

## 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(s) Studied:** PF-07038124

**Protocol Number:** C3941003

**Dates of Study:** 30 June 2021 to 09 September 2021

**Title of this Study:** Study to Evaluate the Safety, Local and Systemic Tolerability, and Pharmacokinetics of Multiple-Dose Topical Administration of PF-07038124 in Japanese Healthy Participants  
[A Phase 1, Randomized, Double-Blind, Vehicle-Controlled, Parallel Cohort Study to Evaluate the Safety, Tolerability, Skin Irritation Potential and Pharmacokinetics of Multiple-Dose, Topical Administration of PF-07038124 to Japanese Healthy Participants]

**Date(s) of this Report:** 19 April 2022

— 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?

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### What are atopic dermatitis and psoriasis?

Atopic dermatitis (AD) and psoriasis are two common diseases that can cause symptoms like redness, itching, pain, and dry or scaly patches of the skin. While researchers think that many things can cause AD or psoriasis, they are made worse by inflammation, which is the body's immune system response.

### What is PF-07038124?

PF-07038124 is an investigational medicine that is being studied to treat AD and psoriasis. An investigational medicine is one that has not been approved for use outside of research studies like this one. PF-07038124 is applied to the skin as an ointment. PF-07038124 may improve symptoms of AD and psoriasis by decreasing inflammation in the skin.

### What was the purpose of this study?

The main purpose of this study was to learn more about the safety and tolerability of PF-07038124 when used in healthy Japanese adults (who did not have AD or psoriasis).

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### Researchers wanted to know:

**What medical problems did participants have?**

**Did participants have skin irritation after applying PF-07038124 or plain ointment?**

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## What happened during the study?

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### How was the study done?

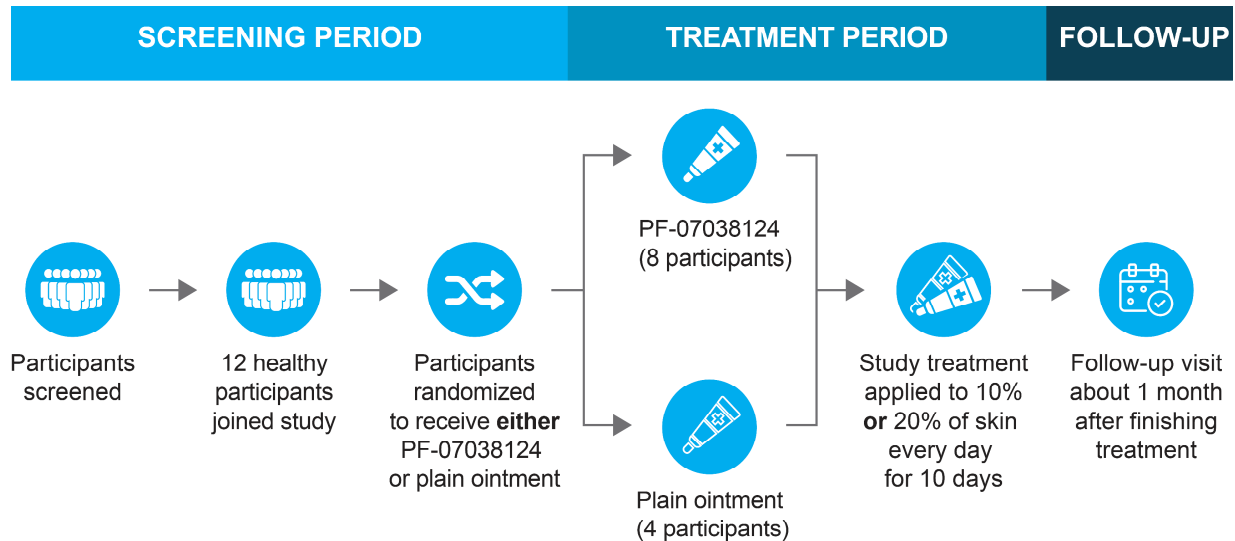
Researchers studied 2 groups of participants to learn more about the safety of PF-07038124. The study included healthy adult participants. Participants included in the study:

- Were ethnically Japanese (all 4 grandparents were Japanese)
- Were at a normal weight
- Did not have any skin damage or skin diseases

Participants were assigned to 1 of 2 treatment groups by chance (like the flip of a coin) to receive either PF-07038124 0.01% or plain ointment applied to the skin. The plain ointment looked just like PF-07038124 but didn't have any medicine in it.

The study treatments were applied to about 10% of the skin or about 20% of the skin. All treatments were applied at the study center by a staff member, every day for 10 days. Neither the study staff, the researchers, nor the participants knew which treatment they received. This is known as a double-blind study. Participants were also expected to attend a follow-up visit about 1 month after finishing study treatment.

The figure below shows what happened during the study.



## Where did this study take place?

The study was conducted at 1 location in Japan.

## When did this study take place?

It began 30 June 2021 and ended 09 September 2021.

## Who participated in this study?

A total of 12 participants joined this study:

- A total of 12 men (100%) participated
- No women (0%) participated
- All participants were between the ages of 33 and 53 years

All 12 participants (100%) completed the study.

## How long did the study last?

Participants could be in the study for up to approximately 10 weeks, which was how long it took to complete the entire study. When the study ended in September 2021, 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?

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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 the 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.

One out of 12 participants (8%) had a medical problem, which was an increase in the liver enzyme “alanine aminotransferase”. This medical problem was not considered to be related to study treatment. No participants stopped taking study treatment because of medical problems.

## Did study participants have skin irritation after applying PF-07038124 or plain ointment?

No participants in this study had visible skin irritation after applying PF-07038124 or plain ointment.

## Did study participants have any serious medical problems?

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A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems. No participants in this study had serious medical problems, and no participants died during the study.



## Where can I learn more about this study?

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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.clinicaltrials.gov](http://www.clinicaltrials.gov)

Use the study identifier **NCT04863417**

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!