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 medication 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.
Medicine Studied:	PF-07242813
Protocol Number:	C4461001
Dates of Study:	10 December 2020 to 27 December 2022
Title of this Study:	A Study of PF-07242813 in Healthy Adults and Adults With Atopic Dermatitis [A Phase 1 First in Human, Randomized, Double Blind, Sponsor Open, Placebo-Controlled, Single- and Multiple Dose Escalation, Parallel Group Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of PF-07242813 in Healthy Participants and Participants With Atopic Dermatitis]
Date of this Report:	01 January 2024

– 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 atopic dermatitis?

Atopic dermatitis (AD), also called **atopic eczema**, is a common skin disease. AD causes itchy, red, and scaly rashes on the skin.

There are treatments available for AD, but not all treatments work well for people with moderate to severe AD.

What is PF-07242813?

PF-07242813 is a study medication that is given by an injection into the vein or under the skin. This is the first time that PF-07242813 was tested in people.

PF-07242813 blocks a part of the immune system that researchers think may be involved in causing AD.

What was the purpose of this study?

The main purpose of this study was to find out if PF-07242813 is safe and tolerable in healthy adults and adults with moderate to severe AD. In this study, PF-07242813 was given as a single dose or as multiple doses.

Researchers wanted to know:

What medical problems did participants have during the study?

What happened during the study?

How was the study done?

In this study, researchers tested PF-07242813 on different groups of participants. Researchers then compared the results of study participants taking PF-07242813 to the results of study participants taking a placebo.

A placebo does not have any medicine in it, but it looks just like the PF-07242813.

The study had 2 parts. Each participant joined only 1 part of the study.

Throughout the study during Parts 1 and 2:

- The study doctors and staff monitored the participants' health and well-being. Participants were asked about their health and medicines they were taking.
- The study participants and researchers did not know if participants got PF-07242813 or a placebo, but the Sponsor knew. This type of study is known as "double-blind" and "Sponsor-open".

  Knowing if participants got PF-07242813 or a placebo allowed the Sponsor to review the safety of participants given a lower dose level before a higher dose level was given to the next participants in this study.

Part 1 − Healthy participants:

This part had 2 main groups: the **single-dose healthy group** and the **multiple-dose healthy group**.

Within each main group were smaller groups of participants called "**cohorts**". Each cohort was enrolled one after another to receive **PF-07242813 or a placebo** by chance.

- Cohorts in the single-dose healthy group were enrolled first. Then, cohorts in the multiple-dose healthy group were enrolled later according to the study plan.
- The first cohort from each group was given the lowest dose level, and study doctors monitored their safety. If the first cohort had no safety concerns with the tested dose level, then the next cohort was given a higher dose level. This step-by-step process continued until all cohorts were enrolled and all dose levels in this study were tested.

Single-dose healthy group:

- Across the 8 cohorts in this group, dose levels from 0.3 milligrams (mg) to 1000 mg were tested. For each cohort, the dose was given 1 time by injection into the vein.
- This group also enrolled a cohort of healthy Japanese participants that were given a dose level of 1000 mg. The dose was given 1 time by injection into the vein.

Multiple-dose healthy group:

- Across the 4 cohorts in this group, dose levels from 15 mg to 300 mg were tested. For each cohort, each dose was given every 2 weeks for a total of 3 doses by injection under the skin.
- This group also enrolled a cohort that was given a dose level of 500 mg. The dose was given every 2 weeks for a total of 3 doses by injection into the vein.

Part 2 started after the study doctors and staff made sure there were no safety concerns in the cohorts from the single-dose healthy group in Part 1.

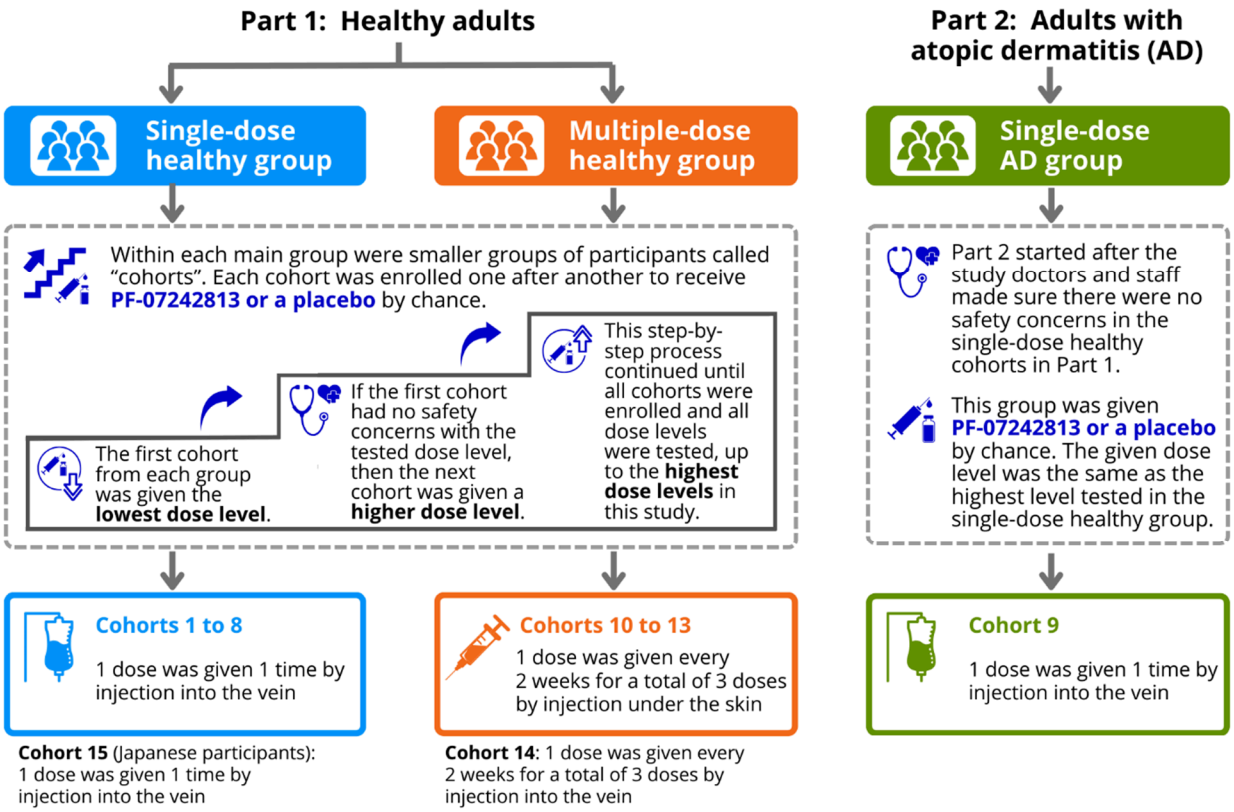
Part 2 – Participants with AD:

This part was done in 1 group of participants with moderate to severe AD who were given a single dose level. This group was called the **AD group**.

Participants got PF-07242813 1000 mg or a placebo by chance. They got their assigned treatment 1 time by injection into the vein.

Figure 1 shows what happened during Part 1 and Part 2 of the study.

Figure 1. What happened in the study?



Where did this study take place?

This study took place at 5 locations in the United States.

When did this study take place?

It began on 10 December 2020 and ended on 27 December 2022.

Who participated in this study?

The study included adults who met different requirements depending on which part of the study they entered.

Part 1: Healthy participants	Part 2: Participants with AD
Male or female adults from **18 to 55 years of age** who were assessed as **healthy** by the study doctor joined Part 1 Healthy adults, whose parents and grandparents were Japanese, also joined Part 1.	Male or female adults from **18 to 65 years of age** who had **moderate to severe AD** joined Part 2. These participants were diagnosed with AD for at least 1 year before they joined the study.

In total, 122 participants entered the study. All participants across the 3 groups were from 20 to 56 years of age.

Part 1: Healthy participants		Part 2: Participants with AD
Single-dose healthy group	**Multiple-dose healthy group**	**Single-dose AD group**
43 men (75.4%) and 14 women (24.6%) participated.	34 men (85.0%) and 6 women (15%) participated.	17 men (68.0%) and 8 women (32.0%) participated.
56 participants (98.2%) finished and 1 participant (1.8%) did not finish the treatment period.	34 participants (85.0%) finished and 6 participants (15.0%) did not finish the treatment period.	22 participants (88.0%) finished and 3 participants (12.0%) did not finish the treatment period.

In Parts 1 and 2, the most common reason for not finishing the treatment period was that participants left before the study was over by their choice. This was seen in the multiple-dose healthy group and single-dose AD group.

How long did the study last?

The length of time that participants were in the study, including the screening period, depended on their group assignment.

Part 1: Healthy participants		**Part 2: Participants with AD**
Single-dose healthy group	**Multiple-dose healthy group**	**Single-dose AD group**
Up to 100 days	Up to 127 days	Up to 141 days

The entire study took about 2 years to complete.

When the study ended in December 2022, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

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 unknown underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medication might have on a participant.

Researchers also recorded the participants' health test results during the study. These tests included:

- Lab tests: blood and urine.
- Vital signs: blood pressure, heart rate, breathing rate, and body temperature.
- Heart health tests, such as an electrocardiogram (ECG).

  An **ECG** is a test that records the heart's electrical activity, including the rate and rhythm.

Researchers found that, during the study:

- There were no safety concerns with the participants' lab tests. They also did not have medically important findings on their vital signs or physical exams.
- All participants who got PF-07242813 and most participants who got a placebo did not have medically important ECG findings.
  One (1) participant from the placebo group had an ECG finding that was reported as a medical problem. This medical problem was a "prolonged QT interval", which means it takes longer than usual for the heart to recharge between beats. The participant's ECG was back to normal after 2 days.

Overall, the study results showed that the tested doses of PF-07242813 were generally safe and well tolerated in:

- Healthy participants when given as a single dose or as multiple doses up to the highest dose level tested in this study.
- Participants with AD when given as a single dose.

The section below describes the medical problems reported by participants who got PF-07242813 or a placebo in Parts 1 and 2 combined.

In total, 41 out of 122 participants (33.6%) had at least 1 medical problem in Part 1 or 2. A total of 2 participants who got PF-07242813 left the study because of medical problems.

Table 1 describes the most common medical problems in the PF-07242813 and placebo groups. These medical problems were reported by more than 3% of the total participants in Parts 1 and 2 of the study.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by more than 3% of the total participants are listed.
- The **2nd** column tells how many of the 86 participants in the PF-07242813 group reported each medical problem. Next to this number is the percentage of the 86 participants in the PF-07242813 group who reported the medical problem.
- The **3rd** column tells how many of the 36 participants in the placebo group reported each medical problem. Next to this number is the percentage of the 36 participants in the placebo group who reported the medical problem.
- The **4th** column tells how many of the 122 participants in the total group reported each medical problem. Next to this number is the percentage of the 122 participants in the total group who reported the medical problem.
- For example, using these instructions, you can see how many participants reported headache:
    - PF-07242813 group: 5 out of 86 participants (5.8%).
    - Placebo group: 1 out of 36 participants (2.8%).
    - Total group: 6 out of 122 participants (4.9%).

Table 1. Commonly reported medical problems by study participants in Parts 1 and 2			
Medical Problem	**PF-07242813 (86 Participants)**	**Placebo (36 Participants)**	**Total (122 Participants)**
Headache	5 out of 86 participants (5.8%)	1 out of 36 participants (2.8%)	6 out of 122 participants (4.9%)
High level of alanine aminotransferase (ALT) in the blood	3 out of 86 participants (3.5%)	3 out of 36 participants (8.3%)	6 out of 122 participants (4.9%)
Infection of the upper lung airways	2 out of 86 participants (2.3%)	2 out of 36 participants (5.6%)	4 out of 122 participants (3.3%)

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.

Overall, 3 of 122 participants (2.5%) had serious medical problems in Part 1 or 2.

- **PF-07242813 group:** 1 participant had a broken bone in the leg and a lung infection.
- **Placebo group:** 1 participant had a positive COVID-19 test, and 1 participant had a severe allergic reaction to a dairy product.

Researchers do not believe that any of these serious medical problems were caused by PF-07242813.

No participant 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 **C4461001**

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

www.clinicaltrials.gov	Use the study identifier **NCT04668066**

Please remember that researchers look at the results of many studies to find out which medicines 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!