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V116: An Investigational Adult Specific Pneumococcal Conjugate Vaccine

Key Results from the Phase 3 Clinical Development Program

ACIP Meeting, 29-Feb-2024

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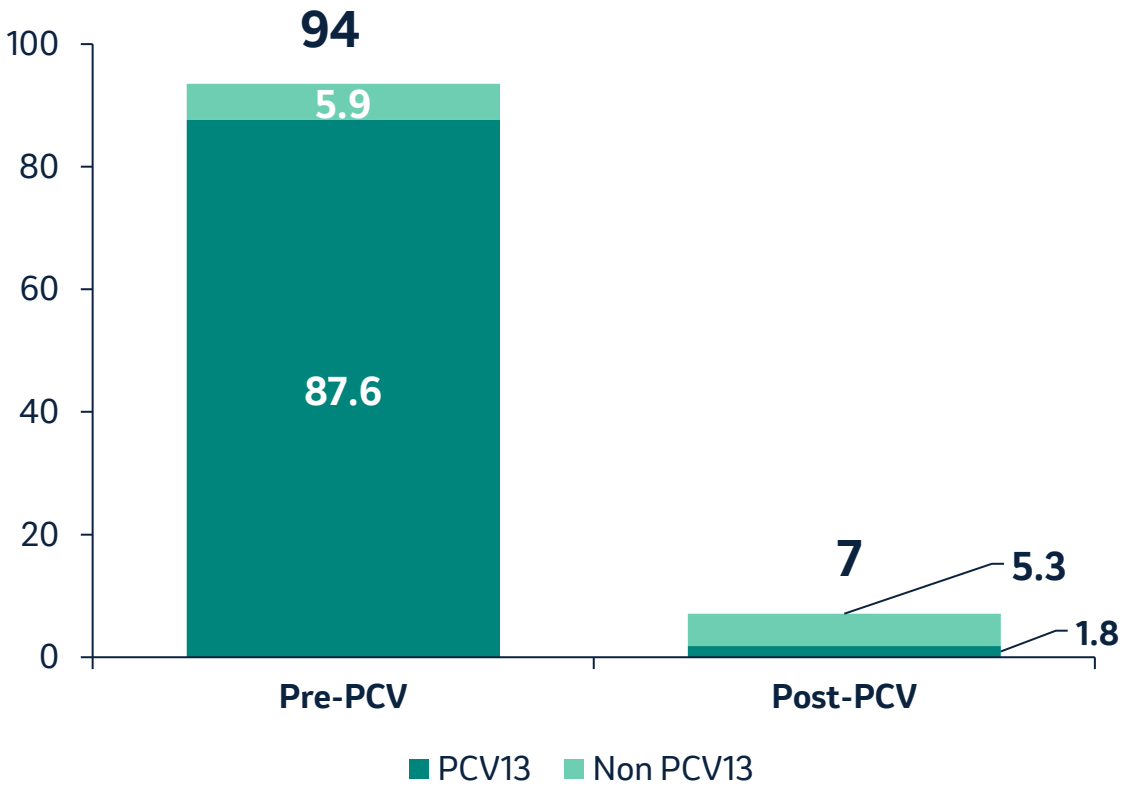
Presentation

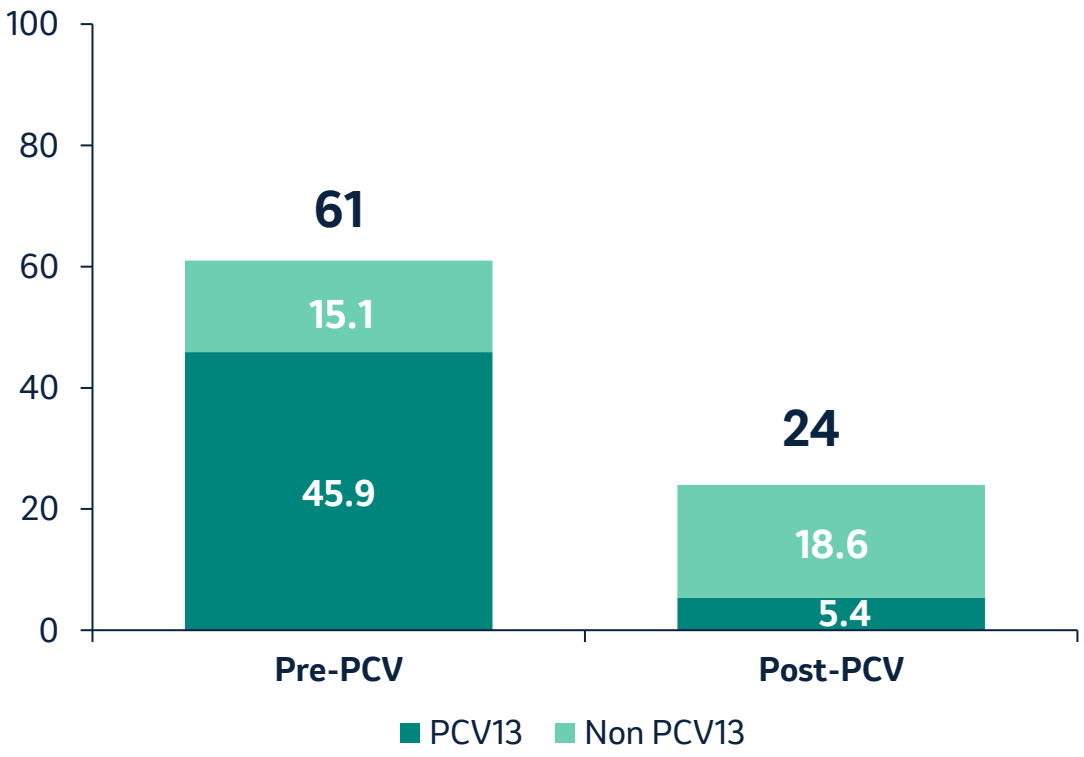
- Rationale for Development of V116
- Overview of V116 Adult Clinical Development Program
- Immunogenicity Results
  - Vaccine naïve adults ≥ 18 years of age
  - Vaccine experienced adults ≥ 50 years of age
- Integrated Summary of Safety
  - Vaccine naïve and vaccine experienced adults ≥ 18 years of age
- Supportive Studies
  - V116 in individuals living with HIV
  - V116 administered with concomitant influenza vaccine
  - V116 lot consistency
- Conclusions
- Questions

The introduction of PCVs has significantly decreased disease incidence in children and changed epidemiology of IPD in adults in the US

IPD cases per 100K in US by serotype, children <5



IPD cases per 100K in US by serotype, adults ≥65

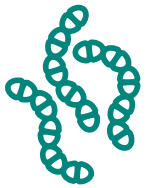


*Centers for Disease Control and Prevention, IPD serotype data 2019, as compiled from data provided through Active Bacterial Core surveillance (ABCs).

Rationale for Development of V116

Indirect protection through pediatric vaccination

PCV use in infants has significantly decreased the burden of disease in adults through **indirect protection**.

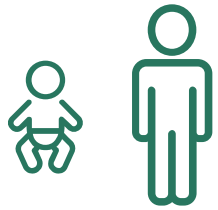


Unmet medical need in adults

The burden of disease in adults remains high; IPD due to **non-vaccine serotypes** has increased in adults.

Population-specific vaccination

V116 being developed as a **population-specific vaccine** to prevent invasive disease and pneumonia in adults.



Complementary to pediatric PCVs

V116 is designed to **complement PCV pediatric immunization** programs.

V116 is an **adult specific** pneumococcal conjugate vaccine (PCV)

- Includes **21 pneumococcal serotypes**, 4µg/PnPs individually conjugated to CRM197 formulated without an adjuvant
- Single dose, 0.5mL **pre-filled syringe**, intramuscular injection for adults 18+
- The serotypes in V116 accounted for **~85% of IPD** and the **8 unique serotypes accounted for ~30%** of IPD in US adults ≥65 years in 2019
- V116 is currently under **Priority Review** by the FDA for the prevention of IPD and pneumonia in adults ≥18 years of age with target action date of June 17, 2024.

	Serotype Composition																													
PCV13	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A																	
PCV15	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A	22F	33F															
PPSV23	4	6B	9V	14	18C	19F	23F	1	3	5		7F	19A	22F	33F	2	8	9N	10A	11A	12F	15B	17F	20						
PCV20	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A	22F	33F		8		10A	11A	12F	15B								
V116									3		6A	7F	19A	22F	33F		8	9N	10A	11A	12F		17F	20A	15A	15C	16F	23A	23B	24F	31	35B

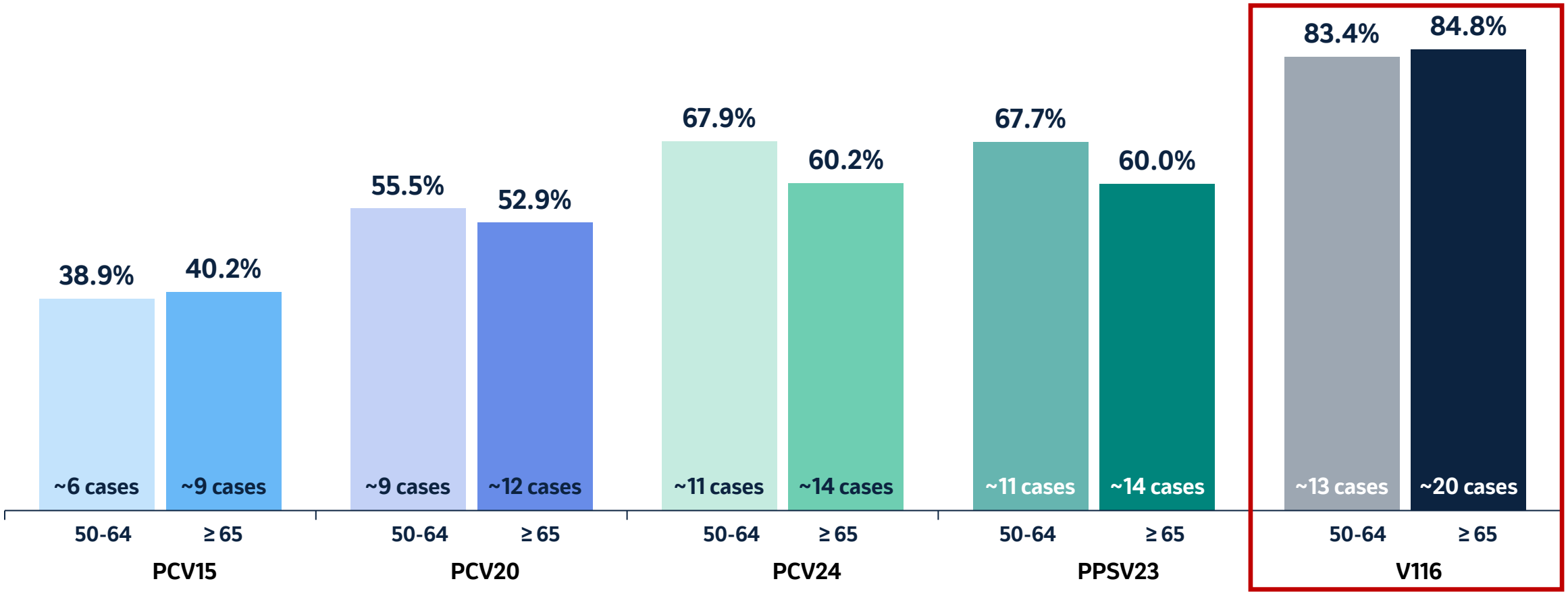
IPD, invasive pneumococcal disease; PCV, pneumococcal conjugate vaccine; PCV13, pneumococcal conjugate vaccine, 13-valent; PCV15 pneumococcal conjugate vaccine, 15-valent, PCV20, pneumococcal conjugate vaccine, 20-valent.

1. **CDC**, IPD Serotype Data 2019, as compiled from data provided through Active Bacterial Core surveillance (ABCs).
2. 2. **Platt H**, Omole T, Cardona J, Fraser NJ, Mularski RA, Andrews C, Daboul N, Gallagher N, Sapre A, Li J, Polis A, Fernsler D, Tamms G, Xu W, Murphy R, Skinner J, Joyce J, Musey L. Safety, tolerability, and immunogenicity of a 21-valent pneumococcal conjugate vaccine, V116, in healthy adults: phase 1/2, randomised, double-blind, active comparator-controlled, multicentre, US-based trial. Lancet Infect Dis. 2023 Feb;23(2):233-246. https://pubmed.ncbi.nlm.nih.gov/36116461/

15C is denoted here to represent the serotype protection proposed with deOAc15B as the molecular structures for deOAc15B and 15C are similar (Jones C, Lemercinier X. 2005. Full NMR assignment and revised structure for the capsular polysaccharide from Streptococcus pneumoniae type 15B. *Carbohydr Res* 340:403-409.)

In adults 50–64 and ≥65 years of age, serotypes in V116 are responsible for the majority of residual IPD in adults

IPD coverage (% of serotypes and cases per 100,000) in US Adults 50–64 and ≥65 years of age, 2019



Source: US Centers for Disease Control and Prevention, IPD serotype data 2019, as compiled from data provided through Active Bacterial Core surveillance (ABC).

V116 Phase 3 Clinical Development Program

V116 Clinical Development Program focused on enrolling participants at risk for pneumococcal disease

V116-P004 **Clinical Lot Consistency** **(n=2040)**	**V116-P003** **Pivotal** **(n=2600)**	**V116-P005** **Concomitant Flu** **(n=1000)**	**V116-P006** **Vaccine Experienced** **(n=700)**
18 – 49 years old	**≥ 18 years old**	**≥ 50 years old**	

V116-007 **High Risk (HIV)** **(n=300)**	**V116-008** **At-Risk Adults** **(n=900)**	**V116-013** **Pediatric with Increased Risk** **(n=820)**
≥ 18 years old	**18 – 64 years old**	**≥ 2 - <18 years old**

4 Studies in the V116 BLA submission represent a broad, diverse patient population

V116-P004 Clinical Lot Consistency (n=2040)	V116-P003 Pivotal (n=2600)	V116-P005 Concomitant Flu (n=1000)	V116-P006 Vaccine Experienced (n=700)
18 – 49 years old	≥ 18 years old	≥ 50 years old	

Immunogenicity & Safety Endpoints in the V116 Program

Immunogenicity Endpoints

OPA responses supported primary objectives:

- Serotype specific OPA Geometric Mean Titers (GMTs)
- Proportion of participants with ≥4-fold rise in OPA responses from baseline to Day 30 postvaccination

OPA and IgG responses supported secondary objectives:

- Serotype specific IgG Geometric Mean Concentrations (GMCs)
- Proportion of participants with ≥4-fold rise in IgG responses from baseline to Day 30 postvaccination
- Geometric Mean Fold Rise (GMFR) of OPA and IgG responses
- Reverse Cumulative Distribution Curves (RCDCs) for OPA and IgG responses

Immune responses were assessed in validated multiplex opsonophagocytic (OPA) and electrochemiluminescence (ECL IgG) assays

Safety Endpoints

Primary Safety Endpoints:

- Solicited injection site events Day 1-5 postvaccination: erythema, swelling, injection-site pain
- Solicited systemic events Days 1-5 postvaccination: headache, myalgia, fatigue
- Serious vaccine-related events Day 1 through the duration of participation in the study

Additional Safety Endpoints:

- Unsolicited AEs, Vaccine related AEs, Any SAE
- Maximum temperature Day 1-5 postvaccination

Participants reported adverse events on an electronic vaccine report card.

V116-003

A Phase 3, Randomized, Double-blind, Active Comparator-controlled Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in Pneumococcal Vaccine-naïve Adults

V116-003 Study Design

Cohort 1 (≥50 years of age)
N=2362 Participants
randomized 1:1,V116 to PCV20
(Stratified by age: 50-64, 65-74, 75-84, ≥85)

Cohort 2 (18-49 years of age)
N=301 Participants
randomized 2:1,V116 to PCV20

1	2	3	4	5
Day 1	Day 5 Day 7	Day 30	Day 90	Month 6

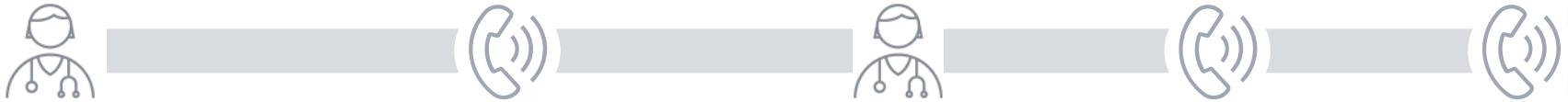
V116 or **PCV20**

Immunogenicity assessment

- **Prevaccination Immunogenicity (Day 1)**
- **Postvaccination Immunogenicity (Day 30)**

Safety assessment

- **eVRC, solicited AEs**
- **Serious and nonserious AEs** → **Serious AEs**



V116-003: Primary study objectives

Primary immunogenicity

In adults ≥50 years:

- Demonstrate that V116 is **noninferior** to PCV20 for 10 common serotypes
  - Lower bound of the 2-sided 95% CI of the OPA GMT ratio (V116/PCV20) to be **>0.5**
- Demonstrate that V116 is **superior** to PCV20 for 11 unique serotypes
  - Lower bound of the 2-sided 95% CI of the OPA GMT ratio (V116/PCV20) to be **>2.0**
  - 2-sided 95% CI of the differences (V116 – PCV20) between the proportions of participants with a ≥4-fold rise to be **>10%**

In adults 18–49 years:

- Demonstrate V116 **immunobridges** to adults 50-64 years of age for 21 serotypes in V116
  - Lower bound of the 2-sided 95% CI of the OPA GMT ratio (V116 18-49/V116 50–64 years) to be **>0.5**

Primary safety

- To evaluate the safety and tolerability of V116 as assessed by the proportion of participants with adverse events (AEs)
  - **Solicited injection site** events Day 1–5 postvaccination: erythema, swelling, injection-site pain
  - **Solicited systemic events** Days 1–5 postvaccination: headache, myalgia, fatigue
  - **Serious vaccine-related events** Day 1 through the duration of participation in the study

V116-003 Baseline Characteristics

In each cohort, baseline characteristics were balanced between the treatment groups

	Cohort 1 (Age ≥50 years)		Cohort 2 (Ages 18-49 years)	
	V116, N=1179	PCV20, N=1177	V116, N=200	PCV20, N=100
Sex				
Female	687 (58.3)	670 (56.9)	137 (68.5)	64 (64.0)
Age (yr)				
Median (min to max)	65 (50-91)	65 (50-97)	36 (18-49)	34 (18-49)
18-49, n (%)	0 (0)	0 (0)	200 (100)	100 (100)
50 to 64, n (%)	589 (50.0)	587 (49.9)	0 (0)	0 (0)
65 to 74, n (%)	464 (39.4)	464 (39.4)	0 (0)	0 (0)
75-84, n (%)	112 (9.5)	113 (9.6)	0 (0)	0 (0)
≥ 85, n (%)	14 (1.2)	13 (1.1)	0 (0)	0 (0)
Race				
Asian	148 (12.6)	168 (14.3)	38 (19.0)	15 (15.0)
Black or African American	116 (9.8)	115 (9.8)	13 (6.5)	14 (14.0)
Multiple	26 (2.2)	30 (2.5)	9 (4.5)	6 (6.0)
White	867 (73.5)	844 (71.7)	139 (69.5)	62 (62.0)
Other	21 (1.8)	19 (1.6)	1 (0.5)	3 (3.0)
Ethnicity				
Hispanic or Latino	259 (22.0)	242 (20.6)	58 (29.0)	24 (24.0)
Pneumococcal Risk Factors				
1 Risk Factor	347 (29.4)	328 (27.9)	45 (22.5)	18 (18.0)
2 or More Risk Factors	100 (8.5)	81 (6.9)	3 (1.5)	1 (1.0)

Risk Factors includes prespecified medical history conditions: Alcoholism, Chronic Heart Disease, Chronic Kidney Disease, Chronic Liver Disease, Chronic Lung Disease, Diabetes, Smoking.

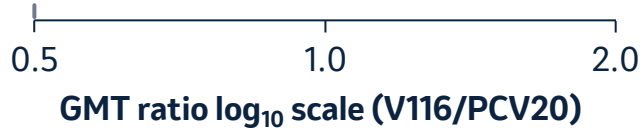
V116-003 Cohort 1: ≥50 years of age
V116 is noninferior to PCV20 for the 10 common serotypes

Primary immunogenicity objective

- V116 is noninferior to PCV20 for the 10 common serotypes.
- The lower bounds of the two-sided 95% confidence intervals (CIs) are greater than 0.5 for all 10 common serotypes.

Postvaccination OPA GMT Ratios for **Common Serotypes**

Pneumococcal serotype	V116 n	V116 GMT	PCV20 n	PCV20 GMT	GMT ratio (95% CI)
3	1154	274.0	1161	176.7	1.55 (1.40, 1.72)
6A	1148	2,302.0	1153	2,972.5	0.77 (0.68, 0.88)
7F	1152	3,637.4	1158	3,429.9	1.06 (0.95, 1.18)
8	1155	2,501.3	1158	1,811.1	1.38 (1.25, 1.53)
10A	1161	3,893.4	1159	4,678.0	0.83 (0.75, 0.93)
11A	1145	3,232.6	1150	2,092.8	1.54 (1.39, 1.72)
12F	1160	2,641.2	1161	2,499.6	1.06 (0.92, 1.21)
19A	1159	2,136.1	1162	2,817.8	0.76 (0.69, 0.84)
22F	1147	3,874.5	1154	4,770.1	0.81 (0.72, 0.92)
33F	1154	13,558.9	1157	11,742.1	1.15 (1.01, 1.32)



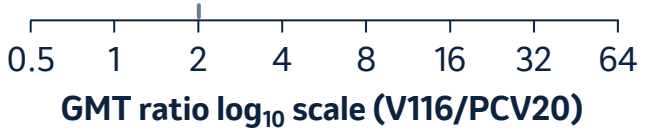
V116-003 Cohort 1: ≥50 years of age
V116 is superior to PCV20 for 10 of 11 unique serotypes

Primary immunogenicity objective

- V116 is superior to PCV20 for 10 of 11 unique serotypes in V116.
- The lower bounds of the two-sided 95% CIs are >2.0 for 10 of 11 unique serotypes in V116.
- For serotype 15C, the lower bound of the 95% CI is 1.77.

Postvaccination OPA GMT Ratios for **Unique Serotypes**

Pneumococcal serotype	V116 n	V116 GMT	PCV20 n	PCV20 GMT	GMT ratio (95% CI)
9N	1147	7,470.7	1150	1,640.4	4.55 (4.12, 5.04)
15A	1107	5,237.2	1102	1,589.0	3.30 (2.91, 3.74)
15C	1153	4,216.2	1158	2,072.3	2.03 (1.77, 2.34)
16F	1151	4,868.2	1153	846.3	5.75 (5.16, 6.41)
17F	1148	7,764.9	1156	460.4	16.86 (14.90, 19.09)
20A	1161	6,099.2	1155	631.1	9.66 (8.66, 10.79)
23A	1132	3,737.2	1104	461.5	8.10 (6.86, 9.55)
23B	1160	1,082.5	1160	107.3	10.09 (8.48, 12.00)
24F	1153	2,728.6	1130	70.5	38.71 (33.87, 44.25)
31	1153	3,132.5	1154	144.4	21.69 (18.68, 25.18)
35B	1153	8,527.8	1159	1,383.0	6.17 (5.59, 6.80)

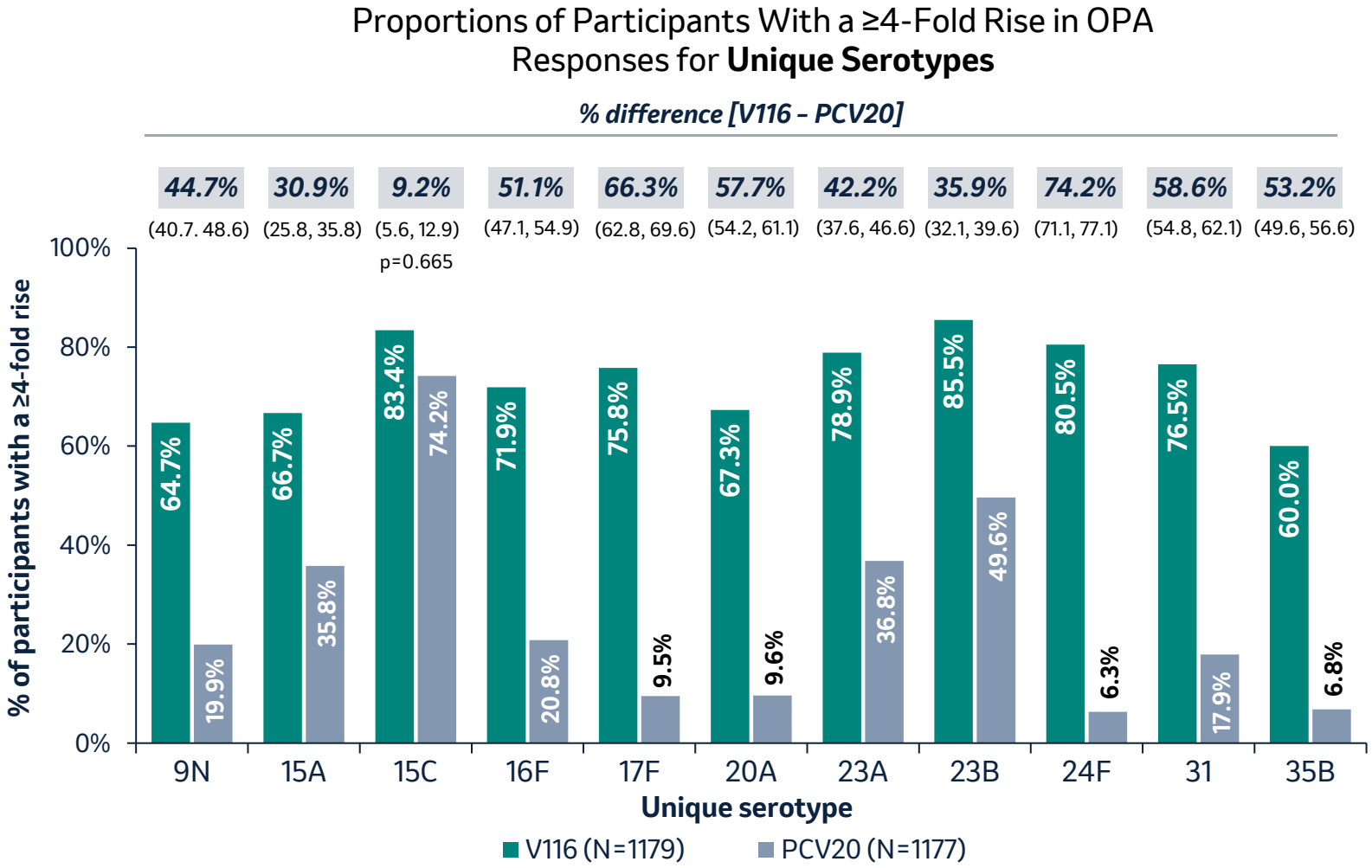


Superiority criteria met if the lower bound of the 95% CI is >2.0

V116-003 Cohort 1: ≥50 years of age
V116 is superior to PCV20 for 10 of 11 unique serotypes

Primary immunogenicity objective

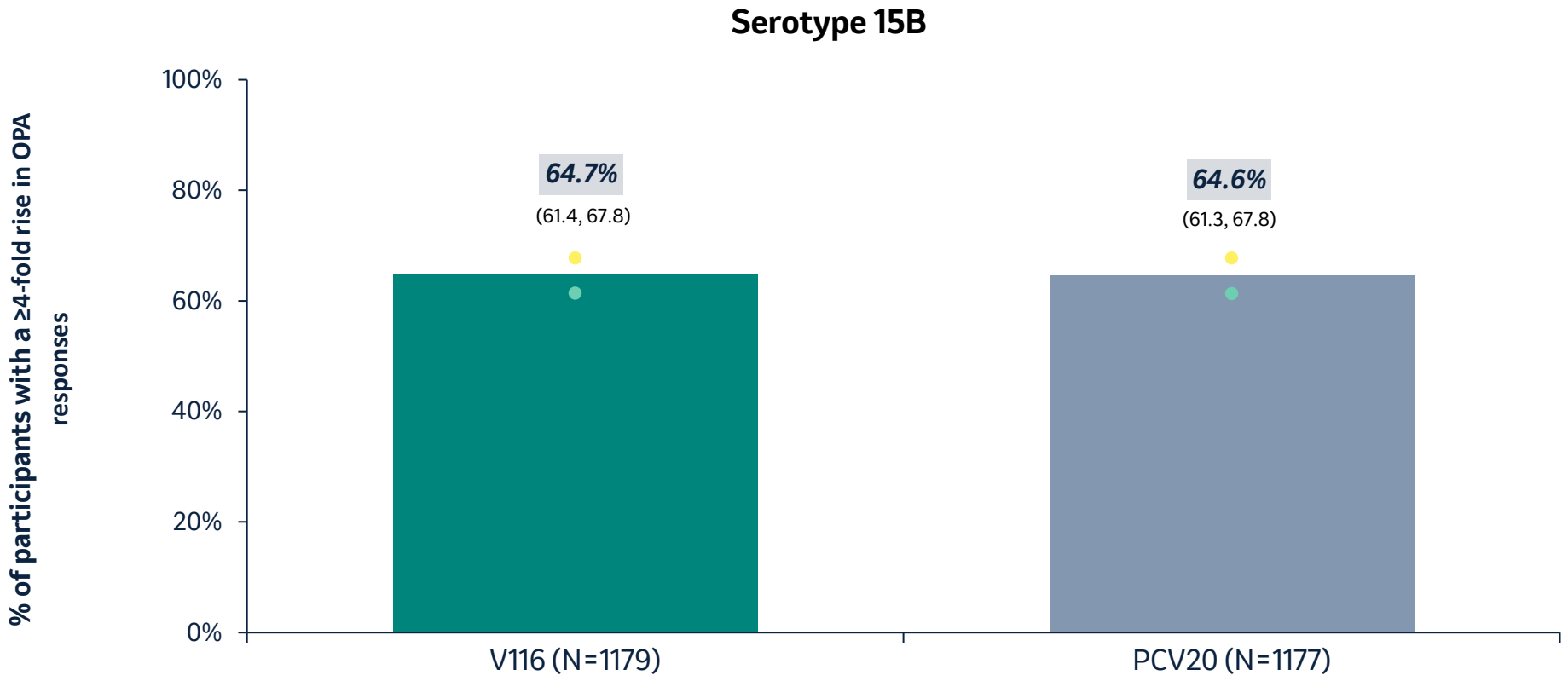
- V116 is superior to PCV20 for 10 of 11 unique serotypes in V116.
- The lower bounds of the 2-sided 95% CIs are > 10 percentage points for 10 of 11 serotypes.



Pivotal Study

V116-003 Cohort 1: ≥50 years of age

V116 elicits robust cross reactive antibody responses to serotype 15B



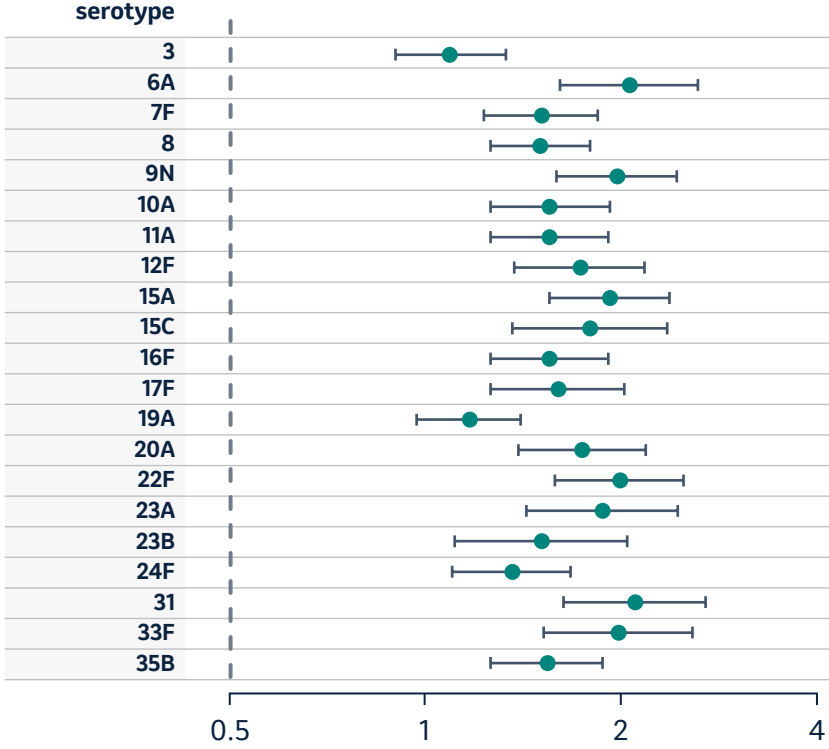
V116 includes serotype 15C and elicited cross-reactive immune responses to 15B

PCV20 includes serotype 15B

V116-003: Cohort 2: 18-49 years of age
V116 immunobridges to participants 50-64 years of age for all 21 serotypes

Primary immunogenicity objective

- V116 in participants 18 to 49 years of age immunobridges to V116 in participants 50 to 64 years of age for the 21 serotypes in V116.
- The lower bound of the two-sided 95% CIs is >0.5 for all 21 serotypes in V116.



Pneumococcal serotype	V116 18–49 years (N = 200) n	V116 18–49 years (N = 200) GMT	V116 50–64 years (N = 589) n	V116 50–64 years (N = 589) GMT	GMT ratio[a] (V116 18–49 years/ V116 50–64 years) (95% CI)
3	194	308.6	572	282.7	1.09 (0.90, 1.33)
6A	196	5,289.6	569	2,572.9	2.06 (1.61, 2.62)
7F	198	6,447.2	571	4,278.8	1.51 (1.23, 1.84)
8	197	4,516.0	571	3,004.7	1.50 (1.26, 1.79)
9N	197	17,283.2	570	8,791.4	1.97 (1.59, 2.43)
10A	197	6,808.1	575	4,382.6	1.55 (1.26, 1.92)
11A	196	5,871.6	564	3,785.8	1.55 (1.26, 1.91)
12F	196	6,150.4	574	3,561.2	1.73 (1.37, 2.17)
15A	184	11,319.2	550	5,901.2	1.92 (1.55, 2.37)
15C	195	10,194.0	570	5,708.0	1.79 (1.36, 2.35)
16F	193	8,877.0	571	5,720.0	1.55 (1.26, 1.91)
17F	194	16,070.6	568	10,068.0	1.60 (1.26, 2.02)
19A	198	2,773.2	574	2,374.6	1.17 (0.97, 1.40)
20A	197	13,150.0	575	7,562.7	1.74 (1.39, 2.18)
22F	198	9,299.6	568	4,683.6	1.99 (1.58, 2.49)
23A	192	8,848.7	561	4,739.5	1.87 (1.43, 2.44)
23B	198	2,140.1	575	1,420.9	1.51 (1.11, 2.04)
24F	197	4,137.6	570	3,047.2	1.36 (1.10, 1.67)
31	195	8,005.6	570	3,820.7	2.10 (1.63, 2.69)
33F	197	34,805.5	570	17,607.4	1.98 (1.52, 2.57)
35B	198	13,933.4	573	9,053.9	1.54 (1.26, 1.87)

V116-006

V116-006: A Phase 3 Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in Pneumococcal Vaccine-Experienced Adults 50 Years of Age or Older

Vaccine-experienced

V116-006 Study Design

	Visit	1	2	3	4	5
	Time	Day 1 Screening/vaccination	Day 7	Day 30	Day 90	Day 180
Cohort 1 : Prior PPSV23 only N=300; Randomized 2:1 (V116:PCV15)		V116 or PCV15				
Cohort 2 : Prior PCV13 only N=300; Randomized 2:1 (V116:PPSV23)		V116 or PPSV23				
Cohort 3 : Prior PCV15, PCV20, PCV13+PPSV23, PCV15+PPSV23 or PPSV23+PCV13 N=100; Open-label V116		V116				
Immunogenicity assessment		Prevaccination Immunogenicity (Day 1)		Postvaccination Immunogenicity (Day 30)		
Safety assessment		eVRC, solicited AEs				
		Serious and nonserious AEs		Serious AEs		

Participants used an electronic Vaccine Report Card (eVRC) to report solicited AEs Days 1-5 postvaccination and other AEs through Day 30 postvaccination

V116-006 Primary study objectives

Primary immunogenicity

In adults ≥50 years:

To evaluate the serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMTs) at 30 days postvaccination for all serotypes included in V116

Primary safety

- To evaluate the safety and tolerability of V116 as assessed by the proportion of participants with adverse events (AEs)
  - **Solicited injection site** events Day 1–5 postvaccination: erythema, swelling, injection-site pain
  - **Solicited systemic events** Days 1–5 postvaccination: headache, myalgia, fatigue
  - **Serious vaccine-related events** Day 1 through the duration of participation in the study

Vaccine-experienced

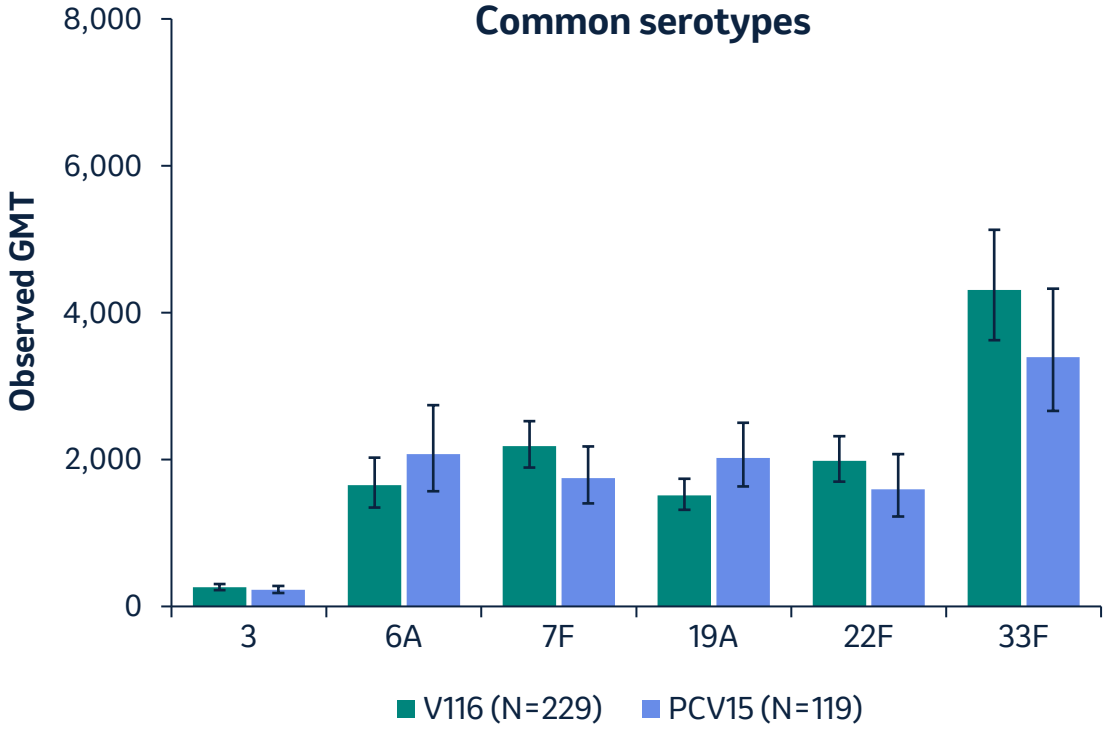
V116-006 Participant Characteristics

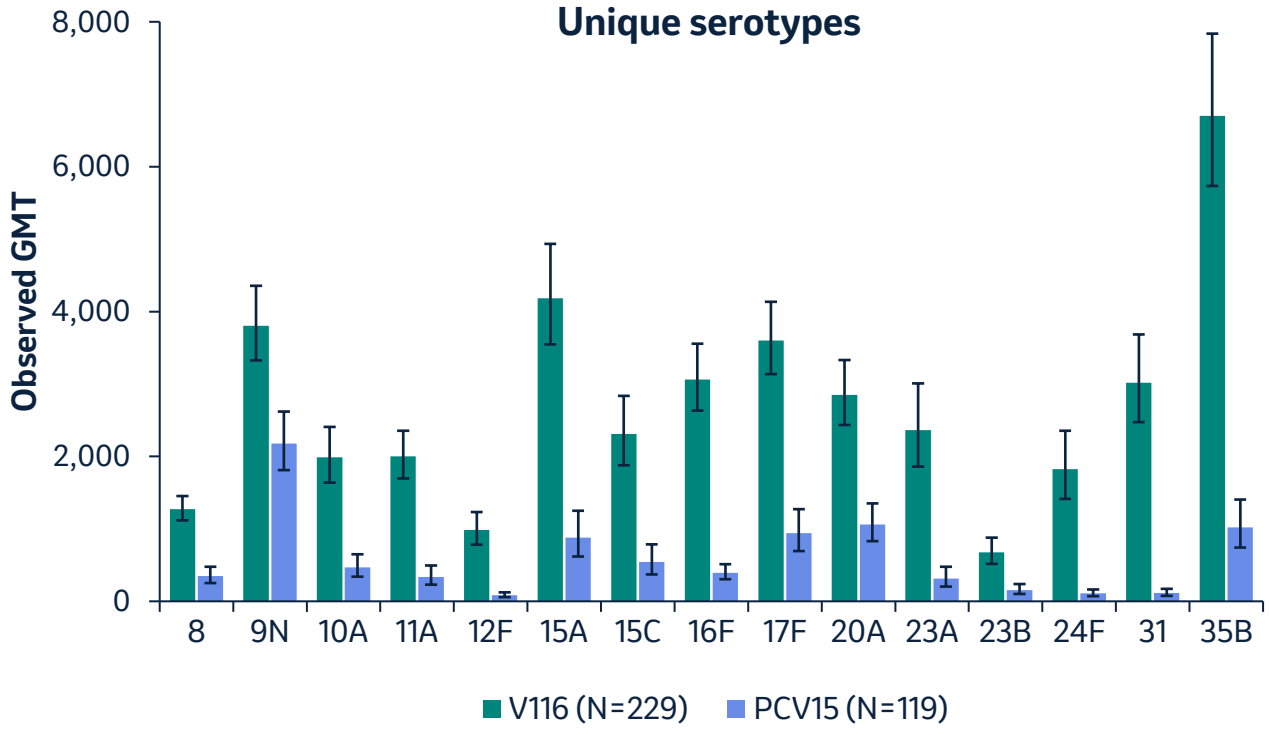
Enrollment is balanced in each cohort and reflects the pneumococcal vaccination history

	Cohort 1 (prior PPSV23)		Cohort 2 (prior PCV13)		Cohort 3
	V116 N=229	PCV15 N=119	V116 N=174	PPSV23 N=85	V116 N=105
Sex					
Male	112 (48.9)	59 (49.6)	74 (42.5)	36 (42.4)	50 (47.6)
Female	117 (51.1)	60 (50.4)	100 (57.5)	49 (57.6)	55 (52.4)
Age (yr)					
50 to 64	48 (21.0)	25 (21.0)	80 (46.0)	39 (45.9)	17 (16.2)
≥65	181 (79.0)	94 (79.0)	94 (54.0)	46 (54.1)	88 (83.8)
Mean ± SD	68.7 ± 7.5	69.0 ± 7.1	65.5 ± 7.8	65.4 ± 6.6	71.0 ± 7.6
Median (range)	69.0 (50 to 86)	69.0 (51 to 88)	66.0 (50 to 83)	65.0 (51 to 81)	71.0 (53 to 91)
Race					
Asian	96 (41.9)	47 (39.5)	55 (31.6)	25 (29.4)	13 (12.4)
Black or African American	6 (2.6)	3 (2.5)	3 (1.7)	1 (1.2)	6 (5.7)
Multiple	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
White	125 (54.6)	69 (58.0)	116 (66.7)	59 (69.4)	85 (81.0)
Ethnicity					
Hispanic or Latino	21 (9.2)	17 (14.3)	34 (19.5)	16 (18.8)	14 (13.3)
Time since last pneumococcal vaccination					
1 to 4 years	108 (47.2)	54 (45.4)	135 (77.6)	66 (77.6)	78 (74.3)
5 to 9 years	85 (37.1)	45 (37.8)	33 (19.0)	18 (21.2)	27 (25.7)
≥10 years	36 (15.7)	20 (16.8)	6 (3.4)	1 (1.2)	0 (0.0)

V116-006 Cohort 1: ≥50 years of age who previously received PPSV23

V116 elicits comparable immune responses to PCV15; higher immune responses for serotypes unique to V116

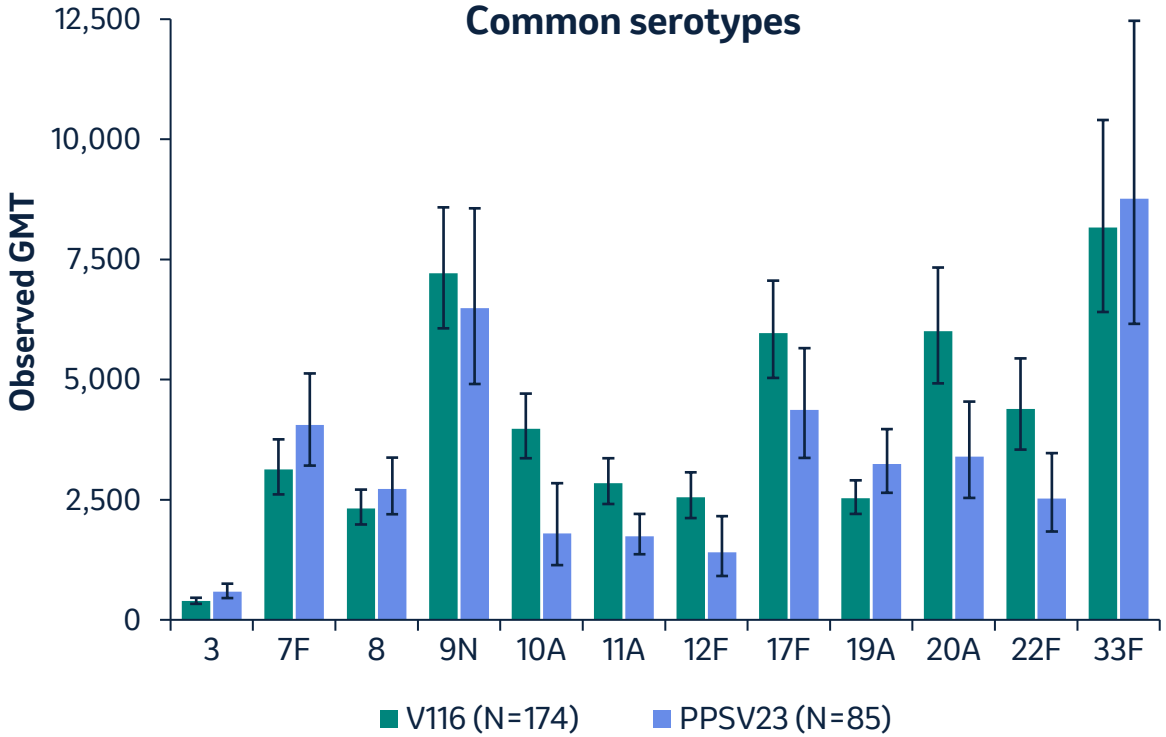


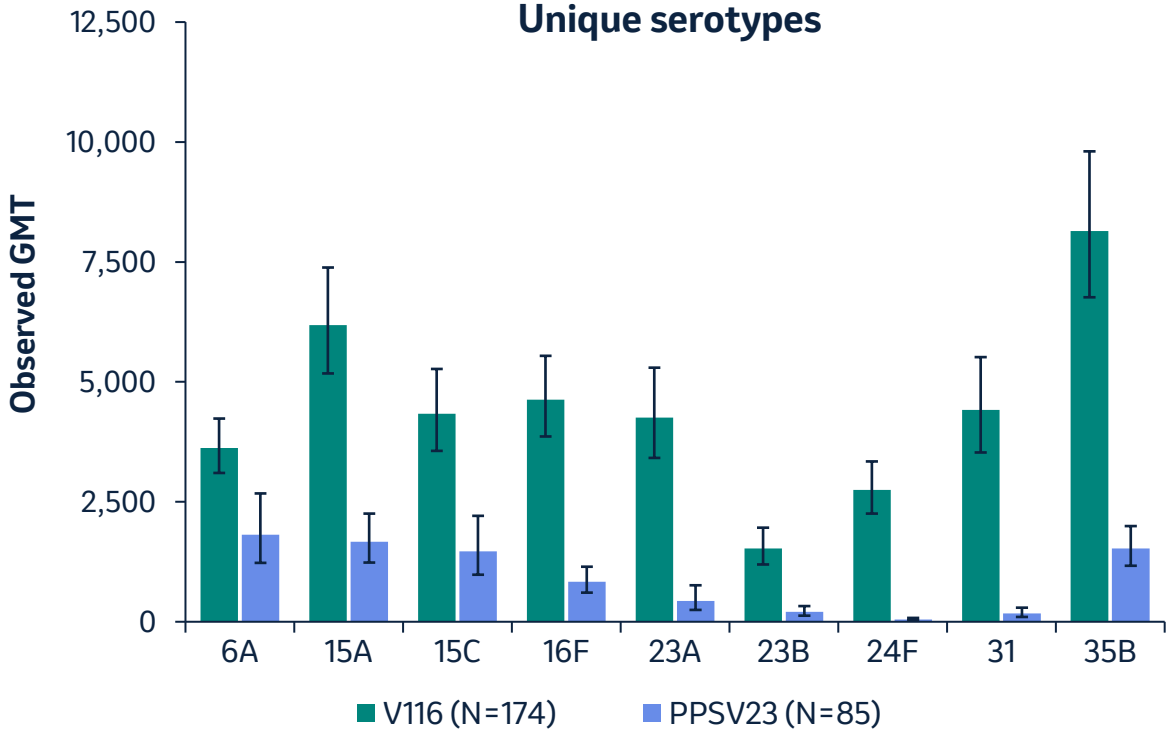


Vaccine-experienced

V116-006 Cohort 2: ≥50 years of age who previously received PCV13

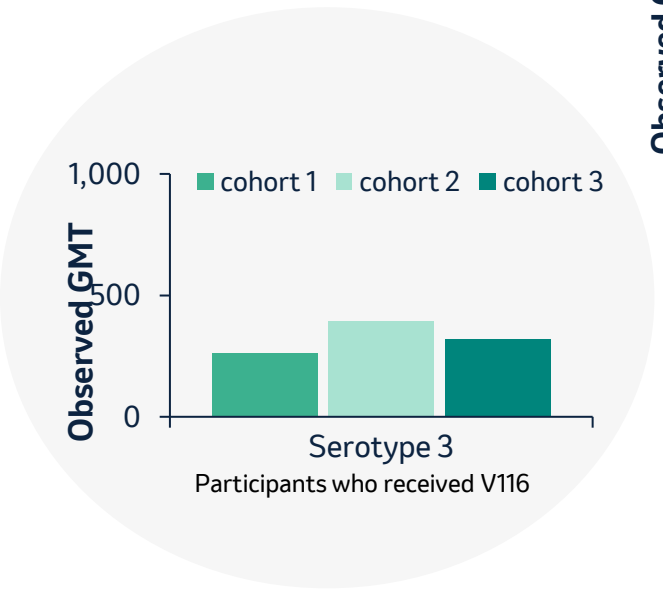
V116 elicits comparable immune responses to PPSV23; higher immune responses for serotypes unique to V116

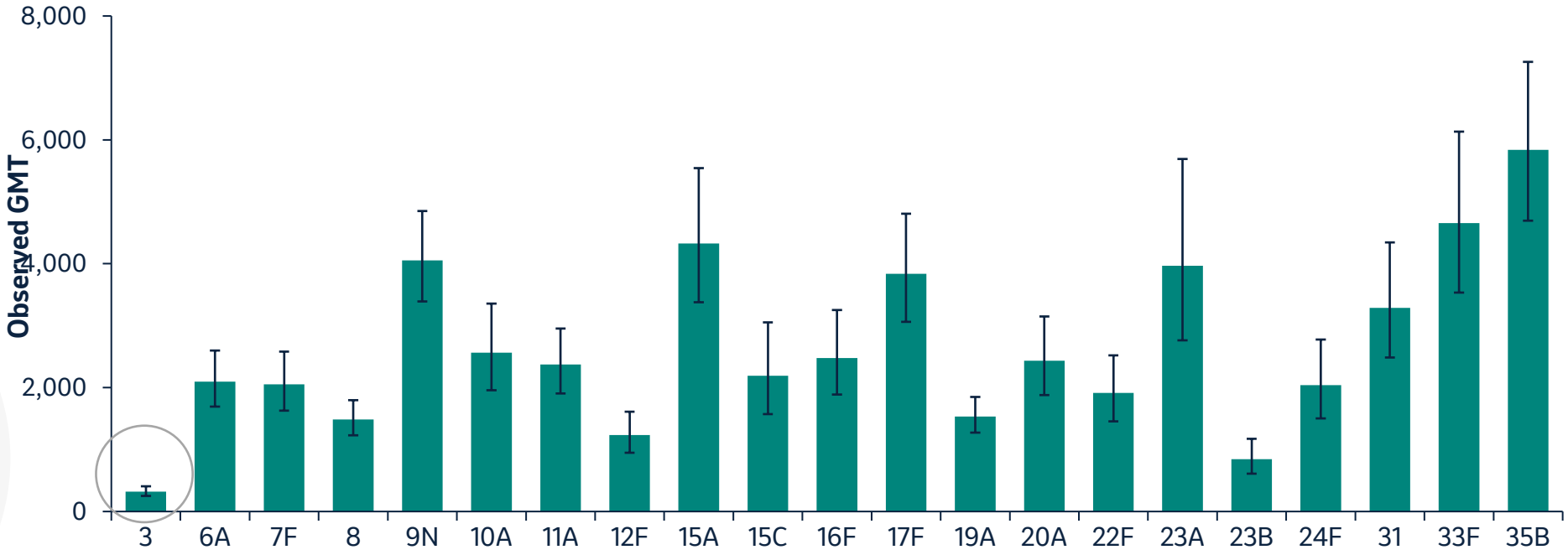




V116-006 Cohort 3: ≥50 years of age who previously received other pneumococcal vaccine(s)*

V116 is immunogenic in individuals who previously received a pneumococcal vaccine





*Prior PCV13+PPSV23 [n=45], PCV15+PPSV23 [n=5], PPSV23+PCV13 [n=54], PCV15 [n=1], or PCV20 [n=0]

Integrated Summary of Safety

Integrated Analysis of Safety in the
Phase 3 Clinical Development Program

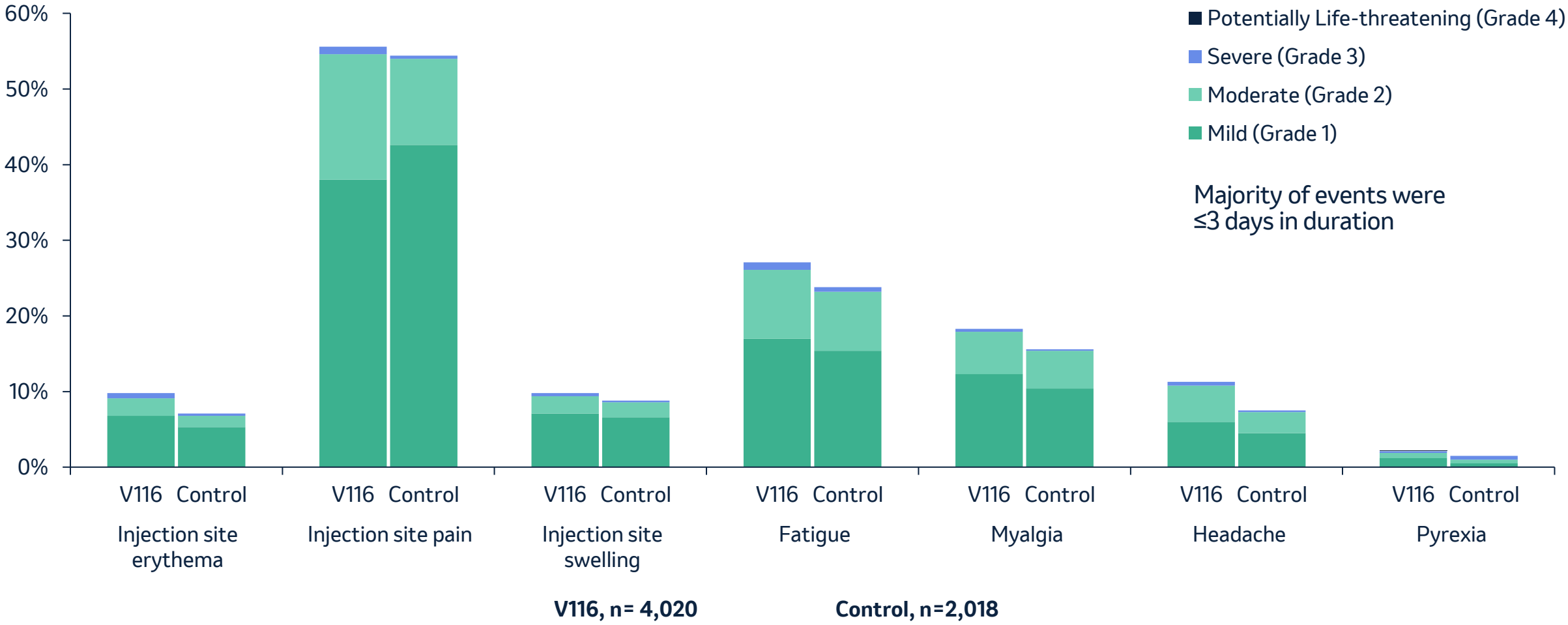
V116 is well tolerated in adults ≥ 18 years of age with a safety profile comparable to currently licensed pneumococcal vaccines

Adverse Event Summary (V116-003, V116-004, V116-005[a], V116-006)	V116 (N=4,020)		Control [b] (N=2,018)	
	n	(%)	n	(%)
With adverse events (Day 1 – 30)	2695	(67.0)	1386	(68.7)
With vaccine-related adverse events (Day 1-30)[c]	2555	(63.3)	1297	(64.3)
Solicited	2516	(62.6)	1279	(63.4)
Unsolicited	313	(7.8)	123	(6.1)
with SAEs (Day 1 - Day 30)	14	(0.3)	7	(0.3)
with vaccine-related SAEs (Day 1 - Day 30)	2	(0.0)	0	(0.0)
with SAEs within 30 minutes postvaccination	1	(0.0)	0	(0.0)
Who died[d]	6	(0.1)	3	(0.1)
with vaccine-related deaths[c]	0	(0.0)	0	(0.0)

[a] Only participants from V116-005 vaccinated with V116 in the sequential group are included in the V116 group.
[b] Control group includes participants vaccinated with PCV15, PCV20, or PPSV23
[c] As determined by the investigator; all injection site adverse events are assessed as vaccine-related
[d] 6 deaths in the V116 group in the Integrated Safety Summary; 7 deaths in the V116 group across the Phase 3 studies when the concomitant group from P005 is included.

Frequency and intensity of solicited adverse events were comparable in V116 and control groups

Solicited adverse events by intensity (%)



Solicited events include erythema, injection site pain, injection site swelling, fatigue, headache, and myalgia were solicited from Day 1 through Day 5 postvaccination. Pyrexia was defined as temperature ≥ 100.4 °F (38.0 C) solicited from Day 1 through Day 5 postvaccination.

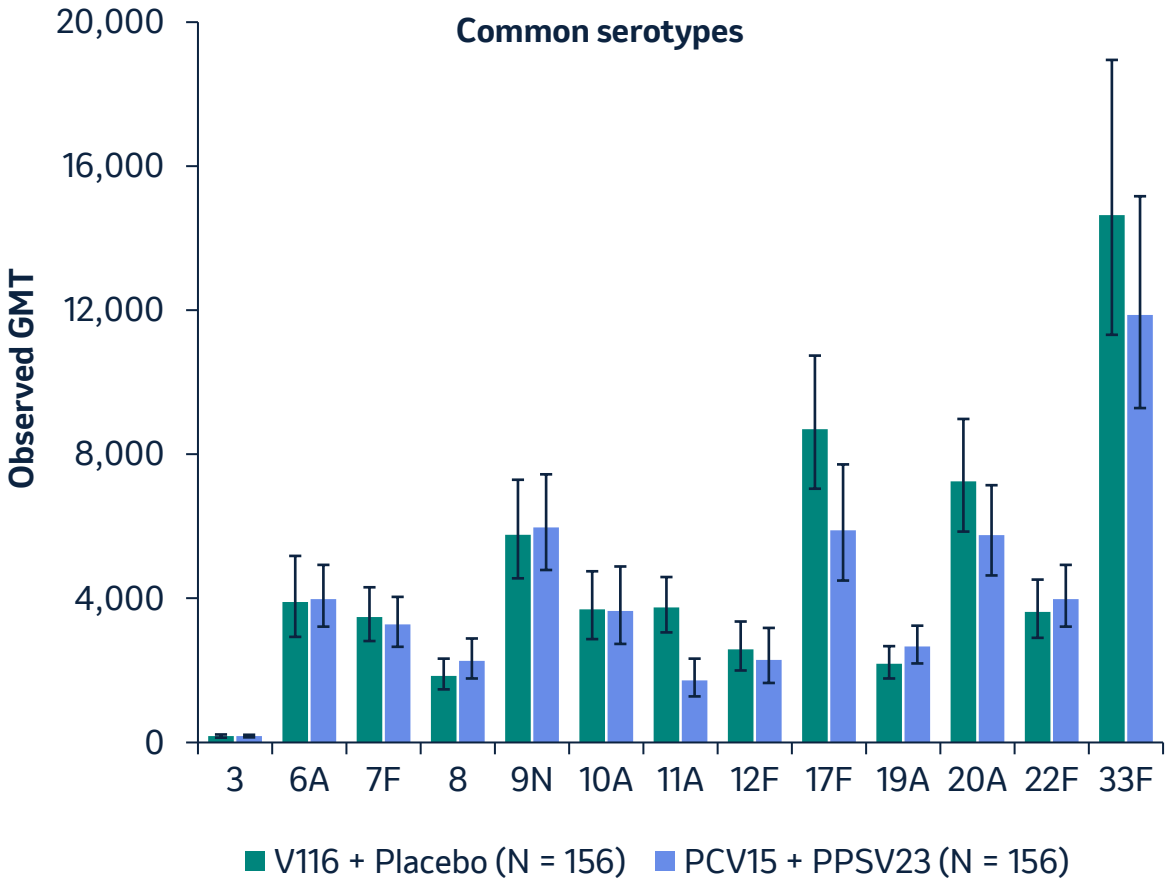
Phase 3 Supportive Studies

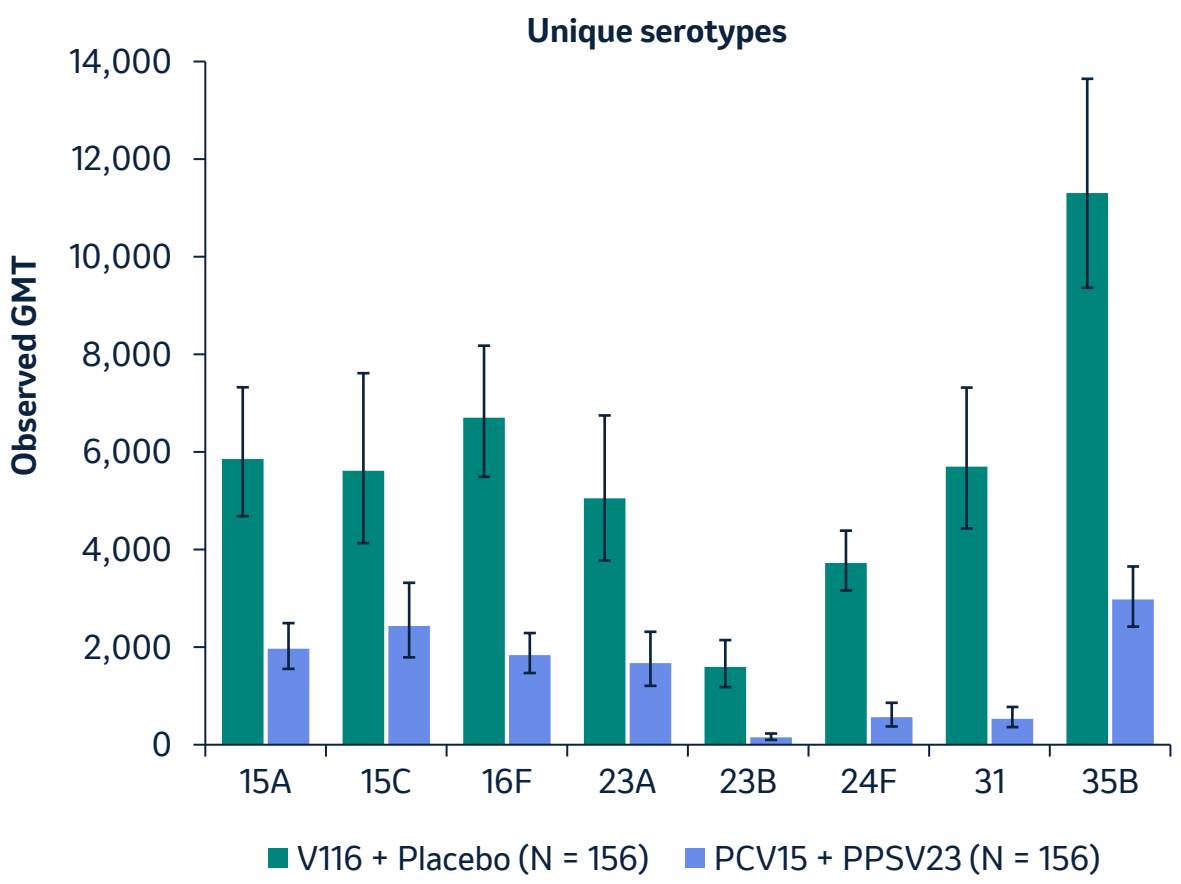
V116-007: V116 in Adults Living with HIV

V116-005: V116 with Concomitant Quadrivalent Influenza Vaccine (QIV)

V116-004: V116 Lot Consistency

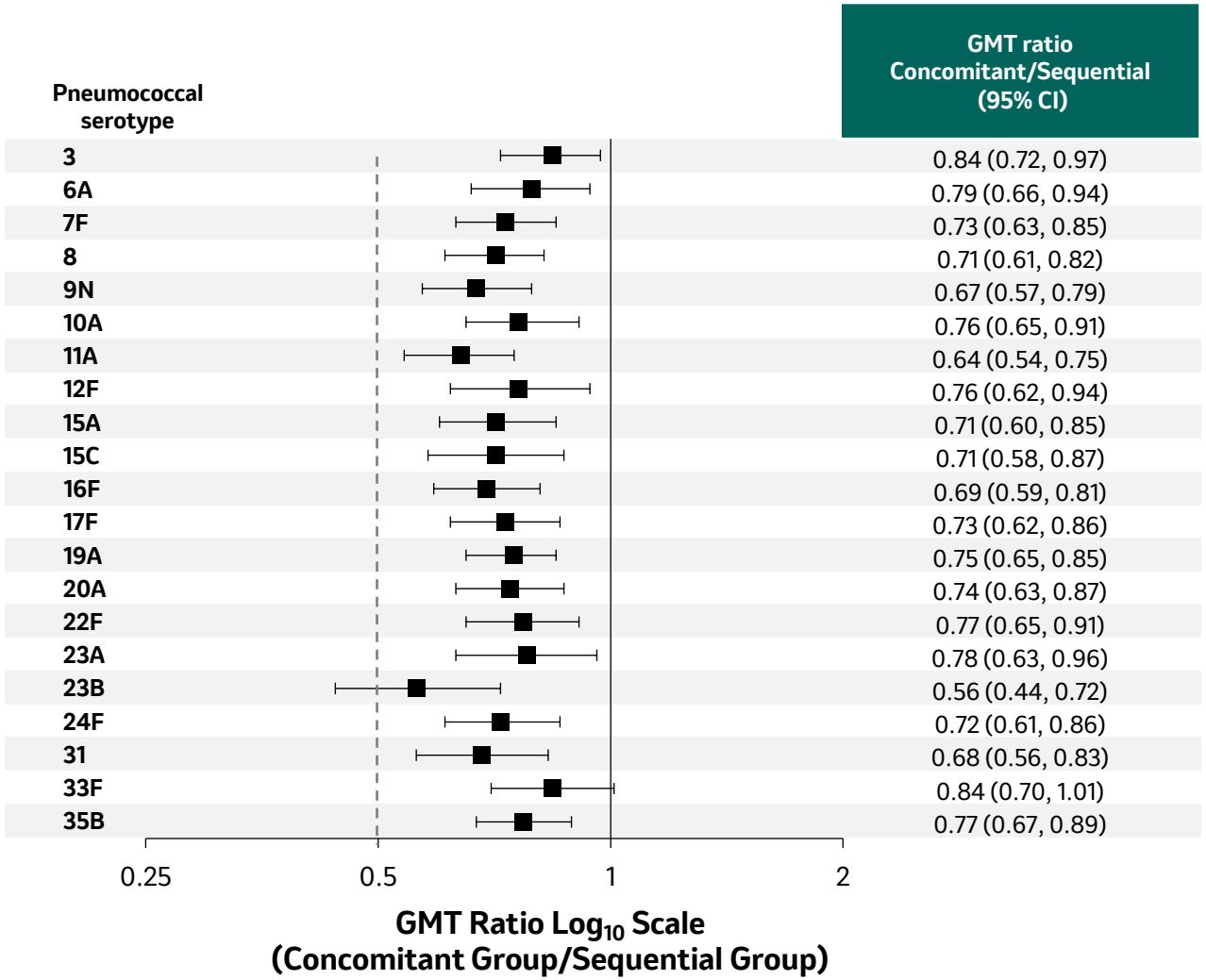
V116-007: In adults living with HIV, V116 elicits comparable immune responses to PCV15+PPSV23, & higher immune responses for unique serotypes



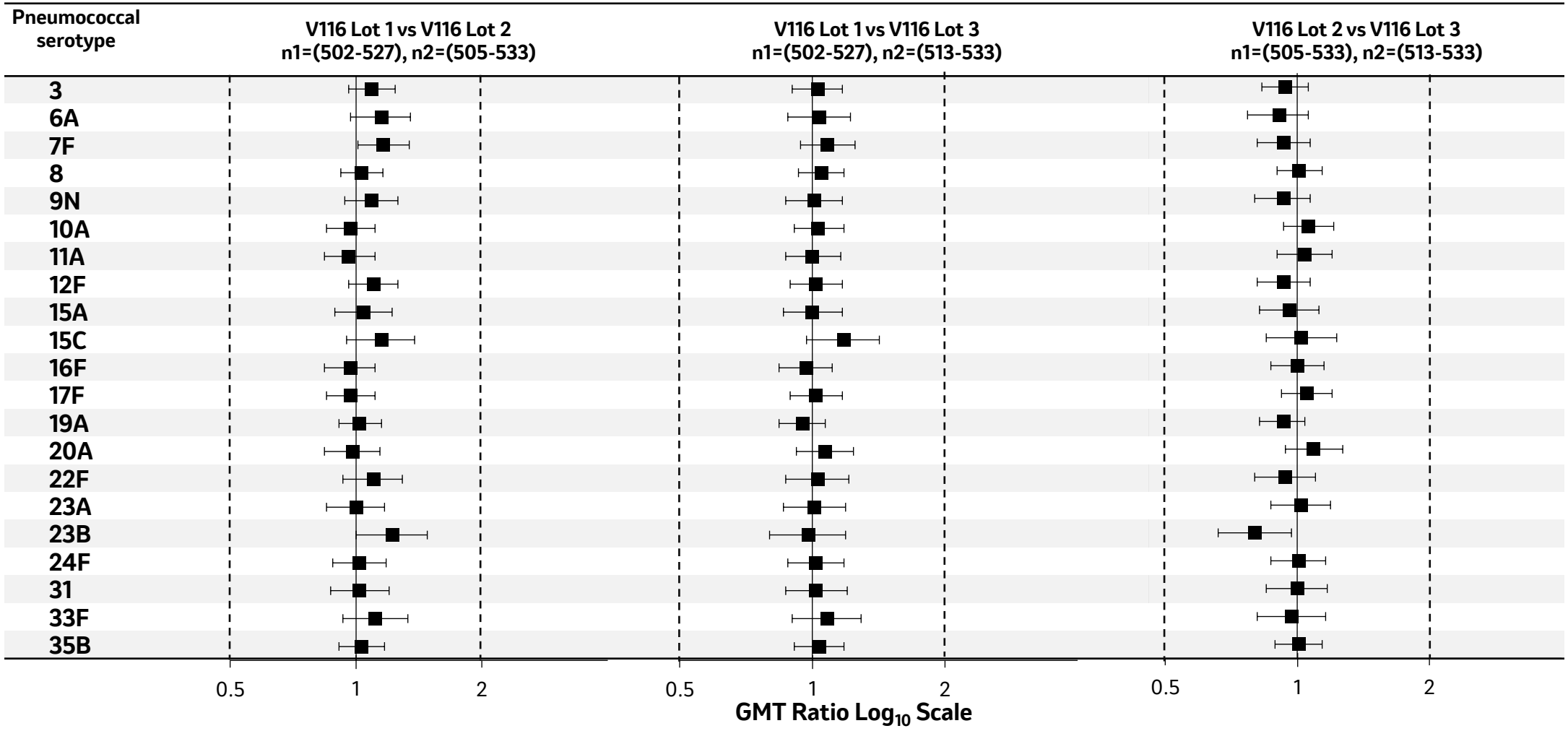


V116-005: V116 elicits robust immune responses when administered concomitantly with influenza vaccine

- V116 administered concomitantly with influenza vaccine is noninferior to V116 administered sequentially with influenza vaccine for 20 of 21 serotypes
- QIV administered concomitantly is noninferior to QIV administered sequentially for 3 of 4 strains



V116-004: V116 Immune responses were equivalent across 3 manufacturing lots



Note: dashed lines indicate the margins for the equivalence test

Phase 3 Summary & Conclusions

V116 Phase 3 Clinical Development Summary

In adults ≥18 years of age, who are pneumococcal vaccine-naïve and vaccine experienced, with and without risk conditions:

- V116 elicits **robust immune responses** to all 21 serotypes contained in the vaccine
- V116 is **noninferior to PCV20** for all common serotypes and **superior to PCV20** for 10 of 11 serotypes unique to V116 in pneumococcal vaccine-naïve adults ≥50 years of age.
- V116 is immunogenic in pneumococcal **vaccine experienced adults**, regardless of the prior vaccine received
- V116 is immunogenic when administered concomitantly with inactivated **influenza vaccine**.
- V116 is **well-tolerated** with a safety profile generally comparable to currently licensed pneumococcal vaccines.

V116 is the first adult specific PCV with the potential for broad public health impact through the prevention of invasive disease and pneumonia due to *S. pneumoniae*.

Thank you

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