Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study vaccine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor:	Pfizer Inc.
Vaccine(s) Studied:	Prevenar 13® (13-valent Pneumococcal Conjugate Vaccine [13vPnC], PF-05208760)
Protocol Number:	B1851214
Dates of Study:	06 October 2022 to 30 November 2022
Title of this Study:	A Study of 13vPnC Safety in Healthy Adults 18 to 49 Years Old in India. [Final Report - A Phase 4, Open-Label, Single-Arm, Multicenter Study to Describe the Safety of 13- Valent Pneumococcal Conjugate Vaccine in Adults 18 to 49 Years of Age in India]
Date(s) of this Report:	26 September 2023

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is *Streptococcus pneumoniae*?

Streptococcus pneumoniae (also known as pneumococcus or *S pneumoniae*) is a kind of germ. It has more than 100 types, but only a few types cause serious diseases.

S pneumoniae can cause infections of the lung, brain lining, blood, and ear. These infections can be serious for some adults.

What is 13-valent pneumococcal conjugate vaccine (13vPnC)?

13vPnC is an injectable vaccine that was tested in this study.

- It can help protect against 13 of the most common types of *S pneumoniae* that cause infections.
- 13vPnC is also known as Prevnar 13® or Prevenar 13®. It is approved in India, United States, Europe, and many other countries to prevent diseases caused by *S pneumoniae* in young children and adults.

What was the purpose of this study?

The purpose of this study was to learn if 13vPnC was safe in healthy adults between the ages of 18 to 49 years in India. As per the request of the Central Drugs Standard Control Organization (CDSCO), a regulatory agency in India, this study was done.

Researchers wanted to know:

- **How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination?**
- **How many participants had fever, tiredness, headache, chills, muscle pain, or joint pain within 7 days after vaccination?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Researchers gave 13vPnC to all participants to learn about its safety. Participants were 18 to 49 years old and had not gotten pneumococcal vaccine before.

This was an “open-label” study, which means that both the researchers and the participants knew the vaccine given in the study. All participants received 1 dose of 13vPnC given as an injection deep into the shoulder muscle.

Figure 1 below shows what happened in this study.

Figure 1. What happened in the study?

Screening	Vaccination	Follow-up
Healthy adults between 18 and 49 years old who had not received a pneumococcal vaccine before joining this study Participants who agreed to join this study were checked to see if they met the study requirements.	**Visit 1:** Day 1 Participants got 1 dose of 13vPnC as an injection deep into the shoulder muscle.	**Visit 2:** 28 to 42 days after Visit 1 Participants returned to the study site for a check-up.

Where did this study take place?

The study took place at 5 locations in India.

When did this study take place?

It began 06 October 2022 and ended 30 November 2022.

Who participated in this study?

The study included healthy adults between 18 years and 49 years old.

All 200 participants who started the study received 1 dose of 13vPnC vaccine. A total of 108 men and 92 women participated. All participants completed the study.

How long did the study last?

Study participants were in the study for about 1 month. The entire study took about 2 months to complete.

When the study ended in November 2022, the Sponsor, Pfizer, began reviewing the information collected and created a report of the results. This is a summary of that report.

What were the results of the study?

How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination?

Within 7 days after getting 13vPnC, 126 out of 200 participants (63%) had any redness, swelling, or pain at the injection site. Most of these injection site reactions were mild to moderate and went away within an average of 1 to 3 days after onset. Injection site pain was the most common of these reactions.

How many participants had fever, tiredness, headache, chills, muscle pain, or joint pain within 7 days after vaccination?

Within 7 days after getting 13vPnC, 100 out of 200 participants (50%) had any fever, tiredness, headache, chills, muscle pain, or joint pain. Most of these symptoms were mild to moderate and went away within an average of 1 day after onset. Muscle pain, tiredness, and headache were the most common of these symptoms.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for

reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study vaccine or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many vaccine groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

How many participants had medical problems within 1 month after vaccination?

One (1) out of 200 participants (less than 1%) in this study had 1 medical problem after they got 13vPnC. On the day of vaccination, the participant had chicken pox, an infection that causes an itchy rash with fluid-filled blisters all over the body. But this infection may have started before they got 13vPnC.

No participants left the study because of medical problems.

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

No participants had serious medical problems or died during the study.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results

Use the protocol number **B1851214**

The full scientific report of this study is available online at:

www.clinicaltrials.gov

Use the study identifier **NCT05329259**

Please remember that researchers look at the results of many studies to find out which vaccines can work and are safe for patients.

Again, if you participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!