Plain Language Clinical Study

Summary

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 medicine 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(s) Studied: PF-07275315

Protocol Number: C4531001

Dates of Study: 09 June 2022 to 13 May 2024

Title of this Study: A Study to Learn About the Safety of Single and Multiple Doses of PF-07275315 in Healthy Participants

[A Phase 1, Randomized, Double-Blind, Sponsor Open, Placebo Controlled, Dose Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Intravenous and Subcutaneous Doses of PF-07275315 in Healthy Participants]

Date(s) of this Report: 15 April 2025

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

Pfizer

– 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. Do you have any questions about the study or the results? If so, please contact the doctor or staff at your study site.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

Pfizer

Why was this study done?

What is atopic dermatitis?

Atopic dermatitis (AD) is a common, long-lasting skin condition that affects both children and adults. AD is also known as eczema (a condition that makes the skin itchy, dry, and irritated). AD weakens the protective outer layer of the skin. This allows germs to grow, causing skin irritation, and increasing water loss from the skin. This results in periodic flare-ups of red and itchy skin.

The main symptoms of AD include dry and cracked skin, itchiness, and thickened skin. Although there are treatment options available, there is still a need for safer and more effective treatments that can work on the reasons that cause AD.

What is PF-07275315?

The study medicine, PF-07275315, is a new type of antibody. An antibody is a protein your body uses to fight off an infection. An antibody can also block other proteins that cause inflammation. PF-07275315 targets 3 proteins that may cause inflammation in people with AD. PF-07275315 is not yet approved for treatment in any country.

In this study, PF-07275315 was given as:

- A drip (infusion) into the vein, also known as “intravenous” (IV).
- An injection under the skin, also known as “subcutaneous” (SC).

What was the purpose of this study?

The main purpose of this study was to learn about the safety and tolerability of different single doses and multiple doses of PF-07275315 when given to healthy adult participants. “Tolerability” means how well participants can tolerate receiving the study medication.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

This study did not test if the drug helps to improve AD or any other disease.

Researchers wanted to know:

- **Did the researchers find any safety concerns in healthy participants who received different doses of PF-07275315?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Researchers tested different doses of PF-07275315 in multiple groups of healthy adult participants to learn about the safety of PF-07275315.

This study was done in 2 parts, Part A and Part B. In Part A, each participant received a single dose of PF-07275315 or "placebo". In Part B, the participants received multiple doses of PF-07275315 or placebo.

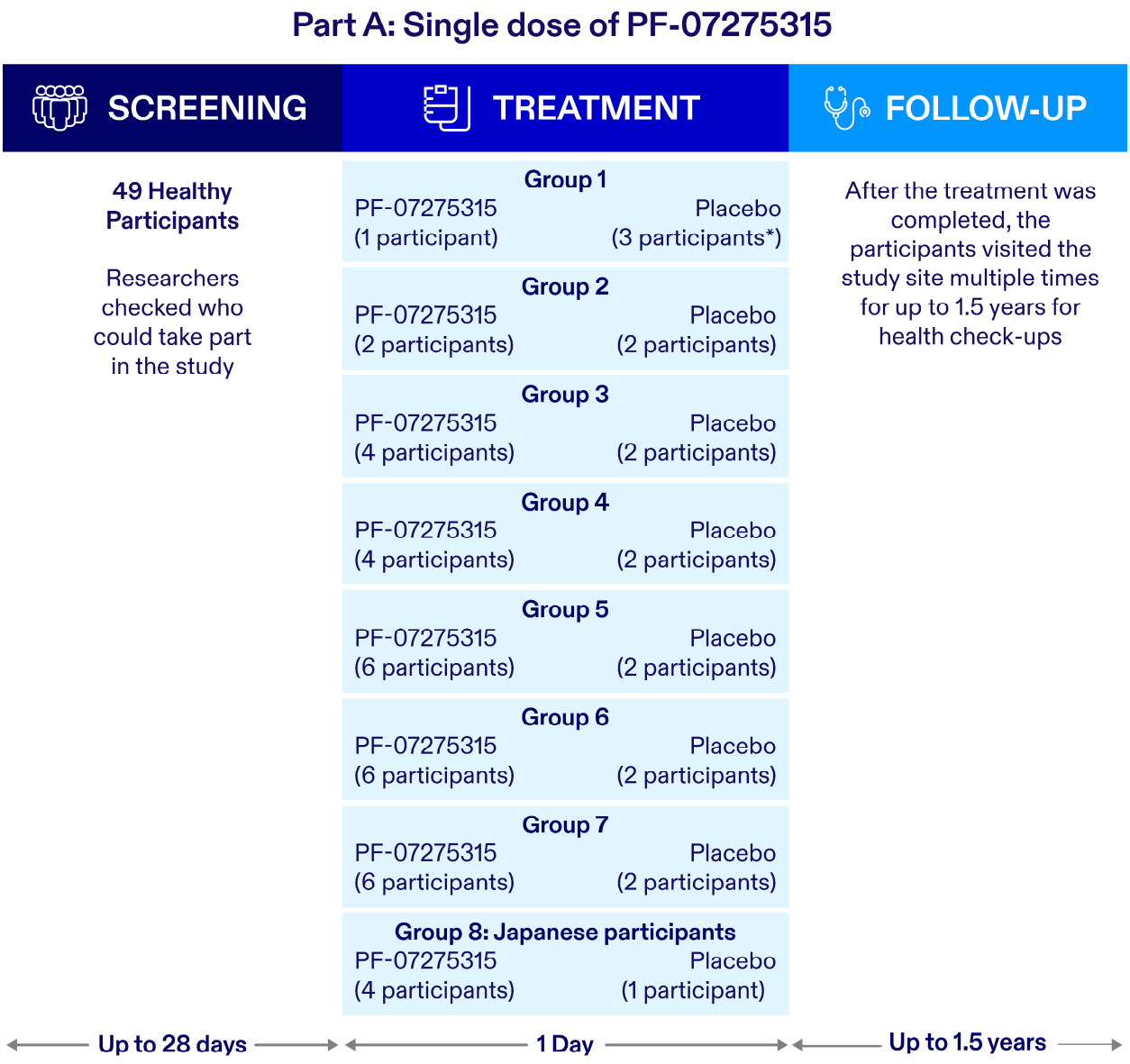
A placebo does not have any medicine in it, but it looks just like the study medicine. A placebo is used to help researchers try to understand if medical problems that participants had during the study could be related to study medicine or related to something else.

The participants and researchers did not know who received different doses of PF-07275315 and who received the placebo. This is known as a "blinded" study. Participants were assigned to each group by chance alone. This is known as "randomization".

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

In **Part A**, there were 8 groups. Each group received a single dose of PF-07275315 or placebo as an IV infusion. The Figure 1 below shows what happened during Part A.

Figure 1. What happened during Part A



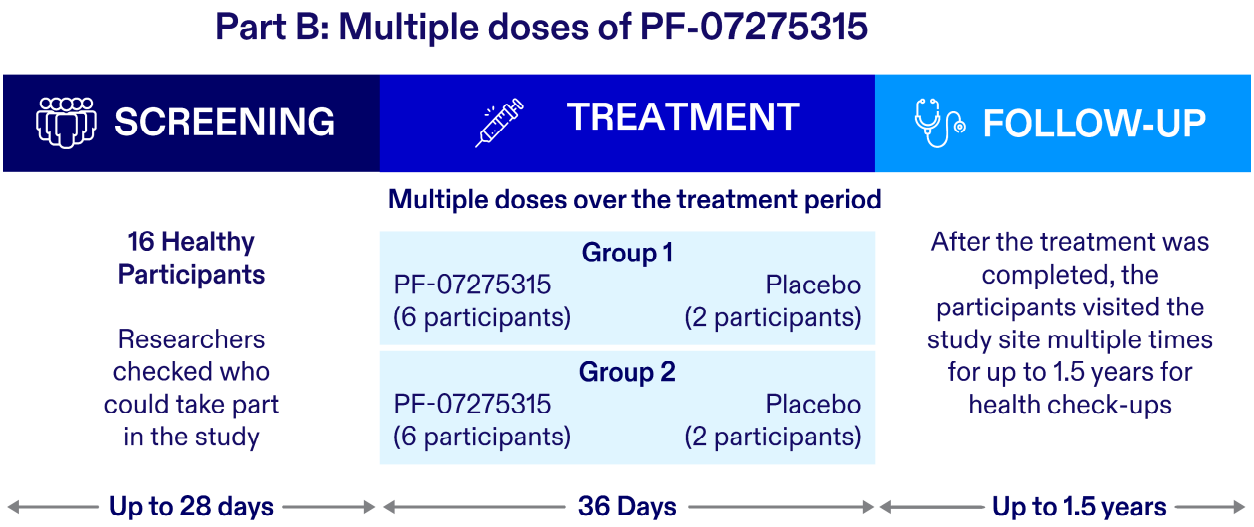
*One (1) participant assigned in Group 1 to receive a single dose of PF-07275315 was administered placebo due to dosing error.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

In **Part B**, there were 2 groups. The participants received multiple doses of PF-07275315 or placebo as an injection.

Figure 2 below shows what happened during Part B.

Figure 2. What happened during Part B



Participants visited the study site after their last dose for up to 1.5 years. During these visits, the researchers collected blood samples for laboratory tests and carried out health checks.

Researchers compared the results from study participants in each treatment group.

Researchers checked the participants' health throughout the study.

Where did this study take place?

The Sponsor ran this study in 4 locations across United States and Belgium in North America and Europe.

When did this study take place?

The study began 09 June 2022 and ended 13 May 2024.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

Who participated in this study?

The study included healthy adult participants with a body mass index (a measure of body weight in relation to height) of 19 to 32 kilograms per square meter (kg/m^2) who weighed more than or equal to 50 kg.

- A total of 40 men participated.
- A total of 25 women participated.
- All participants were between the ages of 20 years and 65 years.

Participants were in the study until there were only low amounts of PF-07275315 in the blood to check for any safety concerns.

All 49 participants who received PF-07275315 in Part A finished the study treatment phase. Two (2) participants from Part A chose to leave the study during the follow-up phase.

Of the 16 participants who started the study in Part B, 15 participants finished the treatment phase and 1 participant stopped receiving PF-07275315 due to a medical problem. All 16 participants completed the follow-up phase of study.

How long did the study last?

Study participants were in the study for about 18 months (1.5 years). The entire study took about 1 year and 11 months to complete.

The Sponsor monitored the data continuously during the study. When the study ended in May 2024, the Sponsor began reviewing all the information collected on both PF-07275315 and placebo. The Sponsor then created a report of the results. This is a summary of that report.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

What were the results of the study?

Did the researchers find any safety concerns in healthy participants who received different doses of PF-07275315?

To answer this question, researchers looked at the results from physical examination, blood and other laboratory tests, vital signs (blood pressure, heart rate, and body temperature), electrocardiogram (ECG) tests, and reports of undesirable effects experienced by participants. An ECG is a test of the heart's activity that looks at how well the heart is working.

The study found that single and multiple doses of PF-07275315 were generally well-tolerated by healthy participants. Overall, the researchers did not find any safety concerns when PF-07275315 was given as a single dose through infusion into the vein, or as multiple doses as an injection under the skin.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

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 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 medicine might have on a participant.

Part A

In Part A:

Sixteen (16) out of 33 participants (48.5%) who received different doses of PF-07275315 had at least 1 medical problem. Six (6) out of 16 participants (37.5%) who received placebo had at least 1 medical problem. No participants left the study during Part A because of medical problems. The most common medical problems – those reported by 2 or more participants – are described below in Table 1.

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 Part A of the study. All medical problems reported by 2 or more participants are listed.
- The **2nd** column tells how many of the 33 participants who received the study medicine reported each medical problem. Below this

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

number is the percentage of the 33 participants receiving the study medicine who reported the medical problem.

- The **3rd** column tells how many of the 16 participants who received a placebo reported each medical problem. Below this number is the percentage of the 16 participants receiving a placebo who reported the medical problem.
- Using these instructions, you can see that 2 out of the 33 participants (6.1%) who took the study medicine reported fall. Zero (0) out of 16 participants (0%) who took a placebo reported a fall.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

Table 1. Commonly reported medical problems by study participants (Part A)		
Medical Problem	**All doses of PF-07275315 (33 Participants)**	**Placebo (16 Participants)**
Fall	2 out of 33 participants (6.1%)	0 out of 16 participants (0%)
Limb injury	2 out of 33 participants (6.1%)	0 out of 16 participants (0%)
Scratch	2 out of 33 participants (6.1%)	0 out of 16 participants (0%)
Muscle protein (creatine phosphokinase) increased in the blood	2 out of 33 participants (6.1%)	1 out of 16 participants (6.3%)
Reddening of the skin at the site of infusion	2 out of 33 participants (6.1%)	0 out of 16 participants (0%)

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

Part B

In Part B, 6 out of 12 participants (50.0%) who received different doses of PF-07275315 had at least 1 medical problem. Zero (0) out of the 4 participants (0%) who received placebo experienced a medical problem. One (1) participant discontinued PF-07275315 because of a medical problem but continued to participate study during Part B. The most common medical problems – those reported by 2 or more participants – are described below in Table 2.

Below are instructions on how to read Table 2.

Instructions for Understanding Table 2.

- The **1st** column of Table 2 lists medical problems that were commonly reported during Part B of the study. All medical problems reported by 2 or more participants are listed.
- The **2nd** column tells how many of the 12 participants who received the study medicine reported each medical problem. Below this number is the percentage of the 12 participants receiving the study medicine who reported the medical problem.
- The **3rd** column tells how many of the 4 participants who received a placebo reported each medical problem. Below this number is the percentage of the 4 participants receiving a placebo who reported the medical problem.
- Using these instructions, you can see that 2 out of the 12 participants (16.7%) who received the study medicine reported nausea. Zero (0) out of 4 participants (0%) who received a placebo reported nausea.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

Table 2. Commonly reported medical problems by study participants (Part B)		
Medical Problem	**All doses of PF-07275315 (12 Participants)**	**Placebo (4 Participants)**
Nausea	2 out of 12 participants (16.7%)	0 out of 4 participants (0%)
Pain, stinging, redness, or swelling where the injection was given	2 out of 12 participants (16.7%)	0 out of 4 participants (0%)
COVID infection	2 out of 12 participants (16.7%)	0 out of 4 participants (0%)

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

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.

None of the participants who received PF-07275315 had serious medical problems in this study. One (1) out of the 16 participants (6.3%) who received placebo in Part A of the study had a serious medical problem of an early pregnancy loss (miscarriage). Researchers do not believe this serious medical problem was related to study treatment.

No participants died during the study.

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

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 **C4531001**

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

https://www.clinicaltrials.gov

Use the study identifier **NCT05411588**

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!

090177e1a34ecb02\Approved\Approved On: 16-Apr-2025 06:41 (GMT)

Pfizer