



## Clinical trial results:

**A phase 2b, open-label study to evaluate the safety, tolerability, and immunogenicity of vaccine candidate BNT162b2 in immunocompromised participants  $\geq 2$  years of age.**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2021-001290-23 |
| Trial protocol           | DE             |
| Global end of trial date | 23 July 2023   |

### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1               |
| This version publication date  | 07 February 2024 |
| First version publication date | 07 February 2024 |

### Trial information

#### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | C4591024 |
|-----------------------|----------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04895982 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

|                              |                                                                                                 |
|------------------------------|-------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | BioNTech SE                                                                                     |
| Sponsor organisation address | An der Goldgrube 12, Mainz, Germany, 55131                                                      |
| Public contact               | BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de |
| Scientific contact           | BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de |

Notes:

### Paediatric regulatory details

|                                                                      |                     |
|----------------------------------------------------------------------|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP)       | Yes                 |
| EMA paediatric investigation plan number(s)                          | EMA-002861-PIP02-20 |
| 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? | Yes                 |

Notes:

## Results analysis stage

|                                                      |                |
|------------------------------------------------------|----------------|
| Analysis stage                                       | Final          |
| Date of interim/final analysis                       | 09 August 2023 |
| Is this the analysis of the primary completion data? | No             |
| Global end of trial reached?                         | Yes            |
| Global end of trial date                             | 23 July 2023   |
| Was the trial ended prematurely?                     | No             |

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this study was to describe the safety, tolerability and immune response to prophylactic BNT162b2 in immunocompromised subjects  $\geq 2$  to  $\geq 18$  years of age without serological or virological evidence of past Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV2) infection and with representative medical conditions. Representative conditions for subjects  $\geq 18$  years of age included non-small cell lung cancer (NSCLC), chronic lymphocytic leukemia (CLL), haemodialysis treatment secondary to end-stage renal disease, or immunomodulator therapy for an autoimmune inflammatory disorder. Representative conditions for subjects  $\geq 2$  to  $< 18$  years of age included those with autoimmune inflammatory disorders receiving immunomodulators, those who had undergone organ transplant and were receiving maintenance antirejection modulators, and those who had undergone bone marrow or stem cell transplant.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment                          | 15 October 2021 |
| Long term follow-up planned                               | No              |
| Independent data monitoring committee (IDMC) involvement? | Yes             |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                   |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Germany: 46       |
| Country: Number of subjects enrolled | Brazil: 25        |
| Country: Number of subjects enrolled | United States: 50 |
| Country: Number of subjects enrolled | Mexico: 3         |
| Worldwide total number of subjects   | 124               |
| EEA total number of subjects         | 46                |

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)                    | 102 |
| Adolescents (12-17 years)                | 15  |
| Adults (18-64 years)                     | 5   |
| From 65 to 84 years                      | 2   |
| 85 years and over                        | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 124 subjects were enrolled in this study.

### Period 1

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

### Arms

|                              |                                             |
|------------------------------|---------------------------------------------|
| Are arms mutually exclusive? | Yes                                         |
| <b>Arm title</b>             | 2 to <5 Years with Immunomodulatory Therapy |

Arm description:

Subjects aged 2 to <5 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 3 microgram (mcg) of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | BNT162b2          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

3 micrograms BNT162b2 administered intramuscularly

|                  |                                            |
|------------------|--------------------------------------------|
| <b>Arm title</b> | 2 to < 5 Years with Solid Organ Transplant |
|------------------|--------------------------------------------|

Arm description:

Subjects aged 2 to <5 years who had solid organ transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | BNT162b2          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

3 micrograms BNT162b2 administered intramuscularly

|                  |                                          |
|------------------|------------------------------------------|
| <b>Arm title</b> | 2 to < 5 Years with Stem Cell Transplant |
|------------------|------------------------------------------|

Arm description:

Subjects aged 2 to <5 years who had stem cell transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|          |              |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

|                                                    |                                              |
|----------------------------------------------------|----------------------------------------------|
| Investigational medicinal product name             | BNT162b2                                     |
| Investigational medicinal product code             |                                              |
| Other name                                         |                                              |
| Pharmaceutical forms                               | Injection                                    |
| Routes of administration                           | Intramuscular use                            |
| Dosage and administration details:                 |                                              |
| 3 micrograms BNT162b2 administered intramuscularly |                                              |
| <b>Arm title</b>                                   | 5 to <12 Years with Immunomodulatory Therapy |

Arm description:

Subjects aged 5 to <12 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                                     |                                            |
|-----------------------------------------------------|--------------------------------------------|
| Arm type                                            | Experimental                               |
| Investigational medicinal product name              | BNT162b2                                   |
| Investigational medicinal product code              |                                            |
| Other name                                          |                                            |
| Pharmaceutical forms                                | Injection                                  |
| Routes of administration                            | Intramuscular use                          |
| Dosage and administration details:                  |                                            |
| 10 micrograms BNT162b2 administered intramuscularly |                                            |
| <b>Arm title</b>                                    | 5 to <12 Years with Solid Organ Transplant |

Arm description:

Subjects aged 5 to <12 years who had solid organ transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                                     |                                          |
|-----------------------------------------------------|------------------------------------------|
| Arm type                                            | Experimental                             |
| Investigational medicinal product name              | BNT162b2                                 |
| Investigational medicinal product code              |                                          |
| Other name                                          |                                          |
| Pharmaceutical forms                                | Injection                                |
| Routes of administration                            | Intramuscular use                        |
| Dosage and administration details:                  |                                          |
| 10 micrograms BNT162b2 administered intramuscularly |                                          |
| <b>Arm title</b>                                    | 5 to <12 Years with Stem Cell Transplant |

Arm description:

Subjects aged 5 to <12 years who had stem cell transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                                     |                                               |
|-----------------------------------------------------|-----------------------------------------------|
| Arm type                                            | Experimental                                  |
| Investigational medicinal product name              | BNT162b2                                      |
| Investigational medicinal product code              |                                               |
| Other name                                          |                                               |
| Pharmaceutical forms                                | Injection                                     |
| Routes of administration                            | Intramuscular use                             |
| Dosage and administration details:                  |                                               |
| 10 micrograms BNT162b2 administered intramuscularly |                                               |
| <b>Arm title</b>                                    | 12 to <18 Years with Immunomodulatory Therapy |

Arm description:

Subjects aged 12 to <18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | BNT162b2          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

|                  |                                             |
|------------------|---------------------------------------------|
| <b>Arm title</b> | 12 to <18 Years with Solid Organ Transplant |
|------------------|---------------------------------------------|

Arm description:

Subjects aged 12 to <18 years who had solid organ transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | BNT162b2          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

|                  |                                           |
|------------------|-------------------------------------------|
| <b>Arm title</b> | 12 to <18 Years with Stem Cell Transplant |
|------------------|-------------------------------------------|

Arm description:

Subjects aged 12 to <18 years who had stem cell transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | BNT162b2          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

|                  |                                          |
|------------------|------------------------------------------|
| <b>Arm title</b> | >=18 Years with Immunomodulatory Therapy |
|------------------|------------------------------------------|

Arm description:

Subjects aged >=18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | BNT162b2          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

|                  |                                            |
|------------------|--------------------------------------------|
| <b>Arm title</b> | >=18 Years with Non-Small Cell Lung Cancer |
|------------------|--------------------------------------------|

Arm description:

Subjects with non-small cell lung cancer aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                                     |                                |
|-----------------------------------------------------|--------------------------------|
| Arm type                                            | Experimental                   |
| Investigational medicinal product name              | BNT162b2                       |
| Investigational medicinal product code              |                                |
| Other name                                          |                                |
| Pharmaceutical forms                                | Injection                      |
| Routes of administration                            | Intramuscular use              |
| Dosage and administration details:                  |                                |
| 30 micrograms BNT162b2 administered intramuscularly |                                |
| <b>Arm title</b>                                    | >= 18 Years with Haemodialysis |

Arm description:

Subjects undergone maintenance haemodialysis treatment aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | BNT162b2          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

| <b>Number of subjects in period 1</b> | 2 to <5 Years with Immunomodulatory Therapy | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant |
|---------------------------------------|---------------------------------------------|--------------------------------------------|------------------------------------------|
| Started                               | 9                                           | 15                                         | 13                                       |
| Dose 1                                | 9                                           | 15                                         | 13                                       |
| Dose 2                                | 9                                           | 15                                         | 12                                       |
| Dose 3                                | 9                                           | 15                                         | 11                                       |
| Dose 4                                | 7                                           | 13                                         | 6                                        |
| Completed                             | 7                                           | 12                                         | 6                                        |
| Not completed                         | 2                                           | 3                                          | 7                                        |
| Refused further study procedures      | -                                           | -                                          | 1                                        |
| Unspecified                           | -                                           | -                                          | 1                                        |
| Lost to follow-up                     | -                                           | -                                          | 1                                        |
| Withdrawal by parent/guardian         | 2                                           | 3                                          | 3                                        |
| Protocol deviation                    | -                                           | -                                          | 1                                        |
| Withdrawal by subject                 | -                                           | -                                          | -                                        |

| <b>Number of subjects in period 1</b> | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |
|---------------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|
| Started                               | 19                                           | 24                                         | 22                                       |
| Dose 1                                | 19                                           | 24                                         | 22                                       |
| Dose 2                                | 19                                           | 24                                         | 22                                       |

|                                  |                   |    |                   |
|----------------------------------|-------------------|----|-------------------|
| Dose 3                           | 17                | 24 | 22                |
| Dose 4                           | 14 <sup>[1]</sup> | 20 | 17 <sup>[2]</sup> |
| Completed                        | 16                | 20 | 18                |
| Not completed                    | 3                 | 4  | 4                 |
| Refused further study procedures | -                 | -  | -                 |
| Unspecified                      | 1                 | -  | -                 |
| Lost to follow-up                | -                 | -  | 1                 |
| Withdrawal by parent/guardian    | 1                 | 3  | 2                 |
| Protocol deviation               | 1                 | 1  | -                 |
| Withdrawal by subject            | -                 | -  | 1                 |

| Number of subjects in period 1   | 12 to <18 Years with Immunomodulatory Therapy | 12 to <18 Years with Solid Organ Transplant | 12 to <18 Years with Stem Cell Transplant |
|----------------------------------|-----------------------------------------------|---------------------------------------------|-------------------------------------------|
|                                  |                                               |                                             |                                           |
| Started                          | 7                                             | 1                                           | 7                                         |
| Dose 1                           | 7                                             | 1                                           | 7                                         |
| Dose 2                           | 7                                             | 1                                           | 7                                         |
| Dose 3                           | 7                                             | 1                                           | 6                                         |
| Dose 4                           | 5                                             | 1                                           | 3                                         |
| Completed                        | 5                                             | 0                                           | 3                                         |
| Not completed                    | 2                                             | 1                                           | 4                                         |
| Refused further study procedures | -                                             | -                                           | -                                         |
| Unspecified                      | -                                             | -                                           | -                                         |
| Lost to follow-up                | -                                             | -                                           | 1                                         |
| Withdrawal by parent/guardian    | 1                                             | -                                           | 3                                         |
| Protocol deviation               | -                                             | 1                                           | -                                         |
| Withdrawal by subject            | 1                                             | -                                           | -                                         |

| Number of subjects in period 1   | >=18 Years with Immunomodulatory Therapy | >=18 Years with Non-Small Cell Lung Cancer | >= 18 Years with Haemodialysis |
|----------------------------------|------------------------------------------|--------------------------------------------|--------------------------------|
|                                  |                                          |                                            |                                |
| Started                          | 5                                        | 1                                          | 1                              |
| Dose 1                           | 5                                        | 1                                          | 1                              |
| Dose 2                           | 5                                        | 1                                          | 1                              |
| Dose 3                           | 5                                        | 1                                          | 1                              |
| Dose 4                           | 3                                        | 1                                          | 0                              |
| Completed                        | 3                                        | 1                                          | 0                              |
| Not completed                    | 2                                        | 0                                          | 1                              |
| Refused further study procedures | -                                        | -                                          | -                              |
| Unspecified                      | 1                                        | -                                          | -                              |
| Lost to follow-up                | -                                        | -                                          | -                              |
| Withdrawal by parent/guardian    | -                                        | -                                          | -                              |
| Protocol deviation               | -                                        | -                                          | -                              |



|                       |   |   |   |
|-----------------------|---|---|---|
| Withdrawal by subject | 1 | - | 1 |
|-----------------------|---|---|---|

---

Notes:

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

Justification: Milestone includes only subjects who received doses. The study completion includes subjects who completed the study 6 months after Dose 3 (per protocol amendment 3) and subjects who completed the study 6 months after Dose 4 (per protocol amendment 4).

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

Justification: Milestone includes only subjects who received doses. The study completion includes subjects who completed the study 6 months after Dose 3 (per protocol amendment 3) and subjects who completed the study 6 months after Dose 4 (per protocol amendment 4).

## Baseline characteristics

### Reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                     |                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 2 to <5 Years with Immunomodulatory Therapy   |
| Reporting group description:<br>Subjects aged 2 to <5 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 3 microgram (mcg) of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3. |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 2 to < 5 Years with Solid Organ Transplant    |
| Reporting group description:<br>Subjects aged 2 to <5 years who had solid organ transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                        |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 2 to < 5 Years with Stem Cell Transplant      |
| Reporting group description:<br>Subjects aged 2 to <5 years who had stem cell transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                          |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 5 to <12 Years with Immunomodulatory Therapy  |
| Reporting group description:<br>Subjects aged 5 to <12 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.           |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 5 to <12 Years with Solid Organ Transplant    |
| Reporting group description:<br>Subjects aged 5 to <12 years who had solid organ transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                      |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 5 to <12 Years with Stem Cell Transplant      |
| Reporting group description:<br>Subjects aged 5 to <12 years who had stem cell transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                        |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 12 to <18 Years with Immunomodulatory Therapy |
| Reporting group description:<br>Subjects aged 12 to <18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.          |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 12 to <18 Years with Solid Organ Transplant   |
| Reporting group description:<br>Subjects aged 12 to <18 years who had solid organ transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                     |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | 12 to <18 Years with Stem Cell Transplant     |
| Reporting group description:<br>Subjects aged 12 to <18 years who had stem cell transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                       |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | >=18 Years with Immunomodulatory Therapy      |
| Reporting group description:<br>Subjects aged >=18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.               |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                               | >=18 Years with Non-Small Cell Lung Cancer    |

Reporting group description:

Subjects with non-small cell lung cancer aged  $\geq 18$  years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                    |
|-----------------------|------------------------------------|
| Reporting group title | $\geq 18$ Years with Haemodialysis |
|-----------------------|------------------------------------|

Reporting group description:

Subjects undergone maintenance haemodialysis treatment aged  $\geq 18$  years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

| Reporting group values                             | 2 to <5 Years with Immunomodulatory Therapy | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant |
|----------------------------------------------------|---------------------------------------------|--------------------------------------------|------------------------------------------|
| Number of subjects                                 | 9                                           | 15                                         | 13                                       |
| Age Categorical<br>Units: Subjects                 |                                             |                                            |                                          |
| In utero                                           | 0                                           | 0                                          | 0                                        |
| Preterm newborn infants (gestational age < 37 wks) | 0                                           | 0                                          | 0                                        |
| Newborns (0-27 days)                               | 0                                           | 0                                          | 0                                        |
| Infants and toddlers (28 days-23 months)           | 0                                           | 0                                          | 0                                        |
| Children (2-11 years)                              | 9                                           | 15                                         | 13                                       |
| Adolescents (12-17 years)                          | 0                                           | 0                                          | 0                                        |
| Adults (18-64 years)                               | 0                                           | 0                                          | 0                                        |
| From 65-84 years                                   | 0                                           | 0                                          | 0                                        |
| 85 years and over                                  | 0                                           | 0                                          | 0                                        |
| Age Continuous<br>Units: years                     |                                             |                                            |                                          |
| median                                             | 3.0                                         | 4.0                                        | 3.0                                      |
| full range (min-max)                               | 2 to 4                                      | 2 to 5                                     | 2 to 4                                   |
| Gender Categorical<br>Units: Subjects              |                                             |                                            |                                          |
| Female                                             | 4                                           | 8                                          | 3                                        |
| Male                                               | 5                                           | 7                                          | 10                                       |
| Race<br>Units: Subjects                            |                                             |                                            |                                          |
| White                                              | 9                                           | 11                                         | 12                                       |
| Black or African American                          | 0                                           | 2                                          | 0                                        |
| Asian                                              | 0                                           | 1                                          | 0                                        |
| Multiracial                                        | 0                                           | 0                                          | 1                                        |
| Not reported                                       | 0                                           | 1                                          | 0                                        |
| American Indian or Alaska Native                   | 0                                           | 0                                          | 0                                        |
| Ethnicity<br>Units: Subjects                       |                                             |                                            |                                          |
| Hispanic/Latino                                    | 1                                           | 1                                          | 4                                        |
| Non-Hispanic/non-Latino                            | 8                                           | 14                                         | 9                                        |
| Not reported                                       | 0                                           | 0                                          | 0                                        |

| Reporting group values | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |
|------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|
| Number of subjects     | 19                                           | 24                                         | 22                                       |

|                                                       |         |         |         |
|-------------------------------------------------------|---------|---------|---------|
| Age Categorical<br>Units: Subjects                    |         |         |         |
| In utero                                              | 0       | 0       | 0       |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0       | 0       | 0       |
| Newborns (0-27 days)                                  | 0       | 0       | 0       |
| Infants and toddlers (28 days-23 months)              | 0       | 0       | 0       |
| Children (2-11 years)                                 | 19      | 24      | 22      |
| Adolescents (12-17 years)                             | 0       | 0       | 0       |
| Adults (18-64 years)                                  | 0       | 0       | 0       |
| From 65-84 years                                      | 0       | 0       | 0       |
| 85 years and over                                     | 0       | 0       | 0       |
| Age Continuous<br>Units: years                        |         |         |         |
| median                                                | 10.0    | 8.0     | 8.5     |
| full range (min-max)                                  | 5 to 11 | 5 to 11 | 6 to 11 |
| Gender Categorical<br>Units: Subjects                 |         |         |         |
| Female                                                | 12      | 9       | 5       |
| Male                                                  | 7       | 15      | 17      |
| Race<br>Units: Subjects                               |         |         |         |
| White                                                 | 17      | 21      | 19      |
| Black or African American                             | 1       | 0       | 3       |
| Asian                                                 | 0       | 1       | 0       |
| Multiracial                                           | 0       | 1       | 0       |
| Not reported                                          | 1       | 1       | 0       |
| American Indian or Alaska Native                      | 0       | 0       | 0       |
| Ethnicity<br>Units: Subjects                          |         |         |         |
| Hispanic/Latino                                       | 6       | 2       | 2       |
| Non-Hispanic/non-Latino                               | 13      | 22      | 19      |
| Not reported                                          | 0       | 0       | 1       |

| <b>Reporting group values</b>                         | 12 to <18 Years<br>with<br>Immunomodulatory<br>Therapy | 12 to <18 Years with<br>Solid Organ<br>Transplant | 12 to <18 Years<br>with Stem Cell<br>Transplant |
|-------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------|-------------------------------------------------|
| Number of subjects                                    | 7                                                      | 1                                                 | 7                                               |
| Age Categorical<br>Units: Subjects                    |                                                        |                                                   |                                                 |
| In utero                                              | 0                                                      | 0                                                 | 0                                               |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0                                                      | 0                                                 | 0                                               |
| Newborns (0-27 days)                                  | 0                                                      | 0                                                 | 0                                               |
| Infants and toddlers (28 days-23 months)              | 0                                                      | 0                                                 | 0                                               |
| Children (2-11 years)                                 | 0                                                      | 0                                                 | 0                                               |
| Adolescents (12-17 years)                             | 7                                                      | 1                                                 | 7                                               |
| Adults (18-64 years)                                  | 0                                                      | 0                                                 | 0                                               |
| From 65-84 years                                      | 0                                                      | 0                                                 | 0                                               |
| 85 years and over                                     | 0                                                      | 0                                                 | 0                                               |

|                                                                  |                  |                  |                  |
|------------------------------------------------------------------|------------------|------------------|------------------|
| Age Continuous<br>Units: years<br>median<br>full range (min-max) | 13.0<br>12 to 16 | 14.0<br>14 to 14 | 12.0<br>12 to 15 |
| Gender Categorical<br>Units: Subjects                            |                  |                  |                  |
| Female                                                           | 2                | 0                | 5                |
| Male                                                             | 5                | 1                | 2                |
| Race<br>Units: Subjects                                          |                  |                  |                  |
| White                                                            | 6                | 1                | 7                |
| Black or African American                                        | 0                | 0                | 0                |
| Asian                                                            | 1                | 0                | 0                |
| Multiracial                                                      | 0                | 0                | 0                |
| Not reported                                                     | 0                | 0                | 0                |
| American Indian or Alaska Native                                 | 0                | 0                | 0                |
| Ethnicity<br>Units: Subjects                                     |                  |                  |                  |
| Hispanic/Latino                                                  | 3                | 0                | 1                |
| Non-Hispanic/non-Latino                                          | 4                | 1                | 6                |
| Not reported                                                     | 0                | 0                | 0                |

| <b>Reporting group values</b>                                    | <b>&gt;=18 Years with<br/>Immunomodulatory<br/>Therapy</b> | <b>&gt;=18 Years with<br/>Non-Small Cell Lung<br/>Cancer</b> | <b>&gt;= 18 Years with<br/>Haemodialysis</b> |
|------------------------------------------------------------------|------------------------------------------------------------|--------------------------------------------------------------|----------------------------------------------|
| Number of subjects                                               | 5                                                          | 1                                                            | 1                                            |
| Age Categorical<br>Units: Subjects                               |                                                            |                                                              |                                              |
| In utero                                                         | 0                                                          | 0                                                            | 0                                            |
| Preterm newborn infants<br>(gestational age < 37 wks)            | 0                                                          | 0                                                            | 0                                            |
| Newborns (0-27 days)                                             | 0                                                          | 0                                                            | 0                                            |
| Infants and toddlers (28 days-23<br>months)                      | 0                                                          | 0                                                            | 0                                            |
| Children (2-11 years)                                            | 0                                                          | 0                                                            | 0                                            |
| Adolescents (12-17 years)                                        | 0                                                          | 0                                                            | 0                                            |
| Adults (18-64 years)                                             | 3                                                          | 1                                                            | 1                                            |
| From 65-84 years                                                 | 2                                                          | 0                                                            | 0                                            |
| 85 years and over                                                | 0                                                          | 0                                                            | 0                                            |
| Age Continuous<br>Units: years<br>median<br>full range (min-max) | 39.0<br>31 to 73                                           | 40.0<br>40 to 40                                             | 62.0<br>62 to 62                             |
| Gender Categorical<br>Units: Subjects                            |                                                            |                                                              |                                              |
| Female                                                           | 3                                                          | 0                                                            | 0                                            |
| Male                                                             | 2                                                          | 1                                                            | 1                                            |
| Race<br>Units: Subjects                                          |                                                            |                                                              |                                              |
| White                                                            | 1                                                          | 0                                                            | 0                                            |
| Black or African American                                        | 2                                                          | 0                                                            | 0                                            |
| Asian                                                            | 0                                                          | 0                                                            | 0                                            |
| Multiracial                                                      | 1                                                          | 0                                                            | 0                                            |

|                                  |   |   |   |
|----------------------------------|---|---|---|
| Not reported                     | 1 | 0 | 1 |
| American Indian or Alaska Native | 0 | 1 | 0 |
| Ethnicity                        |   |   |   |
| Units: Subjects                  |   |   |   |
| Hispanic/Latino                  | 2 | 1 | 1 |
| Non-Hispanic/non-Latino          | 3 | 0 | 0 |
| Not reported                     | 0 | 0 | 0 |

|                                                       |       |  |  |
|-------------------------------------------------------|-------|--|--|
| <b>Reporting group values</b>                         | Total |  |  |
| Number of subjects                                    | 124   |  |  |
| Age Categorical                                       |       |  |  |
| Units: Subjects                                       |       |  |  |
| In utero                                              | 0     |  |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0     |  |  |
| Newborns (0-27 days)                                  | 0     |  |  |
| Infants and toddlers (28 days-23<br>months)           | 0     |  |  |
| Children (2-11 years)                                 | 102   |  |  |
| Adolescents (12-17 years)                             | 15    |  |  |
| Adults (18-64 years)                                  | 5     |  |  |
| From 65-84 years                                      | 2     |  |  |
| 85 years and over                                     | 0     |  |  |
| Age Continuous                                        |       |  |  |
| Units: years                                          |       |  |  |
| median                                                |       |  |  |
| full range (min-max)                                  | -     |  |  |
| Gender Categorical                                    |       |  |  |
| Units: Subjects                                       |       |  |  |
| Female                                                | 51    |  |  |
| Male                                                  | 73    |  |  |
| Race                                                  |       |  |  |
| Units: Subjects                                       |       |  |  |
| White                                                 | 104   |  |  |
| Black or African American                             | 8     |  |  |
| Asian                                                 | 3     |  |  |
| Multiracial                                           | 3     |  |  |
| Not reported                                          | 5     |  |  |
| American Indian or Alaska Native                      | 1     |  |  |
| Ethnicity                                             |       |  |  |
| Units: Subjects                                       |       |  |  |
| Hispanic/Latino                                       | 24    |  |  |
| Non-Hispanic/non-Latino                               | 99    |  |  |
| Not reported                                          | 1     |  |  |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                                                                     |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 2 to <5 Years with Immunomodulatory Therapy   |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 2 to <5 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 3 microgram (mcg) of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3. |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 2 to < 5 Years with Solid Organ Transplant    |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 2 to <5 years who had solid organ transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                        |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 2 to < 5 Years with Stem Cell Transplant      |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 2 to <5 years who had stem cell transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                          |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 5 to <12 Years with Immunomodulatory Therapy  |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 5 to <12 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.           |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 5 to <12 Years with Solid Organ Transplant    |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 5 to <12 years who had solid organ transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                      |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 5 to <12 Years with Stem Cell Transplant      |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 5 to <12 years who had stem cell transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                        |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 12 to <18 Years with Immunomodulatory Therapy |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 12 to <18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.          |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 12 to <18 Years with Solid Organ Transplant   |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 12 to <18 years who had solid organ transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                     |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | 12 to <18 Years with Stem Cell Transplant     |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged 12 to <18 years who had stem cell transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.                                                       |                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                               | >=18 Years with Immunomodulatory Therapy      |
| Reporting group description:                                                                                                                                                                                                                                                                                                                        |                                               |
| Subjects aged >=18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.               |                                               |

|                                                                                                                                                                                                                                                                                                           |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                     | >=18 Years with Non-Small Cell Lung Cancer |
| Reporting group description:                                                                                                                                                                                                                                                                              |                                            |
| Subjects with non-small cell lung cancer aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.               |                                            |
| Reporting group title                                                                                                                                                                                                                                                                                     | >= 18 Years with Haemodialysis             |
| Reporting group description:                                                                                                                                                                                                                                                                              |                                            |
| Subjects undergone maintenance haemodialysis treatment aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3. |                                            |

**Primary: Geometric Mean Titers (GMTs) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS CoV 2) Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged >=2 to <5 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection**

|                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                      | Geometric Mean Titers (GMTs) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS CoV 2) Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged >=2 to <5 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection <sup>[1][2]</sup> |
| End point description:                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                             |
| GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 3 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024. |                                                                                                                                                                                                                                                                             |
| End point type                                                                                                                                                                                                                                       | Primary                                                                                                                                                                                                                                                                     |
| End point timeframe:                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                             |
| 1 Month after Vaccination 3                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                             |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | 2 to <5 Years with Immunomodulatory Therapy | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant |  |
|------------------------------------------|---------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type                       | Reporting group                             | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed              | 0 <sup>[3]</sup>                            | 0 <sup>[4]</sup>                           | 0 <sup>[5]</sup>                         |  |
| Units: Titers                            |                                             |                                            |                                          |  |
| geometric mean (confidence interval 95%) | ( to )                                      | ( to )                                     | ( to )                                   |  |

Notes:

[3] - Results for this endpoint will be posted by March 2024.

[4] - Results for this endpoint will be posted by March 2024.

[5] - Results for this endpoint will be posted by March 2024.

**Statistical analyses**

No statistical analyses for this end point

**Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in**



## Subjects Aged $\geq 5$ to $<12$ Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

|                 |                                                                                                                                                                                                         |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged $\geq 5$ to $<12$ Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection <sup>[6][7]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 3 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

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

### End point timeframe:

1 Month after Vaccination 3

### Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | 5 to $<12$ Years with Immunomodulatory Therapy | 5 to $<12$ Years with Solid Organ Transplant | 5 to $<12$ Years with Stem Cell Transplant |  |
|------------------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type                       | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed              | 0 <sup>[8]</sup>                               | 0 <sup>[9]</sup>                             | 0 <sup>[10]</sup>                          |  |
| Units: Titers                            |                                                |                                              |                                            |  |
| geometric mean (confidence interval 95%) | ( to )                                         | ( to )                                       | ( to )                                     |  |

### Notes:

[8] - Results for this endpoint will be posted by March 2024.

[9] - Results for this endpoint will be posted by March 2024.

[10] - Results for this endpoint will be posted by March 2024.

## Statistical analyses

No statistical analyses for this end point

## Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged $\geq 18$ Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

|                 |                                                                                                                                                                                                   |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged $\geq 18$ Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection <sup>[11][12]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 3 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

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

### End point timeframe:

1 Month after Vaccination 3

### Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | >=18 Years with Immunomodulatory Therapy | >=18 Years with Non-Small Cell Lung Cancer | >= 18 Years with Haemodialysis |  |
|------------------------------------------|------------------------------------------|--------------------------------------------|--------------------------------|--|
| Subject group type                       | Reporting group                          | Reporting group                            | Reporting group                |  |
| Number of subjects analysed              | 0 <sup>[13]</sup>                        | 0 <sup>[14]</sup>                          | 0 <sup>[15]</sup>              |  |
| Units: Titer                             |                                          |                                            |                                |  |
| geometric mean (confidence interval 95%) | ( to )                                   | ( to )                                     | ( to )                         |  |

Notes:

[13] - Results for this endpoint will be posted by March 2024.

[14] - Results for this endpoint will be posted by March 2024.

[15] - Results for this endpoint will be posted by March 2024.

## Statistical analyses

No statistical analyses for this end point

## Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged 12 to <18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

|                 |                                                                                                                                                                                                   |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged 12 to <18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection <sup>[16][17]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 3 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

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

End point timeframe:

1 Month after Vaccination 3

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | 12 to <18 Years with Immunomodulatory Therapy | 12 to <18 Years with Solid Organ Transplant | 12 to <18 Years with Stem Cell Transplant |  |
|------------------------------------------|-----------------------------------------------|---------------------------------------------|-------------------------------------------|--|
| Subject group type                       | Reporting group                               | Reporting group                             | Reporting group                           |  |
| Number of subjects analysed              | 0 <sup>[18]</sup>                             | 0 <sup>[19]</sup>                           | 0 <sup>[20]</sup>                         |  |
| Units: Titers                            |                                               |                                             |                                           |  |
| geometric mean (confidence interval 95%) | ( to )                                        | ( to )                                      | ( to )                                    |  |

Notes:

[18] - Results for this endpoint will be posted by March 2024.

[19] - Results for this endpoint will be posted by March 2024.

[20] - Results for this endpoint will be posted by March 2024.

## Statistical analyses

No statistical analyses for this end point

### Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged $\geq 2$ to $< 5$ Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

|                 |                                                                                                                                                                                                           |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged $\geq 2$ to $< 5$ Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection <sup>[21][22]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 4 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

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

End point timeframe:

1 Month after Vaccination 4

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | 2 to $< 5$ Years with Immunomodulatory Therapy | 2 to $< 5$ Years with Solid Organ Transplant | 2 to $< 5$ Years with Stem Cell Transplant |  |
|------------------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type                       | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed              | 0 <sup>[23]</sup>                              | 0 <sup>[24]</sup>                            | 0 <sup>[25]</sup>                          |  |
| Units: Titer                             |                                                |                                              |                                            |  |
| geometric mean (confidence interval 95%) | ( to )                                         | ( to )                                       | ( to )                                     |  |

Notes:

[23] - Results for this endpoint will be posted by March 2024.

[24] - Results for this endpoint will be posted by March 2024.

[25] - Results for this endpoint will be posted by March 2024.

## Statistical analyses

No statistical analyses for this end point

### Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged $\geq 5$ to $< 12$ Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

|                 |                                                                                                                       |
|-----------------|-----------------------------------------------------------------------------------------------------------------------|
| End point title | GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged $\geq 5$ to $< 12$ Years Without |
|-----------------|-----------------------------------------------------------------------------------------------------------------------|

## End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 4 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

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

## End point timeframe:

1 Month after Vaccination 4

## Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|------------------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type                       | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed              | 0 <sup>[28]</sup>                            | 0 <sup>[29]</sup>                          | 0 <sup>[30]</sup>                        |  |
| Units: Titer                             |                                              |                                            |                                          |  |
| geometric mean (confidence interval 95%) | ( to )                                       | ( to )                                     | ( to )                                   |  |

## Notes:

[28] - Results for this endpoint will be posted by March 2024.

[29] - Results for this endpoint will be posted by March 2024.

[30] - Results for this endpoint will be posted by March 2024.

## Statistical analyses

No statistical analyses for this end point

## Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged 12 to <18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

|                 |                                                                                                                                                                                                   |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged 12 to <18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection <sup>[31][32]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 4 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

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

## End point timeframe:

1 Month after Vaccination 4

## Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline

period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | 12 to <18<br>Years with<br>Immunomodulatory Therapy | 12 to <18<br>Years with<br>Solid Organ<br>Transplant | 12 to <18<br>Years with<br>Stem Cell<br>Transplant |  |
|------------------------------------------|-----------------------------------------------------|------------------------------------------------------|----------------------------------------------------|--|
| Subject group type                       | Reporting group                                     | Reporting group                                      | Reporting group                                    |  |
| Number of subjects analysed              | 0 <sup>[33]</sup>                                   | 0 <sup>[34]</sup>                                    | 0 <sup>[35]</sup>                                  |  |
| Units: Titer                             |                                                     |                                                      |                                                    |  |
| geometric mean (confidence interval 95%) | ( to )                                              | ( to )                                               | ( to )                                             |  |

Notes:

[33] - Results for this endpoint will be posted by March 2024.

[34] - Results for this endpoint will be posted by March 2024.

[35] - Results for this endpoint will be posted by March 2024.

### Statistical analyses

No statistical analyses for this end point

### Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged >=18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

|                 |                                                                                                                                                                                              |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged >=18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection <sup>[36][37]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 4 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

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

End point timeframe:

1 Month after Vaccination 4

Notes:

[36] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | >=18 Years<br>with<br>Immunomodulatory Therapy | >=18 Years<br>with Non-Small<br>Cell Lung<br>Cancer | >= 18 Years<br>with<br>Haemodialysis |  |
|------------------------------------------|------------------------------------------------|-----------------------------------------------------|--------------------------------------|--|
| Subject group type                       | Reporting group                                | Reporting group                                     | Reporting group                      |  |
| Number of subjects analysed              | 0 <sup>[38]</sup>                              | 0 <sup>[39]</sup>                                   | 0 <sup>[40]</sup>                    |  |
| Units: Titer                             |                                                |                                                     |                                      |  |
| geometric mean (confidence interval 95%) | ( to )                                         | ( to )                                              | ( to )                               |  |

Notes:

[38] - Results for this endpoint will be posted by March 2024.

[39] - Results for this endpoint will be posted by March 2024.

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 2$ to $< 5$ Years

|                 |                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 2$ to $< 5$ Years <sup>[41]</sup> <sup>[42]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to 7 after vaccination. Redness and swelling were measured and recorded in measuring device units (mdu) where, 1 mdu = 0.5 cm and were graded as mild ( $> 0.5$  to 2.0 cm), moderate ( $> 2.0$  to 7.0 cm), severe ( $> 7.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (emergency room [ER] visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. Overall Number Analysed (N) = subjects evaluable for

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

#### End point timeframe:

Day 1 to Day 7 after Vaccination 1

#### Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 2 to $< 5$ Years with Immunomodulatory Therapy | 2 to $< 5$ Years with Solid Organ Transplant | 2 to $< 5$ Years with Stem Cell Transplant |  |
|----------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type               | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed      | 9                                              | 15                                           | 13                                         |  |
| Units: Percentage of subjects    |                                                |                                              |                                            |  |
| number (confidence interval 95%) |                                                |                                              |                                            |  |
| Redness: Any                     | 11.1 (0.3 to 48.2)                             | 6.7 (0.2 to 31.9)                            | 0 (0.0 to 24.7)                            |  |
| Redness: Mild                    | 11.1 (0.3 to 48.2)                             | 6.7 (0.2 to 31.9)                            | 0 (0.0 to 24.7)                            |  |
| Redness: Moderate                | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 24.7)                            |  |
| Redness: Severe                  | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 24.7)                            |  |
| Redness: Grade 4                 | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 24.7)                            |  |
| Swelling: Any                    | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 24.7)                            |  |
| Swelling: Mild                   | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 24.7)                            |  |
| Swelling: Moderate               | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 24.7)                            |  |

|                                      |                    |                    |                    |  |
|--------------------------------------|--------------------|--------------------|--------------------|--|
| Swelling: Severe                     | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| Swelling: Grade 4                    | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| Pain at the injection site: Any      | 11.1 (0.3 to 48.2) | 13.3 (1.7 to 40.5) | 23.1 (5.0 to 53.8) |  |
| Pain at the injection site: Mild     | 11.1 (0.3 to 48.2) | 13.3 (1.7 to 40.5) | 23.1 (5.0 to 53.8) |  |
| Pain at the injection site: Moderate | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| Pain at the injection site: Severe   | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| Pain at the injection site: Grade 4  | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 5$ to $<12$ Years

|                 |                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 5$ to $<12$ Years <sup>[43]</sup> <sup>[44]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild ( $>0.5$  to 2.0 cm), moderate ( $>2.0$  to 7.0 cm), severe ( $>7.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[43] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to $<12$ Years with Immunomodulatory Therapy | 5 to $<12$ Years with Solid Organ Transplant | 5 to $<12$ Years with Stem Cell Transplant |  |
|----------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type               | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed      | 19                                             | 24                                           | 22                                         |  |
| Units: Percentage of subjects    |                                                |                                              |                                            |  |
| number (confidence interval 95%) |                                                |                                              |                                            |  |
| Redness: Any                     | 10.5 (1.3 to 33.1)                             | 8.3 (1.0 to 27.0)                            | 9.1 (1.1 to 29.2)                          |  |
| Redness: Mild                    | 10.5 (1.3 to 33.1)                             | 4.2 (0.1 to 21.1)                            | 4.5 (0.1 to 22.8)                          |  |

|                                      |                     |                     |                     |  |
|--------------------------------------|---------------------|---------------------|---------------------|--|
| Redness: Moderate                    | 0 (0.0 to 17.6)     | 4.2 (0.1 to 21.1)   | 4.5 (0.1 to 22.8)   |  |
| Redness: Severe                      | 0 (0.0 to 17.6)     | 0 (0.0 to 14.2)     | 0 (0.0 to 15.4)     |  |
| Redness: Grade 4                     | 0 (0.0 to 17.6)     | 0 (0.0 to 14.2)     | 0 (0.0 to 15.4)     |  |
| Swelling: Any                        | 5.3 (0.1 to 26.0)   | 4.2 (0.1 to 21.1)   | 18.2 (5.2 to 40.3)  |  |
| Swelling: Mild                       | 5.3 (0.1 to 26.0)   | 0 (0.0 to 14.2)     | 13.6 (2.9 to 34.9)  |  |
| Swelling: Moderate                   | 0 (0.0 to 17.6)     | 4.2 (0.1 to 21.1)   | 4.5 (0.1 to 22.8)   |  |
| Swelling: Severe                     | 0 (0.0 to 17.6)     | 0 (0.0 to 14.2)     | 0 (0.0 to 15.4)     |  |
| Swelling: Grade 4                    | 0 (0.0 to 17.6)     | 0 (0.0 to 14.2)     | 0 (0.0 to 15.4)     |  |
| Pain at the injection site: Any      | 73.7 (48.8 to 90.9) | 58.3 (36.6 to 77.9) | 54.5 (32.2 to 75.6) |  |
| Pain at the injection site: Mild     | 52.6 (28.9 to 75.6) | 50.0 (29.1 to 70.9) | 45.5 (24.4 to 67.8) |  |
| Pain at the injection site: Moderate | 21.1 (6.1 to 45.6)  | 8.3 (1.0 to 27.0)   | 9.1 (1.1 to 29.2)   |  |
| Pain at the injection site: Severe   | 0 (0.0 to 17.6)     | 0 (0.0 to 14.2)     | 0 (0.0 to 15.4)     |  |
| Pain at the injection site: Grade 4  | 0 (0.0 to 17.6)     | 0 (0.0 to 14.2)     | 0 (0.0 to 15.4)     |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 12$ to $< 18$ Years

|                 |                                                                                                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 12$ to $< 18$ Years <sup>[45]</sup> <sup>[46]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild (greater than  $>$  2.0 to 5.0 cm), moderate ( $> 5.0$  to 10.0 cm), severe ( $> 10.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[45] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.



| End point values                     | 12 to <18<br>Years with<br>Immunomodulatory Therapy | 12 to <18<br>Years with<br>Solid Organ<br>Transplant | 12 to <18<br>Years with<br>Stem Cell<br>Transplant |  |
|--------------------------------------|-----------------------------------------------------|------------------------------------------------------|----------------------------------------------------|--|
| Subject group type                   | Reporting group                                     | Reporting group                                      | Reporting group                                    |  |
| Number of subjects analysed          | 7                                                   | 1                                                    | 7                                                  |  |
| Units: Percentage of subjects        |                                                     |                                                      |                                                    |  |
| number (confidence interval 95%)     |                                                     |                                                      |                                                    |  |
| Redness: Any                         | 28.6 (3.7 to 71.0)                                  | 0 (0.0 to 97.5)                                      | 14.3 (0.4 to 57.9)                                 |  |
| Redness: Mild                        | 28.6 (3.7 to 71.0)                                  | 0 (0.0 to 97.5)                                      | 14.3 (0.4 to 57.9)                                 |  |
| Redness: Moderate                    | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 41.0)                                    |  |
| Redness: Severe                      | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 41.0)                                    |  |
| Redness: Grade 4                     | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 41.0)                                    |  |
| Swelling: Any                        | 28.6 (3.7 to 71.0)                                  | 100.0 (2.5 to 100.0)                                 | 14.3 (0.4 to 57.9)                                 |  |
| Swelling: Mild                       | 0 (0.0 to 41.0)                                     | 100.0 (2.5 to 100.0)                                 | 0 (0.0 to 41.0)                                    |  |
| Swelling: Moderate                   | 28.6 (3.7 to 71.0)                                  | 0 (0.0 to 97.5)                                      | 14.3 (0.4 to 57.9)                                 |  |
| Swelling: Severe                     | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 41.0)                                    |  |
| Swelling: Grade 4                    | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 41.0)                                    |  |
| Pain at the injection site: Any      | 85.7 (42.1 to 99.6)                                 | 100.0 (2.5 to 100.0)                                 | 57.1 (18.4 to 90.1)                                |  |
| Pain at the injection site: Mild     | 71.4 (29.0 to 96.3)                                 | 100.0 (2.5 to 100.0)                                 | 28.6 (3.7 to 71.0)                                 |  |
| Pain at the injection site: Moderate | 14.3 (0.4 to 57.9)                                  | 0 (0.0 to 97.5)                                      | 28.6 (3.7 to 71.0)                                 |  |
| Pain at the injection site: Severe   | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 41.0)                                    |  |
| Pain at the injection site: Grade 4  | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 41.0)                                    |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged ≥18 Years

|                 |                                                                                                                                                       |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged ≥18 Years <sup>[47][48]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

#### End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[47] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | >=18 Years with Immunomodulatory Therapy | >=18 Years with Non-Small Cell Lung Cancer | >= 18 Years with Haemodialysis |  |
|----------------------------------|------------------------------------------|--------------------------------------------|--------------------------------|--|
| Subject group type               | Reporting group                          | Reporting group                            | Reporting group                |  |
| Number of subjects analysed      | 5                                        | 1                                          | 1                              |  |
| Units: Percentage of subjects    |                                          |                                            |                                |  |
| number (confidence interval 95%) |                                          |                                            |                                |  |
| Redness: Any                     | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Redness: Mild                    | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Redness: Moderate                | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Redness: Severe                  | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Redness: Grade 4                 | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Swelling: Any                    | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Swelling: Mild                   | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Swelling: Moderate               | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Swelling: Severe                 | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Swelling: Grade 4                | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Pain at injection site: Any      | 80.0 (28.4 to 99.5)                      | 100.0 (2.5 to 100.0)                       | 100.0 (2.5 to 100.0)           |  |
| Pain at injection site: Mild     | 40.0 (5.3 to 85.3)                       | 100.0 (2.5 to 100.0)                       | 0 (0.0 to 97.5)                |  |
| Pain at injection site: Moderate | 40.0 (5.3 to 85.3)                       | 0 (0.0 to 97.5)                            | 100.0 (2.5 to 100.0)           |  |
| Pain at injection site: Severe   | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=2 to <5 Years

|                 |                                                                                                                                                             |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=2 to <5 Years <sup>[49][50]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm), moderate(>2.0 to 7.0 cm), severe(>7.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis[redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate(interfered with activity), severe(prevented daily activity), Grade 4(ER visit or hospitalisation for severe pain at injection site).Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention.' N'='

subjects evaluable for this endpoint. Number Analysed ('n')= subjects evaluable for specified rows.

|                                    |         |
|------------------------------------|---------|
| End point type                     | Primary |
| End point timeframe:               |         |
| Day 1 to Day 7 after Vaccination 2 |         |

Notes:

[49] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                             | 2 to <5 Years with Immunomodulatory Therapy | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant |  |
|----------------------------------------------|---------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type                           | Reporting group                             | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed                  | 9                                           | 15                                         | 11                                       |  |
| Units: Percentage of subjects                |                                             |                                            |                                          |  |
| number (confidence interval 95%)             |                                             |                                            |                                          |  |
| Redness: Any (n=9,15,10)                     | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 30.8)                          |  |
| Redness: Mild (n=9,15,10)                    | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 30.8)                          |  |
| Redness: Moderate (n=9,15,10)                | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Redness: Severe (n=9,15,10)                  | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Redness: Grade 4 (n=9,15,10)                 | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Swelling: Any (n=9,15,10)                    | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 30.8)                          |  |
| Swelling: Mild (n=9,15,10)                   | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 30.8)                          |  |
| Swelling: Moderate (n=9,15,10)               | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Swelling: Severe (n=9,15,10)                 | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Swelling: Grade 4 (n=9,15,10)                | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Pain at injection site: Any (n=9,15,11)      | 11.1 (0.3 to 48.2)                          | 20.0 (4.3 to 48.1)                         | 9.1 (0.2 to 41.3)                        |  |
| Pain at injection site: Mild (n=9,15,11)     | 11.1 (0.3 to 48.2)                          | 20.0 (4.3 to 48.1)                         | 9.1 (0.2 to 41.3)                        |  |
| Pain at injection site: Moderate (n=9,15,11) | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Pain at injection site: Severe (n=9,15,11)   | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Pain at injection site: Grade 4 (n=9,15,11)  | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged ≥5 to <12 Years

|                 |                                                                                                                         |
|-----------------|-------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged |
|-----------------|-------------------------------------------------------------------------------------------------------------------------|

## End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

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

## End point timeframe:

Day 1 to Day 7 after Vaccination 2

## Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 19                                           | 24                                         | 22                                       |  |
| Units: Percentage of subjects    |                                              |                                            |                                          |  |
| number (confidence interval 95%) |                                              |                                            |                                          |  |
| Redness: Any                     | 10.5 (1.3 to 33.1)                           | 12.5 (2.7 to 32.4)                         | 22.7 (7.8 to 45.4)                       |  |
| Redness: Mild                    | 10.5 (1.3 to 33.1)                           | 4.2 (0.1 to 21.1)                          | 13.6 (2.9 to 34.9)                       |  |
| Redness: Moderate                | 0 (0.0 to 17.6)                              | 8.3 (1.0 to 27.0)                          | 9.1 (1.1 to 29.2)                        |  |
| Redness: Severe                  | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Redness: Grade 4                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Swelling: Any                    | 10.5 (1.3 to 33.1)                           | 8.3 (1.0 to 27.0)                          | 31.8 (13.9 to 54.9)                      |  |
| Swelling: Mild                   | 10.5 (1.3 to 33.1)                           | 4.2 (0.1 to 21.1)                          | 9.1 (1.1 to 29.2)                        |  |
| Swelling: Moderate               | 0 (0.0 to 17.6)                              | 4.2 (0.1 to 21.1)                          | 22.7 (7.8 to 45.4)                       |  |
| Swelling: Severe                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Swelling: Grade 4                | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Pain at injection site: Any      | 68.4 (43.4 to 87.4)                          | 62.5 (40.6 to 81.2)                        | 50.0 (28.2 to 71.8)                      |  |
| Pain at injection site: Mild     | 52.6 (28.9 to 75.6)                          | 45.8 (25.6 to 67.2)                        | 22.7 (7.8 to 45.4)                       |  |
| Pain at injection site: Moderate | 15.8 (3.4 to 39.6)                           | 16.7 (4.7 to 37.4)                         | 27.3 (10.7 to 50.2)                      |  |
| Pain at injection site: Severe   | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 12$ to $<18$ Years

|                 |                                                                                                                                                                      |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 12$ to $<18$ Years <sup>[53][54]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild (greater than  $>$  2.0 to 5.0 cm), moderate ( $>5.0$  to 10.0 cm), severe ( $>10.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

#### End point timeframe:

Day 1 to Day 7 after Vaccination 2

#### Notes:

[53] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 12 to $<18$ Years with Immunomodulatory Therapy | 12 to $<18$ Years with Solid Organ Transplant | 12 to $<18$ Years with Stem Cell Transplant |  |
|----------------------------------|-------------------------------------------------|-----------------------------------------------|---------------------------------------------|--|
| Subject group type               | Reporting group                                 | Reporting group                               | Reporting group                             |  |
| Number of subjects analysed      | 7                                               | 1                                             | 6                                           |  |
| Units: Percentage of subjects    |                                                 |                                               |                                             |  |
| number (confidence interval 95%) |                                                 |                                               |                                             |  |
| Redness: Any                     | 14.3 (0.4 to 57.9)                              | 0 (0.0 to 97.5)                               | 16.7 (0.4 to 64.1)                          |  |
| Redness: Mild                    | 14.3 (0.4 to 57.9)                              | 0 (0.0 to 97.5)                               | 16.7 (0.4 to 64.1)                          |  |
| Redness: Moderate                | 0 (0.0 to 41.0)                                 | 0 (0.0 to 97.5)                               | 0 (0.0 to 45.9)                             |  |
| Redness: Severe                  | 0 (0.0 to 41.0)                                 | 0 (0.0 to 97.5)                               | 0 (0.0 to 45.9)                             |  |
| Redness: Grade 4                 | 0 (0.0 to 41.0)                                 | 0 (0.0 to 97.5)                               | 0 (0.0 to 45.9)                             |  |
| Swelling: Any                    | 28.6 (3.7 to 71.0)                              | 0 (0.0 to 97.5)                               | 16.7 (0.4 to 64.1)                          |  |
| Swelling: Mild                   | 0 (0.0 to 41.0)                                 | 0 (0.0 to 97.5)                               | 16.7 (0.4 to 64.1)                          |  |

|                                  |                     |                      |                     |  |
|----------------------------------|---------------------|----------------------|---------------------|--|
| Swelling: Moderate               | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)     |  |
| Swelling: Severe                 | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)     |  |
| Swelling: Grade 4                | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)     |  |
| Pain at injection site: Any      | 85.7 (42.1 to 99.6) | 100.0 (2.5 to 100.0) | 57.1 (18.4 to 90.1) |  |
| Pain at injection site: Mild     | 57.1 (18.4 to 90.1) | 100.0 (2.5 to 100.0) | 28.6 (3.7 to 71.0)  |  |
| Pain at injection site: Moderate | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 28.6 (3.7 to 71.0)  |  |
| Pain at injection site: Severe   | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)     |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 41.0)     |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 18$ Years

|                 |                                                                                                                                                             |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 18$ Years <sup>[55][56]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild (greater than [ $>$ ] 2.0 to 5.0 cm), moderate ( $>5.0$  to 10.0 cm), severe ( $>10.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[55] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | $\geq 18$ Years with Immunomodulatory Therapy | $\geq 18$ Years with Non-Small Cell Lung Cancer | $\geq 18$ Years with Haemodialysis |  |
|----------------------------------|-----------------------------------------------|-------------------------------------------------|------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                                 | Reporting group                    |  |
| Number of subjects analysed      | 5                                             | 1                                               | 1                                  |  |
| Units: Percentage of subjects    |                                               |                                                 |                                    |  |
| number (confidence interval 95%) |                                               |                                                 |                                    |  |
| Redness: Any                     | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Redness: Mild                    | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |

|                                  |                     |                      |                 |
|----------------------------------|---------------------|----------------------|-----------------|
| Redness: Moderate                | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Redness: Severe                  | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Redness: Grade 4                 | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Swelling: Any                    | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Swelling: Mild                   | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Swelling: Moderate               | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Swelling: Severe                 | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Swelling: Grade 4                | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Pain at injection site: Any      | 80.0 (28.4 to 99.5) | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5) |
| Pain at injection site: Mild     | 60.0 (14.7 to 94.7) | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5) |
| Pain at injection site: Moderate | 20.0 (0.5 to 71.6)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Pain at injection site: Severe   | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Pain at injection site: Grade 4  | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 2$ to $< 5$ Years

|                 |                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 2$ to $< 5$ Years <sup>[57]</sup> <sup>[58]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild ( $> 0.5$  to  $2.0$  cm), moderate ( $> 2.0$  to  $7.0$  cm), severe ( $> 7.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[57] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 2 to <5 Years with Immunomodulatory Therapy | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant |  |
|----------------------------------|---------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                             | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 9                                           | 15                                         | 11                                       |  |
| Units: Percentage of subjects    |                                             |                                            |                                          |  |
| number (confidence interval 95%) |                                             |                                            |                                          |  |
| Redness: Any                     | 11.1 (0.3 to 48.2)                          | 13.3 (1.7 to 40.5)                         | 0 (0.0 to 28.5)                          |  |
| Redness: Mild                    | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 28.5)                          |  |
| Redness: Moderate                | 11.1 (0.3 to 48.2)                          | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 28.5)                          |  |
| Redness: Severe                  | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Redness: Grade 4                 | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Swelling: Any                    | 11.1 (0.3 to 48.2)                          | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 28.5)                          |  |
| Swelling: Mild                   | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Swelling: Moderate               | 11.1 (0.3 to 48.2)                          | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 28.5)                          |  |
| Swelling: Severe                 | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Swelling: Grade 4                | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Pain at injection site: Any      | 22.2 (2.8 to 60.0)                          | 13.3 (1.7 to 40.5)                         | 9.1 (0.2 to 41.3)                        |  |
| Pain at injection site: Mild     | 0 (0.0 to 33.6)                             | 13.3 (1.7 to 40.5)                         | 9.1 (0.2 to 41.3)                        |  |
| Pain at injection site: Moderate | 22.2 (2.8 to 60.0)                          | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Pain at injection site: Severe   | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 28.5)                          |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged ≥5 to <12 Years

|                 |                                                                                                                                                             |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged ≥5 to <12 Years <sup>[59][60]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild (>0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

### End point timeframe:

Day 1 to Day 7 after Vaccination 3



Notes:

[59] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 17                                           | 23                                         | 21                                       |  |
| Units: Percentage of subjects    |                                              |                                            |                                          |  |
| number (confidence interval 95%) |                                              |                                            |                                          |  |
| Redness: Any                     | 29.4 (10.3 to 56.0)                          | 4.3 (0.1 to 21.9)                          | 14.3 (3.0 to 36.3)                       |  |
| Redness: Mild                    | 17.6 (3.8 to 43.4)                           | 0 (0.0 to 14.8)                            | 9.5 (1.2 to 30.4)                        |  |
| Redness: Moderate                | 11.8 (1.5 to 36.4)                           | 4.3 (0.1 to 21.9)                          | 4.8 (0.1 to 23.8)                        |  |
| Redness: Severe                  | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Redness: Grade 4                 | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Swelling: Any                    | 17.6 (3.8 to 43.4)                           | 8.7 (1.1 to 28.0)                          | 14.3 (3.0 to 36.3)                       |  |
| Swelling: Mild                   | 5.9 (0.1 to 28.7)                            | 0 (0.0 to 14.8)                            | 9.5 (1.2 to 30.4)                        |  |
| Swelling: Moderate               | 11.8 (1.5 to 36.4)                           | 8.7 (1.1 to 28.0)                          | 4.8 (0.1 to 23.8)                        |  |
| Swelling: Severe                 | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Swelling: Grade 4                | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Pain at injection site: Any      | 70.6 (44.0 to 89.7)                          | 26.1 (10.2 to 48.4)                        | 57.1 (34.0 to 78.2)                      |  |
| Pain at injection site: Mild     | 35.3 (14.2 to 61.7)                          | 21.7 (7.5 to 43.7)                         | 42.9 (21.8 to 66.0)                      |  |
| Pain at injection site: Moderate | 35.3 (14.2 to 61.7)                          | 4.3 (0.1 to 21.9)                          | 14.3 (3.0 to 36.3)                       |  |
| Pain at injection site: Severe   | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 12$ to $<18$ Years

|                 |                                                                                                                                                                      |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 12$ to $<18$ Years <sup>[61][62]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild ( $>2.0$  to  $5.0$  cm), moderate ( $>5.0$  to  $10.0$  cm), severe ( $>10.0$  cm) and Grade 4

(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate(interfered with activity), severe(prevented daily activity) and Grade 4(ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population= all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint. 'n'= subjects evaluable for specified rows.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[61] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                            | 12 to <18<br>Years with<br>Immunomodulatory Therapy | 12 to <18<br>Years with<br>Solid Organ Transplant | 12 to <18<br>Years with<br>Stem Cell Transplant |  |
|---------------------------------------------|-----------------------------------------------------|---------------------------------------------------|-------------------------------------------------|--|
| Subject group type                          | Reporting group                                     | Reporting group                                   | Reporting group                                 |  |
| Number of subjects analysed                 | 7                                                   | 1                                                 | 7                                               |  |
| Units: Percentage of subjects               |                                                     |                                                   |                                                 |  |
| number (confidence interval 95%)            |                                                     |                                                   |                                                 |  |
| Redness: Any (n= 7,1,6)                     | 14.3 (0.4 to 57.9)                                  | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Redness: Mild (n= 7,1,6)                    | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Redness: Moderate (n= 7,1,6)                | 14.3 (0.4 to 57.9)                                  | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Redness: Severe (n= 7,1,6)                  | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Redness: Grade 4 (n= 7,1,6)                 | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Swelling: Any (n= 7,1,6)                    | 28.6 (3.7 to 71.0)                                  | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Swelling: Mild (n= 7,1,6)                   | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Swelling: Moderate (n= 7,1,6)               | 28.6 (3.7 to 71.0)                                  | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Swelling: Severe (n= 7,1,6)                 | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Swelling: Grade 4 (n= 7,1,6)                | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Pain at injection site: Any (n= 7,1,7)      | 71.4 (29.0 to 96.3)                                 | 100.0 (2.5 to 100.0)                              | 66.7 (22.3 to 95.7)                             |  |
| Pain at injection site: Mild (n= 7,1,7)     | 28.6 (3.7 to 71.0)                                  | 100.0 (2.5 to 100.0)                              | 33.3 (4.3 to 77.7)                              |  |
| Pain at injection site: Moderate (n= 7,1,7) | 42.9 (9.9 to 81.6)                                  | 0 (0.0 to 97.5)                                   | 33.3 (4.3 to 77.7)                              |  |
| Pain at injection site: Severe (n= 7,1,7)   | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |
| Pain at injection site: Grade 4 (n= 7,1,7)  | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                   | 0 (0.0 to 45.9)                                 |  |

## Statistical analyses

No statistical analyses for this end point

**Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=18 Years**

|                 |                                                                                                                                                                    |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=18 Years <sup>[63]</sup> <sup>[64]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (greater than [ > ] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[63] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | >=18 Years with Immunomodulatory Therapy | >=18 Years with Non-Small Cell Lung Cancer | >= 18 Years with Haemodialysis |  |
|----------------------------------|------------------------------------------|--------------------------------------------|--------------------------------|--|
| Subject group type               | Reporting group                          | Reporting group                            | Reporting group                |  |
| Number of subjects analysed      | 4                                        | 0 <sup>[65]</sup>                          | 1                              |  |
| Units: Percentage of subjects    |                                          |                                            |                                |  |
| number (confidence interval 95%) |                                          |                                            |                                |  |
| Redness: Any                     | 25.0 (0.6 to 80.6)                       | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Redness: Mild                    | 25.0 (0.6 to 80.6)                       | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Redness: Moderate                | 0 (0.0 to 60.2)                          | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Redness: Severe                  | 0 (0.0 to 60.2)                          | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Redness: Grade 4                 | 0 (0.0 to 60.2)                          | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Swelling: Any                    | 25.0 (0.6 to 80.6)                       | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Swelling: Mild                   | 25.0 (0.6 to 80.6)                       | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Swelling: Moderate               | 0 (0.0 to 60.2)                          | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Swelling: Severe                 | 0 (0.0 to 60.2)                          | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Swelling: Grade 4                | 0 (0.0 to 60.2)                          | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Pain at injection site: Any      | 75.0 (19.4 to 99.4)                      | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Pain at injection site: Mild     | 50.0 (6.8 to 93.2)                       | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Pain at injection site: Moderate | 25.0 (0.6 to 80.6)                       | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Pain at injection site: Severe   | 0 (0.0 to 60.2)                          | ( to )                                     | 0 (0.0 to 97.5)                |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 60.2)                          | ( to )                                     | 0 (0.0 to 97.5)                |  |

Notes:

[65] - No subjects were evaluable for this endpoint from this arm.

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 2$ to $< 5$ Years

|                 |                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 2$ to $< 5$ Years <sup>[66]</sup> <sup>[67]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild ( $>0.5$  to 2.0 cm), moderate ( $>2.0$  to 7.0 cm), severe ( $>7.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[66] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 2 to $< 5$ Years with Immunomodulatory Therapy | 2 to $< 5$ Years with Solid Organ Transplant | 2 to $< 5$ Years with Stem Cell Transplant |  |
|----------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type               | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed      | 7                                              | 6                                            | 6                                          |  |
| Units: Percentage of subjects    |                                                |                                              |                                            |  |
| number (confidence interval 95%) |                                                |                                              |                                            |  |
| Redness: Any                     | 28.6 (3.7 to 71.0)                             | 16.7 (0.4 to 64.1)                           | 0 (0.0 to 45.9)                            |  |
| Redness: Mild                    | 14.3 (0.4 to 57.9)                             | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Redness: Moderate                | 14.3 (0.4 to 57.9)                             | 16.7 (0.4 to 64.1)                           | 0 (0.0 to 45.9)                            |  |
| Redness: Severe                  | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Redness: Grade 4                 | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Swelling: Any                    | 14.3 (0.4 to 57.9)                             | 0 (0.0 to 45.9)                              | 16.7 (0.4 to 64.1)                         |  |

|                                  |                    |                 |                    |  |
|----------------------------------|--------------------|-----------------|--------------------|--|
| Swelling: Mild                   | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9) | 16.7 (0.4 to 64.1) |  |
| Swelling: Moderate               | 14.3 (0.4 to 57.9) | 0 (0.0 to 45.9) | 0 (0.0 to 45.9)    |  |
| Swelling: Severe                 | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9) | 0 (0.0 to 45.9)    |  |
| Swelling: Grade 4                | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9) | 0 (0.0 to 45.9)    |  |
| Pain at injection site: Any      | 28.6 (3.7 to 71.0) | 0 (0.0 to 45.9) | 16.7 (0.4 to 64.1) |  |
| Pain at injection site: Mild     | 28.6 (3.7 to 71.0) | 0 (0.0 to 45.9) | 16.7 (0.4 to 64.1) |  |
| Pain at injection site: Moderate | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9) | 0 (0.0 to 45.9)    |  |
| Pain at injection site: Severe   | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9) | 0 (0.0 to 45.9)    |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9) | 0 (0.0 to 45.9)    |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 5$ to $<12$ Years

|                 |                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 5$ to $<12$ Years <sup>[68]</sup> <sup>[69]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild ( $>0.5$  to 2.0 cm), moderate ( $>2.0$  to 7.0 cm), severe ( $>7.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[68] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to $<12$ Years with Immunomodulatory Therapy | 5 to $<12$ Years with Solid Organ Transplant | 5 to $<12$ Years with Stem Cell Transplant |  |
|----------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type               | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed      | 12                                             | 19                                           | 15                                         |  |
| Units: Percentage of subjects    |                                                |                                              |                                            |  |
| number (confidence interval 95%) |                                                |                                              |                                            |  |

|                                  |                     |                     |                     |  |
|----------------------------------|---------------------|---------------------|---------------------|--|
| Redness: Any                     | 8.3 (0.2 to 38.5)   | 5.3 (0.1 to 26.0)   | 20.0 (4.3 to 48.1)  |  |
| Redness: Mild                    | 8.3 (0.2 to 38.5)   | 5.3 (0.1 to 26.0)   | 6.7 (0.2 to 31.9)   |  |
| Redness: Moderate                | 0 (0.0 to 26.5)     | 0 (0.0 to 17.6)     | 13.3 (1.7 to 40.5)  |  |
| Redness: Severe                  | 0 (0.0 to 26.5)     | 0 (0.0 to 17.6)     | 0 (0.0 to 21.8)     |  |
| Redness: Grade 4                 | 0 (0.0 to 26.5)     | 0 (0.0 to 17.6)     | 0 (0.0 to 21.8)     |  |
| Swelling: Any                    | 16.7 (2.1 to 48.4)  | 5.3 (0.1 to 26.0)   | 20.0 (4.3 to 48.1)  |  |
| Swelling: Mild                   | 8.3 (0.2 to 38.5)   | 5.3 (0.1 to 26.0)   | 13.3 (1.7 to 40.5)  |  |
| Swelling: Moderate               | 8.3 (0.2 to 38.5)   | 0 (0.0 to 17.6)     | 6.7 (0.2 to 31.9)   |  |
| Swelling: Severe                 | 0 (0.0 to 26.5)     | 0 (0.0 to 17.6)     | 0 (0.0 to 21.8)     |  |
| Swelling: Grade 4                | 0 (0.0 to 26.5)     | 0 (0.0 to 17.6)     | 0 (0.0 to 21.8)     |  |
| Pain at injection site: Any      | 91.7 (61.5 to 99.8) | 42.1 (20.3 to 66.5) | 40.0 (16.3 to 67.7) |  |
| Pain at injection site: Mild     | 41.7 (15.2 to 72.3) | 31.6 (12.6 to 56.6) | 26.7 (7.8 to 55.1)  |  |
| Pain at injection site: Moderate | 50.0 (21.1 to 78.9) | 10.5 (1.3 to 33.1)  | 13.3 (1.7 to 40.5)  |  |
| Pain at injection site: Severe   | 0 (0.0 to 26.5)     | 0 (0.0 to 17.6)     | 0 (0.0 to 21.8)     |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 26.5)     | 0 (0.0 to 17.6)     | 0 (0.0 to 21.8)     |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 12$ to $< 18$ Years

|                 |                                                                                                                                                                       |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 12$ to $< 18$ Years <sup>[70][71]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild (greater than  $>$ ] 2.0 to 5.0 cm), moderate ( $> 5.0$  to 10.0 cm), severe ( $> 10.0$  cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[70] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 12 to <18<br>Years with<br>Immunomodulatory Therapy | 12 to <18<br>Years with<br>Solid Organ<br>Transplant | 12 to <18<br>Years with<br>Stem Cell<br>Transplant |  |
|----------------------------------|-----------------------------------------------------|------------------------------------------------------|----------------------------------------------------|--|
| Subject group type               | Reporting group                                     | Reporting group                                      | Reporting group                                    |  |
| Number of subjects analysed      | 4                                                   | 1                                                    | 3                                                  |  |
| Units: Percentage of subjects    |                                                     |                                                      |                                                    |  |
| number (confidence interval 95%) |                                                     |                                                      |                                                    |  |
| Redness: Any                     | 75.0 (19.4 to 99.4)                                 | 0 (0.0 to 97.5)                                      | 66.7 (9.4 to 99.2)                                 |  |
| Redness: Mild                    | 75.0 (19.4 to 99.4)                                 | 0 (0.0 to 97.5)                                      | 66.7 (9.4 to 99.2)                                 |  |
| Redness: Moderate                | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 70.8)                                    |  |
| Redness: Severe                  | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 70.8)                                    |  |
| Redness: Grade 4                 | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 70.8)                                    |  |
| Swelling: Any                    | 50.0 (6.8 to 93.2)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Swelling: Mild                   | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Swelling: Moderate               | 50.0 (6.8 to 93.2)                                  | 0 (0.0 to 97.5)                                      | 0 (0.0 to 70.8)                                    |  |
| Swelling: Severe                 | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 70.8)                                    |  |
| Swelling: Grade 4                | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 70.8)                                    |  |
| Pain at injection site: Any      | 75.0 (19.4 to 99.4)                                 | 100.0 (2.5 to 100.0)                                 | 33.3 (0.8 to 90.6)                                 |  |
| Pain at injection site: Mild     | 25.0 (19.4 to 99.4)                                 | 100.0 (2.5 to 100.0)                                 | 0 (0.0 to 70.8)                                    |  |
| Pain at injection site: Moderate | 50.0 (0.6 to 80.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Pain at injection site: Severe   | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 70.8)                                    |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 70.8)                                    |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=18 Years

|                 |                                                                                                                                                        |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=18 Years <sup>[72][73]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu = 0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[72] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[73] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | >=18 Years with Immunomodulatory Therapy | >=18 Years with Non-Small Cell Lung Cancer | >= 18 Years with Haemodialysis |  |
|----------------------------------|------------------------------------------|--------------------------------------------|--------------------------------|--|
| Subject group type               | Reporting group                          | Reporting group                            | Reporting group                |  |
| Number of subjects analysed      | 3                                        | 1                                          | 0 <sup>[74]</sup>              |  |
| Units: Percentage of subjects    |                                          |                                            |                                |  |
| number (confidence interval 95%) |                                          |                                            |                                |  |
| Redness: Any                     | 33.3 (0.8 to 90.6)                       | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Redness: Mild                    | 33.3 (0.8 to 90.6)                       | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Redness: Moderate                | 0 (0.0 to 70.8)                          | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Redness: Severe                  | 0 (0.0 to 70.8)                          | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Redness: Grade 4                 | 0 (0.0 to 70.8)                          | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Swelling: Any                    | 33.3 (0.8 to 90.6)                       | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Swelling: Mild                   | 33.3 (0.8 to 90.6)                       | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Swelling: Moderate               | 0 (0.0 to 70.8)                          | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Swelling: Severe                 | 0 (0.0 to 70.8)                          | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Swelling: Grade 4                | 0 (0.0 to 70.8)                          | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Pain at injection site: Any      | 66.7 (9.4 to 99.2)                       | 100.0 (2.5 to 100.0)                       | ( to )                         |  |
| Pain at injection site: Mild     | 33.3 (0.8 to 90.6)                       | 100.0 (2.5 to 100.0)                       | ( to )                         |  |
| Pain at injection site: Moderate | 33.3 (0.8 to 90.6)                       | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Pain at injection site: Severe   | 0 (0.0 to 70.8)                          | 0 (0.0 to 97.5)                            | ( to )                         |  |
| Pain at injection site: Grade 4  | 0 (0.0 to 70.8)                          | 0 (0.0 to 97.5)                            | ( to )                         |  |

Notes:

[74] - No subjects were evaluable for this endpoint from this arm.

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=2 to <5 Years

|                 |                                                                                                                                                                         |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=2 to <5 Years <sup>[75]</sup> <sup>[76]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after vaccination. Fever:oral temperature >=) 38.0 degree C (C);categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 degree C.Fatigue, headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity), moderate (some interference with activity),severe (prevented daily routine activity).Vomiting: mild: 1-2 times in 24 hours,moderate: >2



times in 24 hours, severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[75] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[76] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 2 to <5 Years with Immunomodulatory Therapy | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant |  |
|----------------------------------|---------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                             | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 9                                           | 15                                         | 13                                       |  |
| Units: Percentage of subjects    |                                             |                                            |                                          |  |
| number (confidence interval 95%) |                                             |                                            |                                          |  |
| Fever: Any                       | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 15.4 (1.9 to 45.4)                       |  |
| Fever: >=38.0 to 38.4 deg C      | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 7.7 (0.2 to 36.0)                        |  |
| Fever: >38.4 to 38.9 deg C       | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Fever: >38.9 to 40.0 deg C       | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 7.7 (0.2 to 36.0)                        |  |
| Fever: >40.0 deg C               | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Fatigue: Any                     | 22.2 (2.8 to 60.0)                          | 6.7 (0.2 to 31.9)                          | 7.7 (0.2 to 36.0)                        |  |
| Fatigue: Mild                    | 11.1 (0.3 to 48.2)                          | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Fatigue: Moderate                | 11.1 (0.3 to 48.2)                          | 6.7 (0.2 to 31.9)                          | 7.7 (0.2 to 36.0)                        |  |
| Fatigue: Severe                  | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Fatigue: Grade 4                 | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Headache: Any                    | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Headache: Mild                   | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Headache: Moderate               | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Headache: Severe                 | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Headache: Grade 4                | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Chills: Any                      | 11.1 (0.3 to 48.2)                          | 0 (0.0 to 21.8)                            | 7.7 (0.2 to 36.0)                        |  |
| Chills: Mild                     | 11.1 (0.3 to 48.2)                          | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Chills: Moderate                 | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 7.7 (0.2 to 36.0)                        |  |
| Chills: Severe                   | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Chills: Grade 4                  | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 24.7)                          |  |
| Vomiting: Any                    | 11.1 (0.3 to 48.2)                          | 0 (0.0 to 21.8)                            | 23.1 (5.0 to 53.8)                       |  |
| Vomiting: Mild                   | 11.1 (0.3 to 48.2)                          | 0 (0.0 to 21.8)                            | 7.7 (0.2 to 36.0)                        |  |

|                                       |                    |                    |                    |  |
|---------------------------------------|--------------------|--------------------|--------------------|--|
| Vomiting: Moderate                    | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 15.4 (1.9 to 45.4) |  |
| Vomiting: Severe                      | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| Vomiting: Grade 4                     | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| Diarrhea: Any                         | 0 (0.0 to 33.6)    | 20.0 (4.3 to 48.1) | 7.7 (0.2 to 36.0)  |  |
| Diarrhea: Mild                        | 0 (0.0 to 33.6)    | 20.0 (4.3 to 48.1) | 0 (0.0 to 24.7)    |  |
| Diarrhea: Moderate                    | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| Diarrhea: Severe                      | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 7.7 (0.2 to 36.0)  |  |
| Diarrhea: Grade 4                     | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened muscle pain: Any      | 11.1 (0.3 to 48.2) | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened muscle pain: Mild     | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened muscle pain: Moderate | 11.1 (0.3 to 48.2) | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened muscle pain: Severe   | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened joint pain: Any       | 11.1 (0.3 to 48.2) | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened joint pain: Mild      | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened joint pain: Moderate  | 11.1 (0.3 to 48.2) | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened joint pain: Severe    | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 24.7)    |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 5$ to $<12$ Years

|                 |                                                                                                                                                                     |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 5$ to $<12$ Years <sup>[77][78]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $>38.4$  to  $38.9$  C,  $>38.9$  to  $40.0$  C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[77] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[78] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 19                                           | 24                                         | 22                                       |  |
| Units: Percentage of subjects    |                                              |                                            |                                          |  |
| number (confidence interval 95%) |                                              |                                            |                                          |  |
| Fever: Any                       | 0 (0.0 to 17.6)                              | 4.2 (0.1 to 21.1)                          | 0 (0.0 to 15.4)                          |  |
| Fever: $\geq 38.0$ to 38.4 deg C | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Fever: $>38.4$ to 38.9 deg C     | 0 (0.0 to 17.6)                              | 4.2 (0.1 to 21.1)                          | 0 (0.0 to 15.4)                          |  |
| Fever: $>38.9$ to 40.0 deg C     | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Fever: $>40.0$ deg C             | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Fatigue: Any                     | 47.4 (24.4 to 71.1)                          | 37.5 (18.8 to 59.4)                        | 22.7 (7.8 to 45.4)                       |  |
| Fatigue: Mild                    | 31.6 (12.6 to 56.6)                          | 20.8 (7.1 to 42.2)                         | 13.6 (2.9 to 34.9)                       |  |
| Fatigue: Moderate                | 15.8 (3.4 to 39.6)                           | 16.7 (4.7 to 37.4)                         | 9.1 (1.1 to 29.2)                        |  |
| Fatigue: Severe                  | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Fatigue: Grade 4                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Headache: Any                    | 42.1 (20.3 to 66.5)                          | 12.5 (2.7 to 32.4)                         | 22.7 (7.8 to 45.4)                       |  |
| Headache: Mild                   | 31.6 (12.6 to 56.6)                          | 12.5 (2.7 to 32.4)                         | 9.1 (1.1 to 29.2)                        |  |
| Headache: Moderate               | 10.5 (1.3 to 33.1)                           | 0 (0.0 to 14.2)                            | 13.6 (2.9 to 34.9)                       |  |
| Headache: Severe                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Headache: Grade 4                | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Chills: Any                      | 5.3 (0.1 to 26.0)                            | 0 (0.0 to 14.2)                            | 4.5 (0.1 to 22.8)                        |  |
| Chills: Mild                     | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 4.5 (0.1 to 22.8)                        |  |
| Chills: Moderate                 | 5.3 (0.1 to 26.0)                            | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Chills: Severe                   | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Chills: Grade 4                  | 0 (0.0 to 17.6)                              | 4.2 (0.1 to 21.1)                          | 0 (0.0 to 15.4)                          |  |
| Vomiting: Any                    | 5.3 (0.1 to 26.0)                            | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Vomiting: Mild                   | 5.3 (0.1 to 26.0)                            | 4.2 (0.1 to 21.1)                          | 0 (0.0 to 15.4)                          |  |
| Vomiting: Moderate               | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Vomiting: Severe                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Vomiting: Grade 4                | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Diarrhea: Any                    | 10.5 (1.3 to 33.1)                           | 0 (0.0 to 14.2)                            | 4.5 (0.1 to 22.8)                        |  |
| Diarrhea: Mild                   | 10.5 (1.3 to 33.1)                           | 0 (0.0 to 14.2)                            | 4.5 (0.1 to 22.8)                        |  |
| Diarrhea: Moderate               | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Diarrhea: Severe                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Diarrhea: Grade 4                | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |

|                                       |                    |                   |                 |  |
|---------------------------------------|--------------------|-------------------|-----------------|--|
| New or worsened muscle pain: Any      | 5.3 (0.1 to 26.0)  | 4.2 (0.1 to 21.1) | 0 (0.0 to 15.4) |  |
| New or worsened muscle pain: Mild     | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)   | 0 (0.0 to 15.4) |  |
| New or worsened muscle pain: Moderate | 5.3 (0.1 to 26.0)  | 4.2 (0.1 to 21.1) | 0 (0.0 to 15.4) |  |
| New or worsened muscle pain: Severe   | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)   | 0 (0.0 to 15.4) |  |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)   | 0 (0.0 to 15.4) |  |
| New or worsened joint pain: Any       | 10.5 (1.3 to 33.1) | 0 (0.0 to 14.2)   | 0 (0.0 to 15.4) |  |
| New or worsened joint pain: Mild      | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)   | 0 (0.0 to 15.4) |  |
| New or worsened joint pain: Moderate  | 10.5 (1.3 to 33.1) | 0 (0.0 to 14.2)   | 0 (0.0 to 15.4) |  |
| New or worsened joint pain: Severe    | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)   | 0 (0.0 to 15.4) |  |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)   | 0 (0.0 to 15.4) |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 12$ to $<18$ Years

|                 |                                                                                                                                                                      |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 12$ to $<18$ Years <sup>[79][80]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $>38.4$  to  $38.9$  C,  $>38.9$  to  $40.0$  C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[79] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 12 to $<18$ Years with Immunomodulatory Therapy | 12 to $<18$ Years with Solid Organ Transplant | 12 to $<18$ Years with Stem Cell Transplant |  |
|----------------------------------|-------------------------------------------------|-----------------------------------------------|---------------------------------------------|--|
| Subject group type               | Reporting group                                 | Reporting group                               | Reporting group                             |  |
| Number of subjects analysed      | 7                                               | 1                                             | 7                                           |  |
| Units: Percentage of subjects    |                                                 |                                               |                                             |  |
| number (confidence interval 95%) |                                                 |                                               |                                             |  |

|                                        |                     |                 |                    |
|----------------------------------------|---------------------|-----------------|--------------------|
| Fever: Any                             | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Fever: $\geq 38.0$ deg C to 38.4 deg C | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Fever: $>38.4$ deg C to 38.9 deg C     | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Fever: $>38.9$ deg C to 40.0 deg C     | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Fever: $>40.0$ deg C                   | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Fatigue: Any                           | 57.1 (18.4 to 90.1) | 0 (0.0 to 97.5) | 42.9 (9.9 to 81.6) |
| Fatigue: Mild                          | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 14.3 (0.4 to 57.9) |
| Fatigue: Moderate                      | 57.1 (18.4 to 90.1) | 0 (0.0 to 97.5) | 28.6 (3.7 to 71.0) |
| Fatigue: Severe                        | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Fatigue: Grade 4                       | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Headache: Any                          | 42.9 (9.9 to 81.6)  | 0 (0.0 to 97.5) | 28.6 (3.7 to 71.0) |
| Headache: Mild                         | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 14.3 (0.4 to 57.9) |
| Headache: Moderate                     | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5) | 14.3 (0.4 to 57.9) |
| Headache: Severe                       | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Headache: Grade 4                      | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Chills: Any                            | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Chills: Mild                           | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Chills: Moderate                       | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Chills: Severe                         | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Chills: Grade 4                        | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Vomiting: Any                          | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Vomiting: Mild                         | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Vomiting: Moderate                     | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Vomiting: Severe                       | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Vomiting: Grade 4                      | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Diarrhea: Any                          | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 28.6 (3.7 to 71.0) |
| Diarrhea: Mild                         | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 28.6 (3.7 to 71.0) |
| Diarrhea: Moderate                     | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Diarrhea: Severe                       | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| Diarrhea: Grade 4                      | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| New or worsened muscle pain: Any       | 42.9 (9.9 to 81.6)  | 0 (0.0 to 97.5) | 42.9 (9.9 to 81.6) |
| New or worsened muscle pain: Mild      | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 42.9 (9.9 to 81.6) |
| New or worsened muscle pain: Moderate  | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| New or worsened muscle pain: Severe    | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| New or worsened muscle pain: Grade 4   | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| New or worsened joint pain: Any        | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| New or worsened joint pain: Mild       | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| New or worsened joint pain: Moderate   | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |
| New or worsened joint pain: Severe     | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5) | 0 (0.0 to 41.0)    |

|                                     |                 |                 |                 |  |
|-------------------------------------|-----------------|-----------------|-----------------|--|
| New or worsened joint pain: Grade 4 | 0 (0.0 to 41.0) | 0 (0.0 to 97.5) | 0 (0.0 to 41.0) |  |
|-------------------------------------|-----------------|-----------------|-----------------|--|

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 18$ Years

|                 |                                                                                                                                                             |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged $\geq 18$ Years <sup>[81][82]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to 38.4 C,  $>38.4$  to 38.9 C,  $>38.9$  to 40.0 C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[81] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[82] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | $\geq 18$ Years with Immunomodulatory Therapy | $\geq 18$ Years with Non-Small Cell Lung Cancer | $\geq 18$ Years with Haemodialysis |  |
|----------------------------------|-----------------------------------------------|-------------------------------------------------|------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                                 | Reporting group                    |  |
| Number of subjects analysed      | 5                                             | 1                                               | 1                                  |  |
| Units: Percentage of subjects    |                                               |                                                 |                                    |  |
| number (confidence interval 95%) |                                               |                                                 |                                    |  |
| Fever: Any                       | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fever: $\geq 38$ to 38.4 deg C   | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fever: $>38.4$ to 38.9 deg C     | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fever: $>38.9$ to 40.0 deg C     | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fever: $>40.0$ deg C             | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fatigue: Any                     | 60.0 (14.7 to 94.7)                           | 100.0 (2.5 to 100.0)                            | 100.0 (2.5 to 100.0)               |  |
| Fatigue: Mild                    | 40.0 (5.3 to 85.3)                            | 100.0 (2.5 to 100.0)                            | 0 (0.0 to 97.5)                    |  |
| Fatigue: Moderate                | 20.0 (0.5 to 71.6)                            | 0 (0.0 to 97.5)                                 | 100.0 (2.5 to 100.0)               |  |

|                                       |                    |                      |                      |
|---------------------------------------|--------------------|----------------------|----------------------|
| Fatigue: Severe                       | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Fatigue: Grade 4                      | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Headache: Any                         | 40.0 (5.3 to 85.3) | 0 (0.0 to 97.5)      | 100.0 (2.5 to 100.0) |
| Headache: Mild                        | 20.0 (0.5 to 71.6) | 0 (0.0 to 97.5)      | 100.0 (2.5 to 100.0) |
| Headache: Moderate                    | 20.0 (0.5 to 71.6) | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Headache: Severe                      | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Headache: Grade 4                     | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Chills: Any                           | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Chills: Mild                          | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Chills: Moderate                      | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Chills: Severe                        | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Chills: Grade 4                       | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Vomiting: Any                         | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Vomiting: Mild                        | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Vomiting: Moderate                    | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Vomiting: Severe                      | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Vomiting: Grade 4                     | 0 (0.0 to 85.3)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Diarrhea: Any                         | 40.0 (5.3 to 85.3) | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5)      |
| Diarrhea: Mild                        | 40.0 (5.3 to 52.2) | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Diarrhea: Moderate                    | 0 (0.0 to 52.2)    | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5)      |
| Diarrhea: Severe                      | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| Diarrhea: Grade 4                     | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| New or worsened muscle pain: Any      | 20.0 (0.5 to 71.6) | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5)      |
| New or worsened muscle pain: Mild     | 0 (0.0 to 52.2)    | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5)      |
| New or worsened muscle pain: Moderate | 20.0 (0.5 to 71.6) | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| New or worsened muscle pain: Severe   | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| New or worsened joint pain: Any       | 20.0 (0.5 to 71.6) | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| New or worsened joint pain: Mild      | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| New or worsened joint pain: Moderate  | 20.0 (0.5 to 71.6) | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| New or worsened joint pain: Severe    | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 52.2)    | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5)      |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 2$ to $< 5$ Years

|                 |                                                                                                                                                                     |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 2$ to $< 5$ Years <sup>[83][84]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|

# End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $>38.4$  to  $38.9$  C,  $>38.9$  to  $40.0$  C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

End point type Primary

## End point timeframe:

Day 1 to Day 7 after Vaccination 2

## Notes:

[83] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[84] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | 2 to <5 Years with Immunomodulatory Therapy | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant |  |
|------------------------------------------|---------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type                       | Reporting group                             | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed              | 9                                           | 15                                         | 10                                       |  |
| Units: Percentage of subjects            |                                             |                                            |                                          |  |
| number (confidence interval 95%)         |                                             |                                            |                                          |  |
| Fever: Any                               | 11.1 (0.3 to 48.2)                          | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Fever: $\geq 38.0$ deg C to $38.4$ deg C | 11.1 (0.3 to 48.2)                          | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Fever: $>38.4$ deg C to $38.9$ deg C     | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Fever: $>38.9$ deg C to $40.0$ deg C     | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Fever: $>40.0$ deg C                     | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Fatigue: Any                             | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 10.0 (0.3 to 44.5)                       |  |
| Fatigue: Mild                            | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 10.0 (0.3 to 44.5)                       |  |
| Fatigue: Moderate                        | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Fatigue: Severe                          | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Fatigue: Grade 4                         | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Headache: Any                            | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 30.8)                          |  |
| Headache: Mild                           | 0 (0.0 to 33.6)                             | 6.7 (0.2 to 31.9)                          | 0 (0.0 to 30.8)                          |  |
| Headache: Moderate                       | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Headache: Severe                         | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Headache: Grade 4                        | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Chills: Any                              | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Chills: Mild                             | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Chills: Moderate                         | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Chills: Severe                           | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |
| Chills: Grade 4                          | 0 (0.0 to 33.6)                             | 0 (0.0 to 21.8)                            | 0 (0.0 to 30.8)                          |  |



|                                       |                    |                    |                    |  |
|---------------------------------------|--------------------|--------------------|--------------------|--|
| Vomiting: Any                         | 0 (0.0 to 33.6)    | 13.3 (1.7 to 40.5) | 10.0 (0.3 to 44.5) |  |
| Vomiting: Mild                        | 0 (0.0 to 33.6)    | 13.3 (1.7 to 40.5) | 0 (0.0 to 30.8)    |  |
| Vomiting: Moderate                    | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 10.0 (0.3 to 44.5) |  |
| Vomiting: Severe                      | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| Vomiting: Grade 4                     | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| Diarrhea: Any                         | 11.1 (0.3 to 48.2) | 6.7 (0.2 to 31.9)  | 10.0 (0.3 to 44.5) |  |
| Diarrhea: Mild                        | 11.1 (0.3 to 48.2) | 6.7 (0.2 to 31.9)  | 10.0 (0.3 to 44.5) |  |
| Diarrhea: Moderate                    | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| Diarrhea: Severe                      | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| Diarrhea: Grade 4                     | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| New or worsened muscle pain: Any      | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| New or worsened muscle pain: Mild     | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| New or worsened muscle pain: Moderate | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| New or worsened muscle pain: Severe   | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| New or worsened joint pain: Any       | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| New or worsened joint pain: Mild      | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 30.8)    |  |
| New or worsened joint pain: Moderate  | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 28.5)    |  |
| New or worsened joint pain: Severe    | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 28.5)    |  |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 33.6)    | 0 (0.0 to 21.8)    | 0 (0.0 to 28.5)    |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 5$ to $<12$ Years

|                 |                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 5$ to $<12$ Years <sup>[85]</sup> <sup>[86]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $>38.4$  to  $38.9$  C,  $>38.9$  to  $40.0$  C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[85] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[86] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                  | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|-----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type                | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed       | 19                                           | 24                                         | 22                                       |  |
| Units: Percentage of subjects     |                                              |                                            |                                          |  |
| number (confidence interval 95%)  |                                              |                                            |                                          |  |
| Fever: Any                        | 5.3 (0.1 to 26.0)                            | 0 (0.0 to 14.2)                            | 4.5 (0.1 to 22.8)                        |  |
| Fever: >=38.0 deg C to 38.4 deg C | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Fever: >38.4 deg C to 38.9 deg C  | 5.3 (0.1 to 26.0)                            | 0 (0.0 to 14.2)                            | 4.5 (0.1 to 22.8)                        |  |
| Fever: >38.9 deg C to 40.0 deg C  | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Fever: >40.0 deg C                | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Fatigue: Any                      | 57.9 (33.5 to 79.7)                          | 37.5 (18.8 to 59.4)                        | 45.5 (24.4 to 67.8)                      |  |
| Fatigue: Mild                     | 26.3 (9.1 to 51.2)                           | 20.8 (7.1 to 42.2)                         | 13.6 (2.9 to 34.9)                       |  |
| Fatigue: Moderate                 | 31.6 (12.6 to 56.6)                          | 16.7 (4.7 to 37.4)                         | 31.8 (13.9 to 54.9)                      |  |
| Fatigue: Severe                   | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Fatigue: Grade 4                  | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Headache: Any                     | 36.8 (16.3 to 61.6)                          | 29.2 (12.6 to 51.1)                        | 18.2 (5.2 to 40.3)                       |  |
| Headache: Mild                    | 15.8 (3.4 to 39.6)                           | 12.5 (2.7 to 32.4)                         | 4.5 (0.1 to 22.8)                        |  |
| Headache: Moderate                | 21.1 (6.1 to 45.6)                           | 16.7 (4.7 to 37.4)                         | 13.6 (2.9 to 34.9)                       |  |
| Headache: Severe                  | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Headache: Grade 4                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Chills: Any                       | 21.1 (6.1 to 45.6)                           | 4.2 (0.1 to 21.1)                          | 4.5 (0.1 to 22.8)                        |  |
| Chills: Mild                      | 10.5 (1.3 to 33.1)                           | 4.2 (0.1 to 21.1)                          | 0 (0.0 to 15.4)                          |  |
| Chills: Moderate                  | 10.5 (1.3 to 33.1)                           | 0 (0.0 to 14.2)                            | 4.5 (0.1 to 22.8)                        |  |
| Chills: Severe                    | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Chills: Grade 4                   | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Vomiting: Any                     | 0 (0.0 to 17.6)                              | 12.5 (2.7 to 32.4)                         | 0 (0.0 to 15.4)                          |  |
| Vomiting: Mild                    | 0 (0.0 to 17.6)                              | 12.5 (2.7 to 32.4)                         | 0 (0.0 to 15.4)                          |  |
| Vomiting: Moderate                | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Vomiting: Severe                  | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Vomiting: Grade 4                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Diarrhea: Any                     | 5.3 (0.1 to 26.0)                            | 8.3 (1.0 to 27.0)                          | 4.5 (0.1 to 22.8)                        |  |
| Diarrhea: Mild                    | 5.3 (0.1 to 26.0)                            | 4.2 (0.1 to 21.1)                          | 0 (0.0 to 15.4)                          |  |
| Diarrhea: Moderate                | 0 (0.0 to 17.6)                              | 4.2 (0.1 to 21.1)                          | 4.5 (0.1 to 22.8)                        |  |
| Diarrhea: Severe                  | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |
| Diarrhea: Grade 4                 | 0 (0.0 to 17.6)                              | 0 (0.0 to 14.2)                            | 0 (0.0 to 15.4)                          |  |

|                                       |                    |                    |                   |  |
|---------------------------------------|--------------------|--------------------|-------------------|--|
| New or worsened muscle pain: Any      | 10.5 (1.3 to 33.1) | 12.5 (2.7 to 32.4) | 4.5 (0.1 to 22.8) |  |
| New or worsened muscle pain: Mild     | 0 (0.0 to 17.6)    | 4.2 (0.1 to 21.1)  | 0 (0.0 to 15.4)   |  |
| New or worsened muscle pain: Moderate | 10.5 (1.3 to 33.1) | 8.3 (1.0 to 27.0)  | 4.5 (0.1 to 22.8) |  |
| New or worsened muscle pain: Severe   | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)    | 0 (0.0 to 15.4)   |  |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)    | 0 (0.0 to 15.4)   |  |
| New or worsened joint pain: Any       | 15.8 (3.4 to 39.6) | 4.2 (0.1 to 21.1)  | 4.5 (0.1 to 22.8) |  |
| New or worsened joint pain: Mild      | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)    | 0 (0.0 to 15.4)   |  |
| New or worsened joint pain: Moderate  | 15.8 (3.4 to 39.6) | 4.2 (0.1 to 21.1)  | 4.5 (0.1 to 22.8) |  |
| New or worsened joint pain: Severe    | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)    | 0 (0.0 to 15.4)   |  |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 17.6)    | 0 (0.0 to 14.2)    | 0 (0.0 to 15.4)   |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 12$ to $<18$ Years

|                 |                                                                                                                                                                                  |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 12$ to $<18$ Years <sup>[87]</sup> <sup>[88]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $>38.4$  to  $38.9$  C,  $>38.9$  to  $40.0$  C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[87] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[88] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values              | 12 to $<18$ Years with Immunomodulatory Therapy | 12 to $<18$ Years with Solid Organ Transplant | 12 to $<18$ Years with Stem Cell Transplant |  |
|-------------------------------|-------------------------------------------------|-----------------------------------------------|---------------------------------------------|--|
| Subject group type            | Reporting group                                 | Reporting group                               | Reporting group                             |  |
| Number of subjects analysed   | 7                                               | 1                                             | 6                                           |  |
| Units: Percentage of subjects |                                                 |                                               |                                             |  |

| number (confidence interval 95%)      |                     |                      |                    |  |
|---------------------------------------|---------------------|----------------------|--------------------|--|
| Fever: Any                            | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Fever: >=38.0 deg C to 38.4 deg C     | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Fever: >38.4 deg C to 38.9 deg C      | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Fever: >38.9 deg C to 40.0 deg C      | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Fever: >40.0 deg C                    | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Fatigue: Any                          | 85.7 (42.1 to 99.6) | 0 (0.0 to 97.5)      | 33.3 (4.3 to 77.7) |  |
| Fatigue: Mild                         | 42.9 (9.9 to 81.6)  | 0 (0.0 to 97.5)      | 33.3 (4.3 to 77.7) |  |
| Fatigue: Moderate                     | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Fatigue: Severe                       | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Fatigue: Grade 4                      | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Headache: Any                         | 71.4 (29.0 to 96.3) | 0 (0.0 to 97.5)      | 16.7 (0.4 to 64.1) |  |
| Headache: Mild                        | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 16.7 (0.4 to 64.1) |  |
| Headache: Moderate                    | 42.9 (9.9 to 81.6)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Headache: Severe                      | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Headache: Grade 4                     | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Chills: Any                           | 42.9 (9.9 to 81.6)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Chills: Mild                          | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Chills: Moderate                      | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Chills: Severe                        | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Chills: Grade 4                       | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Vomiting: Any                         | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Vomiting: Mild                        | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Vomiting: Moderate                    | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Vomiting: Severe                      | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Vomiting: Grade 4                     | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Diarrhea: Any                         | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Diarrhea: Mild                        | 14.3 (0.4 to 57.9)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Diarrhea: Moderate                    | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Diarrhea: Severe                      | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| Diarrhea: Grade 4                     | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| New or worsened muscle pain: Any      | 42.9 (9.9 to 81.6)  | 100.0 (2.5 to 100.0) | 16.7 (0.4 to 64.1) |  |
| New or worsened muscle pain: Mild     | 0 (0.0 to 41.0)     | 100.0 (2.5 to 100.0) | 0 (0.0 to 45.9)    |  |
| New or worsened muscle pain: Moderate | 42.9 (9.9 to 81.6)  | 0 (0.0 to 97.5)      | 16.7 (0.4 to 64.1) |  |
| New or worsened muscle pain: Severe   | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 41.0)     | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |
| New or worsened joint pain: Any       | 28.6 (3.7 to 71.0)  | 0 (0.0 to 97.5)      | 0 (0.0 to 45.9)    |  |

|                                      |                    |                 |                 |  |
|--------------------------------------|--------------------|-----------------|-----------------|--|
| New or worsened joint pain: Mild     | 28.6 (3.7 to 71.0) | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened joint pain: Moderate | 0 (0.0 to 41.0)    | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened joint pain: Severe   | 0 (0.0 to 41.0)    | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened joint pain: Grade 4  | 0 (0.0 to 41.0)    | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 18$ Years

|                 |                                                                                                                                                             |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged $\geq 18$ Years <sup>[89][90]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to 38.4 C,  $>38.4$  to 38.9 C,  $>38.9$  to 40.0 C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[89] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | $\geq 18$ Years with Immunomodulatory Therapy | $\geq 18$ Years with Non-Small Cell Lung Cancer | $\geq 18$ Years with Haemodialysis |  |
|----------------------------------|-----------------------------------------------|-------------------------------------------------|------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                                 | Reporting group                    |  |
| Number of subjects analysed      | 5                                             | 1                                               | 1                                  |  |
| Units: Percentage of subjects    |                                               |                                                 |                                    |  |
| number (confidence interval 95%) |                                               |                                                 |                                    |  |
| Fever: Any                       | 20.0 (0.5 to 71.6)                            | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fever: $\geq 38.0$ to 38.4 deg C | 20.0 (0.5 to 71.6)                            | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fever: $>38.4$ to 38.9 deg C     | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fever: $>38.9$ to 40.0 deg C     | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fever: $>40.0$ deg C             | 0 (0.0 to 52.2)                               | 0 (0.0 to 97.5)                                 | 0 (0.0 to 97.5)                    |  |
| Fatigue: Any                     | 60.0 (14.7 to 94.7)                           | 100.0 (2.5 to 100.0)                            | 0 (0.0 to 97.5)                    |  |

|                                       |                     |                      |                 |
|---------------------------------------|---------------------|----------------------|-----------------|
| Fatigue: Mild                         | 0 (0.0 to 52.2)     | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5) |
| Fatigue: Moderate                     | 60.0 (14.7 to 94.7) | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Fatigue: Severe                       | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Fatigue: Grade 4                      | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Headache: Any                         | 60.0 (14.7 to 94.7) | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5) |
| Headache: Mild                        | 20.0 (0.5 to 71.6)  | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5) |
| Headache: Moderate                    | 40.0 (5.3 to 85.3)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Headache: Severe                      | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Headache: Grade 4                     | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Chills: Any                           | 40.0 (5.3 to 85.3)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Chills: Mild                          | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Chills: Moderate                      | 40.0 (5.3 to 85.3)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Chills: Severe                        | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Chills: Grade 4                       | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Vomiting: Any                         | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Vomiting: Mild                        | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Vomiting: Moderate                    | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Vomiting: Severe                      | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Vomiting: Grade 4                     | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Diarrhea: Any                         | 60.0 (14.7 to 94.7) | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5) |
| Diarrhea: Mild                        | 40.0 (5.3 to 85.3)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Diarrhea: Moderate                    | 20.0 (0.5 to 71.6)  | 100.0 (2.5 to 100.0) | 0 (0.0 to 97.5) |
| Diarrhea: Severe                      | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| Diarrhea: Grade 4                     | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Any      | 20.0 (0.5 to 71.6)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Mild     | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Moderate | 20.0 (0.5 to 71.6)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Severe   | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened joint pain: Any       | 20.0 (0.5 to 71.6)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened joint pain: Mild      | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened joint pain: Moderate  | 20.0 (0.5 to 71.6)  | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened joint pain: Severe    | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 52.2)     | 0 (0.0 to 97.5)      | 0 (0.0 to 97.5) |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity

## Within 7 Days After Vaccination 3 in Subjects Aged $\geq 2$ to $< 5$ Years

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 2$ to $< 5$ Years <sup>[91]</sup> <sup>[92]</sup> |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                 |
| Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature $\geq 38.0$ C; categorised as $\geq 38.0$ to $38.4$ C, $> 38.4$ to $38.9$ C, $> 38.9$ to $40.0$ C and $> 40.0$ C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate: $> 2$ times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint. |                                                                                                                                                                                 |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Primary                                                                                                                                                                         |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                 |
| Day 1 to Day 7 after Vaccination 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                 |

### Notes:

[91] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[92] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | 2 to $< 5$ Years with Immunomodulatory Therapy | 2 to $< 5$ Years with Solid Organ Transplant | 2 to $< 5$ Years with Stem Cell Transplant |  |
|------------------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type                       | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed              | 9                                              | 15                                           | 11                                         |  |
| Units: Percentage of subjects            |                                                |                                              |                                            |  |
| number (confidence interval 95%)         |                                                |                                              |                                            |  |
| Fever: Any                               | 0 (0.0 to 33.6)                                | 6.7 (0.2 to 31.9)                            | 0 (0.0 to 28.5)                            |  |
| Fever: $\geq 38.0$ deg C to $38.4$ deg C | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Fever: $> 38.4$ deg C to $38.9$ deg C    | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Fever: $> 38.9$ deg C to $40.0$ deg C    | 0 (0.0 to 33.6)                                | 6.7 (0.2 to 31.9)                            | 0 (0.0 to 28.5)                            |  |
| Fever: $> 40.0$ deg C                    | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Fatigue: Any                             | 11.1 (0.3 to 48.2)                             | 6.7 (0.2 to 31.9)                            | 0 (0.0 to 28.5)                            |  |
| Fatigue: Mild                            | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Fatigue: Moderate                        | 11.1 (0.3 to 48.2)                             | 6.7 (0.2 to 31.9)                            | 0 (0.0 to 28.5)                            |  |
| Fatigue: Severe                          | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Fatigue: Grade 4                         | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Headache: Any                            | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Headache: Mild                           | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Headache: Moderate                       | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Headache: Severe                         | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Headache: Grade 4                        | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Chills: Any                              | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Chills: Mild                             | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |
| Chills: Moderate                         | 0 (0.0 to 33.6)                                | 0 (0.0 to 21.8)                              | 0 (0.0 to 28.5)                            |  |

|                                       |                 |                   |                 |
|---------------------------------------|-----------------|-------------------|-----------------|
| Chills: Severe                        | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Chills: Grade 4                       | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Vomiting: Any                         | 0 (0.0 to 33.6) | 6.7 (0.2 to 31.9) | 0 (0.0 to 28.5) |
| Vomiting: Mild                        | 0 (0.0 to 33.6) | 6.7 (0.2 to 31.9) | 0 (0.0 to 28.5) |
| Vomiting: Moderate                    | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Vomiting: Severe                      | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Vomiting: Grade 4                     | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Diarrhea: Any                         | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Diarrhea: Mild                        | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Diarrhea: Moderate                    | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Diarrhea: Severe                      | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| Diarrhea: Grade 4                     | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| New or worsened muscle pain: Any      | 0 (0.0 to 33.6) | 6.7 (0.2 to 31.9) | 0 (0.0 to 28.5) |
| New or worsened muscle pain: Mild     | 0 (0.0 to 33.6) | 6.7 (0.2 to 31.9) | 0 (0.0 to 28.5) |
| New or worsened muscle pain: Moderate | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| New or worsened muscle pain: Severe   | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| New or worsened joint pain: Any       | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| New or worsened joint pain: Mild      | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| New or worsened joint pain: Moderate  | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| New or worsened joint pain: Severe    | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 33.6) | 0 (0.0 to 21.8)   | 0 (0.0 to 28.5) |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 5$ to $<12$ Years

|                 |                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 5$ to $<12$ Years <sup>[93]</sup> <sup>[94]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $>38.4$  to  $38.9$  C,  $>38.9$  to  $40.0$  C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 3



Notes:

[93] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[94] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                             | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type                           | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed                  | 17                                           | 23                                         | 21                                       |  |
| Units: Percentage of subjects                |                                              |                                            |                                          |  |
| number (confidence interval 95%)             |                                              |                                            |                                          |  |
| Fever: Any                                   | 17.6 (3.8 to 43.4)                           | 0 (0.0 to 14.8)                            | 19.0 (5.4 to 41.9)                       |  |
| Fever: $\geq 38.0$ to 38.4 deg C             | 11.8 (1.5 to 36.4)                           | 0 (0.0 to 14.8)                            | 14.3 (3.0 to 36.3)                       |  |
| Fever: $>38.4^{\circ}\text{C}$ to 38.9 deg C | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Fever: $>38.9^{\circ}\text{C}$ to 40.0 deg C | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 4.8 (0.1 to 23.8)                        |  |
| Fever: $>40.0$ deg C                         | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Fever: Unknown                               | 5.9 (0.1 to 28.7)                            | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Fatigue: Any                                 | 47.1 (23.0 to 72.2)                          | 34.8 (16.4 to 57.3)                        | 52.4 (47.2 to 74.3)                      |  |
| Fatigue: Mild                                | 35.3 (14.2 to 61.7)                          | 34.8 (16.4 to 57.3)                        | 23.8 (8.2 to 47.2)                       |  |
| Fatigue: Moderate                            | 11.8 (1.5 to 36.4)                           | 21.7 (7.5 to 43.7)                         | 28.6 (11.3 to 52.2)                      |  |
| Fatigue: Severe                              | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Fatigue: Grade 4                             | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Headache: Any                                | 35.3 (14.2 to 61.7)                          | 8.7 (1.1 to 28.0)                          | 28.6 (11.3 to 52.2)                      |  |
| Headache: Mild                               | 29.4 (10.3 to 56.0)                          | 4.3 (0.1 to 21.9)                          | 9.5 (1.2 to 30.4)                        |  |
| Headache: Moderate                           | 5.9 (0.1 to 28.7)                            | 0 (0.0 to 14.8)                            | 19.0 (5.4 to 41.9)                       |  |
| Headache: Severe                             | 0 (0.0 to 19.5)                              | 4.3 (0.1 to 21.9)                          | 0 (0.0 to 16.1)                          |  |
| Headache: Grade 4                            | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Chills: Any                                  | 17.6 (3.8 to 43.4)                           | 4.3 (0.1 to 21.9)                          | 14.3 (3.0 to 36.3)                       |  |
| Chills: Mild                                 | 5.9 (0.1 to 28.7)                            | 4.3 (0.1 to 21.9)                          | 4.8 (0.1 to 23.8)                        |  |
| Chills: Moderate                             | 11.8 (1.5 to 36.4)                           | 0 (0.0 to 14.8)                            | 9.5 (3.0 to 36.3)                        |  |
| Chills: Severe                               | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Chills: Grade 4                              | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Vomiting: Any                                | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 4.8 (0.1 to 23.8)                        |  |
| Vomiting: Mild                               | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |
| Vomiting: Moderate                           | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 4.8 (0.1 to 23.8)                        |  |
| Vomiting: Severe                             | 0 (0.0 to 19.5)                              | 0 (0.0 to 14.8)                            | 0 (0.0 to 16.1)                          |  |

|                                       |                     |                    |                   |
|---------------------------------------|---------------------|--------------------|-------------------|
| Vomiting: Grade 4                     | 0 (0.0 to 19.5)     | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| Diarrhea: Any                         | 11.8 (1.5 to 36.4)  | 0 (0.0 to 14.8)    | 4.8 (0.1 to 23.8) |
| Diarrhea: Mild                        | 11.8 (1.5 to 36.4)  | 0 (0.0 to 14.8)    | 4.8 (0.1 to 23.8) |
| Diarrhea: Moderate                    | 0 (0.0 to 19.5)     | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| Diarrhea: Severe                      | 0 (0.0 to 19.5)     | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| Diarrhea: Grade 4                     | 0 (0.0 to 19.5)     | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| New or worsened muscle pain: Any      | 29.4 (10.3 to 56.0) | 13.0 (2.8 to 33.6) | 4.8 (0.1 to 23.8) |
| New or worsened muscle pain: Mild     | 5.9 (0.1 to 28.7)   | 13.0 (2.8 to 33.6) | 4.8 (0.1 to 23.8) |
| New or worsened muscle pain: Moderate | 23.5 (6.8 to 49.9)  | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| New or worsened muscle pain: Severe   | 0 (0.0 to 19.5)     | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 19.5)     | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| New or worsened joint pain: Any       | 11.8 (1.5 to 36.4)  | 4.3 (2.8 to 33.6)  | 4.8 (0.1 to 23.8) |
| New or worsened joint pain: Mild      | 0 (0.0 to 19.5)     | 4.3 (2.8 to 33.6)  | 4.8 (0.1 to 23.8) |
| New or worsened joint pain: Moderate  | 11.8 (1.5 to 36.4)  | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| New or worsened joint pain: Severe    | 0 (0.0 to 19.5)     | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 19.5)     | 0 (0.0 to 14.8)    | 0 (0.0 to 16.1)   |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 12$ to $< 18$ Years

|                 |                                                                                                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 12$ to $< 18$ Years <sup>[95]</sup> <sup>[96]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $> 38.4$  to  $38.9$  C,  $> 38.9$  to  $40.0$  C and  $> 40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $> 2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[95] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[96] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                      | 12 to <18<br>Years with<br>Immunomodulatory Therapy | 12 to <18<br>Years with<br>Solid Organ<br>Transplant | 12 to <18<br>Years with<br>Stem Cell<br>Transplant |  |
|---------------------------------------|-----------------------------------------------------|------------------------------------------------------|----------------------------------------------------|--|
| Subject group type                    | Reporting group                                     | Reporting group                                      | Reporting group                                    |  |
| Number of subjects analysed           | 7                                                   | 1                                                    | 6                                                  |  |
| Units: Percentage of subjects         |                                                     |                                                      |                                                    |  |
| number (confidence interval 95%)      |                                                     |                                                      |                                                    |  |
| Fever: Any                            | 42.9 (9.9 to 81.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (4.3 to 77.7)                                 |  |
| Fever: >=38.0 to 38.4 deg C           | 28.6 (3.7 to 71.0)                                  | 0 (0.0 to 97.5)                                      | 33.3 (4.3 to 77.7)                                 |  |
| Fever: >38.4°C to 38.9 deg C          | 14.3 (0.4 to 57.9)                                  | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Fever: >38.9°C to 40.0 deg C          | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Fever: >40.0 deg C                    | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Fatigue: Any                          | 85.7 (42.1 to 99.6)                                 | 100.0 (2.5 to 100.0)                                 | 50.0 (11.8 to 88.2)                                |  |
| Fatigue: Mild                         | 14.3 (0.4 to 57.9)                                  | 100.0 (2.5 to 100.0)                                 | 50.0 (11.8 to 88.2)                                |  |
| Fatigue: Moderate                     | 71.4 (29.0 to 96.3)                                 | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Fatigue: Severe                       | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Fatigue: Grade 4                      | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Headache: Any                         | 85.7 (42.1 to 99.6)                                 | 100.0 (2.5 to 100.0)                                 | 66.7 (22.3 to 95.7)                                |  |
| Headache: Mild                        | 28.6 (3.7 to 71.0)                                  | 100.0 (2.5 to 100.0)                                 | 33.3 (4.3 to 77.7)                                 |  |
| Headache: Moderate                    | 57.1 (18.4 to 90.1)                                 | 0 (0.0 to 97.5)                                      | 33.3 (4.3 to 77.7)                                 |  |
| Headache: Severe                      | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Headache: Grade 4                     | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Chills: Any                           | 71.4 (29.0 to 96.3)                                 | 100.0 (2.5 to 100.0)                                 | 16.7 (0.4 to 64.1)                                 |  |
| Chills: Mild                          | 14.3 (0.4 to 57.9)                                  | 100.0 (2.5 to 100.0)                                 | 16.7 (0.4 to 64.1)                                 |  |
| Chills: Moderate                      | 57.1 (18.4 to 90.1)                                 | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Chills: Severe                        | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Chills: Grade 4                       | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Vomiting: Any                         | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Vomiting: Mild                        | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Vomiting: Moderate                    | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Vomiting: Severe                      | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Vomiting: Grade 4                     | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Diarrhea: Any                         | 14.3 (0.4 to 57.9)                                  | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Diarrhea: Mild                        | 14.3 (0.4 to 57.9)                                  | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Diarrhea: Moderate                    | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Diarrhea: Severe                      | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| Diarrhea: Grade 4                     | 0 (0.0 to 41.0)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |
| New or worsened muscle pain: Any      | 28.6 (3.7 to 71.0)                                  | 0 (0.0 to 97.5)                                      | 16.7 (0.4 to 64.1)                                 |  |
| New or worsened muscle pain: Mild     | 14.3 (0.4 to 57.9)                                  | 0 (0.0 to 97.5)                                      | 16.7 (0.4 to 64.1)                                 |  |
| New or worsened muscle pain: Moderate | 14.3 (0.4 to 57.9)                                  | 0 (0.0 to 97.5)                                      | 0 (0.0 to 45.9)                                    |  |

|                                      |                    |                 |                 |  |
|--------------------------------------|--------------------|-----------------|-----------------|--|
| New or worsened muscle pain: Severe  | 0 (0.0 to 41.0)    | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 41.0)    | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened joint pain: Any      | 14.3 (0.4 to 57.9) | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened joint pain: Mild     | 0 (0.0 to 41.0)    | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened joint pain: Moderate | 14.3 (0.4 to 57.9) | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened joint pain: Severe   | 0 (0.0 to 41.0)    | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |
| New or worsened joint pain: Grade 4  | 0 (0.0 to 41.0)    | 0 (0.0 to 97.5) | 0 (0.0 to 45.9) |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 18$ Years

|                 |                                                                                                                                                             |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged $\geq 18$ Years <sup>[97][98]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to 38.4 C,  $>38.4$  to 38.9 C,  $>38.9$  to 40.0 C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[97] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[98] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | $\geq 18$ Years with Immunomodulatory Therapy | $\geq 18$ Years with Non-Small Cell Lung Cancer | $\geq 18$ Years with Haemodialysis |  |
|----------------------------------|-----------------------------------------------|-------------------------------------------------|------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                                 | Reporting group                    |  |
| Number of subjects analysed      | 4                                             | 0 <sup>[99]</sup>                               | 1                                  |  |
| Units: Percentage of subjects    |                                               |                                                 |                                    |  |
| number (confidence interval 95%) |                                               |                                                 |                                    |  |
| Fever: Any                       | 0 (0.0 to 60.2)                               | ( to )                                          | 0 (0.0 to 97.5)                    |  |
| Fever: $\geq 38.0$ to 38.4 deg C | 0 (0.0 to 60.2)                               | ( to )                                          | 0 (0.0 to 97.5)                    |  |
| Fever: $>38.4$ to 38.9 deg C     | 0 (0.0 to 60.2)                               | ( to )                                          | 0 (0.0 to 97.5)                    |  |
| Fever: $>38.9$ to 40.0 deg C     | 0 (0.0 to 60.2)                               | ( to )                                          | 0 (0.0 to 97.5)                    |  |

|                                       |                     |        |                 |
|---------------------------------------|---------------------|--------|-----------------|
| Fever: >40.0 deg C                    | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Fatigue: Any                          | 75.0 (19.4 to 99.4) | ( to ) | 0 (0.0 to 97.5) |
| Fatigue: Mild                         | 50.0 (6.8 to 93.2)  | ( to ) | 0 (0.0 to 97.5) |
| Fatigue: Moderate                     | 25.0 (0.6 to 80.6)  | ( to ) | 0 (0.0 to 97.5) |
| Fatigue: Severe                       | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Fatigue: Grade 4                      | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Headache: Any                         | 75.0 (19.4 to 99.4) | ( to ) | 0 (0.0 to 97.5) |
| Headache: Mild                        | 25.0 (0.6 to 80.6)  | ( to ) | 0 (0.0 to 97.5) |
| Headache: Moderate                    | 50.0 (6.8 to 93.2)  | ( to ) | 0 (0.0 to 97.5) |
| Headache: Severe                      | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Headache: Grade 4                     | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Chills: Any                           | 50.0 (0.6 to 93.2)  | ( to ) | 0 (0.0 to 97.5) |
| Chills: Mild                          | 25.0 (0.6 to 80.6)  | ( to ) | 0 (0.0 to 97.5) |
| Chills: Moderate                      | 25.0 (0.6 to 80.6)  | ( to ) | 0 (0.0 to 97.5) |
| Chills: Severe                        | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Chills: Grade 4                       | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Vomiting: Any                         | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Vomiting: Mild                        | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Vomiting: Moderate                    | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Vomiting: Severe                      | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Vomiting: Grade 4                     | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Diarrhea: Any                         | 25.0 (0.6 to 80.6)  | ( to ) | 0 (0.0 to 97.5) |
| Diarrhea: Mild                        | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Diarrhea: Moderate                    | 25.0 (0.6 to 80.6)  | ( to ) | 0 (0.0 to 97.5) |
| Diarrhea: Severe                      | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| Diarrhea: Grade 4                     | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Any      | 50.0 (6.8 to 93.2)  | ( to ) | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Mild     | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Moderate | 50.0 (6.8 to 93.2)  | ( to ) | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Severe   | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| New or worsened joint pain: Any       | 50.0 (6.8 to 93.2)  | ( to ) | 0 (0.0 to 97.5) |
| New or worsened joint pain: Mild      | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| New or worsened joint pain: Moderate  | 50.0 (6.8 to 93.2)  | ( to ) | 0 (0.0 to 97.5) |
| New or worsened joint pain: Severe    | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 60.2)     | ( to ) | 0 (0.0 to 97.5) |

Notes:

[99] - No subjects were evaluable for this endpoint from this arm.

## Statistical analyses

**Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged  $\geq 2$  to  $< 5$  Years**

|                 |                                                                                                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 2$ to $< 5$ Years <sup>[100]</sup> <sup>[101]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $> 38.4$  to  $38.9$  C,  $> 38.9$  to  $40.0$  C and  $> 40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $> 2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

## End point timeframe:

Day 1 to Day 7 after Vaccination 4

## Notes:

[100] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[101] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                   | 2 to $< 5$ Years with Immunomodulatory Therapy | 2 to $< 5$ Years with Solid Organ Transplant | 2 to $< 5$ Years with Stem Cell Transplant |  |
|------------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type                 | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed        | 7                                              | 6                                            | 6                                          |  |
| Units: Percentage of subjects      |                                                |                                              |                                            |  |
| number (confidence interval 95%)   |                                                |                                              |                                            |  |
| Fever: Any                         | 28.6 (3.7 to 71.0)                             | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Fever: $\geq 38.0$ to $38.4$ deg C | 14.3 (0.4 to 57.9)                             | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Fever: $> 38.4$ to $38.9$ deg C    | 14.3 (0.4 to 57.9)                             | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Fever: $> 38.9$ to $40.0$ deg C    | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Fever: $> 40.0$ deg C              | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Fatigue: Any                       | 14.3 (0.4 to 57.9)                             | 0 (0.0 to 45.9)                              | 16.7 (0.4 to 64.1)                         |  |
| Fatigue: Mild                      | 14.3 (0.4 to 57.9)                             | 0 (0.0 to 45.9)                              | 16.7 (0.4 to 64.1)                         |  |
| Fatigue: Moderate                  | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Fatigue: Severe                    | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Fatigue: Grade 4                   | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Headache: Any                      | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Headache: Mild                     | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Headache: Moderate                 | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |
| Headache: Severe                   | 0 (0.0 to 41.0)                                | 0 (0.0 to 45.9)                              | 0 (0.0 to 45.9)                            |  |

|                                       |                    |                    |                 |
|---------------------------------------|--------------------|--------------------|-----------------|
| Headache: Grade 4                     | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Chills: Any                           | 14.3 (0.4 to 57.9) | 16.7 (0.4 to 64.1) | 0 (0.0 to 45.9) |
| Chills: Mild                          | 0 (0.0 to 41.0)    | 16.7 (0.4 to 64.1) | 0 (0.0 to 45.9) |
| Chills: Moderate                      | 14.3 (0.4 to 57.9) | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Chills: Severe                        | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Chills: Grade 4                       | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Vomiting: Any                         | 0 (0.0 to 41.0)    | 16.7 (0.4 to 64.1) | 0 (0.0 to 45.9) |
| Vomiting: Mild                        | 0 (0.0 to 41.0)    | 16.7 (0.4 to 64.1) | 0 (0.0 to 45.9) |
| Vomiting: Moderate                    | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Vomiting: Severe                      | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Vomiting: Grade 4                     | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Diarrhea: Any                         | 14.3 (0.4 to 57.9) | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Diarrhea: Mild                        | 14.3 (0.4 to 57.9) | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Diarrhea: Moderate                    | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Diarrhea: Severe                      | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| Diarrhea: Grade 4                     | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened muscle pain: Any      | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened muscle pain: Mild     | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened muscle pain: Moderate | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened muscle pain: Severe   | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened joint pain: Any       | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened joint pain: Mild      | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened joint pain: Moderate  | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened joint pain: Severe    | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 41.0)    | 0 (0.0 to 45.9)    | 0 (0.0 to 45.9) |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 5$ to $<12$ Years

|                 |                                                                                                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 5$ to $<12$ Years <sup>[102]</sup> <sup>[103]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $>38.4$  to  $38.9$  C,  $>38.9$  to  $40.0$  C and  $>40.0$  degree C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[102] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[103] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 12                                           | 19                                         | 15                                       |  |
| Units: Percentage of subjects    |                                              |                                            |                                          |  |
| number (confidence interval 95%) |                                              |                                            |                                          |  |
| Fever: Any                       | 8.3 (0.2 to 38.5)                            | 5.3 (0.1 to 26.0)                          | 6.7 (0.2 to 31.9)                        |  |
| Fever: >=38.0 to 38.4 deg C      | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Fever: >38.4 to 38.9 deg C       | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Fever: >38.9 to 40.0 deg C       | 8.3 (0.2 to 38.5)                            | 5.3 (0.1 to 26.0)                          | 6.7 (0.2 to 31.9)                        |  |
| Fever: >40.0 deg C               | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Fatigue: Any                     | 50.0 (21.1 to 78.9)                          | 26.3 (9.1 to 51.2)                         | 33.3 (11.8 to 61.6)                      |  |
| Fatigue: Mild                    | 33.3 (9.9 to 65.1)                           | 10.5 (1.3 to 33.1)                         | 13.3 (1.7 to 40.5)                       |  |
| Fatigue: Moderate                | 16.7 (2.1 to 48.4)                           | 15.8 (3.4 to 39.6)                         | 20.0 (4.3 to 48.1)                       |  |
| Fatigue: Severe                  | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Fatigue: Grade 4                 | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Headache: Any                    | 33.3 (9.9 to 65.1)                           | 21.1 (6.1 to 45.6)                         | 13.3 (1.7 to 40.5)                       |  |
| Headache: Mild                   | 8.3 (0.2 to 38.5)                            | 15.8 (3.4 to 39.6)                         | 0 (0.0 to 21.8)                          |  |
| Headache: Moderate               | 25.0 (5.5 to 57.2)                           | 5.3 (0.1 to 26.0)                          | 6.7 (0.2 to 31.9)                        |  |
| Headache: Severe                 | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 6.7 (0.2 to 31.9)                        |  |
| Headache: Grade 4                | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Chills: Any                      | 8.3 (0.2 to 38.5)                            | 5.3 (0.1 to 26.0)                          | 13.3 (1.7 to 40.5)                       |  |
| Chills: Mild                     | 8.3 (0.2 to 38.5)                            | 5.3 (0.1 to 26.0)                          | 0 (0.0 to 21.8)                          |  |
| Chills: Moderate                 | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 13.3 (1.7 to 40.5)                       |  |
| Chills: Severe                   | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Chills: Grade 4                  | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Vomiting: Any                    | 8.3 (0.2 to 38.5)                            | 5.3 (0.1 to 26.0)                          | 0 (0.0 to 21.8)                          |  |
| Vomiting: Mild                   | 8.3 (0.2 to 38.5)                            | 5.3 (0.1 to 26.0)                          | 0 (0.0 to 21.8)                          |  |
| Vomiting: Moderate               | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |
| Vomiting: Severe                 | 0 (0.0 to 26.5)                              | 0 (0.0 to 17.6)                            | 0 (0.0 to 21.8)                          |  |



|                                       |                    |                    |                   |  |
|---------------------------------------|--------------------|--------------------|-------------------|--|
| Vomiting: Grade 4                     | 0 (0.0 to 26.5)    | 0 (0.0 to 17.6)    | 0 (0.0 to 21.8)   |  |
| Diarrhea: Any                         | 25.0 (5.5 to 57.2) | 15.8 (3.4 to 39.6) | 6.7 (0.2 to 31.9) |  |
| Diarrhea: Mild                        | 25.0 (5.5 to 57.2) | 10.5 (1.3 to 33.1) | 6.7 (0.2 to 31.9) |  |
| Diarrhea: Moderate                    | 0 (0.0 to 26.5)    | 5.3 (0.1 to 26.0)  | 0 (0.0 to 21.8)   |  |
| Diarrhea: Severe                      | 0 (0.0 to 26.5)    | 0 (0.0 to 17.6)    | 0 (0.0 to 21.8)   |  |
| Diarrhea: Grade 4                     | 0 (0.0 to 26.5)    | 0 (0.0 to 17.6)    | 0 (0.0 to 21.8)   |  |
| New or worsened muscle pain: Any      | 16.7 (2.1 to 48.4) | 15.8 (3.4 to 39.6) | 6.7 (0.2 to 31.9) |  |
| New or worsened muscle pain: Mild     | 0 (0.0 to 26.5)    | 15.8 (3.4 to 39.6) | 0 (0.0 to 21.8)   |  |
| New or worsened muscle pain: Moderate | 8.3 (0.2 to 38.5)  | 0 (0.0 to 17.6)    | 6.7 (0.2 to 31.9) |  |
| New or worsened muscle pain: Severe   | 8.3 (0.2 to 38.5)  | 0 (0.0 to 17.6)    | 0 (0.0 to 21.8)   |  |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 26.5)    | 0 (0.0 to 17.6)    | 0 (0.0 to 21.8)   |  |
| New or worsened joint pain: Any       | 25.0 (5.5 to 57.2) | 0 (0.0 to 17.6)    | 6.7 (0.2 to 31.9) |  |
| New or worsened joint pain: Mild      | 8.3 (0.2 to 38.5)  | 0 (0.0 to 17.6)    | 6.7 (0.2 to 31.9) |  |
| New or worsened joint pain: Moderate  | 16.7 (2.1 to 48.4) | 0 (0.0 to 17.6)    | 0 (0.0 to 21.8)   |  |
| New or worsened joint pain: Severe    | 0 (0.0 to 26.5)    | 0 (0.0 to 17.6)    | 0 (0.0 to 21.8)   |  |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 26.5)    | 0 (0.0 to 17.6)    | 0 (0.0 to 21.8)   |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 12$ to $< 18$ Years

|                 |                                                                                                                                                                         |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 12$ to $< 18$ Years <sup>[104][105]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to  $38.4$  C,  $> 38.4$  to  $38.9$  C,  $> 38.9$  to  $40.0$  C and  $> 40.0$  degree C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $> 2$  times in 24 hours, severe: required intravenous hydration: Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[104] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[105] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all

the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| <b>End point values</b>          | 12 to <18<br>Years with<br>Immunomodulatory Therapy | 12 to <18<br>Years with<br>Solid Organ<br>Transplant | 12 to <18<br>Years with<br>Stem Cell<br>Transplant |  |
|----------------------------------|-----------------------------------------------------|------------------------------------------------------|----------------------------------------------------|--|
| Subject group type               | Reporting group                                     | Reporting group                                      | Reporting group                                    |  |
| Number of subjects analysed      | 4                                                   | 1                                                    | 3                                                  |  |
| Units: Percentage of subjects    |                                                     |                                                      |                                                    |  |
| number (confidence interval 95%) |                                                     |                                                      |                                                    |  |
| Fever: Any                       | 25.0 (0.6 to 80.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Fever: $\geq 38.0$ to 38.4 deg C | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Fever: $>38.4$ to 38.9 deg C     | 25.0 (0.6 to 80.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Fever: $>38.9$ to 40.0 deg C     | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Fever: $>40.0$ deg C             | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Fatigue: Any                     | 50.0 (6.8 to 93.2)                                  | 100.0 (2.5 to 100.0)                                 | 66.7 (9.4 to 99.2)                                 |  |
| Fatigue: Mild                    | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Fatigue: Moderate                | 50.0 (6.8 to 93.2)                                  | 100.0 (2.5 to 100.0)                                 | 33.3 (0.8 to 90.6)                                 |  |
| Fatigue: Severe                  | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Fatigue: Grade 4                 | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Headache: Any                    | 25.0 (0.6 to 80.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Headache: Mild                   | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Headache: Moderate               | 25.0 (0.6 to 80.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Headache: Severe                 | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Headache: Grade 4                | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Chills: Any                      | 25.0 (0.6 to 80.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Chills: Mild                     | 25.0 (0.6 to 80.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Chills: Moderate                 | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Chills: Severe                   | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Chills: Grade 4                  | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Vomiting: Any                    | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Vomiting: Mild                   | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Vomiting: Moderate               | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Vomiting: Severe                 | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Vomiting: Grade 4                | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Diarrhea: Any                    | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Diarrhea: Mild                   | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Diarrhea: Moderate               | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| Diarrhea: Severe                 | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |
| Diarrhea: Grade 4                | 0 (0.0 to 60.2)                                     | 0 (0.0 to 97.5)                                      | 0 (0.0 to 97.5)                                    |  |
| New or worsened muscle pain: Any | 25.0 (0.6 to 80.6)                                  | 0 (0.0 to 97.5)                                      | 33.3 (0.8 to 90.6)                                 |  |

|                                       |                    |                 |                    |  |
|---------------------------------------|--------------------|-----------------|--------------------|--|
| New or worsened muscle pain: Mild     | 0 (0.0 to 60.2)    | 0 (0.0 to 97.5) | 0 (0.0 to 97.5)    |  |
| New or worsened muscle pain: Moderate | 25.0 (0.6 to 80.6) | 0 (0.0 to 97.5) | 33.3 (0.8 to 90.6) |  |
| New or worsened muscle pain: Severe   | 0 (0.0 to 60.2)    | 0 (0.0 to 97.5) | 0 (0.0 to 97.5)    |  |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 60.2)    | 0 (0.0 to 97.5) | 0 (0.0 to 97.5)    |  |
| New or worsened joint pain: Any       | 0 (0.0 to 60.2)    | 0 (0.0 to 97.5) | 0 (0.0 to 97.5)    |  |
| New or worsened joint pain: Mild      | 0 (0.0 to 60.2)    | 0 (0.0 to 97.5) | 0 (0.0 to 97.5)    |  |
| New or worsened joint pain: Moderate  | 0 (0.0 to 60.2)    | 0 (0.0 to 97.5) | 0 (0.0 to 97.5)    |  |
| New or worsened joint pain: Severe    | 0 (0.0 to 60.2)    | 0 (0.0 to 97.5) | 0 (0.0 to 97.5)    |  |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 60.2)    | 0 (0.0 to 97.5) | 0 (0.0 to 97.5)    |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 18$ Years

|                 |                                                                                                                                                                           |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged $\geq 18$ Years <sup>[106]</sup> <sup>[107]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded in e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature  $\geq 38.0$  C; categorised as  $\geq 38.0$  to 38.4 C,  $>38.4$  to 38.9 C,  $>38.9$  to 40.0 C and  $>40.0$  C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate:  $>2$  times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population: 'N' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[106] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[107] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | $\geq 18$ Years with Immunomodulatory Therapy | $\geq 18$ Years with Non-Small Cell Lung Cancer | $\geq 18$ Years with Haemodialysis |  |
|----------------------------------|-----------------------------------------------|-------------------------------------------------|------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                                 | Reporting group                    |  |
| Number of subjects analysed      | 3                                             | 1                                               | 0 <sup>[108]</sup>                 |  |
| Units: Percentage of subjects    |                                               |                                                 |                                    |  |
| number (confidence interval 95%) |                                               |                                                 |                                    |  |
| Fever: Any                       | 0 (0.0 to 70.8)                               | 0 (0.0 to 97.5)                                 | ( to )                             |  |
| Fever: $\geq 38.0$ to 38.4 deg C | 0 (0.0 to 70.8)                               | 0 (0.0 to 97.5)                                 | ( to )                             |  |
| Fever: $>38.4$ to 38.9 deg C     | 0 (0.0 to 70.8)                               | 0 (0.0 to 97.5)                                 | ( to )                             |  |

|                                       |                    |                 |        |  |
|---------------------------------------|--------------------|-----------------|--------|--|
| Fever: >38.9 to 40.0 deg C            | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Fever: >40.0 deg C                    | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Fatigue: Any                          | 66.7 (9.4 to 99.2) | 0 (0.0 to 97.5) | ( to ) |  |
| Fatigue: Mild                         | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| Fatigue: Moderate                     | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| Fatigue: Severe                       | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Fatigue: Grade 4                      | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Headache: Any                         | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| Headache: Mild                        | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| Headache: Moderate                    | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Headache: Severe                      | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Headache: Grade 4                     | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Chills: Any                           | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| Chills: Mild                          | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Chills: Moderate                      | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| Chills: Severe                        | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Chills: Grade 4                       | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Vomiting: Any                         | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Vomiting: Mild                        | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Vomiting: Moderate                    | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Vomiting: Severe                      | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Vomiting: Grade 4                     | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Diarrhea: Any                         | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Diarrhea: Mild                        | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Diarrhea: Moderate                    | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Diarrhea: Severe                      | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| Diarrhea: Grade 4                     | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened muscle pain: Any      | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened muscle pain: Mild     | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened muscle pain: Moderate | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened muscle pain: Severe   | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened joint pain: Any       | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened joint pain: Mild      | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened joint pain: Moderate  | 33.3 (0.8 to 90.6) | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened joint pain: Severe    | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 70.8)    | 0 (0.0 to 97.5) | ( to ) |  |

Notes:

[108] - No subjects were evaluable for this endpoint from this arm.

## Statistical analyses

No statistical analyses for this end point

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**Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged  $\geq 2$  to  $< 5$  Years**

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|                 |                                                                                                                                                                                         |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged $\geq 2$ to $< 5$ Years <sup>[109]</sup> <sup>[110]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**End point description:**

An adverse event (AE) was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 1 to 1 month after vaccination 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

**End point timeframe:**

From Vaccination 1 to 1 month after Vaccination 2

**Notes:**

[109] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[110] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 2 to $< 5$ Years with Immunomodulatory Therapy | 2 to $< 5$ Years with Solid Organ Transplant | 2 to $< 5$ Years with Stem Cell Transplant |  |
|----------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type               | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed      | 9                                              | 15                                           | 13                                         |  |
| Units: Percentage of subjects    |                                                |                                              |                                            |  |
| number (confidence interval 95%) | 44.4 (13.7 to 78.8)                            | 33.3 (11.8 to 61.6)                          | 38.5 (13.9 to 68.4)                        |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged  $\geq 5$  to  $< 12$  Years**

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|                 |                                                                                                                                                                                          |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged $\geq 5$ to $< 12$ Years <sup>[111]</sup> <sup>[112]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**End point description:**

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 1 to 1 month after vaccination 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

**End point timeframe:**

From Vaccination 1 to 1 month after Vaccination 2

Notes:

[111] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[112] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 19                                           | 24                                         | 22                                       |  |
| Units: Percentage of subjects    |                                              |                                            |                                          |  |
| number (confidence interval 95%) | 36.8 (16.3 to 61.6)                          | 8.3 (1.0 to 27.0)                          | 27.3 (0.7 to 50.2)                       |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged $\geq 5$ to <12 Years

|                 |                                                                                                                                                                                      |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged $\geq 5$ to <12 Years <sup>[113]</sup> <sup>[114]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention.

Percentage of subjects reporting AEs after vaccination 3 to 1 month after vaccination 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

End point timeframe:

From Vaccination 3 to 1 month after Vaccination 3

Notes:

[113] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[114] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 17                                           | 23                                         | 22                                       |  |
| Units: Percentage of subjects    |                                              |                                            |                                          |  |
| number (confidence interval 95%) | 29.4 (10.3 to                                | 8.7 (1.1 to                                | 4.5 (0.1 to                              |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged $\geq 2$ to $< 5$ Years

|                 |                                                                                                                                                                                        |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged $\geq 2$ to $< 5$ Years <sup>[115]</sup> <sup>[116]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 3 to 1 month after vaccination 3 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

#### End point timeframe:

From Vaccination 3 to 1 month after Vaccination 3

#### Notes:

[115] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[116] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 2 to $< 5$ Years with Immunomodulatory Therapy | 2 to $< 5$ Years with Solid Organ Transplant | 2 to $< 5$ Years with Stem Cell Transplant |  |
|----------------------------------|------------------------------------------------|----------------------------------------------|--------------------------------------------|--|
| Subject group type               | Reporting group                                | Reporting group                              | Reporting group                            |  |
| Number of subjects analysed      | 9                                              | 15                                           | 11                                         |  |
| Units: Percentage of subjects    |                                                |                                              |                                            |  |
| number (confidence interval 95%) | 33.3 (7.5 to 70.1)                             | 40.0 (16.3 to 67.7)                          | 0 (0.0 to 28.5)                            |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged $\geq 12$ to $< 18$ Years

|                 |                                                                                                                                                                                           |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged $\geq 12$ to $< 18$ Years <sup>[117]</sup> <sup>[118]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**End point description:**

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 1 to 1 month after vaccination 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

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**End point timeframe:**

From Vaccination 1 to 1 month after Vaccination 2

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**Notes:**

[117] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[118] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 12 to <18 Years with Immunomodulatory Therapy | 12 to <18 Years with Solid Organ Transplant | 12 to <18 Years with Stem Cell Transplant |  |
|----------------------------------|-----------------------------------------------|---------------------------------------------|-------------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                             | Reporting group                           |  |
| Number of subjects analysed      | 7                                             | 1                                           | 7                                         |  |
| Units: Percentage of subjects    |                                               |                                             |                                           |  |
| number (confidence interval 95%) | 14.3 (0.4 to 57.9)                            | 0 (0.0 to 97.5)                             | 14.3 (0.4 to 57.9)                        |  |

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**Statistical analyses**

No statistical analyses for this end point

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**Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged ≥18 Years**

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|                 |                                                                                                                                                               |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged ≥18 Years <sup>[119][120]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**End point description:**

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 1 to 1 month after vaccination 2 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

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**End point timeframe:**

From Vaccination 1 to 1 month after Vaccination 2

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**Notes:**

[119] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[120] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline



period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | >=18 Years with Immunomodulatory Therapy | >=18 Years with Non-Small Cell Lung Cancer | >= 18 Years with Haemodialysis |  |
|----------------------------------|------------------------------------------|--------------------------------------------|--------------------------------|--|
| Subject group type               | Reporting group                          | Reporting group                            | Reporting group                |  |
| Number of subjects analysed      | 5                                        | 1                                          | 1                              |  |
| Units: Percentage of subjects    |                                          |                                            |                                |  |
| number (confidence interval 95%) | 20.0 (0.5 to 71.6)                       | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=18 Years

|                 |                                                                                                                                                                |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=18 Years <sup>[121][122]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 3 to 1 month after vaccination 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

End point timeframe:

From Vaccination 3 to 1 month after Vaccination 3

Notes:

[121] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[122] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | >=18 Years with Immunomodulatory Therapy | >=18 Years with Non-Small Cell Lung Cancer | >= 18 Years with Haemodialysis |  |
|----------------------------------|------------------------------------------|--------------------------------------------|--------------------------------|--|
| Subject group type               | Reporting group                          | Reporting group                            | Reporting group                |  |
| Number of subjects analysed      | 5                                        | 1                                          | 1                              |  |
| Units: Percentage of subjects    |                                          |                                            |                                |  |
| number (confidence interval 95%) | 0 (0.0 to 52.2)                          | 0 (0.0 to 97.5)                            | 0 (0.0 to 97.5)                |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged $\geq 2$ to $<5$ Years

|                 |                                                                                                                                                                           |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged $\geq 2$ to $<5$ Years <sup>[123][124]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 4 to 1 month after vaccination 4 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

End point timeframe:

From Vaccination 4 to 1 month after Vaccination 4

Notes:

[123] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[124] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 2 to $<5$ Years with Immunomodulatory Therapy | 2 to $<5$ Years with Solid Organ Transplant | 2 to $<5$ Years with Stem Cell Transplant |  |
|----------------------------------|-----------------------------------------------|---------------------------------------------|-------------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                             | Reporting group                           |  |
| Number of subjects analysed      | 7                                             | 6                                           | 6                                         |  |
| Units: Percentage of subjects    |                                               |                                             |                                           |  |
| number (confidence interval 95%) | 14.3 (0.4 to 57.9)                            | 16.7 (0.4 to 64.1)                          | 0 (0.0 to 45.9)                           |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged $\geq 5$ to $<12$ Years

|                 |                                                                                                                                                                            |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged $\geq 5$ to $<12$ Years <sup>[125][126]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 4 to 1 month after vaccination 4 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

End point timeframe:

From Vaccination 4 to 1 month after Vaccination 4

Notes:

[125] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[126] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 12                                           | 19                                         | 15                                       |  |
| Units: Percentage of subjects    |                                              |                                            |                                          |  |
| number (confidence interval 95%) | 0 (0.0 to 26.5)                              | 36.8 (16.3 to 61.6)                        | 0 (0.0 to 21.8)                          |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged $\geq 12$ to <18 Years

|                 |                                                                                                                                                                           |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged $\geq 12$ to <18 Years <sup>[127][128]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention.

Percentage of subjects reporting AEs after vaccination 3 to 1 month after vaccination 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

End point timeframe:

From Vaccination 3 to 1 month after Vaccination 3

Notes:

[127] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[128] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 12 to <18 Years with Immunomodulatory Therapy | 12 to <18 Years with Solid Organ Transplant | 12 to <18 Years with Stem Cell Transplant |  |
|----------------------------------|-----------------------------------------------|---------------------------------------------|-------------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                             | Reporting group                           |  |
| Number of subjects analysed      | 7                                             | 1                                           | 6                                         |  |
| Units: Percentage of subjects    |                                               |                                             |                                           |  |
| number (confidence interval 95%) | 14.3 (0.4 to 57.9)                            | 0 (0.0 to 97.5)                             | 16.7 (0.4 to 64.1)                        |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting SAEs From Vaccination 1 Through the Duration of the Study in Subjects Aged $\geq 5$ to <12 Years

|                 |                                                                                                                                                                     |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting SAEs From Vaccination 1 Through the Duration of the Study in Subjects Aged $\geq 5$ to <12 Years <sup>[129]</sup> <sup>[130]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, and other situations as medical judgement of investigator. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all subjects who received at least 1 dose of the study intervention.

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

End point timeframe:

From Vaccination 1 to 6 month after Vaccination 4 (approximately 14 months)

Notes:

[129] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[130] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 5 to <12 Years with Immunomodulatory Therapy | 5 to <12 Years with Solid Organ Transplant | 5 to <12 Years with Stem Cell Transplant |  |
|----------------------------------|----------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                              | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 19                                           | 24                                         | 22                                       |  |
| Units: Percentage of subjects    |                                              |                                            |                                          |  |
| number (confidence interval 95%) | 15.8 (3.4 to 39.6)                           | 20.8 (7.1 to 42.2)                         | 13.6 (2.9 to 34.9)                       |  |

## Statistical analyses

**Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged  $\geq 12$  to  $<18$  Years**

|                 |                                                                                                                                                                             |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged $\geq 12$ to $<18$ Years <sup>[131][132]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention.

Percentage of subjects reporting AEs after vaccination 4 to 1 month after vaccination 4 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

## End point timeframe:

From Vaccination 4 to 1 month after Vaccination 4

## Notes:

[131] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[132] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 12 to $<18$ Years with Immunomodulatory Therapy | 12 to $<18$ Years with Solid Organ Transplant | 12 to $<18$ Years with Stem Cell Transplant |  |
|----------------------------------|-------------------------------------------------|-----------------------------------------------|---------------------------------------------|--|
| Subject group type               | Reporting group                                 | Reporting group                               | Reporting group                             |  |
| Number of subjects analysed      | 4                                               | 1                                             | 3                                           |  |
| Units: Percentage of subjects    |                                                 |                                               |                                             |  |
| number (confidence interval 95%) | 0 (0.0 to 60.2)                                 | 0 (0.0 to 97.5)                               | 0 (0.0 to 70.8)                             |  |

**Statistical analyses**

No statistical analyses for this end point

**Primary: Percentage of Subjects Reporting Serious Adverse Events (SAEs) From Vaccination 1 Through the Duration of the Study in Subjects Aged  $\geq 2$  to  $<5$  Years**

|                 |                                                                                                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Serious Adverse Events (SAEs) From Vaccination 1 Through the Duration of the Study in Subjects Aged $\geq 2$ to $<5$ Years <sup>[133][134]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, and other situations as medical judgement of investigator. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all subjects who received at least 1 dose of the study intervention.

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

## End point timeframe:

From Vaccination 1 to 6 month after Vaccination 4 (approximately 14 months)

Notes:

[133] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[134] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 2 to <5 Years with Immunomodulatory Therapy | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant |  |
|----------------------------------|---------------------------------------------|--------------------------------------------|------------------------------------------|--|
| Subject group type               | Reporting group                             | Reporting group                            | Reporting group                          |  |
| Number of subjects analysed      | 9                                           | 15                                         | 13                                       |  |
| Units: Percentage of subjects    |                                             |                                            |                                          |  |
| number (confidence interval 95%) | 0 (0.0 to 33.6)                             | 53.3 (26.6 to 78.7)                        | 23.1 (5.0 to 53.8)                       |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged $\geq 18$ Years

|                 |                                                                                                                                                                     |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged $\geq 18$ Years <sup>[135][136]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention.

Percentage of subjects reporting AEs after vaccination 4 to 1 month after vaccination 4 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

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

End point timeframe:

From Vaccination 4 to 1 month after Vaccination 4

Notes:

[135] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[136] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | $\geq 18$ Years with Immunomodulatory Therapy | $\geq 18$ Years with Non-Small Cell Lung Cancer | $\geq 18$ Years with Haemodialysis |  |
|----------------------------------|-----------------------------------------------|-------------------------------------------------|------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                                 | Reporting group                    |  |
| Number of subjects analysed      | 3                                             | 1                                               | 0 <sup>[137]</sup>                 |  |
| Units: Percentage of subjects    |                                               |                                                 |                                    |  |
| number (confidence interval 95%) | 0 (0.0 to 70.8)                               | 100.0 (2.5 to                                   | ( to )                             |  |

Notes:

[137] - No subjects were evaluable for this endpoint.

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting SAEs From Dose 1 Through the Duration of the Study in Subjects Aged $\geq 18$ Years

|                 |                                                                                                                                                        |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting SAEs From Dose 1 Through the Duration of the Study in Subjects Aged $\geq 18$ Years <sup>[138]</sup> <sup>[139]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, and other situations as medical judgement of investigator. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all subjects who received at least 1 dose of the study intervention.

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

End point timeframe:

From Vaccination 1 to 6 month after Vaccination 4 (approximately 14 months)

Notes:

[138] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[139] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | $\geq 18$ Years with Immunomodulatory Therapy | $\geq 18$ Years with Non-Small Cell Lung Cancer | $\geq 18$ Years with Haemodialysis |  |
|----------------------------------|-----------------------------------------------|-------------------------------------------------|------------------------------------|--|
| Subject group type               | Reporting group                               | Reporting group                                 | Reporting group                    |  |
| Number of subjects analysed      | 5                                             | 1                                               | 1                                  |  |
| Units: Percentage of subjects    |                                               |                                                 |                                    |  |
| number (confidence interval 95%) | 20.0 (0.5 to 71.6)                            | 0 (0.0 to 97.5)                                 | 100.0 (2.5 to 100.0)               |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting SAEs From Vaccination 1 Through the Duration of the Study in Subjects Aged $\geq 12$ to $< 18$ Years

|                 |                                                                                                                                                                         |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting SAEs From Vaccination 1 Through the Duration of the Study in Subjects Aged $\geq 12$ to $< 18$ Years <sup>[140]</sup> <sup>[141]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

---

**End point description:**

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, and other situations as medical judgement of investigator. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all subjects who received at least 1 dose of the study intervention.

---

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

---

**End point timeframe:**

From Vaccination 1 to 6 month after Vaccination 4 (approximately 14 months)

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**Notes:**

[140] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[141] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                 | 12 to <18<br>Years with<br>Immunomodul<br>atory Therapy | 12 to <18<br>Years with<br>Solid Organ<br>Transplant | 12 to <18<br>Years with<br>Stem Cell<br>Transplant |  |
|----------------------------------|---------------------------------------------------------|------------------------------------------------------|----------------------------------------------------|--|
| Subject group type               | Reporting group                                         | Reporting group                                      | Reporting group                                    |  |
| Number of subjects analysed      | 7                                                       | 1                                                    | 7                                                  |  |
| Units: Percentage of subjects    |                                                         |                                                      |                                                    |  |
| number (confidence interval 95%) | 0 (0.0 to 41.0)                                         | 0 (0.0 to 97.5)                                      | 0 (0.0 to 41.0)                                    |  |

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**Statistical analyses**

No statistical analyses for this end point

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## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Local reactions/systemic events up to Day 7 each dose. AEs were reported from first dose of study treatment up to 1 month after last dose of study treatment (approximately 9 months). For SAE, from Dose 1 to 6 month after Dose 4 (approximately 14 months).

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE but are distinct events. An event may be categorised as serious in 1 subject and non-serious in another, or a subject may have experienced both SAE and non-SAE.

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 26.0 |
|--------------------|------|

### Reporting groups

|                       |                                            |
|-----------------------|--------------------------------------------|
| Reporting group title | 2 to < 5 Years with Solid Organ Transplant |
|-----------------------|--------------------------------------------|

Reporting group description:

Subjects aged 2 to <5 years who had solid organ transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                          |
|-----------------------|------------------------------------------|
| Reporting group title | 2 to < 5 Years with Stem Cell Transplant |
|-----------------------|------------------------------------------|

Reporting group description:

Subjects aged 2 to <5 years who had stem cell transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                              |
|-----------------------|----------------------------------------------|
| Reporting group title | 5 to <12 Years with Immunomodulatory Therapy |
|-----------------------|----------------------------------------------|

Reporting group description:

Subjects aged 5 to <12 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                            |
|-----------------------|--------------------------------------------|
| Reporting group title | 5 to <12 Years with Solid Organ Transplant |
|-----------------------|--------------------------------------------|

Reporting group description:

Subjects aged 5 to <12 years who had solid organ transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                             |
|-----------------------|---------------------------------------------|
| Reporting group title | 2 to <5 Years with Immunomodulatory Therapy |
|-----------------------|---------------------------------------------|

Reporting group description:

Subjects aged 2 to <5 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 3 microgram (mcg) of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                          |
|-----------------------|------------------------------------------|
| Reporting group title | 5 to <12 Years with Stem Cell Transplant |
|-----------------------|------------------------------------------|

Reporting group description:

Subjects aged 5 to <12 years who had stem cell transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                               |
|-----------------------|-----------------------------------------------|
| Reporting group title | 12 to <18 Years with Immunomodulatory Therapy |
|-----------------------|-----------------------------------------------|

Reporting group description:

Subjects aged 12 to <18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                             |
|-----------------------|---------------------------------------------|
| Reporting group title | 12 to <18 Years with Solid Organ Transplant |
|-----------------------|---------------------------------------------|

Reporting group description:

Subjects aged 12 to <18 years who had solid organ transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                           |
|-----------------------|-------------------------------------------|
| Reporting group title | 12 to <18 Years with Stem Cell Transplant |
|-----------------------|-------------------------------------------|

Reporting group description:

Subjects aged 12 to <18 years who had stem cell transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                          |
|-----------------------|------------------------------------------|
| Reporting group title | >=18 Years with Immunomodulatory Therapy |
|-----------------------|------------------------------------------|

Reporting group description:

Subjects aged >=18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                            |
|-----------------------|--------------------------------------------|
| Reporting group title | >=18 Years with Non-Small Cell Lung Cancer |
|-----------------------|--------------------------------------------|

Reporting group description:

Subjects with non-small cell lung cancer aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | >= 18 Years with Haemodialysis |
|-----------------------|--------------------------------|

Reporting group description:

Subjects undergone maintenance haemodialysis treatment aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

| Serious adverse events                               | 2 to < 5 Years with Solid Organ Transplant | 2 to < 5 Years with Stem Cell Transplant | 5 to <12 Years with Immunomodulatory Therapy |
|------------------------------------------------------|--------------------------------------------|------------------------------------------|----------------------------------------------|
| Total subjects affected by serious adverse events    |                                            |                                          |                                              |
| subjects affected / exposed                          | 8 / 15 (53.33%)                            | 3 / 13 (23.08%)                          | 3 / 19 (15.79%)                              |
| number of deaths (all causes)                        | 0                                          | 0                                        | 0                                            |
| number of deaths resulting from adverse events       | 0                                          | 0                                        | 0                                            |
| Vascular disorders                                   |                                            |                                          |                                              |
| Hypertension                                         |                                            |                                          |                                              |
| subjects affected / exposed                          | 0 / 15 (0.00%)                             | 0 / 13 (0.00%)                           | 0 / 19 (0.00%)                               |
| occurrences causally related to treatment / all      | 0 / 0                                      | 0 / 0                                    | 0 / 0                                        |
| deaths causally related to treatment / all           | 0 / 0                                      | 0 / 0                                    | 0 / 0                                        |
| Surgical and medical procedures                      |                                            |                                          |                                              |
| Catheter removal                                     |                                            |                                          |                                              |
| subjects affected / exposed                          | 0 / 15 (0.00%)                             | 0 / 13 (0.00%)                           | 0 / 19 (0.00%)                               |
| occurrences causally related to treatment / all      | 0 / 0                                      | 0 / 0                                    | 0 / 0                                        |
| deaths causally related to treatment / all           | 0 / 0                                      | 0 / 0                                    | 0 / 0                                        |
| General disorders and administration site conditions |                                            |                                          |                                              |
| Influenza like illness                               |                                            |                                          |                                              |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (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          |
| Pyrexia                                         |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 1 / 13 (7.69%) | 0 / 19 (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          |
| Immune system disorders                         |                |                |                |
| Anaphylactic reaction                           |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Kidney transplant rejection                     |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                |                |                |
| Pulmonary vein stenosis                         |                |                |                |
| subjects affected / exposed                     | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (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          |
| Injury, poisoning and procedural complications  |                |                |                |
| Arthropod sting                                 |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Postoperative ileus                             |                |                |                |
| subjects affected / exposed                     | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Nervous system disorders                        |                |                |                |
| Epilepsy                                        |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders            |                |                |                |
| Anaemia                                         |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                      |                |                |                |
| Dental caries                                   |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 1 / 13 (7.69%) | 0 / 19 (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          |
| Diarrhoea                                       |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Intestinal obstruction                          |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Melaena                                         |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                |                |                |
| Dermatomyositis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |                |                |                |
| Renal colic                                     |                |                |                |

|                                                 |                 |                |                |
|-------------------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Azotaemia                                       |                 |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Acute kidney injury                             |                 |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |                 |                |                |
| Myositis                                        |                 |                |                |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                 |                |                |
| Bronchiolitis                                   |                 |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 1 / 13 (7.69%) | 0 / 19 (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          |
| Adenovirus infection                            |                 |                |                |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Device related infection                        |                 |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Gastroenteritis                                 |                 |                |                |
| subjects affected / exposed                     | 2 / 15 (13.33%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |

|                                                 |                 |                |                |
|-------------------------------------------------|-----------------|----------------|----------------|
| Gangrene                                        |                 |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Epstein-Barr virus infection                    |                 |                |                |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 0 / 19 (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          |
| Herpes zoster                                   |                 |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Urinary tract infection                         |                 |                |                |
| subjects affected / exposed                     | 2 / 15 (13.33%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Rhinovirus infection                            |                 |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Respiratory syncytial virus infection           |                 |                |                |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |                 |                |                |
| Hyponatraemia                                   |                 |                |                |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                     | 5 to <12 Years with Solid Organ Transplant | 2 to <5 Years with Immunomodulatory Therapy | 5 to <12 Years with Stem Cell Transplant |
|---------------------------------------------------|--------------------------------------------|---------------------------------------------|------------------------------------------|
| Total subjects affected by serious adverse events |                                            |                                             |                                          |
| subjects affected / exposed                       | 5 / 24 (20.83%)                            | 0 / 9 (0.00%)                               | 3 / 22 (13.64%)                          |
| number of deaths (all causes)                     | 0                                          | 0                                           | 0                                        |

|                                                      |                |               |                |
|------------------------------------------------------|----------------|---------------|----------------|
| number of deaths resulting from adverse events       | 0              | 0             | 0              |
| Vascular disorders                                   |                |               |                |
| Hypertension                                         |                |               |                |
| subjects affected / exposed                          | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (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          |
| Surgical and medical procedures                      |                |               |                |
| Catheter removal                                     |                |               |                |
| subjects affected / exposed                          | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |
| General disorders and administration site conditions |                |               |                |
| Influenza like illness                               |                |               |                |
| subjects affected / exposed                          | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |
| Pyrexia                                              |                |               |                |
| subjects affected / exposed                          | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |
| Immune system disorders                              |                |               |                |
| Anaphylactic reaction                                |                |               |                |
| subjects affected / exposed                          | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (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          |
| Kidney transplant rejection                          |                |               |                |
| subjects affected / exposed                          | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                |               |                |
| Pulmonary vein stenosis                              |                |               |                |
| subjects affected / exposed                          | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| Injury, poisoning and procedural complications  |                |               |                |
| Arthropod sting                                 |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Postoperative ileus                             |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Nervous system disorders                        |                |               |                |
| Epilepsy                                        |                |               |                |
| subjects affected / exposed                     | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (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          |
| Blood and lymphatic system disorders            |                |               |                |
| Anaemia                                         |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Gastrointestinal disorders                      |                |               |                |
| Dental caries                                   |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Diarrhoea                                       |                |               |                |
| subjects affected / exposed                     | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (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          |
| Intestinal obstruction                          |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Melaena                                         |                |               |                |



|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                |               |                |
| Dermatomyositis                                 |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Renal and urinary disorders                     |                |               |                |
| Renal colic                                     |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Azotaemia                                       |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Acute kidney injury                             |                |               |                |
| subjects affected / exposed                     | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (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          |
| Musculoskeletal and connective tissue disorders |                |               |                |
| Myositis                                        |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Infections and infestations                     |                |               |                |
| Bronchiolitis                                   |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Adenovirus infection                            |                |               |                |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Device related infection                        |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Gastroenteritis                                 |                |               |                |
| subjects affected / exposed                     | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (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          |
| Gangrene                                        |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Epstein-Barr virus infection                    |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Herpes zoster                                   |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Urinary tract infection                         |                |               |                |
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Rhinovirus infection                            |                |               |                |
| subjects affected / exposed                     | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Respiratory syncytial virus infection           |                |               |                |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Metabolism and nutrition disorders              |                |               |                |
| Hyponatraemia                                   |                |               |                |
| subjects affected / exposed                     | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |

| <b>Serious adverse events</b>                        | 12 to <18 Years with Immunomodulatory Therapy | 12 to <18 Years with Solid Organ Transplant | 12 to <18 Years with Stem Cell Transplant |
|------------------------------------------------------|-----------------------------------------------|---------------------------------------------|-------------------------------------------|
| Total subjects affected by serious adverse events    |                                               |                                             |                                           |
| subjects affected / exposed                          | 0 / 7 (0.00%)                                 | 0 / 1 (0.00%)                               | 0 / 7 (0.00%)                             |
| number of deaths (all causes)                        | 0                                             | 0                                           | 0                                         |
| number of deaths resulting from adverse events       | 0                                             | 0                                           | 0                                         |
| Vascular disorders                                   |                                               |                                             |                                           |
| Hypertension                                         |                                               |                                             |                                           |
| subjects affected / exposed                          | 0 / 7 (0.00%)                                 | 0 / 1 (0.00%)                               | 0 / 7 (0.00%)                             |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0                                       | 0 / 0                                     |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0                                       | 0 / 0                                     |
| Surgical and medical procedures                      |                                               |                                             |                                           |
| Catheter removal                                     |                                               |                                             |                                           |
| subjects affected / exposed                          | 0 / 7 (0.00%)                                 | 0 / 1 (0.00%)                               | 0 / 7 (0.00%)                             |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0                                       | 0 / 0                                     |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0                                       | 0 / 0                                     |
| General disorders and administration site conditions |                                               |                                             |                                           |
| Influenza like illness                               |                                               |                                             |                                           |
| subjects affected / exposed                          | 0 / 7 (0.00%)                                 | 0 / 1 (0.00%)                               | 0 / 7 (0.00%)                             |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0                                       | 0 / 0                                     |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0                                       | 0 / 0                                     |
| Pyrexia                                              |                                               |                                             |                                           |
| subjects affected / exposed                          | 0 / 7 (0.00%)                                 | 0 / 1 (0.00%)                               | 0 / 7 (0.00%)                             |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0                                       | 0 / 0                                     |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0                                       | 0 / 0                                     |
| Immune system disorders                              |                                               |                                             |                                           |

|                                                 |               |               |               |
|-------------------------------------------------|---------------|---------------|---------------|
| Anaphylactic reaction                           |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Kidney transplant rejection                     |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Respiratory, thoracic and mediastinal disorders |               |               |               |
| Pulmonary vein stenosis                         |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Injury, poisoning and procedural complications  |               |               |               |
| Arthropod sting                                 |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Postoperative ileus                             |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Nervous system disorders                        |               |               |               |
| Epilepsy                                        |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Blood and lymphatic system disorders            |               |               |               |
| Anaemia                                         |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Gastrointestinal disorders                      |               |               |               |
| Dental caries                                   |               |               |               |

|                                                 |               |               |               |
|-------------------------------------------------|---------------|---------------|---------------|
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Diarrhoea                                       |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Intestinal obstruction                          |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Melaena                                         |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Skin and subcutaneous tissue disorders          |               |               |               |
| Dermatomyositis                                 |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Renal and urinary disorders                     |               |               |               |
| Renal colic                                     |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Azotaemia                                       |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Acute kidney injury                             |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Musculoskeletal and connective tissue           |               |               |               |

|                                                 |               |               |               |
|-------------------------------------------------|---------------|---------------|---------------|
| disorders                                       |               |               |               |
| Myositis                                        |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Infections and infestations                     |               |               |               |
| Bronchiolitis                                   |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Adenovirus infection                            |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Device related infection                        |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Gastroenteritis                                 |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Gangrene                                        |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Epstein-Barr virus infection                    |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Herpes zoster                                   |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |

|                                                 |               |               |               |
|-------------------------------------------------|---------------|---------------|---------------|
| Urinary tract infection                         |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Rhinovirus infection                            |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Respiratory syncytial virus infection           |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Metabolism and nutrition disorders              |               |               |               |
| Hyponatraemia                                   |               |               |               |
| subjects affected / exposed                     | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |

| <b>Serious adverse events</b>                        | <b>&gt;=18 Years with Immunomodulatory Therapy</b> | <b>&gt;=18 Years with Non-Small Cell Lung Cancer</b> | <b>&gt;= 18 Years with Haemodialysis</b> |
|------------------------------------------------------|----------------------------------------------------|------------------------------------------------------|------------------------------------------|
| Total subjects affected by serious adverse events    |                                                    |                                                      |                                          |
| subjects affected / exposed                          | 1 / 5 (20.00%)                                     | 0 / 1 (0.00%)                                        | 1 / 1 (100.00%)                          |
| number of deaths (all causes)                        | 0                                                  | 0                                                    | 0                                        |
| number of deaths resulting from adverse events       | 0                                                  | 0                                                    | 0                                        |
| Vascular disorders                                   |                                                    |                                                      |                                          |
| Hypertension                                         |                                                    |                                                      |                                          |
| subjects affected / exposed                          | 0 / 5 (0.00%)                                      | 0 / 1 (0.00%)                                        | 0 / 1 (0.00%)                            |
| occurrences causally related to treatment / all      | 0 / 0                                              | 0 / 0                                                | 0 / 0                                    |
| deaths causally related to treatment / all           | 0 / 0                                              | 0 / 0                                                | 0 / 0                                    |
| Surgical and medical procedures                      |                                                    |                                                      |                                          |
| Catheter removal                                     |                                                    |                                                      |                                          |
| subjects affected / exposed                          | 0 / 5 (0.00%)                                      | 0 / 1 (0.00%)                                        | 0 / 1 (0.00%)                            |
| occurrences causally related to treatment / all      | 0 / 0                                              | 0 / 0                                                | 0 / 0                                    |
| deaths causally related to treatment / all           | 0 / 0                                              | 0 / 0                                                | 0 / 0                                    |
| General disorders and administration site conditions |                                                    |                                                      |                                          |

|                                                 |               |               |               |
|-------------------------------------------------|---------------|---------------|---------------|
| Influenza like illness                          |               |               |               |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Pyrexia                                         |               |               |               |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Immune system disorders                         |               |               |               |
| Anaphylactic reaction                           |               |               |               |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Kidney transplant rejection                     |               |               |               |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Respiratory, thoracic and mediastinal disorders |               |               |               |
| Pulmonary vein stenosis                         |               |               |               |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Injury, poisoning and procedural complications  |               |               |               |
| Arthropod sting                                 |               |               |               |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Postoperative ileus                             |               |               |               |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Nervous system disorders                        |               |               |               |
| Epilepsy                                        |               |               |               |



|                                                 |               |               |                 |
|-------------------------------------------------|---------------|---------------|-----------------|
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Blood and lymphatic system disorders            |               |               |                 |
| Anaemia                                         |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Gastrointestinal disorders                      |               |               |                 |
| Dental caries                                   |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Diarrhoea                                       |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Intestinal obstruction                          |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Melaena                                         |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Skin and subcutaneous tissue disorders          |               |               |                 |
| Dermatomyositis                                 |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Renal and urinary disorders                     |               |               |                 |
| Renal colic                                     |               |               |                 |

|                                                 |                |               |                 |
|-------------------------------------------------|----------------|---------------|-----------------|
| subjects affected / exposed                     | 1 / 5 (20.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Azotaemia                                       |                |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Acute kidney injury                             |                |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Musculoskeletal and connective tissue disorders |                |               |                 |
| Myositis                                        |                |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Infections and infestations                     |                |               |                 |
| Bronchiolitis                                   |                |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Adenovirus infection                            |                |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Device related infection                        |                |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Gastroenteritis                                 |                |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |

|                                                 |               |               |                 |
|-------------------------------------------------|---------------|---------------|-----------------|
| Gangrene                                        |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Epstein-Barr virus infection                    |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Herpes zoster                                   |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Urinary tract infection                         |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Rhinovirus infection                            |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Respiratory syncytial virus infection           |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |
| Metabolism and nutrition disorders              |               |               |                 |
| Hyponatraemia                                   |               |               |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0           |

Frequency threshold for reporting non-serious adverse events: 1 %

| <b>Non-serious adverse events</b>                                   | <b>2 to &lt; 5 Years with Solid Organ Transplant</b> | <b>2 to &lt; 5 Years with Stem Cell Transplant</b> | <b>5 to &lt;12 Years with Immunomodulatory Therapy</b> |
|---------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------------|--------------------------------------------------------|
| Total subjects affected by non-serious adverse events               |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 13 / 15 (86.67%)                                     | 10 / 13 (76.92%)                                   | 18 / 19 (94.74%)                                       |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                      |                                                    |                                                        |
| Metastases to bone                                                  |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 0 / 15 (0.00%)                                       | 0 / 13 (0.00%)                                     | 0 / 19 (0.00%)                                         |
| occurrences (all)                                                   | 0                                                    | 0                                                  | 0                                                      |
| General disorders and administration site conditions                |                                                      |                                                    |                                                        |
| Fatigue (FATIGUE)                                                   |                                                      |                                                    |                                                        |
| alternative assessment type: Systematic                             |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 3 / 15 (20.00%)                                      | 3 / 13 (23.08%)                                    | 14 / 19 (73.68%)                                       |
| occurrences (all)                                                   | 3                                                    | 3                                                  | 34                                                     |
| Erythema (REDNESS)                                                  |                                                      |                                                    |                                                        |
| alternative assessment type: Systematic                             |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 3 / 15 (20.00%)                                      | 0 / 13 (0.00%)                                     | 7 / 19 (36.84%)                                        |
| occurrences (all)                                                   | 5                                                    | 0                                                  | 10                                                     |
| Chills (CHILLS)                                                     |                                                      |                                                    |                                                        |
| alternative assessment type: Systematic                             |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 1 / 15 (6.67%)                                       | 1 / 13 (7.69%)                                     | 7 / 19 (36.84%)                                        |
| occurrences (all)                                                   | 1                                                    | 1                                                  | 9                                                      |
| Chills                                                              |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 0 / 15 (0.00%)                                       | 0 / 13 (0.00%)                                     | 0 / 19 (0.00%)                                         |
| occurrences (all)                                                   | 0                                                    | 0                                                  | 0                                                      |
| Chest pain                                                          |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 0 / 15 (0.00%)                                       | 0 / 13 (0.00%)                                     | 1 / 19 (5.26%)                                         |
| occurrences (all)                                                   | 0                                                    | 0                                                  | 1                                                      |
| Medical device site inflammation                                    |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 1 / 15 (6.67%)                                       | 0 / 13 (0.00%)                                     | 0 / 19 (0.00%)                                         |
| occurrences (all)                                                   | 1                                                    | 0                                                  | 0                                                      |
| Pyrexia                                                             |                                                      |                                                    |                                                        |
| subjects affected / exposed                                         | 2 / 15 (13.33%)                                      | 1 / 13 (7.69%)                                     | 0 / 19 (0.00%)                                         |
| occurrences (all)                                                   | 2                                                    | 1                                                  | 0                                                      |
| Injection site pain (PAIN AT INJECTION SITE)                        |                                                      |                                                    |                                                        |
| alternative assessment type: Systematic                             |                                                      |                                                    |                                                        |

|                                                                                                                       |                      |                      |                        |
|-----------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)                                                                      | 3 / 15 (20.00%)<br>6 | 4 / 13 (30.77%)<br>4 | 16 / 19 (84.21%)<br>50 |
| Injection site pain<br>subjects affected / exposed<br>occurrences (all)                                               | 1 / 15 (6.67%)<br>1  | 1 / 13 (7.69%)<br>2  | 1 / 19 (5.26%)<br>1    |
| Injection site erythema<br>subjects affected / exposed<br>occurrences (all)                                           | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 0 / 19 (0.00%)<br>0    |
| Injection site bruising<br>subjects affected / exposed<br>occurrences (all)                                           | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 0 / 19 (0.00%)<br>0    |
| Pyrexia (FEVER)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)     | 1 / 15 (6.67%)<br>1  | 2 / 13 (15.38%)<br>2 | 2 / 19 (10.53%)<br>4   |
| Swelling (SWELLING)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 1 / 15 (6.67%)<br>2  | 1 / 13 (7.69%)<br>1  | 5 / 19 (26.32%)<br>8   |
| Reproductive system and breast disorders<br>Breast enlargement<br>subjects affected / exposed<br>occurrences (all)    | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 1 / 19 (5.26%)<br>1    |
| Breast pain<br>subjects affected / exposed<br>occurrences (all)                                                       | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 1 / 19 (5.26%)<br>1    |
| Respiratory, thoracic and mediastinal disorders<br>Dyspnoea<br>subjects affected / exposed<br>occurrences (all)       | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 1 / 19 (5.26%)<br>1    |
| Cough<br>subjects affected / exposed<br>occurrences (all)                                                             | 1 / 15 (6.67%)<br>1  | 0 / 13 (0.00%)<br>0  | 0 / 19 (0.00%)<br>0    |
| Psychiatric disorders                                                                                                 |                      |                      |                        |

|                                                                                                                                                                |                     |                     |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------|
| Attention deficit hyperactivity disorder<br>subjects affected / exposed<br>occurrences (all)                                                                   | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Investigations<br>Body temperature increased<br>subjects affected / exposed<br>occurrences (all)                                                               | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 1 / 19 (5.26%)<br>1 |
| Blood iron decreased<br>subjects affected / exposed<br>occurrences (all)                                                                                       | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 1 / 19 (5.26%)<br>1 |
| Donor specific antibody present<br>subjects affected / exposed<br>occurrences (all)                                                                            | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Injury, poisoning and procedural complications<br>Radius fracture<br>subjects affected / exposed<br>occurrences (all)                                          | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Foreign body in eye<br>subjects affected / exposed<br>occurrences (all)                                                                                        | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 1 / 19 (5.26%)<br>1 |
| Fall<br>subjects affected / exposed<br>occurrences (all)                                                                                                       | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Skin abrasion<br>subjects affected / exposed<br>occurrences (all)                                                                                              | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 1 / 19 (5.26%)<br>1 |
| Congenital, familial and genetic disorders<br>Tumour necrosis factor receptor-associated periodic syndrome<br>subjects affected / exposed<br>occurrences (all) | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 1 / 19 (5.26%)<br>1 |
| Cardiac disorders<br>Palpitations<br>subjects affected / exposed<br>occurrences (all)                                                                          | 0 / 15 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 | 1 / 19 (5.26%)<br>1 |
| Nervous system disorders                                                                                                                                       |                     |                     |                     |

|                                            |                |                |                  |
|--------------------------------------------|----------------|----------------|------------------|
| Headache                                   |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)   |
| occurrences (all)                          | 0              | 0              | 0                |
| Dizziness                                  |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)   |
| occurrences (all)                          | 0              | 0              | 0                |
| Headache (HEADACHE)                        |                |                |                  |
| alternative assessment type:<br>Systematic |                |                |                  |
| subjects affected / exposed                | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 11 / 19 (57.89%) |
| occurrences (all)                          | 1              | 0              | 25               |
| Blood and lymphatic system disorders       |                |                |                  |
| Neutropenia                                |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)   |
| occurrences (all)                          | 0              | 0              | 0                |
| Lymphadenopathy                            |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%)   |
| occurrences (all)                          | 0              | 0              | 1                |
| Lymphadenitis                              |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)   |
| occurrences (all)                          | 0              | 0              | 0                |
| Leukopenia                                 |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)   |
| occurrences (all)                          | 0              | 0              | 0                |
| Ear and labyrinth disorders                |                |                |                  |
| Ear pain                                   |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%)   |
| occurrences (all)                          | 0              | 0              | 1                |
| Eye disorders                              |                |                |                  |
| Amblyopia                                  |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 1 / 13 (7.69%) | 0 / 19 (0.00%)   |
| occurrences (all)                          | 0              | 1              | 0                |
| Eye inflammation                           |                |                |                  |
| subjects affected / exposed                | 0 / 15 (0.00%) | 1 / 13 (7.69%) | 1 / 19 (5.26%)   |
| occurrences (all)                          | 0              | 1              | 1                |
| Eye discharge                              |                |                |                  |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all)           | 0              | 0              | 1              |
| Eye irritation              |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Ocular discomfort           |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all)           | 0              | 0              | 1              |
| Eye pain                    |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all)           | 0              | 0              | 1              |
| Photophobia                 |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all)           | 0              | 0              | 1              |
| Uveitis                     |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Gastrointestinal disorders  |                |                |                |
| Abdominal pain upper        |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all)           | 0              | 0              | 1              |
| Abdominal pain              |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Gastritis                   |                |                |                |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Diarrhoea                   |                |                |                |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Dental caries               |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all)           | 0              | 0              | 1              |
| Crohn's disease             |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all)           | 0              | 0              | 1              |



|                                                                                                                        |                      |                      |                      |
|------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|----------------------|
| Vomiting (VOMITING)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)  | 3 / 15 (20.00%)<br>4 | 4 / 13 (30.77%)<br>4 | 2 / 19 (10.53%)<br>2 |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                                                           | 1 / 15 (6.67%)<br>1  | 0 / 13 (0.00%)<br>0  | 0 / 19 (0.00%)<br>0  |
| Diarrhoea (DIARRHEA)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 3 / 15 (20.00%)<br>4 | 2 / 13 (15.38%)<br>2 | 5 / 19 (26.32%)<br>8 |
| Hepatobiliary disorders<br>Cholelithiasis<br>subjects affected / exposed<br>occurrences (all)                          | 1 / 15 (6.67%)<br>1  | 0 / 13 (0.00%)<br>0  | 0 / 19 (0.00%)<br>0  |
| Skin and subcutaneous tissue disorders<br>Acne<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 1 / 19 (5.26%)<br>1  |
| Dermatitis<br>subjects affected / exposed<br>occurrences (all)                                                         | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 1 / 19 (5.26%)<br>1  |
| Purpura<br>subjects affected / exposed<br>occurrences (all)                                                            | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 0 / 19 (0.00%)<br>0  |
| Rash<br>subjects affected / exposed<br>occurrences (all)                                                               | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 1 / 19 (5.26%)<br>1  |
| Rash erythematous<br>subjects affected / exposed<br>occurrences (all)                                                  | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 0 / 19 (0.00%)<br>0  |
| Musculoskeletal and connective tissue disorders<br>Synovitis<br>subjects affected / exposed<br>occurrences (all)       | 0 / 15 (0.00%)<br>0  | 0 / 13 (0.00%)<br>0  | 0 / 19 (0.00%)<br>0  |
| Muscular weakness                                                                                                      |                      |                      |                      |

|                                              |                |                |                 |
|----------------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed                  | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)  |
| occurrences (all)                            | 0              | 0              | 0               |
| Myalgia (NEW OR WORSENERED<br>MUSCLE PAIN)   |                |                |                 |
| alternative assessment type:<br>Systematic   |                |                |                 |
| subjects affected / exposed                  | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 6 / 19 (31.58%) |
| occurrences (all)                            | 1              | 0              | 10              |
| Arthralgia (NEW OR WORSENERED<br>JOINT PAIN) |                |                |                 |
| alternative assessment type:<br>Systematic   |                |                |                 |
| subjects affected / exposed                  | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 4 / 19 (21.05%) |
| occurrences (all)                            | 0              | 0              | 10              |
| Infections and infestations                  |                |                |                 |
| Conjunctivitis                               |                |                |                 |
| subjects affected / exposed                  | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)  |
| occurrences (all)                            | 1              | 0              | 0               |
| Clostridium difficile colitis                |                |                |                 |
| subjects affected / exposed                  | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)  |
| occurrences (all)                            | 1              | 0              | 0               |
| Dengue fever                                 |                |                |                 |
| subjects affected / exposed                  | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)  |
| occurrences (all)                            | 1              | 0              | 0               |
| Cytomegalovirus viraemia                     |                |                |                 |
| subjects affected / exposed                  | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)  |
| occurrences (all)                            | 1              | 0              | 0               |
| Gastroenteritis                              |                |                |                 |
| subjects affected / exposed                  | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 1 / 19 (5.26%)  |
| occurrences (all)                            | 1              | 0              | 1               |
| Gastrointestinal infection                   |                |                |                 |
| subjects affected / exposed                  | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)  |
| occurrences (all)                            | 0              | 0              | 0               |
| Impetigo                                     |                |                |                 |
| subjects affected / exposed                  | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%)  |
| occurrences (all)                            | 0              | 0              | 0               |
| Influenza                                    |                |                |                 |

|                                   |                 |                |                |
|-----------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed       | 1 / 15 (6.67%)  | 1 / 13 (7.69%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 1               | 1              | 0              |
| Epstein-Barr viraemia             |                 |                |                |
| subjects affected / exposed       | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 1               | 0              | 0              |
| Stoma site cellulitis             |                 |                |                |
| subjects affected / exposed       | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 1               | 0              | 0              |
| Sinusitis                         |                 |                |                |
| subjects affected / exposed       | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Pharyngitis streptococcal         |                 |                |                |
| subjects affected / exposed       | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Otitis media chronic              |                 |                |                |
| subjects affected / exposed       | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Otitis media                      |                 |                |                |
| subjects affected / exposed       | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all)                 | 1               | 0              | 1              |
| Otitis externa                    |                 |                |                |
| subjects affected / exposed       | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Nasopharyngitis                   |                 |                |                |
| subjects affected / exposed       | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 1               | 0              | 0              |
| Urinary tract infection           |                 |                |                |
| subjects affected / exposed       | 3 / 15 (20.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 3               | 0              | 0              |
| Upper respiratory tract infection |                 |                |                |
| subjects affected / exposed       | 0 / 15 (0.00%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Tracheitis                        |                 |                |                |
| subjects affected / exposed       | 1 / 15 (6.67%)  | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                 | 2               | 0              | 0              |
| Tooth infection                   |                 |                |                |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Tonsillitis                 |                |                |                |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Vulvovaginitis              |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Viral sinusitis             |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Viral rhinitis              |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Viral rash                  |                |                |                |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 13 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |

| <b>Non-serious adverse events</b>                                   | 5 to <12 Years with Solid Organ Transplant | 2 to <5 Years with Immunomodulatory Therapy | 5 to <12 Years with Stem Cell Transplant |
|---------------------------------------------------------------------|--------------------------------------------|---------------------------------------------|------------------------------------------|
| Total subjects affected by non-serious adverse events               |                                            |                                             |                                          |
| subjects affected / exposed                                         | 23 / 24 (95.83%)                           | 8 / 9 (88.89%)                              | 22 / 22 (100.00%)                        |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                            |                                             |                                          |
| Metastases to bone                                                  |                                            |                                             |                                          |
| subjects affected / exposed                                         | 0 / 24 (0.00%)                             | 0 / 9 (0.00%)                               | 0 / 22 (0.00%)                           |
| occurrences (all)                                                   | 0                                          | 0                                           | 0                                        |
| General disorders and administration site conditions                |                                            |                                             |                                          |
| Fatigue (FATIGUE)                                                   |                                            |                                             |                                          |
| alternative assessment type: Systematic                             |                                            |                                             |                                          |
| subjects affected / exposed                                         | 17 / 24 (70.83%)                           | 3 / 9 (33.33%)                              | 14 / 22 (63.64%)                         |
| occurrences (all)                                                   | 31                                         | 4                                           | 31                                       |
| Erythema (REDNESS)                                                  |                                            |                                             |                                          |
| alternative assessment type: Systematic                             |                                            |                                             |                                          |
| subjects affected / exposed                                         | 5 / 24 (20.83%)                            | 3 / 9 (33.33%)                              | 6 / 22 (27.27%)                          |
| occurrences (all)                                                   | 7                                          | 4                                           | 13                                       |
| Chills (CHILLS)                                                     |                                            |                                             |                                          |

|                                                 |                  |                |                  |
|-------------------------------------------------|------------------|----------------|------------------|
| alternative assessment type:<br>Systematic      |                  |                |                  |
| subjects affected / exposed                     | 3 / 24 (12.50%)  | 2 / 9 (22.22%) | 5 / 22 (22.73%)  |
| occurrences (all)                               | 3                | 2              | 7                |
| Chills                                          |                  |                |                  |
| subjects affected / exposed                     | 0 / 24 (0.00%)   | 0 / 9 (0.00%)  | 0 / 22 (0.00%)   |
| occurrences (all)                               | 0                | 0              | 0                |
| Chest pain                                      |                  |                |                  |
| subjects affected / exposed                     | 0 / 24 (0.00%)   | 0 / 9 (0.00%)  | 0 / 22 (0.00%)   |
| occurrences (all)                               | 0                | 0              | 0                |
| Medical device site inflammation                |                  |                |                  |
| subjects affected / exposed                     | 0 / 24 (0.00%)   | 0 / 9 (0.00%)  | 0 / 22 (0.00%)   |
| occurrences (all)                               | 0                | 0              | 0                |
| Pyrexia                                         |                  |                |                  |
| subjects affected / exposed                     | 0 / 24 (0.00%)   | 0 / 9 (0.00%)  | 0 / 22 (0.00%)   |
| occurrences (all)                               | 0                | 0              | 0                |
| Injection site pain (PAIN AT<br>INJECTION SITE) |                  |                |                  |
| alternative assessment type:<br>Systematic      |                  |                |                  |
| subjects affected / exposed                     | 18 / 24 (75.00%) | 4 / 9 (44.44%) | 19 / 22 (86.36%) |
| occurrences (all)                               | 43               | 6              | 40               |
| Injection site pain                             |                  |                |                  |
| subjects affected / exposed                     | 0 / 24 (0.00%)   | 0 / 9 (0.00%)  | 1 / 22 (4.55%)   |
| occurrences (all)                               | 0                | 0              | 2                |
| Injection site erythema                         |                  |                |                  |
| subjects affected / exposed                     | 0 / 24 (0.00%)   | 0 / 9 (0.00%)  | 1 / 22 (4.55%)   |
| occurrences (all)                               | 0                | 0              | 1                |
| Injection site bruising                         |                  |                |                  |
| subjects affected / exposed                     | 1 / 24 (4.17%)   | 0 / 9 (0.00%)  | 0 / 22 (0.00%)   |
| occurrences (all)                               | 1                | 0              | 0                |
| Pyrexia (FEVER)                                 |                  |                |                  |
| alternative assessment type:<br>Systematic      |                  |                |                  |
| subjects affected / exposed                     | 2 / 24 (8.33%)   | 2 / 9 (22.22%) | 5 / 22 (22.73%)  |
| occurrences (all)                               | 2                | 3              | 6                |
| Swelling (SWELLING)                             |                  |                |                  |
| alternative assessment type:<br>Systematic      |                  |                |                  |

|                                                                                                                                                                                                                                                                             |                                                                                   |                                                                                |                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                            | 4 / 24 (16.67%)<br>6                                                              | 1 / 9 (11.11%)<br>2                                                            | 8 / 22 (36.36%)<br>17                                                             |
| Reproductive system and breast disorders<br>Breast enlargement<br>subjects affected / exposed<br>occurrences (all)<br><br>Breast pain<br>subjects affected / exposed<br>occurrences (all)                                                                                   | <br><br>0 / 24 (0.00%)<br>0<br><br>0 / 24 (0.00%)<br>0                            | <br><br>0 / 9 (0.00%)<br>0<br><br>0 / 9 (0.00%)<br>0                           | <br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0                            |
| Respiratory, thoracic and mediastinal disorders<br>Dyspnoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Cough<br>subjects affected / exposed<br>occurrences (all)                                                                                            | <br><br>0 / 24 (0.00%)<br>0<br><br>0 / 24 (0.00%)<br>0                            | <br><br>0 / 9 (0.00%)<br>0<br><br>0 / 9 (0.00%)<br>0                           | <br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0                            |
| Psychiatric disorders<br>Attention deficit hyperactivity disorder<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                       | <br><br>0 / 24 (0.00%)<br>0                                                       | <br><br>0 / 9 (0.00%)<br>0                                                     | <br><br>1 / 22 (4.55%)<br>1                                                       |
| Investigations<br>Body temperature increased<br>subjects affected / exposed<br>occurrences (all)<br><br>Blood iron decreased<br>subjects affected / exposed<br>occurrences (all)<br><br>Donor specific antibody present<br>subjects affected / exposed<br>occurrences (all) | <br><br>0 / 24 (0.00%)<br>0<br><br>0 / 24 (0.00%)<br>0<br><br>1 / 24 (4.17%)<br>1 | <br><br>0 / 9 (0.00%)<br>0<br><br>0 / 9 (0.00%)<br>0<br><br>0 / 9 (0.00%)<br>0 | <br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0 |
| Injury, poisoning and procedural complications<br>Radius fracture<br>subjects affected / exposed<br>occurrences (all)<br><br>Foreign body in eye                                                                                                                            | <br><br>0 / 24 (0.00%)<br>0<br><br>                                               | <br><br>1 / 9 (11.11%)<br>1<br><br>                                            | <br><br>0 / 22 (0.00%)<br>0<br><br>                                               |

|                                                                                                                                                                |                        |                     |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------------|-----------------------|
| subjects affected / exposed<br>occurrences (all)                                                                                                               | 0 / 24 (0.00%)<br>0    | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0   |
| Fall<br>subjects affected / exposed<br>occurrences (all)                                                                                                       | 0 / 24 (0.00%)<br>0    | 1 / 9 (11.11%)<br>1 | 0 / 22 (0.00%)<br>0   |
| Skin abrasion<br>subjects affected / exposed<br>occurrences (all)                                                                                              | 0 / 24 (0.00%)<br>0    | 1 / 9 (11.11%)<br>1 | 0 / 22 (0.00%)<br>0   |
| Congenital, familial and genetic disorders<br>Tumour necrosis factor receptor-associated periodic syndrome<br>subjects affected / exposed<br>occurrences (all) | 0 / 24 (0.00%)<br>0    | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0   |
| Cardiac disorders<br>Palpitations<br>subjects affected / exposed<br>occurrences (all)                                                                          | 0 / 24 (0.00%)<br>0    | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0   |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)                                                                       | 0 / 24 (0.00%)<br>0    | 0 / 9 (0.00%)<br>0  | 1 / 22 (4.55%)<br>1   |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                                                                                                  | 0 / 24 (0.00%)<br>0    | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0   |
| Headache (HEADACHE)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all)                                             | 11 / 24 (45.83%)<br>16 | 0 / 9 (0.00%)<br>0  | 9 / 22 (40.91%)<br>17 |
| Blood and lymphatic system disorders<br>Neutropenia<br>subjects affected / exposed<br>occurrences (all)                                                        | 0 / 24 (0.00%)<br>0    | 1 / 9 (11.11%)<br>1 | 0 / 22 (0.00%)<br>0   |
| Lymphadenopathy<br>subjects affected / exposed<br>occurrences (all)                                                                                            | 0 / 24 (0.00%)<br>0    | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0   |
| Lymphadenitis                                                                                                                                                  |                        |                     |                       |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Leukopenia                  |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 9 (11.11%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Ear and labyrinth disorders |                |                |                |
| Ear pain                    |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Eye disorders               |                |                |                |
| Amblyopia                   |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Eye inflammation            |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Eye discharge               |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Eye irritation              |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%)  | 1 / 22 (4.55%) |
| occurrences (all)           | 0              | 0              | 1              |
| Ocular discomfort           |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Eye pain                    |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Photophobia                 |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Uveitis                     |                |                |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 9 (11.11%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 2              | 0              |
| Gastrointestinal disorders  |                |                |                |



|                                                                                                                        |                      |                     |                     |
|------------------------------------------------------------------------------------------------------------------------|----------------------|---------------------|---------------------|
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)                                               | 0 / 24 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 1 / 22 (4.55%)<br>1 |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)                                                     | 2 / 24 (8.33%)<br>2  | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0 |
| Gastritis<br>subjects affected / exposed<br>occurrences (all)                                                          | 0 / 24 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0 |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                                                          | 1 / 24 (4.17%)<br>1  | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0 |
| Dental caries<br>subjects affected / exposed<br>occurrences (all)                                                      | 0 / 24 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0 |
| Crohn's disease<br>subjects affected / exposed<br>occurrences (all)                                                    | 0 / 24 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0 |
| Vomiting (VOMITING)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)  | 4 / 24 (16.67%)<br>5 | 1 / 9 (11.11%)<br>1 | 1 / 22 (4.55%)<br>1 |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                                                           | 2 / 24 (8.33%)<br>2  | 1 / 9 (11.11%)<br>1 | 2 / 22 (9.09%)<br>2 |
| Diarrhoea (DIARRHEA)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 5 / 24 (20.83%)<br>5 | 2 / 9 (22.22%)<br>2 | 2 / 22 (9.09%)<br>4 |
| Hepatobiliary disorders<br>Cholelithiasis<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 24 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 0 / 22 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>Acne                                                                         |                      |                     |                     |

|                                                 |                 |                |                 |
|-------------------------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Dermatitis                                      |                 |                |                 |
| subjects affected / exposed                     | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Purpura                                         |                 |                |                 |
| subjects affected / exposed                     | 0 / 24 (0.00%)  | 1 / 9 (11.11%) | 0 / 22 (0.00%)  |
| occurrences (all)                               | 0               | 1              | 0               |
| Rash                                            |                 |                |                 |
| subjects affected / exposed                     | 1 / 24 (4.17%)  | 1 / 9 (11.11%) | 0 / 22 (0.00%)  |
| occurrences (all)                               | 1               | 1              | 0               |
| Rash erythematous                               |                 |                |                 |
| subjects affected / exposed                     | 0 / 24 (0.00%)  | 1 / 9 (11.11%) | 0 / 22 (0.00%)  |
| occurrences (all)                               | 0               | 1              | 0               |
| Musculoskeletal and connective tissue disorders |                 |                |                 |
| Synovitis                                       |                 |                |                 |
| subjects affected / exposed                     | 0 / 24 (0.00%)  | 1 / 9 (11.11%) | 0 / 22 (0.00%)  |
| occurrences (all)                               | 0               | 1              | 0               |
| Muscular weakness                               |                 |                |                 |
| subjects affected / exposed                     | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Myalgia (NEW OR WORSENERED MUSCLE PAIN)         |                 |                |                 |
| alternative assessment type: Systematic         |                 |                |                 |
| subjects affected / exposed                     | 8 / 24 (33.33%) | 1 / 9 (11.11%) | 3 / 22 (13.64%) |
| occurrences (all)                               | 10              | 1              | 3               |
| Arthralgia (NEW OR WORSENERED JOINT PAIN)       |                 |                |                 |
| alternative assessment type: Systematic         |                 |                |                 |
| subjects affected / exposed                     | 2 / 24 (8.33%)  | 1 / 9 (11.11%) | 3 / 22 (13.64%) |
| occurrences (all)                               | 2               | 1              | 3               |
| Infections and infestations                     |                 |                |                 |
| Conjunctivitis                                  |                 |                |                 |
| subjects affected / exposed                     | 2 / 24 (8.33%)  | 0 / 9 (0.00%)  | 1 / 22 (4.55%)  |
| occurrences (all)                               | 2               | 0              | 1               |
| Clostridium difficile colitis                   |                 |                |                 |

|                             |                |               |                |
|-----------------------------|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0             | 0              |
| Dengue fever                |                |               |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0             | 0              |
| Cytomegalovirus viraemia    |                |               |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0             | 0              |
| Gastroenteritis             |                |               |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0             | 0              |
| Gastrointestinal infection  |                |               |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all)           | 0              | 0             | 1              |
| Impetigo                    |                |               |                |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 1              | 0             | 0              |
| Influenza                   |                |               |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0             | 0              |
| Epstein-Barr viraemia       |                |               |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0             | 0              |
| Stoma site cellulitis       |                |               |                |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 0              | 0             | 0              |
| Sinusitis                   |                |               |                |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 1              | 0             | 0              |
| Pharyngitis streptococcal   |                |               |                |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 1              | 0             | 0              |
| Otitis media chronic        |                |               |                |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 9 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all)           | 1              | 0             | 0              |
| Otitis media                |                |               |                |

|                                   |                 |                |                |
|-----------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed       | 0 / 24 (0.00%)  | 1 / 9 (11.11%) | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 1              | 0              |
| Otitis externa                    |                 |                |                |
| subjects affected / exposed       | 3 / 24 (12.50%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)                 | 3               | 0              | 0              |
| Nasopharyngitis                   |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Urinary tract infection           |                 |                |                |
| subjects affected / exposed       | 3 / 24 (12.50%) | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)                 | 6               | 0              | 0              |
| Upper respiratory tract infection |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Tracheitis                        |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Tooth infection                   |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Tonsillitis                       |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Vulvovaginitis                    |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 0 / 9 (0.00%)  | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 0              | 0              |
| Viral sinusitis                   |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 1 / 9 (11.11%) | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 1              | 0              |
| Viral rhinitis                    |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 1 / 9 (11.11%) | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 1              | 0              |
| Viral rash                        |                 |                |                |
| subjects affected / exposed       | 0 / 24 (0.00%)  | 1 / 9 (11.11%) | 0 / 22 (0.00%) |
| occurrences (all)                 | 0               | 1              | 0              |

| <b>Non-serious adverse events</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 12 to <18 Years with Immunomodulatory Therapy                                                                                                                                                                 | 12 to <18 Years with Solid Organ Transplant                                                                                                                                        | 12 to <18 Years with Stem Cell Transplant                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 7 / 7 (100.00%)                                                                                                                                                                                               | 1 / 1 (100.00%)                                                                                                                                                                    | 6 / 7 (85.71%)                                                                                                                                                                       |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps)<br>Metastases to bone<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 0 / 7 (0.00%)<br>0                                                                                                                                                                                            | 0 / 1 (0.00%)<br>0                                                                                                                                                                 | 0 / 7 (0.00%)<br>0                                                                                                                                                                   |
| General disorders and administration site conditions<br>Fatigue (FATIGUE)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Erythema (REDNESS)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Chills (CHILLS)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Chills<br>subjects affected / exposed<br>occurrences (all)<br><br>Chest pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Medical device site inflammation<br>subjects affected / exposed<br>occurrences (all)<br><br>Pyrexia<br>subjects affected / exposed<br>occurrences (all)<br><br>Injection site pain (PAIN AT INJECTION SITE)<br>alternative assessment type: | 6 / 7 (85.71%)<br>18<br><br>3 / 7 (42.86%)<br>7<br><br>5 / 7 (71.43%)<br>10<br><br>0 / 7 (0.00%)<br>0<br><br>0 / 7 (0.00%)<br>0<br><br>0 / 7 (0.00%)<br>0<br><br>0 / 7 (0.00%)<br>0<br><br>0 / 7 (0.00%)<br>0 | 1 / 1 (100.00%)<br>2<br><br>0 / 1 (0.00%)<br>0<br><br>1 / 1 (100.00%)<br>1<br><br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0 | 5 / 7 (71.43%)<br>10<br><br>2 / 7 (28.57%)<br>4<br><br>1 / 7 (14.29%)<br>2<br><br>1 / 7 (14.29%)<br>1<br><br>0 / 7 (0.00%)<br>0<br><br>0 / 7 (0.00%)<br>0<br><br>1 / 7 (14.29%)<br>1 |

|                                                 |                |                 |                |
|-------------------------------------------------|----------------|-----------------|----------------|
| Systematic                                      |                |                 |                |
| subjects affected / exposed                     | 6 / 7 (85.71%) | 1 / 1 (100.00%) | 5 / 7 (71.43%) |
| occurrences (all)                               | 20             | 4               | 12             |
| Injection site pain                             |                |                 |                |
| subjects affected / exposed                     | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 1 / 7 (14.29%) |
| occurrences (all)                               | 0              | 0               | 1              |
| Injection site erythema                         |                |                 |                |
| subjects affected / exposed                     | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Injection site bruising                         |                |                 |                |
| subjects affected / exposed                     | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Pyrexia (FEVER)                                 |                |                 |                |
| alternative assessment type:<br>Systematic      |                |                 |                |
| subjects affected / exposed                     | 3 / 7 (42.86%) | 0 / 1 (0.00%)   | 3 / 7 (42.86%) |
| occurrences (all)                               | 7              | 0               | 3              |
| Swelling (SWELLING)                             |                |                 |                |
| alternative assessment type:<br>Systematic      |                |                 |                |
| subjects affected / exposed                     | 2 / 7 (28.57%) | 1 / 1 (100.00%) | 2 / 7 (28.57%) |
| occurrences (all)                               | 8              | 1               | 3              |
| Reproductive system and breast disorders        |                |                 |                |
| Breast enlargement                              |                |                 |                |
| subjects affected / exposed                     | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Breast pain                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Respiratory, thoracic and mediastinal disorders |                |                 |                |
| Dyspnoea                                        |                |                 |                |
| subjects affected / exposed                     | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Cough                                           |                |                 |                |
| subjects affected / exposed                     | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Psychiatric disorders                           |                |                 |                |

|                                                                                                                                                                |                    |                    |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|
| Attention deficit hyperactivity disorder<br>subjects affected / exposed<br>occurrences (all)                                                                   | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Investigations<br>Body temperature increased<br>subjects affected / exposed<br>occurrences (all)                                                               | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Blood iron decreased<br>subjects affected / exposed<br>occurrences (all)                                                                                       | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Donor specific antibody present<br>subjects affected / exposed<br>occurrences (all)                                                                            | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Injury, poisoning and procedural complications<br>Radius fracture<br>subjects affected / exposed<br>occurrences (all)                                          | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Foreign body in eye<br>subjects affected / exposed<br>occurrences (all)                                                                                        | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Fall<br>subjects affected / exposed<br>occurrences (all)                                                                                                       | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Skin abrasion<br>subjects affected / exposed<br>occurrences (all)                                                                                              | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Congenital, familial and genetic disorders<br>Tumour necrosis factor receptor-associated periodic syndrome<br>subjects affected / exposed<br>occurrences (all) | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Cardiac disorders<br>Palpitations<br>subjects affected / exposed<br>occurrences (all)                                                                          | 0 / 7 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0 |
| Nervous system disorders                                                                                                                                       |                    |                    |                    |

|                                            |                 |                 |                |
|--------------------------------------------|-----------------|-----------------|----------------|
| Headache                                   |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 1 / 7 (14.29%) |
| occurrences (all)                          | 0               | 0               | 4              |
| Dizziness                                  |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 1 / 7 (14.29%) |
| occurrences (all)                          | 0               | 0               | 1              |
| Headache (HEADACHE)                        |                 |                 |                |
| alternative assessment type:<br>Systematic |                 |                 |                |
| subjects affected / exposed                | 7 / 7 (100.00%) | 1 / 1 (100.00%) | 6 / 7 (85.71%) |
| occurrences (all)                          | 15              | 1               | 8              |
| Blood and lymphatic system disorders       |                 |                 |                |
| Neutropenia                                |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                          | 0               | 0               | 0              |
| Lymphadenopathy                            |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                          | 0               | 0               | 0              |
| Lymphadenitis                              |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                          | 0               | 0               | 0              |
| Leukopenia                                 |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                          | 0               | 0               | 0              |
| Ear and labyrinth disorders                |                 |                 |                |
| Ear pain                                   |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                          | 0               | 0               | 0              |
| Eye disorders                              |                 |                 |                |
| Amblyopia                                  |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                          | 0               | 0               | 0              |
| Eye inflammation                           |                 |                 |                |
| subjects affected / exposed                | 0 / 7 (0.00%)   | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                          | 0               | 0               | 0              |
| Eye discharge                              |                 |                 |                |



|                             |               |               |               |
|-----------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Eye irritation              |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Ocular discomfort           |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Eye pain                    |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Photophobia                 |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Uveitis                     |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Gastrointestinal disorders  |               |               |               |
| Abdominal pain upper        |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Abdominal pain              |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Gastritis                   |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Diarrhoea                   |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Dental caries               |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Crohn's disease             |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |

|                                                                                                                        |                     |                    |                     |
|------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|---------------------|
| Vomiting (VOMITING)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)  | 3 / 7 (42.86%)<br>3 | 0 / 1 (0.00%)<br>0 | 1 / 7 (14.29%)<br>1 |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                                                           | 0 / 7 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0  |
| Diarrhoea (DIARRHEA)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 2 / 7 (28.57%)<br>3 | 0 / 1 (0.00%)<br>0 | 2 / 7 (28.57%)<br>5 |
| Hepatobiliary disorders<br>Cholelithiasis<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 7 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0  |
| Skin and subcutaneous tissue disorders<br>Acne<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 7 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0  |
| Dermatitis<br>subjects affected / exposed<br>occurrences (all)                                                         | 0 / 7 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0  |
| Purpura<br>subjects affected / exposed<br>occurrences (all)                                                            | 0 / 7 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0  |
| Rash<br>subjects affected / exposed<br>occurrences (all)                                                               | 0 / 7 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0  |
| Rash erythematous<br>subjects affected / exposed<br>occurrences (all)                                                  | 0 / 7 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0  |
| Musculoskeletal and connective tissue disorders<br>Synovitis<br>subjects affected / exposed<br>occurrences (all)       | 0 / 7 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0 | 0 / 7 (0.00%)<br>0  |
| Muscular weakness                                                                                                      |                     |                    |                     |

|                                           |                |                 |                |
|-------------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed               | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 0              | 0               | 0              |
| Myalgia (NEW OR WORSENERED MUSCLE PAIN)   |                |                 |                |
| alternative assessment type: Systematic   |                |                 |                |
| subjects affected / exposed               | 3 / 7 (42.86%) | 1 / 1 (100.00%) | 3 / 7 (42.86%) |
| occurrences (all)                         | 9              | 1               | 6              |
| Arthralgia (NEW OR WORSENERED JOINT PAIN) |                |                 |                |
| alternative assessment type: Systematic   |                |                 |                |
| subjects affected / exposed               | 2 / 7 (28.57%) | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 4              | 0               | 0              |
| Infections and infestations               |                |                 |                |
| Conjunctivitis                            |                |                 |                |
| subjects affected / exposed               | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 0              | 0               | 0              |
| Clostridium difficile colitis             |                |                 |                |
| subjects affected / exposed               | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 0              | 0               | 0              |
| Dengue fever                              |                |                 |                |
| subjects affected / exposed               | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 0              | 0               | 0              |
| Cytomegalovirus viraemia                  |                |                 |                |
| subjects affected / exposed               | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 0              | 0               | 0              |
| Gastroenteritis                           |                |                 |                |
| subjects affected / exposed               | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 0              | 0               | 0              |
| Gastrointestinal infection                |                |                 |                |
| subjects affected / exposed               | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 0              | 0               | 0              |
| Impetigo                                  |                |                 |                |
| subjects affected / exposed               | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%)  |
| occurrences (all)                         | 0              | 0               | 0              |
| Influenza                                 |                |                 |                |

|                                   |                |                 |               |
|-----------------------------------|----------------|-----------------|---------------|
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Epstein-Barr viraemia             |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Stoma site cellulitis             |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Sinusitis                         |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Pharyngitis streptococcal         |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Otitis media chronic              |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Otitis media                      |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Otitis externa                    |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Nasopharyngitis                   |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Urinary tract infection           |                |                 |               |
| subjects affected / exposed       | 1 / 7 (14.29%) | 1 / 1 (100.00%) | 0 / 7 (0.00%) |
| occurrences (all)                 | 2              | 1               | 0             |
| Upper respiratory tract infection |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Tracheitis                        |                |                 |               |
| subjects affected / exposed       | 0 / 7 (0.00%)  | 0 / 1 (0.00%)   | 0 / 7 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0             |
| Tooth infection                   |                |                 |               |

|                             |               |               |               |
|-----------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Tonsillitis                 |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Vulvovaginitis              |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Viral sinusitis             |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Viral rhinitis              |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Viral rash                  |               |               |               |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |

| <b>Non-serious adverse events</b>                                   | <b>&gt;=18 Years with Immunomodulatory Therapy</b> | <b>&gt;=18 Years with Non-Small Cell Lung Cancer</b> | <b>&gt;= 18 Years with Haemodialysis</b> |
|---------------------------------------------------------------------|----------------------------------------------------|------------------------------------------------------|------------------------------------------|
| Total subjects affected by non-serious adverse events               |                                                    |                                                      |                                          |
| subjects affected / exposed                                         | 4 / 5 (80.00%)                                     | 1 / 1 (100.00%)                                      | 1 / 1 (100.00%)                          |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                    |                                                      |                                          |
| Metastases to bone                                                  |                                                    |                                                      |                                          |
| subjects affected / exposed                                         | 0 / 5 (0.00%)                                      | 1 / 1 (100.00%)                                      | 0 / 1 (0.00%)                            |
| occurrences (all)                                                   | 0                                                  | 1                                                    | 0                                        |
| General disorders and administration site conditions                |                                                    |                                                      |                                          |
| Fatigue (FATIGUE)                                                   |                                                    |                                                      |                                          |
| alternative assessment type: Systematic                             |                                                    |                                                      |                                          |
| subjects affected / exposed                                         | 4 / 5 (80.00%)                                     | 1 / 1 (100.00%)                                      | 1 / 1 (100.00%)                          |
| occurrences (all)                                                   | 11                                                 | 2                                                    | 1                                        |
| Erythema (REDNESS)                                                  |                                                    |                                                      |                                          |
| alternative assessment type: Systematic                             |                                                    |                                                      |                                          |
| subjects affected / exposed                                         | 1 / 5 (20.00%)                                     | 0 / 1 (0.00%)                                        | 0 / 1 (0.00%)                            |
| occurrences (all)                                                   | 2                                                  | 0                                                    | 0                                        |
| Chills (CHILLS)                                                     |                                                    |                                                      |                                          |

|                                                 |                |                 |                 |
|-------------------------------------------------|----------------|-----------------|-----------------|
| alternative assessment type:<br>Systematic      |                |                 |                 |
| subjects affected / exposed                     | 2 / 5 (40.00%) | 0 / 1 (0.00%)   | 1 / 1 (100.00%) |
| occurrences (all)                               | 5              | 0               | 1               |
| Chills                                          |                |                 |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%)   |
| occurrences (all)                               | 0              | 0               | 0               |
| Chest pain                                      |                |                 |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%)   |
| occurrences (all)                               | 0              | 0               | 0               |
| Medical device site inflammation                |                |                 |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%)   |
| occurrences (all)                               | 0              | 0               | 0               |
| Pyrexia                                         |                |                 |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%)   |
| occurrences (all)                               | 0              | 0               | 0               |
| Injection site pain (PAIN AT<br>INJECTION SITE) |                |                 |                 |
| alternative assessment type:<br>Systematic      |                |                 |                 |
| subjects affected / exposed                     | 4 / 5 (80.00%) | 1 / 1 (100.00%) | 1 / 1 (100.00%) |
| occurrences (all)                               | 13             | 3               | 1               |
| Injection site pain                             |                |                 |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%)   |
| occurrences (all)                               | 0              | 0               | 0               |
| Injection site erythema                         |                |                 |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%)   |
| occurrences (all)                               | 0              | 0               | 0               |
| Injection site bruising                         |                |                 |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%)   |
| occurrences (all)                               | 0              | 0               | 0               |
| Pyrexia (FEVER)                                 |                |                 |                 |
| alternative assessment type:<br>Systematic      |                |                 |                 |
| subjects affected / exposed                     | 1 / 5 (20.00%) | 0 / 1 (0.00%)   | 0 / 1 (0.00%)   |
| occurrences (all)                               | 1              | 0               | 0               |
| Swelling (SWELLING)                             |                |                 |                 |
| alternative assessment type:<br>Systematic      |                |                 |                 |

|                                                                                                                                                                                                                                                                             |                                                                            |                                                                            |                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------|
| subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                            | 1 / 5 (20.00%)<br>2                                                        | 0 / 1 (0.00%)<br>0                                                         | 0 / 1 (0.00%)<br>0                                                         |
| Reproductive system and breast disorders<br>Breast enlargement<br>subjects affected / exposed<br>occurrences (all)<br><br>Breast pain<br>subjects affected / exposed<br>occurrences (all)                                                                                   | <br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0                           | <br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0                           | <br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0                           |
| Respiratory, thoracic and mediastinal disorders<br>Dyspnoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Cough<br>subjects affected / exposed<br>occurrences (all)                                                                                            | <br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0                           | <br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0                           | <br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0                           |
| Psychiatric disorders<br>Attention deficit hyperactivity disorder<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                       | <br>0 / 5 (0.00%)<br>0                                                     | <br>0 / 1 (0.00%)<br>0                                                     | <br>0 / 1 (0.00%)<br>0                                                     |
| Investigations<br>Body temperature increased<br>subjects affected / exposed<br>occurrences (all)<br><br>Blood iron decreased<br>subjects affected / exposed<br>occurrences (all)<br><br>Donor specific antibody present<br>subjects affected / exposed<br>occurrences (all) | <br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0 | <br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0 | <br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0 |
| Injury, poisoning and procedural complications<br>Radius fracture<br>subjects affected / exposed<br>occurrences (all)<br><br>Foreign body in eye                                                                                                                            | <br>0 / 5 (0.00%)<br>0<br><br>                                             | <br>0 / 1 (0.00%)<br>0<br><br>                                             | <br>0 / 1 (0.00%)<br>0<br><br>                                             |

|                                                                                                                                                                |                     |                      |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|--------------------|
| subjects affected / exposed<br>occurrences (all)                                                                                                               | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Fall<br>subjects affected / exposed<br>occurrences (all)                                                                                                       | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Skin abrasion<br>subjects affected / exposed<br>occurrences (all)                                                                                              | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Congenital, familial and genetic disorders<br>Tumour necrosis factor receptor-associated periodic syndrome<br>subjects affected / exposed<br>occurrences (all) | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Cardiac disorders<br>Palpitations<br>subjects affected / exposed<br>occurrences (all)                                                                          | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)                                                                       | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                                                                                                  | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Headache (HEADACHE)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all)                                             | 4 / 5 (80.00%)<br>9 | 1 / 1 (100.00%)<br>1 | 0 / 1 (0.00%)<br>0 |
| Blood and lymphatic system disorders<br>Neutropenia<br>subjects affected / exposed<br>occurrences (all)                                                        | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Lymphadenopathy<br>subjects affected / exposed<br>occurrences (all)                                                                                            | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Lymphadenitis                                                                                                                                                  |                     |                      |                    |



|                             |               |               |               |
|-----------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Leukopenia                  |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Ear and labyrinth disorders |               |               |               |
| Ear pain                    |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Eye disorders               |               |               |               |
| Amblyopia                   |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Eye inflammation            |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Eye discharge               |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Eye irritation              |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Ocular discomfort           |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Eye pain                    |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Photophobia                 |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Uveitis                     |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Gastrointestinal disorders  |               |               |               |

|                                                                                                                        |                     |                      |                    |
|------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|--------------------|
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)                                               | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)                                                     | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Gastritis<br>subjects affected / exposed<br>occurrences (all)                                                          | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                                                          | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Dental caries<br>subjects affected / exposed<br>occurrences (all)                                                      | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Crohn's disease<br>subjects affected / exposed<br>occurrences (all)                                                    | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Vomiting (VOMITING)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)  | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                                                           | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Diarrhoea (DIARRHEA)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 3 / 5 (60.00%)<br>6 | 1 / 1 (100.00%)<br>2 | 0 / 1 (0.00%)<br>0 |
| Hepatobiliary disorders<br>Cholelithiasis<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 5 (0.00%)<br>0  | 0 / 1 (0.00%)<br>0   | 0 / 1 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>Acne                                                                         |                     |                      |                    |

|                                                        |                |                 |               |
|--------------------------------------------------------|----------------|-----------------|---------------|
| subjects affected / exposed                            | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 0              | 0               | 0             |
| <b>Dermatitis</b>                                      |                |                 |               |
| subjects affected / exposed                            | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 0              | 0               | 0             |
| <b>Purpura</b>                                         |                |                 |               |
| subjects affected / exposed                            | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 0              | 0               | 0             |
| <b>Rash</b>                                            |                |                 |               |
| subjects affected / exposed                            | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 0              | 0               | 0             |
| <b>Rash erythematous</b>                               |                |                 |               |
| subjects affected / exposed                            | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 0              | 0               | 0             |
| <b>Musculoskeletal and connective tissue disorders</b> |                |                 |               |
| <b>Synovitis</b>                                       |                |                 |               |
| subjects affected / exposed                            | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 0              | 0               | 0             |
| <b>Muscular weakness</b>                               |                |                 |               |
| subjects affected / exposed                            | 1 / 5 (20.00%) | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 1              | 0               | 0             |
| <b>Myalgia (NEW OR WORSENERED MUSCLE PAIN)</b>         |                |                 |               |
| alternative assessment type:<br>Systematic             |                |                 |               |
| subjects affected / exposed                            | 2 / 5 (40.00%) | 1 / 1 (100.00%) | 0 / 1 (0.00%) |
| occurrences (all)                                      | 5              | 1               | 0             |
| <b>Arthralgia (NEW OR WORSENERED JOINT PAIN)</b>       |                |                 |               |
| alternative assessment type:<br>Systematic             |                |                 |               |
| subjects affected / exposed                            | 2 / 5 (40.00%) | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 5              | 0               | 0             |
| <b>Infections and infestations</b>                     |                |                 |               |
| <b>Conjunctivitis</b>                                  |                |                 |               |
| subjects affected / exposed                            | 0 / 5 (0.00%)  | 0 / 1 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                      | 0              | 0               | 0             |
| <b>Clostridium difficile colitis</b>                   |                |                 |               |

|                             |               |               |               |
|-----------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Dengue fever                |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Cytomegalovirus viraemia    |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Gastroenteritis             |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Gastrointestinal infection  |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Impetigo                    |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Influenza                   |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Epstein-Barr viraemia       |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Stoma site cellulitis       |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Sinusitis                   |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Pharyngitis streptococcal   |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Otitis media chronic        |               |               |               |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Otitis media                |               |               |               |

|                                   |                |               |               |
|-----------------------------------|----------------|---------------|---------------|
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |
| Otitis externa                    |                |               |               |
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |
| Nasopharyngitis                   |                |               |               |
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |
| Urinary tract infection           |                |               |               |
| subjects affected / exposed       | 1 / 5 (20.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 1              | 0             | 0             |
| Upper respiratory tract infection |                |               |               |
| subjects affected / exposed       | 1 / 5 (20.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 1              | 0             | 0             |
| Tracheitis                        |                |               |               |
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |
| Tooth infection                   |                |               |               |
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |
| Tonsillitis                       |                |               |               |
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |
| Vulvovaginitis                    |                |               |               |
| subjects affected / exposed       | 1 / 5 (20.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 1              | 0             | 0             |
| Viral sinusitis                   |                |               |               |
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |
| Viral rhinitis                    |                |               |               |
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |
| Viral rash                        |                |               |               |
| subjects affected / exposed       | 0 / 5 (0.00%)  | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all)                 | 0              | 0             | 0             |



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment                                                                                                                                                                                                                                                                                                                                                        |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 24 June 2021    | Amendment 1: Updated section 2.3- Added safety text indicating that no specific safety concerns were identified by subgroup analysis by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.                                                                                                                                              |
| 05 August 2021  | Amendment 2: Updated Section 2.3.1– Risk Assessment for subjects, Updated section 3: Added primary and exploratory safety, tolerability, and immune response objectives for the expanded cohort of subjects on active immunomodulator therapy.                                                                                                                   |
| 21 January 2022 | Amendment 4: Reduced the Visit 5 window for provision of Dose 3; Clarified that if Visit 4 and Visit 5 occur on the same day, duplicate procedures need not be conducted; Updated procedures to allow vaccination with the age-appropriate dose removed; immunogenicity blood collection at Visit 5 and Visit 6; Removed PBMC collection at Visit 5 and Visit 7. |
| 13 January 2023 | Amendment 5: Updated Sections 1.1 - Number of subjects in each group based on actual recruitment figures; Updated Sections 8.9.8, 8.9.9, 8.9.10: clarifying the requirements for study procedures after protocol amendment 4.                                                                                                                                    |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported