2 SYNOPSIS

SPONSOR: Merck Sharp & Dohme Corp, a Subsidiary of Merck & Co, Inc, NJ, USA (MSD)

COMPOUND NAME: V110/PNEUMOVAX™ 23 (pneumococcal vaccine polyvalent)

PROTOCOL TITLE: Sequential Administration of Prevnar 13™ and PNEUMOVAX™ 23 in Healthy Subjects 50 Years of Age and Older

STUDY IDENTIFIERS:

IND: 00618	EudraCT: 2013-003027-11	WHO: N/A	NCT: NCT02225587

STUDY PHASE: 3

INDICATION: Prevention of pneumococcal disease

STUDY CENTERS: This study was conducted at 20 centers in the United States.

STUDY STATUS: This study was completed; this report is based on the final analysis.

First Patient, First Visit	Last Patient, Last Visit	Data Cut-off or Database Lock Date
08-SEP-2014	06-JUL-2015	20-JUN-2019

METHODOLOGY: This was a randomized, placebo-controlled, multicenter, double-blind trial of sequential administration of Prevnar 13™ (pneumococcal 13-valent conjugate vaccine [diphtheria CRM_{197} protein], also referred to as PCV13, Wyeth Pharmaceuticals Inc, a subsidiary of Pfizer Inc, Philadelphia, PA, USA) followed 8 weeks later or approximately 6 months (26 weeks) later by PNEUMOVAX™ 23 (pneumococcal vaccine polyvalent, in adult participants 50 years of age and older in good health (any underlying chronic illness must be documented to be in stable condition) to be conducted in conformance with Good Clinical Practices (GCP).

Intervention	Unit Dose and Frequency	Route of Administration
Prevnar 13™ (PCV13)	0.5 mL, 1 dose	intramuscular
PNEUMOVAX™ 23	0.5 mL, 1 dose	intramuscular
Placebo (Sterile Diluent)	0.5 mL, 1 dose	intramuscular

ELIGIBILITY CRITERIA: Participants were male and female adults age ≥50 years and in good health. Any chronic illness had to be documented as stable. They could not have had any prior administration of any pneumococcal vaccine or known history of culture-positive pneumococcal disease.

OBJECTIVES AND ENDPOINTS:

Primary Objective(s)	Primary Endpoint(s)
1. To describe the safety and tolerability profiles of the sequential administration of Prevnar 13™ followed by PNEUMOVAX™ 23 when given either 8 weeks apart (Group 1: Prevnar 13™ → PNEUMOVAX™ 23 → placebo) or 26 weeks apart (Group 2: Prevnar 13™ → placebo → PNEUMOVAX™ 23).	The safety parameters (Tier 1 AEs) for the key safety assessment included proportions of participants reporting the following solicited AEs occurring Days 1 through 5 postvaccination, including the day of vaccination: • elevated body temperature • injection site swelling • injection site redness • injection site pain/tenderness And solicited systemic AEs occurring Days 1 through 14 postvaccination, including the day of vaccination of • muscle pain • joint pain • headache • tiredness. Other measures for an overall assessment of safety (Tier 2 and Tier 3) included proportions of participants with • any AE through 14 days after each injection • any injection site AE through 14 days after each injection • any systemic AE through 14 days after each injection • any SAE through Visit 5 (Week 30) • any vaccine-related SAE and any deaths through Visit 5 (Week 30) • any serious and vaccine-related AE through Visit 5 (Week 30) • any discontinuation due to an AE • specific AEs or SOCs (reported in ≥4 subjects in any vaccination group)

2. To demonstrate that the opsonophagocytic activity (OPA) geometric mean titers (GMTs) to pneumococcal serotypes 22F and 33F (2 serotypes in PNEUMOVAX™ 23 but not in Prevnar 13™) measured at Week 12 in Group 1 (Prevnar 13™ → PNEUMOVAX™ 23 → placebo) are superior to the OPA GMTs for those serotypes measured at Week 12 in Group 2 (Prevnar 13™ → placebo → PNEUMOVAX™ 23).	The primary immunogenicity endpoints were • serotype-specific OPA GMTs to 2 serotypes in PNEUMOVAX™ 23 but not in Prevnar 13™ (22F, 33F) measured at 12 weeks after the first dose[a] and,
3. To demonstrate that the OPA GMTs to the 12 shared pneumococcal serotypes contained in PNEUMOVAX™ 23 and Prevnar 13™ (1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) measured at Week 12 in Group 1 (Prevnar 13™ → PNEUMOVAX™ 23 → placebo) are noninferior to the OPA GMTs for those serotypes at Week 12 in Group 2 (Prevnar 13™ → placebo → PNEUMOVAX™ 23).	• serotype-specific OPA GMTs to 12 shared serotypes contained in both vaccines (1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) measured at 12 weeks after the first dose.[b]

Secondary Objective(s)	Secondary Endpoint(s)
1. To compare OPA GMTs to pneumococcal serotypes unique to PNEUMOVAX™ 23 (22F, 33F) and 12 pneumococcal serotypes contained in both Prevnar 13™ and PNEUMOVAX™ 23 (1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 19A and 23F) at 4 weeks after receipt of PNEUMOVAX™ 23 in the 2 vaccination groups: Week 12 for Group 1 (Prevnar 13™ → PNEUMOVAX™ 23 → placebo) versus Week 30 for Group 2 (Prevnar 13™ → placebo → PNEUMOVAX™ 23).	OPA GMTs to pneumococcal serotypes (2 serotypes in PNEUMOVAX™ 23 but not in Prevnar 13™, and 12 shared serotypes) at Week 12 for Group 1 and Week 30 for Group 2[c]
2. To summarize OPA GMTs to 15 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F) at Week 8, Week 26, and Week 30 in Group 1 (Prevnar 13™ → PNEUMOVAX™ 23 → placebo) and Group 2 (Prevnar 13™ → placebo → PNEUMOVAX™ 23).	OPA GMTs to 15 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F) at Week 8, Week 26, and Week 30 for Groups 1 and 2
3. To describe the safety and tolerability profiles of the sequential administration of Prevnar 13™ followed by PNEUMOVAX™ 23 during the 14 days following each injection when the 2 vaccines were given either 8 weeks apart (Group 1: Prevnar 13™ → PNEUMOVAX™ 23 → placebo) or 26 weeks apart (Group 2: Prevnar 13™ → placebo → PNEUMOVAX™ 23).	Tier 1 (Days 1-5): injection site redness, swelling, or pain or tenderness, and temperature elevation Tier 1) (Days 1-14): muscle or joint pain, headache, and tiredness Tier 2: any AE, SAE (through entire safety follow-up period/specific comparison period), vaccine-related AE, any serious and vaccine-related AE (through entire safety follow-up period/specific comparison period), discontinuation due to AE, specific AEs or SOCs[‡] (reported in ≥4 subjects in any vaccination group Tier 3: specific AEs or SOCs (reported in <4 subjects in any vaccination group)

[a] OPA GMTs measured at Week 12 for the 2 serotypes unique to PNEUMOVAX™ 23 in Group 1 (4 weeks after receiving Prevnar 13™ on Day 1 and PNEUMOVAX™ 23 at Week 8) versus Group 2 (4 weeks after receiving Prevnar 13™ on Day 1 and Placebo at Week 8). OPA GMTs at Week 12 were compared between the 2 groups with adjustment of the baseline titers (measured prior to the first vaccination at Day 1).

[b] OPA GMTs measured at Week 12 for the 12 shared serotypes between Prevnar 13™ and PNEUMOVAX™ 23 in Group 1 (4 weeks after receiving Prevnar 13™ on Day 1 and PNEUMOVAX™ 23 at Week 8) versus Group 2 (4 weeks after receiving Prevnar 13™ on Day 1 and Placebo at Week 8). OPA GMTs measured at Week 12 were compared between the 2 groups with adjustment of the baseline titers (measured prior to the first vaccination at Day 1).

[c] OPA GMTs measured at Week 12 for the 12 shared serotypes and the 2 serotypes unique to PNEUMOVAX™ 23 in Group 1 were compared with those measured at Week 30 in Group 2, both timepoints corresponding to approximately 4 weeks after receipt of PNEUMOVAX™ 23 for each vaccination group.

NUMBER OF PARTICIPANTS (planned and analyzed): A total of 400 participants was planned to be enrolled/randomized. As of the data cutoff date for this report, 400 participants were enrolled/randomized (200 in intervention Group 1, 200 in intervention Group 2).

STATISTICAL and ANALYSIS METHODS:

Primary Immunogenicity Analysis

For the primary immunogenicity hypothesis evaluating the superiority of Group 1 versus Group 2 for the 2 serotypes (22F, 33F) unique to PNEUMOVAX™ 23 at Week 12, Group 1 was considered superior to Group 2 if the lower bound of the 2-sided 95% confidence interval (CI) of the GMT ratio (Group 1/Group 2) being >2 for both 22F and 33F at Week 12. For the primary hypothesis evaluating noninferiority of Group 1 to Group 2 for the 12 shared serotypes between Prevnar 13™ and PNEUMOVAX™ 23 at Week 12, Group 1 was considered noninferior to Group 2 if the lower bound of the 2-sided 95% CI of the GMT ratio (Group 1/Group 2) being >0.5 for all 12 shared serotypes at Week 12. Because both primary hypotheses must be demonstrated in order to declare a success, each of the primary hypotheses were tested at the 1-sided α=0.025 level. The overall α-level for testing both hypotheses was $\leq$0.025. No multiplicity adjustment was taken relative to the 2 primary hypotheses.

The Per Protocol (PP) population served as the primary population for the analysis of immunogenicity data in this study. The PP population consisted of those participants who were not considered protocol violators. Immunogenicity measurements were taken at all 5 study visits, and were collected prior to vaccination on Visit 1, Visit 2, and Visit 4. The primary hypothesis was evaluated by comparing Group 1 to Group 2 based on OPA GMTs at Week 12.

Safety Analysis

There were no safety hypotheses for this study. Safety and tolerability were assessed by statistical and clinical review of all safety data. The analysis of safety results followed a tiered approach. The tiered approach was used for the comparison of adverse events (AEs) occurring during 14 days after each injection (study vaccine or placebo) between the 2 vaccination groups, as well as the comparison of AEs after the receipt of PNEUMOVAX™ 23 between vaccination groups. The tiers differed with respect to the analyses that were performed. Safety parameters or AEs of special interest that were identified a priori constituted “Tier 1” safety endpoints that were subject to inferential testing for statistical significance with p-values and 95% CIs provided for between-group comparisons (Group 1 versus Group 2). Other safety parameters were considered Tier 2 or Tier 3. Tier 2 parameters were assessed via point estimates with 95% CIs provided for

between-group comparisons (Group 1 versus Group 2); only point estimates by group were provided for Tier 3 safety parameters.

The All Subjects as Treated (ASaT) population was used for the analysis of safety data in this study. The ASaT population consisted of all randomized participants who received at least 1 dose of study vaccine and had follow-up for safety.

RESULTS:

Disposition, Demographics and Baseline Characteristics:

Number of participants randomized/treated/ongoing/discontinued:

- In intervention Group 1, 200 participants were randomized; all (100%) participants were treated, 172 (86.0%) completed the study, and 28 (14.0%) discontinued study intervention.

- In intervention Group 2, 200 participants were randomized; all (100%) were treated, 162 (81.0%) completed the study, and 38 (19%) discontinued study intervention.

Overall Mean Age (Standard Deviation [SD]): 64.2 (8.7) years
Sex: 181 (45.3%) male, 219 (54.8%) female
Ethnicity: 322 (80.5%) Not Hispanic or Latino, 75 (18.8%) Hispanic or Latino, 1 (0.3%) not reported, and 2 (0.5%) unknown.
Race: 339 (84.8%) white, 37 (9.3%) black or African American, 15 (3.8%) multi-racial, 4 (1.0%) American Indian or Alaska native, 4 (1.0%) Asian, and 1 (0.3%) native Hawaiian or other Pacific Islander.

Safety

- The proportions of subjects reporting any AE, injection site AEs, and noninjection site AEs from Days 1 to 14 following any vaccination were generally comparable between Group 1 and Group 2. Of note, more subjects in Group 1 (SSo ™ 23 given 8 weeks after Prevnar 13™) than Group 2 (PNEUMOVAX™ 23 given 26 weeks after Prevnar 13™) reported an injection site AE during Days 1 to 14 following receipt of PNEUMOVAX™ 23, with reporting rates of 81.9% and 64.0%, respectively.

- From Days 1 to 14 following receipt of any vaccination, the incidence of vaccine-related AEs, vaccine-related injection site AEs, and vaccine-related noninjection site AEs occurred in generally comparable proportions between Group 1 and Group 2.

- During Day 1 to Day 14 post any vaccination, only 2 participants had SAEs; with 1 participant who was prematurely discontinued from the study due to an SAE.

- There were no participants who had vaccine-related SAEs.

- There were no subjects who died during the protocol-specified safety follow-up period.

There were few subjects (<2%) in Group 1 or Group 2 during Days 1 to 14 who were prematurely discontinued from the study due to an AE.

Summary of Adverse Events Occurring on Days 1 to 14 After Any Vaccination
(All Subjects as Treated)

	Group 1 (Prevnar 13 -> PNEUMOVAX 23 -> Placebo)		Group 2 (Prevnar 13 -> Placebo -> PNEUMOVAX 23)		Total	
	n	(%)	n	(%)	n	(%)
Subjects in population with follow-up	198		199		397	
with one or more adverse events	178	(89.9)	168	(84.4)	346	(87.2)
injection site	171	(86.4)	155	(77.9)	326	(82.1)
noninjection site	152	(76.8)	148	(74.4)	300	(75.6)
with no adverse event	20	(10.1)	31	(15.6)	51	(12.8)
with vaccine-related† adverse events	174	(87.9)	162	(81.4)	336	(84.6)
injection site	171	(86.4)	155	(77.9)	326	(82.1)
noninjection site	134	(67.7)	126	(63.3)	260	(65.5)
with serious adverse events	1	(0.5)	1	(0.5)	2	(0.5)
with serious vaccine-related adverse events	0	(0.0)	0	(0.0)	0	(0.0)
who died‡	0	(0.0)	0	(0.0)	0	(0.0)
discontinuedβ due to an adverse event	4	(2.0)	1	(0.5)	5	(1.3)
discontinued due to a vaccine-related adverse event	2	(1.0)	1	(0.5)	3	(0.8)
discontinued due to a serious adverse event	1	(0.5)	0	(0.0)	1	(0.3)
discontinued due to a serious vaccine-related adverse event	0	(0.0)	0	(0.0)	0	(0.0)

Every subject was counted a single time for each applicable row and column.

† Determined by the investigator to be related to the vaccine.

‡ Any deaths that occurred prior to the subject completing the trial was reported. One death due to brain injury (secondary to trauma/fall) was reported 95 days after receiving PNEUMOVAX™ 23. The event was determined by the investigator to be unrelated to study vaccine.

β Study medication withdrawn.

Data Source: [P029V01V110: analysis-adsl] [P029V01V110: tabulations-ae; dm; sc; se; sv]

Source: T-AE-SUM-ANY.sas, QUINTILES (US) 03JUL2019 14:54 DATA TRANSFER: 21JUN2019

Source: Table 14.3.2.1.1

Immunogenicity

Primary Immunogenicity Endpoints

- At Week 12, OPA GMTs to 2 pneumococcal serotypes unique to PNEUMOVAX™ 23 (serotypes 22F and 33F) in Group 1 (recipients of Prevnar 13™ followed 8 weeks later by PNEUMOVAX™ 23) were superior to OPA GMTs in Group 2 (recipients of Prevnar 13™ followed 8 weeks later by Placebo).

- At Week 12, OPA GMTs to 12 shared pneumococcal serotypes contained in both PNEUMOVAX™ 23 and Prevnar 13™ (serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in Group 1 (recipients of Prevnar 13™ followed 8 weeks later by PNEUMOVAX™ 23) were noninferior to OPA GMTs in Group 2 (Prevnar 13™ followed 8 weeks later by Placebo).

Secondary Immunogenicity Endpoints

- At 4 weeks after receipt of PNEUMOVAX™ 23 (Week 12 in Group 1 and Week 30 in Group 2), OPA GMTs to 2 serotypes unique to PNEUMOVAX™ 23 (serotypes 22F and 33F) and to 12 serotypes in common between Prevnar 13™ and PNEUMOVAX™ 23 were generally comparable between the 2 groups.

Analysis of Postvaccination OPA GMTs to Pneumococcal Serotypes 22F and 33F (2 Serotypes in PNEUMOVAX™ 23 but not in Prevnar 13™) at Week 12 (Per Protocol Population)

Pneumococcal Serotype	Group 1 (Prevnar 13 -> PNEUMOVAX 23 -> Placebo) (N=200) Estimated Response†		Group 2 (Prevnar 13 -> Placebo -> PNEUMOVAX 23) (N=200) Estimated Response†		Estimated GMT Ratio† [Group 1 / Group 2] (95% CI)†‡	p-Value†‡
	n	GMT	n	GMT		
22F	193	1720.3	191	42.4	40.6 (27.9, 59.1)	<0.001
33F	195	11026.0	195	1123.2	9.9 (7.2, 13.7)	<0.001

†Estimated GMTs, GMT ratio, 95% CI, and p-value are obtained from a cLDA model.

‡A conclusion of superiority is based on the lower bound of the 95% CI on the estimated ratio being >2 (one-sided p-value < 0.025).

N = Number of subjects randomized and vaccinated.

n = Number of subjects who had results either at prevaccination/baseline or 4 weeks post Vaccination 2 thus contributing to the immunogenicity analysis.

GMT = Geometric mean titer.

CI = Confidence interval.

Data Source: [P029V01V110: analysis-adsl; adimm]

Source: T-OPA-GMT-PP.sas, QUINTILES (US) 07AUG2019 09:40 DATA TRANSFER: 21JUN2019

Source: Table 14.2.1.1

Analysis of Postvaccination OPA GMTs to the 12 Shared Pneumococcal Serotypes Contained in PNEUMOVAX™ 23 and Prevnar 13™ at Week 12 (Per Protocol Population)

Pneumococcal Serotype	Group 1 (Prevnar 13 -> PNEUMOVAX 23 -> Placebo) (N=200) Estimated Response†		Group 2 (Prevnar 13 -> Placebo -> PNEUMOVAX 23) (N=200) Estimated Response†		Estimated GMT Ratio† [Group 1 / Group 2] (95% CI)†‡	p-Value†‡
	n	GMT	n	GMT		
1	196	83.3	198	59.0	1.4 (0.9, 2.1)	<0.001
3	193	42.4	198	17.7	2.4 (1.7, 3.4)	<0.001
4	194	1087.2	193	772.6	1.4 (1.1, 1.9)	<0.001
5	197	206.5	198	150.8	1.4 (0.9, 2.1)	<0.001
6B	196	2013.1	198	1131.9	1.8 (1.3, 2.5)	<0.001
7F	196	2264.3	197	1745.8	1.3 (1.0, 1.7)	<0.001
9V	193	1451.5	198	1058.0	1.4 (1.0, 1.9)	<0.001
14	196	2127.2	198	1912.8	1.1 (0.8, 1.5)	<0.001
18C	194	2129.4	196	1583.1	1.3 (1.0, 1.8)	<0.001
19A	197	1814.2	197	1431.8	1.3 (1.0, 1.6)	<0.001
19F	193	1042.7	198	650.1	1.6 (1.2, 2.2)	<0.001
23F	194	1215.4	196	692.2	1.8 (1.2, 2.6)	<0.001

†Estimated GMTs, GMT ratio, 95% CI, and p-value are obtained from a cLDA model.

‡A conclusion of noninferiority is based on the lower bound of the 95% CI on the estimated ratio being >0.5 (one-sided p-value < 0.025).

N = Number of subjects randomized and vaccinated.

n = Number of subjects who had results either at prevaccination/baseline or 4 weeks post Vaccination 2 thus contributing to the immunogenicity analysis.

GMT = Geometric mean titer.

CI = Confidence interval.

Data Source: [P029V01V110: analysis-adsl; adimm]

Source: T-OPA-GMT-12S-PP.sas, QUINTILES (US) 07AUG2019 10:23 DATA TRANSFER: 21JUN2019

Source: Table 14.2.2.1

Analysis of Postvaccination OPA GMTs to Pneumococcal Serotypes 22F and 33F (2 Serotypes in PNEUMOVAX™ 23 but not in Prevnar 13™)
Week 12 for Group 1 vs. Week 30 for Group 2 (Per Protocol Population)

Pneumococcal Serotype	Group 1 (Prevnar 13 -> PNEUMOVAX 23 -> Placebo) (N=200) Estimated Response†		Group 2 (Prevnar 13 -> Placebo -> PNEUMOVAX 23) (N=200) Estimated Response†		Estimated GMT Ratio† [Group 1 / Group 2] (95% CI)†
	n	GMT	n	GMT	
22F	193	1753.5	190	964.8	1.8 (1.1, 2.9)
33F	195	10806.5	192	7497.2	1.5 (1.0, 2.1)

†Estimated GMTs, GMT ratio, and 95% CI are obtained from a cLDA model.

N = Number of subjects randomized and vaccinated.

n = Number of subjects who had results either at prevaccination/baseline or 4 weeks post PNEUMOVAX 23 thus contributing to the immunogenicity analysis.

GMT = Geometric mean titer.

CI = Confidence interval.

Data Source: [P029V01V110: analysis-adsl; adimm]

Source: T-OPA-GMT-PP.sas, QUINTILES (US) 07AUG2019 09:40 DATA TRANSFER: 21JUN2019

Source: Table 14.2.3.1

Analysis of Postvaccination OPA GMTs to the 12 Shared Pneumococcal Serotypes Contained in PNEUMOVAX™ 23 and Prevnar 13™
Week 12 for Group 1 vs. Week 30 for Group 2 (Per Protocol Population)

Pneumococcal Serotype	Group 1 (Prevnar 13 -> PNEUMOVAX 23 -> Placebo) (N=200) Estimated Response†		Group 2 (Prevnar 13 -> Placebo -> PNEUMOVAX 23) (N=200) Estimated Response†		Estimated GMT Ratio† [Group 1 / Group 2] (95% CI)†
	n	GMT	n	GMT	
1	196	83.1	197	49.9	1.7 (1.0, 2.7)
3	193	42.4	194	32.8	1.3 (0.9, 1.9)
4	194	1085.5	181	1053.8	1.0 (0.7, 1.4)
5	197	206.5	191	123.9	1.7 (1.1, 2.7)
6B	196	2007.2	188	1400.7	1.4 (1.0, 2.0)
7F	196	2259.6	189	1233.6	1.8 (1.3, 2.5)
9V	193	1456.5	187	1150.5	1.3 (0.9, 1.8)
14	196	2129.4	192	1936.3	1.1 (0.8, 1.6)
18C	194	2125.4	190	1089.2	1.9 (1.4, 2.7)
19A	197	1808.7	194	1212.8	1.5 (1.1, 1.9)
19F	193	1043.3	191	902.6	1.2 (0.8, 1.6)
23F	194	1207.1	186	754.8	1.6 (1.0, 2.5)

†Estimated GMTs, GMT ratio, and 95% CI are obtained from a cLDA model.

N = Number of subjects randomized and vaccinated.

n = Number of subjects who had results either at prevaccination/baseline or 4 weeks postPNEUMOVAX™ 23 thus contributing to the immunogenicity analysis.

GMT = Geometric mean titer.

CI = Confidence interval.

Data Source: [P029V01V110: analysis-adsl; adimm]

Source: T-OPA-GMT-12S-WK30-PP.sas, QUINTILES (US) 07AUG2019 10:26 DATA TRANSFER: 21JUN2019

Source: Table 14.2.4.1

CONCLUSIONS:

Sequential administration of Prevnar 13™ followed by PNEUMOVAX™ 23 given at either 2-month or 6-month intervals was generally well-tolerated as measured by the nature, frequency, and intensity of reported AEs in the 2 vaccination groups. Although a shorter interval (2 months) was associated with higher frequency of injection site pain, the observed difference was not clinically significant as most AEs were transient and mild to moderate in intensity.

Serotype-specific OPA GMTs measured following receipt of PNEUMOVAX™ 23 were generally comparable between the 2 groups, regardless of the interval between receipt of Prevnar 13™ and PNEUMOVAX™ 23 for the 2 serotypes unique to PNEUMOVAX™ 23 and the 12 shared serotypes between Prevnar 13™ and PNEUMOVAX™ 23. In addition, administration of PNEUMOVAX™ 23 given either 8 weeks or 26 weeks following Prevnar 13™ did not hinder the immune responses induced by Prevnar 13™ as OPA GMTs increased for most shared serotypes at 4 weeks following receipt of PNEUMOVAX™ 23. Furthermore, administration of PNEUMOVAX™ 23 given either 8 weeks or 26 weeks after Prevnar 13™ elicited serotype-specific OPA GMTs to the serotypes unique to PNEUMOVAX™ 23, which could provide earlier protection against pneumococcal disease caused by these serotypes in comparison with the current Advisory Committee on Immunization Practices (ACIP) recommended interval of at least 12 months.

PUBLICATION(S): As of the date of this report, there are no publications based on this study.

REPORT DATE: 08-OCT-2019