 / 10 (0.00%)      | 1 / 3 (33.33%)     | 0 / 6 (0.00%)       |
| occurrences (all)                                | 0                   | 1                  | 0                   |
| Dental discomfort                                |                     |                    |                     |
| subjects affected / exposed                      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      | 1 / 6 (16.67%)      |
| occurrences (all)                                | 0                   | 0                  | 1                   |
| Dry mouth                                        |                     |                    |                     |
| subjects affected / exposed                      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      | 1 / 6 (16.67%)      |
| occurrences (all)                                | 0                   | 0                  | 1                   |
| Gastritis                                        |                     |                    |                     |
| subjects affected / exposed                      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      | 0 / 6 (0.00%)       |
| occurrences (all)                                | 0                   | 0                  | 0                   |
| Oral hyperkeratosis                              |                     |                    |                     |
| subjects affected / exposed                      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      | 0 / 6 (0.00%)       |
| occurrences (all)                                | 0                   | 0                  | 0                   |
| Oral pain                                        |                     |                    |                     |

|                                                 |                 |               |                |
|-------------------------------------------------|-----------------|---------------|----------------|
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0             | 0              |
| Vomiting                                        |                 |               |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0             | 0              |
| Skin and subcutaneous tissue disorders          |                 |               |                |
| Hyperhidrosis                                   |                 |               |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)                               | 0               | 0             | 1              |
| Actinic keratosis                               |                 |               |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)                               | 0               | 0             | 1              |
| Erythema                                        |                 |               |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 0               | 0             | 0              |
| Pruritus                                        |                 |               |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0             | 0              |
| Rash maculo-papular                             |                 |               |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 0               | 0             | 0              |
| Skin discharge                                  |                 |               |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0             | 0              |
| Renal and urinary disorders                     |                 |               |                |
| Chronic kidney disease                          |                 |               |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 2               | 0             | 0              |
| Pollakiuria                                     |                 |               |                |
| subjects affected / exposed                     | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 0               | 0             | 0              |
| Musculoskeletal and connective tissue disorders |                 |               |                |
| Arthralgia                                      |                 |               |                |
| subjects affected / exposed                     | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                               | 1               | 0             | 0              |
| Back pain                                       |                 |               |                |

|                                                                                 |                      |                     |                     |
|---------------------------------------------------------------------------------|----------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                | 0 / 10 (0.00%)<br>0  | 1 / 3 (33.33%)<br>1 | 0 / 6 (0.00%)<br>0  |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Trismus<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Infections and infestations                                                     |                      |                     |                     |
| Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)             | 1 / 10 (10.00%)<br>1 | 1 / 3 (33.33%)<br>1 | 0 / 6 (0.00%)<br>0  |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)     | 1 / 10 (10.00%)<br>1 | 1 / 3 (33.33%)<br>1 | 0 / 6 (0.00%)<br>0  |
| COVID-19<br>subjects affected / exposed<br>occurrences (all)                    | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Cellulitis<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Gingivitis<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Oral candidiasis<br>subjects affected / exposed<br>occurrences (all)            | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  | 1 / 6 (16.67%)<br>1 |
| Tooth abscess<br>subjects affected / exposed<br>occurrences (all)               | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Wound infection pseudomonas<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  |
| Metabolism and nutrition disorders                                              |                      |                     |                     |
| Hyponatraemia                                                                   |                      |                     |                     |

|                             |                 |               |                |
|-----------------------------|-----------------|---------------|----------------|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)           | 1               | 0             | 1              |
| Decreased appetite          |                 |               |                |
| subjects affected / exposed | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)           | 0               | 0             | 1              |
| Dehydration                 |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |
| Hypoalbuminaemia            |                 |               |                |
| subjects affected / exposed | 0 / 10 (0.00%)  | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)           | 0               | 0             | 1              |
| Hypokalaemia                |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |
| Hypomagnesaemia             |                 |               |                |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)           | 1               | 0             | 0              |

|                                                                     |                   |  |  |
|---------------------------------------------------------------------|-------------------|--|--|
| <b>Non-serious adverse events</b>                                   | Arm B: Regimen 3: |  |  |
| Total subjects affected by non-serious adverse events               |                   |  |  |
| subjects affected / exposed                                         | 6 / 6 (100.00%)   |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                   |  |  |
| Tumour pain                                                         |                   |  |  |
| subjects affected / exposed                                         | 0 / 6 (0.00%)     |  |  |
| occurrences (all)                                                   | 0                 |  |  |
| Skin neoplasm bleeding                                              |                   |  |  |
| subjects affected / exposed                                         | 0 / 6 (0.00%)     |  |  |
| occurrences (all)                                                   | 0                 |  |  |
| Tumour haemorrhage                                                  |                   |  |  |
| subjects affected / exposed                                         | 0 / 6 (0.00%)     |  |  |
| occurrences (all)                                                   | 0                 |  |  |
| Tumour ulceration                                                   |                   |  |  |
| subjects affected / exposed                                         | 1 / 6 (16.67%)    |  |  |
| occurrences (all)                                                   | 1                 |  |  |
| Vascular disorders                                                  |                   |  |  |

|                                                      |                |  |  |
|------------------------------------------------------|----------------|--|--|
| Hypertension                                         |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| Lymphoedema                                          |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| Lymphorrhoea                                         |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| Scalp haematoma                                      |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| General disorders and administration site conditions |                |  |  |
| Fatigue                                              |                |  |  |
| subjects affected / exposed                          | 2 / 6 (33.33%) |  |  |
| occurrences (all)                                    | 2              |  |  |
| Asthenia                                             |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| Pain                                                 |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| Chest pain                                           |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| Extravasation                                        |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| General physical health deterioration                |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| Influenza like illness                               |                |  |  |
| subjects affected / exposed                          | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                                    | 0              |  |  |
| Infusion site paraesthesia                           |                |  |  |

|                                                 |                |  |  |
|-------------------------------------------------|----------------|--|--|
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Oedema peripheral                               |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Respiratory, thoracic and mediastinal disorders |                |  |  |
| Dry throat                                      |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Dyspnoea                                        |                |  |  |
| subjects affected / exposed                     | 1 / 6 (16.67%) |  |  |
| occurrences (all)                               | 1              |  |  |
| Pulmonary hypertension                          |                |  |  |
| subjects affected / exposed                     | 1 / 6 (16.67%) |  |  |
| occurrences (all)                               | 1              |  |  |
| Rhinorrhoea                                     |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Psychiatric disorders                           |                |  |  |
| Anxiety                                         |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Depressed mood                                  |                |  |  |
| subjects affected / exposed                     | 1 / 6 (16.67%) |  |  |
| occurrences (all)                               | 0              |  |  |
| Depression                                      |                |  |  |
| subjects affected / exposed                     | 1 / 6 (16.67%) |  |  |
| occurrences (all)                               | 1              |  |  |
| Panic attack                                    |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Sleep disorder                                  |                |  |  |
| subjects affected / exposed                     | 1 / 6 (16.67%) |  |  |
| occurrences (all)                               | 1              |  |  |
| Investigations                                  |                |  |  |

|                                                                                    |                     |  |  |
|------------------------------------------------------------------------------------|---------------------|--|--|
| Weight decreased<br>subjects affected / exposed<br>occurrences (all)               | 0 / 6 (0.00%)<br>0  |  |  |
| Blood creatinine increased<br>subjects affected / exposed<br>occurrences (all)     | 0 / 6 (0.00%)<br>0  |  |  |
| Intraocular pressure increased<br>subjects affected / exposed<br>occurrences (all) | 1 / 6 (16.67%)<br>1 |  |  |
| Lipase increased<br>subjects affected / exposed<br>occurrences (all)               | 0 / 6 (0.00%)<br>0  |  |  |
| Lymphocyte count decreased<br>subjects affected / exposed<br>occurrences (all)     | 0 / 6 (0.00%)<br>0  |  |  |
| SARS-CoV-2 test positive<br>subjects affected / exposed<br>occurrences (all)       | 0 / 6 (0.00%)<br>0  |  |  |
| Thyroxine free increased<br>subjects affected / exposed<br>occurrences (all)       | 1 / 6 (16.67%)<br>1 |  |  |
| Injury, poisoning and procedural complications                                     |                     |  |  |
| Fall<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 6 (0.00%)<br>0  |  |  |
| Contusion<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 6 (0.00%)<br>0  |  |  |
| Osteoradionecrosis<br>subjects affected / exposed<br>occurrences (all)             | 1 / 6 (16.67%)<br>1 |  |  |
| Traumatic haematoma<br>subjects affected / exposed<br>occurrences (all)            | 0 / 6 (0.00%)<br>0  |  |  |
| Wound complication                                                                 |                     |  |  |

|                                                                                                     |                     |  |  |
|-----------------------------------------------------------------------------------------------------|---------------------|--|--|
| subjects affected / exposed<br>occurrences (all)                                                    | 0 / 6 (0.00%)<br>0  |  |  |
| Wound haemorrhage<br>subjects affected / exposed<br>occurrences (all)                               | 0 / 6 (0.00%)<br>0  |  |  |
| Cardiac disorders<br>Cardiac failure<br>subjects affected / exposed<br>occurrences (all)            | 0 / 6 (0.00%)<br>0  |  |  |
| Palpitations<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 6 (0.00%)<br>0  |  |  |
| Nervous system disorders<br>Dizziness<br>subjects affected / exposed<br>occurrences (all)           | 1 / 6 (16.67%)<br>1 |  |  |
| Dementia<br>subjects affected / exposed<br>occurrences (all)                                        | 0 / 6 (0.00%)<br>0  |  |  |
| Headache<br>subjects affected / exposed<br>occurrences (all)                                        | 0 / 6 (0.00%)<br>0  |  |  |
| Neuropathy peripheral<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 6 (0.00%)<br>0  |  |  |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all) | 1 / 6 (16.67%)<br>1 |  |  |
| Anaemia of chronic disease<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 6 (0.00%)<br>0  |  |  |
| Eosinophilia<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 6 (0.00%)<br>0  |  |  |
| Eye disorders                                                                                       |                     |  |  |

|                                                                         |                     |  |  |
|-------------------------------------------------------------------------|---------------------|--|--|
| Vitreous floaters<br>subjects affected / exposed<br>occurrences (all)   | 1 / 6 (16.67%)<br>1 |  |  |
| Gastrointestinal disorders                                              |                     |  |  |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)           | 1 / 6 (16.67%)<br>1 |  |  |
| Constipation<br>subjects affected / exposed<br>occurrences (all)        | 0 / 6 (0.00%)<br>0  |  |  |
| Dental discomfort<br>subjects affected / exposed<br>occurrences (all)   | 0 / 6 (0.00%)<br>0  |  |  |
| Dry mouth<br>subjects affected / exposed<br>occurrences (all)           | 0 / 6 (0.00%)<br>0  |  |  |
| Gastritis<br>subjects affected / exposed<br>occurrences (all)           | 1 / 6 (16.67%)<br>1 |  |  |
| Oral hyperkeratosis<br>subjects affected / exposed<br>occurrences (all) | 1 / 6 (16.67%)<br>1 |  |  |
| Oral pain<br>subjects affected / exposed<br>occurrences (all)           | 0 / 6 (0.00%)<br>0  |  |  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)            | 0 / 6 (0.00%)<br>0  |  |  |
| Skin and subcutaneous tissue disorders                                  |                     |  |  |
| Hyperhidrosis<br>subjects affected / exposed<br>occurrences (all)       | 1 / 6 (16.67%)<br>1 |  |  |
| Actinic keratosis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 6 (0.00%)<br>0  |  |  |
| Erythema                                                                |                     |  |  |

|                                                 |                |  |  |
|-------------------------------------------------|----------------|--|--|
| subjects affected / exposed                     | 1 / 6 (16.67%) |  |  |
| occurrences (all)                               | 1              |  |  |
| Pruritus                                        |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Rash maculo-papular                             |                |  |  |
| subjects affected / exposed                     | 1 / 6 (16.67%) |  |  |
| occurrences (all)                               | 1              |  |  |
| Skin discharge                                  |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Renal and urinary disorders                     |                |  |  |
| Chronic kidney disease                          |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Pollakiuria                                     |                |  |  |
| subjects affected / exposed                     | 1 / 6 (16.67%) |  |  |
| occurrences (all)                               | 1              |  |  |
| Musculoskeletal and connective tissue disorders |                |  |  |
| Arthralgia                                      |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Back pain                                       |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Myalgia                                         |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Trismus                                         |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Infections and infestations                     |                |  |  |
| Nasopharyngitis                                 |                |  |  |
| subjects affected / exposed                     | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                               | 0              |  |  |
| Urinary tract infection                         |                |  |  |

|                                    |                |  |  |
|------------------------------------|----------------|--|--|
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |
| COVID-19                           |                |  |  |
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |
| Cellulitis                         |                |  |  |
| subjects affected / exposed        | 1 / 6 (16.67%) |  |  |
| occurrences (all)                  | 1              |  |  |
| Gingivitis                         |                |  |  |
| subjects affected / exposed        | 1 / 6 (16.67%) |  |  |
| occurrences (all)                  | 1              |  |  |
| Oral candidiasis                   |                |  |  |
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |
| Tooth abscess                      |                |  |  |
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |
| Wound infection pseudomonas        |                |  |  |
| subjects affected / exposed        | 1 / 6 (16.67%) |  |  |
| occurrences (all)                  | 2              |  |  |
| Metabolism and nutrition disorders |                |  |  |
| Hyponatraemia                      |                |  |  |
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |
| Decreased appetite                 |                |  |  |
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |
| Dehydration                        |                |  |  |
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |
| Hypoalbuminaemia                   |                |  |  |
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |
| Hypokalaemia                       |                |  |  |
| subjects affected / exposed        | 0 / 6 (0.00%)  |  |  |
| occurrences (all)                  | 0              |  |  |

|                                                                     |                    |  |  |
|---------------------------------------------------------------------|--------------------|--|--|
| Hypomagnesaemia<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 |  |  |
|---------------------------------------------------------------------|--------------------|--|--|

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment                                                                                                           |
|------------------|---------------------------------------------------------------------------------------------------------------------|
| 18 December 2020 | This is the clinical study protocol version 2.2, which is the first version patients were enrolled with.            |
| 12 May 2021      | This is the clinical study protocol version 4.0, which is the second and last version, patients were enrolled with. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

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

The study was prematurely terminated due to a strategic decision by the sponsor. Therefore, the total number of participants enrolled is smaller than planned (actually enrolled and treated: 25, planned: 70).

Notes: