



Clinical trial results:

A Phase 3 Randomized, Double-blind, Active Comparator-controlled, Lot-to-Lot Consistency Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in Adults 18 to 49 Years of Age

Summary

EudraCT number	2022-000265-41
Trial protocol	FI ES AT DK PL
Global end of trial date	25 May 2023

Results information

Result version number	v1 (current)
This version publication date	22 May 2024
First version publication date	22 May 2024

Trial information

Trial identification

Sponsor protocol code	V116-004
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05464420
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, NJ, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, 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	25 May 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 May 2023
Global end of trial reached?	Yes
Global end of trial date	25 May 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study will evaluate the safety, tolerability, and immunogenicity of a pneumococcal 21-valent conjugate vaccine (V116) in pneumococcal vaccine-naïve adults 18 to 49 years of age. The primary study hypothesis is that all 3 lots of V116 are equivalent as assessed by the serotype-specific opsonophagocytic activity (OPA) Geometric Mean Titers (GMTs) at 30 days postvaccination for all serotypes included in V116.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 August 2022
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	Austria: 113
Country: Number of subjects enrolled	Canada: 111
Country: Number of subjects enrolled	Denmark: 120
Country: Number of subjects enrolled	Finland: 138
Country: Number of subjects enrolled	Israel: 280
Country: Number of subjects enrolled	Poland: 122
Country: Number of subjects enrolled	Spain: 228
Country: Number of subjects enrolled	United States: 1050
Worldwide total number of subjects	2162
EEA total number of subjects	721

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)	2162
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

2162 participants were randomized and 2157 were vaccinated and included in the safety analysis population. One participant initially randomized to the V116 Lot 2 arm received V116 Lot 1, one participant initially randomized to the V116 Lot 1 arm received V116 Lot 3, and one participant initially randomized to the V116 Lot 2 arm received PPSV23.

Pre-assignment

Screening details:

Healthy pneumococcal vaccine-naïve adults between 18 and 49 years of age were enrolled in this study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	V116 Lot 1

Arm description:

Participants received a single 0.5 mL intramuscular (IM) dose of V116 Lot 1 on Day 1.

Arm type	Experimental
Investigational medicinal product name	V116
Investigational medicinal product code	
Other name	Pneumococcal 21-valent Conjugate Vaccine
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Pneumococcal 21-valent conjugate vaccine with 4 µg of each of the following pneumococcal polysaccharides (PnPs) antigen: 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in each 0.5 mL sterile solution

Arm title	V116 Lot 2
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Arm description:

Participants received a single 0.5 mL IM dose of V116 Lot 2 on Day 1.

Arm type	Experimental
Investigational medicinal product name	V116
Investigational medicinal product code	
Other name	Pneumococcal 21-valent Conjugate Vaccine
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Pneumococcal 21-valent conjugate vaccine with 4 µg of each of the following pneumococcal polysaccharides (PnPs) antigen: 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in each 0.5 mL sterile solution

Arm title	V116 Lot 3
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Arm description:

Participants received a single 0.5 mL IM dose of V116 Lot 3 on Day 1.

Arm type	Experimental
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Investigational medicinal product name	V116
Investigational medicinal product code	
Other name	Pneumococcal 21-valent Conjugate Vaccine
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Pneumococcal 21-valent conjugate vaccine with 4 µg of each of the following pneumococcal polysaccharides (PnPs) antigen: 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in each 0.5 mL sterile solution

Arm title	PPSV23
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Arm description:

Participants received a single 0.5 mL IM dose of PPSV23 on Day 1.

Arm type	Active comparator
Investigational medicinal product name	PPSV23
Investigational medicinal product code	
Other name	PNEUMOVAX™23
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Pneumococcal 23-valent conjugate vaccine with 25 µg of each of the following PnPs antigen: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F in each 0.5 mL sterile solution

Number of subjects in period 1	V116 Lot 1	V116 Lot 2	V116 Lot 3
Started	541	540	541
Vaccinated	539	538	540
Completed	521	520	525
Not completed	20	20	16
Consent withdrawn by subject	4	8	3
Unable to adhere to study schedule	-	-	1
Randomized in Error Without Study Treatment	-	1	-
Death	-	-	-
Lost to follow-up	16	11	11
Protocol deviation	-	-	1

Number of subjects in period 1	PPSV23
Started	540
Vaccinated	540
Completed	526
Not completed	14
Consent withdrawn by subject	1
Unable to adhere to study schedule	-
Randomized in Error Without Study Treatment	-
Death	1

Lost to follow-up	11
Protocol deviation	1

Baseline characteristics

Reporting groups

Reporting group title	V116 Lot 1
Reporting group description:	
Participants received a single 0.5 mL intramuscular (IM) dose of V116 Lot 1 on Day 1.	
Reporting group title	V116 Lot 2
Reporting group description:	
Participants received a single 0.5 mL IM dose of V116 Lot 2 on Day 1.	
Reporting group title	V116 Lot 3
Reporting group description:	
Participants received a single 0.5 mL IM dose of V116 Lot 3 on Day 1.	
Reporting group title	PPSV23
Reporting group description:	
Participants received a single 0.5 mL IM dose of PPSV23 on Day 1.	

Reporting group values	V116 Lot 1	V116 Lot 2	V116 Lot 3
Number of subjects	541	540	541
Age categorical			
Units: Participants			
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)	541	540	541
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	34.8	34.8	34.3
standard deviation	± 9.3	± 9.2	± 9.3
Sex: Female, Male			
Units: Participants			
Female	305	321	311
Male	236	219	230
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	6	2	4
Asian	9	12	6
Native Hawaiian or Other Pacific Islander	2	1	0
Black or African American	49	43	55
White	458	458	458
More than one race	16	24	16
Unknown or Not Reported	1	0	2
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino	98	104	113
Not Hispanic or Latino	440	434	420
Unknown or Not Reported	3	2	8

Reporting group values	PPSV23	Total	
Number of subjects	540	2162	
Age categorical			
Units: Participants			
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)	540	2162	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous			
Units: Years			
arithmetic mean	34.4		
standard deviation	± 9.2	-	
Sex: Female, Male			
Units: Participants			
Female	310	1247	
Male	230	915	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	4	16	
Asian	8	35	
Native Hawaiian or Other Pacific Islander	1	4	
Black or African American	48	195	
White	453	1827	
More than one race	26	82	
Unknown or Not Reported	0	3	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	107	422	
Not Hispanic or Latino	430	1724	
Unknown or Not Reported	3	16	

End points

End points reporting groups

Reporting group title	V116 Lot 1
Reporting group description: Participants received a single 0.5 mL intramuscular (IM) dose of V116 Lot 1 on Day 1.	
Reporting group title	V116 Lot 2
Reporting group description: Participants received a single 0.5 mL IM dose of V116 Lot 2 on Day 1.	
Reporting group title	V116 Lot 3
Reporting group description: Participants received a single 0.5 mL IM dose of V116 Lot 3 on Day 1.	
Reporting group title	PPSV23
Reporting group description: Participants received a single 0.5 mL IM dose of PPSV23 on Day 1.	
Subject analysis set title	V116 Lot 1
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received a single 0.5 mL intramuscular (IM) dose of V116 Lot 1 on Day 1.	
Subject analysis set title	V116 Lot 2
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received a single 0.5 mL IM dose of V116 Lot 2 on Day 1.	
Subject analysis set title	V116 Lot 3
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received a single 0.5 mL IM dose of V116 Lot 3 on Day 1.	
Subject analysis set title	V116 Combined Lots 1, 2, and 3
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received a single 0.5 mL IM dose of either V116 Lot 1, 2, or 3 on Day 1.	
Subject analysis set title	PPSV23
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received a single 0.5 mL IM dose of PPSV23 on Day 1.	
Subject analysis set title	V116 Combined Lots 1, 2, and 3
Subject analysis set type	Per protocol
Subject analysis set description: Participants received a single 0.5 mL IM dose of either V116 Lot 1, 2, or 3 on Day 1.	
Subject analysis set title	PPSV23
Subject analysis set type	Per protocol
Subject analysis set description: Participants received a single 0.5 mL IM dose of PPSV23 on Day 1.	

Primary: Percentage of participants with solicited injection-site adverse events (AEs) following vaccination with separate V116 lots

End point title	Percentage of participants with solicited injection-site adverse events (AEs) following vaccination with separate V116 lots ^[1]
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End point description:

An AE was 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 included pain/tenderness, redness/erythema, and swelling. Per protocol, the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. Per protocol, all randomized participants who received one of three lots of V116 were analyzed according to the vaccination they received. One participant randomized to the V116 Lot 1 arm received V116 Lot 3, one participant randomized to the V116 Lot 2 arm received V116 Lot 1, and one participant randomized to the V116 Lot 2 arm received PPSV23.

End point type	Primary
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End point timeframe:

Up to 5 days

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: Per protocol, only descriptive statistics are presented.

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	536	541	0 ^[2]
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site erythema	13.4 (10.6 to 16.5)	14.2 (11.3 to 17.4)	13.1 (10.4 to 16.3)	(to)
Injection site pain	72.9 (68.9 to 76.6)	72.9 (69.0 to 76.7)	73.9 (70.0 to 77.6)	(to)
Injection site swelling	12.4 (9.8 to 15.5)	15.3 (12.4 to 18.6)	11.8 (9.2 to 14.9)	(to)

Notes:

[2] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants with solicited injection-site AEs following vaccination: combined lots of V116 or PPSV23

End point title	Percentage of participants with solicited injection-site AEs following vaccination: combined lots of V116 or PPSV23
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End point description:

An AE was 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 included pain/tenderness, redness/erythema, and swelling. Per the statistical analysis plan, no within group method of dispersion (MOD) were planned or calculated. All randomized participants who received study vaccination were analyzed according to the vaccination they received. One participant randomized into the V116 Lot 2 group incorrectly received PPSV23.

End point type	Primary
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End point timeframe:

Up to 5 days

End point values	V116 Combined Lots 1, 2, and 3	PPSV23		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1616	541		
Units: Percentage of Participants				
number (not applicable)				
Injection site erythema	13.6	7.6		
Injection site pain	73.3	60.6		
Injection site swelling	13.2	7.6		

Statistical analyses

Statistical analysis title	Injection site erythema: V116 Combined Lots-PPSV23
Statistical analysis description:	
Estimated difference in percentage and 95% confidence intervals (CI) were based on the Miettinen & Nurminen method.	
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimated difference in percentage
Point estimate	6
Confidence interval	
level	95 %
sides	2-sided
lower limit	3
upper limit	8.6

Statistical analysis title	Injection site swelling:V116 Combined Lots-PPSV23
Statistical analysis description:	
Estimated difference in percentage and 95% CI were based on the Miettinen & Nurminen method.	
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimated difference in percentage
Point estimate	5.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	8.2

Statistical analysis title	Injection site pain: V116 Combined Lots - PPSV23
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Statistical analysis description:

Estimated difference in percentage and 95% CI were based on the Miettinen & Nurminen method.

Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimated difference in percentage
Point estimate	12.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	8
upper limit	17.3

Primary: Percentage of participants with solicited systemic AEs following vaccination with separate V116 lots

End point title	Percentage of participants with solicited systemic AEs following vaccination with separate V116 lots ^[3]
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End point description:

An AE was 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 included headache, muscle aches/myalgia, tiredness/fatigue, and pyrexia. Per protocol, the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. Per protocol, all randomized participants who received one of three lots of V116 were analyzed according to the vaccination they received. One participant randomized to the V116 Lot 1 arm received V116 Lot 3, one participant randomized to the V116 Lot 2 arm received V116 Lot 1, and one participant randomized to the V116 Lot 2 arm received PPSV23.

End point type	Primary
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End point timeframe:

Up to 5 days

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: Per protocol, only descriptive statistics are presented.

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	536	541	0 ^[4]
Units: Percentage of Participants				
number (confidence interval 95%)				
Fatigue	38.0 (33.9 to 42.3)	34.0 (30.0 to 38.1)	34.4 (30.4 to 38.6)	(to)
Headache	28.0 (24.3 to 32.0)	26.1 (22.4 to 30.1)	27.5 (23.8 to 31.5)	(to)
Myalgia	18.2 (15.0 to 21.7)	13.6 (10.8 to 16.8)	17.2 (14.1 to 20.6)	(to)
Pyrexia	3.2 (1.8 to 5.0)	2.2 (1.2 to 3.9)	3.5 (2.1 to 5.4)	(to)

Notes:

[4] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

Primary: Percentage of participants with solicited systemic AEs following vaccination: combined lots of V116 or PPSV23

End point title	Percentage of participants with solicited systemic AEs following vaccination: combined lots of V116 or PPSV23
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End point description:

An AE was 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 included headache, muscle aches/myalgia, tiredness/fatigue, and pyrexia. Per the statistical analysis plan, no within group method of dispersion (MOD) were planned or calculated. All randomized participants who received study vaccination were analyzed according to the vaccination they received. One participant randomized into the V116 Lot 2 group incorrectly received PPSV23.

End point type	Primary
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End point timeframe:

Up to 5 days

End point values	V116 Combined Lots 1, 2, and 3	PPSV23		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1616	541		
Units: Percentage of Participants				
number (not applicable)				
Fatigue	35.5	34.0		
Headache	27.2	21.4		
Myalgia	16.3	8.7		
Pyrexia	3.0	2.2		

Statistical analyses

Statistical analysis title	Fatigue: V116 Combined Lots - PPSV23
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Statistical analysis description:

Estimated difference in percentage and 95% CI were based on the Miettinen & Nurminen method.

Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimated difference in percentage
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	6

Statistical analysis title	Pyrexia: V116 Combined Lots - PPSV23
Statistical analysis description:	
Estimated difference in percentage and 95% CI were based on the Miettinen & Nurminen method.	
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimated difference in percentage
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	2.1

Statistical analysis title	Myalgia: V116 Combined Lots - PPSV23
Statistical analysis description:	
Estimated difference in percentage and 95% CI were based on the Miettinen & Nurminen method.	
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimated difference in percentage
Point estimate	7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.5
upper limit	10.5

Statistical analysis title	Headache: V116 Combined Lots - PPSV23
Statistical analysis description:	
Estimated difference in percentage and 95% CI were based on the Miettinen & Nurminen method.	
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimated difference in percentage
Point estimate	5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	9.7

Primary: Percentage of participants with vaccine-related serious adverse events (SAEs) following vaccination with separate V116 lots

End point title	Percentage of participants with vaccine-related serious adverse events (SAEs) following vaccination with separate V116 lots ^[5]
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End point description:

An SAE was any untoward medical occurrence that, at any dose, resulted in death, was life threatening, required inpatient hospitalization or prolonged existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, or was another important medical event. SAEs that were reported to be at least possibly related by the investigator to study vaccination were reported. Per protocol, the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. Per protocol, all randomized participants who received one of three lots of V116 were analyzed according to the vaccination they received. One participant randomized to the V116 Lot 1 arm received V116 Lot 3, one participant randomized to the V116 Lot 2 arm received V116 Lot 1, and one participant randomized to the V116 Lot 2 arm received PPSV23.

End point type	Primary
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End point timeframe:

Up to 194 days

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: Per protocol, only descriptive statistics are presented.

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	536	541	0 ^[6]
Units: Percentage of Participants				
number (confidence interval 95%)	0.0 (0.0 to 0.7)	0.0 (0.0 to 0.7)	0.0 (0.0 to 0.7)	(to)

Notes:

[6] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants with vaccine-related SAEs following vaccination: combined lots of V116 or PPSV23

End point title	Percentage of participants with vaccine-related SAEs following vaccination: combined lots of V116 or PPSV23
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End point description:

An SAE was any untoward medical occurrence that, at any dose, resulted in death, was life threatening, required inpatient hospitalization or prolonged existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, or was another important medical event. SAEs that were reported to be at least possibly related by the investigator to study vaccination were reported. Per the statistical analysis plan, no within group MOD were planned or calculated. All randomized participants who received study vaccination were analyzed according to the vaccination they received. One participant randomized into the V116 Lot 2 group incorrectly received PPSV23.

End point type	Primary
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End point timeframe:

Up to 194 days

End point values	V116 Combined Lots 1, 2, and 3	PPSV23		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1616	541		
Units: Percentage of Participants				
number (not applicable)	0.0	0.0		

Statistical analyses

Statistical analysis title	Vaccine-related SAEs: V116 Combined Lots - PPSV23
Statistical analysis description:	
Estimated difference in percentage and 95% CI were based on the Miettinen & Nurminen method.	
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimated difference in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	0.2

Primary: Geometric mean titers (GMTs) of serotype-specific opsonophagocytic activity (OPA) for all serotypes in V116 following vaccination with separate V116 lots

End point title	Geometric mean titers (GMTs) of serotype-specific opsonophagocytic activity (OPA) for all serotypes in V116 following vaccination with separate V116 lots
End point description:	
Serotype-specific OPA titers for all serotypes in V116 following vaccination were determined using multiplex opsonophagocytic assay (MOPA). Serotype-specific OPA GMTs and GMT ratios with 95% confidence intervals (CIs) were calculated using a constrained longitudinal data analysis (cLDA) model. Per protocol, within-group CIs were not calculated and the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. A value of 99999 indicates that no MOD were calculated. Per protocol, all randomized participants who were vaccinated with V116 and were without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.	
End point type	Primary
End point timeframe:	
Day 30	

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	538	540	0 ^[7]
Units: Titers				
geometric mean (confidence interval 95%)				
Serotype 3 (n=524, 525, 525)	327.2 (-99999 to 99999)	299.0 (-99999 to 99999)	318.8 (-99999 to 99999)	(to)
Serotype 6A (n=515, 523, 524)	6901.9 (-99999 to 99999)	6014.9 (-99999 to 99999)	6641.2 (-99999 to 99999)	(to)
Serotype 7F (n=522, 531, 527)	7219.8 (-99999 to 99999)	6201.8 (-99999 to 99999)	6657.0 (-99999 to 99999)	(to)
Serotype 8 (n=527, 530, 528)	3935.5 (-99999 to 99999)	3812.8 (-99999 to 99999)	3765.8 (-99999 to 99999)	(to)
Serotype 9N (n=526, 533, 531)	18747.4 (-99999 to 99999)	17201.6 (-99999 to 99999)	18557.8 (-99999 to 99999)	(to)
Serotype 10A (n=524, 529, 533)	7570.2 (-99999 to 99999)	7796.9 (-99999 to 99999)	7330.4 (-99999 to 99999)	(to)
Serotype 11A (n=518, 531, 532)	6396.0 (-99999 to 99999)	6630.9 (-99999 to 99999)	6374.5 (-99999 to 99999)	(to)
Serotype 12F (n=523, 532, 528)	7478.5 (-99999 to 99999)	6803.0 (-99999 to 99999)	7329.9 (-99999 to 99999)	(to)
Serotype 15A (n=502, 505, 513)	10698.5 (-99999 to 99999)	10253.9 (-99999 to 99999)	10692.3 (-99999 to 99999)	(to)
Serotype 15C (n=522, 527, 522)	13133.8 (-99999 to 99999)	11441.3 (-99999 to 99999)	11177.1 (-99999 to 99999)	(to)
Serotype 16F (n=521, 521, 521)	9239.1 (-99999 to 99999)	9550.8 (-99999 to 99999)	9530.1 (-99999 to 99999)	(to)
Serotype 17F (n=525, 531, 532)	17185.3 (-99999 to 99999)	17718.6 (-99999 to 99999)	16886.7 (-99999 to 99999)	(to)
Serotype 19A (n=527, 533, 533)	3187.1 (-99999 to 99999)	3123.3 (-99999 to 99999)	3368.0 (-99999 to 99999)	(to)
Serotype 20A (n=524, 525, 525)	16339.3 (-99999 to 99999)	16676.2 (-99999 to 99999)	15302.4 (-99999 to 99999)	(to)
Serotype 22F (n=521, 523, 529)	11638.5 (-99999 to 99999)	10614.3 (-99999 to 99999)	11346.7 (-99999 to 99999)	(to)
Serotype 23A (n=509, 521, 520)	8437.4 (-99999 to 99999)	8459.8 (-99999 to 99999)	8322.8 (-99999 to 99999)	(to)
Serotype 23B (n=526, 530, 527)	2964.1 (-99999 to 99999)	2435.5 (-99999 to 99999)	3035.5 (-99999 to 99999)	(to)

Serotype 24F (n=522, 522, 524)	4861.3 (-99999 to 99999)	4783.4 (-99999 to 99999)	4758.8 (-99999 to 99999)	(to)
Serotype 31 (n=516, 527, 522)	9052.0 (-99999 to 99999)	8831.6 (-99999 to 99999)	8870.7 (-99999 to 99999)	(to)
Serotype 33F (n=521, 529, 526)	37994.1 (-99999 to 99999)	34227.3 (-99999 to 99999)	35182.5 (-99999 to 99999)	(to)
Serotype 35B (n=523, 528, 527)	12971.8 (-99999 to 99999)	12586.6 (-99999 to 99999)	12494.5 (-99999 to 99999)	(to)

Notes:

[7] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

Statistical analysis title	Serotype 3: GMT Ratio V116 Lot 1/ V116 Lot 2
Statistical analysis description:	
Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.	
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[8]
P-value	< 0.001 ^[9]
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:

[8] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[9] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 3: GMT Ratio V116 Lot 2/ V116 Lot 3
Statistical analysis description:	
Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.	
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[10]
P-value	< 0.001 ^[11]
Method	cLDA Model
Parameter estimate	GMT Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.06

Notes:

[10] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[11] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 3: GMT Ratio V116 Lot 1/ V116 Lot 3
Statistical analysis description:	
Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.	
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[12]
P-value	< 0.001 ^[13]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.17

Notes:

[12] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[13] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 6A: GMT Ratio V116 Lot 1/ V116 Lot 2
Statistical analysis description:	
Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.	
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[14]
P-value	< 0.001 ^[15]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.35

Notes:

[14] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[15] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 6A: GMT Ratio V116 Lot 1/ V116 Lot 3
Statistical analysis description:	
Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.	
Comparison groups	V116 Lot 1 v V116 Lot 3

Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[16]
P-value	< 0.001 ^[17]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.22

Notes:

[16] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[17] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 7F: GMT Ratio V116 Lot 1/ V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
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	0.94
upper limit	1.25

Notes:

[18] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[19] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 6A: GMT Ratio V116 Lot 2/ V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[20]
P-value	< 0.001 ^[21]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.91

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.06

Notes:

[20] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[21] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 7F: V116 Lot 1/ V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[22]
P-value	< 0.001 ^[23]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.16

Confidence interval

level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.34

Notes:

[22] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[23] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 7F: GMT Ratio V116 Lot 2/ V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[24]
P-value	< 0.001 ^[25]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.93

Confidence interval

level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.07

Notes:

[24] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[25] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 8 GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[26]
P-value	< 0.001 ^[27]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.16

Notes:

[26] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5 .

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0 .

[27] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 9N: GMT Ratio V116 Lot 1/ V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[28]
P-value	< 0.001 ^[29]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.26

Notes:

[28] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5 .

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0 .

[29] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 8: GMT Ratio V116 Lot 2/ V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[30]
P-value	< 0.001 ^[31]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.14

Notes:

[30] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[31] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 8: GMT Ratio V116 Lot 1/ V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[32]
P-value	< 0.001 ^[33]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.18

Notes:

[32] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[33] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 9N: GMT Ratio V116 Lot 1/ V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[34]
P-value	< 0.001 ^[35]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.17

Notes:

[34] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[35] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 10A: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[36]
P-value	< 0.001 ^[37]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.21

Notes:

[36] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[37] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 10A: GMT Ratio V116 Lot 1/ V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[38]
P-value	< 0.001 ^[39]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.18

Notes:

[38] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[39] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 10A: GMT Ratio V116 Lot 1/ V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[40]
P-value	< 0.001 ^[41]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.11

Notes:

[40] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[41] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 9N: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[42]
P-value	< 0.001 ^[43]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.93

Confidence interval

level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.07

Notes:

[42] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[43] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 11A: GMT Ratio V116 Lot 1/ V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[44]
P-value	< 0.001 ^[45]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.96

Confidence interval

level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.11

Notes:

[44] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[45] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 11A: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[46]
P-value	< 0.001 ^[47]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.16

Notes:

[46] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[47] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 11A: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[48]
P-value	< 0.001 ^[49]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.2

Notes:

[48] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[49] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 12F: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[50]
P-value	< 0.001 ^[51]
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:

[50] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[51] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 15A: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[52]
P-value	< 0.001 ^[53]
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:

[52] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[53] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 15A: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[54]
P-value	< 0.001 ^[55]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.22

Notes:

[54] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[55] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 12F: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[56]
P-value	< 0.001 ^[57]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.07

Notes:

[56] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[57] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 12F: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[58]
P-value	< 0.001 ^[59]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.17

Notes:

[58] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[59] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 15A: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[60]
P-value	< 0.001 ^[61]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.17

Notes:

[60] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[61] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 16F: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[62]
P-value	< 0.001 ^[63]
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:

[62] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[63] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 15C: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[64]
P-value	< 0.001 ^[65]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02

Confidence interval

level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.23

Notes:

[64] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[65] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 15C: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[66]
P-value	< 0.001 ^[67]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.42

Notes:

[66] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5 .

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0 .

[67] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 15C: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[68]
P-value	< 0.001 ^[69]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.38

Notes:

[68] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5 .

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0 .

[69] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 16F: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
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	0.84
upper limit	1.11

Notes:

[70] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[71] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 19A: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[72]
P-value	< 0.001 ^[73]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.15

Notes:

[72] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[73] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 17F: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[74]
P-value	< 0.001 ^[75]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.2

Notes:

[74] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[75] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 17F: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[76]
P-value	< 0.001 ^[77]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.17

Notes:

[76] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5 .

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0 .

[77] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 17F: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[78]
P-value	< 0.001 ^[79]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.11

Notes:

[78] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5 .

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0 .

[79] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 16F: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[80]
P-value	< 0.001 ^[81]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.15

Notes:

[80] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[81] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 19A: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[82]
P-value	< 0.001 ^[83]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.04

Notes:

[82] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[83] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 19A: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[84]
P-value	< 0.001 ^[85]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.07

Notes:

[84] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[85] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 20A: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[86]
P-value	< 0.001 ^[87]
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:

[86] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[87] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 20A: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[88]
P-value	< 0.001 ^[89]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.24

Notes:

[88] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[89] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 23A: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[90]
P-value	< 0.001 ^[91]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.19

Notes:

[90] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[91] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 22F: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[92]
P-value	< 0.001 ^[93]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.1

Confidence interval

level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.29

Notes:

[92] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[93] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 22F: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[94]
P-value	< 0.001 ^[95]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.03

Confidence interval

level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.21

Notes:

[94] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[95] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 22F: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[96]
P-value	< 0.001 ^[97]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.1

Notes:

[96] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[97] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 23A: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[98]
P-value	< 0.001 ^[99]
Method	cDLA model
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.17

Notes:

[98] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[99] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 20A: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[100]
P-value	< 0.001 ^[101]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.09

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.27

Notes:

[100] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[101] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 23B: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[102]
P-value	< 0.001 ^[103]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.22

Confidence interval

level	95 %
sides	2-sided
lower limit	1
upper limit	1.48

Notes:

[102] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[103] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 23A: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[104]
P-value	< 0.001 ^[105]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02

Confidence interval

level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.19

Notes:

[104] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[105] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 23B: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[106]
P-value	< 0.001 ^[107]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.19

Notes:

[106] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[107] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 31: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[108]
P-value	< 0.001 ^[109]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.17

Notes:

[108] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[109] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 31: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[110]
P-value	< 0.001 ^[111]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.2

Notes:

[110] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[111] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 31: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[112]
P-value	< 0.001 ^[113]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.2

Notes:

[112] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[113] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 24F: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[114]
P-value	< 0.001 ^[115]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.16

Notes:

[114] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[115] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 24F: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[116]
P-value	< 0.001 ^[117]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.18

Notes:

[116] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[117] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 23B: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[118]
P-value	< 0.001 ^[119]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.97

Notes:

[118] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[119] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 24F: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[120]
P-value	< 0.001 ^[121]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.18

Notes:

[120] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[121] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 33F: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[122]
P-value	< 0.001 ^[123]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	0.97

Confidence interval

level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.16

Notes:

[122] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[123] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 35B: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[124]
P-value	< 0.001 ^[125]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.03

Confidence interval

level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.17

Notes:

[124] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[125] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 35B: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[126]
P-value	< 0.001 ^[127]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.18

Notes:

[126] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5 .

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0 .

[127] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 33F: GMT Ratio V116 Lot 1/V116 Lot 2
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	equivalence ^[128]
P-value	< 0.001 ^[129]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.33

Notes:

[128] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5 .

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0 .

[129] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 33F: GMT Ratio V116 Lot 1/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025 .

Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	equivalence ^[130]
P-value	< 0.001 ^[131]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.08

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.29

Notes:

[130] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[131] - Identical p-values for the lower and upper bounds.

Statistical analysis title	Serotype 35B: GMT Ratio V116 Lot 2/V116 Lot 3
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Statistical analysis description:

Equivalence can be concluded if both the lower tailed and upper tailed p-values are < 0.025.

Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	equivalence ^[132]
P-value	< 0.001 ^[133]
Method	cLDA model
Parameter estimate	GMT Ratio
Point estimate	1.01

Confidence interval

level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.14

Notes:

[132] - P value for testing the lower bound of the 95% CI for GMT ratio was >0.5.

P value for testing the upper bound of the 95% CI for GMT ratio was <2.0.

[133] - Identical p-values for the lower and upper bounds.

Secondary: GMTs of serotype-specific OPA for all serotypes in V116 following vaccination: combined lots of V116 or PPSV23

End point title	GMTs of serotype-specific OPA for all serotypes in V116 following vaccination: combined lots of V116 or PPSV23
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End point description:

Serotype-specific OPA titers for all serotypes in V116 following vaccination were determined using MOPA. Serotype-specific OPA GMTs and GMT ratios with 95% CI were calculated using a constrained longitudinal data analysis (cLDA) model. Per protocol, within-group CIs were not calculated and a value of 99999 means that no MOD was calculated. All randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.

End point type	Secondary
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End point timeframe:

Day 30

End point values	PPSV23	V116 Combined Lots 1, 2, and 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	541	1617		
Units: Titers				
geometric mean (confidence interval 95%)				
Serotype 3 (n= 1574, 534)	339.8 (-99999 to 99999)	316.5 (-99999 to 99999)		
Serotype 6A (n= 1562, 529)	1866.4 (- 99999 to 99999)	6491.7 (- 99999 to 99999)		
Serotype 7F (n= 1580, 531)	5058.1 (- 99999 to 99999)	6702.2 (- 99999 to 99999)		
Serotype 8 (n= 1585, 537)	4543.3 (- 99999 to 99999)	3847.3 (- 99999 to 99999)		
Serotype 9N (n= 1590, 533)	19031.9 (- 99999 to 99999)	18166.7 (- 99999 to 99999)		
Serotype 10A (n= 1586, 534)	5763.0 (- 99999 to 99999)	7618.2 (- 99999 to 99999)		
Serotype 11A (n= 1581, 534)	3728.0 (- 99999 to 99999)	6494.4 (- 99999 to 99999)		
Serotype 12F (n= 1583, 534)	5207.5 (- 99999 to 99999)	7196.9 (- 99999 to 99999)		
Serotype 15A (n= 1520, 512)	2608.5 (- 99999 to 99999)	10520.0 (- 99999 to 99999)		
Serotype 15C (n= 1571, 529)	4112.0 (- 99999 to 99999)	11922.3 (- 99999 to 99999)		
Serotype 16F (n= 1563, 527)	2532.2 (- 99999 to 99999)	9415.3 (- 99999 to 99999)		
Serotype 17F (n= 1588, 536)	10159.9 (- 99999 to 99999)	17330.5 (- 99999 to 99999)		
Serotype 19A (n= 1593, 533)	3474.7 (- 99999 to 99999)	3222.9 (- 99999 to 99999)		
Serotype 20A (n= 1574, 533)	10994.2 (- 99999 to 99999)	16183.8 (- 99999 to 99999)		
Serotype 22F (n= 1573, 530)	8308.0 (- 99999 to 99999)	11118.1 (- 99999 to 99999)		
Serotype 23A (n= 1550, 519)	1056.1 (- 99999 to 99999)	8428.3 (- 99999 to 99999)		
Serotype 23B (n= 1583, 533)	119.1 (-99999 to 99999)	2825.4 (- 99999 to 99999)		
Serotype 24F (n= 1568, 518)	250.3 (-99999 to 99999)	4892.9 (- 99999 to 99999)		
Serotype 31 (n= 1565, 531)	654.5 (-99999 to 99999)	8865.6 (- 99999 to 99999)		

Serotype 33F (n= 1576, 533)	42515.6 (-99999 to 99999)	35684.3 (-99999 to 99999)		
Serotype 35B (n= 1578, 537)	3452.1 (-99999 to 99999)	12798.6 (-99999 to 99999)		

Statistical analyses

Statistical analysis title	Serotype 7F: GMT Ratio V116 Combined Lots / PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[134]
Parameter estimate	GMT Ratio
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.18
upper limit	1.49

Notes:

[134] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 6A: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[135]
Parameter estimate	GMT Ratio
Point estimate	3.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.01
upper limit	4.02

Notes:

[135] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 3: GMT Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[136]
Parameter estimate	GMT Ratio
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.03

Notes:

[136] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 8: GMT Ratio V116 Combined Lots / PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[137]
Parameter estimate	GMT Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.93

Notes:

[137] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 9N: GMT Ratio V116 Combined Lots / PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[138]
Parameter estimate	GMT Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.08

Notes:

[138] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 10A: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[139]
Parameter estimate	GMT Ratio
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.18
upper limit	1.48

Notes:

[139] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 11A: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[140]
Parameter estimate	GMT Ratio
Point estimate	1.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.56
upper limit	1.95

Notes:

[140] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15C: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[141]
Parameter estimate	GMT Ratio
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.49
upper limit	3.38

Notes:

[141] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15A: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[142]
Parameter estimate	GMT Ratio
Point estimate	4.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.56
upper limit	4.56

Notes:

[142] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 12F: GMT Ratio V116 Combined Lots/PPSV23
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Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[143]
Parameter estimate	GMT Ratio
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.22
upper limit	1.56

Notes:

[143] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 16F: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[144]
Parameter estimate	GMT Ratio
Point estimate	3.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.32
upper limit	4.17

Notes:

[144] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 17F: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[145]
Parameter estimate	GMT Ratio
Point estimate	1.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.53
upper limit	1.91

Notes:

[145] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 19A: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23

Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[146]
Parameter estimate	GMT Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.03

Notes:

[146] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 20A: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[147]
Parameter estimate	GMT Ratio
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	1.67

Notes:

[147] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 22F: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[148]
Parameter estimate	GMT Ratio
Point estimate	1.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.17
upper limit	1.53

Notes:

[148] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23A: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23

Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[149]
Parameter estimate	GMT Ratio
Point estimate	7.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.84
upper limit	9.31

Notes:

[149] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23B: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[150]
Parameter estimate	GMT Ratio
Point estimate	23.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.71
upper limit	28.55

Notes:

[150] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 24F: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[151]
Parameter estimate	GMT Ratio
Point estimate	19.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.7
upper limit	22.88

Notes:

[151] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 31: GMT Ratio V116 Combined Lots / PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23

Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[152]
Parameter estimate	GMT Ratio
Point estimate	13.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.68
upper limit	15.71

Notes:

[152] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 33F: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[153]
Parameter estimate	GMT Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.97

Notes:

[153] - GMT Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 35B: GMT Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2158
Analysis specification	Pre-specified
Analysis type	other ^[154]
Parameter estimate	GMT Ratio
Point estimate	3.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.36
upper limit	4.09

Notes:

[154] - GMT Ratio and 95% CI were estimated from a cLDA model.

Secondary: Geometric mean concentrations (GMCs) of serotype-specific Immunoglobulin G (IgG) for all serotypes in V116 following vaccination with separate V116 lots

End point title	Geometric mean concentrations (GMCs) of serotype-specific Immunoglobulin G (IgG) for all serotypes in V116 following vaccination with separate V116 lots
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End point description:

Serotype-specific IgG concentrations for all serotypes in V116 following vaccination were determined

using pneumococcal electrochemiluminescence (PnECL). Serotype-specific pneumococcal IgG GMCs and GMC ratios with 95% confidence intervals were calculated using a cLDA model. Per protocol, within-group CIs were not calculated and the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. A value of 99999 indicates that no MOD were calculated. Per protocol, all randomized participants who were vaccinated with V116 and were without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.

End point type	Secondary
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End point timeframe:

Day 30

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	538	540	0 ^[155]
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 3 (n=532, 535, 536)	0.83 (-99999 to 99999)	0.85 (-99999 to 99999)	0.87 (-99999 to 99999)	(to)
Serotype 6A (n=532, 535, 536)	5.94 (-99999 to 99999)	5.29 (-99999 to 99999)	5.84 (-99999 to 99999)	(to)
Serotype 7F (n=532, 535, 536)	5.13 (-99999 to 99999)	5.29 (-99999 to 99999)	4.99 (-99999 to 99999)	(to)
Serotype 8 (n=532, 535, 536)	10.32 (-99999 to 99999)	10.52 (-99999 to 99999)	10.42 (-99999 to 99999)	(to)
Serotype 9N (n=532, 535, 536)	5.37 (-99999 to 99999)	5.11 (-99999 to 99999)	6.03 (-99999 to 99999)	(to)
Serotype 10A (n=532, 535, 536)	9.63 (-99999 to 99999)	9.52 (-99999 to 99999)	9.97 (-99999 to 99999)	(to)
Serotype 11A (n=532, 535, 536)	6.33 (-99999 to 99999)	6.28 (-99999 to 99999)	6.21 (-99999 to 99999)	(to)
Serotype 12F (n=532, 535, 536)	1.65 (-99999 to 99999)	1.75 (-99999 to 99999)	1.65 (-99999 to 99999)	(to)
Serotype 15A (n=532, 535, 536)	13.63 (-99999 to 99999)	13.00 (-99999 to 99999)	14.20 (-99999 to 99999)	(to)
Serotype 15C (n=532, 535, 536)	14.32 (-99999 to 99999)	13.54 (-99999 to 99999)	13.85 (-99999 to 99999)	(to)
Serotype 16F (n=532, 535, 536)	1.77 (-99999 to 99999)	1.97 (-99999 to 99999)	1.96 (-99999 to 99999)	(to)
Serotype 17F (n=532, 535, 536)	14.05 (-99999 to 99999)	13.37 (-99999 to 99999)	13.14 (-99999 to 99999)	(to)
Serotype 19A (n=532, 535, 536)	7.70 (-99999 to 99999)	7.94 (-99999 to 99999)	8.51 (-99999 to 99999)	(to)
Serotype 20A (n=532, 535, 536)	13.54 (-99999 to 99999)	14.18 (-99999 to 99999)	14.09 (-99999 to 99999)	(to)
Serotype 22F (n=532, 535, 536)	7.02 (-99999 to 99999)	6.97 (-99999 to 99999)	6.99 (-99999 to 99999)	(to)
Serotype 23A (n=532, 535, 536)	4.26 (-99999 to 99999)	4.34 (-99999 to 99999)	4.34 (-99999 to 99999)	(to)
Serotype 23B (n=532, 535, 536)	6.77 (-99999 to 99999)	6.65 (-99999 to 99999)	7.39 (-99999 to 99999)	(to)
Serotype 24F (n=532, 535, 536)	4.32 (-99999 to 99999)	4.55 (-99999 to 99999)	4.34 (-99999 to 99999)	(to)
Serotype 31 (n=532, 535, 536)	3.47 (-99999 to 99999)	3.94 (-99999 to 99999)	3.47 (-99999 to 99999)	(to)

Serotype 33F (n=532, 535, 536)	8.03 (-99999 to 99999)	7.94 (-99999 to 99999)	8.00 (-99999 to 99999)	(to)
Serotype 35B (n=532, 535, 536)	11.84 (-99999 to 99999)	11.56 (-99999 to 99999)	11.94 (-99999 to 99999)	(to)

Notes:

[155] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

Statistical analysis title	Serotype 7F: GMC Ratio V116 Lot 1/ V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[156]
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.11

Notes:

[156] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 6A: GMC Ratio V116 Lot 2/ V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[157]
Parameter estimate	GMC Ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.07

Notes:

[157] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 6A: GMC Ratio V116 Lot 1/ V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[158]
Parameter estimate	GMC Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.2

Notes:

[158] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 6A: GMC Ratio V116 Lot 1/ V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[159]
Parameter estimate	GMC Ratio
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.32

Notes:

[159] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 3: GMC Ratio V116 Lot 2/ V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[160]
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.08

Notes:

[160] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 3: GMC Ratio V116 Lot 1/ V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[161]
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.05

Notes:

[161] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 3: GMC Ratio V116 Lot 1/ V116 Lot 2
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Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[162]
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.09

Notes:

[162] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 9N: GMC Ratio V116 Lot 1/ V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[163]
Parameter estimate	GMC Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.03

Notes:

[163] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 9N: GMC Ratio V116 Lot 1/ V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[164]
Parameter estimate	GMC Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.21

Notes:

[164] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 8: GMC Ratio V116 Lot 2/ V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[165]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.15

Notes:

[165] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 8: GMC Ratio V116 Lot 1/ V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[166]
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.13

Notes:

[166] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 8: GMC Ratio V116 Lot 1/ V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[167]
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.12

Notes:

[167] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 7F: GMC Ratio V116 Lot 2/ V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[168]
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.21

Notes:

[168] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 7F: GMC Ratio V116 Lot 1/ V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[169]
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.18

Notes:

[169] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 9N: GMC Ratio V116 Lot 2/ V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[170]
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.98

Notes:

[170] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 11A: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2

Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[171]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.14

Notes:

[171] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 10A: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[172]
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.11

Notes:

[172] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 10A: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[173]
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.13

Notes:

[173] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 10A: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2

Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[174]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.18

Notes:

[174] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 11A: GMC Ratio V116 Lot 1/ V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[175]
Parameter estimate	GMC Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.15

Notes:

[175] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 11A: GMC Ratio V116 Lot 2/ V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[176]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.14

Notes:

[176] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 12F: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2

Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[177]
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.12

Notes:

[177] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 12F: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[178]
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.18

Notes:

[178] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 12F: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[179]
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.25

Notes:

[179] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15C: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[180]
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.14

Notes:

[180] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15C: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[181]
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.2

Notes:

[181] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15C: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[182]
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.23

Notes:

[182] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15A: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[183]
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.05

Notes:

[183] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15A: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[184]
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.11

Notes:

[184] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15A: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[185]
Parameter estimate	GMC Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.21

Notes:

[185] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 16F: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2

Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[186]
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.03

Notes:

[186] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 16F: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[187]
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.04

Notes:

[187] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 20A: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[188]
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.1

Notes:

[188] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 19A: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[189]
Parameter estimate	GMC Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.07

Notes:

[189] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 19A: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[190]
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.04

Notes:

[190] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 19A: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[191]
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.11

Notes:

[191] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 17F: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[192]
Parameter estimate	GMC Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.17

Notes:

[192] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 17F: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[193]
Parameter estimate	GMC Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.23

Notes:

[193] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 17F: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[194]
Parameter estimate	GMC Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.21

Notes:

[194] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 16F: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[195]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.15

Notes:

[195] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 20A: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[196]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.16

Notes:

[196] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 20A: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[197]
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.1

Notes:

[197] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 22F: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2

Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[198]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.16

Notes:

[198] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 22F: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[199]
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.16

Notes:

[199] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23B: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[200]
Parameter estimate	GMC Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.18

Notes:

[200] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23A: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2

Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[201]
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.16

Notes:

[201] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23A: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[202]
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.15

Notes:

[202] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23A: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[203]
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.17

Notes:

[203] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 22F: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[204]
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.15

Notes:

[204] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23B: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[205]
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.05

Notes:

[205] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23B: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[206]
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.07

Notes:

[206] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 24F: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2

Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[207]
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.13

Notes:

[207] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 31: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[208]
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1

Notes:

[208] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 31: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[209]
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.14

Notes:

[209] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 31: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[210]
Parameter estimate	GMC Ratio
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	1.3

Notes:

[210] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 24F: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[211]
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.19

Notes:

[211] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 24F: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[212]
Parameter estimate	GMC Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.25

Notes:

[212] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 33F: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3

Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[213]
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.15

Notes:

[213] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 33F: GMC Ratio V116 Lot 1/V116 Lot 2
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[214]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.16

Notes:

[214] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 35B: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 3
Number of subjects included in analysis	1079
Analysis specification	Pre-specified
Analysis type	other ^[215]
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.13

Notes:

[215] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 33F: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3

Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[216]
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.13

Notes:

[216] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 35B: GMC Ratio V116 Lot 1/V116 Lot 3
Comparison groups	V116 Lot 1 v V116 Lot 2
Number of subjects included in analysis	1077
Analysis specification	Pre-specified
Analysis type	other ^[217]
Parameter estimate	GMC Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.17

Notes:

[217] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 35B: GMC Ratio V116 Lot 2/V116 Lot 3
Comparison groups	V116 Lot 2 v V116 Lot 3
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	other ^[218]
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.1

Notes:

[218] - GMC Ratio and 95% CI were estimated from a cLDA model.

Secondary: GMCs of serotype-specific IgG for all serotypes in V116 following vaccination: combined lots of V116 or PPSV23

End point title	GMCs of serotype-specific IgG for all serotypes in V116 following vaccination: combined lots of V116 or PPSV23
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End point description:

Serotype-specific IgG concentrations for all serotypes in V116 following vaccination were determined using PnECL. Serotype-specific pneumococcal IgG GMCs and GMC ratios with 95% confidence intervals were calculated using a cLDA model. Per protocol, within-group CIs were not calculated and a value of

99999 means that no MOD were calculated. All randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.

End point type	Secondary
End point timeframe:	
Day 30	

End point values	V116 Combined Lots 1, 2, and 3	PPSV23		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1617	540		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 3 (n=1603, 539)	0.85 (-99999 to 99999)	0.77 (-99999 to 99999)		
Serotype 6A (n=1603, 539)	5.67 (-99999 to 99999)	1.45 (-99999 to 99999)		
Serotype 7F (n=1603, 539)	5.19 (-99999 to 99999)	3.36 (-99999 to 99999)		
Serotype 8 (n=1603, 539)	10.34 (-99999 to 99999)	12.85 (-99999 to 99999)		
Serotype 9N (n=1603, 539)	5.51 (-99999 to 99999)	5.41 (-99999 to 99999)		
Serotype 10A (n=1603, 539)	9.58 (-99999 to 99999)	6.52 (-99999 to 99999)		
Serotype 11A (n=1603, 539)	6.29 (-99999 to 99999)	4.55 (-99999 to 99999)		
Serotype 12F (n=1603, 539)	1.69 (-99999 to 99999)	1.20 (-99999 to 99999)		
Serotype 15A (n=1603, 539)	13.55 (-99999 to 99999)	1.99 (-99999 to 99999)		
Serotype 15C (n=1603, 539)	13.90 (-99999 to 99999)	4.29 (-99999 to 99999)		
Serotype 16F (n=1603, 539)	1.91 (-99999 to 99999)	0.30 (-99999 to 99999)		
Serotype 17F (n=1603, 539)	13.46 (-99999 to 99999)	7.28 (-99999 to 99999)		
Serotype 19A (n=1603, 539)	8.01 (-99999 to 99999)	7.29 (-99999 to 99999)		
Serotype 20A (n=1603, 539)	13.82 (-99999 to 99999)	9.03 (-99999 to 99999)		
Serotype 22F (n=1603, 539)	7.04 (-99999 to 99999)	5.34 (-99999 to 99999)		
Serotype 23A (n=1603, 539)	4.29 (-99999 to 99999)	0.53 (-99999 to 99999)		
Serotype 23B (n=1603, 539)	6.96 (-99999 to 99999)	1.21 (-99999 to 99999)		
Serotype 24F (n=1603, 539)	4.44 (-99999 to 99999)	0.31 (-99999 to 99999)		
Serotype 31 (n=1603, 539)	3.62 (-99999 to 99999)	0.38 (-99999 to 99999)		
Serotype 33F (n=1603, 539)	8.00 (-99999 to 99999)	9.82 (-99999 to 99999)		

Serotype 35B (n=1603, 539)	11.71 (-99999 to 99999)	1.66 (-99999 to 99999)		
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Statistical analyses

Statistical analysis title	Serotype 3: GMC Ratio V116 Combined Lots/PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[219]
Parameter estimate	GMC Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.21

Notes:

[219] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 7F: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[220]
Parameter estimate	GMC Ratio
Point estimate	1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.38
upper limit	1.72

Notes:

[220] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 6A: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[221]
Parameter estimate	GMC Ratio
Point estimate	3.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.43
upper limit	4.45

Notes:

[221] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 11A: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[222]
Parameter estimate	GMC Ratio
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.26
upper limit	1.52

Notes:

[222] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 12F: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[223]
Parameter estimate	GMC Ratio
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	1.62

Notes:

[223] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15A: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[224]
Parameter estimate	GMC Ratio
Point estimate	6.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.08
upper limit	7.65

Notes:

[224] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 15C: GMC Ratio V116 Combined Lots/ PPSV23
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Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[225]
Parameter estimate	GMC Ratio
Point estimate	3.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.86
upper limit	3.67

Notes:

[225] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 10A: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[226]
Parameter estimate	GMC Ratio
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	1.66

Notes:

[226] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 9N: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[227]
Parameter estimate	GMC Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.14

Notes:

[227] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 8: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23

Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[228]
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.89

Notes:

[228] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 16F: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[229]
Parameter estimate	GMC Ratio
Point estimate	6.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.83
upper limit	7.19

Notes:

[229] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 19A: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[230]
Parameter estimate	GMC Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.22

Notes:

[230] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 17F: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23

Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[231]
Parameter estimate	GMC Ratio
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.66
upper limit	2.07

Notes:

[231] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 20A: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[232]
Parameter estimate	GMC Ratio
Point estimate	1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.37
upper limit	1.71

Notes:

[232] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 22F: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[233]
Parameter estimate	GMC Ratio
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.17
upper limit	1.49

Notes:

[233] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23A: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23

Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[234]
Parameter estimate	GMC Ratio
Point estimate	8.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.19
upper limit	9.23

Notes:

[234] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 23B: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[235]
Parameter estimate	GMC Ratio
Point estimate	5.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.08
upper limit	6.48

Notes:

[235] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 24F: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[236]
Parameter estimate	GMC Ratio
Point estimate	14.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.77
upper limit	16.4

Notes:

[236] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 33F: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23

Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[237]
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.91

Notes:

[237] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 31: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[238]
Parameter estimate	GMC Ratio
Point estimate	9.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.61
upper limit	10.59

Notes:

[238] - GMC Ratio and 95% CI were estimated from a cLDA model.

Statistical analysis title	Serotype 35B: GMC Ratio V116 Combined Lots/ PPSV23
Comparison groups	V116 Combined Lots 1, 2, and 3 v PPSV23
Number of subjects included in analysis	2157
Analysis specification	Pre-specified
Analysis type	other ^[239]
Parameter estimate	GMC Ratio
Point estimate	7.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.41
upper limit	7.77

Notes:

[239] - GMC Ratio and 95% CI were estimated from a cLDA model.

Secondary: Geometric mean fold rise (GMFR) in serotype-specific OPA for all serotypes in V116 following vaccination with separate V116 Lots

End point title	Geometric mean fold rise (GMFR) in serotype-specific OPA for all serotypes in V116 following vaccination with separate V116 Lots
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End point description:

Serotype-specific OPA GMFR for all serotypes in V116 following vaccination were determined using MOPA. The GMFR of each pneumococcal serotype was calculated as Day 30 GMT/Day 1 GMT. The 95%

CIs were calculated based on the t-distribution. Per protocol, the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. Per protocol, all randomized participants who were vaccinated with V116 and were without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.

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

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	538	540	0 ^[240]
Units: Ratio				
geometric mean (confidence interval 95%)				
Serotype 3 (n=413, 427, 429)	8.2 (7.2 to 9.4)	8.1 (7.2 to 9.1)	8.2 (7.3 to 9.3)	(to)
Serotype 6A (n=366, 393, 403)	46.8 (38.5 to 56.8)	37.8 (31.1 to 45.9)	35.8 (29.7 to 43.2)	(to)
Serotype 7F (n=438, 435, 428)	17.6 (14.6 to 21.2)	14.2 (11.8 to 17.0)	14.8 (12.4 to 17.6)	(to)
Serotype 8 (n=450, 456, 466)	17.6 (14.7 to 21.1)	16.2 (13.6 to 19.2)	15.4 (12.9 to 18.5)	(to)
Serotype 9N (n=438, 439, 434)	10.1 (8.8 to 11.7)	10.4 (9.0 to 12.0)	10.5 (9.0 to 12.2)	(to)
Serotype 10A (n=432, 450, 458)	14.1 (11.8 to 16.7)	15.2 (12.8 to 18.0)	15.9 (13.3 to 18.9)	(to)
Serotype 11A (n=428, 432, 450)	11.5 (9.5 to 14.0)	11.3 (9.3 to 13.8)	9.3 (7.8 to 11.1)	(to)
Serotype 12F (n=433, 457, 432)	173.7 (144.8 to 208.5)	152.0 (127.5 to 181.2)	194.1 (162.5 to 231.7)	(to)
Serotype 15A (n=305, 325, 320)	9.3 (7.8 to 11.2)	8.8 (7.5 to 10.5)	9.5 (7.9 to 11.3)	(to)
Serotype 15C (n=391, 411, 393)	86.0 (68.7 to 107.8)	78.8 (64.0 to 97.0)	63.8 (51.2 to 79.5)	(to)
Serotype 16F (n=382, 402, 403)	7.1 (6.2 to 8.2)	7.6 (6.6 to 8.8)	6.9 (6.2 to 7.8)	(to)
Serotype 17F (n=445, 457, 458)	17.8 (15.3 to 20.9)	18.5 (15.8 to 21.6)	16.9 (14.4 to 19.8)	(to)
Serotype 19A (n=446, 468, 468)	8.9 (7.7 to 10.3)	8.5 (7.4 to 9.9)	8.9 (7.8 to 10.3)	(to)
Serotype 20A (n=376, 396, 403)	10.6 (9.1 to 12.3)	11.7 (10.2 to 13.4)	9.5 (8.3 to 10.8)	(to)
Serotype 22F (n=409, 404, 417)	20.0 (16.1 to 24.7)	15.4 (12.6 to 18.8)	18.1 (14.9 to 22.0)	(to)
Serotype 23A (n=344, 373, 357)	30.9 (24.8 to 38.4)	27.7 (22.6 to 34.1)	30.0 (24.5 to 36.7)	(to)
Serotype 23B (n=428, 448, 444)	104.1 (85.2 to 127.2)	91.0 (74.5 to 111.2)	106.0 (87.2 to 128.8)	(to)
Serotype 24F (n=383, 399, 407)	27.0 (22.2 to 32.9)	24.0 (19.6 to 29.2)	25.4 (20.8 to 31.0)	(to)
Serotype 31 (n=383, 406, 398)	25.1 (20.3 to 31.2)	25.7 (20.9 to 31.6)	21.2 (17.2 to 26.1)	(to)
Serotype 33F (n=393, 411, 425)	13.1 (11.2 to 15.2)	12.5 (10.7 to 14.5)	12.3 (10.6 to 14.2)	(to)
Serotype 35B (n=420, 434, 441)	4.6 (4.1 to 5.2)	5.0 (4.4 to 5.7)	4.7 (4.1 to 5.3)	(to)

Notes:

[240] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with ≥ 4 -fold rise in serotype-specific OPA for all serotypes in V116 following vaccination with separate V116 Lots

End point title	Percentage of participants with ≥ 4 -fold rise in serotype-specific OPA for all serotypes in V116 following vaccination with separate V116 Lots
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End point description:

Serotype-specific OPA titer were determined using MOPA. The percentage of participants with a ≥ 4 -fold rise in serotype-specific OPA for all serotypes in V116 following vaccination were reported. The 95% CIs were calculated based on the exact binomial method proposed by Clopper and Pearson. Per protocol, the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. Per protocol, all randomized participants who were vaccinated with V116 and were without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Day 30

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	538	540	0 ^[241]
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 3 (n=413, 427, 429)	70.7 (66.1 to 75.1)	71.0 (66.4 to 75.2)	70.6 (66.1 to 74.9)	(to)
Serotype 6A (n=366, 393, 403)	87.2 (83.3 to 90.4)	86.5 (82.7 to 89.7)	85.6 (81.8 to 88.9)	(to)
Serotype 7F (n=438, 435, 428)	73.5 (69.1 to 77.6)	69.7 (65.1 to 73.9)	71.7 (67.2 to 75.9)	(to)
Serotype 8 (n=450, 456, 458)	72.7 (68.3 to 76.7)	75.9 (71.7 to 79.7)	70.4 (66.0 to 74.5)	(to)
Serotype 9N (n=438, 439, 434)	69.6 (65.1 to 73.9)	70.4 (65.9 to 74.6)	72.1 (67.6 to 76.3)	(to)
Serotype 10A (n=432, 450, 458)	70.6 (66.1 to 74.9)	75.1 (70.8 to 79.0)	73.8 (69.5 to 77.8)	(to)
Serotype 11A (n=428, 432, 450)	64.3 (59.5 to 68.8)	66.0 (61.3 to 70.4)	61.3 (56.7 to 65.9)	(to)
Serotype 12F (n=433, 457, 432)	94.5 (91.9 to 96.4)	94.5 (92.0 to 96.4)	95.6 (93.2 to 97.3)	(to)
Serotype 15A (n=305, 325, 320)	66.9 (61.3 to 72.1)	66.2 (60.7 to 71.3)	67.5 (62.1 to 72.6)	(to)
Serotype 15C (n=391, 411, 393)	87.5 (83.8 to 90.6)	90.3 (87.0 to 93.0)	88.3 (84.7 to 91.3)	(to)

Serotype 16F (n=382, 402, 403)	66.0 (61.0 to 70.7)	63.7 (58.8 to 68.4)	62.5 (57.6 to 67.3)	(to)
Serotype 17F (n=445, 457, 458)	82.0 (78.1 to 85.5)	81.4 (77.5 to 84.9)	80.8 (76.9 to 84.3)	(to)
Serotype 19A (n=446, 468, 468)	65.2 (60.6 to 69.7)	65.0 (60.4 to 69.3)	66.2 (61.8 to 70.5)	(to)
Serotype 20A (n=376, 396, 403)	72.3 (67.5 to 76.8)	77.8 (73.4 to 81.8)	72.7 (68.1 to 77.0)	(to)
Serotype 22F (n=409, 404, 417)	76.3 (71.9 to 80.3)	73.3 (68.7 to 77.5)	78.4 (74.2 to 82.3)	(to)
Serotype 23A (n=344, 373, 357)	79.7 (75.0 to 83.8)	79.4 (74.9 to 83.4)	82.1 (77.7 to 85.9)	(to)
Serotype 23B (n=428, 448, 444)	91.4 (88.3 to 93.8)	89.3 (86.0 to 92.0)	90.3 (87.2 to 92.9)	(to)
Serotype 24F (n=383, 399, 407)	78.9 (74.4 to 82.8)	78.2 (73.8 to 82.2)	76.7 (72.2 to 80.7)	(to)
Serotype 31 (n=383, 406, 398)	78.3 (73.9 to 82.4)	79.1 (74.8 to 82.9)	77.6 (73.2 to 81.6)	(to)
Serotype 33F (n=413, 427, 429)	75.3 (70.7 to 79.5)	73.2 (68.7 to 77.5)	75.1 (70.7 to 79.1)	(to)
Serotype 35B (n=420, 434, 441)	52.9 (48.0 to 57.7)	49.5 (44.7 to 54.3)	48.5 (43.8 to 53.3)	(to)

Notes:

[241] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR in serotype-specific IgG for all serotypes in V116 following vaccination with separate V116 Lots

End point title	GMFR in serotype-specific IgG for all serotypes in V116 following vaccination with separate V116 Lots
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End point description:

Serotype-specific IgG GMFR for all serotypes in V116 following vaccination were determined using PnECL. The GMFR for each pneumococcal IgG serotype was calculated as Day 30 GMC/Day 1 GMC. The 95% CIs were calculated based on the t-distribution. Per protocol, the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. Per protocol, all randomized participants who were vaccinated with V116 and were without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Day 30

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	538	540	0 ^[242]
Units: Ratio				
geometric mean (confidence interval 95%)				
Serotype 3 (n=494, 502, 506)	4.4 (4.0 to 4.8)	4.7 (4.3 to 5.2)	4.6 (4.1 to 5.0)	(to)
Serotype 6A (n=493, 502, 506)	21.2 (18.7 to 24.1)	18.8 (16.6 to 21.5)	21.0 (18.7 to 23.7)	(to)

Serotype 7F (n=493, 502, 506)	13.7 (12.3 to 15.2)	13.4 (12.1 to 14.8)	12.6 (11.3 to 14.0)	(to)
Serotype 8 (n=493, 502, 506)	14.3 (12.7 to 16.2)	15.2 (13.5 to 17.0)	14.5 (12.8 to 16.4)	(to)
Serotype 9N (n=493, 502, 505)	15.9 (14.3 to 17.8)	15.3 (13.6 to 17.3)	17.1 (15.2 to 19.3)	(to)
Serotype 10A (n=494, 501, 506)	15.0 (13.4 to 16.8)	15.2 (13.5 to 17.1)	15.7 (14.0 to 17.6)	(to)
Serotype 11A (n=494, 502, 506)	7.2 (6.5 to 8.0)	7.2 (6.5 to 8.0)	7.0 (6.3 to 7.8)	(to)
Serotype 12F (n=494, 502, 505)	16.3 (14.4 to 18.4)	17.1 (15.1 to 19.3)	15.8 (14.1 to 17.8)	(to)
Serotype 15A (n=492, 502, 505)	23.1 (20.6 to 25.9)	22.8 (20.4 to 25.5)	23.4 (20.9 to 26.3)	(to)
Serotype 15C (n=494, 502, 505)	28.5 (25.3 to 32.2)	27.8 (24.7 to 31.3)	27.3 (24.2 to 30.9)	(to)
Serotype 16F (n=493, 502, 505)	8.4 (7.6 to 9.3)	8.8 (7.9 to 9.9)	9.1 (8.2 to 10.1)	(to)
Serotype 17F (n=494, 502, 506)	23.5 (21.0 to 26.3)	23.1 (20.6 to 25.9)	21.5 (19.2 to 24.1)	(to)
Serotype 19A (n=494, 502, 506)	5.5 (4.9 to 6.1)	5.8 (5.2 to 6.4)	6.0 (5.4 to 6.7)	(to)
Serotype 20A (n=494, 502, 504)	9.2 (8.3 to 10.3)	9.8 (8.8 to 10.9)	9.8 (8.8 to 10.9)	(to)
Serotype 22F (n=493, 502, 506)	20.4 (17.9 to 23.3)	19.1 (16.6 to 22.0)	19.4 (17.0 to 22.2)	(to)
Serotype 23A (n=492, 502, 504)	20.3 (18.0 to 22.8)	20.1 (17.9 to 22.5)	20.3 (18.0 to 22.9)	(to)
Serotype 23B (n=492, 502, 505)	13.9 (12.2 to 15.7)	14.0 (12.2 to 16.0)	15.0 (13.2 to 17.1)	(to)
Serotype 24F (n=492, 502, 506)	14.7 (13.0 to 16.6)	15.4 (13.6 to 17.5)	14.6 (12.9 to 16.6)	(to)
Serotype 31 (n=492, 502, 505)	13.6 (12.3 to 15.0)	15.7 (14.1 to 17.5)	13.0 (11.7 to 14.5)	(to)
Serotype 33F (n=494, 502, 505)	8.8 (7.9 to 9.8)	9.1 (8.2 to 10.1)	9.1 (8.2 to 10.0)	(to)
Serotype 35B (n=494, 502, 505)	7.3 (6.5 to 8.1)	7.3 (6.6 to 8.1)	7.2 (6.5 to 8.0)	(to)

Notes:

[242] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with ≥ 4 -fold rise in serotype-specific IgG for all serotypes in V116 following vaccination with separate V116 Lots

End point title	Percentage of participants with ≥ 4 -fold rise in serotype-specific IgG for all serotypes in V116 following vaccination with separate V116 Lots
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End point description:

Serotype-specific IgG concentrations were determined using PnECL. The percentage of participants with a ≥ 4 -fold rise in serotype-specific IgG for all serotypes in V116 were reported. The 95% CIs were calculated based on the exact binomial method proposed by Clopper and Pearson. Per protocol, the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. Per protocol, all randomized participants who were vaccinated with V116 and were without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.

End point type	Secondary
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End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	538	540	0 ^[243]
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 3 (n=494, 502, 506)	51.8 (47.3 to 56.3)	54.4 (49.9 to 58.8)	52.0 (47.5 to 56.4)	(to)
Serotype 6A (n=493, 502, 506)	87.8 (84.6 to 90.6)	85.3 (81.9 to 88.2)	89.3 (86.3 to 91.9)	(to)
Serotype 7F (n=493, 502, 506)	83.2 (79.6 to 86.4)	84.1 (80.6 to 87.2)	82.6 (79.0 to 85.8)	(to)
Serotype 8 (n=493, 502, 506)	80.5 (76.8 to 83.9)	82.7 (79.1 to 85.9)	81.4 (77.8 to 84.7)	(to)
Serotype 9N (n=493, 502, 505)	86.0 (82.6 to 88.9)	84.1 (80.6 to 87.2)	82.8 (79.2 to 86.0)	(to)
Serotype 10A (n=494, 501, 506)	82.8 (79.2 to 86.0)	82.4 (78.8 to 85.7)	83.4 (79.9 to 86.5)	(to)
Serotype 11A (n=494, 502, 506)	67.4 (63.1 to 71.5)	67.3 (63.0 to 71.4)	63.8 (59.5 to 68.0)	(to)
Serotype 12F (n=494, 502, 505)	83.8 (80.3 to 86.9)	85.1 (81.6 to 88.1)	84.4 (80.9 to 87.4)	(to)
Serotype 15A (n=492, 502, 505)	91.1 (88.2 to 93.4)	89.2 (86.2 to 91.8)	90.3 (87.4 to 92.7)	(to)
Serotype 15C (n=494, 502, 505)	90.9 (88.0 to 93.3)	90.8 (88.0 to 93.2)	90.1 (87.2 to 92.6)	(to)
Serotype 16F (n=493, 502, 505)	73.2 (69.1 to 77.1)	72.5 (68.4 to 76.4)	74.7 (70.6 to 78.4)	(to)
Serotype 17F (n=494, 502, 506)	90.3 (87.3 to 92.7)	91.0 (88.2 to 93.4)	87.7 (84.6 to 90.5)	(to)
Serotype 19A (n=494, 502, 506)	58.5 (54.0 to 62.9)	58.6 (54.1 to 62.9)	59.3 (54.9 to 63.6)	(to)
Serotype 20A (n=494, 502, 504)	72.9 (68.7 to 76.7)	76.1 (72.1 to 79.8)	74.8 (70.8 to 78.5)	(to)
Serotype 22F (n=493, 502, 506)	84.2 (80.7 to 87.3)	79.5 (75.7 to 82.9)	84.2 (80.7 to 87.3)	(to)
Serotype 23A (n=492, 502, 504)	89.0 (85.9 to 91.6)	88.8 (85.8 to 91.5)	86.3 (83.0 to 89.2)	(to)
Serotype 23B (n=492, 502, 505)	77.6 (73.7 to 81.2)	77.1 (73.2 to 80.7)	78.6 (74.8 to 82.1)	(to)
Serotype 24F (n=492, 502, 506)	81.1 (77.4 to 84.5)	80.9 (77.2 to 84.2)	79.6 (75.9 to 83.1)	(to)
Serotype 31 (n=492, 502, 505)	85.8 (82.4 to 88.7)	84.3 (80.8 to 87.3)	82.4 (78.8 to 85.6)	(to)
Serotype 33F (n=494, 502, 505)	73.5 (69.4 to 77.3)	71.7 (67.6 to 75.6)	73.7 (69.6 to 77.5)	(to)
Serotype 35B (n=494, 502, 505)	67.8 (63.5 to 71.9)	66.7 (62.4 to 70.8)	64.2 (59.8 to 68.3)	(to)

Notes:

[243] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs of serotype-specific OPA for cross-reactive serotypes following vaccination with separate V116 Lots

End point title	GMTs of serotype-specific OPA for cross-reactive serotypes following vaccination with separate V116 Lots
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End point description:

Serotype-specific OPA titers for cross-reactive serotypes (6A, 6C, 15B, and 15C) were determined using MOPA. The 95% CIs for serotype-specific OPA GMTs were calculated based on the t-distribution. Per protocol, the PPSV23 treatment group was not included as it was not analyzed with the individual lots of V116. Per protocol, all randomized participants who were vaccinated with V116 and were without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint and who had sufficient data to perform the analysis were analyzed. Deviations include, but are not limited to the following: randomized but not vaccinated, blood drawn out of time window, prohibited concomitant medication or vaccination.

End point type	Secondary
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End point timeframe:

Day 30

End point values	V116 Lot 1	V116 Lot 2	V116 Lot 3	PPSV23
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	539	538	540	0 ^[244]
Units: Titers				
geometric mean (confidence interval 95%)				
Serotype 6A (n=428, 451, 442)	6849.6 (6120.8 to 7665.0)	6009.2 (5348.8 to 6751.0)	6724.3 (5967.6 to 7577.0)	(to)
Serotype 6C (n=434, 442, 438)	3972.7 (3501.8 to 4506.9)	3421.5 (3006.5 to 3893.8)	3750.9 (3298.0 to 4265.9)	(to)
Serotype 15B (n=416, 437, 417)	11799.5 (10317.9 to 13493.8)	10062.4 (8838.3 to 11456.1)	11139.5 (9619.7 to 12899.4)	(to)
Serotype 15C (n=429, 442, 422)	13079.8 (11543.5 to 14820.6)	11332.5 (9905.9 to 12964.7)	11290.9 (9805.6 to 13001.2)	(to)

Notes:

[244] - Per protocol, the PPSV23 treatment group was not analyzed with the separate V116 lots.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious adverse events were collected up to 30 days postvaccination. Serious adverse events and all-cause mortality were reported throughout the duration of the study, up to 194 days.

Adverse event reporting additional description:

All-Cause Mortality included all randomized participants. The safety analysis population included all randomized participants who were vaccinated according to the vaccination they received. One participant in the V116 Lot 1 arm received V116 Lot 3, two participants randomized to the V116 Lot 2 arm received V116 Lot 1 and PPSV23, respectively.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.0
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Reporting groups

Reporting group title	V116 Lot 1
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Reporting group description:

Participants received a single 0.5 mL intramuscular (IM) dose of V116 Lot 1 on Day 1.

Reporting group title	PPSV23
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Reporting group description:

Participants received a single 0.5 mL IM dose of PPSV23 on Day 1.

Reporting group title	V116 Lot 3
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Reporting group description:

Participants received a single 0.5 mL IM dose of V116 Lot 3 on Day 1.

Reporting group title	V116 Lot 2
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Reporting group description:

Participants received a single 0.5 mL IM dose of V116 Lot 2 on Day 1.

Serious adverse events	V116 Lot 1	PPSV23	V116 Lot 3
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 539 (1.48%)	6 / 541 (1.11%)	1 / 541 (0.18%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oligodendroglioma			
subjects affected / exposed	1 / 539 (0.19%)	0 / 541 (0.00%)	0 / 541 (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
Endometrial cancer			

subjects affected / exposed	0 / 539 (0.00%)	0 / 541 (0.00%)	0 / 541 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 539 (0.19%)	0 / 541 (0.00%)	0 / 541 (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			
subjects affected / exposed	1 / 539 (0.19%)	0 / 541 (0.00%)	0 / 541 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 539 (0.19%)	0 / 541 (0.00%)	0 / 541 (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
Road traffic accident			
subjects affected / exposed	0 / 539 (0.00%)	1 / 541 (0.18%)	0 / 541 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 539 (0.00%)	0 / 541 (0.00%)	0 / 541 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal perforation			
subjects affected / exposed	1 / 539 (0.19%)	0 / 541 (0.00%)	0 / 541 (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
Psychiatric disorders			
Major depression			

subjects affected / exposed	0 / 539 (0.00%)	0 / 541 (0.00%)	0 / 541 (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
Depression			
subjects affected / exposed	0 / 539 (0.00%)	0 / 541 (0.00%)	0 / 541 (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
Bipolar disorder			
subjects affected / exposed	0 / 539 (0.00%)	0 / 541 (0.00%)	1 / 541 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 539 (0.19%)	0 / 541 (0.00%)	0 / 541 (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
Psychotic disorder			
subjects affected / exposed	1 / 539 (0.19%)	0 / 541 (0.00%)	0 / 541 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 539 (0.19%)	0 / 541 (0.00%)	0 / 541 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 539 (0.00%)	1 / 541 (0.18%)	0 / 541 (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
Pelvic abscess			
subjects affected / exposed	0 / 539 (0.00%)	1 / 541 (0.18%)	0 / 541 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 539 (0.00%)	1 / 541 (0.18%)	0 / 541 (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
Sepsis			
subjects affected / exposed	0 / 539 (0.00%)	1 / 541 (0.18%)	0 / 541 (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
Infectious mononucleosis			
subjects affected / exposed	0 / 539 (0.00%)	1 / 541 (0.18%)	0 / 541 (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

Serious adverse events	V116 Lot 2		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 536 (0.93%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oligodendroglioma			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial cancer			
subjects affected / exposed	1 / 536 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 536 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Intestinal perforation			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Major depression			
subjects affected / exposed	1 / 536 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	1 / 536 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bipolar disorder			
subjects affected / exposed	1 / 536 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol withdrawal syndrome			

subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic abscess			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infectious mononucleosis			
subjects affected / exposed	0 / 536 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	V116 Lot 1	PPSV23	V116 Lot 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	428 / 539 (79.41%)	388 / 541 (71.72%)	421 / 541 (77.82%)
Nervous system disorders			
Headache			
subjects affected / exposed	165 / 539 (30.61%)	131 / 541 (24.21%)	154 / 541 (28.47%)
occurrences (all)	172	140	163
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	206 / 539 (38.22%)	184 / 541 (34.01%)	187 / 541 (34.57%)
occurrences (all)	206	186	188
Injection site erythema			
subjects affected / exposed	74 / 539 (13.73%)	41 / 541 (7.58%)	71 / 541 (13.12%)
occurrences (all)	74	41	71
Injection site pain			
subjects affected / exposed	393 / 539 (72.91%)	328 / 541 (60.63%)	400 / 541 (73.94%)
occurrences (all)	394	328	401
Injection site swelling			
subjects affected / exposed	68 / 539 (12.62%)	41 / 541 (7.58%)	64 / 541 (11.83%)
occurrences (all)	68	41	64
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	98 / 539 (18.18%)	49 / 541 (9.06%)	95 / 541 (17.56%)
occurrences (all)	98	49	95

Non-serious adverse events	V116 Lot 2		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	415 / 536 (77.43%)		
Nervous system disorders			
Headache			
subjects affected / exposed	154 / 536 (28.73%)		
occurrences (all)	166		
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	184 / 536 (34.33%)		
occurrences (all)	186		
Injection site erythema			
subjects affected / exposed	79 / 536 (14.74%)		
occurrences (all)	80		
Injection site pain			
subjects affected / exposed	391 / 536 (72.95%)		
occurrences (all)	392		
Injection site swelling			
subjects affected / exposed	82 / 536 (15.30%)		
occurrences (all)	82		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	75 / 536 (13.99%)		
occurrences (all)	75		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 November 2022	AM1: The purpose of the amendment was to update the Sponsor's entity name and address change.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported