



## Clinical trial results:

### A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of Catch-up Vaccination Regimens of V114 in Healthy Infants, Children, and Adolescents (PNEU-PLAN)

#### Summary

|                          |                      |
|--------------------------|----------------------|
| EudraCT number           | 2018-003706-88       |
| Trial protocol           | FI PL Outside EU/EEA |
| Global end of trial date | 09 December 2020     |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 20 June 2021 |
| First version publication date | 20 June 2021 |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | V114-024 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |                          |
|------------------------------------|--------------------------|
| ISRCTN number                      | -                        |
| ClinicalTrials.gov id (NCT number) | NCT03885934              |
| WHO universal trial number (UTN)   | -                        |
| Other trial identifiers            | Study Acronym: PNEU-PLAN |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Merck Sharp & Dohme Corp.  |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, United States, 07033                                   |
| Public contact               | Clinical Trials Disclosure, Merck Sharp & Dohme Corp.,<br>ClinicalTrialsDisclosure@merck.com |
| Scientific contact           | Clinical Trials Disclosure, Merck Sharp & Dohme Corp.,<br>ClinicalTrialsDisclosure@merck.com |

Notes:

#### Paediatric regulatory details

|  |                     |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP)       | Yes                 |
| EMA paediatric investigation plan number(s)                          | EMA-002215-PIP01-17 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No                  |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No                  |

Notes:

## Results analysis stage

|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 09 December 2020 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 09 December 2020 |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 09 December 2020 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

The purpose of this study is 1) to evaluate the safety and tolerability of V114 with respect to the proportion of participants with adverse events (AEs) and 2) to evaluate the anti-pneumococcal polysaccharide (PnPs) serotype-specific Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) at 30 days following the last dose for each vaccination group. There is no formal hypothesis testing in this study.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

|   |              |
|---|--------------|
| Actual start date of recruitment                          | 25 June 2019 |
| 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 | Finland: 167           |
| Country: Number of subjects enrolled | Malaysia: 65           |
| Country: Number of subjects enrolled | Poland: 94             |
| Country: Number of subjects enrolled | Russian Federation: 19 |
| Country: Number of subjects enrolled | Thailand: 261          |
| Worldwide total number of subjects   | 606                    |
| EEA total number of subjects         | 261                    |

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)  | 254 |
| Children (2-11 years)                     | 288 |

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

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of approximately 600 participants were planned for enrollment. Randomization was stratified by age and pneumococcal conjugate vaccine (PCV) history.

### Period 1

|                              |                          |
|------------------------------|--------------------------|
| Period 1 title               | Overall (overall period) |
| Is this the baseline period? | Yes                      |
| Allocation method            | Randomised - controlled  |
| Blinding used                | Double blind             |
| Roles blinded                | Subject, Investigator    |

### Arms

|                              |  |
|------------------------------|--|
| Are arms mutually exclusive? | Yes  |
| <b>Arm title</b>             | V114, Schedule A: Participants 7-11 months |

Arm description:

Each participant received a 0.5 mL intramuscular (IM) injection for 7 to 11 months of age (Pneumococcal conjugate vaccine [PCV]-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and  $\geq 12$  months of age.

|  |                          |
|--|--------------------------|
| Arm type                               | Experimental             |
| Investigational medicinal product name | V114                     |
| Investigational medicinal product code |                          |
| Other name                             |                          |
| Pharmaceutical forms                   | Suspension for injection |
| Routes of administration               | Intramuscular use        |

Dosage and administration details:

V114 15-valent pneumococcal conjugate vaccine (PCV) containing 13 serotypes present in Prevnar 13® (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) and 2 unique serotypes (22F and 33F) in each 0.5 mL IM administration

|                  |   |
|------------------|---|
| <b>Arm title</b> | Prevnar 13®, Schedule A: Participants 7-11 months |
|------------------|---|

Arm description:

Each participant received a 0.5 mL IM injection for 7 to 11 months of age (PCV-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and  $\geq 12$  months of age.

|  |                          |
|--|--------------------------|
| Arm type                               | Active comparator        |
| Investigational medicinal product name | Prevnar 13®              |
| Investigational medicinal product code |                          |
| Other name                             | PCV13                    |
| Pharmaceutical forms                   | Suspension for injection |
| Routes of administration               | Intramuscular use        |

Dosage and administration details:

Prevnar 13® 13-valent PCV containing 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in each 0.5 mL IM administration.

|                  |   |
|------------------|---|
| <b>Arm title</b> | V114, Schedule B: Participants 12-23 months |
|------------------|---|

Arm description:

Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.

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

|  |                          |
|--|--------------------------|
| Investigational medicinal product name | V114                     |
| Investigational medicinal product code |                          |
| Other name                             |                          |
| Pharmaceutical forms                   | Suspension for injection |
| Routes of administration               | Intramuscular use        |

**Dosage and administration details:**

V114 15-valent PCV containing 13 serotypes present in Prevnar 13® (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) and 2 unique serotypes (22F and 33F) in each 0.5 mL IM administration

|                  |  |
|------------------|--|
| <b>Arm title</b> | Prevnar 13®, Schedule B: Participants 12-23 months |
|------------------|--|

**Arm description:**

Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.

|  |                          |
|--|--------------------------|
| Arm type                               | Active comparator        |
| Investigational medicinal product name | Prevnar 13®              |
| Investigational medicinal product code |                          |
| Other name                             | PCV13                    |
| Pharmaceutical forms                   | Suspension for injection |
| Routes of administration               | Intramuscular use        |

**Dosage and administration details:**

Prevnar 13® 13-valent PCV containing 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in each 0.5 mL IM administration.

|                  |   |
|------------------|---|
| <b>Arm title</b> | V114, Schedule C: Participants 2-17 years |
|------------------|---|

**Arm description:**

Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced) (1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.

|  |                          |
|--|--------------------------|
| Arm type                               | Experimental             |
| Investigational medicinal product name | V114                     |
| Investigational medicinal product code |                          |
| Other name                             |                          |
| Pharmaceutical forms                   | Suspension for injection |
| Routes of administration               | Intramuscular use        |

**Dosage and administration details:**

V114 15-valent PCV containing 13 serotypes present in Prevnar 13® (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) and 2 unique serotypes (22F and 33F) in each 0.5 mL IM administration

|                  |  |
|------------------|--|
| <b>Arm title</b> | Prevnar 13®, Schedule C: Participants 2-17 years |
|------------------|--|

**Arm description:**

Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced)(1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.

|  |                          |
|--|--------------------------|
| Arm type                               | Active comparator        |
| Investigational medicinal product name | Prevnar 13®              |
| Investigational medicinal product code |                          |
| Other name                             | PCV13                    |
| Pharmaceutical forms                   | Suspension for injection |
| Routes of administration               | Intramuscular use        |

**Dosage and administration details:**

Prevnar 13® 13-valent PCV containing 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in each 0.5 mL IM administration.

| Number of subjects in period 1 | V114, Schedule A:<br>Participants 7-11<br>months | Prevnam 13®,<br>Schedule A:<br>Participants 7-11<br>months | V114, Schedule B:<br>Participants 12-23<br>months |
|--------------------------------|--|--|---|
|                                |  |  |   |
| Started                        | 64   | 64   | 62  |
| PCV Dose 1                     | 64   | 64   | 62  |
| PCV Dose 2                     | 63   | 64   | 62  |
| PCV Dose 3                     | 63   | 64   | 0 <sup>[1]</sup>                                  |
| Completed                      | 63   | 64   | 62  |
| Not completed                  | 1  | 0  | 0   |
| Withdrawn by Parent/Guardian   | 1  | -  | -   |

| Number of subjects in period 1 | Prevnam 13®,<br>Schedule B:<br>Participants 12-23<br>months | V114, Schedule C:<br>Participants 2-17<br>years | Prevnam 13®,<br>Schedule C:<br>Participants 2-17<br>years |
|--------------------------------|---|---|---|
|                                |   |   |   |
| Started                        | 64  | 177   | 175   |
| PCV Dose 1                     | 64  | 177   | 175   |
| PCV Dose 2                     | 64  | 0 <sup>[2]</sup>                                | 0 <sup>[3]</sup>  |
| PCV Dose 3                     | 0 <sup>[4]</sup>  | 0 <sup>[5]</sup>                                | 0 <sup>[6]</sup>  |
| Completed                      | 64  | 177   | 175   |
| Not completed                  | 0   | 0   | 0   |
| Withdrawn by Parent/Guardian   | -   | -   | -   |

#### 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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

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

Justification: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[4] - 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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[5] - 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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[6] - 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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

## Baseline characteristics

### Reporting groups

|   |  |
|---|--|
| Reporting group title   | V114, Schedule A: Participants 7-11 months         |
| Reporting group description:  |  |
| Each participant received a 0.5 mL intramuscular (IM) injection for 7 to 11 months of age (Pneumococcal conjugate vaccine [PCV]-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age. |  |
| Reporting group title   | Prevnar 13®, Schedule A: Participants 7-11 months  |
| Reporting group description:  |  |
| Each participant received a 0.5 mL IM injection for 7 to 11 months of age (PCV-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.  |  |
| Reporting group title   | V114, Schedule B: Participants 12-23 months        |
| Reporting group description:  |  |
| Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.  |  |
| Reporting group title   | Prevnar 13®, Schedule B: Participants 12-23 months |
| Reporting group description:  |  |
| Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.  |  |
| Reporting group title   | V114, Schedule C: Participants 2-17 years          |
| Reporting group description:  |  |
| Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced) (1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.                              |  |
| Reporting group title   | Prevnar 13®, Schedule C: Participants 2-17 years   |
| Reporting group description:  |  |
| Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced)(1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.                               |  |

| Reporting group values  | V114, Schedule A:<br>Participants 7-11<br>months | Prevnar 13®,<br>Schedule A:<br>Participants 7-11<br>months | V114, Schedule B:<br>Participants 12-23<br>months |
|---|--|--|---|
| Number of subjects  | 64   | 64   | 62  |
| Age Categorical<br>Units: Subjects  |  |  |   |
| In utero<br>Preterm newborn infants<br>(gestational age < 37 wks)<br>Newborns (0-27 days)<br>Infants and toddlers (28 days-23<br>months)<br>Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over |  |  |   |
| Age Continuous<br>Units: years  |  |  |   |
| arithmetic mean   | 0  | 0  | 0   |
| standard deviation  | ± 0  | ± 0  | ± 0   |

|                                       |       |       |       |
|---------------------------------------|-------|-------|-------|
| Gender Categorical<br>Units: Subjects |       |       |       |
| Female                                | 29    | 33    | 30    |
| Male                                  | 35    | 31    | 32    |
| Race<br>Units: Subjects               |       |       |       |
| Asian                                 | 53    | 53    | 52    |
| Multiple                              | 0     | 0     | 0     |
| White                                 | 11    | 11    | 10    |
| Ethnicity<br>Units: Subjects          |       |       |       |
| Hispanic or Latino                    | 0     | 0     | 0     |
| Not Hispanic or Latino                | 64    | 64    | 62    |
| Not Reported                          | 0     | 0     | 0     |
| Age Continuous<br>Units: Months       |       |       |       |
| arithmetic mean                       | 8.6   | 8.8   | 17.7  |
| standard deviation                    | ± 1.4 | ± 1.6 | ± 3.2 |

| <b>Reporting group values</b>   | Prevnar 13®,<br>Schedule B:<br>Participants 12-23<br>months | V114, Schedule C:<br>Participants 2-17<br>years | Prevnar 13®,<br>Schedule C:<br>Participants 2-17<br>years |
|---|---|---|---|
| Number of subjects  | 64  | 177   | 175   |
| Age Categorical<br>Units: Subjects  |   |   |   |
| In utero<br>Preterm newborn infants<br>(gestational age < 37 wks)<br>Newborns (0-27 days)<br>Infants and toddlers (28 days-23<br>months)<br>Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over |   |   |   |
| Age Continuous<br>Units: years  |   |   |   |
| arithmetic mean   | 0   | 6.5   | 6.5   |
| standard deviation  | ± 0   | ± 4.7   | ± 4.7   |
| Gender Categorical<br>Units: Subjects   |   |   |   |
| Female  | 38  | 85  | 83  |
| Male  | 26  | 92  | 92  |
| Race<br>Units: Subjects   |   |   |   |
| Asian   | 53  | 60  | 56  |
| Multiple  | 0   | 0   | 1   |
| White   | 11  | 117   | 118   |
| Ethnicity<br>Units: Subjects  |   |   |   |
| Hispanic or Latino  | 1   | 0   | 0   |

|                        |    |     |     |
|------------------------|----|-----|-----|
| Not Hispanic or Latino | 63 | 176 | 174 |
| Not Reported           | 0  | 1   | 1   |

|                    |       |     |     |
|--------------------|-------|-----|-----|
| Age Continuous     |       |     |     |
| Units: Months      |       |     |     |
| arithmetic mean    | 17.8  | 0   | 0   |
| standard deviation | ± 3.3 | ± 0 | ± 0 |

|  |       |  |  |
|--|-------|--|--|
| <b>Reporting group values</b>                      | Total |  |  |
| Number of subjects                                 | 606   |  |  |
| Age Categorical                                    |       |  |  |
| Units: Subjects                                    |       |  |  |
| In utero   | 0     |  |  |
| Preterm newborn infants (gestational age < 37 wks) | 0     |  |  |
| Newborns (0-27 days)                               | 0     |  |  |
| Infants and toddlers (28 days-23 months)           | 0     |  |  |
| Children (2-11 years)                              | 0     |  |  |
| Adolescents (12-17 years)                          | 0     |  |  |
| Adults (18-64 years)                               | 0     |  |  |
| From 65-84 years                                   | 0     |  |  |
| 85 years and over                                  | 0     |  |  |
| Age Continuous                                     |       |  |  |
| Units: years                                       |       |  |  |
| arithmetic mean                                    | -     |  |  |
| standard deviation                                 | -     |  |  |
| Gender Categorical                                 |       |  |  |
| Units: Subjects                                    |       |  |  |
| Female   | 298   |  |  |
| Male   | 308   |  |  |
| Race   |       |  |  |
| Units: Subjects                                    |       |  |  |
| Asian  | 327   |  |  |
| Multiple   | 1     |  |  |
| White  | 278   |  |  |
| Ethnicity  |       |  |  |
| Units: Subjects                                    |       |  |  |
| Hispanic or Latino                                 | 1     |  |  |
| Not Hispanic or Latino                             | 603   |  |  |
| Not Reported                                       | 2     |  |  |
| Age Continuous                                     |       |  |  |
| Units: Months                                      |       |  |  |
| arithmetic mean                                    | -     |  |  |
| standard deviation                                 | -     |  |  |

## End points

### End points reporting groups

|   |  |
|---|--|
| Reporting group title   | V114, Schedule A: Participants 7-11 months         |
| Reporting group description:<br>Each participant received a 0.5 mL intramuscular (IM) injection for 7 to 11 months of age (Pneumococcal conjugate vaccine [PCV]-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age. |  |
| Reporting group title   | Prevnar 13®, Schedule A: Participants 7-11 months  |
| Reporting group description:<br>Each participant received a 0.5 mL IM injection for 7 to 11 months of age (PCV-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.  |  |
| Reporting group title   | V114, Schedule B: Participants 12-23 months        |
| Reporting group description:<br>Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.  |  |
| Reporting group title   | Prevnar 13®, Schedule B: Participants 12-23 months |
| Reporting group description:<br>Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.  |  |
| Reporting group title   | V114, Schedule C: Participants 2-17 years          |
| Reporting group description:<br>Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced) (1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.                              |  |
| Reporting group title   | Prevnar 13®, Schedule C: Participants 2-17 years   |
| Reporting group description:<br>Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced)(1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.                               |  |

### Primary: Geometric Mean Concentration of Serotype-specific Immunoglobulin G - Schedule A: 7-11 Months

|  |  |
|--|--|
| End point title  | Geometric Mean Concentration of Serotype-specific Immunoglobulin G - Schedule A: 7-11 Months <sup>[1][2]</sup> |
| End point description:<br>The geometric mean concentration (GMC) of immunoglobulin G (IgG) serotype-specific antibodies to the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13®; and two serotypes (22F and 33F) which are unique to V114 was determined. Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using pneumococcal electrochemiluminescence (PnECL). The 95% CIs were derived by exponentiating the CIs of the mean of the natural log values based on the t-distribution. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint. |  |
| End point type   | Primary  |
| End point timeframe:<br>30 days post last vaccination  |  |
| Notes:<br>[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.<br>Justification: No statistical analyses were planned or conducted for this endpoint.<br>[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.<br>Justification: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11  |  |

months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

| End point values                         | V114, Schedule A: Participants 7-11 months | Prevnar 13®, Schedule A: Participants 7-11 months |  |  |
|--|--|---|--|--|
| Subject group type                       | Reporting group                            | Reporting group                                   |  |  |
| Number of subjects analysed              | 64   | 64  |  |  |
| Units: µg/mL                             |  |   |  |  |
| geometric mean (confidence interval 95%) |  |   |  |  |
| Serotype 1 (n=60,59)                     | 2.47 (2.09 to 2.92)                        | 3.66 (2.98 to 4.50)                               |  |  |
| Serotype 3 (n=60,59)                     | 2.65 (2.30 to 3.05)                        | 1.71 (1.40 to 2.08)                               |  |  |
| Serotype 4 (n=60,59)                     | 2.21 (1.82 to 2.68)                        | 3.85 (3.12 to 4.76)                               |  |  |
| Serotype 5 (n=60,59)                     | 3.82 (3.14 to 4.63)                        | 4.56 (3.58 to 5.80)                               |  |  |
| Serotype 6A (n=60,59)                    | 2.23 (1.71 to 2.91)                        | 4.30 (3.28 to 5.65)                               |  |  |
| Serotype 6B (n=60,59)                    | 3.03 (2.41 to 3.82)                        | 4.17 (3.25 to 5.36)                               |  |  |
| Serotype 7F (n=60,59)                    | 5.16 (4.27 to 6.23)                        | 6.42 (5.25 to 7.85)                               |  |  |
| Serotype 9V (n=60,59)                    | 2.61 (2.09 to 3.26)                        | 3.59 (2.86 to 4.51)                               |  |  |
| Serotype 14 (n=60,59)                    | 9.62 (7.94 to 11.67)                       | 13.07 (10.40 to 16.42)                            |  |  |
| Serotype 18C (n=60,59)                   | 3.45 (2.80 to 4.24)                        | 3.50 (2.75 to 4.45)                               |  |  |
| Serotype 19A (n=60,59)                   | 4.59 (3.95 to 5.33)                        | 5.81 (4.92 to 6.85)                               |  |  |
| Serotype 19F (n=60,59)                   | 3.49 (2.94 to 4.15)                        | 4.83 (4.03 to 5.79)                               |  |  |
| Serotype 23F (n=60,59)                   | 2.62 (2.02 to 3.39)                        | 2.79 (2.10 to 3.69)                               |  |  |
| Serotype 22F (n=60,58)                   | 9.04 (7.48 to 10.93)                       | 0.14 (0.10 to 0.19)                               |  |  |
| Serotype 33F (n=60,59)                   | 3.37 (2.78 to 4.10)                        | 0.13 (0.10 to 0.16)                               |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: GMC of Serotype-specific IgG - Schedule B: 12-23 Months

|                 |   |
|-----------------|---|
| End point title | GMC of Serotype-specific IgG - Schedule B: 12-23 Months <sup>[3][4]</sup> |
|-----------------|---|

End point description:

The geometric mean concentration of IgG serotype-specific antibodies to the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13®; and two serotypes (22F and 33F) which are unique to V114 was determined. Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using pneumococcal electrochemiluminescence (PnECL). The 95% CIs were derived by exponentiating the CIs of the mean of the natural log values based on the t-distribution. The analysis population included all randomized

participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

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

End point timeframe:

30 days post last vaccination

Notes:

[3] - 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: No statistical analyses were planned or conducted for this endpoint.

[4] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

| End point values                         | V114, Schedule B: Participants 12-23 months | Prevnam 13®, Schedule B: Participants 12-23 months |  |  |
|--|---|--|--|--|
| Subject group type                       | Reporting group                             | Reporting group                                    |  |  |
| Number of subjects analysed              | 62  | 64   |  |  |
| Units: µg/mL                             |   |  |  |  |
| geometric mean (confidence interval 95%) |   |  |  |  |
| Serotype 1 (n=56,60)                     | 3.83 (3.07 to 4.77)                         | 4.20 (3.30 to 5.34)                                |  |  |
| Serotype 3 (n=56,60)                     | 2.96 (2.44 to 3.58)                         | 1.68 (1.29 to 2.20)                                |  |  |
| Serotype 4 (n=56,60)                     | 3.46 (2.67 to 4.50)                         | 4.89 (3.76 to 6.36)                                |  |  |
| Serotype 5 (n=56,60)                     | 3.39 (2.65 to 4.34)                         | 3.12 (2.52 to 3.88)                                |  |  |
| Serotype 6A (n=56,60)                    | 2.05 (1.30 to 3.23)                         | 3.73 (2.64 to 5.29)                                |  |  |
| Serotype 6B (n=56,60)                    | 2.69 (1.70 to 4.25)                         | 2.87 (1.92 to 4.30)                                |  |  |
| Serotype 7F (n=56,60)                    | 4.80 (3.63 to 6.34)                         | 5.42 (4.30 to 6.82)                                |  |  |
| Serotype 9V (n=56,60)                    | 2.48 (1.97 to 3.11)                         | 2.89 (2.21 to 3.78)                                |  |  |
| Serotype 14 (n=56,60)                    | 8.23 (6.19 to 10.94)                        | 8.30 (6.56 to 10.51)                               |  |  |
| Serotype 18C (n=56,60)                   | 5.09 (3.98 to 6.52)                         | 3.68 (2.85 to 4.75)                                |  |  |
| Serotype 19A (n=56,60)                   | 6.74 (5.29 to 8.60)                         | 5.87 (4.85 to 7.11)                                |  |  |
| Serotype 19F (n=56,60)                   | 5.90 (4.69 to 7.43)                         | 5.92 (4.93 to 7.11)                                |  |  |
| Serotype 23F (n=56,60)                   | 2.85 (1.99 to 4.07)                         | 2.18 (1.54 to 3.07)                                |  |  |
| Serotype 22F (n=56,60)                   | 15.90 (12.16 to 20.78)                      | 0.12 (0.09 to 0.16)                                |  |  |
| Serotype 33F (n=56,60)                   | 5.17 (3.96 to 6.74)                         | 0.15 (0.12 to 0.19)                                |  |  |

## Statistical analyses

**Primary: GMC of Serotype-specific IgG - Schedule C: 2-17 Years**

|                 |   |
|-----------------|---|
| End point title | GMC of Serotype-specific IgG - Schedule C: 2-17 Years <sup>[5][6]</sup> |
|-----------------|---|

End point description:

The geometric mean concentration of IgG serotype-specific antibodies to the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13®; and two serotypes (22F and 33F) which are unique to V114 was determined. Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using pneumococcal electrochemiluminescence (PnECL). The 95% CIs were derived by exponentiating the CIs of the mean of the natural log values based on the t-distribution. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

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

End point timeframe:

30 days post vaccination

Notes:

[5] - 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: No statistical analyses were planned or conducted for this endpoint.

[6] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

| End point values                         | V114, Schedule C: Participants 2-17 years | Prevnar 13®, Schedule C: Participants 2-17 years |  |  |
|--|---|--|--|--|
| Subject group type                       | Reporting group                           | Reporting group                                  |  |  |
| Number of subjects analysed              | 177                                       | 175  |  |  |
| Units: µg/mL                             |   |  |  |  |
| geometric mean (confidence interval 95%) |   |  |  |  |
| Serotype 1 (n=162,162)                   | 3.00 (2.60 to 3.46)                       | 3.99 (3.48 to 4.58)                              |  |  |
| Serotype 3 (n=162,162)                   | 1.37 (1.19 to 1.58)                       | 1.03 (0.88 to 1.21)                              |  |  |
| Serotype 4 (n=162,162)                   | 2.53 (2.17 to 2.96)                       | 5.22 (4.52 to 6.03)                              |  |  |
| Serotype 5 (n=162,162)                   | 3.43 (2.89 to 4.07)                       | 4.24 (3.46 to 5.20)                              |  |  |
| Serotype 6A (n=162,162)                  | 9.03 (7.07 to 11.53)                      | 8.81 (6.96 to 11.14)                             |  |  |
| Serotype 6B (n=162,161)                  | 13.55 (10.52 to 17.46)                    | 10.51 (8.01 to 13.78)                            |  |  |
| Serotype 7F (n=162,162)                  | 4.03 (3.46 to 4.70)                       | 4.63 (3.92 to 5.46)                              |  |  |
| Serotype 9V (n=162,162)                  | 3.60 (3.06 to 4.24)                       | 4.35 (3.65 to 5.20)                              |  |  |
| Serotype 14 (n=162,162)                  | 9.21 (7.11 to 11.92)                      | 8.04 (6.24 to 10.36)                             |  |  |
| Serotype 18C (n=162,162)                 | 7.16 (6.03 to 8.52)                       | 4.46 (3.76 to 5.30)                              |  |  |
| Serotype 19A (n=162,162)                 | 10.99 (9.12 to 13.26)                     | 14.90 (12.23 to 18.16)                           |  |  |
| Serotype 19F (n=162,162)                 | 8.95 (7.45 to 10.76)                      | 12.28 (10.07 to 14.97)                           |  |  |
| Serotype 23F (n=162,162)                 | 5.36 (4.41 to 6.50)                       | 5.12 (4.12 to 6.37)                              |  |  |

|                          |                        |                     |  |  |
|--------------------------|------------------------|---------------------|--|--|
| Serotype 22F (n=162,159) | 14.99 (12.73 to 17.66) | 0.31 (0.24 to 0.38) |  |  |
| Serotype 33F (n=162,160) | 4.89 (4.12 to 5.80)    | 0.27 (0.22 to 0.32) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants with Solicited Injection-site Adverse Events - Schedule A: 7-11 Months

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants with Solicited Injection-site Adverse Events - Schedule A: 7-11 Months <sup>[7]</sup> <sup>[8]</sup> |
|-----------------|---|

End point description:

An adverse event (AE) is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any vaccination report card (VRC)-prompted injection-site AEs that occurred in the 14 days after any vaccination. The percentage of participants with an injection-site AE prompted on the VRC (redness/erythema, hardness/induration, swelling, and pain) was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

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

End point timeframe:

Up to Day 14 post any vaccination

Notes:

[7] - 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: No statistical analyses were planned or conducted for this endpoint.

[8] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

|                                   |  |  |  |  |
|-----------------------------------|--|--|--|--|
| <b>End point values</b>           | V114, Schedule A: Participants 7-11 months | Pprevnar 13®, Schedule A: Participants 7-11 months |  |  |
| Subject group type                | Reporting group                            | Reporting group                                    |  |  |
| Number of subjects analysed       | 64   | 64   |  |  |
| Units: Percentage of Participants |  |  |  |  |
| number (confidence interval 95%)  |  |  |  |  |
| Redness/erythema                  | 28.1 (17.6 to 40.8)                        | 34.4 (22.9 to 47.3)                                |  |  |
| Hardness/induration               | 17.2 (8.9 to 28.7)                         | 14.1 (6.6 to 25.0)                                 |  |  |
| Pain                              | 18.8 (10.1 to 30.5)                        | 7.8 (2.6 to 17.3)                                  |  |  |
| Swelling                          | 18.8 (10.1 to 30.5)                        | 15.6 (7.8 to 26.9)                                 |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants with Solicited Injection-site AEs - Schedule B: 12-23 Months

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants with Solicited Injection-site AEs - Schedule B: 12-23 Months <sup>[9][10]</sup> |
|-----------------|--|

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any vaccination report card (VRC)-prompted injection-site AEs that occurred in the 14 days after any vaccination. The percentage of participants with an injection-site AE prompted on the VRC (redness/erythema, hardness/induration, swelling, and pain) was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

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

End point timeframe:

Up to 14 days post any vaccination

Notes:

[9] - 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: No statistical analyses were planned or conducted for this endpoint.

[10] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

| End point values                  | V114, Schedule B: Participants 12-23 months | Pprevnar 13®, Schedule B: Participants 12-23 months |  |  |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group                             | Reporting group                                     |  |  |
| Number of subjects analysed       | 62  | 64  |  |  |
| Units: Percentage of Participants |   |   |  |  |
| number (confidence interval 95%)  |   |   |  |  |
| Redness/erythema                  | 21.0 (11.7 to 33.2)                         | 21.9 (12.5 to 34.0)                                 |  |  |
| Hardness/induration               | 8.1 (2.7 to 17.8)                           | 9.4 (3.5 to 19.3)                                   |  |  |
| Pain                              | 33.9 (22.3 to 47.0)                         | 23.4 (13.8 to 35.7)                                 |  |  |
| Swelling                          | 14.5 (6.9 to 25.8)                          | 12.5 (5.6 to 23.2)                                  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants with Solicited Injection-site AEs - Schedule C: 2-17 Years

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants with Solicited Injection-site AEs - Schedule C: 2-17 Years <sup>[11][12]</sup> |
|-----------------|---|

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the

presence of any vaccination report card (VRC)-prompted injection-site AEs that occurred in the 14 days after any vaccination. The percentage of participants with an injection-site AE prompted on the VRC (redness/erythema, hardness/induration, swelling, and pain) was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

|                                |         |
|--------------------------------|---------|
| End point type                 | Primary |
| End point timeframe:           |         |
| Up to 14 days post vaccination |         |

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: No statistical analyses were planned or conducted for this 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

|                                   |   |  |  |  |
|-----------------------------------|---|--|--|--|
| <b>End point values</b>           | V114, Schedule C: Participants 2-17 years | Prevnar 13®, Schedule C: Participants 2-17 years |  |  |
| Subject group type                | Reporting group                           | Reporting group                                  |  |  |
| Number of subjects analysed       | 177                                       | 175  |  |  |
| Units: Percentage of Participants |   |  |  |  |
| number (confidence interval 95%)  |   |  |  |  |
| Redness/erythema                  | 19.2 (13.7 to 25.8)                       | 21.1 (15.3 to 27.9)                              |  |  |
| Hardness/induration               | 6.8 (3.6 to 11.5)                         | 14.9 (9.9 to 21.0)                               |  |  |
| Pain                              | 54.8 (47.2 to 62.3)                       | 56.6 (48.9 to 64.0)                              |  |  |
| Swelling                          | 20.9 (15.2 to 27.6)                       | 24.0 (17.9 to 31.0)                              |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants With Solicited Systemic AEs - Schedule A: 7-11 Months

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants With Solicited Systemic AEs - Schedule A: 7-11 Months <sup>[13][14]</sup> |
|-----------------|--|

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any VRC-prompted systemic AEs that occurred in the 14 days after any vaccination. For participants 7 months to <3 years of age at enrollment, solicited systemic AEs include irritability, drowsiness/somnolence, appetite lost/decreased appetite, and hives or welts/urticaria. The percentage of participants with a systemic AE was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

|                                   |         |
|-----------------------------------|---------|
| End point type                    | Primary |
| End point timeframe:              |         |
| Up to Day 14 post any vaccination |         |

Notes:

[13] - 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: No statistical analyses were planned or conducted for this endpoint.

[14] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

|                                   |  |  |  |  |
|-----------------------------------|--|--|--|--|
| <b>End point values</b>           | V114, Schedule A: Participants 7-11 months | Prevna 13®, Schedule A: Participants 7-11 months |  |  |
| Subject group type                | Reporting group                            | Reporting group                                  |  |  |
| Number of subjects analysed       | 64   | 64   |  |  |
| Units: Percentage of Participants |  |  |  |  |
| number (confidence interval 95%)  |  |  |  |  |
| Decreased appetite                | 15.6 (7.8 to 26.9)                         | 18.8 (10.1 to 30.5)                              |  |  |
| Irritability                      | 32.8 (21.6 to 45.7)                        | 43.8 (31.4 to 56.7)                              |  |  |
| Drowsiness/Somnolence             | 21.9 (12.5 to 34.0)                        | 15.6 (7.8 to 26.9)                               |  |  |
| Hives or Welts/Urticaria          | 1.6 (0.0 to 8.4)                           | 4.7 (1.0 to 13.1)                                |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants With Solicited Systemic AEs - Schedule B: 12-23 Months

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants With Solicited Systemic AEs - Schedule B: 12-23 Months <sup>[15][16]</sup> |
|-----------------|---|

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any VRC-prompted systemic AEs that occurred in the 14 days after any vaccination. For participants 7 months to <3 years of age at enrollment, solicited systemic AEs include irritability, drowsiness/somnolence, appetite lost/decreased appetite, and hives or welts/urticaria. The percentage of participants with a systemic AE was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

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

End point timeframe:

Up to 14 days post any vaccination

Notes:

[15] - 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: No statistical analyses were planned or conducted for this endpoint.

[16] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

| End point values                  | V114, Schedule B: Participants 12-23 months | Pprevnar 13®, Schedule B: Participants 12-23 months |  |  |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group                             | Reporting group                                     |  |  |
| Number of subjects analysed       | 62  | 64  |  |  |
| Units: Percentage of Participants |   |   |  |  |
| number (confidence interval 95%)  |   |   |  |  |
| Decreased appetite                | 22.6 (12.9 to 35.0)                         | 18.8 (10.1 to 30.5)                                 |  |  |
| Irritability                      | 35.5 (23.7 to 48.7)                         | 21.9 (12.5 to 34.0)                                 |  |  |
| Drowsiness/Somnolence             | 24.2 (14.2 to 36.7)                         | 17.2 (8.9 to 28.7)                                  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants With Solicited Systemic AEs - Schedule C: 2-17 Years

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants With Solicited Systemic AEs - Schedule C: 2-17 Years <sup>[17][18]</sup> |
|-----------------|---|

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any VRC-prompted systemic AEs that occurred in the 14 days after any vaccination. For participants 7 months to <3 years of age at enrollment, solicited systemic AEs include irritability, drowsiness/somnolence, appetite lost/decreased appetite, and hives or welts/urticaria. For participants ≥3 years to of age at enrollment, solicited systemic AEs include muscle pain/ myalgia, joint pain/arthritis, headache, tiredness/fatigue, and hives or welts/urticaria. The percentage of participants with a systemic AE was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

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

End point timeframe:

Up to 14 days post vaccination

Notes:

[17] - 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: No statistical analyses were planned or conducted for this endpoint.

[18] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

| End point values                  | V114, Schedule C: Participants 2-17 years | Pprevnar 13®, Schedule C: Participants 2-17 years |  |  |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group                           | Reporting group                                   |  |  |
| Number of subjects analysed       | 177                                       | 175   |  |  |
| Units: Percentage of Participants |   |   |  |  |
| number (confidence interval 95%)  |   |   |  |  |
| Joint pain/arthritis              | 0.0 (0.0 to 2.1)                          | 1.7 (0.4 to 4.9)                                  |  |  |

|                          |                     |                     |  |  |
|--------------------------|---------------------|---------------------|--|--|
| Decreased Appetite       | 2.3 (0.6 to 5.7)    | 2.9 (0.9 to 6.5)    |  |  |
| Tiredness/Fatigue        | 15.8 (10.8 to 22.0) | 17.1 (11.9 to 23.6) |  |  |
| Headache                 | 11.9 (7.5 to 17.6)  | 13.7 (9.0 to 19.7)  |  |  |
| Irritability             | 2.8 (0.9 to 6.5)    | 4.0 (1.6 to 8.1)    |  |  |
| Muscle pain/Myalgia      | 23.7 (17.7 to 30.7) | 16.6 (11.4 to 22.9) |  |  |
| Sleepiness/Somnolence    | 2.8 (0.9 to 6.5)    | 2.9 (0.9 to 6.5)    |  |  |
| Hives or Welts/Urticaria | 1.1 (0.1 to 4.0)    | 1.1 (0.1 to 4.1)    |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants With at Least 1 Vaccine-related Serious Adverse Event - Schedule A: 7-11 Months

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants With at Least 1 Vaccine-related Serious Adverse Event - Schedule A: 7-11 Months <sup>[19][20]</sup> |
|-----------------|--|

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that, at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is another important medical event. SAEs that are reported to be at least possibly related by the investigator to study vaccination will be summarized. Estimated CIs are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants who received at least 1 dose of study intervention.

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

End point timeframe:

Up to ~6 months post final vaccination

Notes:

[19] - 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: No statistical analyses were planned or conducted for this endpoint.

[20] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

|                                   |  |  |  |  |
|-----------------------------------|--|--|--|--|
| <b>End point values</b>           | V114, Schedule A: Participants 7-11 months | Pprevnar 13®, Schedule A: Participants 7-11 months |  |  |
| Subject group type                | Reporting group                            | Reporting group                                    |  |  |
| Number of subjects analysed       | 64   | 64   |  |  |
| Units: Percentage of Participants |  |  |  |  |
| number (confidence interval 95%)  | 0.0 (0.0 to 5.6)                           | 0.0 (0.0 to 5.6)                                   |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants with at Least 1 Vaccine-related SAE - Schedule B: 12-23 Months

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants with at Least 1 Vaccine-related SAE - Schedule B: 12-23 Months <sup>[21][22]</sup> |
|-----------------|---|

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that, at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is another important medical event. SAEs that are reported to be at least possibly related by the investigator to study vaccination will be summarized. Estimated CIs are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants who received at least 1 dose of study intervention.

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

End point timeframe:

Up to ~6 months post final vaccination

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: No statistical analyses were planned or conducted for this 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

|                                   |   |   |  |  |
|-----------------------------------|---|---|--|--|
| End point values                  | V114, Schedule B: Participants 12-23 months | Pprevnar 13®, Schedule B: Participants 12-23 months |  |  |
| Subject group type                | Reporting group                             | Reporting group                                     |  |  |
| Number of subjects analysed       | 62  | 64  |  |  |
| Units: Percentage of Participants |   |   |  |  |
| number (confidence interval 95%)  | 0.0 (0.0 to 5.8)                            | 0.0 (0.0 to 5.6)                                    |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants with at Least 1 Vaccine-related SAE - Schedule C: 2-17 Years

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants with at Least 1 Vaccine-related SAE - Schedule C: 2-17 Years <sup>[23][24]</sup> |
|-----------------|---|

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that, at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is another important medical event. SAEs that are reported to be at least possibly related by the investigator to study vaccination will be summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

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

End point timeframe:

Up to ~6 months post vaccination

Notes:

[23] - 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: No statistical analyses were planned or conducted for this endpoint.

[24] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

|                                   |   |   |  |  |
|-----------------------------------|---|---|--|--|
| <b>End point values</b>           | V114, Schedule C: Participants 2-17 years | Pprevnar 13®, Schedule C: Participants 2-17 years |  |  |
| Subject group type                | Reporting group                           | Reporting group                                   |  |  |
| Number of subjects analysed       | 177                                       | 175   |  |  |
| Units: Percentage of Participants |   |   |  |  |
| number (confidence interval 95%)  | 0.0 (0.0 to 2.1)                          | 0.0 (0.0 to 2.1)                                  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Meeting Serotype-specific IgG Threshold Value of $\geq 0.35$ $\mu\text{g/mL}$ for Each of the 15 Serotypes - Schedule A: 7-11 Months

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Meeting Serotype-specific IgG Threshold Value of $\geq 0.35$ $\mu\text{g/mL}$ for Each of the 15 Serotypes - Schedule A: 7-11 Months <sup>[25]</sup> |
|-----------------|---|

End point description:

Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using PnECL. The percentage that achieved the GMC threshold value of  $\geq 0.35$   $\mu\text{g/mL}$  was summarized. Estimated confidence intervals (CIs) are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

30 days post final vaccination

Notes:

[25] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

|                                   |  |  |  |  |
|-----------------------------------|--|--|--|--|
| <b>End point values</b>           | V114, Schedule A: Participants 7-11 months | Pprevnar 13®, Schedule A: Participants 7-11 months |  |  |
| Subject group type                | Reporting group                            | Reporting group                                    |  |  |
| Number of subjects analysed       | 64   | 64   |  |  |
| Units: Percentage of Participants |  |  |  |  |
| number (confidence interval 95%)  |  |  |  |  |
| Serotype 1 (n=60,59)              | 100.0 (94.0 to 100.0)                      | 100.0 (93.9 to 100.0)                              |  |  |

|                        |                       |                       |  |  |
|------------------------|-----------------------|-----------------------|--|--|
| Serotype 3 (n=60,59)   | 100.0 (94.0 to 100.0) | 96.6 (88.3 to 99.6)   |  |  |
| Serotype 4 (n=60,59)   | 100.0 (94.0 to 100.0) | 100.0 (93.9 to 100.0) |  |  |
| Serotype 5 (n=60,59)   | 100.0 (94.0 to 100.0) | 100.0 (93.9 to 100.0) |  |  |
| Serotype 6A (n=60,59)  | 95.0 (86.1 to 99.0)   | 98.3 (90.9 to 100.0)  |  |  |
| Serotype 6B (n=60,59)  | 96.7 (88.5 to 99.6)   | 100.0 (93.9 to 100.0) |  |  |
| Serotype 7F (n=60,59)  | 100.0 (94.0 to 100.0) | 100.0 (93.9 to 100.0) |  |  |
| Serotype 9V (n=60,59)  | 98.3 (91.1 to 100.0)  | 100.0 (93.9 to 100.0) |  |  |
| Serotype 14 (n=60,59)  | 100.0 (94.0 to 100.0) | 100.0 (93.9 to 100.0) |  |  |
| Serotype 18C (n=60,59) | 100.0 (94.0 to 100.0) | 100.0 (93.9 to 100.0) |  |  |
| Serotype 19A (n=60,59) | 100.0 (94.0 to 100.0) | 100.0 (93.9 to 100.0) |  |  |
| Serotype 19F (n=60,59) | 100.0 (94.0 to 100.0) | 100.0 (93.9 to 100.0) |  |  |
| Serotype 23F (n=60,59) | 98.3 (91.1 to 100.0)  | 100.0 (93.9 to 100.0) |  |  |
| Serotype 22F (n=60,58) | 100.0 (94.0 to 100.0) | 13.8 (6.1 to 25.4)    |  |  |
| Serotype 33F (n=60,59) | 100.0 (94.0 to 100.0) | 11.9 (4.9 to 22.9)    |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Meeting Serotype-specific IgG Threshold Value of $\geq 0.35$ $\mu\text{g/mL}$ for Each of the 15 Serotypes - Schedule B: 12-23 Months

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Meeting Serotype-specific IgG Threshold Value of $\geq 0.35$ $\mu\text{g/mL}$ for Each of the 15 Serotypes - Schedule B: 12-23 Months <sup>[26]</sup> |
|-----------------|--|

End point description:

Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using PnECL. The percentage that achieved the GMC threshold value of  $\geq 0.35$   $\mu\text{g/mL}$  was summarized. Estimated CIs are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

30 days post final vaccination

Notes:

[26] - 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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

| End point values                  | V114, Schedule B: Participants 12-23 months | Pprevnar 13®, Schedule B: Participants 12-23 months |  |  |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group                             | Reporting group                                     |  |  |
| Number of subjects analysed       | 62  | 64  |  |  |
| Units: Percentage of Participants |   |   |  |  |
| number (confidence interval 95%)  |   |   |  |  |
| Serotype 1 (n=56,60)              | 100.0 (93.6 to 100.0)                       | 98.3 (91.1 to 100.0)                                |  |  |
| Serotype 3 (n=56,60)              | 98.2 (90.4 to 100.0)                        | 90.0 (79.5 to 96.2)                                 |  |  |
| Serotype 4 (n=56,60)              | 100.0 (93.6 to 100.0)                       | 96.7 (88.5 to 99.6)                                 |  |  |
| Serotype 5 (n=56,60)              | 98.2 (90.4 to 100.0)                        | 98.3 (91.1 to 100.0)                                |  |  |
| Serotype 6A (n=56,60)             | 83.9 (71.7 to 92.4)                         | 95.0 (86.1 to 99.0)                                 |  |  |
| Serotype 6B (n=56,60)             | 89.3 (78.1 to 96.0)                         | 88.3 (77.4 to 95.2)                                 |  |  |
| Serotype 7F (n=56,60)             | 98.2 (90.4 to 100.0)                        | 100.0 (94.0 to 100.0)                               |  |  |
| Serotype 9V (n=56,60)             | 98.2 (90.4 to 100.0)                        | 96.7 (88.5 to 99.6)                                 |  |  |
| Serotype 14 (n=56,60)             | 98.2 (90.4 to 100.0)                        | 100.0 (94.0 to 100.0)                               |  |  |
| Serotype 18C (n=56,60)            | 96.4 (87.7 to 99.6)                         | 98.3 (91.1 to 100.0)                                |  |  |
| Serotype 19A (n=56,60)            | 98.2 (90.4 to 100.0)                        | 100.0 (94.0 to 100.0)                               |  |  |
| Serotype 19F (n=56,60)            | 100.0 (93.6 to 100.0)                       | 100.0 (94.0 to 100.0)                               |  |  |
| Serotype 23F (n=56,60)            | 94.6 (85.1 to 98.9)                         | 88.3 (77.4 to 95.2)                                 |  |  |
| Serotype 22F (n=56,60)            | 100.0 (93.6 to 100.0)                       | 6.7 (1.8 to 16.2)                                   |  |  |
| Serotype 33F (n=56,60)            | 94.6 (85.1 to 98.9)                         | 15.0 (7.1 to 26.6)                                  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Meeting Serotype-specific IgG Threshold Value of $\geq 0.35$ $\mu\text{g/mL}$ for Each of the 15 Serotypes - Schedule C: 2-17 Years

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Meeting Serotype-specific IgG Threshold Value of $\geq 0.35$ $\mu\text{g/mL}$ for Each of the 15 Serotypes - Schedule C: 2-17 Years <sup>[27]</sup> |
|-----------------|--|

End point description:

Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using PnECL. The percentage that achieved the GMC threshold value of  $\geq 0.35$   $\mu\text{g/mL}$  was summarized. Estimated CIs are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

30 days post vaccination

Notes:

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

| End point values                  | V114, Schedule C: Participants 2-17 years | Prevnar 13®, Schedule C: Participants 2-17 years |  |  |
|-----------------------------------|---|--|--|--|
| Subject group type                | Reporting group                           | Reporting group                                  |  |  |
| Number of subjects analysed       | 177                                       | 175  |  |  |
| Units: Percentage of Participants |   |  |  |  |
| number (confidence interval 95%)  |   |  |  |  |
| Serotype 1 (n=162,162)            | 99.4 (96.6 to 100.0)                      | 100.0 (97.7 to 100.0)                            |  |  |
| Serotype 3 (n=162,162)            | 95.7 (91.3 to 98.2)                       | 87.7 (81.6 to 92.3)                              |  |  |
| Serotype 4 (n=162,162)            | 98.8 (95.6 to 99.9)                       | 100.0 (97.7 to 100.0)                            |  |  |
| Serotype 5 (n=162,162)            | 99.4 (96.6 to 100.0)                      | 99.4 (96.6 to 100.0)                             |  |  |
| Serotype 6A (n=162,162)           | 98.1 (94.7 to 99.6)                       | 98.1 (94.7 to 99.6)                              |  |  |
| Serotype 6B (n=162,162)           | 98.1 (94.7 to 99.6)                       | 96.9 (92.9 to 99.0)                              |  |  |
| Serotype 7F (n=162,162)           | 99.4 (96.6 to 100.0)                      | 100.0 (97.7 to 100.0)                            |  |  |
| Serotype 9V (n=162,162)           | 100.0 (97.7 to 100.0)                     | 98.8 (95.6 to 99.9)                              |  |  |
| Serotype 14 (n=162,162)           | 99.4 (96.6 to 100.0)                      | 98.1 (94.7 to 99.6)                              |  |  |
| Serotype 18C (n=162,162)          | 100.0 (97.7 to 100.0)                     | 100.0 (97.7 to 100.0)                            |  |  |
| Serotype 19A (n=162,162)          | 100.0 (97.7 to 100.0)                     | 100.0 (97.7 to 100.0)                            |  |  |
| Serotype 19F (n=162,162)          | 99.4 (96.6 to 100.0)                      | 100.0 (97.7 to 100.0)                            |  |  |
| Serotype 23F (n=162,162)          | 99.4 (96.6 to 100.0)                      | 95.7 (91.3 to 98.2)                              |  |  |
| Serotype 22F (n=162,159)          | 100.0 (97.7 to 100.0)                     | 37.7 (30.2 to 45.8)                              |  |  |
| Serotype 33F (n=162,160)          | 99.4 (96.6 to 100.0)                      | 37.5 (30.0 to 45.5)                              |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Non-serious adverse events: Up to 14 days after vaccination; Serious adverse events and all-cause mortality: Up to ~6 months after the last vaccination.

Adverse event reporting additional description:

The analysis population included all randomized participants who received at least 1 dose of study intervention.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 23.1 |
|--------------------|------|

### Reporting groups

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | V114 (7-11 months) |
|-----------------------|--------------------|

Reporting group description:

Each participant received a 0.5 mL intramuscular (IM) injection for 7 to 11 months of age (Pneumococcal conjugate vaccine [PCV]-naïve). 3 doses. Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.

|                       |                        |
|-----------------------|------------------------|
| Reporting group title | Pprevnar (7-11 months) |
|-----------------------|------------------------|

Reporting group description:

Each participant received a 0.5 mL IM injection for 7 to 11 months of age (PCV-naïve). 3 doses. Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.

|                       |                     |
|-----------------------|---------------------|
| Reporting group title | V114 (12-23 months) |
|-----------------------|---------------------|

Reporting group description:

Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve), 2 doses: Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Pprevnar (12-23 months) |
|-----------------------|-------------------------|

Reporting group description:

Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve), 2 doses: Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | V114 (2-17 years) |
|-----------------------|-------------------|

Reporting group description:

Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV experienced): Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.

|                       |                       |
|-----------------------|-----------------------|
| Reporting group title | Pprevnar (2-17 years) |
|-----------------------|-----------------------|

Reporting group description:

Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced): Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.

| Serious adverse events                            | V114 (7-11 months) | Pprevnar (7-11 months) | V114 (12-23 months) |
|---|--------------------|------------------------|---------------------|
| Total subjects affected by serious adverse events |                    |                        |                     |
| subjects affected / exposed                       | 7 / 64 (10.94%)    | 5 / 64 (7.81%)         | 4 / 62 (6.45%)      |
| number of deaths (all causes)                     | 0                  | 0                      | 0                   |
| number of deaths resulting from adverse events    | 0                  | 0                      | 0                   |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Injury, poisoning and procedural complications  |                |                |                |
| Limb injury                                     |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 1 / 62 (1.61%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Concussion                                      |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 0 / 62 (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                     | 1 / 64 (1.56%) | 1 / 64 (1.56%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Croup infectious                                |                |                |                |
| subjects affected / exposed                     | 1 / 64 (1.56%) | 0 / 64 (0.00%) | 0 / 62 (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          |
| Gastroenteritis                                 |                |                |                |
| subjects affected / exposed                     | 2 / 64 (3.13%) | 0 / 64 (0.00%) | 0 / 62 (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          |
| Gastroenteritis salmonella                      |                |                |                |
| subjects affected / exposed                     | 1 / 64 (1.56%) | 0 / 64 (0.00%) | 0 / 62 (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          |
| Pharyngitis                                     |                |                |                |
| subjects affected / exposed                     | 1 / 64 (1.56%) | 0 / 64 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumonia bacterial                             |                |                |                |
| subjects affected / exposed                     | 1 / 64 (1.56%) | 0 / 64 (0.00%) | 0 / 62 (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          |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Exanthema subitum                               |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 1 / 64 (1.56%) | 0 / 62 (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          |
| Tracheobronchitis                               |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 1 / 64 (1.56%) | 0 / 62 (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          |
| Pneumonia respiratory syncytial viral           |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 1 / 64 (1.56%) | 0 / 62 (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          |
| Chikungunya virus infection                     |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 1 / 62 (1.61%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Nasopharyngitis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 0 / 62 (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          |
| Pyelonephritis acute                            |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 0 / 62 (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          |
| Influenza                                       |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumonia                                       |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 0 / 62 (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          |
| Tonsillitis                                     |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 0 / 62 (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          |
| Wound abscess                                   |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumonia viral                                 |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 1 / 62 (1.61%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Bacteraemia                                     |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 1 / 64 (1.56%) | 0 / 62 (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          |
| Gastroenteritis viral                           |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 1 / 62 (1.61%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Tuberculosis                                    |                |                |                |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 64 (0.00%) | 0 / 62 (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>                     | Prevnam (12-23 months) | V114 (2-17 years) | Prevnam (2-17 years) |
|---|------------------------|-------------------|----------------------|
| Total subjects affected by serious adverse events |                        |                   |                      |
| subjects affected / exposed                       | 4 / 64 (6.25%)         | 4 / 177 (2.26%)   | 4 / 175 (2.29%)      |
| number of deaths (all causes)                     | 0                      | 0                 | 0                    |
| number of deaths resulting from adverse events    | 0                      | 0                 | 0                    |
| Injury, poisoning and procedural complications    |                        |                   |                      |
| Limb injury                                       |                        |                   |                      |
| subjects affected / exposed                       | 0 / 64 (0.00%)         | 0 / 177 (0.00%)   | 0 / 175 (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                |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| Concussion                                      |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Infections and infestations                     |                |                 |                 |
| Bronchiolitis                                   |                |                 |                 |
| subjects affected / exposed                     | 1 / 64 (1.56%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Croup infectious                                |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (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                     | 1 / 64 (1.56%) | 1 / 177 (0.56%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Gastroenteritis salmonella                      |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Pharyngitis                                     |                |                 |                 |
| subjects affected / exposed                     | 1 / 64 (1.56%) | 0 / 177 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Pneumonia bacterial                             |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Exanthema subitum                               |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Tracheobronchitis                               |                |                 |                 |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Pneumonia respiratory syncytial viral           |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Chikungunya virus infection                     |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Nasopharyngitis                                 |                |                 |                 |
| subjects affected / exposed                     | 1 / 64 (1.56%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Pyelonephritis acute                            |                |                 |                 |
| subjects affected / exposed                     | 1 / 64 (1.56%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Influenza                                       |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 1 / 177 (0.56%) | 0 / 175 (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           |
| Pneumonia                                       |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 1 / 177 (0.56%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Tonsillitis                                     |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Wound abscess                                   |                |                 |                 |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Pneumonia viral                                 |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Bacteraemia                                     |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (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 viral                           |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 0 / 177 (0.00%) | 0 / 175 (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           |
| Tuberculosis                                    |                |                 |                 |
| subjects affected / exposed                     | 0 / 64 (0.00%) | 1 / 177 (0.56%) | 0 / 175 (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           |

Frequency threshold for reporting non-serious adverse events: 5 %

| <b>Non-serious adverse events</b>                     | V114 (7-11 months) | Prevnar (7-11 months) | V114 (12-23 months) |
|---|--------------------|-----------------------|---------------------|
| Total subjects affected by non-serious adverse events |                    |                       |                     |
| subjects affected / exposed                           | 44 / 64 (68.75%)   | 47 / 64 (73.44%)      | 46 / 62 (74.19%)    |
| Nervous system disorders                              |                    |                       |                     |
| Somnolence  |                    |                       |                     |
| subjects affected / exposed                           | 14 / 64 (21.88%)   | 10 / 64 (15.63%)      | 15 / 62 (24.19%)    |
| occurrences (all)                                     | 22                 | 15                    | 29                  |
| Headache  |                    |                       |                     |
| subjects affected / exposed                           | 0 / 64 (0.00%)     | 0 / 64 (0.00%)        | 0 / 62 (0.00%)      |
| occurrences (all)                                     | 0                  | 0                     | 0                   |
| General disorders and administration site conditions  |                    |                       |                     |

|  |                        |                        |                        |
|--|------------------------|------------------------|------------------------|
| Injection site erythema<br>subjects affected / exposed<br>occurrences (all)                                    | 18 / 64 (28.13%)<br>29 | 22 / 64 (34.38%)<br>36 | 13 / 62 (20.97%)<br>14 |
| Injection site induration<br>subjects affected / exposed<br>occurrences (all)                                  | 11 / 64 (17.19%)<br>20 | 9 / 64 (14.06%)<br>16  | 5 / 62 (8.06%)<br>8    |
| Injection site swelling<br>subjects affected / exposed<br>occurrences (all)                                    | 12 / 64 (18.75%)<br>23 | 10 / 64 (15.63%)<br>17 | 9 / 62 (14.52%)<br>11  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)  | 20 / 64 (31.25%)<br>26 | 14 / 64 (21.88%)<br>16 | 9 / 62 (14.52%)<br>11  |
| Injection site pain<br>subjects affected / exposed<br>occurrences (all)  | 12 / 64 (18.75%)<br>19 | 5 / 64 (7.81%)<br>6    | 21 / 62 (33.87%)<br>27 |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)  | 0 / 64 (0.00%)<br>0    | 0 / 64 (0.00%)<br>0    | 0 / 62 (0.00%)<br>0    |
| Gastrointestinal disorders<br>Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                    | 4 / 64 (6.25%)<br>4    | 3 / 64 (4.69%)<br>3    | 0 / 62 (0.00%)<br>0    |
| Psychiatric disorders<br>Irritability<br>subjects affected / exposed<br>occurrences (all)                      | 21 / 64 (32.81%)<br>39 | 28 / 64 (43.75%)<br>41 | 22 / 62 (35.48%)<br>33 |
| Musculoskeletal and connective tissue disorders<br>Myalgia<br>subjects affected / exposed<br>occurrences (all) | 0 / 64 (0.00%)<br>0    | 0 / 64 (0.00%)<br>0    | 0 / 62 (0.00%)<br>0    |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)             | 2 / 64 (3.13%)<br>2    | 6 / 64 (9.38%)<br>7    | 8 / 62 (12.90%)<br>11  |
| Upper respiratory tract infection  |                        |                        |                        |

|  |                        |                        |                        |
|--|------------------------|------------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)   | 0 / 64 (0.00%)<br>0    | 0 / 64 (0.00%)<br>0    | 4 / 62 (6.45%)<br>5    |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all) | 10 / 64 (15.63%)<br>15 | 12 / 64 (18.75%)<br>17 | 14 / 62 (22.58%)<br>21 |

| <b>Non-serious adverse events</b>   | Prevnar (12-23 months) | V114 (2-17 years)        | Prevnar (2-17 years)     |
|---|------------------------|--------------------------|--------------------------|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed  | 36 / 64 (56.25%)       | 125 / 177 (70.62%)       | 125 / 175 (71.43%)       |
| Nervous system disorders<br>Somnolence<br>subjects affected / exposed<br>occurrences (all)  | 11 / 64 (17.19%)<br>11 | 0 / 177 (0.00%)<br>0     | 0 / 175 (0.00%)<br>0     |
| Headache<br>subjects affected / exposed<br>occurrences (all)  | 0 / 64 (0.00%)<br>0    | 21 / 177 (11.86%)<br>32  | 24 / 175 (13.71%)<br>33  |
| General disorders and administration site conditions<br>Injection site erythema<br>subjects affected / exposed<br>occurrences (all) | 14 / 64 (21.88%)<br>16 | 34 / 177 (19.21%)<br>37  | 37 / 175 (21.14%)<br>37  |
| Injection site induration<br>subjects affected / exposed<br>occurrences (all)   | 6 / 64 (9.38%)<br>9    | 12 / 177 (6.78%)<br>13   | 26 / 175 (14.86%)<br>28  |
| Injection site swelling<br>subjects affected / exposed<br>occurrences (all)   | 8 / 64 (12.50%)<br>8   | 37 / 177 (20.90%)<br>39  | 42 / 175 (24.00%)<br>43  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)   | 7 / 64 (10.94%)<br>7   | 13 / 177 (7.34%)<br>14   | 13 / 175 (7.43%)<br>14   |
| Injection site pain<br>subjects affected / exposed<br>occurrences (all)   | 15 / 64 (23.44%)<br>17 | 97 / 177 (54.80%)<br>111 | 99 / 175 (56.57%)<br>106 |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)   | 0 / 64 (0.00%)<br>0    | 28 / 177 (15.82%)<br>42  | 30 / 175 (17.14%)<br>38  |

|   |                  |                   |                   |
|---|------------------|-------------------|-------------------|
| Gastrointestinal disorders                      |                  |                   |                   |
| Diarrhoea                                       |                  |                   |                   |
| subjects affected / exposed                     | 0 / 64 (0.00%)   | 0 / 177 (0.00%)   | 0 / 175 (0.00%)   |
| occurrences (all)                               | 0                | 0                 | 0                 |
| Psychiatric disorders                           |                  |                   |                   |
| Irritability                                    |                  |                   |                   |
| subjects affected / exposed                     | 14 / 64 (21.88%) | 0 / 177 (0.00%)   | 0 / 175 (0.00%)   |
| occurrences (all)                               | 18               | 0                 | 0                 |
| Musculoskeletal and connective tissue disorders |                  |                   |                   |
| Myalgia   |                  |                   |                   |
| subjects affected / exposed                     | 0 / 64 (0.00%)   | 42 / 177 (23.73%) | 30 / 175 (17.14%) |
| occurrences (all)                               | 0                | 46                | 34                |
| Infections and infestations                     |                  |                   |                   |
| Nasopharyngitis                                 |                  |                   |                   |
| subjects affected / exposed                     | 7 / 64 (10.94%)  | 0 / 177 (0.00%)   | 0 / 175 (0.00%)   |
| occurrences (all)                               | 7                | 0                 | 0                 |
| Upper respiratory tract infection               |                  |                   |                   |
| subjects affected / exposed                     | 1 / 64 (1.56%)   | 0 / 177 (0.00%)   | 0 / 175 (0.00%)   |
| occurrences (all)                               | 1                | 0                 | 0                 |
| Metabolism and nutrition disorders              |                  |                   |                   |
| Decreased appetite                              |                  |                   |                   |
| subjects affected / exposed                     | 12 / 64 (18.75%) | 0 / 177 (0.00%)   | 0 / 175 (0.00%)   |
| occurrences (all)                               | 19               | 0                 | 0                 |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported