



Clinical trial results:

A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-controlled, Lot-to-Lot Consistency Study to Evaluate the Safety, Tolerability, and Immunogenicity of V114 in Healthy Adults 50 Years of Age or Older (PNEU-TRUE)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2018-004266-33 |
| Trial protocol | GB FI DK |
| Global end of trial date | 03 April 2020 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 02 April 2021 |
| First version publication date | 02 April 2021 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | V114-020 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03950856 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 03 April 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 03 April 2020 |
| Global end of trial reached? | Yes |
| Global end of trial date | 03 April 2020 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objectives were to evaluate the safety and tolerability of V114 and to compare the serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMTs) across 3 different lots of V114. The primary hypothesis is that all 3 lots of V114 are equivalent as measured by the serotype-specific OPA GMTs for 15 serotypes in V114 at 30 days post-vaccination.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable countryand/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 | 12 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 | Australia: 109 |
| Country: Number of subjects enrolled | Chile: 190 |
| Country: Number of subjects enrolled | Denmark: 466 |
| Country: Number of subjects enrolled | Finland: 473 |
| Country: Number of subjects enrolled | United Kingdom: 46 |
| Country: Number of subjects enrolled | United States: 1056 |
| Worldwide total number of subjects | 2340 |
| EEA total number of subjects | 939 |

Notes:

Subjects enrolled per age group

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

| | |
|---------------------------|------|
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 1039 |
| From 65 to 84 years | 1288 |
| 85 years and over | 13 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Healthy males or females ≥ 50 years of age without a history of invasive pneumococcal disease or prior administration of any pneumococcal vaccine were enrolled in this study.

Period 1

| | |
|------------------------------|-----------------------------|
| Period 1 title | Randomized (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 |
| Arm title | V114 Lot 1 |

Arm description:

Single intramuscular (IM) dose at 0.5 mL of V114 Lot 1 pneumococcal conjugate vaccine at Visit 1 (Day 1)

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | 15-valent pneumococcal conjugate vaccine with serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in each 0.5 mL dose. |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single intramuscular (IM) dose at 0.5 mL of V114 pneumococcal conjugate vaccine at Visit 1 (Day 1)

| | |
|------------------|------------|
| Arm title | V114 Lot 2 |
|------------------|------------|

Arm description:

Single IM dose at 0.5 mL of V114 Lot 2 pneumococcal conjugate vaccine at Visit 1 (Day 1)

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | 15-valent pneumococcal conjugate vaccine with serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in each 0.5 mL dose. |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single intramuscular (IM) dose at 0.5 mL of V114 pneumococcal conjugate vaccine at Visit 1 (Day 1)

| | |
|------------------|------------|
| Arm title | V114 Lot 3 |
|------------------|------------|

Arm description:

Single IM dose at 0.5 mL of V114 Lot 3 pneumococcal conjugate vaccine at Visit 1 (Day 1)

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

| | |
|--|---|
| Investigational medicinal product name | 15-valent pneumococcal conjugate vaccine with serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in each 0.5 mL dose. |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Single intramuscular (IM) dose at 0.5 mL of V114 pneumococcal conjugate vaccine at Visit 1 (Day 1) | |
| Arm title | Prevnam 13™ |
| Arm description: | |
| Single IM dose at 0.5 mL of Prevnam 13™ at Visit 1 (Day 1) | |
| Arm type | Active comparator |
| Investigational medicinal product name | 13-valent pneumococcal conjugate vaccine with serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F in each 0.5. mL dose. |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Single IM dose at Visit 1 (Day 1) | |

| Number of subjects in period 1 | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 |
|---------------------------------------|------------|------------|------------|
| Started | 702 | 704 | 701 |
| Vaccinated | 698 | 704 | 700 |
| Completed | 683 | 689 | 683 |
| Not completed | 19 | 15 | 18 |
| Adverse event, serious fatal | 1 | 2 | - |
| Consent withdrawn by subject | 4 | 1 | 3 |
| Unable to phone | 7 | 6 | 7 |
| Lost to follow-up | 5 | 6 | 8 |
| Protocol deviation | 2 | - | - |

| Number of subjects in period 1 | Prevnam 13™ |
|---------------------------------------|-------------|
| Started | 233 |
| Vaccinated | 231 |
| Completed | 227 |
| Not completed | 6 |
| Adverse event, serious fatal | - |
| Consent withdrawn by subject | 1 |
| Unable to phone | 2 |
| Lost to follow-up | 2 |
| Protocol deviation | 1 |

Baseline characteristics

Reporting groups

| | |
|--|-------------|
| Reporting group title | V114 Lot 1 |
| Reporting group description: | |
| Single intramuscular (IM) dose at 0.5 mL of V114 Lot 1 pneumococcal conjugate vaccine at Visit 1 (Day 1) | |
| Reporting group title | V114 Lot 2 |
| Reporting group description: | |
| Single IM dose at 0.5 mL of V114 Lot 2 pneumococcal conjugate vaccine at Visit 1 (Day 1) | |
| Reporting group title | V114 Lot 3 |
| Reporting group description: | |
| Single IM dose at 0.5 mL of V114 Lot 3 pneumococcal conjugate vaccine at Visit 1 (Day 1) | |
| Reporting group title | Prevnar 13™ |
| Reporting group description: | |
| Single IM dose at 0.5 mL of Prevnar 13™ at Visit 1 (Day 1) | |

| Reporting group values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 |
|--|------------|------------|------------|
| Number of subjects | 702 | 704 | 701 |
| Age Categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 313 | 312 | 311 |
| From 65-84 years | 385 | 388 | 387 |
| 85 years and over | 4 | 4 | 3 |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 64.4 | 64.4 | 64.3 |
| standard deviation | ± 7.5 | ± 7.8 | ± 7.4 |
| Gender Categorical | | | |
| Units: Subjects | | | |
| Female | 387 | 422 | 404 |
| Male | 315 | 282 | 297 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 1 | 4 | 0 |
| Asian | 18 | 34 | 36 |
| Native Hawaiian or Other Pacific Islander | 1 | 0 | 0 |
| Black or African American | 35 | 41 | 34 |
| White | 644 | 621 | 628 |
| More than one race | 3 | 4 | 3 |
| Unknown or Not Reported | 0 | 0 | 0 |

| | | | |
|-------------------------|-----|-----|-----|
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 131 | 154 | 138 |
| Not Hispanic or Latino | 560 | 540 | 558 |
| Unknown or Not Reported | 11 | 10 | 5 |

| Reporting group values | Prevnar 13™ | Total | |
|---|-------------|-------|--|
| Number of subjects | 233 | 2340 | |
| Age Categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 103 | 1039 | |
| From 65-84 years | 128 | 1288 | |
| 85 years and over | 2 | 13 | |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 64.2 | | |
| standard deviation | ± 8.0 | - | |
| Gender Categorical | | | |
| Units: Subjects | | | |
| Female | 133 | 1346 | |
| Male | 100 | 994 | |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 5 | |
| Asian | 10 | 98 | |
| Native Hawaiian or Other Pacific Islander | 0 | 1 | |
| Black or African American | 20 | 130 | |
| White | 203 | 2096 | |
| More than one race | 0 | 10 | |
| Unknown or Not Reported | 0 | 0 | |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 41 | 464 | |
| Not Hispanic or Latino | 190 | 1848 | |
| Unknown or Not Reported | 2 | 28 | |

End points

End points reporting groups

| | |
|--|------------------------------|
| Reporting group title | V114 Lot 1 |
| Reporting group description: Single intramuscular (IM) dose at 0.5 mL of V114 Lot 1 pneumococcal conjugate vaccine at Visit 1 (Day 1) | |
| Reporting group title | V114 Lot 2 |
| Reporting group description: Single IM dose at 0.5 mL of V114 Lot 2 pneumococcal conjugate vaccine at Visit 1 (Day 1) | |
| Reporting group title | V114 Lot 3 |
| Reporting group description: Single IM dose at 0.5 mL of V114 Lot 3 pneumococcal conjugate vaccine at Visit 1 (Day 1) | |
| Reporting group title | Prevnar 13™ |
| Reporting group description: Single IM dose at 0.5 mL of Prevnar 13™ at Visit 1 (Day 1) | |
| Subject analysis set title | V114 Combined Lots 1,2 and 3 |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Single IM dose at 0.5 mL of either V114 Lots 1,2 or 3 pneumococcal conjugate vaccine at Visit 1 (Day 1) | |
| Subject analysis set title | Pprevnar 13™ |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Single IM dose at 0.5 mL of Prevnar 13™ at Visit 1 (Day 1) | |

Primary: Percentage of Participants with a Solicited Injection-site Adverse Event Following Vaccination With Separate V114 Lots

| | |
|--|---|
| End point title | Percentage of Participants with a Solicited Injection-site Adverse Event Following Vaccination With Separate V114 Lots ^[1] |
| End point description: An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Solicited injection-site AEs consisted of redness/erythema, swelling, and tenderness/pain. The 95% confidence interval (CI) were based on the exact binomial method proposed by Clopper and Pearson. Following vaccination with the three lots of V114 the percentage of participants with solicited injection-site AEs was assessed. Per the statistical analysis plan, the Prevnar 13™ treatment group was not included as it was not analyzed with the same approach as the separate V114 lots. The population analyzed was randomized participants according to the intervention they actually received. One participant randomized to the Prevnar 13™ group incorrectly received V114 Lot 1. | |
| End point type | Primary |
| End point timeframe: Up to Day 5 | |

Notes:

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

Justification: Comparison of treatment arms was not performed for this endpoint per the statistical analysis plan.

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnar 13™ |
|-----------------------------------|---------------------|---------------------|---------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 699 | 704 | 700 | 0 ^[2] |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Injection site erythema | 10.2 (8.0 to 12.6) | 11.5 (9.2 to 14.1) | 11.0 (8.8 to 13.6) | (to) |
| Injection site pain | 66.1 (62.5 to 69.6) | 67.0 (63.4 to 70.5) | 67.3 (63.7 to 70.8) | (to) |
| Injection site swelling | 15.6 (13.0 to 18.5) | 15.8 (13.2 to 18.7) | 14.7 (12.2 to 17.6) | (to) |

Notes:

[2] - The Prevnar 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with a Solicited Injection-site Adverse Event Following Vaccination: Combined Lots of V114 or Prevnar 13™

| | |
|-----------------|--|
| End point title | Percentage of Participants with a Solicited Injection-site Adverse Event Following Vaccination: Combined Lots of V114 or Prevnar 13™ |
|-----------------|--|

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Solicited injection-site AEs consisted of redness/erythema, swelling, and tenderness/pain. Per the statistical analysis plan, within-group CIs were not calculated. The population analyzed was randomized participants according to the intervention they actually received. One participant randomized to the Prevnar 13™ group incorrectly received V114 Lot 1.

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

End point timeframe:

Up to Day 5

| End point values | V114 Combined Lots 1,2 and 3 | Prevnar 13™ | | |
|-----------------------------------|------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2103 | 230 | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Injection site erythema | 10.9 | 9.6 | | |
| Injection site pain | 66.8 | 52.2 | | |
| Injection site swelling | 15.4 | 14.3 | | |

Statistical analyses

| | |
|----------------------------|-------------------------|
| Statistical analysis title | Injection site erythema |
|----------------------------|-------------------------|

| | |
|---|--|
| Statistical analysis description: | |
| V114 Combined Lots minus Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.538 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Difference in Percentage |
| Point estimate | 1.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.3 |
| upper limit | 4.8 |

| | |
|---|--|
| Statistical analysis title | Injection site pain |
| Statistical analysis description: | |
| V114 Combined Lots minus Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.001 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Difference in Percentage |
| Point estimate | 14.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.9 |
| upper limit | 21.4 |

| | |
|---|--|
| Statistical analysis title | Injection site swelling |
| Statistical analysis description: | |
| V114 Combined Lots minus Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.686 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Difference in Percentage |
| Point estimate | 1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.3 |
| upper limit | 5.3 |

Primary: Percentage of Participants with a Solicited Systemic Adverse Event Following Vaccination With Separate V114 Lots

| | |
|-----------------|---|
| End point title | Percentage of Participants with a Solicited Systemic Adverse Event Following Vaccination With Separate V114 Lots ^[3] |
|-----------------|---|

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Solicited systemic AEs consisted of muscle pain/myalgia, joint pain/arthritis, headache, and tiredness/fatigue. The 95% CI were based on the exact binomial method proposed by Clopper and Pearson. Following vaccination with the three lots of V114 the percentage of participants with solicited systemic AEs was assessed. Per the statistical analysis plan, the Prevnar 13™ treatment group was not included as it was not analyzed with the same approach as the separate V114 lots. The population analyzed was randomized participants according to the intervention they actually received. One participant randomized to the Prevnar 13™ group incorrectly received V114 Lot 1.

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

End point timeframe:

Up to Day 14

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: Comparison of treatment arms was not performed for this endpoint per the statistical analysis plan.

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnar 13™ |
|-----------------------------------|---------------------|---------------------|---------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 699 | 704 | 700 | 0 ^[4] |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Arthralgia | 7.6 (5.7 to 9.8) | 7.0 (5.2 to 9.1) | 8.4 (6.5 to 10.7) | (to) |
| Fatigue | 22.0 (19.0 to 25.3) | 20.9 (17.9 to 24.1) | 21.6 (18.6 to 24.8) | (to) |
| Headache | 18.2 (15.4 to 21.2) | 19.9 (17.0 to 23.0) | 18.6 (15.8 to 21.7) | (to) |
| Myalgia | 28.0 (24.7 to 31.5) | 24.3 (21.2 to 27.6) | 28.4 (25.1 to 31.9) | (to) |

Notes:

[4] - The Prevnar 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with a Solicited Systemic Adverse Event Following Vaccination: Combined Lots of V114 or Prevnar 13™

| | |
|-----------------|--|
| End point title | Percentage of Participants with a Solicited Systemic Adverse Event Following Vaccination: Combined Lots of V114 or Prevnar |
|-----------------|--|

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Solicited systemic AEs consisted of muscle pain/myalgia, joint pain/arthralgia, headache, and tiredness/fatigue. Per the statistical analysis plan, within-group CIs were not calculated. The population analyzed was randomized participants according to the intervention they actually received. One participant randomized to the Pevnar 13™ group incorrectly received V114 Lot 1.

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

End point timeframe:

Up to Day 14

| End point values | V114 Combined Lots 1,2 and 3 | Pevnar 13™ | | |
|-----------------------------------|------------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2103 | 230 | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Arthralgia | 7.7 | 5.7 | | |
| Fatigue | 21.5 | 22.2 | | |
| Headache | 18.9 | 18.7 | | |
| Myalgia | 26.9 | 21.7 | | |

Statistical analyses

| | |
|----------------------------|------------|
| Statistical analysis title | Arthralgia |
|----------------------------|------------|

Statistical analysis description:

V114 Combined Lots minus Pevnar 13™

| | |
|---|---|
| Comparison groups | V114 Combined Lots 1,2 and 3 v Pevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.272 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Difference in Percentage |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.9 |
| upper limit | 4.7 |

| | |
|----------------------------|---------|
| Statistical analysis title | Fatigue |
|----------------------------|---------|

Statistical analysis description:

V114 Combined Lots minus Pevnar 13™

| | |
|---|---|
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevna 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.812 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Difference in Percentage |
| Point estimate | -0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.7 |
| upper limit | 4.5 |

| | |
|--|---|
| Statistical analysis title | Headache |
| Statistical analysis description: V114 Combined Lots minus Prevna 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevna 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.947 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Difference in Percentage |
| Point estimate | 0.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.6 |
| upper limit | 5 |

| | |
|--|---|
| Statistical analysis title | Myalgia |
| Statistical analysis description: V114 Combined Lots minus Prevna 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevna 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.091 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Difference in Percentage |
| Point estimate | 5.2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.9 |
| upper limit | 10.4 |

Primary: Percentage of Participants with a Vaccine-related Serious Adverse Event Following Vaccination With Separate V114 Lots

| | |
|-----------------|--|
| End point title | Percentage of Participants with a Vaccine-related Serious Adverse Event Following Vaccination With Separate V114 Lots ^[5] |
|-----------------|--|

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. Relatedness of an SAE to the study vaccine is determined by the investigator. The 95% CI were based on the exact binomial method proposed by Clopper and Pearson. Following vaccination with the three lots of V114 the percentage of participants with SAEs was assessed. Per the statistical analysis plan, the Prevnar 13™ treatment group was not included as it was not analyzed with the same approach as the separate V114 lots. The population analyzed was randomized participants according to the intervention they actually received. One participant randomized to the Prevnar 13™ group incorrectly received V114 Lot 1.

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

End point timeframe:

Up to Month 6

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: Comparison of treatment arms was not performed for this endpoint per the statistical analysis plan.

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnar 13™ |
|-----------------------------------|------------------|------------------|------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 699 | 704 | 700 | 0 ^[6] |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.0 (0.0 to 0.4) | 0.0 (0.0 to 0.4) | 0.0 (0.0 to 0.4) | (to) |

Notes:

[6] - The Prevnar 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with a Vaccine-related Serious Adverse Event Following Vaccination: Combined Lots of V114 or Prevnar 13™

| | |
|-----------------|---|
| End point title | Percentage of Participants with a Vaccine-related Serious Adverse Event Following Vaccination: Combined Lots of V114 or Prevnar 13™ |
|-----------------|---|

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. Relatedness of an SAE to the study vaccine is determined by the investigator. Per the statistical analysis plan, within-group CIs were not calculated. The population analyzed was

randomized participants according to the intervention they actually received. One participant randomized to the Prevnar 13™ group incorrectly received V114 Lot 1.

| | |
|----------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| Up to Month 6 | |

| End point values | V114 Combined Lots 1,2 and 3 | Prevnar 13™ | | |
|-----------------------------------|------------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2103 | 230 | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 0.0 | 0.0 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Vaccine-related SAEs |
| Statistical analysis description: | |
| V114 Combined Lots minus Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | Difference in Percentage |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.6 |
| upper limit | 0.2 |

Primary: Geometric Mean Titer of Serotype-specific Opsonophagocytic Activity (OPA) Following Vaccination With Separate V114 Lots

| | |
|---|---|
| End point title | Geometric Mean Titer of Serotype-specific Opsonophagocytic Activity (OPA) Following Vaccination With Separate V114 Lots |
| End point description: | |
| <p>Sera from participants was used to measure geometric mean titer (GMT) of 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, using the Multiplexed Opsonophagocytic Assay (MOPA). The brackets next to each serotype show the number of participants analyzed for Lots 1, 2 and 3. Per the statistical analysis plan, within-group CIs were not calculated, but 95% CIs were calculated for the GMT ratios between pairs of V114 lots by a constrained longitudinal data analysis (cLDA) model. The population analyzed was all randomized participants without deviations from the protocol that may substantially affect the results of the endpoint. Deviations include randomized but not vaccinated, missing results for serotypes, blood drawn out of time window, prohibited concomitant medication or vaccination.</p> | |
| End point type | Primary |

End point timeframe:

Day 30

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnam 13™ |
|------------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 698 | 704 | 700 | 0 ^[7] |
| Units: 1/dil | | | | |
| number (not applicable) | | | | |
| Serotype 1 (n=693,693,688) | 248.5 | 251.6 | 239.4 | |
| Serotype 3 (n=693,693,688) | 198.3 | 232.2 | 214.4 | |
| Serotype 4 (n=693,692,688) | 1073.1 | 1303.7 | 1074.4 | |
| Serotype 5 (n=693,693,688) | 389.8 | 461.6 | 391.3 | |
| Serotype 6A (n=688,691,686) | 5845.0 | 6077.6 | 6123.8 | |
| Serotype 6B (n=693,692,688) | 5160.6 | 5362.7 | 5109.5 | |
| Serotype 7F (n=692,692,687) | 3757.7 | 4590.5 | 4202.0 | |
| Serotype 9V (n=691,693,688) | 1708.4 | 1690.6 | 1749.9 | |
| Serotype 14 (n=693,693,687) | 2364.8 | 2509.6 | 2050.6 | |
| Serotype 18C (n=693,692,688) | 3880.8 | 3522.4 | 3381.0 | |
| Serotype 19A (n=693,693,688) | 3384.7 | 3774.8 | 3498.5 | |
| Serotype 19F (n=693,692,688) | 1866.4 | 2017.8 | 1993.2 | |
| Serotype 23F (n=690,692,686) | 2222.9 | 2417.8 | 2133.0 | |
| Serotype 22F (n=688,692,684) | 2617.4 | 2761.6 | 2676.0 | |
| Serotype 33F (n=691,690,688) | 7758.1 | 7736.9 | 7365.6 | |

Notes:

[7] - The Prevnam 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

| Statistical analysis title | Serotype 1 |
|--|----------------------------|
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 2 v V114 Lot 1 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[8] |
| P-value | < 0.001 ^[9] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.18 |

Notes:

[8] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[9] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a

conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 1 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[10] |
| P-value | < 0.001 ^[11] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.87 |
| upper limit | 1.24 |

Notes:

[10] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[11] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 1 |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[12] |
| P-value | < 0.001 ^[13] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.88 |
| upper limit | 1.25 |

Notes:

[12] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[13] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 3 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |

| | |
|---|-----------------------------|
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[14] |
| P-value | < 0.001 ^[15] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.85 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.75 |
| upper limit | 0.97 |

Notes:

[14] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[15] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 3 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[16] |
| P-value | < 0.001 ^[17] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.81 |
| upper limit | 1.05 |

Notes:

[16] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[17] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 3 |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[18] |
| P-value | < 0.001 ^[19] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.08 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.95 |
| upper limit | 1.23 |

Notes:

[18] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[19] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 4 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[20] |
| P-value | < 0.001 ^[21] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.82 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 0.97 |

Notes:

[20] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[21] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 4 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[22] |
| P-value | < 0.001 ^[23] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.85 |
| upper limit | 1.18 |

Notes:

[22] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[23] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 4 |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[24] |
| P-value | < 0.001 ^[25] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.21 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.03 |
| upper limit | 1.43 |

Notes:

[24] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[25] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 5 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[26] |
| P-value | < 0.001 ^[27] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.84 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 1.02 |

Notes:

[26] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[27] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 5 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |

| | |
|---|-----------------------------|
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[28] |
| P-value | < 0.001 ^[29] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.2 |

Notes:

[28] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[29] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|------------|
| Statistical analysis title | Serotype 5 |
|-----------------------------------|------------|

Statistical analysis description:

GMT Ratio V114 Lot 2 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[30] |
| P-value | < 0.001 ^[31] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.18 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.98 |
| upper limit | 1.42 |

Notes:

[30] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[31] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 6A |
|-----------------------------------|-------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 2

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[32] |
| P-value | < 0.001 ^[33] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.96 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.12 |

Notes:

[32] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[33] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 6A |
|-----------------------------------|-------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[34] |
| P-value | < 0.001 ^[35] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.95 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.12 |

Notes:

[34] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[35] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 6A |
|-----------------------------------|-------------|

Statistical analysis description:

GMT Ratio V114 Lot 2 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[36] |
| P-value | < 0.001 ^[37] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.99 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.85 |
| upper limit | 1.16 |

Notes:

[36] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[37] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 6B |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[38] |
| P-value | < 0.001 ^[39] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.96 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.12 |

Notes:

[38] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[39] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 6B |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[40] |
| P-value | < 0.001 ^[41] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.01 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.18 |

Notes:

[40] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[41] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 6B |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |

| | |
|---|-----------------------------|
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[42] |
| P-value | < 0.001 ^[43] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.23 |

Notes:

[42] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[43] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 7F |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[44] |
| P-value | < 0.001 ^[45] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.82 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.72 |
| upper limit | 0.93 |

Notes:

[44] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[45] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 7F |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[46] |
| P-value | < 0.001 ^[47] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.89 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.01 |

Notes:

[46] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[47] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 7F |
|-----------------------------------|-------------|

Statistical analysis description:

GMT Ratio V114 Lot 2 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[48] |
| P-value | < 0.001 ^[49] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.09 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.96 |
| upper limit | 1.24 |

Notes:

[48] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[49] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 9V |
|-----------------------------------|-------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 2

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[50] |
| P-value | < 0.001 ^[51] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.01 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.88 |
| upper limit | 1.16 |

Notes:

[50] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[51] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 9V |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[52] |
| P-value | < 0.001 ^[53] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.85 |
| upper limit | 1.12 |

Notes:

[52] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[53] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 9V |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[54] |
| P-value | < 0.001 ^[55] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.97 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.11 |

Notes:

[54] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[55] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 14 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |

| | |
|---|-----------------------------|
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[56] |
| P-value | < 0.001 ^[57] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.81 |
| upper limit | 1.1 |

Notes:

[56] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[57] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 14 |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[58] |
| P-value | < 0.001 ^[59] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.99 |
| upper limit | 1.34 |

Notes:

[58] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[59] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 14 |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[60] |
| P-value | < 0.001 ^[61] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.22 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.05 |
| upper limit | 1.43 |

Notes:

[60] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[61] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 18C |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 2

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[62] |
| P-value | < 0.001 ^[63] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.1 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.96 |
| upper limit | 1.26 |

Notes:

[62] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[63] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 18C |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[64] |
| P-value | < 0.001 ^[65] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.15 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 1 |
| upper limit | 1.31 |

Notes:

[64] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[65] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 18C |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[66] |
| P-value | < 0.001 ^[67] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.91 |
| upper limit | 1.19 |

Notes:

[66] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[67] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 19A |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[68] |
| P-value | < 0.001 ^[69] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.02 |

Notes:

[68] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[69] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 19A |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |

| | |
|---|-----------------------------|
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[70] |
| P-value | < 0.001 ^[71] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.97 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.85 |
| upper limit | 1.1 |

Notes:

[70] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[71] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 19A |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 2 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[72] |
| P-value | < 0.001 ^[73] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.08 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.95 |
| upper limit | 1.22 |

Notes:

[72] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[73] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 19F |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 2

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[74] |
| P-value | < 0.001 ^[75] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.92 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.81 |
| upper limit | 1.05 |

Notes:

[74] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[75] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 19F |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[76] |
| P-value | < 0.001 ^[77] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.94 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.07 |

Notes:

[76] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[77] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 19F |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 2 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[78] |
| P-value | < 0.001 ^[79] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.01 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.89 |
| upper limit | 1.15 |

Notes:

[78] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[79] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 23F |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[80] |
| P-value | < 0.001 ^[81] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.77 |
| upper limit | 1.1 |

Notes:

[80] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[81] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 23F |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[82] |
| P-value | < 0.001 ^[83] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.87 |
| upper limit | 1.24 |

Notes:

[82] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[83] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 23F |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |

| | |
|---|-----------------------------|
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[84] |
| P-value | < 0.001 ^[85] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.95 |
| upper limit | 1.35 |

Notes:

[84] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[85] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 22F |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 2

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[86] |
| P-value | < 0.001 ^[87] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.95 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.81 |
| upper limit | 1.11 |

Notes:

[86] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[87] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 22F |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[88] |
| P-value | < 0.001 ^[89] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.98 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.14 |

Notes:

[88] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[89] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 22F |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 2 / V114 Lot 3

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[90] |
| P-value | < 0.001 ^[91] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.03 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.88 |
| upper limit | 1.21 |

Notes:

[90] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[91] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 33F |
|-----------------------------------|--------------|

Statistical analysis description:

GMT Ratio V114 Lot 1 / V114 Lot 2

| | |
|---|-----------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[92] |
| P-value | < 0.001 ^[93] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.16 |

Notes:

[92] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[93] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 33F |
| Statistical analysis description: GMT Ratio V114 Lot 1 / V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[94] |
| P-value | < 0.001 ^[95] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.91 |
| upper limit | 1.22 |

Notes:

[94] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[95] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

| | |
|--|-----------------------------|
| Statistical analysis title | Serotype 33F |
| Statistical analysis description: GMT Ratio V114 Lot 2 / V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[96] |
| P-value | < 0.001 ^[97] |
| Method | cLDA model |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.22 |

Notes:

[96] - P-value for the comparison of the GMT ratio to the lower bound (0.5). P-value for the comparison of the GMT ratio to the upper bound (2.0).

[97] - Identical p-values for the lower and upper bounds. Lower and upper p-values ≤ 0.025 support a conclusion of equivalence.

Secondary: Geometric Mean Concentration of Serotype-specific Immunoglobulin G (IgG) Following Vaccination With Separate V114 Lots

| | |
|-----------------|--|
| End point title | Geometric Mean Concentration of Serotype-specific Immunoglobulin G (IgG) Following Vaccination With Separate V114 Lots |
|-----------------|--|

End point description:

The geometric mean concentration (GMC) of IgG serotype-specific antibodies to the 13 pneumococcal polysaccharide serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) contained in V114 and Prevnar 13™; and two serotypes (22F and 33F) which are unique to V114, were quantitated from participants' sera by multiplex electrochemiluminescence (ECL) using the pneumococcal electrochemiluminescence (PnECL) v2.0 assay. The brackets next to each serotype show the number of

participants analyzed for Lots 1, 2 and 3. Per the statistical analysis plan, within-group CIs were not calculated, but 95% CIs for the GMC ratios between pairs of V114 lots were based on a cLDA model. The population analyzed was all randomized participants without deviations from the protocol that may substantially affect the results of the endpoint. Deviations include randomized but not vaccinated, missing results for serotypes, blood drawn out of time window, prohibited concomitant medication or vaccination.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 30 | |

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnam 13™ |
|------------------------------|-----------------|-----------------|-----------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 698 | 704 | 700 | 0 ^[98] |
| Units: µg/mL | | | | |
| number (not applicable) | | | | |
| Serotype 1 (n=693,693,688) | 3.91 | 4.05 | 3.83 | |
| Serotype 3 (n=693,693,688) | 0.74 | 0.86 | 0.73 | |
| Serotype 4 (n=693,692,688) | 1.79 | 2.18 | 1.67 | |
| Serotype 5 (n=693,693,688) | 3.81 | 4.63 | 3.96 | |
| Serotype 6A (n=693,693,688) | 8.09 | 8.84 | 8.16 | |
| Serotype 6B (n=693,693,688) | 10.92 | 11.46 | 10.44 | |
| Serotype 7F (n=693,693,688) | 5.71 | 7.11 | 5.94 | |
| Serotype 9V (n=693,693,688) | 4.20 | 4.44 | 4.26 | |
| Serotype 14 (n=693,693,688) | 9.82 | 11.38 | 8.66 | |
| Serotype 18C (n=693,693,688) | 14.07 | 11.81 | 10.66 | |
| Serotype 19A (n=693,693,688) | 15.45 | 17.34 | 15.81 | |
| Serotype 19F (n=693,693,688) | 9.78 | 11.22 | 10.65 | |
| Serotype 23F (n=693,693,688) | 7.38 | 7.97 | 7.44 | |
| Serotype 22F (n=693,693,688) | 4.12 | 4.41 | 3.80 | |
| Serotype 33F (n=693,693,688) | 9.92 | 10.88 | 9.45 | |

Notes:

[98] - The Prevnam 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 1 |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.96 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.1 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 1 |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.02 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.89 |
| upper limit | 1.17 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 1 |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.92 |
| upper limit | 1.21 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 3 |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.01 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.91 |
| upper limit | 1.13 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 3 |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.85 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.77 |
| upper limit | 0.95 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 3 |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.18 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.06 |
| upper limit | 1.32 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 4 |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |

| | |
|---|---------------|
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.82 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.72 |
| upper limit | 0.94 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 4 |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.07 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.94 |
| upper limit | 1.23 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 5 |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.82 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.72 |
| upper limit | 0.95 |

| | |
|---|------------|
| Statistical analysis title | Serotype 4 |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.31 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.14 |
| upper limit | 1.5 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 5 |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.96 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.11 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 5 |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.17 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.02 |
| upper limit | 1.35 |

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 6A |
|-----------------------------------|-------------|

Statistical analysis description:

GMC Ratio V114 Lot 1 divided by V114 Lot 2

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.78 |
| upper limit | 1.07 |

Statistical analysis title

Serotype 6A

Statistical analysis description:

GMC Ratio V114 Lot 1 divided by V114 Lot 3

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.85 |
| upper limit | 1.16 |

Statistical analysis title

Serotype 6B

Statistical analysis description:

GMC Ratio V114 Lot 1 divided by V114 Lot 2

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.95 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.11 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 6A |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.08 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.93 |
| upper limit | 1.27 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 6B |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.22 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 6B |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.94 |
| upper limit | 1.28 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 7F |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 0.92 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 7F |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.96 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.1 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 7F |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.04 |
| upper limit | 1.37 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 9V |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.95 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.08 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 9V |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.87 |
| upper limit | 1.13 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 9V |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |

| | |
|---|---------------|
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.91 |
| upper limit | 1.19 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 14 |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.86 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.75 |
| upper limit | 1 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 14 |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.98 |
| upper limit | 1.31 |

| | |
|---|-------------|
| Statistical analysis title | Serotype 14 |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.31 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.14 |
| upper limit | 1.52 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 18C |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.04 |
| upper limit | 1.36 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 18C |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.32 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.15 |
| upper limit | 1.51 |

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 18C |
|-----------------------------------|--------------|

Statistical analysis description:

GMC Ratio V114 Lot 2 divided by V114 Lot 3

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.11 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.97 |
| upper limit | 1.27 |

Statistical analysis title

Serotype 19A

Statistical analysis description:

GMC Ratio V114 Lot 1 divided by V114 Lot 2

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.89 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.78 |
| upper limit | 1.02 |

Statistical analysis title

Serotype 19A

Statistical analysis description:

GMC Ratio V114 Lot 1 divided by V114 Lot 3

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.11 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 19A |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.96 |
| upper limit | 1.25 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 19F |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 1.05 |

| | |
|--|-------------------------|
| Statistical analysis title | Serotype 19F |
| Statistical analysis description: | |
| GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.76 |
| upper limit | 1 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 19F |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.92 |
| upper limit | 1.21 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 23F |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.93 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 1.07 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 23F |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.99 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.15 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 23F |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.07 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.93 |
| upper limit | 1.24 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 22F |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.93 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.81 |
| upper limit | 1.08 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 22F |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |

| | |
|---|---------------|
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1 |
| upper limit | 1.35 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 22F |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.08 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.93 |
| upper limit | 1.26 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 33F |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 2 | |
| Comparison groups | V114 Lot 1 v V114 Lot 2 |
| Number of subjects included in analysis | 1402 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.91 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.06 |

| | |
|---|--------------|
| Statistical analysis title | Serotype 33F |
| Statistical analysis description: GMC Ratio V114 Lot 1 divided by V114 Lot 3 | |

| | |
|---|-------------------------|
| Comparison groups | V114 Lot 1 v V114 Lot 3 |
| Number of subjects included in analysis | 1398 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.22 |

| | |
|---|-------------------------|
| Statistical analysis title | Serotype 33F |
| Statistical analysis description: GMC Ratio V114 Lot 2 divided by V114 Lot 3 | |
| Comparison groups | V114 Lot 2 v V114 Lot 3 |
| Number of subjects included in analysis | 1404 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.99 |
| upper limit | 1.34 |

Secondary: Geometric Mean Concentration of Serotype-specific IgG Following Vaccination: Combined Lots of V114 or Prevnar 13™

| | |
|---|---|
| End point title | Geometric Mean Concentration of Serotype-specific IgG Following Vaccination: Combined Lots of V114 or Prevnar 13™ |
| End point description: The GMC of IgG serotype-specific antibodies to the 13 pneumococcal polysaccharide serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) contained in V114 and Prevnar 13™; and two serotypes (22F and 33F) which are unique to V114, were quantitated from participants' sera by ECL. The brackets next to each serotype show the number of participants analyzed for combined V114 lots and Prevnar 13™ respectively. Per the statistical analysis plan, within-group CIs were not calculated. The population analyzed was all randomized participants without deviations from the protocol that may substantially affect the results of the endpoint. Deviations include randomized but not vaccinated, missing results for serotypes, blood drawn out of time window, prohibited concomitant medication or vaccination. | |
| End point type | Secondary |
| End point timeframe: Day 30 | |

| End point values | V114 Combined Lots 1,2 and 3 | Prevnar 13™ | | |
|-----------------------------|------------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2102 | 231 | | |
| Units: µg/mL | | | | |
| number (not applicable) | | | | |
| Serotype 1 (n=2074,225) | 3.91 | 5.22 | | |
| Serotype 3 (n=2074,225) | 0.77 | 0.55 | | |
| Serotype 4 (n=2073,225) | 1.87 | 2.38 | | |
| Serotype 5 (n=2074,225) | 4.14 | 4.66 | | |
| Serotype 6A (n=2074,225) | 8.38 | 7.20 | | |
| Serotype 6B (n=2074,225) | 10.92 | 7.28 | | |
| Serotype 7F (n=2074,225) | 6.19 | 7.12 | | |
| Serotype 9V (n=2074,225) | 4.30 | 4.97 | | |
| Serotype 14 (n=2074,225) | 9.89 | 9.97 | | |
| Serotype 18C (n=2074,225) | 12.08 | 9.58 | | |
| Serotype 19A (n=2074,225) | 16.18 | 16.66 | | |
| Serotype 19F (n=2074,225) | 10.52 | 10.25 | | |
| Serotype 23F (n=2074,225) | 7.58 | 6.03 | | |
| Serotype 22F (n=2074,225) | 4.10 | 0.34 | | |
| Serotype 33F (n=2074,225) | 10.03 | 1.07 | | |

Statistical analyses

| Statistical analysis title | Serotype 1 |
|--|--|
| Statistical analysis description: GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.75 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.62 |
| upper limit | 0.91 |

| Statistical analysis title | Serotype 3 |
|--|--|
| Statistical analysis description: GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |

| | |
|---|---------------|
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.39 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.2 |
| upper limit | 1.61 |

| | |
|---|--|
| Statistical analysis title | Serotype 4 |
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.79 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.66 |
| upper limit | 0.94 |

| | |
|---|--|
| Statistical analysis title | Serotype 5 |
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.89 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.74 |
| upper limit | 1.07 |

| | |
|---|-------------|
| Statistical analysis title | Serotype 6A |
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |

| | |
|---|--|
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.95 |
| upper limit | 1.43 |

| | |
|--|--|
| Statistical analysis title | Serotype 6B |
| Statistical analysis description: GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.21 |
| upper limit | 1.86 |

| | |
|--|--|
| Statistical analysis title | Serotype 7F |
| Statistical analysis description: GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.73 |
| upper limit | 1.04 |

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 9V |
|-----------------------------------|-------------|

| | |
|---|--|
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.72 |
| upper limit | 1.04 |

| | |
|---|--|
| Statistical analysis title | Serotype 14 |
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.2 |

| | |
|---|--|
| Statistical analysis title | Serotype 18C |
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.26 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.05 |
| upper limit | 1.51 |

| | |
|---|--|
| Statistical analysis title | Serotype 19A |
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.97 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.15 |

| | |
|---|--|
| Statistical analysis title | Serotype 19F |
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.03 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.23 |

| | |
|---|--|
| Statistical analysis title | Serotype 23F |
| Statistical analysis description: | |
| GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.26 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.03 |
| upper limit | 1.54 |

| | |
|--|--|
| Statistical analysis title | Serotype 22F |
| Statistical analysis description: GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 12.21 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 10.11 |
| upper limit | 14.74 |

| | |
|--|--|
| Statistical analysis title | Serotype 33F |
| Statistical analysis description: GMC Ratio V114 Combined Lots divided by Prevnar 13™ | |
| Comparison groups | V114 Combined Lots 1,2 and 3 v Prevnar 13™ |
| Number of subjects included in analysis | 2333 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | GMC Ratio |
| Point estimate | 9.42 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.96 |
| upper limit | 11.13 |

Secondary: Geometric Mean Fold Rise (GMFR) in Serotype-specific OPA Following Vaccination With Separate V114 Lots

| | |
|--|--|
| End point title | Geometric Mean Fold Rise (GMFR) in Serotype-specific OPA Following Vaccination With Separate V114 Lots |
| End point description: Sera from participants was used to measure GMT of 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, using the MOPA which reads the reciprocal of the highest dilution that gives ≥50% bacterial killing. The brackets next to each serotype show the number of participants analyzed for Lots 1, 2 and 3. The Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratio Day 30/Day 1 OPA responses. The within-group 95% CIs are obtained by exponentiating the CIs of the mean of the natural log values based on the t-distribution. The population analyzed was all randomized participants without deviations from the protocol that may substantially affect the results of the endpoint. Deviations include randomized but not vaccinated, missing results for serotypes, blood drawn out of time window, prohibited concomitant medication or vaccination. | |
| End point type | Secondary |

End point timeframe:

Day 1 (Baseline) and Day 30

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnam 13™ |
|----------------------------------|---------------------|---------------------|---------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 698 | 704 | 700 | 0 ^[99] |
| Units: Ratio | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1 (n=676,667,661) | 15.9 (13.9 to 18.2) | 16.5 (14.6 to 18.8) | 15.4 (13.6 to 17.4) | (to) |
| Serotype 3 (n=666,665,657) | 6.5 (5.9 to 7.2) | 7.6 (6.8 to 8.4) | 6.9 (6.2 to 7.6) | (to) |
| Serotype 4 (n=670,663,658) | 17.4 (15.4 to 19.8) | 20.7 (18.3 to 23.4) | 16.5 (14.6 to 18.7) | (to) |
| Serotype 5 (n=676,675,665) | 11.2 (9.9 to 12.8) | 13.3 (11.8 to 15.1) | 11.1 (9.8 to 12.7) | (to) |
| Serotype 6A (n=620,618,611) | 13.7 (12.1 to 15.5) | 14.1 (12.5 to 16.0) | 14.6 (12.8 to 16.5) | (to) |
| Serotype 6B (n=659,658,653) | 33.4 (29.0 to 38.5) | 31.2 (27.0 to 36.1) | 34.9 (30.2 to 40.3) | (to) |
| Serotype 7F (n=648,638,646) | 11.9 (10.4 to 13.7) | 14.3 (12.4 to 16.5) | 12.9 (11.3 to 14.8) | (to) |
| Serotype 9V (n=652,650,641) | 4.8 (4.4 to 5.3) | 4.8 (4.3 to 5.3) | 5.0 (4.5 to 5.6) | (to) |
| Serotype 14 (n=671,667,662) | 7.6 (6.6 to 8.6) | 7.6 (6.7 to 8.7) | 6.2 (5.4 to 7.0) | (to) |
| Serotype 18C (n=669,662,651) | 16.7 (14.9 to 18.8) | 15.0 (13.4 to 16.8) | 14.1 (12.6 to 15.8) | (to) |
| Serotype 19A (n=665,660,650) | 10.4 (9.2 to 11.8) | 11.0 (9.6 to 12.5) | 11.7 (10.3 to 13.4) | (to) |
| Serotype 19F (n=663,667,659) | 6.5 (5.9 to 7.3) | 6.8 (6.1 to 7.6) | 7.3 (6.5 to 8.1) | (to) |
| Serotype 23F (n=609,626,633) | 16.8 (14.6 to 19.4) | 17.4 (15.2 to 20.0) | 17.0 (14.8 to 19.4) | (to) |
| Serotype 22F (n=610,597,602) | 27.2 (22.3 to 33.1) | 31.1 (25.6 to 38.0) | 28.3 (23.4 to 34.3) | (to) |
| Serotype 33F (n=647,641,641) | 8.4 (7.2 to 9.7) | 7.7 (6.6 to 8.9) | 7.5 (6.5 to 8.7) | (to) |

Notes:

[99] - The Prevnam 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR in Serotype-specific IgG Following Vaccination With Separate V114 Lots

| | |
|-----------------|---|
| End point title | GMFR in Serotype-specific IgG Following Vaccination With Separate V114 Lots |
|-----------------|---|

End point description:

The geometric mean concentration (GMC) of IgG serotype-specific antibodies to the 13 pneumococcal polysaccharide serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) contained in V114 and Prevnam 13™; and two serotypes (22F and 33F) which are unique to V114, were quantitated from participants' sera by ECL. The brackets next to each serotype show the number of participants analyzed for Lots 1, 2 and 3. The GMFR is the geometric mean of the ratio of Day 30/Day 1 IgG concentration. The within-group 95% CIs are obtained by exponentiating the CIs of the mean of the natural log values based on the t-distribution. The population analyzed was all randomized participants without deviations from the protocol that may substantially affect the results of the endpoint. Deviations include randomized but not vaccinated, missing results for serotypes, blood drawn out of time window,

prohibited concomitant medication or vaccination.

| | |
|-----------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 1 (Baseline) and Day 30 | |

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnar 13™ |
|----------------------------------|---------------------|---------------------|---------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 698 | 704 | 700 | 0 ^[100] |
| Units: Ratio | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1 (n=677,674,666) | 10.9 (9.8 to 12.2) | 11.2 (10.1 to 12.4) | 10.3 (9.2 to 11.5) | (to) |
| Serotype 3 (n=677,674,666) | 5.4 (4.9 to 5.9) | 6.3 (5.7 to 6.9) | 5.2 (4.8 to 5.7) | (to) |
| Serotype 4 (n=673,672,664) | 8.6 (7.8 to 9.5) | 10.5 (9.5 to 11.6) | 7.9 (7.1 to 8.7) | (to) |
| Serotype 5 (n=677,674,666) | 4.5 (4.1 to 5.0) | 5.5 (4.9 to 6.0) | 4.7 (4.2 to 5.2) | (to) |
| Serotype 6A (n=677,674,666) | 22.6 (20.1 to 25.3) | 24.1 (21.5 to 27.1) | 22.9 (20.4 to 25.8) | (to) |
| Serotype 6B (n=676,674,666) | 23.5 (21.0 to 26.3) | 24.1 (21.5 to 27.0) | 22.1 (19.7 to 24.8) | (to) |
| Serotype 7F (n=677,674,666) | 11.7 (10.5 to 13.1) | 14.8 (13.2 to 16.6) | 12.0 (10.7 to 13.3) | (to) |
| Serotype 9V (n=676,673,665) | 9.5 (8.6 to 10.5) | 9.8 (8.9 to 10.9) | 9.6 (8.6 to 10.6) | (to) |
| Serotype 14 (n=676,674,666) | 6.5 (5.8 to 7.3) | 6.8 (6.1 to 7.7) | 5.2 (4.7 to 5.8) | (to) |
| Serotype 18C (n=676,674,666) | 20.6 (18.3 to 23.1) | 17.0 (15.1 to 19.1) | 15.9 (14.2 to 17.9) | (to) |
| Serotype 19A (n=677,674,666) | 9.1 (8.2 to 10.0) | 10.6 (9.6 to 11.7) | 9.5 (8.6 to 10.5) | (to) |
| Serotype 19F (n=677,673,665) | 12.3 (11.1 to 13.7) | 13.8 (12.5 to 15.4) | 13.1 (11.8 to 14.5) | (to) |
| Serotype 23F (n=677,674,665) | 14.3 (12.7 to 16.1) | 16.2 (14.4 to 18.1) | 14.8 (13.2 to 16.6) | (to) |
| Serotype 22F (n=677,674,666) | 12.8 (11.4 to 14.4) | 13.4 (11.8 to 15.1) | 11.1 (9.9 to 12.5) | (to) |
| Serotype 33F (n=677,673,666) | 9.2 (8.3 to 10.3) | 9.5 (8.6 to 10.6) | 7.9 (7.1 to 8.8) | (to) |

Notes:

[100] - The Prevnar 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥4 Fold Change in Serotype-specific OPA Following Vaccination With Separate V114 Lots

| | |
|-----------------|---|
| End point title | Percentage of Participants with ≥4 Fold Change in Serotype-specific OPA Following Vaccination With Separate V114 Lots |
|-----------------|---|

End point description:

Sera from participants was used to measure GMT of 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, with the MOPA which reads the reciprocal of the highest dilution (1/dil) that gives ≥50% bacterial killing. The brackets next to each serotype show the number of participants analyzed for Lots 1, 2 and 3. Percentage of participants with a ≥ 4-fold change GMFR from Day 1 (baseline) to Day

30 are presented. The within-group 95% CIs are based on the exact binomial method proposed by Clopper and Pearson. The population analyzed was all randomized participants without deviations from the protocol that may substantially affect the results of the endpoint. Deviations include randomized but not vaccinated, missing results for serotypes, blood drawn out of time window, prohibited concomitant medication or vaccination.

| | |
|-----------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 1 (Baseline) and Day 30 | |

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnar 13™ |
|-----------------------------------|---------------------|---------------------|---------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 698 | 704 | 700 | 0 ^[101] |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1 (n=676,667,661) | 74.4 (70.9 to 77.7) | 76.8 (73.4 to 79.9) | 77.2 (73.8 to 80.3) | (to) |
| Serotype 3 (n=666,665,657) | 64.7 (61.0 to 68.3) | 68.9 (65.2 to 72.4) | 64.8 (61.1 to 68.5) | (to) |
| Serotype 4 (n=670,663,658) | 79.4 (76.1 to 82.4) | 83.6 (80.5 to 86.3) | 79.5 (76.2 to 82.5) | (to) |
| Serotype 5 (n=676,675,665) | 71.3 (67.7 to 74.7) | 76.1 (72.7 to 79.3) | 69.5 (65.8 to 73.0) | (to) |
| Serotype 6A (n=620,618,611) | 78.5 (75.1 to 81.7) | 77.8 (74.3 to 81.0) | 76.9 (73.4 to 80.2) | (to) |
| Serotype 6B (n=659,658,653) | 83.3 (80.2 to 86.1) | 83.6 (80.5 to 86.3) | 84.5 (81.5 to 87.2) | (to) |
| Serotype 7F (n=648,638,646) | 69.4 (65.7 to 73.0) | 71.6 (68.0 to 75.1) | 70.4 (66.7 to 73.9) | (to) |
| Serotype 9V (n=652,650,641) | 53.4 (49.5 to 57.3) | 51.2 (47.3 to 55.1) | 53.2 (49.3 to 57.1) | (to) |
| Serotype 14 (n=671,667,662) | 56.8 (52.9 to 60.6) | 57.6 (53.7 to 61.4) | 52.3 (48.4 to 56.1) | (to) |
| Serotype 18C (n=669,662,651) | 80.1 (76.9 to 83.1) | 79.0 (75.7 to 82.0) | 78.3 (75.0 to 81.4) | (to) |
| Serotype 19A (n=665,660,650) | 67.8 (64.1 to 71.4) | 69.8 (66.2 to 73.3) | 71.2 (67.6 to 74.7) | (to) |
| Serotype 19F (n=663,667,659) | 60.8 (57.0 to 64.5) | 61.9 (58.1 to 65.6) | 63.0 (59.2 to 66.7) | (to) |
| Serotype 23F (n=609,626,633) | 75.4 (71.7 to 78.7) | 78.3 (74.8 to 81.4) | 78.2 (74.8 to 81.4) | (to) |
| Serotype 22F (n=610,597,602) | 71.1 (67.4 to 74.7) | 73.4 (69.6 to 76.9) | 72.8 (69.0 to 76.3) | (to) |
| Serotype 33F (n=647,641,641) | 59.5 (55.6 to 63.3) | 58.3 (54.4 to 62.2) | 56.8 (52.8 to 60.7) | (to) |

Notes:

[101] - The Prevnar 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥4 Fold Change in Serotype-specific IgG Following Vaccination With Separate V114 Lots

| | |
|-----------------|---|
| End point title | Percentage of Participants with ≥4 Fold Change in Serotype-specific IgG Following Vaccination With Separate V114 Lots |
|-----------------|---|

End point description:

The geometric mean concentration of IgG serotype-specific antibodies to the 13 pneumococcal polysaccharide serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) contained in V114 and Prevnar 13™; and two serotypes (22F and 33F) which are unique to V114, were quantitated from participants' sera by ECL. The brackets next to each serotype show the number of participants analyzed for Lots 1, 2 and 3. Percentage of participants with a ≥ 4 -fold change GMFR from Day 1 (baseline) to Day 30 are presented. The within-group 95% CIs are based on the exact binomial method proposed by Clopper and Pearson. The population analyzed was all randomized participants without deviations from the protocol that may substantially affect the results of endpoint. Deviations include randomized but not vaccinated, missing results for serotypes, blood drawn out of time window, prohibited concomitant medication or vaccination.

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

End point timeframe:

Day 1 (Baseline) and Day 30

| End point values | V114 Lot 1 | V114 Lot 2 | V114 Lot 3 | Prevnar 13™ |
|-----------------------------------|---------------------|---------------------|---------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 698 | 704 | 700 | 0 ^[102] |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1 (n=677,674,666) | 73.9 (70.4 to 77.1) | 75.2 (71.8 to 78.4) | 73.0 (69.4 to 76.3) | (to) |
| Serotype 3 (n=677,674,666) | 58.6 (54.8 to 62.4) | 61.9 (58.1 to 65.6) | 54.7 (50.8 to 58.5) | (to) |
| Serotype 4 (n=673,672,664) | 68.8 (65.1 to 72.3) | 73.8 (70.3 to 77.1) | 65.7 (61.9 to 69.3) | (to) |
| Serotype 5 (n=677,674,666) | 45.6 (41.8 to 49.5) | 52.5 (48.7 to 56.3) | 45.9 (42.1 to 49.8) | (to) |
| Serotype 6A (n=677,674,666) | 86.6 (83.8 to 89.0) | 87.2 (84.5 to 89.7) | 83.8 (80.8 to 86.5) | (to) |
| Serotype 6B (n=676,674,666) | 87.0 (84.2 to 89.4) | 85.6 (82.7 to 88.2) | 84.2 (81.2 to 86.9) | (to) |
| Serotype 7F (n=677,674,666) | 75.3 (71.9 to 78.5) | 78.8 (75.5 to 81.8) | 74.8 (71.3 to 78.0) | (to) |
| Serotype 9V (n=676,673,665) | 72.6 (69.1 to 76.0) | 73.0 (69.4 to 76.3) | 71.6 (68.0 to 75.0) | (to) |
| Serotype 14 (n=676,674,666) | 54.4 (50.6 to 58.2) | 57.9 (54.0 to 61.6) | 48.3 (44.5 to 55.2) | (to) |
| Serotype 18C (n=676,674,666) | 84.6 (81.7 to 87.3) | 78.6 (75.3 to 81.7) | 76.7 (73.3 to 79.9) | (to) |
| Serotype 19A (n=677,674,666) | 70.6 (67.0 to 74.0) | 74.2 (70.7 to 77.5) | 71.0 (67.4 to 74.4) | (to) |
| Serotype 19F (n=677,673,665) | 77.8 (74.5 to 80.9) | 79.0 (75.8 to 82.1) | 78.6 (75.3 to 81.7) | (to) |
| Serotype 23F (n=677,674,665) | 76.1 (72.7 to 79.2) | 80.7 (77.5 to 83.6) | 76.7 (73.3 to 79.9) | (to) |
| Serotype 22F (n=677,674,666) | 75.3 (71.9 to 78.5) | 75.4 (71.9 to 78.6) | 72.1 (68.5 to 75.5) | (to) |
| Serotype 33F (n=677,673,666) | 69.4 (65.8 to 72.9) | 70.9 (67.3 to 74.3) | 66.1 (62.3 to 69.7) | (to) |

Notes:

[102] - The Prevnar 13™ treatment group was not analyzed per the statistical analysis plan.

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious adverse events (AEs) were reported from Day 1 through Day 14 following vaccination. Serious AEs (SAEs) were reported from Day 1 following vaccination up to Month 6. All-Cause Mortality were reported from randomization up to Month 6.

Adverse event reporting additional description:

For SAEs and Non-serious AEs the population analyzed was randomized participants according to the intervention they actually received. One participant randomized to the Prevnar 13™ group incorrectly received V114 Lot 1. For All-Cause Mortality the population analyzed was all randomized participants.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 23.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | V114 Lot 1 |
|-----------------------|------------|

Reporting group description:

Single intramuscular (IM) dose at 0.5 mL of V114 Lot 1 pneumococcal conjugate vaccine at Visit 1 (Day 1)

| | |
|-----------------------|------------|
| Reporting group title | V114 Lot 3 |
|-----------------------|------------|

Reporting group description:

Single intramuscular (IM) dose at 0.5 mL of V114 Lot 3 pneumococcal conjugate vaccine at Visit 1 (Day 1)

| | |
|-----------------------|-------------|
| Reporting group title | Prevnar 13™ |
|-----------------------|-------------|

Reporting group description:

Single IM dose at 0.5 mL of Prevnar 13™ at Visit 1 (Day 1)

| | |
|-----------------------|------------|
| Reporting group title | V114 Lot 2 |
|-----------------------|------------|

Reporting group description:

Single intramuscular (IM) dose at 0.5 mL of V114 Lot 2 pneumococcal conjugate vaccine at Visit 1 (Day 1)

| Serious adverse events | V114 Lot 1 | V114 Lot 3 | Prevnar 13™ |
|---|------------------|-----------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 12 / 699 (1.72%) | 7 / 700 (1.00%) | 5 / 230 (2.17%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | 1 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Breast cancer | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Breast cancer female | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric cancer | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 1 / 230 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Invasive breast carcinoma | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 1 / 700 (0.14%) | 0 / 230 (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 |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 1 / 230 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to peritoneum | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| Prostate cancer | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 699 (0.00%) | 1 / 700 (0.14%) | 0 / 230 (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 |
| Rectal cancer | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 1 / 700 (0.14%) | 0 / 230 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Pelvic fracture | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 1 / 700 (0.14%) | 0 / 230 (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 |
| Cardiac disorders | | | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 1 / 230 (0.43%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Angina unstable | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 1 / 700 (0.14%) | 0 / 230 (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 |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Nervous system disorders | | | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Migraine | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Seizure | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Death | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Eye disorders | | | |
| Blindness | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Reproductive system and breast disorders | | | |
| Prostatitis | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 1 / 700 (0.14%) | 0 / 230 (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 |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 1 / 230 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 1 / 700 (0.14%) | 0 / 230 (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 |
| Respiratory failure | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 1 / 700 (0.14%) | 0 / 230 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 1 / 230 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diverticulitis | | | |
| subjects affected / exposed | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Peritonitis | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (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 | 1 / 699 (0.14%) | 0 / 700 (0.00%) | 0 / 230 (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 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 699 (0.00%) | 0 / 700 (0.00%) | 0 / 230 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|------------------|--|--|
| Serious adverse events | V114 Lot 2 | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 19 / 704 (2.70%) | | |
| number of deaths (all causes) | 2 | | |
| number of deaths resulting from adverse events | 2 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Breast cancer | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Breast cancer female | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastric cancer | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Invasive breast carcinoma | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metastases to peritoneum | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rectal cancer | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Pelvic fracture | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Angina unstable | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Migraine | | | |

| | | | |
|--|-----------------|--|--|
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Seizure | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Death | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Eye disorders | | | |
| Blindness | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Prostatitis | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 2 / 704 (0.28%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 2 / 704 (0.28%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cystitis | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 704 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Peritonitis | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sepsis | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 704 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | V114 Lot 1 | V114 Lot 3 | Prevnar 13™ |
|---|--------------------|--------------------|--------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 548 / 699 (78.40%) | 535 / 700 (76.43%) | 151 / 230 (65.65%) |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 127 / 699 (18.17%) | 130 / 700 (18.57%) | 43 / 230 (18.70%) |
| occurrences (all) | 166 | 171 | 53 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 154 / 699 (22.03%) | 151 / 700 (21.57%) | 51 / 230 (22.17%) |
| occurrences (all) | 202 | 189 | 74 |
| Injection site erythema | | | |
| subjects affected / exposed | 77 / 699 (11.02%) | 89 / 700 (12.71%) | 22 / 230 (9.57%) |
| occurrences (all) | 82 | 91 | 24 |
| Injection site pain | | | |
| subjects affected / exposed | 464 / 699 (66.38%) | 471 / 700 (67.29%) | 122 / 230 (53.04%) |
| occurrences (all) | 518 | 514 | 134 |
| Injection site swelling | | | |
| subjects affected / exposed | 111 / 699 (15.88%) | 106 / 700 (15.14%) | 34 / 230 (14.78%) |
| occurrences (all) | 115 | 109 | 34 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 53 / 699 (7.58%) | 59 / 700 (8.43%) | 13 / 230 (5.65%) |
| occurrences (all) | 68 | 75 | 14 |
| Myalgia | | | |
| subjects affected / exposed | 196 / 699 (28.04%) | 199 / 700 (28.43%) | 50 / 230 (21.74%) |
| occurrences (all) | 226 | 226 | 54 |

| Non-serious adverse events | V114 Lot 2 | | |
|--|------------|--|--|
| Total subjects affected by non-serious | | | |

| | | | |
|--|--------------------|--|--|
| adverse events | | | |
| subjects affected / exposed | 534 / 704 (75.85%) | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 140 / 704 (19.89%) | | |
| occurrences (all) | 170 | | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 147 / 704 (20.88%) | | |
| occurrences (all) | 182 | | |
| Injection site erythema | | | |
| subjects affected / exposed | 86 / 704 (12.22%) | | |
| occurrences (all) | 91 | | |
| Injection site pain | | | |
| subjects affected / exposed | 475 / 704 (67.47%) | | |
| occurrences (all) | 520 | | |
| Injection site swelling | | | |
| subjects affected / exposed | 115 / 704 (16.34%) | | |
| occurrences (all) | 117 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 49 / 704 (6.96%) | | |
| occurrences (all) | 54 | | |
| Myalgia | | | |
| subjects affected / exposed | 171 / 704 (24.29%) | | |
| occurrences (all) | 196 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported