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Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Prevenar 13

pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)

Procedure no: EMA/PAM/0000355407

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.



Status of this report and steps taken for the assessment			
Current step	Description	Planned date	Actual Date
☐	Start date	22 June 2026	22 June 2026
☐	CHMP Rapporteur AR	27 July 2026	16 June 2026
☐	CHMP comments	10 August 2026	10 August 2026
☐	Updated CHMP Rapporteur AR	13 August 2026	12 August 2026
☒	CHMP outcome	20 August 2026	20 August 2026

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LIST OF ABBREVIATIONS

Abbreviation	Term
13vPnC	13-valent pneumococcal conjugate vaccine
20vPnC	20-valent pneumococcal conjugate vaccine
AE	adverse event
AOM	acute otitis media
CI	confidence interval
CRM197	cross-reactive material 197
CSR	clinical study report
EU	European Union
EC	European Commission
eCRF	electronic case report form
GMC	geometric mean concentration
GMFR	geometric mean fold rise
GMR	geometric mean ratio
GMT	geometric mean titer
IgG	immunoglobulin G
IN	India
IP	investigational product
IPD	invasive pneumococcal disease
LLOQ	lower limit of quantitation
MAH	Marketing Authorisation Holder
MedDRA	Medical Dictionary for Regulatory Activities
NIP	national immunisation program
OPA	opsonophagocytic activity
PCV	pneumococcal conjugate vaccine
PD	post-dose
PT	pertussis toxin
SAE	serious adverse event
SmPC	Summary of Product Characteristics
<i>S pneumoniae</i>	<i>Streptococcus pneumoniae</i>
TW	Taiwan
vs	versus

1. Introduction

On 4 June 2026, the MAH submitted a completed paediatric study for Prevenar 13, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

A short critical expert overview has also been provided.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that Study B7471024 - A Phase 3 Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine Given in a Series of 3 Infant Doses and 1 Toddler Dose in Infants in India and Taiwan is a stand alone study.

2.2. Information on the pharmaceutical formulation used in the study

13vPnC is a sterile liquid suspension formulation containing saccharides from pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F individually conjugated to CRM197. The vaccine is formulated to contain 2.2 µg of each saccharide, except for 4.4 µg of 6B, per 0.5-mL dose. The vaccine contains succinate buffer, sodium chloride, polysorbate 80, and 125 µg aluminum as aluminum phosphate, per 0.5-mL dose.

20vPnC contains the serotypes present in 13vPnC, and 7 new serotypes (8, 10A, 11A, 12F, 15B, 22F, and 33F), individually conjugated to CRM197. 20vPnC uses the same platform and contains the same excipients as 13vPnC (Prevnam 13®/Prevenar 13®).

2.3. Clinical aspects

Introduction

The MAH submitted a final report for:

- Study B7471024 - A Phase 3 Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine Given in a Series of 3 Infant Doses and 1 Toddler Dose in Infants in India and Taiwan.

The marketing authorisation for 13vPnC for the immunisation of children 6 weeks to 5 years of age was approved in the EU on 09 December 2009 with the following indication:

- *Active immunisation for the prevention of invasive disease, pneumonia, and AOM caused by S pneumoniae in infants and children from 6 weeks to 5 years of age.*

Later on, based on results from additional clinical trials, the indication of 13vPnC was extended for all children from 6 weeks of age and adults. Since 26 February 2015, the current EU-approved indications for the use of 13vPnC are therefore:

- *Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to 17 years of age;*
- *Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in adults ≥18 years of age and the elderly.*

The marketing authorisation for 20vPnC for the immunisation of adults at least 18 years of age was approved in the EU on 14 February 2022 with the following indication:

Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age and older.

The marketing authorisation for 20vPnC for the immunisation of children 6 weeks to 18 years of age was approved in the EU on 11 March 2024 with the following indication:

Active immunisation for the prevention of invasive disease, pneumonia, and acute otitis media caused by Streptococcus pneumoniae in infants, children, and adolescents from 6 weeks to less than 18 years of age.

Clinical study

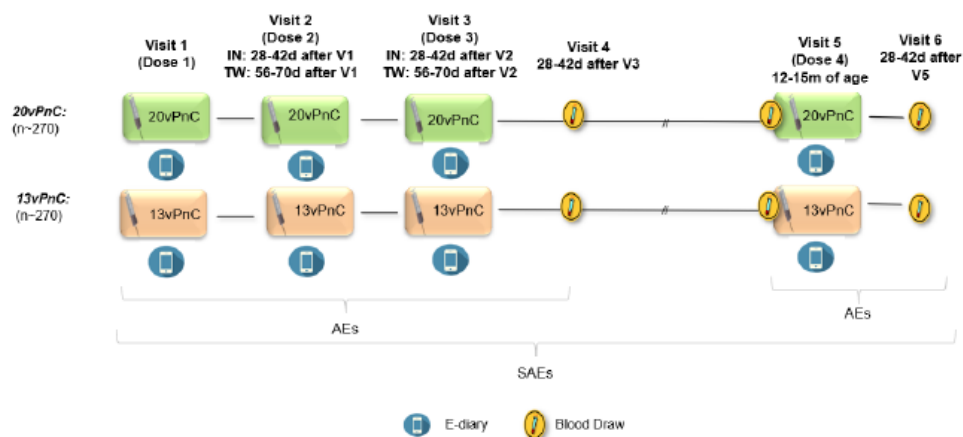
Study B7471024 - A Phase 3 Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine Given in a Series of 3 Infant Doses and 1 Toddler Dose in Infants in India and Taiwan

Description

The purpose of this Phase 3, multicenter, randomised, double-blind study was to assess the safety and immunogenicity of 20vPnC in infants and to provide key safety data to support licensure in this population in India and Taiwan. The targeted age of the population for this study, infants ≥ 42 to ≤ 84 days of age, has been selected as this is the range that encompasses the routinely recommended age for initial vaccination with PCVs and other vaccines in infants in India and Taiwan. The specific dosing was given according to a local recommended schedule. 13vPnC has been used as an active comparator in this study. Please see the details of the study design in figure below.

Methods

Figure 1. Study Design B7471024



Study participants and treatments

Approximately 540 healthy infants ≥ 42 to ≤ 84 days of age in India (approximately 350 infants) and Taiwan (approximately 190 infants) were to be enrolled and randomised (1:1) to receive either 20vPnC or 13vPnC. The infants were to receive vaccine according to a schedule of 3 infant doses and a toddler dose. The specific dosing was to be given according to the local recommended schedule. In India, the infant doses were given at approximately 6, 10, and 14 weeks of age, and in Taiwan the infant doses were given at approximately 8, 16, and 24 weeks of age. All toddler doses were given at

approximately 12 to 15 months of age. Most other routine paediatric vaccines were generally permitted according to official local recommendations/regulations at any time throughout study participation.

Each participant was planned to participate in the study for up to approximately 15 months.

Objectives, Outcomes/endpoints

Primary Safety Objective	Primary Safety Endpoints	Primary Safety Estimands
To describe the safety profile of 20vPnC in healthy infants in India and Taiwan, separately by country	- Prompted local reactions (redness, swelling, and pain at the injection site) - Prompted systemic events (fever, decreased appetite, drowsiness/increased sleep, and irritability) - AEs - SAEs	In participants receiving at least 1 dose of study intervention with safety follow-up after any vaccination, the percentage of participants reporting: - Prompted local reactions at the injection site of study intervention within 7 days after each dose in each group - Prompted systemic events within 7 days after each dose in each group - AEs from Dose 1 through 1 month after Dose 3 in each group - AEs from Dose 4 through 1 month after Dose 4 in each group - SAEs from Dose 1 through 1 month after Dose 4 in each group
Primary Immunogenicity Objective (India Participants Only)	Primary Immunogenicity Endpoint (India Participants Only)	Primary Immunogenicity Estimand (India Participants Only)
To describe the immunogenicity of 20vPnC in healthy infants in India after Dose 4	Pneumococcal IgG concentration	In participants who are in compliance with the key protocol criteria (evaluable participants) in India at 1 month after Dose 4 in each group: IgG GMCs for the 20vPnC serotypes
Secondary Immunogenicity Objectives	Secondary Immunogenicity Endpoints	Secondary Immunogenicity Estimands
To describe the immunogenicity of 20vPnC in healthy infants after Dose 3, separately by country	Pneumococcal IgG concentration	In evaluable participants at 1 month after Dose 3 in each group: - IgG GMCs for the 20vPnC serotypes - Percentages of participants with predefined serotype-specific IgG concentration for the 20vPnC serotypes
To describe the immunogenicity of 20vPnC in healthy infants after Dose 4, separately by country	Pneumococcal IgG concentration	In evaluable participants at 1 month after Dose 4 in each group: - IgG GMCs for the 20vPnC serotypes (Taiwan participants only) - Percentages of participants with predefined serotype-specific IgG concentration for the 20vPnC serotypes
Exploratory Objective	Exploratory Endpoints	Exploratory Estimands

To further describe the immunogenicity of 20vPnC, separately by country	- Pneumococcal OPA titers - Pneumococcal IgG concentrations	In evaluable participants in each group: - OPA GMTs 1 month after Dose 3 - OPA GMTs 1 month after Dose 4 - IgG GMFRs from 1 month after Dose 3 to 1 month after Dose 4 - IgG GMFRs from before Dose 4 to 1 month after Dose 4
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Sample size

The study size is not based on any formal statistical hypothesis test as this is a descriptive study. The sample size calculation for Indian cohort based on primary immunogenicity objective and for Taiwanese cohort on primary safety objective.

In the India Cohort (excluding Site 1012),

- 250 (99.6%) participants were included in the safety population: 125 (100.0%) and 125 (99.2%) participants in the 20vPnC and 13vPnC groups, respectively.
- 235 (93.6%) participants were included in the Dose 3 evaluable immunogenicity population: 119 (95.2%) and 116 (92.1%) participants in the 20vPnC and 13vPnC groups, respectively.
- 216 (86.1%) participants were included in the Dose 4 evaluable immunogenicity population: 112 (89.6%) and 104 (82.5%) participants in the 20vPnC and 13vPnC groups, respectively.

In the Taiwan Cohort,

- 190 (100.0%) participants were included in the safety population: 94 (100.0%) and 96 (100.0%) participants in the 20vPnC and 13vPnC groups, respectively.
- 186 (97.9%) participants were included in the Dose 3 evaluable immunogenicity population: 92 (97.9%) and 94 (97.9%) participants in the 20vPnC and 13vPnC groups, respectively.
- 180 (94.7%) participants were included in the Dose 4 evaluable immunogenicity population: 88 (93.6%) and 92 (95.8%) participants in the 20vPnC and 13vPnC groups, respectively.

Randomisation and blinding (masking)

This was a double-blind study. All participants were randomized to study intervention using an IRT.

Statistical Methods

The primary safety objective was evaluated by descriptive summary statistics for local reactions, systemic events, and AEs (including SAEs). AEs were categorized according to the MedDRA. Local reactions (redness, swelling, and pain at the injection site) and systemic events (fever, decreased appetite, drowsiness/increased sleep, and irritability) were prompted for and collected daily by the participants' parents/legal guardians using an e-diary application, for 7 days following each dose (Days 1 through 7, where Day 1 was the day of vaccination).

AEs were collected from the time the participants' parents/legal guardians provided informed consent through 1 month after Dose 3 (Visit 4) and from Dose 4 (Visit 5) through 1 month after Dose 4 (Visit 6). SAEs were collected from informed consent through 1 month after Dose 4 (Visit 6).

The primary and/or secondary immunogenicity objectives were evaluated by descriptive summary statistics for serotype-specific IgG results 1 month after Dose 3 and 1 month after Dose 4. The

exploratory immunogenicity objectives were evaluated by descriptive summary statistics. Blood samples (approximately 5 mL per sample) were collected from all participants at Visit 4 (1 month after Dose 3), Visit 5 (prior to administration of Dose 4), and Visit 6 (1 month after Dose 4) for measurement of IgG concentrations and OPA titers. OPA titers were measured in randomly selected subsets of participants from each vaccine group.

Results

Participant flow

India

Safety and immunogenicity data from all participants enrolled at Site 1012 were excluded from the analysis presented in the CSR body due to the audit findings.

Excluding Site 1012, 251 participants were randomized; 241 (96.0%) participants completed all 3 infant doses, 240 (95.6%) participants completed the follow-up visit after Dose 3, 226 (90.0%) participants received all 4 doses, and 224 (89.2%) participants completed all visits per protocol. Disposition of all randomized participants was similar in the 20vPnC and 13vPnC groups.

A total of 27 (10.8%) participants were withdrawn from the trial due to: withdrawal by parent/guardian (7), protocol deviation (7, participants received prohibited vaccines, lost to follow-up (6), no longer meeting eligibility criteria (6), and physician decision (1), see the table below.

Table 4. Analysis Populations – India Participants (Excluding Site 1012) (Protocol B7471024)

	Vaccine Group (as Randomized)		Total n ^a (%)
	20vPnC n ^a (%)	13vPnC n ^a (%)	
Randomized ^b	125 (100.0)	126 (100.0)	251 (100.0)
Vaccinated	125 (100.0)	125 (99.2)	250 (99.6)
Safety population	125 (100.0)	125 (99.2)	250 (99.6)
Excluded from safety population	0	1 (0.8)	1 (0.4)
Reason for exclusion ^c			
Did not receive any vaccination	0	1 (0.8)	1 (0.4)
Did not have safety follow - up	0	0	0
All - available immunogenicity population	121 (96.8)	118 (93.7)	239 (95.2)
Excluded from all - available immunogenicity population	4 (3.2)	8 (6.3)	12 (4.8)
Reason for exclusion ^c			
Did not receive any vaccination	0	1 (0.8)	1 (0.4)
Did not have at least 1 valid immunogenicity result	4 (3.2)	7 (5.6)	11 (4.4)
Dose 3 evaluable immunogenicity population	119 (95.2)	116 (92.1)	235 (93.6)
Excluded from Dose 3 evaluable immunogenicity population	6 (4.8)	10 (7.9)	16 (6.4)
Reason for exclusion ^c			
Not eligible at randomization/dose ^d	0	0	0
Not 42 to 84 days of age at Dose 1	0	0	0
Did not receive first 3 vaccinations as randomized	4 (3.2)	6 (4.8)	10 (4.0)
No blood drawn within 27 to 56 days after Dose 3	2 (1.6)	3 (2.4)	5 (2.0)
Other major protocol deviation	0	1 (0.8)	1 (0.4)
Dose 4 evaluable immunogenicity population	112 (89.6)	104 (82.5)	216 (86.1)
Excluded from Dose 4 evaluable immunogenicity population	13 (10.4)	22 (17.5)	35 (13.9)
Reason for exclusion ^c			
Not eligible at randomization/dose ^d	0	0	0
Not 42 to 84 days of age at Dose 1	0	0	0
Not 365 to 455 days of age at Dose 4	0	1 (0.8)	1 (0.4)
Did not receive 4 vaccinations as randomized	7 (5.6)	18 (14.3)	25 (10.0)
No blood drawn within 27 to 56 days after Dose 4	6 (4.8)	3 (2.4)	9 (3.6)
Other major protocol deviation	0	0	0

a. n = Number of participants with the specified characteristic.

b. These values are the denominators for the percentage calculations.

c. Reasons are listed in hierarchical order. Each excluded participant is counted only once under the first applicable reason.

d. Violation of any protocol defined inclusion or exclusion criteria.

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(Database snapshot date : 09JAN2026) Output File: /nda1/B7471024_INDIA_CSR/adsl_all_eval_wt1012

Table 14.1.1.2.1 PF-06482077 is for Pfizer internal use.

Taiwan

A total of 190 participants were randomized, see the table below; 188 (98.9%) participants completed all 3 infant doses, 187 (98.4%) participants completed the follow-up visit after Dose 3, 184 (96.8%) participants received all 4 doses, and 182 (95.8%) participants completed all visits per protocol. Disposition of all randomized participants was similar in the 20vPnC and 13vPnC groups.

A total of 8 (4.2%) participants were withdrawn from the trial due to: no longer meeting eligibility criteria (5), withdrawal by parent/guardian (2), and AE (1, COVID-19,). Of the 5 participants no longer meeting eligibility criteria, 3 were related to caregiver(s) no longer agreeing to study interventions (refusing blood collection) and 2 were due to the family moving away from treatment area. The 1 withdrawal due to an AE of COVID-19 was due to that participant receiving immunoglobulin treatment for COVID-related neurologic symptoms.

Table 3. Analysis Populations

	Vaccine Group (as Randomized)		Total n ^a (%)
	20vPnC n ^a (%)	13vPnC n ^a (%)	
Randomized ^b	94 (100.0)	96 (100.0)	190 (100.0)
Vaccinated	94 (100.0)	96 (100.0)	190 (100.0)
Safety population	94 (100.0)	96 (100.0)	190 (100.0)
Excluded from safety population	0	0	0
Reason for exclusion ^c			
Did not receive any vaccination	0	0	0
Did not have safety follow-up	0	0	0
All-available immunogenicity population	92 (97.9)	95 (99.0)	187 (98.4)
Excluded from all-available immunogenicity population	2 (2.1)	1 (1.0)	3 (1.6)
Reason for exclusion ^c			
Did not receive any vaccination	0	0	0
Did not have at least 1 valid immunogenicity result	2 (2.1)	1 (1.0)	3 (1.6)
Dose 3 evaluable immunogenicity population	92 (97.9)	94 (97.9)	186 (97.9)
Excluded from Dose 3 evaluable immunogenicity population	2 (2.1)	2 (2.1)	4 (2.1)
Reason for exclusion ^c			
Not eligible at randomization/dose ^d	0	0	0
Not 56 to 84 days of age at Dose 1	0	0	0
Did not receive first 3 vaccinations as randomized	2 (2.1)	0	2 (1.1)
No blood drawn within 27 to 56 days after Dose 3	0	2 (2.1)	2 (1.1)
Other major protocol deviation	0	0	0
Dose 4 evaluable immunogenicity population	88 (93.6)	92 (95.8)	180 (94.7)
Excluded from Dose 4 evaluable immunogenicity population	6 (6.4)	4 (4.2)	10 (5.3)
Reason for exclusion ^c			
Not eligible at randomization/dose ^d	0	0	0
Not 56 to 84 days of age at Dose 1	0	0	0
Not 365 to 455 days of age at Dose 4	0	0	0
Did not receive all 4 vaccinations as randomized	4 (4.3)	2 (2.1)	6 (3.2)
No blood drawn within 27 to 56 days after Dose 4	1 (1.1)	1 (1.0)	2 (1.1)
Other major protocol deviation	1 (1.1)	1 (1.0)	2 (1.1)

a. n = Number of participants with the specified characteristic.

b. These values are the denominators for the percentage calculations.

c. Reasons are listed in hierarchical order. Each excluded participant is counted only once under the first applicable reason.

d. Violation of any protocol defined inclusion or exclusion criteria.

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Output File: /nda1/B7471024_CSR_SERO/adsl_all_eval

Recruitment

	India	Taiwan
Study initiation date	02 May 2024	16 September 2022
Interim cut-off	20 September 2025	22 May 2024

Baseline data

Demographic and baseline characteristics of race, ethnicity, and age for the safety population were similar in the 2 vaccine groups, see the tables below.

India

Table 5. Demographic Characteristics – India Participants (Excluding Site 1012) – Safety Population (Protocol B7471024)

	Vaccine Group (as Administered)		Total (N ^a =250) n ^b (%)
	20vPnC (N ^a =125) n ^b (%)	13vPnC (N ^a =125) n ^b (%)	
Sex			
Male	59 (47.2)	62 (49.6)	121 (48.4)
Female	66 (52.8)	63 (50.4)	129 (51.6)
Race			
Asian	125 (100.0)	125 (100.0)	250 (100.0)
Ethnicity			
Non-Hispanic/non-Latino	125 (100.0)	125 (100.0)	250 (100.0)
Racial Designation			
Indian Subcontinent Asian	124 (99.2)	123 (98.4)	247 (98.8)
Southeast Asian	1 (0.8)	2 (1.6)	3 (1.2)
Country			
India	125 (100.0)	125 (100.0)	250 (100.0)
Age at Dose 1 (days)			
Mean (SD)	50.2 (7.24)	50.9 (6.98)	50.5 (7.11)
Median	48.0	49.0	48.5
Min, max	(43, 78)	(43, 76)	(43, 78)
Age at Dose 4 (days)			
Mean (SD)	385.2 (17.62)	385.5 (16.63)	385.3 (17.12)
Median	378.5	381.0	381.0
Min, max	(367, 455)	(367, 457)	(367, 457)

a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.

b. n = Number of participants with the specified characteristic.

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(Database snapshot date : 09JAN2026) Output File: /nda1/B7471024_INDIA_CSR/adsl_demo_saf_wtt1012

Table 14.1.2.1.1 PF-06482077 is for Pfizer internal use.

Taiwan

Table 4. Demographic Characteristics – Safety Population

	Vaccine Group (as Administered)		Total (N ^a =190) n ^b (%)
	20vPnC (N ^a =94) n ^b (%)	13vPnC (N ^a =96) n ^b (%)	
Sex			
Male	43 (45.7)	57 (59.4)	100 (52.6)
Female	51 (54.3)	39 (40.6)	90 (47.4)
Race			
Asian	94 (100.0)	96 (100.0)	190 (100.0)
Ethnicity			
Non-Hispanic/non-Latino	94 (100.0)	96 (100.0)	190 (100.0)
Racial designation			
Chinese	2 (2.1)	0	2 (1.1)
Taiwanese	92 (97.9)	96 (100.0)	188 (98.9)
Country			
Taiwan	94 (100.0)	96 (100.0)	190 (100.0)
Age at Dose 1 (days)			
Mean (SD)	67.5 (4.79)	67.3 (5.17)	67.4 (4.97)
Median	67.0	66.0	67.0
Min, max	(58, 82)	(57, 83)	(57, 83)
Age at Dose 4 (days)			
Mean (SD)	375.7 (10.42)	376.7 (12.33)	376.2 (11.42)
Median	372.0	372.0	372.0
Min, max	(366, 428)	(366, 446)	(366, 446)

a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.

b. n = Number of participants with the specified characteristic.

PFIZER CONFIDENTIAL SDTM Creation: 18APR2024 (09:55) Source Data: adsl Table Generation: 15MAY2024 (07:52)

Output File: /nda1/B7471024_CSR_TWN/adsl_demo_saf

Number analysed

Safety population	20vPnC	13vPnC	Total
India	125	125	250
Taiwan	94	96	190

Efficacy results

In the India Cohort (excluding Site 1012),

- At 1 month after Dose 4, the observed serotype-specific IgG GMCs for all 13 matched serotypes in the 20vPnC group were generally similar to the GMCs for the corresponding serotypes in the 13vPnC group, see the results in table below.
- At 1 month after Dose 3, the observed serotype-specific IgG GMCs for all 13 matched serotypes in the 20vPnC group were similar to the GMCs for the corresponding serotypes in the 13vPnC group.
- For the 13 matched serotypes, the percentages of participants with predefined serotype specific IgG concentrations were $\geq 85.1\%$ in the 13vPnC group 1 month after Dose 3, and $\geq 97.1\%$ 1 month after Dose 4.
- 13vPnC also elicited functional OPA responses to all vaccine serotypes, based on the observed OPA GMTs, GMFRs, percentages of participants with OPA titers $\geq$ LLOQ at 1 month after Dose 3 and 1 month after Dose 4, and percentages of participants with ≥ 4 -fold rise at 1 month after Dose 4.

Table 7. Pneumococcal IgG GMCs At Each Specified Sampling Time Point – India Participants (Excluding Site 1012) – Evaluable Immunogenicity Population (Protocol B7471024)

Serotype	Sampling Time Point	Vaccine Group (as Randomized)					
		n ^a	20vPnC		n ^a	13vPnC	
			GMC ^b	(95% CI ^b)		GMC ^b	(95% CI ^b)
13vPnC							
1	1 Month after Dose 3	118	1.17	(0.95, 1.44)	116	1.61	(1.35, 1.92)
	Before Dose 4	116	0.27	(0.22, 0.34)	107	0.36	(0.29, 0.45)
	1 Month after Dose 4	112	3.31	(2.76, 3.98)	104	5.05	(4.26, 5.98)
3	1 Month after Dose 3	119	0.73	(0.65, 0.83)	116	0.97	(0.83, 1.13)
	Before Dose 4	116	0.11	(0.08, 0.14)	107	0.12	(0.10, 0.15)
	1 Month after Dose 4	112	1.19	(1.00, 1.40)	104	1.83	(1.56, 2.14)
4	1 Month after Dose 3	119	1.32	(1.06, 1.64)	116	1.60	(1.32, 1.94)
	Before Dose 4	116	0.39	(0.31, 0.50)	107	0.51	(0.41, 0.63)
	1 Month after Dose 4	112	8.80	(7.21, 10.74)	104	12.21	(10.12, 14.74)
5	1 Month after Dose 3	119	0.83	(0.63, 1.09)	116	1.16	(0.91, 1.49)
	Before Dose 4	116	0.29	(0.23, 0.37)	107	0.36	(0.29, 0.44)
	1 Month after Dose 4	112	3.74	(3.10, 4.52)	104	6.01	(5.10, 7.09)
6A	1 Month after Dose 3	119	1.18	(0.89, 1.58)	116	1.73	(1.32, 2.27)
	Before Dose 4	116	0.69	(0.54, 0.90)	107	1.00	(0.77, 1.31)
	1 Month after Dose 4	112	13.65	(10.83, 17.20)	104	23.45	(19.50, 28.19)

Table 7. Pneumococcal IgG GMCs At Each Specified Sampling Time Point – India Participants (Excluding Site 1012) – Evaluable Immunogenicity Population (Protocol B7471024)

Serotype	Sampling Time Point	Vaccine Group (as Randomized)					
		20vPnC			13vPnC		
		n ^a	GMC ^b	(95% CI ^b)	n ^a	GMC ^b	(95% CI ^b)
6B	1 Month after Dose 3	119	0.39	(0.27, 0.57)	114	0.61	(0.44, 0.83)
	Before Dose 4	116	0.44	(0.34, 0.59)	107	0.61	(0.47, 0.78)
	1 Month after Dose 4	112	7.84	(6.30, 9.74)	104	13.65	(11.20, 16.64)
7F	1 Month after Dose 3	119	1.95	(1.65, 2.32)	116	2.20	(1.88, 2.58)
	Before Dose 4	116	0.96	(0.82, 1.12)	107	1.06	(0.92, 1.22)
	1 Month after Dose 4	112	5.35	(4.59, 6.23)	104	7.03	(6.06, 8.16)
9V	1 Month after Dose 3	119	1.57	(1.24, 1.97)	116	2.06	(1.66, 2.56)
	Before Dose 4	116	0.48	(0.37, 0.62)	107	0.47	(0.39, 0.57)
	1 Month after Dose 4	112	5.53	(4.35, 7.03)	104	7.36	(5.95, 9.09)
14	1 Month after Dose 3	119	1.67	(1.30, 2.14)	116	1.76	(1.34, 2.32)
	Before Dose 4	116	1.19	(0.86, 1.63)	107	1.48	(1.13, 1.93)
	1 Month after Dose 4	112	10.30	(8.04, 13.21)	104	13.51	(10.60, 17.23)
18C	1 Month after Dose 3	119	1.59	(1.26, 2.00)	116	1.79	(1.47, 2.19)
	Before Dose 4	116	0.38	(0.31, 0.47)	107	0.38	(0.32, 0.46)
	1 Month after Dose 4	112	5.07	(4.29, 5.99)	104	6.38	(5.33, 7.63)
19A	1 Month after Dose 3	119	1.99	(1.63, 2.43)	116	2.26	(1.86, 2.74)
	Before Dose 4	116	0.43	(0.31, 0.58)	107	0.33	(0.25, 0.44)
	1 Month after Dose 4	112	8.66	(6.93, 10.81)	104	11.87	(10.08, 13.97)
19F	1 Month after Dose 3	119	2.63	(2.18, 3.16)	116	2.96	(2.48, 3.54)
	Before Dose 4	116	0.60	(0.45, 0.80)	107	0.64	(0.48, 0.84)
	1 Month after Dose 4	111	11.18	(9.05, 13.82)	104	17.96	(14.85, 21.72)
23F	1 Month after Dose 3	119	1.11	(0.85, 1.45)	116	1.60	(1.26, 2.04)
	Before Dose 4	116	0.30	(0.23, 0.39)	107	0.38	(0.29, 0.50)
	1 Month after Dose 4	112	5.26	(4.16, 6.65)	104	8.31	(6.54, 10.57)
7 Additional							
8	1 Month after Dose 3	119	2.36	(1.92, 2.90)	116	0.04	(0.03, 0.05)
	Before Dose 4	116	0.39	(0.33, 0.47)	107	0.07	(0.05, 0.09)
	1 Month after Dose 4	112	6.76	(5.29, 8.64)	104	0.14	(0.10, 0.20)
10A	1 Month after Dose 3	119	0.48	(0.34, 0.69)	116	0.03	(0.02, 0.04)
	Before Dose 4	116	0.80	(0.61, 1.05)	107	0.02	(0.02, 0.03)
	1 Month after Dose 4	112	7.24	(5.70, 9.21)	104	0.03	(0.02, 0.05)
11A	1 Month after Dose 3	119	3.58	(2.93, 4.39)	116	0.04	(0.03, 0.05)
	Before Dose 4	116	0.46	(0.37, 0.57)	107	0.03	(0.02, 0.04)
	1 Month after Dose 4	112	4.90	(3.84, 6.24)	104	0.04	(0.03, 0.06)
12F	1 Month after Dose 3	119	0.44	(0.31, 0.62)	116	0.01	(0.01, 0.02)
	Before Dose 4	116	0.20	(0.16, 0.25)	107	0.01	(0.01, 0.02)
	1 Month after Dose 4	112	2.86	(2.30, 3.55)	104	0.02	(0.01, 0.02)
15B	1 Month after Dose 3	119	6.31	(5.06, 7.87)	116	0.05	(0.04, 0.07)
	Before Dose 4	116	1.50	(1.13, 1.98)	107	0.03	(0.02, 0.03)
	1 Month after Dose 4	112	17.92	(13.27, 24.20)	104	0.05	(0.04, 0.07)

Table 7. Pneumococcal IgG GMCs At Each Specified Sampling Time Point – India Participants (Excluding Site 1012) – Evaluable Immunogenicity Population (Protocol B7471024)

Serotype	Sampling Time Point	n ^a	Vaccine Group (as Randomized)				
			20vPnC		13vPnC		
			GMC ^b	(95% CI ^b)	n ^a	GMC ^b	(95% CI ^b)
22F	1 Month after Dose 3	119	4.00	(3.09, 5.18)	116	0.01	(0.01, 0.02)
	Before Dose 4	116	1.07	(0.82, 1.40)	107	0.02	(0.01, 0.03)
	1 Month after Dose 4	112	9.50	(6.87, 13.15)	104	0.03	(0.02, 0.05)
33F	1 Month after Dose 3	119	1.44	(1.10, 1.89)	116	0.06	(0.04, 0.08)
	Before Dose 4	115	1.53	(1.23, 1.91)	107	0.03	(0.02, 0.05)
	1 Month after Dose 4	112	11.69	(9.30, 14.70)	104	0.04	(0.03, 0.07)

Abbreviation(s): GMC = geometric mean concentration; IgG = immunoglobulin G; LLOQ = lower limit of quantitation.

Note: The Dose 3 evaluable immunogenicity population was used for all time points except for 1 month after Dose 4 time point, which used the Dose 4 evaluable immunogenicity population.

Note: Assay results below the LLOQ were set to 0.5×LLOQ in the analysis.

a. n = Number of participants with valid IgG titers for the specified serotype at the given sampling time point.

b. GMCs and 2-sided confidence intervals (CIs) were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution).

PFIZER CONFIDENTIAL SDTM Creation: 13JAN2026 (03:33) Source Data: adva Table Generation: 29APR2026 (05:10) (Database snapshot date : 09JAN2026) Output File: /nda1/B7471024_INDIA_CSR/adva_s001_igg_gmc_eval_wtt1012 Table 14.2.2.4.1.1 PF-06482077 is for Pfizer internal use.

In the Taiwan Cohort,

- At 1 month after Dose 4, the observed serotype-specific IgG GMCs for all 13 matched serotypes in the 20vPnC group were similar to the GMCs for the corresponding serotypes in the 13vPnC group, see the results in table below.
- At 1 month after Dose 3, the observed serotype-specific IgG GMCs for all 13 matched serotypes in the 20vPnC group were generally similar to the GMCs for the corresponding serotypes in the 13vPnC group.
- For the 13 matched serotypes, the percentages of participants with predefined serotype specific IgG concentrations in the 13vPnC group were ≥94.7% 1 month after Dose 3, and ≥97.8% 1 month after Dose 4.
- 13vPnC also elicited functional OPA responses to all vaccine serotypes, based on the observed OPA GMTs, GMFRs, percentages of participants with OPA titers ≥ LLOQ at 1month after Dose 3 and 1 month after Dose 4, and percentages of participants with ≥4-fold rise at 1 month after Dose 4.

Table 8. Pneumococcal IgG GMCs – 1 Month After Dose 4 – Dose 4 Evaluable Immunogenicity Population

Serotype	Vaccine Group (as Randomized)					
	n ^a	GMC ^b	20vPnC (95% CI ^b)	n ^a	GMC ^b	13vPnC (95% CI ^b)
13vPnC						
1	88	4.10	(3.41, 4.94)	92	4.60	(3.74, 5.67)
3	88	1.56	(1.28, 1.90)	92	1.71	(1.43, 2.05)
4	88	7.83	(6.41, 9.57)	92	8.13	(6.69, 9.88)
5	88	5.48	(4.50, 6.68)	92	5.69	(4.62, 7.01)
6A	88	14.72	(12.13, 17.87)	92	15.34	(12.52, 18.80)
6B	88	7.10	(5.78, 8.71)	92	8.63	(6.79, 10.96)
7F	88	8.08	(6.74, 9.67)	92	9.51	(7.82, 11.56)
9V	88	6.61	(5.47, 8.00)	92	7.98	(6.53, 9.75)
14	88	11.39	(9.53, 13.61)	92	9.82	(8.21, 11.75)
18C	88	9.07	(7.48, 10.99)	92	9.83	(7.93, 12.18)
19A	88	5.60	(4.55, 6.90)	92	6.62	(5.53, 7.91)
19F	88	8.12	(6.60, 9.99)	92	10.23	(8.52, 12.27)
23F	88	10.35	(8.22, 13.04)	92	12.49	(9.94, 15.69)
7 Additional						
8	88	8.29	(6.88, 9.99)	85	0.04	(0.03, 0.05)
10A	88	13.75	(11.21, 16.86)	92	0.01	(0.01, 0.02)
11A	88	7.25	(6.00, 8.77)	92	0.01	(0.01, 0.01)
12F	88	3.96	(3.19, 4.92)	92	0.01	(0.01, 0.01)
15B	88	23.35	(19.33, 28.20)	92	0.03	(0.02, 0.03)
22F	88	26.05	(21.22, 31.98)	92	0.01	(0.00, 0.01)
33F	88	14.95	(12.22, 18.30)	92	0.01	(0.01, 0.01)

Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; LLOQ = lower limit of quantitation.

Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

a. n = Number of participants with valid IgG concentrations for the specified serotype at the given sampling time point.

b. GMCs and 2-sided CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution).

PFIZER CONFIDENTIAL SDTM Creation: 30MAY2024 (02:07) Source Data: adva Table Generation: 11JUN2024 (09:24)

Output File: /nda1/B7471024_CSR_SERO/adva_s001_14_aftd4_eval

Table 6. Pneumococcal IgG GMCs – 1 Month After Dose 3 – Dose 3 Evaluable Immunogenicity Population

Serotype	Vaccine Group (as Randomized)					
	n ^a	GMC ^b	20vPnC (95% CI ^b)	n ^a	GMC ^b	13vPnC (95% CI ^b)
13vPnC						
1	92	2.76	(2.32, 3.27)	94	3.00	(2.42, 3.72)
3	92	1.05	(0.92, 1.21)	94	1.22	(1.04, 1.42)
4	92	3.90	(3.27, 4.64)	94	3.92	(3.16, 4.87)
5	92	3.37	(2.82, 4.01)	94	3.49	(2.80, 4.35)
6A	92	5.28	(4.42, 6.31)	94	6.13	(5.08, 7.40)
6B	91	1.85	(1.50, 2.28)	94	2.53	(2.06, 3.09)
7F	92	4.26	(3.65, 4.98)	94	4.90	(4.05, 5.93)
9V	92	3.17	(2.67, 3.75)	94	3.69	(3.01, 4.52)
14	92	6.56	(5.56, 7.74)	94	5.59	(4.30, 7.25)
18C	92	3.94	(3.44, 4.51)	94	4.04	(3.26, 5.01)
19A	92	1.74	(1.50, 2.03)	94	2.21	(1.85, 2.64)
19F	92	4.40	(3.80, 5.10)	94	5.61	(4.78, 6.59)
23F	92	2.93	(2.44, 3.52)	94	3.71	(3.05, 4.53)
7 Additional						
8	92	4.61	(4.03, 5.28)	86	0.02	(0.02, 0.03)
10A	92	3.27	(2.60, 4.11)	94	0.01	(0.01, 0.01)
11A	92	5.28	(4.50, 6.18)	94	0.01	(0.01, 0.01)
12F	92	2.05	(1.72, 2.43)	94	0.01	(0.01, 0.01)
15B	92	14.76	(12.49, 17.44)	94	0.02	(0.02, 0.03)
22F	92	14.55	(12.42, 17.04)	94	0.00	(0.00, 0.01)
33F	92	4.04	(3.18, 5.14)	94	0.02	(0.02, 0.02)

Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; LLOQ = lower limit of quantitation.
Note: Assay results below the LLOQ were set to $0.5 \times \text{LLOQ}$ in the analysis.

a. n = Number of participants with valid IgG concentrations for the specified serotype at the given sampling time point.

b. GMCs and 2-sided CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution).

PFIZER CONFIDENTIAL SDTM Creation: 30MAY2024 (02:07) Source Data: adva Table Generation: 11JUN2024 (09:24)

Output File: /nda1/B7471024_CSR_SERO/adva s001 13 aftd3 eval

Safety results

In the India Cohort (excluding Site 1012),

- The percentages of participants with prompted local reactions were generally similar in the 20vPnC and 13vPnC groups after each dose. The most frequently reported local reaction was pain at the injection site (32.2% to 58.1% in the 20vPnC group and 35.2% to 68.0% in the 13vPnC group). Most local reactions were mild or moderate in severity and generally resolved with median durations between 1 to 2 days in both groups, see the results in table below.

- The percentages of participants with prompted systemic events were generally similar in the 20vPnC and 13vPnC groups after each dose. The most frequently reported systemic events were irritability (18.6% to 66.1% in the 20vPnC group and 19.4% to 67.2% in the 13vPnC group) and drowsiness (6.8% to 32.3% in the 20vPnC group and 6.5% to 33.6% in the 13vPnC group). Most systemic events were mild or moderate in severity and generally resolved with median duration between 1 to 3 days and 1 to 5 days for 20vPnC and 13vPnC, respectively. The percentages of participants with any fever of $\geq 38.0^{\circ}\text{C}$ were similar in the 20vPnC (1.7% to 18.5%) and 13vPnC groups (2.8% to 15.2%), and fever of $>38.9^{\circ}\text{C}$ was reported infrequently.
- The percentages of participants with AEs were similar in the 20vPnC and 13vPnC groups from Dose 1 to 1 month after Dose 3 (16.8% vs 22.4%) and from Dose 4 to 1 month after Dose 4 (6.8% vs 3.7%). No safety concerns were identified.
- No SAEs were reported in the 20vPnC group after Dose 1. Two SAEs were reported in the 13vPnC group from Dose 1 to 1 month after Dose 3 and were assessed by the investigator as not related to study intervention.

Safety analysis from the participants from Site 1012 in the India Cohort did not demonstrate any new safety signal for the 20vPnC or 13vPnC profile.

Local Reactions

Table 10. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – India Participants (Excluding Site 1012) – Safety Population (Protocol B7471024)

Dose	Local Reaction	Vaccine Group (as Administered)					
		N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
Dose 1	Redness ^d						
	Any	124	11 (8.9)	(4.5, 15.3)	125	12 (9.6)	(5.1, 16.2)
	Mild	124	7 (5.6)	(2.3, 11.3)	125	10 (8.0)	(3.9, 14.2)
	Moderate	124	4 (3.2)	(0.9, 8.1)	125	2 (1.6)	(0.2, 5.7)
	Severe	124	0	(0.0, 2.9)	125	0	(0.0, 2.9)
	Swelling ^d						
	Any	124	15 (12.1)	(6.9, 19.2)	125	21 (16.8)	(10.7, 24.5)
	Mild	124	7 (5.6)	(2.3, 11.3)	125	15 (12.0)	(6.9, 19.0)
	Moderate	124	8 (6.5)	(2.8, 12.3)	125	6 (4.8)	(1.8, 10.2)
	Severe	124	0	(0.0, 2.9)	125	0	(0.0, 2.9)
	Pain at the injection site ^e						

Table 10. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – India Participants (Excluding Site 1012) – Safety Population (Protocol B7471024)

Dose	Local Reaction	Vaccine Group (as Administered)					
		20vPnC			13vPnC		
		N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
Dose 2	Any	124	72 (58.1)	(48.9, 66.9)	125	85 (68.0)	(59.1, 76.1)
	Mild	124	42 (33.9)	(25.6, 42.9)	125	50 (40.0)	(31.3, 49.1)
	Moderate	124	29 (23.4)	(16.3, 31.8)	125	33 (26.4)	(18.9, 35.0)
	Severe	124	1 (0.8)	(0.0, 4.4)	125	2 (1.6)	(0.2, 5.7)
	Any local reaction ^f	124	79 (63.7)	(54.6, 72.2)	125	88 (70.4)	(61.6, 78.2)
	Redness ^d						
	Any	121	7 (5.8)	(2.4, 11.6)	120	10 (8.3)	(4.1, 14.8)
	Mild	121	5 (4.1)	(1.4, 9.4)	120	10 (8.3)	(4.1, 14.8)
	Moderate	121	2 (1.7)	(0.2, 5.8)	120	0	(0.0, 3.0)
	Severe	121	0	(0.0, 3.0)	120	0	(0.0, 3.0)
	Swelling ^d						
	Any	121	16 (13.2)	(7.8, 20.6)	120	20 (16.7)	(10.5, 24.6)
	Mild	121	10 (8.3)	(4.0, 14.7)	120	16 (13.3)	(7.8, 20.7)
	Moderate	121	6 (5.0)	(1.8, 10.5)	120	4 (3.3)	(0.9, 8.3)
	Severe	121	0	(0.0, 3.0)	120	0	(0.0, 3.0)
	Pain at the injection site ^e						
	Any	121	61 (50.4)	(41.2, 59.6)	120	68 (56.7)	(47.3, 65.7)
	Mild	121	39 (32.2)	(24.0, 41.3)	120	42 (35.0)	(26.5, 44.2)
	Moderate	121	22 (18.2)	(11.8, 26.2)	120	26 (21.7)	(14.7, 30.1)
	Severe	121	0	(0.0, 3.0)	120	0	(0.0, 3.0)
	Any local reaction ^f	121	66 (54.5)	(45.2, 63.6)	120	74 (61.7)	(52.4, 70.4)
Dose 3	Redness ^d						
	Any	118	10 (8.5)	(4.1, 15.0)	120	11 (9.2)	(4.7, 15.8)
	Mild	118	8 (6.8)	(3.0, 12.9)	120	9 (7.5)	(3.5, 13.8)
	Moderate	118	2 (1.7)	(0.2, 6.0)	120	2 (1.7)	(0.2, 5.9)
	Severe	118	0	(0.0, 3.1)	120	0	(0.0, 3.0)
	Swelling ^d						
	Any	118	18 (15.3)	(9.3, 23.0)	120	11 (9.2)	(4.7, 15.8)
	Mild	118	11 (9.3)	(4.7, 16.1)	120	6 (5.0)	(1.9, 10.6)
	Moderate	118	7 (5.9)	(2.4, 11.8)	120	5 (4.2)	(1.4, 9.5)
	Severe	118	0	(0.0, 3.1)	120	0	(0.0, 3.0)
	Pain at the injection site ^e						
	Any	118	58 (49.2)	(39.8, 58.5)	120	60 (50.0)	(40.7, 59.3)
	Mild	118	45 (38.1)	(29.4, 47.5)	120	39 (32.5)	(24.2, 41.7)
	Moderate	118	13 (11.0)	(6.0, 18.1)	120	21 (17.5)	(11.2, 25.5)
	Severe	118	0	(0.0, 3.1)	120	0	(0.0, 3.0)
	Any local reaction ^f	118	62 (52.5)	(43.1, 61.8)	120	62 (51.7)	(42.4, 60.9)
Dose 4	Redness ^d						
	Any	118	1 (0.8)	(0.0, 4.6)	108	6 (5.6)	(2.1, 11.7)

Table 10. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – India Participants (Excluding Site 1012) – Safety Population (Protocol B7471024)

Dose	Local Reaction	Vaccine Group (as Administered)					
		20vPnC			13vPnC		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
	Mild	118	0	(0.0, 3.1)	108	5 (4.6)	(1.5, 10.5)
	Moderate	118	1 (0.8)	(0.0, 4.6)	108	1 (0.9)	(0.0, 5.1)
	Severe	118	0	(0.0, 3.1)	108	0	(0.0, 3.4)
	Swelling ^d						
	Any	118	3 (2.5)	(0.5, 7.3)	108	5 (4.6)	(1.5, 10.5)
	Mild	118	2 (1.7)	(0.2, 6.0)	108	4 (3.7)	(1.0, 9.2)
	Moderate	118	1 (0.8)	(0.0, 4.6)	108	1 (0.9)	(0.0, 5.1)
	Severe	118	0	(0.0, 3.1)	108	0	(0.0, 3.4)
	Pain at the injection site ^e						
	Any	118	38 (32.2)	(23.9, 41.4)	108	38 (35.2)	(26.2, 45.0)
	Mild	118	30 (25.4)	(17.9, 34.3)	108	33 (30.6)	(22.1, 40.2)
	Moderate	118	8 (6.8)	(3.0, 12.9)	108	5 (4.6)	(1.5, 10.5)
	Severe	118	0	(0.0, 3.1)	108	0	(0.0, 3.4)
	Any local reaction ^f	118	38 (32.2)	(23.9, 41.4)	108	43 (39.8)	(30.5, 49.7)

Note: Local reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. If a severe reaction was identified by the investigator as a Grade 4 reaction at a follow-up assessment, it was also reported as an adverse event.

a. N = number of participants with any e-diary data reported after the specified dose. This value is the denominator for the percentage calculations.

b. n = Number of participants with the specified characteristic.

c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.

d. Mild: >0.0 to 2.0 cm; moderate: >2.0 to 7.0 cm; severe: >7.0 cm.

e. Mild: hurts if gently touched; moderate: hurts if gently touched with crying; severe: causes limitation of limb movement.

f. Any local reaction: any redness >0.0 cm, any swelling >0.0 cm, any pain at the injection site.

PFIZER CONFIDENTIAL SDTM Creation: 13JAN2026 (03:33) Source Data: adfacevd Table Generation: 29APR2026 (06:07)

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Table 14.3.1.1.1 PF-06482077 is for Pfizer internal use.

Systemic Events

Table 11. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – India Participants (Excluding Site 1012) – Safety Population (Protocol B7471024)

Dose	Systemic Event	Vaccine Group (as Administered)					
		20vPnC			13vPnC		
		N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
Dose 1	Fever						
	≥38.0°C	124	23 (18.5)	(12.1, 26.5)	125	19 (15.2)	(9.4, 22.7)
	≥38.0°C to 38.4°C	124	17 (13.7)	(8.2, 21.0)	125	11 (8.8)	(4.5, 15.2)
	>38.4°C to 38.9°C	124	4 (3.2)	(0.9, 8.1)	125	7 (5.6)	(2.3, 11.2)
	>38.9°C to 40.0°C	124	2 (1.6)	(0.2, 5.7)	125	1 (0.8)	(0.0, 4.4)
	>40.0°C	124	0	(0.0, 2.9)	125	0	(0.0, 2.9)
	Decreased appetite ^d						
	Any	124	27 (21.8)	(14.9, 30.1)	125	31 (24.8)	(17.5, 33.3)
	Mild	124	18 (14.5)	(8.8, 22.0)	125	19 (15.2)	(9.4, 22.7)
	Moderate	124	9 (7.3)	(3.4, 13.3)	125	9 (7.2)	(3.3, 13.2)
	Severe	124	0	(0.0, 2.9)	125	3 (2.4)	(0.5, 6.9)
	Drowsiness ^e						
	Any	124	40 (32.3)	(24.1, 41.2)	125	42 (33.6)	(25.4, 42.6)
	Mild	124	19 (15.3)	(9.5, 22.9)	125	16 (12.8)	(7.5, 20.0)
	Moderate	124	20 (16.1)	(10.1, 23.8)	125	24 (19.2)	(12.7, 27.2)
	Severe	124	1 (0.8)	(0.0, 4.4)	125	2 (1.6)	(0.2, 5.7)
	Irritability ^f						
	Any	124	82 (66.1)	(57.1, 74.4)	125	84 (67.2)	(58.2, 75.3)
	Mild	124	45 (36.3)	(27.8, 45.4)	125	52 (41.6)	(32.9, 50.8)
	Moderate	124	35 (28.2)	(20.5, 37.0)	125	29 (23.2)	(16.1, 31.6)
	Severe	124	2 (1.6)	(0.2, 5.7)	125	3 (2.4)	(0.5, 6.9)
	Any systemic event ^g	124	99 (79.8)	(71.7, 86.5)	125	100 (80.0)	(71.9, 86.6)
Dose 2	Fever						
	≥38.0°C	121	14 (11.6)	(6.5, 18.7)	120	11 (9.2)	(4.7, 15.8)
	≥38.0°C to 38.4°C	121	12 (9.9)	(5.2, 16.7)	120	7 (5.8)	(2.4, 11.6)

Table 11. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – India Participants (Excluding Site 1012) – Safety Population (Protocol B7471024)

Dose	Systemic Event	Vaccine Group (as Administered)					
		20vPnC			13vPnC		
		N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
	>38.4°C to 38.9°C	121	1 (0.8)	(0.0, 4.5)	120	3 (2.5)	(0.5, 7.1)
	>38.9°C to 40.0°C	121	1 (0.8)	(0.0, 4.5)	120	1 (0.8)	(0.0, 4.6)
	>40.0°C	121	0	(0.0, 3.0)	120	0	(0.0, 3.0)
	Decreased appetite ^d						
	Any	121	16 (13.2)	(7.8, 20.6)	120	19 (15.8)	(9.8, 23.6)
	Mild	121	8 (6.6)	(2.9, 12.6)	120	16 (13.3)	(7.8, 20.7)
	Moderate	121	8 (6.6)	(2.9, 12.6)	120	3 (2.5)	(0.5, 7.1)
	Severe	121	0	(0.0, 3.0)	120	0	(0.0, 3.0)
	Drowsiness ^e						
	Any	121	26 (21.5)	(14.5, 29.9)	120	22 (18.3)	(11.9, 26.4)
	Mild	121	17 (14.0)	(8.4, 21.5)	120	16 (13.3)	(7.8, 20.7)
	Moderate	121	9 (7.4)	(3.5, 13.7)	120	6 (5.0)	(1.9, 10.6)
	Severe	121	0	(0.0, 3.0)	120	0	(0.0, 3.0)
	Irritability ^f						
	Any	121	66 (54.5)	(45.2, 63.6)	120	60 (50.0)	(40.7, 59.3)
	Mild	121	43 (35.5)	(27.0, 44.8)	120	35 (29.2)	(21.2, 38.2)
	Moderate	121	22 (18.2)	(11.8, 26.2)	120	25 (20.8)	(14.0, 29.2)
	Severe	121	1 (0.8)	(0.0, 4.5)	120	0	(0.0, 3.0)
	Any systemic event ^g	121	76 (62.8)	(53.6, 71.4)	120	69 (57.5)	(48.1, 66.5)
Dose 3	Fever						
	≥38.0°C	118	3 (2.5)	(0.5, 7.3)	120	4 (3.3)	(0.9, 8.3)
	≥38.0°C to 38.4°C	118	2 (1.7)	(0.2, 6.0)	120	3 (2.5)	(0.5, 7.1)
	>38.4°C to 38.9°C	118	1 (0.8)	(0.0, 4.6)	120	1 (0.8)	(0.0, 4.6)
	>38.9°C to 40.0°C	118	0	(0.0, 3.1)	120	0	(0.0, 3.0)
	>40.0°C	118	0	(0.0, 3.1)	120	0	(0.0, 3.0)
	Decreased appetite ^d						
	Any	118	12 (10.2)	(5.4, 17.1)	120	13 (10.8)	(5.9, 17.8)
	Mild	118	9 (7.6)	(3.5, 14.0)	120	11 (9.2)	(4.7, 15.8)
	Moderate	118	3 (2.5)	(0.5, 7.3)	120	2 (1.7)	(0.2, 5.9)
	Severe	118	0	(0.0, 3.1)	120	0	(0.0, 3.0)
	Drowsiness ^e						
	Any	118	24 (20.3)	(13.5, 28.7)	120	14 (11.7)	(6.5, 18.8)
	Mild	118	17 (14.4)	(8.6, 22.1)	120	8 (6.7)	(2.9, 12.7)
	Moderate	118	7 (5.9)	(2.4, 11.8)	120	6 (5.0)	(1.9, 10.6)
	Severe	118	0	(0.0, 3.1)	120	0	(0.0, 3.0)
	Irritability ^f						
	Any	118	55 (46.6)	(37.4, 56.0)	120	59 (49.2)	(39.9, 58.4)
	Mild	118	36 (30.5)	(22.4, 39.7)	120	41 (34.2)	(25.8, 43.4)
	Moderate	118	18 (15.3)	(9.3, 23.0)	120	18 (15.0)	(9.1, 22.7)
	Severe	118	1 (0.8)	(0.0, 4.6)	120	0	(0.0, 3.0)

Table 11. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – India Participants (Excluding Site 1012) – Safety Population (Protocol B7471024)

Dose	Systemic Event	Vaccine Group (as Administered)					
		N ^a	20vPnC		N ^a	13vPnC	
			n ^b (%)	(95% CI) ^c		n ^b (%)	(95% CI) ^c
Dose 4	Any systemic event ^g	118	65 (55.1)	(45.7, 64.3)	120	62 (51.7)	(42.4, 60.9)
	Fever						
	≥38.0°C	118	2 (1.7)	(0.2, 6.0)	108	3 (2.8)	(0.6, 7.9)
	≥38.0°C to 38.4°C	118	1 (0.8)	(0.0, 4.6)	108	1 (0.9)	(0.0, 5.1)
	>38.4°C to 38.9°C	118	1 (0.8)	(0.0, 4.6)	108	1 (0.9)	(0.0, 5.1)
	>38.9°C to 40.0°C	118	0	(0.0, 3.1)	108	1 (0.9)	(0.0, 5.1)
	>40.0°C	118	0	(0.0, 3.1)	108	0	(0.0, 3.4)
	Decreased appetite ^d						
	Any	118	10 (8.5)	(4.1, 15.0)	108	11 (10.2)	(5.2, 17.5)
	Mild	118	7 (5.9)	(2.4, 11.8)	108	6 (5.6)	(2.1, 11.7)
	Moderate	118	3 (2.5)	(0.5, 7.3)	108	5 (4.6)	(1.5, 10.5)
	Severe	118	0	(0.0, 3.1)	108	0	(0.0, 3.4)
	Drowsiness ^e						
	Any	118	8 (6.8)	(3.0, 12.9)	108	7 (6.5)	(2.6, 12.9)
	Mild	118	6 (5.1)	(1.9, 10.7)	108	4 (3.7)	(1.0, 9.2)
	Moderate	118	2 (1.7)	(0.2, 6.0)	108	3 (2.8)	(0.6, 7.9)
	Severe	118	0	(0.0, 3.1)	108	0	(0.0, 3.4)
	Irritability ^f						
	Any	118	22 (18.6)	(12.1, 26.9)	108	21 (19.4)	(12.5, 28.2)
Mild	118	18 (15.3)	(9.3, 23.0)	108	13 (12.0)	(6.6, 19.7)	
Moderate	118	4 (3.4)	(0.9, 8.5)	108	8 (7.4)	(3.3, 14.1)	
Severe	118	0	(0.0, 3.1)	108	0	(0.0, 3.4)	
Any systemic event ^g	118	33 (28.0)	(20.1, 37.0)	108	27 (25.0)	(17.2, 34.3)	

Note: Systemic events were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. If a severe event was identified by the investigator as a Grade 4 event at a follow-up assessment, it was also reported as an adverse event.

a. N = number of participants with any e-diary data reported after the specified dose. This value is the denominator for the percentage calculations.

b. n = Number of participants with the specified characteristic.

c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.

d. Mild: decreased interest in eating; moderate: decreased oral intake; severe: refusal to feed.

e. Mild: increased or prolonged sleeping bouts; moderate: slightly subdued interfering with daily activity; severe: disabling not interested in usual daily activity.

f. Mild: easily consolable; moderate: requiring increased attention; severe: inconsolable; crying cannot be comforted.

g. Any systemic event: any fever ≥38.0°C, any decreased appetite, any drowsiness, any irritability after the specified dose.

PFIZER CONFIDENTIAL SDTM Creation: 13JAN2026 (03:33) Source Data: adfacevd Table Generation: 29APR2026 (06:41)

(Database snapshot date : 09JAN2026) Output File: /nda1/B7471024_INDIA_CSR/adce_s020_se_maxsev_wtt1012

Table 14.3.1.2.1 PF-06482077 is for Pfizer internal use.

In the Taiwan Cohort,

- The percentages of participants with prompted local reactions were generally similar in the 20vPnC and 13vPnC groups after each dose. The most frequently reported local reaction was swelling (9.6% to 27.8% in the 20vPnC group and 15.6% to 30.2% in the 13vPnC group). Most local reactions

were mild or moderate in severity and generally resolved with median durations between 1 and 6 days in the 20vPnC group and 1 and 4 days in the 13vPnC group, see the results in table below.

- The percentages of participants with prompted systemic events were generally similar in both the 20vPnC and 13vPnC groups after each dose. The most frequently reported systemic events were irritability (31.1% to 43.0% in the 20vPnC group and 35.1% to 46.9% in the 13vPnC group) and drowsiness (23.3% to 52.1% in the 20vPnC group and 33.0% to 50.0% in the 13vPnC group). Most systemic events were mild or moderate in severity and generally resolved with median durations between 1 to 3 days. The percentages of participants with any fever of $\geq 38.0^{\circ}\text{C}$ were similar in the 20vPnC (4.3% to 15.6%) and 13vPnC groups (6.3% to 13.8%), and fever of $>38.9^{\circ}\text{C}$ was reported infrequently.
- The percentages of participants with AEs were similar in the 20vPnC and 13vPnC groups from Dose 1 to 1 month after Dose 3 (46.8% vs 45.8%) and from Dose 4 to 1 month after Dose 4 (12.2% vs 17.0%). No safety concerns were identified.
- The percentages of participants with SAEs from Dose 1 to 1 month after Dose 4 were similar in the 20vPnC and 13vPnC groups (19.1% vs 12.5%). All SAEs were assessed by the investigator as not related to study intervention.

Local Reactions

Table 10. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered)					
		N ^a	20vPnC n ^b (%) (95% CI ^c)	N ^a	13vPnC n ^b (%) (95% CI ^c)		
Dose 1	Redness ^d						
	Any	94	16 (17.0) (10.1, 26.2)	96	15 (15.6) (9.0, 24.5)		
	Mild	94	13 (13.8) (7.6, 22.5)	96	12 (12.5) (6.6, 20.8)		
	Moderate	94	3 (3.2) (0.7, 9.0)	96	3 (3.1) (0.6, 8.9)		
	Severe	94	0 (0.0, 3.8)	96	0 (0.0, 3.8)		
	Swelling ^d						
	Any	94	9 (9.6) (4.5, 17.4)	96	15 (15.6) (9.0, 24.5)		
	Mild	94	9 (9.6) (4.5, 17.4)	96	12 (12.5) (6.6, 20.8)		
	Moderate	94	0 (0.0, 3.8)	96	3 (3.1) (0.6, 8.9)		
	Severe	94	0 (0.0, 3.8)	96	0 (0.0, 3.8)		
	Pain at injection site ^e						
	Any	94	18 (19.1) (11.8, 28.6)	96	17 (17.7) (10.7, 26.8)		
	Mild	94	13 (13.8) (7.6, 22.5)	96	9 (9.4) (4.4, 17.1)		
	Moderate	94	5 (5.3) (1.7, 12.0)	96	8 (8.3) (3.7, 15.8)		
	Severe	94	0 (0.0, 3.8)	96	0 (0.0, 3.8)		
	Any local reaction ^f	94	28 (29.8) (20.8, 40.1)	96	29 (30.2) (21.3, 40.4)		
Dose 2	Redness ^d						
	Any	93	27 (29.0) (20.1, 39.4)	96	24 (25.0) (16.7, 34.9)		
	Mild	93	23 (24.7) (16.4, 34.8)	96	16 (16.7) (9.8, 25.6)		
	Moderate	93	4 (4.3) (1.2, 10.6)	96	7 (7.3) (3.0, 14.4)		
	Severe	93	0 (0.0, 3.9)	96	1 (1.0) (0.0, 5.7)		
	Swelling ^d						
	Any	93	23 (24.7) (16.4, 34.8)	96	22 (22.9) (15.0, 32.6)		
	Mild	93	18 (19.4) (11.9, 28.9)	96	15 (15.6) (9.0, 24.5)		
	Moderate	93	5 (5.4) (1.8, 12.1)	96	7 (7.3) (3.0, 14.4)		
	Severe	93	0 (0.0, 3.9)	96	0 (0.0, 3.8)		
	Pain at injection site ^e						
	Any	93	22 (23.7) (15.5, 33.6)	96	22 (22.9) (15.0, 32.6)		
	Mild	93	16 (17.2) (10.2, 26.4)	96	13 (13.5) (7.4, 22.0)		
	Moderate	93	6 (6.5) (2.4, 13.5)	96	9 (9.4) (4.4, 17.1)		
	Severe	93	0 (0.0, 3.9)	96	0 (0.0, 3.8)		
	Any local reaction ^f	93	40 (43.0) (32.8, 53.7)	96	37 (38.5) (28.8, 49.0)		
Dose 3	Redness ^d						
	Any	92	24 (26.1) (17.5, 36.3)	96	23 (24.0) (15.8, 33.7)		
	Mild	92	18 (19.6) (12.0, 29.1)	96	17 (17.7) (10.7, 26.8)		
	Moderate	92	6 (6.5) (2.4, 13.7)	96	6 (6.3) (2.3, 13.1)		
	Severe	92	0 (0.0, 3.9)	96	0 (0.0, 3.8)		
	Swelling ^d						
	Any	92	20 (21.7) (13.8, 31.6)	96	29 (30.2) (21.3, 40.4)		
	Mild	92	13 (14.1) (7.7, 23.0)	96	22 (22.9) (15.0, 32.6)		

Table 10. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered)					
		20vPnC			13vPnC		
		N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
	Moderate	92	7 (7.6)	(3.1, 15.1)	96	7 (7.3)	(3.0, 14.4)
	Severe	92	0	(0.0, 3.9)	96	0	(0.0, 3.8)
	Pain at injection site ^a						
	Any	92	16 (17.4)	(10.3, 26.7)	96	22 (22.9)	(15.0, 32.6)
	Mild	92	13 (14.1)	(7.7, 23.0)	96	16 (16.7)	(9.8, 25.6)
	Moderate	92	3 (3.3)	(0.7, 9.2)	96	6 (6.3)	(2.3, 13.1)
	Severe	92	0	(0.0, 3.9)	96	0	(0.0, 3.8)
	Any local reaction ^f	92	35 (38.0)	(28.1, 48.8)	96	35 (36.5)	(26.9, 46.9)
Dose 4	Redness ^d						
	Any	90	21 (23.3)	(15.1, 33.4)	94	16 (17.0)	(10.1, 26.2)
	Mild	90	10 (11.1)	(5.5, 19.5)	94	12 (12.8)	(6.8, 21.2)
	Moderate	90	11 (12.2)	(6.3, 20.8)	94	4 (4.3)	(1.2, 10.5)
	Severe	90	0	(0.0, 4.0)	94	0	(0.0, 3.8)
	Swelling ^d						
	Any	90	25 (27.8)	(18.9, 38.2)	94	17 (18.1)	(10.9, 27.4)
	Mild	90	13 (14.4)	(7.9, 23.4)	94	15 (16.0)	(9.2, 25.0)
	Moderate	90	12 (13.3)	(7.1, 22.1)	94	2 (2.1)	(0.3, 7.5)
	Severe	90	0	(0.0, 4.0)	94	0	(0.0, 3.8)
	Pain at injection site ^a						
	Any	90	20 (22.2)	(14.1, 32.2)	94	12 (12.8)	(6.8, 21.2)
	Mild	90	18 (20.0)	(12.3, 29.8)	94	11 (11.7)	(6.0, 20.0)
	Moderate	90	2 (2.2)	(0.3, 7.8)	94	1 (1.1)	(0.0, 5.8)
	Severe	90	0	(0.0, 4.0)	94	0	(0.0, 3.8)
	Any local reaction ^f	90	33 (36.7)	(26.8, 47.5)	94	24 (25.5)	(17.1, 35.6)

Note: Local reactions were collected in the e-diary from Day 1 through Day 7 after each dose. If a severe reaction was identified by the investigator as a Grade 4 reaction at a follow-up assessment, it was also reported as an adverse event.

a. N = number of participants with any e-diary data reported after the specified dose. This value is the denominator for the percentage calculations.

b. n = Number of participants with the specified characteristic.

c. Exact 2-sided CI, based on the Clopper and Pearson method.

d. Mild: >0.0 to 2.0 cm; moderate: >2.0 to 7.0 cm; severe: >7.0 cm.

e. Mild: hurts if gently touched; moderate: hurts if gently touched with crying; severe: causes limitation of limb movement.

f. Any local reaction: any redness >0.0 cm, any swelling >0.0 cm, any pain at the injection site.

PFIZER CONFIDENTIAL SDTM Creation: 18APR2024 (09:55) Source Data: adfacevd Table Generation: 15MAY2024 (07:52)

Output File: /nda1/B7471024_CSR_TWN/adce_s010_lr_maxsev

Systemic Events

Table 11. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered)					
		20vPnC			13vPnC		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
Dose 1	Fever						
	≥38.0°C	94	4 (4.3)	(1.2, 10.5)	96	6 (6.3)	(2.3, 13.1)
	≥38.0°C to 38.4°C	94	2 (2.1)	(0.3, 7.5)	96	5 (5.2)	(1.7, 11.7)
	>38.4°C to 38.9°C	94	2 (2.1)	(0.3, 7.5)	96	1 (1.0)	(0.0, 5.7)
	>38.9°C to 40.0°C	94	0	(0.0, 3.8)	96	0	(0.0, 3.8)
	>40.0°C	94	0	(0.0, 3.8)	96	0	(0.0, 3.8)
	Decreased appetite ^d						
	Any	94	30 (31.9)	(22.7, 42.3)	96	27 (28.1)	(19.4, 38.2)
	Mild	94	10 (10.6)	(5.2, 18.7)	96	12 (12.5)	(6.6, 20.8)
	Moderate	94	20 (21.3)	(13.5, 30.9)	96	14 (14.6)	(8.2, 23.3)
	Severe	94	0	(0.0, 3.8)	96	1 (1.0)	(0.0, 5.7)
	Drowsiness ^e						
	Any	94	49 (52.1)	(41.6, 62.5)	96	46 (47.9)	(37.6, 58.4)
	Mild	94	42 (44.7)	(34.4, 55.3)	96	41 (42.7)	(32.7, 53.2)
	Moderate	94	7 (7.4)	(3.0, 14.7)	96	4 (4.2)	(1.1, 10.3)
	Severe	94	0	(0.0, 3.8)	96	1 (1.0)	(0.0, 5.7)
	Irritability ^f						
	Any	94	40 (42.6)	(32.4, 53.2)	96	39 (40.6)	(30.7, 51.1)
	Mild	94	14 (14.9)	(8.4, 23.7)	96	13 (13.5)	(7.4, 22.0)
	Moderate	94	21 (22.3)	(14.4, 32.1)	96	24 (25.0)	(16.7, 34.9)
	Severe	94	5 (5.3)	(1.7, 12.0)	96	2 (2.1)	(0.3, 7.3)
	Any systemic event ^g	94	64 (68.1)	(57.7, 77.3)	96	67 (69.8)	(59.6, 78.7)
Dose 2	Fever						
	≥38.0°C	93	14 (15.1)	(8.5, 24.0)	96	11 (11.5)	(5.9, 19.6)
	≥38.0°C to 38.4°C	93	8 (8.6)	(3.8, 16.2)	96	8 (8.3)	(3.7, 15.8)
	>38.4°C to 38.9°C	93	4 (4.3)	(1.2, 10.6)	96	2 (2.1)	(0.3, 7.3)
	>38.9°C to 40.0°C	93	1 (1.1)	(0.0, 5.8)	96	1 (1.0)	(0.0, 5.7)
	>40.0°C	93	1 (1.1)	(0.0, 5.8)	96	0	(0.0, 3.8)
	Decreased appetite ^d						
	Any	93	34 (36.6)	(26.8, 47.2)	96	29 (30.2)	(21.3, 40.4)
	Mild	93	20 (21.5)	(13.7, 31.2)	96	8 (8.3)	(3.7, 15.8)
	Moderate	93	13 (14.0)	(7.7, 22.7)	96	21 (21.9)	(14.1, 31.5)
	Severe	93	1 (1.1)	(0.0, 5.8)	96	0	(0.0, 3.8)
	Drowsiness ^e						
	Any	93	45 (48.4)	(37.9, 59.0)	96	48 (50.0)	(39.6, 60.4)
	Mild	93	38 (40.9)	(30.8, 51.5)	96	42 (43.8)	(33.6, 54.3)
	Moderate	93	7 (7.5)	(3.1, 14.9)	96	6 (6.3)	(2.3, 13.1)
	Severe	93	0	(0.0, 3.9)	96	0	(0.0, 3.8)
	Irritability ^f						
	Any	93	40 (43.0)	(32.8, 53.7)	96	45 (46.9)	(36.6, 57.3)
	Mild	93	13 (14.0)	(7.7, 22.7)	96	11 (11.5)	(5.9, 19.6)
	Moderate	93	24 (25.8)	(17.3, 35.9)	96	30 (31.3)	(22.2, 41.5)
	Severe	93	3 (3.2)	(0.7, 9.1)	96	4 (4.2)	(1.1, 10.3)
	Any systemic event ^g	93	69 (74.2)	(64.1, 82.7)	96	70 (72.9)	(62.9, 81.5)
Dose 3	Fever						
	≥38.0°C	92	7 (7.6)	(3.1, 15.1)	96	13 (13.5)	(7.4, 22.0)
	≥38.0°C to 38.4°C	92	4 (4.3)	(1.2, 10.8)	96	8 (8.3)	(3.7, 15.8)
	>38.4°C to 38.9°C	92	3 (3.3)	(0.7, 9.2)	96	3 (3.1)	(0.6, 8.9)
	>38.9°C to 40.0°C	92	0	(0.0, 3.9)	96	2 (2.1)	(0.3, 7.3)
	>40.0°C	92	0	(0.0, 3.9)	96	0	(0.0, 3.8)
	Decreased appetite ^d						
	Any	92	22 (23.9)	(15.6, 33.9)	96	25 (26.0)	(17.6, 36.0)
	Mild	92	15 (16.3)	(9.4, 25.5)	96	12 (12.5)	(6.6, 20.8)
	Moderate	92	7 (7.6)	(3.1, 15.1)	96	13 (13.5)	(7.4, 22.0)
	Severe	92	0	(0.0, 3.9)	96	0	(0.0, 3.8)
	Drowsiness ^e						
	Any	92	33 (35.9)	(26.1, 46.5)	96	36 (37.5)	(27.8, 48.0)

Table 11. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered)					
		20vPnC			13vPnC		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
	Mild	92	29 (31.5)	(22.2, 42.0)	96	29 (30.2)	(21.3, 40.4)
	Moderate	92	4 (4.3)	(1.2, 10.8)	96	7 (7.3)	(3.0, 14.4)
	Severe	92	0	(0.0, 3.9)	96	0	(0.0, 3.8)
	Irritability ^f						
	Any	92	38 (41.3)	(31.1, 52.1)	96	37 (38.5)	(28.8, 49.0)
	Mild	92	13 (14.1)	(7.7, 23.0)	96	9 (9.4)	(4.4, 17.1)
	Moderate	92	23 (25.0)	(16.6, 35.1)	96	27 (28.1)	(19.4, 38.2)
	Severe	92	2 (2.2)	(0.3, 7.6)	96	1 (1.0)	(0.0, 5.7)
	Any systemic event ^g	92	61 (66.3)	(55.7, 75.8)	96	64 (66.7)	(56.3, 76.0)
Dose 4	Fever						
	≥38.0°C	90	14 (15.6)	(8.8, 24.7)	94	13 (13.8)	(7.6, 22.5)
	≥38.0°C to 38.4°C	90	7 (7.8)	(3.2, 15.4)	94	8 (8.5)	(3.7, 16.1)
	>38.4°C to 38.9°C	90	6 (6.7)	(2.5, 13.9)	94	4 (4.3)	(1.2, 10.5)
	>38.9°C to 40.0°C	90	1 (1.1)	(0.0, 6.0)	94	1 (1.1)	(0.0, 5.8)
	>40.0°C	90	0	(0.0, 4.0)	94	0	(0.0, 3.8)
	Decreased appetite ^d						
	Any	90	18 (20.0)	(12.3, 29.8)	94	19 (20.2)	(12.6, 29.8)
	Mild	90	7 (7.8)	(3.2, 15.4)	94	11 (11.7)	(6.0, 20.0)
	Moderate	90	11 (12.2)	(6.3, 20.8)	94	7 (7.4)	(3.0, 14.7)
	Severe	90	0	(0.0, 4.0)	94	1 (1.1)	(0.0, 5.8)
	Drowsiness ^e						
	Any	90	21 (23.3)	(15.1, 33.4)	94	31 (33.0)	(23.6, 43.4)
	Mild	90	19 (21.1)	(13.2, 31.0)	94	26 (27.7)	(18.9, 37.8)
	Moderate	90	2 (2.2)	(0.3, 7.8)	94	5 (5.3)	(1.7, 12.0)
	Severe	90	0	(0.0, 4.0)	94	0	(0.0, 3.8)
	Irritability ^f						
	Any	90	28 (31.1)	(21.8, 41.7)	94	33 (35.1)	(25.5, 45.6)
	Mild	90	13 (14.4)	(7.9, 23.4)	94	18 (19.1)	(11.8, 28.6)
	Moderate	90	15 (16.7)	(9.6, 26.0)	94	13 (13.8)	(7.6, 22.5)
	Severe	90	0	(0.0, 4.0)	94	2 (2.1)	(0.3, 7.5)
	Any systemic event ^g	90	45 (50.0)	(39.3, 60.7)	94	54 (57.4)	(46.8, 67.6)

Note: Systemic events and use of antipyretic or pain medication were collected in the e-diary from Day 1 through Day 7 after each dose. If a severe event was identified by the investigator as a Grade 4 event at a follow-up assessment, it was also reported as an adverse event.

a. N = number of participants with any e-diary data reported after the specified dose. This value is the denominator for the percentage calculations.

b. n = Number of participants with the specified characteristic.

c. Exact 2-sided CI, based on the Clopper and Pearson method.

d. Mild: decreased interest in eating; moderate: decreased oral intake; severe: refusal to feed.

e. Mild: increased or prolonged sleeping bouts; moderate: slightly subdued interfering with daily activity; severe: disabling not interested in usual daily activity.

f. Mild: easily consolable; moderate: requiring increased attention; severe: inconsolable; crying cannot be comforted.

g. Any systemic event: any fever ≥38.0°C, any decreased appetite, any drowsiness, or any irritability.

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Discussion on clinical aspects

The study Study B7471024 was conducted to support licensure for this population in India and Taiwan, respectively. The study used 13vPnC as an active comparator and, as a result, the results for Study

B7471024 are being submitted according to Article 46, though the intent of the study is to support the clinical development and licensure of 20vPnC outside Europe. In Indian and Taiwanese infants, 20vPnC was observed to have a tolerability and safety profile similar to that of 13vPnC. The 4-dose series of 20vPnC elicits robust immune responses that are expected to provide protection against pneumococcal disease due to the 20 serotypes in Indian and Taiwanese infants.

Safety and immunogenicity results with 13vPnC from this study are consistent with the known profile of 13vPnC as reflected in the EU SmPC and support the continued use of 13vPnC. The submitted study does not change the benefit-risk balance for Prevenar 13.

3. CHMP overall conclusion and recommendation

The study confirms what is already known about immune responses and safety of Prevenar 13. No changes are being proposed to the Prevenar 13 label in this submission and this is acceptable. The P46 procedure is considered fulfilled.

☒ **Fulfilled:**

No regulatory action required.