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	Prevnar 13™

Arm description:

Single IM dose at 0.5 mL of Prevnar 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	Prevnar 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	Prevnar 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/arthralgia, 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

	13™

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 Prevnar 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	Prevnar 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 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	= 0.272
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 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	= 0.812
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 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	= 0.947
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 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	= 0.091
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:

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.

End point type	Primary

End point timeframe:
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[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 Prevnar 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	Prevnar 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 Prevnar 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	Prevnar 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 Prevnar 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 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. 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

No statistical analyses for this end point

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