



Clinical trial results:

A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in Adults Living With HIV

Summary

EudraCT number	2021-006710-36
Trial protocol	BE FR
Global end of trial date	25 January 2024

Results information

Result version number	v1 (current)
This version publication date	06 June 2025
First version publication date	06 June 2025

Trial information

Trial identification

Sponsor protocol code	v116-007
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05393037
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 January 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 July 2023
Global end of trial reached?	Yes
Global end of trial date	25 January 2024
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 persons living with human immunodeficiency virus (HIV), for the prevention of pneumococcal disease caused by the serotypes in the vaccine.

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	13 July 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	Belgium: 38
Country: Number of subjects enrolled	Chile: 58
Country: Number of subjects enrolled	France: 38
Country: Number of subjects enrolled	South Africa: 68
Country: Number of subjects enrolled	Thailand: 32
Country: Number of subjects enrolled	United States: 79
Worldwide total number of subjects	313
EEA total number of subjects	76

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)	292
From 65 to 84 years	20
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study is conducted in two parts. Part A evaluated V116 and the comparator regimen of PCV15 followed by PPSV23. Part B evaluated safety and immunogenicity of PCV15 in participants who received V116 in Part A.

Period 1

Period 1 title	Part A
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	V116 + Placebo (Part A), PCV15 (Part B)

Arm description:

Participants received a single intramuscular (IM) dose of V116 on Day 1 and a single IM dose of placebo on Week 8 in Part A. In Part B, a single IM dose of PCV15 was given approximately between 10 to 18 months after V116.

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 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

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo solution matched to V116 in each 0.5 mL sterile solution

Investigational medicinal product name	PCV15
Investigational medicinal product code	
Other name	VAXNEUVANCE™
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Pneumococcal 15-valent conjugate vaccine with 2 µg of each of the PnPs antigen: 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F, and 4 µg of 6B in each 0.5 mL sterile suspension

Arm title	PCV15 + PPSV23 (Part A)
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Arm description:

Participants received a single IM dose of PCV15 on Day 1, and a single IM dose of PPSV23 on Week 8 in Part A of the study.

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 vaccine with 25 µg of each of the 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 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)
Started	156	157
Vaccination 1- V116	155	0 [1]
Vaccination 1- PCV15	1 [2]	156
Vaccination 2- Placebo	154	0 [3]
Vaccination 2-PCV15	0 [4]	1 [5]
Vaccination 2-PPSV23	0 [6]	151 [7]
Completed	152	152
Not completed	4	5
Adverse event, serious fatal	1	-
Consent withdrawn by subject	2	4
Lost to follow-up	1	1

Notes:

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

Justification: PCV15 + PPSV23 (Part A) participants could have been considered to complete the study with the receipt of Vaccination 2-PPSV23

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

Justification: V116 + Placebo (Part A), PCV15 (Part B) group participants, could have been considered to complete the study without the receipt of Vaccination 2-PPSV23.

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

Justification: PCV15 + PPSV23 (Part A) participants could have been considered to complete the study without the receipt of Vaccination 1- V116.

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

Justification: One participant in V116 + Placebo (Part A), PCV15 (Part B) group could have been considered to complete the study with the receipt of Vaccination 1- PCV 15.

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

Justification: Of the 155 participants who received V116 in Part A, 126 participants received PCV15 in Part B. All but 1 participant completed Part B.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the

arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: V116 + Placebo (Part A), PCV15 (Part B) group participants, could have been considered to complete the study without the receipt of Vaccination 2-PPSV23.

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

Justification: V116 + Placebo (Part A), PCV15 (Part B) group participants could have been considered to complete the study without the receipt of vaccination 2- PCV 15.

Period 2

Period 2 title	Part B
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	V116 + Placebo (Part A), PCV15 (Part B)
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Arm description:

Participants received a single intramuscular (IM) dose of V116 on Day 1 and a single IM dose of placebo on Week 8 in Part A. In Part B, a single IM dose of PCV15 was given approximately between 10 to 18 months after V116.

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 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

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo solution matched to V116 in each 0.5 mL sterile solution

Investigational medicinal product name	PCV15
Investigational medicinal product code	
Other name	VAXNEUVANCE™
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Pneumococcal 15-valent conjugate vaccine with 2 µg of each of the PnPs antigen: 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F, and 4 µg of 6B in each 0.5 mL sterile suspension

Number of subjects in period 2^[8]	V116 + Placebo (Part A), PCV15 (Part B)
Started	126
Completed	125
Not completed	1
Lost to follow-up	1

Notes:

[8] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: One participant in PCV15 + PPSV23 (Part A) group could have been considered to complete the study with the receipt of Vaccination 2- PCV 15.

Baseline characteristics

Reporting groups

Reporting group title	V116 + Placebo (Part A), PCV15 (Part B)
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Reporting group description:

Participants received a single intramuscular (IM) dose of V116 on Day 1 and a single IM dose of placebo on Week 8 in Part A. In Part B, a single IM dose of PCV15 was given approximately between 10 to 18 months after V116.

Reporting group title	PCV15 + PPSV23 (Part A)
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Reporting group description:

Participants received a single IM dose of PCV15 on Day 1, and a single IM dose of PPSV23 on Week 8 in Part A of the study.

Reporting group values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)	Total
Number of subjects	156	157	313
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	147	145	292
From 65-84 years	8	12	20
85 years and over	1	0	1
Age Continuous Units: Years			
arithmetic mean	44.0	46.7	-
standard deviation	± 12.6	± 12.3	-
Sex: Female, Male Units: Participants			
Female	42	50	92
Male	114	107	221
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	1	2
Asian	21	12	33
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	62	63	125
White	70	79	149
More than one race	1	2	3
Unknown or Not Reported	1	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	32	44	76
Not Hispanic or Latino	124	112	236

Unknown or Not Reported	0	1	1
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End points

End points reporting groups

Reporting group title	V116 + Placebo (Part A), PCV15 (Part B)
Reporting group description: Participants received a single intramuscular (IM) dose of V116 on Day 1 and a single IM dose of placebo on Week 8 in Part A. In Part B, a single IM dose of PCV15 was given approximately between 10 to 18 months after V116.	
Reporting group title	PCV15 + PPSV23 (Part A)
Reporting group description: Participants received a single IM dose of PCV15 on Day 1, and a single IM dose of PPSV23 on Week 8 in Part A of the study.	
Reporting group title	V116 + Placebo (Part A), PCV15 (Part B)
Reporting group description: Participants received a single intramuscular (IM) dose of V116 on Day 1 and a single IM dose of placebo on Week 8 in Part A. In Part B, a single IM dose of PCV15 was given approximately between 10 to 18 months after V116.	

Primary: Percentage of participants with solicited injection-site AEs from Day 1 through Day 5 postvaccination in Part A

End point title	Percentage of participants with solicited injection-site AEs from Day 1 through Day 5 postvaccination in Part A ^[1]
End point description: An adverse event (AE) is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. The percentage of participants with solicited injection-site AEs after any vaccination was assessed. The solicited injection-site AEs assessed were redness/erythema, swelling, and tenderness/pain. All participants who were randomized and received at least 1 dose of study intervention. Participants were included in the intervention group according to the study intervention actually received. Two participants received the incorrect study intervention that resulted in a regimen inconsistent with the 2 designated regimens planned in this study. Both participants were excluded from the safety analysis population.	
End point type	Primary
End point timeframe: Up to 5 days after each vaccination in Part A	

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: V116 + Placebo (Part A), PCV15 (Part B) group participants, could have been considered to complete the study without the receipt of Vaccination 2-PPSV23.

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	155		
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site erythema	3.9 (1.4 to 8.2)	11.0 (6.5 to 17.0)		
Injection site pain	50.3 (42.2 to 58.4)	82.6 (75.7 to 88.2)		
Injection site swelling	7.1 (3.6 to 12.3)	20.6 (14.6 to 27.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants with solicited systemic AEs from Day 1 through Day 5 postvaccination in Part A

End point title	Percentage of participants with solicited systemic AEs from Day 1 through Day 5 postvaccination in Part A ^[2]
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End point description:

An adverse event (AE) is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. The percentage of participants with solicited systemic AEs was assessed following any vaccination. The solicited systemic AEs assessed were fatigue, headache, myalgia, and pyrexia. All participants who were randomized and received at least 1 dose of study intervention. Participants were included in the intervention group according to the study intervention actually received. Two participants received the incorrect study intervention that resulted in a regimen inconsistent with the 2 designated regimens planned in this study. Both participants were excluded from the safety analysis population.

End point type	Primary
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End point timeframe:

Up to 5 days after each vaccination in Part A

Notes:

[2] - 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: V116 + Placebo (Part A), PCV15 (Part B) group participants, could have been considered to complete the study without the receipt of Vaccination 2-PPSV23.

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	155		
Units: Percentage of Participants				
number (confidence interval 95%)				
Fatigue	34.2 (26.8 to 42.2)	30.3 (23.2 to 38.2)		
Headache	19.4 (13.5 to 26.5)	21.9 (15.7 to 29.3)		
Myalgia	15.5 (10.2 to 22.2)	12.3 (7.5 to 18.5)		
Pyrexia	3.2 (1.1 to 7.4)	1.9 (0.4 to 5.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants with vaccine-related serious adverse events (SAEs) from Day 1 through the duration of participation in Part A

End point title	Percentage of participants with vaccine-related serious adverse events (SAEs) from Day 1 through the duration of participation in Part A ^[3]
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End point description:

A serious adverse event (SAE) is an AE that is life-threatening, requires or prolongs an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or is another important medical event deemed such by medical or scientific judgment. Relatedness of an SAE to the study vaccine was determined by the investigator. Following any vaccination, the percentage of serious adverse events was assessed. All participants who were randomized and received at least 1 dose of study intervention. Participants were included in the intervention group according to the study intervention actually received. Two participants received the incorrect study intervention that resulted in a regimen inconsistent with the 2 designated regimens planned in this study. Both participants were excluded from the safety analysis population.

End point type	Primary
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End point timeframe:

Up to 194 days in Part A

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: V116 + Placebo (Part A), PCV15 (Part B) group participants, could have been considered to complete the study without the receipt of Vaccination 2-PPSV23.

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	155		
Units: Percentage of Participants				
number (confidence interval 95%)	0.0 (0.0 to 2.4)	0.0 (0.0 to 2.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Serotype-specific Opsonophagocytic activity (OPA) geometric mean titers (GMT) postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116

End point title	Serotype-specific Opsonophagocytic activity (OPA) geometric mean titers (GMT) postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116 ^[4]
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End point description:

Serotype-specific OPA to the 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116 were determined using a multiplex opsonophagocytic assay (MOPA). GMT is defined as geometric mean titer (1/dil). Serotype-specific OPA GMTs with 95% confidence intervals are presented. Overall participants analyzed included all randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity analyses. The number analyzed for each serotype is the subset of overall participants analyzed without protocol deviation such as failure to receive study vaccine, failure to receive correct clinical material as per randomization schedule, or receipt of a prohibited medication or prohibited vaccine prior to study vaccination.

End point type	Primary
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End point timeframe:

Up to 114 days

Notes:

[4] - 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: V116 + Placebo (Part A), PCV15 (Part B) group participants, could have been considered to complete the study without the receipt of Vaccination 2-PPSV23.

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	156		
Units: Titers				
geometric mean (confidence interval 95%)				
Serotype 3 (Shared)	170.7 (132.5 to 220.0)	172.0 (138.4 to 213.7)		
Serotype 6A (Shared)	3896.0 (2929.7 to 5181.1)	3979.5 (3210.6 to 4932.5)		
Serotype 7F (Shared)	3482.3 (2815.8 to 4306.6)	3275.6 (2658.1 to 4036.6)		
Serotype 8 (Shared)	1847.5 (1470.9 to 2320.6)	2262.9 (1776.5 to 2882.5)		
Serotype 9N (Shared)	5763.0 (4552.8 to 7294.7)	5970.0 (4786.9 to 7445.6)		
Serotype 10A (Shared)	3693.0 (2870.2 to 4751.5)	3652.8 (2731.4 to 4885.1)		
Serotype 11A (Shared)	3742.5 (3050.7 to 4591.1)	1722.3 (1277.1 to 2322.7)		
Serotype 12F (Shared)	2585.4 (1993.5 to 3353.0)	2292.4 (1653.2 to 3178.8)		
Serotype 17F (Shared)	8698.6 (7046.1 to 10738.5)	5886.3 (4489.8 to 7717.1)		
Serotype 19A (Shared)	2178.9 (1777.1 to 2671.7)	2667.0 (2193.2 to 3243.1)		
Serotype 20A (Shared)	7249.1 (5854.9 to 8975.4)	5753.3 (4634.0 to 7143.0)		
Serotype 22F (Shared)	3622.4 (2902.8 to 4520.4)	3979.8 (3214.5 to 4927.1)		
Serotype 33F (Shared)	14642.5 (11314.9 to 18948.6)	11864.5 (9283.8 to 15162.5)		
Serotype 15A (Unique to V116)	5859.0 (4684.9 to 7327.4)	1970.5 (1555.1 to 2496.8)		
Serotype 15C (Unique to V116)	5613.0 (4136.7 to 7616.3)	2438.0 (1791.5 to 3317.7)		
Serotype 16F (Unique to V116)	6703.0 (5494.0 to 8178.1)	1839.0 (1474.3 to 2293.9)		

Serotype 23A (Unique to V116)	5053.5 (3781.3 to 6753.5)	1674.9 (1209.9 to 2318.7)		
Serotype 23B (Unique to V116)	1593.8 (1182.7 to 2147.9)	151.0 (98.1 to 232.6)		
Serotype 24B (Unique to V116)	3725.6 (3161.1 to 4391.0)	567.9 (375.4 to 859.1)		
Serotype 31 (Unique to V116)	5699.4 (4435.1 to 7324.2)	530.8 (364.2 to 773.7)		
Serotype 35B (Unique to V116)	11306.2 (9364.7 to 13650.1)	2977.7 (2425.5 to 3655.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serotype-specific Immunoglobulin G (IgG) geometric mean concentration (GMC) postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116

End point title	Serotype-specific Immunoglobulin G (IgG) geometric mean concentration (GMC) postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116
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End point description:

The GMC of IgG serotype-specific antibodies to the 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116 were quantitated from participants' sera by a multiplex electrochemiluminescence (ECL) assay. Overall participants analyzed included all randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity analyses. The number analyzed for each serotype is the subset of overall participants analyzed without protocol deviation such as failure to receive study vaccine, failure to receive correct clinical material as per randomization schedule, or receipt of a prohibited medication or prohibited vaccine prior to study vaccination.

End point type	Secondary
End point timeframe:	Up to 114 days

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	156		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 3 (Shared)	0.50 (0.43 to 0.59)	0.58 (0.49 to 0.67)		
Serotype 6A (Shared)	3.79 (2.77 to 5.18)	2.80 (2.02 to 3.89)		
Serotype 7F (Shared)	2.95 (2.31 to 3.77)	1.81 (1.49 to 2.21)		

Serotype 8 (Shared)	7.05 (5.76 to 8.64)	8.10 (6.66 to 9.85)		
Serotype 9N (Shared)	5.02 (4.01 to 6.28)	3.36 (2.73 to 4.14)		
Serotype 10A (Shared)	7.15 (5.24 to 9.75)	3.73 (2.78 to 5.00)		
Serotype 11A (Shared)	4.40 (3.55 to 5.45)	2.64 (2.13 to 3.27)		
Serotype 12F (Shared)	1.10 (0.83 to 1.47)	0.71 (0.51 to 0.99)		
Serotype 17F (Shared)	10.34 (8.24 to 12.96)	4.43 (3.49 to 5.61)		
Serotype 19A (Shared)	5.96 (4.88 to 7.30)	5.99 (4.83 to 7.43)		
Serotype 20A (Shared)	7.08 (5.60 to 8.95)	4.94 (3.81 to 6.41)		
Serotype 22F (Shared)	3.70 (2.96 to 4.61)	2.99 (2.40 to 3.72)		
Serotype 33F (Shared)	7.55 (5.90 to 9.65)	5.56 (4.41 to 7.01)		
Serotype 15A (Unique to V116)	5.67 (4.37 to 7.36)	1.02 (0.80 to 1.31)		
Serotype 15C (Unique to V116)	6.92 (5.15 to 9.29)	2.68 (2.07 to 3.49)		
Serotype 16F (Unique to V116)	1.55 (1.23 to 1.95)	0.21 (0.16 to 0.26)		
Serotype 23F (Unique to V116)	2.54 (1.85 to 3.50)	0.41 (0.30 to 0.55)		
Serotype 23B (Unique to V116)	3.27 (2.51 to 4.25)	0.99 (0.75 to 1.31)		
Serotype 24F (Unique to V116)	1.80 (1.25 to 2.59)	0.17 (0.13 to 0.21)		
Serotype 31 (Unique to V116)	2.20 (1.78 to 2.72)	0.25 (0.20 to 0.31)		
Serotype 35B (Unique to V116)	10.26 (7.96 to 13.22)	0.90 (0.73 to 1.10)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serotype-specific OPA geometric mean fold rises (GMFRs) postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116

End point title	Serotype-specific OPA geometric mean fold rises (GMFRs) postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116
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End point description:

Activity for the serotypes contained in V116 and PCV15+PPSV23 (13 serotypes shared with PCV15 and PPSV23 and 8 serotypes unique to V116) was determined using a Multiplexed Opsonophagocytic Assay (MOPA). Geometric mean fold rise (GMFR) is the geometric mean of fold rise from baseline to postvaccination with V116 and PCV15 + PPSV23. Overall participants analyzed included all randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity analyses. The number analyzed for each serotype is the subset of overall participants analyzed without protocol deviation such as failure to receive study vaccine, failure to receive correct clinical material as per randomization schedule, or receipt of a prohibited medication or prohibited vaccine prior to study vaccination.

End point type	Secondary
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End point timeframe:

Baseline, 30 days post vaccination day 1 (V116), and 30 days post vaccination week 8 (PCV15 + PPSV23)

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	156		
Units: Ratio				
geometric mean (confidence interval 95%)				
Serotype 3 (Shared)	5.5 (4.3 to 7.1)	5.3 (4.3 to 6.7)		
Serotype 6A (Shared)	14.3 (10.3 to 19.9)	15.3 (11.3 to 20.7)		
Serotype 7F (Shared)	12.3 (9.1 to 16.3)	7.4 (5.4 to 10.3)		
Serotype 8 (Shared)	11.9 (8.6 to 16.3)	15.0 (10.4 to 21.8)		
Serotype 9N (Shared)	6.7 (5.0 to 8.9)	5.9 (4.5 to 7.7)		
Serotype 10A (Shared)	9.4 (7.1 to 12.6)	7.4 (5.4 to 10.2)		
Serotype 11A (Shared)	9.2 (6.4 to 13.4)	3.8 (2.7 to 5.3)		
Serotype 12F (Shared)	57.3 (42.0 to 78.0)	46.7 (31.4 to 69.4)		
Serotype 17F (Shared)	15.1 (11.2 to 20.2)	8.5 (6.4 to 11.5)		
Serotype 19A (Shared)	5.0 (3.9 to 6.3)	5.6 (4.4 to 7.2)		
Serotype 20A (Shared)	7.1 (5.5 to 9.2)	4.7 (3.7 to 6.0)		
Serotype 22F (Shared)	19.2 (13.2 to 28.1)	19.3 (12.7 to 29.4)		
Serotype 33F (Shared)	7.5 (5.6 to 10.1)	6.8 (5.2 to 9.1)		
Serotype 15A (Unique to V116)	5.7 (4.2 to 7.7)	1.4 (1.1 to 1.8)		
Serotype 15C (Unique to V116)	27.8 (18.7 to 41.4)	16.3 (10.9 to 24.3)		
Serotype 16F (Unique to V116)	6.3 (4.8 to 8.2)	1.7 (1.4 to 2.0)		
Serotype 23A (Unique to V116)	9.0 (6.0 to 13.7)	2.8 (1.7 to 4.8)		
Serotype 23B (Unique to V116)	52.0 (35.7 to 75.6)	7.2 (4.9 to 10.4)		
Serotype 24F (Unique to V116)	5.8 (4.0 to 8.3)	1.0 (0.8 to 1.3)		
Serotype 31 (Unique to V116)	19.9 (13.8 to 28.6)	1.5 (1.1 to 2.0)		
Serotype 35B (Unique to V116)	5.4 (4.3 to 6.8)	1.3 (1.1 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serotype-specific IgG GMFRs postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116

End point title	Serotype-specific IgG GMFRs postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116
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End point description:

The GMC of IgG serotype-specific antibodies to the 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116 were quantitated from participants' sera by a multiplex electrochemiluminescence (ECL) assay. Geometric mean fold rise (GMFR) is the geometric mean of fold rise from baseline to postvaccination with V116 and PCV15 + PPSV23. Overall participants analyzed included all randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity analyses. The number analyzed for each serotype is the subset of overall participants analyzed without protocol deviation such as failure to receive study vaccine, failure to receive correct clinical material as per randomization schedule, or receipt of a prohibited medication or prohibited vaccine prior to study vaccination.

End point type	Secondary
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End point timeframe:

Baseline, 30 days post vaccination day 1 (V116), and 30 days post vaccination week 8 (PCV15 + PPSV23)

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	156		
Units: Ratio				
geometric mean (confidence interval 95%)				
Serotype 3 (Shared)	3.7 (3.2 to 4.3)	4.0 (3.4 to 4.6)		
Serotype 6A (Shared)	11.4 (8.8 to 14.6)	9.2 (7.1 to 11.8)		
Serotype 7F (Shared)	9.1 (7.3 to 11.3)	5.7 (4.7 to 6.8)		
Serotype 8 (Shared)	8.1 (6.5 to 10.1)	10.0 (7.9 to 12.8)		
Serotype 9N (Shared)	10.4 (8.3 to 13.0)	7.8 (6.3 to 9.6)		
Serotype 10A (Shared)	12.2 (9.7 to 15.3)	8.2 (6.7 to 10.0)		
Serotype 11A (Shared)	6.6 (5.5 to 7.9)	4.5 (3.8 to 5.3)		
Serotype 12F (Shared)	9.7 (7.7 to 12.4)	6.7 (5.1 to 8.8)		
Serotype 17F (Shared)	13.8 (11.1 to 17.1)	7.5 (6.2 to 9.1)		
Serotype 19A (Shared)	3.8 (3.2 to 4.6)	4.8 (4.1 to 5.6)		
Serotype 20A (Shared)	7.3 (6.0 to 8.9)	5.4 (4.5 to 6.5)		
Serotype 22F (Shared)	13.7 (10.7 to 17.5)	10.4 (8.4 to 13.0)		
Serotype 33F (Shared)	8.1 (6.6 to 10.0)	5.9 (4.9 to 7.1)		
Serotype 15A (unique to V116)	16.1 (13.1 to 19.9)	2.4 (2.1 to 2.8)		
Serotype 15C (unique to V116)	16.6 (13.3 to 20.8)	6.1 (5.0 to 7.5)		
Serotype 16F (unique to V116)	8.8 (7.3 to 10.7)	1.4 (1.3 to 1.6)		

Serotype 23A (unique to V116)	15.8 (12.3 to 20.3)	2.8 (2.3 to 3.4)		
Serotype 23B (unique to V116)	10.0 (8.0 to 12.6)	3.6 (2.9 to 4.4)		
Serotype 24F (unique to V116)	10.9 (8.3 to 14.2)	1.0 (0.9 to 1.1)		
Serotype 31 (unique to V116)	11.6 (9.6 to 14.0)	1.4 (1.3 to 1.6)		
Serotype 35B (unique to V116)	11.8 (9.4 to 14.7)	1.1 (1.0 to 1.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a ≥ 4 -fold rise in OPA responses from baseline (Day 1) to postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116

End point title	Percentage of participants with a ≥ 4 -fold rise in OPA responses from baseline (Day 1) to postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116
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End point description:

Activity for the serotypes contained in V116 and PCV15+PPSV23 (13 serotypes shared with PCV15 and PPSV23 and 8 serotypes unique to V116) was determined using MOPA. The percentage of participants who had ≥ 4 -fold rise in OPA titers were calculated from baseline to postvaccination with V116 and PCV15 + PPSV23. Overall participants analyzed included all randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity analyses. The number analyzed for each serotype is the subset of overall participants analyzed without protocol deviation such as failure to receive study vaccine, failure to receive correct clinical material as per randomization schedule, or receipt of a prohibited medication or prohibited vaccine prior to study vaccination.

End point type	Secondary
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End point timeframe:

Baseline, 30 days post vaccination day 1 (V116), and 30 days post vaccination week 8 (PCV15 + PPSV23)

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	156		
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 3 (Shared)	58.7 (49.4 to 67.6)	61.9 (52.5 to 70.6)		
Serotype 6A (Shared)	73.8 (65.0 to 81.3)	80.2 (71.7 to 87.0)		
Serotype 7F (Shared)	69.0 (60.3 to 76.8)	59.2 (49.8 to 68.0)		
Serotype 8 (Shared)	66.9 (58.3 to 74.7)	70.1 (61.3 to 77.9)		

Serotype 9N (Shared)	56.3 (47.2 to 65.2)	57.7 (48.5 to 66.6)		
Serotype 10A (Shared)	62.2 (53.2 to 70.7)	60.5 (50.9 to 69.6)		
Serotype 11A (Shared)	53.6 (44.5 to 62.6)	43.6 (34.4 to 53.1)		
Serotype 12F (Shared)	92.2 (86.1 to 96.2)	83.3 (75.4 to 89.5)		
Serotype 17F (Shared)	77.1 (68.9 to 84.0)	64.7 (55.4 to 73.2)		
Serotype 19A (Shared)	49.2 (40.4 to 58.1)	55.9 (46.8 to 64.7)		
Serotype 20A (Shared)	59.2 (50.3 to 67.8)	49.2 (40.1 to 58.3)		
Serotype 22F (Shared)	76.0 (67.4 to 83.3)	71.7 (62.4 to 79.8)		
Serotype 33F (Shared)	61.9 (52.3 to 70.9)	58.8 (49.4 to 67.8)		
Serotype 15A (Unique to V116)	59.3 (49.4 to 68.6)	21.1 (14.0 to 29.7)		
Serotype 16F (Unique to V116)	53.6 (44.5 to 62.6)	16.8 (10.6 to 24.8)		
Serotype 23A (Unique to V116)	57.9 (47.3 to 68.0)	32.5 (22.2 to 44.1)		
Serotype 23B (Unique to V116)	87.0 (79.7 to 92.4)	50.0 (40.7 to 59.3)		
Serotype 24F (Unique to V116)	53.8 (43.1 to 64.4)	7.2 (2.4 to 16.1)		
Serotype 31 (Unique to V116)	73.7 (65.3 to 80.9)	16.5 (10.4 to 24.4)		
Serotype 35B (Unique to V116)	55.6 (46.8 to 64.2)	5.6 (2.3 to 11.2)		
Serotype 15C (Unique to V116)	80.4 (71.8 to 87.3)	71.0 (61.5 to 79.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a ≥ 4 -fold rise in IgG responses from baseline (Day 1) to postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116

End point title	Percentage of participants with a ≥ 4 -fold rise in IgG responses from baseline (Day 1) to postvaccination in Part A for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116
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End point description:

The GMC of IgG serotype-specific antibodies to the 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116 were quantitated from participants' sera by a multiplex ECL assay. The percentage of participants who had ≥ 4 -fold rise in IgG concentration was calculated from baseline to postvaccination with V116 and PCV15 + PPSV23. Overall participants analyzed included all randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity analyses. The number analyzed for each serotype is the subset of overall participants analyzed without protocol deviation such as failure to receive study vaccine, failure to receive correct clinical material as per randomization schedule, or receipt of a prohibited medication or prohibited vaccine prior to study vaccination.

End point type	Secondary
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End point timeframe:

Baseline, 30 days post vaccination day 1 (V116), and 30 days post vaccination week 8 (PCV15 + PPSV23)

End point values	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	156		
Units: Percentage of participants				
number (confidence interval 95%)				
Serotype 3 (Shared)	42.3 (33.9 to 51.1)	50.4 (41.6 to 59.2)		
Serotype 6A (Shared)	70.8 (62.4 to 78.3)	68.2 (59.5 to 76.0)		
Serotype 7F (Shared)	70.1 (61.7 to 77.6)	57.9 (49.0 to 66.4)		
Serotype 8 (Shared)	66.4 (57.9 to 74.3)	73.7 (65.3 to 80.9)		
Serotype 9N (Shared)	75.2 (67.1 to 82.2)	67.7 (59.0 to 75.5)		
Serotype 10A (Shared)	76.6 (68.7 to 83.4)	68.4 (59.8 to 76.2)		
Serotype 11A (Shared)	66.4 (57.9 to 74.3)	54.1 (45.3 to 62.8)		
Serotype 12F (Shared)	67.9 (59.4 to 75.6)	60.2 (51.3 to 68.5)		
Serotype 17F (Shared)	83.9 (76.7 to 89.7)	73.7 (65.3 to 80.9)		
Serotype 19A (Shared)	43.8 (35.3 to 52.5)	58.6 (49.8 to 67.1)		
Serotype 20A (Shared)	67.2 (58.6 to 74.9)	57.1 (48.3 to 65.7)		
Serotype 22F (Shared)	76.6 (68.7 to 83.4)	78.9 (71.0 to 85.5)		
Serotype 33F (Shared)	67.9 (59.4 to 75.6)	63.2 (54.4 to 71.4)		
Serotype 15A (Unique to V116)	83.9 (76.7 to 89.7)	21.8 (15.1 to 29.8)		
Serotype 15C (Unique to V116)	82.5 (75.1 to 88.4)	61.7 (52.8 to 69.9)		
Serotype 16F (Unique to V116)	73.7 (65.5 to 80.9)	9.0 (4.7 to 15.2)		
Serotype 23A (Unique to V116)	82.5 (75.1 to 88.4)	29.3 (21.8 to 37.8)		
Serotype 23B (Unique to V116)	72.3 (64.0 to 79.6)	37.6 (29.3 to 46.4)		
Serotype 24F (Unique to V116)	70.1 (61.7 to 77.6)	0.0 (0.0 to 2.7)		
Serotype 31 (Unique to V116)	83.2 (75.9 to 89.0)	6.8 (3.1 to 12.5)		
Serotype 35B (Unique to V116)	75.9 (67.9 to 82.8)	0.8 (0.0 to 4.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with solicited systemic AEs from Day 1 of Part B through Day 5 postvaccination in Part B

End point title	Percentage of participants with solicited systemic AEs from Day 1 of Part B through Day 5 postvaccination in Part B
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End point description:

An adverse event (AE) is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. The percentage of participants with solicited systemic AEs was assessed following any vaccination. The solicited systemic AEs assessed were fatigue, headache, myalgia, and pyrexia. Percentage of participants with solicited systemic AEs from Day 1 of Part B through Day 5 postvaccination in Part B. All participants who were randomized and received at least 1 dose of study intervention in part B. Participants were included in the intervention group according to the study intervention actually received.

End point type	Secondary
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End point timeframe:

Up to 5 days after vaccination in Part B

End point values	V116 + Placebo (Part A), PCV15 (Part B)			
Subject group type	Reporting group			
Number of subjects analysed	126			
Units: Percentage of Participants				
number (confidence interval 95%)				
Fatigue	22.2 (15.3 to 30.5)			
Headache	14.3 (8.7 to 21.6)			
Myalgia	11.1 (6.2 to 17.9)			
Pyrexia	0.8 (0.0 to 4.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with solicited injection-site AEs from Day 1 of Part B through Day 5 postvaccination in Part B

End point title	Percentage of participants with solicited injection-site AEs from
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End point description:

An adverse event (AE) is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. The percentage of participants with solicited injection-site AEs after any vaccination was assessed. The solicited injection-site AEs assessed were redness/erythema, swelling, and tenderness/pain. Percentage of participants with solicited injection-site AEs from Day 1 of Part B through Day 5 postvaccination in Part B. All participants who were randomized and received at least 1 dose of study intervention in part B. Participants were included in the intervention group according to the study intervention actually received.

End point type	Secondary
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End point timeframe:

Up to 5 days after vaccination in Part B

End point values	V116 + Placebo (Part A), PCV15 (Part B)			
Subject group type	Reporting group			
Number of subjects analysed	126			
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site erythema	3.2 (0.9 to 7.9)			
Injection site pain	61.9 (52.8 to 70.4)			
Injection site swelling	6.3 (2.8 to 12.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with vaccine-related SAEs from Day 1 of Part B through the duration of participation in Part B

End point title	Percentage of participants with vaccine-related SAEs from Day 1 of Part B through the duration of participation in Part B
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End point description:

A serious adverse event (SAE) is an AE that is life-threatening, requires or prolongs an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or is another important medical event deemed such by medical or scientific judgment. Relatedness of an SAE to the study vaccine was determined by the investigator. Following any vaccination, the percentage of serious adverse events was assessed. Percentage of participants with vaccine-related SAEs from Day 1 of Part B through the duration of participation in Part B. All participants who were randomized and received at least 1 dose of study intervention in part B. Participants were included in the intervention group according to the study intervention actually received.

End point type	Secondary
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End point timeframe:

Up to 44 days after vaccination in Part B

End point values	V116 + Placebo (Part A), PCV15 (Part B)			
Subject group type	Reporting group			
Number of subjects analysed	126			
Units: Percentage of Participants				
number (confidence interval 95%)	0.0 (0.0 to 2.9)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Part A - Non-serious adverse events (NSAEs): Up to 30 days after each vaccination; SAEs and ACM: Up to 194 days after the first vaccination. Part B - NSAEs: Up to 30 days after vaccination; SAEs and ACM: Up to 44 days after vaccination.

Adverse event reporting additional description:

The ACM, SAE and AE population includes all randomized participants. Two participants received incorrect study intervention that resulted in a regimen inconsistent with the 2 planned regimens. Both participants were excluded from the safety analysis population.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.0
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Reporting groups

Reporting group title	V116 + Placebo (Part A)
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Reporting group description:

Participants received a single intramuscular (IM) dose of V116 on Day 1 and a single IM dose of placebo on Week 8 in Part A.

Reporting group title	V116 + Placebo (Part A), PCV15 (Part B)
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Reporting group description:

In Part B, a single IM dose of PCV15 was given approximately between 10 to 18 months after V116 in participant who received V116 in Part A.

Reporting group title	PCV15 + PPSV23 (Part A)
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Reporting group description:

Participants received a single IM dose of PCV15 on Day 1, and a single IM dose of PPSV23 on Week 8 in Part A of the study.

Serious adverse events	V116 + Placebo (Part A)	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 155 (2.58%)	1 / 126 (0.79%)	6 / 155 (3.87%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to meninges			
subjects affected / exposed	0 / 155 (0.00%)	0 / 126 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			

subjects affected / exposed	0 / 155 (0.00%)	0 / 126 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 155 (0.65%)	0 / 126 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	1 / 155 (0.65%)	0 / 126 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 155 (0.65%)	0 / 126 (0.00%)	0 / 155 (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
Seizure			
subjects affected / exposed	0 / 155 (0.00%)	0 / 126 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 155 (0.00%)	1 / 126 (0.79%)	0 / 155 (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
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 155 (0.65%)	0 / 126 (0.00%)	0 / 155 (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
Death			

subjects affected / exposed	1 / 155 (0.65%)	0 / 126 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 155 (0.00%)	0 / 126 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurosyphilis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 126 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 126 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	V116 + Placebo (Part A)	V116 + Placebo (Part A), PCV15 (Part B)	PCV15 + PPSV23 (Part A)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	96 / 155 (61.94%)	82 / 126 (65.08%)	136 / 155 (87.74%)
Nervous system disorders			
Headache			
subjects affected / exposed	38 / 155 (24.52%)	19 / 126 (15.08%)	31 / 155 (20.00%)
occurrences (all)	48	20	35
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	6 / 155 (3.87%)	4 / 126 (3.17%)	17 / 155 (10.97%)
occurrences (all)	8	4	19
Fatigue			
subjects affected / exposed	47 / 155 (30.32%)	28 / 126 (22.22%)	53 / 155 (34.19%)
occurrences (all)	56	28	68
Injection site pain			

subjects affected / exposed occurrences (all)	78 / 155 (50.32%) 93	78 / 126 (61.90%) 78	128 / 155 (82.58%) 199
Injection site swelling subjects affected / exposed occurrences (all)	11 / 155 (7.10%) 13	8 / 126 (6.35%) 8	32 / 155 (20.65%) 36
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	2 / 155 (1.29%) 2	1 / 126 (0.79%) 1	9 / 155 (5.81%) 9
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	20 / 155 (12.90%) 22	14 / 126 (11.11%) 14	24 / 155 (15.48%) 29

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported