Initial Approval: 30 December 2019
Last Revision: 20 January 2021

Package Insert
13-valent Pneumococcal Polysaccharide Conjugate Vaccine

Please read the package insert carefully and follow the physician's guidance to use.

1 PRODUCT NAME

Trade Name: **WEUPHORIA**
Generic Name: 13-valent Pneumococcal Polysaccharide Conjugate Vaccine

2 PRODUCT DESCRIPTION

The 13-valent Pneumococcal Polysaccharide Conjugate Vaccine (PCV13-TT) is formulated by compounding the capsular polysaccharide antigen of *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F, individually conjugated to tetanus toxoid carrier protein. The individual polysaccharides are extracted from the cultures of *Streptococcus pneumoniae*, and purified through centrifugation, precipitation, and ultrafiltration. The polysaccharides are chemically activated and derivatized, and then conjugated to tetanus toxoid carrier protein to form the glycoconjugate, with aluminum phosphate as the adjuvant. The vaccine should be shaken well to obtain a homogeneous milky white suspension. During storage, a white deposit and clear supernatant might be observed due to adjuvant precipitation.

Active substances: capsular polysaccharides of *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F conjugated to tetanus toxoid carrier protein.

Excipients: sodium chloride, sodium dihydrogen phosphate, disodium hydrogen phosphate, and aluminum phosphate.

3 ELIGIBLES

The vaccine is indicated for use in infants and children 6 weeks through 5 years of age (before the 6th birthday).

4 INDICATION

The vaccine elicits immune responses in recipients following immunization, and is indicated for the prevention of invasive diseases caused by 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) of *Streptococcus pneumoniae*.

The vaccine does not protect against diseases caused by *Streptococcus pneumoniae* serotypes that are not contained in the vaccine.

5 NAME AND STRENGTH OF ACTIVE SUBSTANCES

The vaccine is supplied as 0.5 mL/vial or in a single-dose pre-filled syringe with 0.5 mL suspension for intramuscular injection. Each dose (0.5 mL) of the vaccine contains:

Pneumococcal polysaccharide serotype 1	2.6 μg	Pneumococcal polysaccharide serotype 14	2.75 μg
Pneumococcal polysaccharide serotype 3	2.5 μg	Pneumococcal polysaccharide serotype 18C	3.25 μg
Pneumococcal polysaccharide serotype 4	3.0 μg	Pneumococcal polysaccharide serotype 19A	2.6 μg
Pneumococcal polysaccharide serotype 5	2.5 μg	Pneumococcal polysaccharide serotype 19F	2.75 μg
Pneumococcal polysaccharide serotype 6A	2.5 μg	Pneumococcal polysaccharide serotype 23F	3.0 μg
Pneumococcal polysaccharide serotype 7F	2.85 μg	Pneumococcal polysaccharide serotype 6B	6.0 μg
Pneumococcal polysaccharide serotype 9V	2.5 μg		

6 DOSAGE AND ADMINISTRATION

Since this product is a suspension containing an adjuvant, shake vigorously immediately prior to use to obtain a homogenous, white suspension in the vaccine container. This product is for intramuscular injection only. The preferred sites for injection are the anterolateral aspect of the thigh in infants and the deltoid muscle of the upper arm in toddlers and children. The injection volume is 0.5 mL for each single human dose. The vaccine should not be injected in and/or near the areas where nerve trunks and/or blood vessels may locate.

Vaccination schedules for infants and toddlers

The product is to be administered as a four-dose series at 2, 4, 6, and 12-15 months of age or 3, 4, 5, and 12-15 months of age, respectively, as described in Table 1 and Table 2.

Table 1 Vaccination Schedule for Infants 2 Months of Age

Dose	Dose 1[a,b]	Dose 2[b]	Dose 3[b]	Dose 4[c]
Age at Dose	2 months	4 months	6 months	12-15 months

a Dose 1 may be given as early as 6 weeks of age.
b The recommended dosing interval is 8 weeks.
c The fourth dose should be administered at approximately 12-15 months of age, and at least 2 months after the third dose.

Table 2 Vaccination Schedule for Infants 3 Months of Age

Dose	Dose 1[a]	Dose 2[a]	Dose 3[a]	Dose 4[b]
Age at Dose	3 months	4 months	5 months	12-15 months

a The recommended dosing interval is 4 weeks.
b The fourth dose should be administered at approximately 12-15 months of age, and at least 2 months after the third dose.

For children 7 months through 5 years of age who have not received the product, the catch-up schedule in Table 3 applies:

Table 3 Vaccination Schedule for Infants and Toddlers 7 Months through 5 Years of Age

Age at First Dose	Total Number of 0.5 mL Doses
7-11 months of age	3[a]
12-23 months of age	2[b]
24 months through 5 years of age (prior to the 6th birthday)	1

a The first 2 doses at least 4 weeks apart; the third dose after the one-year birthday, separated from the second dose by at least 2 months.
b Two doses at least 2 months apart.

7 ADVERSE REACTIONS

7.1 Clinical Trials for PCV13-TT

Two clinical trials (phase I and III) of the vaccine (PCV13-TT) were conducted in China, including 120 and 2760 subjects, respectively; among all subjects (2880), 1754 had been vaccinated with at least one dose of PCV13-TT. The safety observations were conducted in a systematic fashion for all subjects, starting from the first dose of vaccination, and the safety observation lasted for 30 days post each dose of vaccination. For a majority of subjects excluding the dropout, the long-term safety observation period started from the first vaccination till 180 days post the last dose of vaccination (after complete series).

7.1.1 Summary

The incidence rates of adverse reactions reported in clinical trials, according to the guidance on classifications of adverse events recommended by The Council for International Organizations of Medical Sciences (CIOMS), are classified as: very common (⩾ 10%), common (⩾ 1% to < 10%), uncommon (⩾ 0.1% to < 1%), rare (⩾ 0.01% to < 0.1%) and very rare (< 0.01%). The safety data for the primary series of PCV13-TT collected from both phase I and phase III clinical trials of all subjects are summarized as follows:

(1)Systemic adverse reactions
Very common: fever, diarrhea
Common: crying, cough, nausea/vomiting, fatigue/somnolence, allergic reaction
Uncommon: myalgia

(2)Local adverse reactions
Very common: redness
Common: swelling, pain, induration
Uncommon: itching
Rare: rash (vaccination site)

(3)Serious adverse reactions
One case of serious adverse event (SAE) was reported during the primary series in the 3-month age group. This SAE was reported to be fever and considered to be possibly related to PCV13-TT. Other serious adverse events were adjudicated to be irrelevant to PCV13-TT.

7.1.2 Adverse Reactions in Phase III Clinical Trial

(1)The incidence rates and severity of solicited adverse reactions

The incidence rates and severity of solicited adverse reactions post primary and booster immunization in phase III clinical trial of PCV13-TT comparing to the comparator vaccine (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein], referred to as Prevnar®) are summarized in Table 4 and Table 5.

Table 4 Incidence Rates of Solicited Local Adverse Reactions in Phase III Clinical Trial in China

Symptoms and Grading of Local Adverse Reactions	3, 4, 5 and 12 Months		2[a], 4, 6 and 12 Months	7-11 Months		12-23 Months		2-5 Years	
	PCV13-TT	Prevnar®	PCV13-TT	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®
	N*=488-519	N*=493-519	N*= 487-517	N*=186-198	N*=191-200	N*= 200	N*=200	N*= 200	N*=200
	%[b]	%[b]	%[b]	%[b]	%[b]	%	%	%	%
Pain									
Any	0.20-2.31	0.00-1.93	0.21-1.93	0.54-7.07	0.52-3.50	5.00	1.50	9.50	10.00
Grade 1[d]	0.20-2.31	0.00-1.93	0.21-1.55	0.54-6.57	0.52-3.50	5.00	1.00	9.50	9.50
Grade 2[d]	0.00	0.00	0.00-0.39	0.00-0.51	0.00	0.00	0.50	0.00	0.50
Grade 3[d]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Redness									
Any	1.02-10.60	0.61-13.68	0.41-7.93	0.54-16.67	1.05-12.50	8.00	7.00	9.50	8.00
Grade 1[c]	0.20-6.74	0.20-8.67	0.21-5.42	0.00-9.09	1.05-11.50	4.50	3.50	4.50	5.00
Grade 2[c]	0.61-3.08	0.41-5.78	0.21-2.32	0.54-5.56	0.00-1.00	1.50	2.50	3.00	1.50
Grade 3[c]	0.20-1.16	0.00-0.19	0.00-0.19	0.00-2.02	0.00	2.00	1.00	2.00	1.50
Swelling									
Any	0.82-1.93	0.41-3.47	0.62-3.29	1.61-7.58	1.05-3.50	6.50	3.00	12.50	8.00
Grade 1[c]	0.20-0.77	0.20-2.31	0.62-1.93	1.08-1.52	1.05-3.00	1.50	1.50	4.50	4.00
Grade 2[c]	0.41-0.96	0.20-1.16	0.00-1.35	0.54-4.55	0.00-0.50	3.00	1.00	4.50	2.50
Grade 3[c]	0.20-0.39	0.00-0.19	0.00-0.19	0.00-1.52	0.00	2.00	0.50	3.50	1.50
Induration									
Any	0.20-2.89	0.00-3.47	0.00-2.71	0.00-3.03	0.00-0.50	0.50	0.50	2.50	0.50
Grade 1[c]	0.00-0.58	0.00-1.73	0.00-1.55	0.00-1.52	0.00-0.50	0.50	0.00	1.00	0.50
Grade 2[c]	0.20-1.93	0.00-1.35	0.00-1.35	0.00-0.51	0.00	0.00	0.50	1.50	0.00
Grade 3[c]	0.00-0.58	0.00-0.39	0.00	0.00-1.01	0.00	0.00	0.00	0.00	0.00
Itching									
Any	0.00-0.39	0.00-0.39	0.00	0.00-0.51	0.00-0.50	1.00	0.00	5.00	1.00
Grade 1[e]	0.00-0.39	0.00-0.39	0.00	0.00-0.51	0.00-0.50	1.00	0.00	5.00	1.00
Grade 2[e]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Grade 3[e]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Rash (vaccination site)									
Any	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00
Grade 1[c]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Grade 2[c]	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00
Grade 3[c]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Any local reactions	1.64-13.49	0.61-15.61	1.03-10.44	2.15-21.21	2.09-14.50	10.50	9.00	21.00	18.00
Grade 1	0.41-8.48	0.20-11.18	0.82-7.54	1.61-16.67	2.09-13.50	9.50	5.50	17.00	15.00
Grade 2	1.23-4.82	0.41-6.17	0.21-4.06	0.54-8.59	0.00-1.50	3.50	3.50	7.00	4.00
Grade 3	0.20-1.54	0.00-0.58	0.00-0.39	0.00-3.54	0.00	2.50	1.00	4.00	1.50

* N=number of subjects reporting "yes" for at least 1 day, or "no" for all 30 days.
a. Minimum age: 6 weeks.
b. The minimum and maximum incidence rates for local adverse reactions after primary and booster immunizations.
c. Grade 1, < 15 mm; grade 2, 15-30 mm; grade 3, > 30 mm.
d. Grade 1, not affecting activities; grade 2, affecting activities or multiple use of non-narcotic analgesics; grade 3, affecting daily activities or multiple use of narcotic analgesics.
e. Grade 1, mild itching in vaccination site; grade 2, moderate itching in limbs with vaccination; grade 3, systemic itching.

Table 5 Incidence Rates of Solicited Systemic Adverse Reactions in Phase III Clinical Trial in China

Symptoms and Grading of Systemic Adverse Reactions	3, 4, 5 and 12 Months		2[a], 4, 6 and 12 Months	7-11 Months		12-23 Months		2-5 Years	
	PCV13-TT	Prevnar®	PCV13-TT	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®
	N*=488-519	N*=493-519	N*=487-517	N*=186-198	N*=191-200	N*= 200	N*=200	N*=200	N*=200
	%[b]	%[b]	%[b]	%[b]	%[b]	%	%	%	%
Fever									
Any	28.07-58.00	27.38-66.28	21.56-61.12	20.43-53.54	20.94-61.50	41.50	44.00	20.50	23.50
Grade 1[#]	17.01-48.17	18.05-57.61	15.40-52.22	11.83-35.86	13.09-41.00	30.00	29.00	8.50	15.50
Grade 2[#]	10.86-17.73	9.53-22.35	6.78-18.18	9.14-23.23	7.85-30.50	14.50	17.00	10.00	8.00
Grade 3[#]	1.23-0.39	0.61-0.39	0.00-0.39	0.00-3.03	0.00-1.50	0.50	1.00	2.00	1.00
Grade 4[#]	0.00-0.19	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Fatigue / Somnolence									
Any	0.20-6.17	0.20-5.20	0.00-3.09	0.00-1.52	0.00-2.50	1.00	1.00	2.50	1.50
Grade 1[c]	0.20-5.01	0.20-4.24	0.00-2.71	0.00-1.52	0.00-2.00	0.50	0.50	2.50	1.50
Grade 2[c]	0.00-1.73	0.00-0.96	0.00-0.39	0.00	0.00-0.50	0.50	0.50	0.00	0.00
Grade 3[c]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Nausea / Vomiting									
Any	1.64-5.78	0.81-3.66	0.21-6.00	0.00-5.56	1.05-4.00	1.50	2.50	1.00	2.50
Grade 1[d]	0.82-4.62	0.61-2.31	0.21-4.26	0.00-4.55	1.05-3.50	1.00	2.50	0.50	2.50
Grade 2[d]	0.61-1.35	0.20-1.54	0.00-2.13	0.00-1.52	0.00-0.50	0.50	0.00	0.50	0.00
Grade 3[d]	0.00-0.20	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Diarrhea									
Any	2.46-12.91	2.23-11.95	0.41-11.03	1.61-7.07	1.05-9.00	4.00	1.50	1.00	2.00
Grade 1[e]	1.23-7.32	1.01-6.17	0.21-4.64	0.54-4.55	0.00-7.00	3.00	1.50	1.00	1.50
Grade 2[e]	1.23-5.78	1.01-6.17	0.21-7.74	1.08-2.53	1.05-2.50	1.00	0.00	0.00	0.50
Grade 3[e]	0.00-0.58	0.20-0.19	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Myalgia									
Any	0.00-0.19	0.00-0.39	0.00-0.19	0.00	0.00-0.50	0.00	0.00	0.50	0.50
Grade 1[f]	0.00-0.19	0.00-0.39	0.00-0.19	0.00	0.00-0.50	0.00	0.00	0.50	0.50
Grade 2[f]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Grade 3[f]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Cough									
Any	0.82-7.32	1.22-6.55	0.21-5.61	0.54-5.05	1.05-4.50	5.00	5.50	4.00	5.50
Grade 1[g]	0.20-5.01	0.61-4.05	0.21-4.64	0.00-2.53	0.52-2.50	1.00	2.00	3.00	2.00
Grade 2[g]	0.61-2.31	0.61-2.70	0.00-0.77	0.54-2.53	0.52-2.00	4.00	3.50	1.00	3.00
Grade 3[g]	0.00	0.00-0.19	0.00	0.00	0.00	0.00	0.00	0.00	0.50
Grade 4[g]	0.00	0.00	0.00-0.19	0.00	0.00	0.00	0.00	0.00	0.00
Abnormal Crying									
Any	0.82-10.40	0.61-9.44	0.21-10.44	1.08-6.57	0.00-6.00	2.50	1.50	0.00	1.50
Grade 1[h]	0.61-6.94	0.20-6.74	0.00-6.77	0.00-5.05	0.00-4.50	0.50	0.50	0.00	1.00
Grade 2[h]	0.20-3.85	0.20-3.66	0.21-4.64	1.08-1.52	0.00-1.50	2.00	1.00	0.00	0.50
Grade 3[h]	0.00-0.19	0.19-0.20	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Allergic Reaction									
Any	0.00-0.58	0.00-0.58	0.00-0.58	0.00	0.52-3.00	1.50	3.50	1.50	1.00
Grade 1[i]	0.00-0.19	0.00-0.19	0.00-0.39	0.00	0.00-0.50	0.50	1.50	0.00	0.00
Grade 2[i]	0.00-0.19	0.00-0.39	0.00	0.00	0.52-1.00	0.50	1.00	1.50	0.50
Grade 3[i]	0.00-0.19	0.00	0.00-0.19	0.00	0.00-1.50	0.50	1.00	0.00	0.50
Any Systemic Reactions[j]	30.33-67.82	29.21-71.48	22.38-67.12	22.04-58.59	22.51-66.00	46.50	50.00	24.00	28.50
Grade 1	19.06-57.61	19.27-62.81	15.81-57.64	12.37-42.93	14.14-49.00	33.50	34.00	13.00	19.50
Grade 2	12.91-25.82	10.75-30.83	7.19-27.08	10.22-27.27	9.42-34.50	20.50	20.50	12.00	11.50
Grade 3	1.43-1.35	0.81-0.96	0.00-0.58	0.00-3.03	0.00-3.00	1.00	2.00	2.00	2.00
Grade 4	0.00-0.19	0.00	0.00-0.19	0.00	0.00	0.00	0.00	0.00	0.00

* N=number of subjects reporting "yes" for at least 1 day, or "no" for all 30 days.
a. Minimum age: 6 weeks.
b. The minimum and maximum incidence rates for systemic adverse reactions after primary and booster immunizations.
\# Grade 1, 37.1-37.5 °C; grade 2, 37.6-39.0 °C; grade 3, > 39.0 °C.
c. Grade 1, slight reduction in normal activities for < 48 h, not affecting daily activities; grade 2, 20%-50% reduction in normal activities for > 48 h, affecting daily activities mildly; grade 3, > 50% reduction in normal activities, affecting daily activities severely and is unable to work.
d. Grade 1, once or twice/24 h, with basically normal intake and will not affect activities; grade 2, 2-5 times/24 h, with significantly reduced intake or restricted activities; grade 3, > 6 times/24 h, with no significant intake, and in need of intravenous infusion.
e. Grade 1, mild or transient with 2-3 times of loose stools/day, or mild diarrhea lasting < 1 week; grade 2, moderate or persistent diarrhea, 4-5 times/day, or diarrhea lasting > 1 week; grade 3, > 6 times of watery stool/day, or bloody diarrhea, orthostatic hypotension, electrolyte imbalance, in need of intravenous infusion of > 2 L.
f. Grade 1, not affecting daily activities; grade 2, tender muscles in non-vaccination sites, affecting daily activities mildly; grade 3, severe tender muscles, affecting daily activities severely.
g. Grade 1, transient, no treatment required; grade 2, persistent and controllable cough; grade 3, uncontrollable paroxysmal cough; grade 4, emergency care required.
h. Grade 1, slight increase in frequency than usual; grade 2, doubled frequency than usual; grade 3, doubled frequency than usual, and lasts > 3 days.
i. Grade 1, itching with no rash; grade 2, local urticaria; grade 3, extensive urticaria, angioedema.
j. All systemic reactions, including body temperature ⩾ 37.1 °C, fatigue/somnolence, nausea/vomiting, diarrhea, myalgia, cough, abnormal crying, and allergic reactions.

(2) Incidence rates and severity of unsolicited adverse reactions

The incidence rates of unsolicited adverse reactions for PCV13-TT were 0.06%-0.73% with most episodes being grade 1 in severity. The documented symptoms include: nasal obstruction, rhinorrhea, nasopharyngitis, upper respiratory tract infection, oral ulcer, abdominal pain, abdominal distension, decreased appetite, hyperhidrosis, increased tearing and eye discharge and red eyelids.

8 CONTRAINDICATIONS

Hypersensitivity to any component of the product, including active substances, excipients, or tetanus toxoid, etc.

9 PRECAUTIONS

(1) Do not vaccinate via intravenous route or by gluteal intramuscular injection, and ensure the syringe needle is not puncturing blood vessels during inoculation.

(2) Check if the package, container, label, appearance and expiration date of the vaccine are in compliance with corresponding requirements before administration. Do not use the vaccine in case that there is any crack in the container, loosened stopper, detached label, foreign particle(s) or discoloring inside the container, etc. Do not use the vaccine after the expiration date.

(3) Use immediately after unsealing. A single human dose shall be used up each time according to prescribing information.

(4) The vaccination should be postponed in case of fever, acute disease, and acute attack of chronic disease.

(5) Appropriate monitoring and medical care and rescue measures should be readily available in case of occurrence of rare hypersensitivity reactions during vaccination. If allergic reactions occur after vaccination, please go to the vaccination site or hospital in time.

(6) Cautions should be taken for vaccination in recipients with thrombocytopenia, any coagulopathy or those who are receiving anticoagulant treatment.

(7) Preterm infants should be monitored for the potential risk of apnea during primary series. For preterm infants under hospitalization (gestational age ⩽ 30 weeks at birth) vaccinated with PCV13-TT according to the recommended immunization schedule, at least 48 hours of monitoring should be considered. Given the benefit of vaccination in preterm infants, discontinued or deferred vaccination of the product is not recommended.

(8) Given there is still no available safety and immunogenicity data for PCV3-TT in immuno-compromised individuals (e.g., malignancy or nephrotic syndrome), vaccination in this special group should be considered on an individual basis.

(9) The use of PCV13-TT does not replace the use of 23-valent Pneumococcal Polysaccharide Vaccine in children ⩾ 24 months of age with conditions such as sickle cell disease, asplenia, HIV infection, chronic illness, or those who are immuno-compromised.

(10) Under no circumstances shall the tetanus toxoid contained in the vaccine replace the routine immunization of tetanus vaccine or tetanus-containing vaccine.

(11) This product cannot guarantee all recipients can be protected from any diseases caused by *Streptococcus pneumoniae*.

10 PREGNANCY AND LACTATION

10.1 Pregnancy

No data are available for using the product in pregnant women.

10.2 Lactation

Whether this product is excreted into human milk remains unknown.

11 INTERACTIONS WITH OTHER MEDICAMENTS

No concomitant immunization data are available either inside or outside of China for the product. During the phase III clinical trial of the product, the interval between vaccination of the product and any other diphtheria, tetanus, and acellular pertussis (DTaP)-containing vaccine was ⩾ 10 days. No adverse impact of DTaP-containing vaccine was observed on the immunogenicity of PCV13-TT under the indicated immunization interval.

12 OVERDOSE AND TREATMENT

Overdose with PCV13-TT is unlikely due to its presentation as a single-dose vial or a single-dose pre-filled syringe. There is no overdose data available for the product in recipients.

13 PHARMACODYNAMIC/PHARMACOKINETICS

Not applicable.

14 CLINICAL TRIALS

In China, the pivotal phase III clinical trial of PCV13-TT was a randomized and blinded non-inferiority study comparing to Prevnar®. This study evaluated the immunogenicity and safety of PCV13-TT and Prevnar® in 2760 subjects 2 through 71 months of age (at least 6 weeks of age). A total of 1040 infants aged 3 months were randomized in a 1:1 ratio as the study group and the control group, with PCV13-TT or Prevnar® given at 3, 4, 5, and 12-15 months of age, respectively; for 520 infants aged 2 months (at least 6 weeks of age), PCV13-TT was vaccinated at 2, 4, 6 and 12-15 months of age. 1200 children of 7 through 71 months of age, including children 7 months through 11 months of age, 12 months through 23 months of age and 24 months through 5 years of age (prior to the 6th birthday) who were naïve to the pneumococcal conjugate vaccine, were split into three age groups with each containing 400 subjects randomized in a 1:1 ratio given 3, 2 or 1 dose of PCV13-TT or Prevnar®, respectively, according to the age-appropriate schedules in Table 1 and Table 2. Enzyme-linked immunosorbent assay (ELISA) was utilized to detect the IgG antibody concentration in all serum samples collected from each group; additionally, a subset of sera randomly obtained from 100 subjects in each age group for PCV13-TT and Prevnar®, totaling 900, were tested by opsonophagocytic assay (OPA) to measure the ability of serotype-specific functional antibodies to eliminate corresponding pneumococci by promoting complement-mediated phagocytosis.

The main target population of the pivotal trial was infants of 2 and 3 months of age (at least 6 weeks of age). For immunogenicity, the PCV13-TT (3 months) group was compared with the Prevnar® (3 months) group in the first place, followed by the comparison between the PCV13-TT (2 months) group versus the Prevnar® (3 months) group and then the comparison between the PCV13-TT (2 months) versus the PCV13-TT (3 months) group. The immunogenicity endpoints included the percentage of subjects with IgG antibody concentration was ⩾ 0.35 μg/mL (positive rate) and the geometric mean concentration (GMC) of serotype-specific IgG antibody one month post the final dose of primary series and booster dose, as well as the percentage of subjects with vaccine serotype-specific OPA titer was ⩾ 1:8 (positive rate) and OPA geometric mean titer (GMT) one month post the final dose of primary series and booster dose.

The non-inferiority comparison was performed for the immune responses of 7 common serotypes between PCV13-TT and Prevnar®. For the 6 additional serotypes, if the lower limits of 95% CI for IgG antibody positive rate in the study group achieved ⩾ 70%, superiority assessment was then performed to compare the immune responses to 6 additional serotypes and corresponding serotypes in the control group; meanwhile, the 6 additional serotypes in the study group were compared with the serotype with the lowest response among all the 7 common serotypes in the control group to determine the non-inferiority. The non-inferiority can be established either through demonstrating the lower limit of 97.5% CI for the difference of positive rate between groups (study group - control group) were > -10%, or the lower limit of 97.5% CI for IgG geometric mean concentration (GMC) ratio (study group/control group) was > 0.5; whereas the superiority can only be demonstrated when both lower limit of 95% CI for the difference of positive rates between groups (study group - control group) were > 0, and the lower limit of 95% CI for the IgG GMC ratio (study group/control group) was > 1. The results are shown as below:

In subjects aged 3 months, after primary series (3 doses), the IgG antibody was compared between the PCV13-TT group and the Prevnar® group. Six out of seven common serotypes met the non-inferiority criteria with the exception of 6B; the 6 additional serotypes reached superiority threshold; besides, the 6 additional serotypes in the PCV13-TT group were non-inferior to the serotype with the lowest response among all the 7 common serotypes in the Prevnar® group.

In subjects aged 3 months, after complete series (4 doses), the IgG antibody was compared between the PCV13-TT group and the Prevnar® group. All 7 common serotypes met the non-inferiority criteria; the 6 additional serotypes reached superiority threshold; besides, the 6 additional serotypes in the PCV13-TT group were non-inferior to the serotype with the lowest response among all the 7 common serotypes in the Prevnar® group.

In subjects aged 2 months (at least 6 weeks of age), after primary series (3 doses), the IgG antibody was firstly compared between the PCV13-TT (2 months) group and the Prevnar® (3 months) group, showing that all 7 common serotypes met the non-inferiority criteria and the 6 additional serotypes reached superiority threshold; besides, the 6 additional serotypes in the PCV13-TT (2 months) group were non-inferior to the serotype with the lowest IgG response among all 7 common serotypes in the Prevnar® (3 months) group. The IgG antibody was then compared between the PCV13-TT (2 months) group and the PCV13-TT (3 months) group. Twelve out of the thirteen serotypes met the non-inferiority criterion with the exception of serotype 5.

In subjects aged 2 months (at least 6 weeks of age), after complete series (4 doses), the IgG antibody was firstly compared between the PCV13-TT (2 months) group and the Prevnar® (3 months) group. All 7 common serotypes met the non-inferiority criteria and the 6 additional serotypes reached superiority threshold; besides, the 6 additional serotypes in the PCV13-TT (2 months) group were non-inferior to the serotype with the lowest IgG response among all 7 common serotypes in the Prevnar® (3 months) group. The IgG antibody was then compared between the PCV13-TT (2 months) group and the PCV13-TT (3 months) group. All the 13 serotypes met the non-inferiority criteria.

The testing results of OPA antibody demonstrated that all 13 serotypes of PCV13-TT were capable of inducing anti-pneumococcal OPA antibodies in all age groups in the study group.

The immunogenicity data from subjects 2 months (at least 6 weeks of age) through 71 months of age are shown in Table 6 to Table 11.

Table 6 Proportion of Subjects with IgG Antibody Concentration ⩾ 0.35 μg/mL in Subjects Aged 2 Months and 3 Months (PPS)

Serotypes		Post Primary Immunizations						Post Booster Immunization					
		PCV13-TT (3m) N=471 (95%CI)	Prevnar® (3m) N=487 (95%CI)	PCV13-TT (2m) N=482 (95%CI)	% (PCV13-TT [3m] - Prevnar® [3m]) (CI*)	% (PCV13-TT [2m] – Prevnar® [3m]) (CI*)	% (PCV13-TT [2m] – PCV13-TT [3m] (CI*)	PCV13-TT (3m) N=475 (95%CI)	Prevnar® (3m) N=487 (95%CI)	PCV13-TT (2m) N=476 (95%CI)	% (PCV13-TT [3m] - Prevnar® [3m]) (CI*)	% (PCV13-TT [2m] – Prevnar® [3m]) (CI*)	% (PCV13-TT [2m] – PCV13-TT [3m] (CI*)
Common	4	100.0 (99.22-100.0)	99.18 (97.91-99.78)	100.0 (99.24-100.0)	0.82 (-0.10,1.74)	0.82 (-0.10,1.74)	0.00 (-0.93,0.91)	99.79 (98.83-99.99)	99.79 (98.86-99.99)	99.37 (98.17-99.87)	-0.01 (-0.66,0.65)	-0.42 (-1.36,0.51)	-0.42 (-1.36,0.52)
	6B	90.45 (87.42-92.95)	98.97 (97.62-99.67)	97.72 (95.95-98.86)	-8.53 (-11.73,-5.32)	-1.26 (-3.09,0.58)	7.27 (3.87,10.67)	100.0 (99.23-100.0)	99.79 (98.86-99.99)	100.0 (99.23-100.0)	0.21 (-0.25,0.67)	0.21 (-0.25,0.67)	0.00 (-0.92,0.92)
	9V	99.15 (97.84-99.77)	99.79 (98.86-99.99)	99.79 (98.85-99.99)	-0.64 (-1.70,0.41)	-0.00 (-0.66,0.65)	0.64 (-0.41,1.70)	100.0 (99.23-100.0)	100.0 (99.25-100.0)	100.0 (99.23-100.0)	0.00 (-0.90,0.92)	0.00 (-0.90,0.92)	0.00 (-0.92,0.92)
	14	100.0 (99.22-100.0)	99.79 (98.86-99.99)	99.79 (98.85-99.99)	0.21 (-0.25,0.67)	-0.00 (-0.66,0.65)	-0.21 (-0.67,0.26)	99.79 (98.83-99.99)	100.0 (99.25-100.0)	100.0 (99.23-100.0)	-0.21 (-0.68,0.26)	0.00 (-0.90,0.92)	0.21 (-0.26,0.68)
	18C	98.30 (96.68-99.26)	97.74 (95.99-98.87)	98.96 (97.60-99.66)	0.56 (-1.45,2.57)	1.22 (-0.61,3.05)	0.66 (-1.03,2.35)	99.79 (98.83-99.99)	99.59 (98.52-99.95)	99.58 (98.49-99.95)	0.20 (-0.60,1.00)	-0.01 (-0.94,0.92)	-0.21 (-1.02,0.61)
	19F	100.0 (99.22-100.0)	100.0 (99.25-100.0)	100.0 (99.24-100.0)	0.00 (-0.90,0.93)	0.00 (-0.90,0.91)	0.00 (-0.93,0.91)	100.0 (99.23-100.0)	100.0 (99.25-100.0)	100.0 (99.23-100.0)	0.00 (-0.90,0.92)	0.00 (-0.90,0.92)	0.00 (-0.92,0.92)
	23F	97.24 (95.33-98.52)	98.56 (97.06-99.42)	99.79 (98.85-99.99)	-1.32 (-3.40,0.76)	1.23 (-0.07,2.52)	2.55 (0.80,4.31)	100.0 (99.23-100.0)	99.79 (98.86-99.99)	99.79 (98.84-99.99)	0.21 (-0.25,0.67)	-0.00 (-0.66,0.65)	-0.21 (-0.68,0.26)
Additional (vs. corresponding serotypes)	1	99.58 (98.47-99.95)	57.49 (52.97-61.93)	100.0 (99.24-100.0)	42.08 (37.65,46.51)	42.51 (38.11,46.90)	0.42 (-0.25,1.10)	99.79 (98.83-99.99)	91.38 (88.52-93.71)	99.79 (98.84-99.99)	8.41 (5.89,10.94)	8.41 (5.89,10.94)	0.00 (-0.67,0.67)
	3	98.09 (96.40-99.12)	45.17 (40.69-49.72)	96.06 (93.91-97.61)	52.91 (48.32,57.50)	50.88 (46.13,55.63)	-2.03 (-4.47,0.41)	99.16 (97.86-99.77)	92.20 (89.45-94.42)	98.95 (97.57-99.66)	6.96 (4.44,9.48)	6.75 (4.20,9.30)	-0.21 (-1.62,1.20)
	5	98.51 (96.96-99.40)	16.63 (13.43-20.24)	90.87 (87.94-93.29)	81.88 (78.40,85.36)	74.24 (70.05,78.43)	-7.64 (-10.84,-4.45)	97.89 (96.16-98.99)	40.04 (35.66-44.55)	97.27 (95.38-98.54)	57.85 (53.31,62.39)	57.23 (52.64,61.82)	-0.63 (-2.86,1.61)
	6A	96.82 (94.80-98.21)	78.44 (74.52-82.01)	99.17 (97.89-99.77)	18.38 (14.39,22.36)	20.73 (16.99,24.47)	2.35 (0.32,4.39)	99.58 (98.49-99.95)	97.74 (95.99-98.87)	99.58 (98.49-99.95)	1.84 (0.40,3.28)	1.84 (0.40,3.28)	0.00 (-0.94,0.94)
	7F	99.58 (98.47-99.95)	24.23 (20.49-28.29)	99.59 (98.51-99.95)	75.35 (71.49,79.20)	75.36 (71.51,79.20)	0.01 (-0.93,0.95)	100.0 (99.23-100.0)	66.74 (62.36-70.91)	100.0 (99.23-100.0)	33.26 (29.08,37.45)	33.26 (29.08,37.45)	0.00 (-0.92,0.92)
	19A	100.0 (99.22-100.0)	97.13 (95.22-98.42)	100.0 (99.24-100.0)	2.87 (1.39,4.36)	2.87 (1.39,4.36)	0.00 (-0.93,0.91)	100.0 (99.23-100.0)	99.79 (98.86-99.99)	100.0 (99.23-100.0)	0.21 (-0.20,0.61)	0.21 (-0.20,0.61)	0.00 (-0.92,0.92)
Additional (vs. serotype with the lowest response among all 7 common serotypes)	1	99.58 (98.47-99.95)	97.74 (95.99-98.87)	\	1.83 (0.18,3.49)	2.26 (0.94,3.58)	\	99.79 (98.83-99.99)	99.59 (98.52-99.95)	\	0.20 (-0.60,1.00)	0.20 (-0.50,0.90)	\
	3	98.09 (96.40-99.12)	97.74 (95.99-98.87)	\	0.35 (-1.72,2.42)	-1.68 (-3.86,0.50)	\	99.16 (97.86-99.77)	99.59 (98.52-99.95)	\	-0.43 (-1.57,0.71)	-0.64 (-1.72,0.44)	\
	5	98.51 (96.96-99.40)	97.74 (95.99-98.87)	\	0.77 (-1.19,2.73)	-6.87 (-9.76,-3.98)	\	97.89 (96.16-98.99)	99.59 (98.52-99.95)	\	-1.69 (-3.31,-0.08)	-2.32 (-3.89,-0.75)	\
	6A	96.82 (94.80-98.21)	97.74 (95.99-98.87)	\	-0.93 (-3.29,1.43)	1.43 (-0.12,2.98)	\	99.58 (98.49-99.95)	99.59 (98.52-99.95)	\	-0.01 (-0.94,0.92)	-0.01 (-0.82,0.80)	\
	7F	99.58 (98.47-99.95)	97.74 (95.99-98.87)	\	1.83 (0.18,3.49)	1.84 (0.40,3.28)	\	100.0 (99.23-100.0)	99.59 (98.52-99.95)	\	0.41 (-0.24,1.06)	0.41 (-0.16,0.98)	\
	19A	100.0 (99.22-100.0)	97.74 (95.99-98.87)	\	2.26 (0.75,3.77)	2.26 (0.94,3.58)	\	100.0 (99.23-100.0)	99.59 (98.52-99.95)	\	0.41 (-0.24,1.06)	0.41 (-0.16,0.98)	\

Note: PCV13-TT (2m): PCV13-TT recipients 2 months of age; Prevnar® (3m): Prevnar® recipients 3 months of age; PCV13-TT (3m): PCV13-TT recipients 3 months of age; N: subjects included in PPS; %: IgG antibody positive rate; CI*: 2-sided 97.5% CI for common serotypes, 2-sided 97.5% CI for additional serotypes (vs. serotype with the lowest response among all 7 common serotypes), 2-sided 95% CI for additional serotypes (vs. corresponding serotypes).

Table 7 IgG Antibody GMCs in Subjects Aged 2 Months and 3 Months (PPS)

Serotypes		Post Primary Immunizations						Post Booster Immunization					
		PCV13-TT (3m)	Prevnar® (3m)	PCV13-TT (2m)	Ratio (PCV13-TT [3m] /Prevnar® [3m]) (CI*)	Ratio (PCV13-TT [2m] /Prevnar® [3m]) (CI*)	Ratio (PCV13-TT [2m] /PCV13-TT [3m]) (CI*)	PCV13-TT (3m)	Prevnar® (3m)	PCV13-TT (2m)	Ratio (PCV13-TT [3m] /Prevnar® [3m]) (CI*)	Ratio (PCV13-TT [2m] /Prevnar® [3m]) (CI*)	Ratio (PCV13-TT [2m] /PCV13-TT [3m]) (CI*)
		N=471	N=487	N=482				N=475	N=487	N=476			
		(95%CI)	(95%CI)	(95%CI)				(95%CI)	(95%CI)	(95%CI)			
Common	4	4.51 (4.20-4.84)	7.79 (7.22-8.41)	2.43 (2.28-2.60)	0.58 (0.51,0.65)	0.31 (0.28,0.35)	0.54 (0.48,0.60)	3.19 (2.96-3.44)	4.27 (3.98-4.59)	2.07 (1.92-2.22)	0.75 (0.66,0.84)	0.48 (0.43,0.54)	0.65 (0.58,0.73)
	6B	1.25 (1.11-1.42)	3.52 (3.25-3.81)	3.72 (3.37-4.10)	0.36 (0.30,0.42)	1.06 (0.91,1.22)	2.97 (2.47,3.56)	10.01 (9.30-10.79)	11.70 (10.78-12.70)	8.6 (7.93-9.3)	0.86 (0.75,0.97)	0.73 (0.64,0.84)	0.86 (0.76,0.97)
	9V	3.72 (3.45-4.02)	4.47 (4.19-4.78)	3.66 (3.40-3.94)	0.83 (0.74,0.93)	0.82 (0.73,0.92)	0.98 (0.87,1.11)	4.22 (3.90-4.56)	3.87 (3.62-4.14)	3.83 (3.56-4.1)	1.09 (0.97,1.23)	0.99 (0.88,1.11)	0.91 (0.80,1.03)
	14	10.38 (9.57-11.27)	16.53 (15.09-18.11)	10.25 (9.46-11.11)	0.63 (0.55,0.72)	0.62 (0.54,0.71)	0.99 (0.87,1.13)	13.97 (12.94-15.09)	17.89 (16.77-19.09)	11.61 (10.85-12.44)	0.78 (0.70,0.88)	0.65 (0.58,0.72)	0.83 (0.74,0.93)
	18C	2.91 (2.68-3.15)	4.80 (4.37-5.28)	2.04 (1.87-2.23)	0.61 (0.52,0.70)	0.43 (0.37,0.49)	0.70 (0.61,0.81)	2.44 (2.27-2.63)	3.90 (3.59-4.23)	2.04 (1.90-2.18)	0.63 (0.55,0.71)	0.52 (0.46,0.59)	0.83 (0.74,0.94)
	19F	6.95 (6.49-7.45)	9.00 (8.43-9.60)	5.46 (5.14-5.80)	0.77 (0.69,0.86)	0.61 (0.55,0.67)	0.79 (0.71,0.87)	12.18 (11.25-13.20)	7.84 (7.33-8.38)	8.76 (8.16-9.39)	1.56 (1.38,1.75)	1.12 (1.00,1.25)	0.72 (0.64,0.81)
	23F	2.93 (2.65-3.23)	4.44 (4.08-4.82)	3.86 (3.53-4.21)	0.66 (0.57,0.76)	0.87 (0.76,1.00)	1.32 (1.13,1.53)	6.9 (6.39-7.45)	10.81 (9.91-11.80)	5.70 (5.25-6.18)	0.64 (0.56,0.73)	0.53 (0.46,0.60)	0.83 (0.73,0.94)
Additional (vs. corresponding serotypes)	1	2.15 (2.01-2.30)	0.30 (0.26-0.34)	2.09 (1.95-2.23)	7.17 (6.14,8.37)	6.96 (5.97,8.12)	0.97 (0.87,1.09)	2.79 (2.61-2.99)	0.67 (0.62-0.72)	1.98 (1.86-2.12)	4.18 (3.76,4.65)	2.97 (2.68,3.30)	0.71 (0.64,0.79)
	3	1.67 (1.56-1.79)	0.33 (0.31-0.36)	1.41 (1.32-1.50)	5.02 (4.55,5.53)	4.22 (3.83,4.65)	0.84 (0.76,0.94)	1.89 (1.77-2.01)	1.02 (0.95-1.09)	1.53 (1.44-1.64)	1.86 (1.69,2.04)	1.51 (1.37,1.66)	0.81 (0.73,0.90)
	5	1.88 (1.75-2.02)	0.05 (0.04-0.06)	0.79 (0.73-0.85)	40.29 (32.02,50.69)	16.88 (13.42,21.24)	0.42 (0.37,0.47)	1.58 (1.47-1.70)	0.16 (0.14-0.19)	1.13 (1.06-1.21)	9.63 (8.06,11.51)	6.92 (5.80,8.25)	0.72 (0.64,0.80)
	6A	1.96 (1.77-2.16)	0.58 (0.50-0.67)	3.28 (3.01-3.57)	3.38 (2.83,4.03)	5.65 (4.78,6.69)	1.67 (1.44,1.95)	5.82 (5.32-6.37)	3.80 (3.44-4.21)	4.79 (4.39-5.22)	1.53 (1.34,1.75)	1.26 (1.10,1.44)	0.82 (0.71,0.95)
	7F	5.47 (5.06-5.92)	0.05 (0.04-0.07)	4.76 (4.42-5.13)	105.38 (82.43,134.72)	91.73 (72.03,116.82)	0.87 (0.77,0.98)	4.59 (4.29-4.91)	0.31 (0.26-0.36)	4.05 (3.79-4.32)	15.01 (12.58,17.91)	13.22 (11.09,15.76)	0.88 (0.79,0.98)
	19A	3.85 (3.62-4.09)	1.06 (0.97-1.16)	3.12 (2.95-3.30)	3.63 (3.25,4.06)	2.94 (2.64,3.28)	0.81 (0.74,0.89)	13.34 (12.37-14.39)	3.00 (2.78-3.24)	9.32 (8.66-10.03)	4.45 (4.00,4.95)	3.11 (2.80,3.45)	0.70 (0.62,0.79)
Additional (vs. serotype with the lowest response among all 7 common serotypes)	1	2.15 (2.01-2.30)	3.52 (3.25-3.81)	\	0.61 (0.54,0.69)	0.59 (0.53,0.66)	\	2.79 (2.61-2.99)	3.87 (3.62-4.14)	\	0.72 (0.65,0.80)	0.51 (0.47,0.56)	\
	3	1.67 (1.56-1.79)	3.52 (3.25-3.81)	\	0.48 (0.42,0.54)	0.40 (0.36,0.44)	\	1.89 (1.77-2.01)	3.87 (3.62-4.14)	\	0.49 (0.44,0.54)	0.40 (0.36,0.44)	\
	5	1.88 (1.75-2.02)	3.52 (3.25-3.81)	\	0.54 (0.47,0.61)	0.22 (0.20,0.25)	\	1.58 (1.47-1.70)	3.87 (3.62-4.14)	\	0.41 (0.37,0.46)	0.29 (0.27,0.32)	\
	6A	1.96 (1.77-2.16)	3.52 (3.25-3.81)	\	0.56 (0.48,0.64)	0.93 (0.83,1.05)	\	5.82 (5.32-6.37)	3.87 (3.62-4.14)	\	1.50 (1.32,1.71)	1.24 (1.11,1.38)	\
	7F	5.47 (5.06-5.92)	3.52 (3.25-3.81)	\	1.56 (1.37,1.77)	1.35 (1.22,1.51)	\	4.59 (4.29-4.91)	3.87 (3.62-4.14)	\	1.19 (1.06,1.32)	1.05 (0.95,1.15)	\
	19A	3.85 (3.62-4.09)	3.52 (3.25-3.81)	\	1.09 (0.97,1.23)	0.89 (0.80,0.98)	\	13.34 (12.37-14.39)	3.87 (3.62-4.14)	\	3.45 (3.07,3.87)	2.41 (2.18,2.66)	\

Note: PCV13-TT (2m): PCV13-TT recipients 2 months of age; Prevnar® (3m): Prevnar® recipients 3 months of age; PCV13-TT (3m): PCV13-TT recipients 3 months of age; N: subjects included in PPS; Ratio: GMC/GMC; CI*: 2-sided 97.5% CI for common serotypes, 2-sided 97.5% CI for additional serotypes (vs. serotype with the lowest response among all 7 common serotypes), 2-sided 95% CI for additional serotypes (vs. corresponding serotypes).

Table 8 Proportion of Subjects with IgG Antibody Concentration ⩾ 0.35 μg/mL in Subjects Aged 7 through 71 Months (PPS)

Serotypes		Post Primary Immunizations						Post Booster Immunization	
		7-11 Months		12-23 Months		24-71 Months		7-11 Months	
		PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®
		N=185	N=189	N=189	N=189	N=198	N=199	N=186	N=189
		% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)
Common	4	100.0(98.03-100.0)	100.0(98.07-100.0)	100.0(98.07-100.0)	99.47(97.09-99.99)	100.0(98.15-100.0)	100.0(98.16-100.0)	100.0(98.04-100.0)	100.0(98.07-100.0)
	6B	96.76(93.07-98.80)	99.47(97.09-99.99)	100.0(98.07-100.0)	98.41(95.43-99.67)	100.0(98.15-100.0)	98.99(96.42-99.88)	100.0(98.04-100.0)	100.0(98.07-100.0)
	9V	97.30(93.81-99.12)	97.88(94.67-99.42)	100.0(98.07-100.0)	98.94(96.23-99.87)	98.48(95.64-99.69)	98.99(96.42-99.88)	99.46(97.04-99.99)	100.0(98.07-100.0)
	14	100.0(98.03-100.0)	100.0(98.07-100.0)	100.0(98.07-100.0)	100.0(98.07-100.0)	99.49(97.22-99.99)	99.50(97.23-99.99)	100.0(98.04-100.0)	100.0(98.07-100.0)
	18C	99.46(97.03-99.99)	99.47(97.09-99.99)	100.0(98.07-100.0)	100.0(98.07-100.0)	98.99(96.40-99.88)	100.0(98.16-100.0)	99.46(97.04-99.99)	99.47(97.09-99.99)
	19F	100.0(98.03-100.0)	100.0(98.07-100.0)	100.0(98.07-100.0)	100.0(98.07-100.0)	100.0(98.15-100.0)	100.0(98.16-100.0)	100.0(98.04-100.0)	100.0(98.07-100.0)
	23F	97.30(93.81-99.12)	96.83(93.22-98.83)	99.47(97.09-99.99)	99.47(97.09-99.99)	98.99(96.40-99.88)	97.99(94.93-99.45)	100.0(98.04-100.0)	100.0(98.07-100.0)
Additional (vs. corresponding serotypes)	1	98.92(96.15-99.87)	75.66(68.90-81.60)	100.0(98.07-100.0)	70.37(63.31-76.78)	98.48(95.64-99.69)	66.33(59.31-72.86)	100.0(98.04-100.0)	82.54(76.36-87.67)
	3	97.84(94.56-99.41)	61.90(54.57-68.86)	98.41(95.43-99.67)	47.62(40.32-54.99)	88.89(83.66-92.90)	44.72(37.69-51.92)	98.92(96.17-99.87)	68.78(61.65-75.31)
	5	91.35(86.34-94.98)	44.44(37.23-51.83)	96.83(93.22-98.83)	53.44(46.06-60.71)	98.48(95.64-99.69)	63.82(56.72-70.50)	93.01(88.34-96.23)	40.74(33.67-48.11)
	6A	95.68(91.66-98.11)	77.78(71.17-83.49)	98.41(95.43-99.67)	93.65(89.17-96.68)	96.46(92.85-98.57)	91.96(87.27-95.33)	98.39(95.36-99.67)	93.12(88.53-96.29)
	7F	99.46(97.03-99.99)	46.03(38.77-53.42)	100.0(98.07-100.0)	71.43(64.42-77.75)	98.99(96.40-99.88)	71.36(64.54-77.53)	100.0(98.04-100.0)	73.02(66.09-79.20)
	19A	100.0(98.03-100.0)	97.88(94.67-99.42)	100.0(98.07-100.0)	99.47(97.09-99.99)	100.0(98.15-100.0)	99.50(97.23-99.99)	100.0(98.04-100.0)	100.0(98.07-100.0)
Additional (vs. serotype with t he lowest response among all 7 common serotypes)	1	98.92(96.15-99.87)	96.83(93.22-98.83)	100.0(98.07-100.0)	98.41(95.43-99.67)	98.48(95.64-99.69)	97.99(94.93-99.45)	100.0(98.04-100.0)	99.47(97.09-99.99)
	3	97.84(94.56-99.41)	96.83(93.22-98.83)	98.41(95.43-99.67)	98.41(95.43-99.67)	88.89(83.66-92.90)	97.99(94.93-99.45)	98.92(96.17-99.87)	99.47(97.09-99.99)
	5	91.35(86.34-94.98)	96.83(93.22-98.83)	96.83(93.22-98.83)	98.41(95.43-99.67)	98.48(95.64-99.69)	97.99(94.93-99.45)	93.01(88.34-96.23)	99.47(97.09-99.99)
	6A	95.68(91.66-98.11)	96.83(93.22-98.83)	98.41(95.43-99.67)	98.41(95.43-99.67)	96.46(92.85-98.57)	97.99(94.93-99.45)	98.39(95.36-99.67)	99.47(97.09-99.99)
	7F	99.46(97.03-99.99)	96.83(93.22-98.83)	100.0(98.07-100.0)	98.41(95.43-99.67)	98.99(96.40-99.88)	97.99(94.93-99.45)	100.0(98.04-100.0)	99.47(97.09-99.99)
	19A	100.0(98.03-100.0)	96.83(93.22-98.83)	100.0(98.07-100.0)	98.41(95.43-99.67)	100.0(98.15-100.0)	97.99(94.93-99.45)	100.0(98.04-100.0)	99.47(97.09-99.99)

Note: N: subjects included in PPS; CI*: 2-sided 95% CI for IgG antibody positive rate.

Table 9 IgG Antibody GMCs in Subjects Aged 7 through 71 Months (PPS)

Serotypes		Post Primary Immunizations						Post Booster Immunization	
		7-11 Months		12-23 Months		24-71 Months		7-11 Months	
		PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®
		N=185	N=189	N=189	N=189	N=198	N=199	N=186	N=189
		GMC (CI*)	GMC (CI*)	GMC (CI*)	GMC (CI*)	GMC (CI*)	GMC (CI*)	GMC (CI*)	GMC (CI*)
Common	4	4.26(3.86-4.71)	4.23(3.88-4.62)	5.01(4.60-5.45)	5.08(4.63-5.58)	8.90(7.95-9.96)	8.58(7.63-9.66)	3.06(2.76-3.38)	3.12(2.85-3.41)
	6B	2.90(2.46-3.42)	2.20(1.92-2.52)	5.42(4.86-6.04)	2.71(2.35-3.11)	7.75(6.58-9.12)	3.63(3.04-4.32)	5.62(5.01-6.32)	4.57(4.08-5.11)
	9V	2.38(2.09-2.71)	2.76(2.43-3.12)	2.97(2.68-3.30)	2.95(2.64-3.30)	3.84(3.35-4.41)	3.94(3.36-4.62)	2.91(2.58-3.29)	3.67(3.31-4.07)
	14	8.54(7.60-9.60)	16.17(14.53-17.99)	9.20(8.28-10.22)	14.98(13.51-16.61)	10.20(8.40-12.38)	15.75(12.82-19.34)	13.94(12.54-15.51)	19.49(17.94-21.17)
	18C	3.78(3.30-4.34)	3.44(3.08-3.84)	5.03(4.63-5.46)	3.92(3.56-4.31)	8.82(7.56-10.29)	7.47(6.45-8.66)	2.97(2.62-3.36)	3.32(3.00-3.67)
	19F	7.21(6.43-8.08)	4.09(3.70-4.52)	8.80(8.10-9.55)	4.20(3.79-4.65)	11.45(10.05-13.04)	5.71(4.98-6.54)	7.54(6.84-8.31)	3.92(3.56-4.31)
	23F	3.56(3.10-4.10)	2.70(2.36-3.09)	4.32(3.89-4.79)	2.96(2.61-3.36)	4.42(3.80-5.14)	4.29(3.56-5.17)	4.53(4.01-5.12)	4.21(3.77-4.71)
Additional (vs. corresponding serotypes)	1	2.23(2.03-2.45)	0.47(0.40-0.56)	2.25(2.07-2.44)	0.42(0.35-0.50)	2.06(1.84-2.30)	0.31(0.26-0.39)	1.98(1.82-2.15)	0.58(0.53-0.65)
	3	1.32(1.20-1.45)	0.46(0.41-0.51)	1.06(0.98-1.14)	0.39(0.34-0.45)	0.84(0.75-0.94)	0.38(0.33-0.45)	1.51(1.38-1.66)	0.53(0.48-0.59)
	5	0.82(0.73-0.91)	0.19(0.15-0.25)	1.01(0.91-1.12)	0.27(0.22-0.32)	1.60(1.43-1.79)	0.31(0.25-0.38)	0.86(0.78-0.95)	0.24(0.20-0.29)
	6A	1.79(1.51-2.12)	0.54(0.41-0.72)	2.46(2.08-2.92)	1.17(1.01-1.35)	2.35(2.00-2.76)	1.29(1.05-1.60)	2.99(2.64-3.37)	1.63(1.43-1.87)
	7F	5.73(5.04-6.51)	0.14(0.10-0.20)	5.47(5.04-5.94)	0.41(0.33-0.52)	4.60(4.00-5.28)	0.43(0.33-0.56)	4.91(4.46-5.39)	0.46(0.39-0.55)
	19A	5.06(4.54-5.64)	1.50(1.29-1.74)	7.81(7.08-8.61)	2.67(2.28-3.12)	9.56(8.47-10.79)	3.32(2.85-3.88)	6.28(5.71-6.91)	2.17(1.96-2.40)
Additional (vs. serotype with the lowest response among all 7 common serotypes)	1	2.23(2.03-2.45)	2.20(1.92-2.52)	2.25(2.07-2.44)	2.71(2.35-3.11)	2.06(1.84-2.30)	3.63(3.04-4.32)	1.98(1.82-2.15)	3.12(2.85-3.41)
	3	1.32(1.20-1.45)	2.20(1.92-2.52)	1.06(0.98-1.14)	2.71(2.35-3.11)	0.84(0.75-0.94)	3.63(3.04-4.32)	1.51(1.38-1.66)	3.12(2.85-3.41)
	5	0.82(0.73-0.91)	2.20(1.92-2.52)	1.01(0.91-1.12)	2.71(2.35-3.11)	1.60(1.43-1.79)	3.63(3.04-4.32)	0.86(0.78-0.95)	3.12(2.85-3.41)
	6A	1.79(1.51-2.12)	2.20(1.92-2.52)	2.46(2.08-2.92)	2.71(2.35-3.11)	2.35(2.00-2.76)	3.63(3.04-4.32)	2.99(2.64-3.37)	3.12(2.85-3.41)
	7F	5.73(5.04-6.51)	2.20(1.92-2.52)	5.47(5.04-5.94)	2.71(2.35-3.11)	4.60(4.00-5.28)	3.63(3.04-4.32)	4.91(4.46-5.39)	3.12(2.85-3.41)
	19A	5.06(4.54-5.64)	2.20(1.92-2.52)	7.81(7.08-8.61)	2.71(2.35-3.11)	9.56(8.47-10.79)	3.63(3.04-4.32)	6.28(5.71-6.91)	3.12(2.85-3.41)

Note: N: subjects included in PPS; CI*: 2-sided 95% CI for IgG GMC.

Table 10 Proportion of Subjects with OPA Antibody Titer ⩾1:8 in Each Age Group (PPS)

Serotypes		Post Primary Immunizations									Post Booster Immunization				
		3 Months		2 Months	7-11 Months		12-23 Months		24-71 Months		3 Months		2 Months	7-11 Months	
		PCV13-TT	Prevnar®	PCV13-TT	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	PCV13-TT	Prevnar®
		N=93	N=96	N=97	N=96	N=95	N=92	N=93	N=99	N=100	N=96	N=97	N=92	N=93	N=95
		% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)	% (CI*)
Common	4	100.0 (96.11-100.0)	100.0 (96.23-100.0)	98.97 (94.39-99.97)	100.0 (96.23-100.0)	100.0 (96.19-100.0)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	100.0 (96.34-100.0)	96.00 (90.07-98.90)	100.0 (96.23-100.0)	100.0 (96.27-100.0)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	100.0 (96.19-100.0)
	6B	89.25 (81.11-94.72)	98.96 (94.33-99.97)	92.78 (85.70-97.05)	81.25 (72.00-88.49)	89.47 (81.49-94.84)	94.57 (87.77-98.21)	91.40 (83.75-96.21)	97.98 (92.89-99.75)	98.00 (92.96-99.76)	98.96 (94.33-99.97)	97.94 (92.75-99.75)	100.0 (96.07-100.0)	93.55 (86.48-97.60)	95.79 (89.57-98.84)
	9V	100.0 (96.11-100.0)	100.0 (96.23-100.0)	100.0 (96.27-100.0)	100.0 (96.23-100.0)	100.0 (96.19-100.0)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	100.0 (96.34-100.0)	100.0 (96.38-100.0)	100.0 (96.23-100.0)	100.0 (96.27-100.0)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	100.0 (96.19-100.0)
	14	100.0 (96.11-100.0)	100.0 (96.23-100.0)	100.0 (96.27-100.0)	98.96 (94.33-99.97)	97.89 (92.60-99.74)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	92.93 (85.97-97.11)	95.00 (88.72-98.36)	100.0 (96.23-100.0)	100.0 (96.27-100.0)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	100.0 (96.19-100.0)
	18C	100.0 (96.11-100.0)	98.96 (94.33-99.97)	100.0 (96.27-100.0)	98.96 (94.33-99.97)	98.95 (94.27-99.97)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	100.0 (96.34-100.0)	99.00 (94.55-99.97)	100.0 (96.23-100.0)	98.97 (94.39-99.97)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	98.95 (94.27-99.97)
	19F	100.0 (96.11-100.0)	97.92 (92.68-99.75)	98.97 (94.39-99.97)	98.96 (94.33-99.97)	91.58 (84.08-96.29)	98.91 (94.09-99.97)	92.47 (85.10-96.92)	98.99 (94.50-99.97)	94.00 (87.40-97.77)	100.0 (96.23-100.0)	96.91 (91.23-99.36)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	93.68 (86.76-97.65)
	23F	95.70 (89.35-98.82)	98.96 (94.33-99.97)	95.88 (89.78-98.87)	91.67 (84.24-96.33)	94.74 (88.14-98.27)	98.91 (94.09-99.97)	96.77 (90.86-99.33)	96.97 (91.40-99.37)	99.00 (94.55-99.97)	98.96 (94.33-99.97)	98.97 (94.39-99.97)	100.0 (96.07-100.0)	97.85 (92.45-99.74)	95.79 (89.57-98.84)
Additional (vs. corresponding serotypes)	1	83.87 (74.80-90.68)	0.00 (0.00-3.77)	91.75 (84.39-96.37)	92.71 (85.55-97.02)	5.26 (1.73-11.86)	88.04 (79.61-93.88)	3.23 (0.67-9.14)	43.43 (33.50-53.77)	1.00 (0.03-5.45)	97.92 (92.68-99.75)	4.12 (1.13-10.22)	95.65 (89.24-98.80)	94.62 (87.90-98.23)	6.32 (2.35-13.24)
	3	96.77 (90.86-99.33)	15.63 (9.02-24.46)	100.0 (96.27-100.0)	100.0 (96.23-100.0)	46.32 (36.02-56.85)	100.0 (96.07-100.0)	75.27 (65.24-83.63)	100.0 (96.34-100.0)	48.00 (37.90-58.22)	97.92 (92.68-99.75)	37.11 (27.52-47.52)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	56.84 (46.28-66.97)
	5	98.92 (94.15-99.97)	4.17 (1.15-10.33)	100.0 (96.27-100.0)	97.92 (92.68-99.75)	7.37 (3.01-14.59)	98.91 (94.09-99.97)	7.53 (3.08-14.90)	95.96 (89.98-98.89)	9.00 (4.20-16.40)	100.0 (96.23-100.0)	5.15 (1.69-11.62)	100.0 (96.07-100.0)	98.92 (94.15-99.97)	5.26 (1.73-11.86)
	6A	97.85 (92.45-99.74)	80.21 (70.83-87.64)	97.94 (92.75-99.75)	89.58 (81.68-94.89)	65.26 (54.80-74.74)	96.74 (90.77-99.32)	78.49 (68.76-86.34)	94.95 (88.61-98.34)	95.00 (88.72-98.36)	95.83 (89.67-98.85)	92.78 (85.70-97.05)	97.83 (92.37-99.74)	95.70 (89.35-98.82)	81.05 (71.72-88.37)
	7F	100.0 (96.11-100.0)	37.50 (27.82-47.97)	100.0 (96.27-100.0)	100.0 (96.23-100.0)	35.79 (26.21-46.28)	100.0 (96.07-100.0)	49.46 (38.93-60.03)	100.0 (96.34-100.0)	75.00 (65.34-83.12)	100.0 (96.23-100.0)	52.58 (42.18-62.81)	98.91 (94.09-99.97)	100.0 (96.11-100.0)	42.11 (32.04-52.67)
	19A	100.0 (96.11-100.0)	44.79 (34.63-55.29)	100.0 (96.27-100.0)	100.0 (96.23-100.0)	78.95 (69.38-86.64)	100.0 (96.07-100.0)	88.17 (79.82-93.95)	100.0 (96.34-100.0)	92.00 (84.84-96.48)	100.0 (96.23-100.0)	79.38 (69.97-86.93)	100.0 (96.07-100.0)	100.0 (96.11-100.0)	78.95 (69.38-86.64)

Note: N: subjects included in PPS; CI*: 2-sided 95% CI for OPA antibody positive rate.

Table 11 OPA Antibody GMTs in Subjects of Each Age Group (PPS)

Serotypes		Post Primary Immunizations									Post Booster Immunization				
		3 Months		2 Months	7-11 Months		12-23 Months		24-71 Months		3 Months		2 Months	7-11 Months	
		PCV13-TT	Prevnar®	PCV13-TT	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	Prevnar®	PCV13-TT	PCV13-TT	Prevnar®
		N=93	N=96	N=97	N=96	N=95	N=92	N=93	N=99	N=100	N=96	N=97	N=92	N=93	N=95
		GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)	GMT (CI*)
Common	4	1227.93 (992.5-1519.2)	2291.32 (1947.8-2695.4)	1214.42 (940.3-1568.5)	1014.62 (866.1-1188.7)	1214.37 (1022.4-1442.4)	1756.58 (1426.1-2163.6)	1993.15 (1667.7-2382.2)	2710.14 (2176.9-3374.1)	1924.49 (1331.2-2782.2)	6182.37 (4931.4-7750.7)	6208.15 (4950.8-7784.8)	3440.10 (2690.0-4399.3)	1549.33 (1288.7-1862.7)	1465.72 (1253.1-1714.4)
	6B	528.67 (329.58-848.02)	2928.36 (2233.9-3838.7)	811.17 (542.0-1214.1)	237.34 (142.61-395.00)	599.57 (373.97-961.29)	923.67 (611.9-1394.4)	1530.14 (921.8-2539.9)	2511.69 (1829.2-3448.8)	2511.16 (1760.5-3581.9)	2661.93 (1948.9-3635.9)	7564.42 (5345-10705)	1948.21 (1460.3-2599.2)	890.24 (599.4-1322.2)	1843.95 (1265.7-2686.4)
	9V	1922.48 (1518.9-2433.2)	1974.62 (1612.0-2418.9)	2192.74 (1728.3-2781.9)	1425.78 (1153.3-1762.6)	1692.48 (1371.4-2088.7)	3219.64 (2417.8-4287.4)	2824.34 (2057.1-3877.8)	2174.68 (1710.1-2765.4)	1980.18 (1547.4-2534.1)	6184.75 (4870.3-7854.0)	5484.79 (4453.1-6755.5)	3719.77 (2889.7-4788.3)	2075.15 (1697.0-2537.6)	2264.80 (1886.3-2719.2)
	14	4511.21 (3494.9-5823.1)	5594.48 (4188.4-7472.5)	3571.78 (2833.6-4502.3)	2538.79 (1929.1-3341.2)	3060.32 (2260.7-4142.7)	6373.82 (5041.8-8057.8)	7303.79 (5760.0-9261.3)	2534.19 (1586.7-4047.4)	3395.54 (2193.4-5256.5)	7686.96 (6160.6-9591.5)	6221.93 (4855.7-7972.5)	6173.16 (4922.7-7741.3)	3761.98 (3002.8-4713.1)	2883.34 (2359.5-3523.5)
	18C	1356.26 (1094.5-1680.7)	3129.49 (2353.5-4161.3)	518.67 (417.13-644.92)	952.30 (748.0-1212.4)	1157.93 (908.2-1476.4)	3133.89 (2557.9-3839.5)	3971.64 (3197.8-4932.8)	3572.76 (2952.0-4324.1)	3330.72 (2548.4-4353.1)	4173.73 (3269.4-5328.2)	5507.66 (4094.6-7408.5)	1117.88 (899.5-1389.3)	1491.46 (1230.2-1808.2)	1677.92 (1331.9-2146.1)
	19F	652.57 (547.97-777.14)	540.56 (423.02-690.76)	769.17 (617.10-958.72)	518.08 (412.37-650.89)	240.27 (170.50-338.60)	816.50 (653.5-1020.2)	331.18 (230.91-474.99)	1133.78 (876.5-1466.6)	333.59 (233.90-475.75)	2359.26 (1898.8-2931.3)	815.68 (600.1-1108.8)	1966.07 (1496.8-2582.5)	751.55 (635.68-888.54)	258.60 (190.65-350.77)
	23F	2090.78 (1452.4-3009.7)	5939.64 (4465.8-7899.8)	1072.95 (738.0-1560.0)	669.00 (444.5-1006.8)	1699.27 (1116.1-2587.2)	2069.47 (1616.3-2649.7)	3784.23 (2584.5-5540.9)	2025.10 (1465.3-2798.7)	3468.13 (2544.3-4727.4)	4943.66 (3817.5-6402.1)	16131.84 (11742-22163)	2529.55 (1959.0-3266.3)	1577.42 (1197.5-2077.9)	3607.17 (2428.0-5359.1)
Additional (vs. corresponding serotypes)	1	62.13 (42.64-90.51)	2.00 (2.00-2.00)	92.51 (66.48-128.75)	56.40 (43.54-73.05)	2.24 (2.01-2.50)	42.36 (31.65-56.70)	2.23 (1.97-2.52)	8.16 (5.78-11.52)	2.07 (1.94-2.21)	321.14 (239.43-430.74)	2.28 (2.00-2.61)	158.59 (115.59-217.59)	87.89 (67.11-115.11)	2.34 (2.06-2.67)
	3	511.70 (376.29-695.83)	2.80 (2.35-3.33)	575.94 (444.43-746.38)	316.46 (264.28-378.94)	6.62 (4.88-8.97)	361.20 (304.70-428.17)	14.09 (10.43-19.04)	121.39 (101.55-145.11)	9.67 (6.60-14.16)	678.98 (523.20-881.14)	5.03 (3.77-6.72)	586.01 (440.25-780.04)	431.54 (359.88-517.48)	8.12 (6.04-10.91)
	5	450.24 (358.12-566.05)	2.24 (1.99-2.51)	411.73 (317.12-534.56)	115.18 (90.52-146.55)	2.43 (2.10-2.82)	192.91 (155.85-238.79)	2.80 (2.17-3.62)	84.80 (64.41-111.65)	2.51 (2.16-2.93)	1375.13 (1061.9-1780.8)	2.61 (2.07-3.29)	1027.83 (796.4-1326.6)	222.49 (173.71-284.98)	2.41 (2.02-2.87)
	6A	1079.96 (792.9-1471.0)	275.54 (159.69-475.44)	1202.17 (895.0-1614.8)	442.24 (286.46-682.71)	95.37 (51.43-176.86)	1434.20 (1009.8-2037.0)	487.96 (251.04-948.50)	1737.99 (1185.4-2548.1)	970.59 (655.6-1437.0)	3254.75 (2221.0-4769.7)	1562.59 (972.9-2509.6)	2546.12 (1780.8-3640.3)	1234.03 (866.0-1758.5)	416.90 (234.51-741.16)
	7F	7741.10 (6383.8-9387.0)	12.76 (7.68-21.19)	2414.63 (1872.4-3113.9)	3589.60 (2955.9-4359.2)	16.04 (8.94-28.80)	5524.63 (4317.5-7069.2)	32.24 (17.72-58.68)	5886.86 (4802.3-7216.3)	171.55 (98.79-297.89)	7244.42 (6006.0-8738.3)	41.47 (22.27-77.21)	2616.75 (1938.6-3532.1)	4276.87 (3488.6-5243.3)	21.71 (12.04-39.14)
	19A	777.70 (638.69-946.97)	11.50 (7.55-17.51)	659.70 (532.25-817.66)	692.99 (565.53-849.18)	57.76 (38.19-87.34)	1368.75 (1110.8-1686.6)	166.43 (110.60-250.45)	2070.66 (1638.8-2616.3)	303.83 (200.97-459.33)	5503.11 (4501.2-6728.1)	72.99 (46.46-114.65)	2546.03 (2030.4-3192.6)	1141.93 (928.0-1405.2)	71.60 (45.99-111.47)

Note: N: subjects included in PPS; CI*: 2-sided 95% CI for OPA antibody GMT.

15 STORAGE CONDITION

Transport and store refrigerated at 2°C to 8°C, protect from light.
DO NOT FREEZE. Discard if the vaccine has been frozen.
Keep the product in places out of children's reach.

16 DOSAGE FORMS AND PACKAGING AVAILABLE

Vial, 1 × 0.5 mL single human dose, 20 vials per package.
Pre-filled syringe, 1 × 0.5 mL single human dose, 1 dose per package.

17 INCOMPATIBILITIES

This vaccine should not be mixed with other medicinal products considering that no compatibility studies have been conducted.

18 SHELF LIFE

The shelf life of the vaccine is 24 months. Please use before the expiration date printed on the label or small box.

19 APPROVAL NUMBER

S20190046

20 NAME AND ADDRESS OF MANUFACTURER

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