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-07038124
Protocol Number:	C3941005
Dates of Study:	26 September 2022 to 31 July 2023
Title of this Study:	A Study of PF-07038124 Ointment in Participants With Atopic Dermatitis or Plaque Psoriasis [A Phase 2b, Randomized, Double Blind, Vehicle Controlled, Parallel Group Study to Assess the Efficacy, Safety, Tolerability and Pharmacokinetics of Multiple Dose Levels of PF-07038124 Ointment for 12 Weeks in Participants 12 Years and Older and With Mild-to-Moderate Atopic Dermatitis or Mild-to-Severe Plaque Psoriasis]
Date of this Report:	16 January 2024

– Thank You –

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

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

Why was this study done?

What are atopic dermatitis and plaque psoriasis?

Atopic dermatitis, or **AD**, is a common skin disease that can cause many symptoms, such as itching, redness, and a rash that is scaling or oozing. Symptoms of AD can look different on different people. People with AD often have this skin disease for many years, and may have "flare ups", which are times when their symptoms are worse.

Plaque psoriasis, or **PsO**, is also a skin disease. Like in AD, people with PsO may also have flare ups. During a flare up, the skin usually has red, scaly, and raised patches called plaques.

What is PF-07038124?

PF-07038124 is a study medication that is applied on the affected skin as an ointment. It is designed to block a part of the immune system that may be involved in causing AD and PsO.

The use of PF-07038124 in this study was investigational, which means it is not approved for use in people with AD or PsO outside of research studies.

What was the purpose of this study?

The main purpose of this study was to find out if PF-07038124 ointment could help participants with their AD or PsO symptoms.

In this study, PF-07038124 was compared to a vehicle ointment. A vehicle ointment does not have any medicine in it, but it looks like the PF-07038124 ointment.

Researchers wanted to know:

- **Did more participants who used PF-07038124 ointment have little to no AD or PsO symptoms after treatment compared to those who used a vehicle ointment?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Study doctors checked whether participants met the study requirements. Then, participants were placed into 1 of 3 treatment groups if they had AD and 1 of 4 treatment groups if they had PsO. They were randomly placed in a treatment group by a computer.

Participants with AD

They were assigned to be in 1 of 3 groups:

- PF-07038124 0.01% group
- PF-07038124 0.03% group
- Vehicle group

Participants with PsO

They were assigned to be in 1 of 4 groups:

- PF-07038124 0.01% group
- PF-07038124 0.03% group
- PF-07038124 0.06% group
- Vehicle group

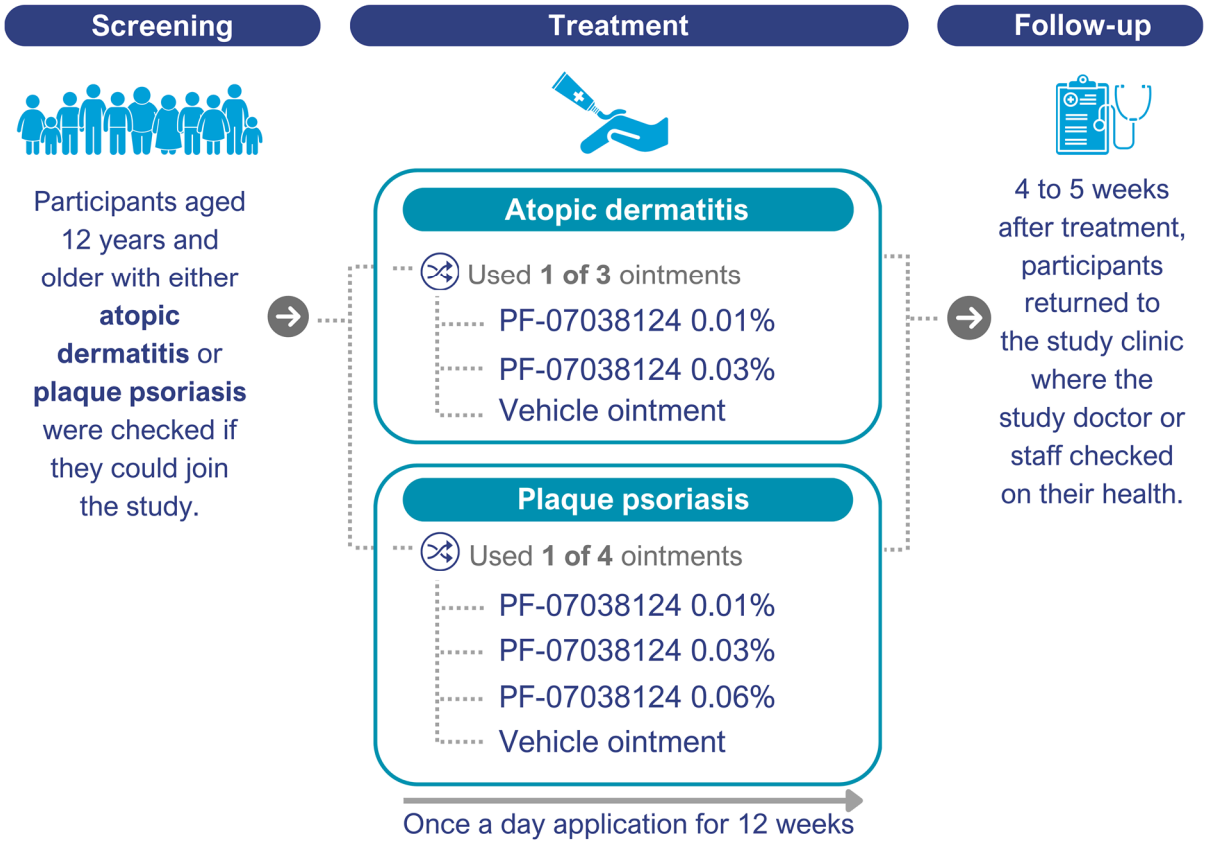
Participants were to apply their assigned ointment on affected skin once a day for 12 weeks.

The participants and researchers did not know during the study who used PF-07038124 ointment and who used a vehicle ointment. This is known as a “blinded” study.

After the treatment period, participants continued to be in the study for 4 to 5 more weeks so study doctors could continue to monitor their health.

Figure 1 below shows how the study was done.

Figure 1. How was this study done?



Throughout the study, participants visited a study clinic regularly. During these visits, participants:

- had blood and urine samples taken.

- answered questions about their overall health.
- got checked for their AD or PsO.

Researchers checked how many participants who used PF-07038124 had little to no AD or PsO symptoms after treatment. Researchers then compared the results from participants using PF-07038124 ointment to the results from participants using a vehicle ointment.

Where did this study take place?

The Sponsor ran this study at 31 locations in Canada, Japan, United Kingdom, and United States.

When did this study take place?

It began on 26 September 2022 and ended on 31 July 2023.

Who participated in this study?

The study included participants who have mild to moderate AD or mild to severe PsO. Participants were from 13 to 87 years old.

Participants with AD:

Out of 128 participants:

- 57 boys or men (44.5%) and 71 girls or women (55.5%) participated.
- 95 participants (74.2%) finished, and 33 participants (25.8%) did not finish the treatment period.

Participants with PsO:

Out of 135 participants:

- 79 boys or men (58.5%) and 56 girls or women (41.5%) participated.
- 112 participants (83.0%) finished, and 23 participants (17.0%) did not finish the treatment period.

Most of the participants who did not finish treatment decided on their own to stop using their assigned ointment.

How long did the study last?

Study participants were in the study for about 21 weeks (or about 5 months). The entire study took about 10 months to complete.

When the study ended in July 2023, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Did more participants who used PF-07038124 ointment have little to no AD or PsO symptoms after treatment compared to those who used a vehicle ointment?

Researchers looked at the results of 2 tests to answer this question:

Investigator Global Assessment, or **IGA**, for participants with AD.

Physician Global Assessment, or **PGA**, for participants with PsO.

Study doctors used IGA and PGA to assess the participants' skin and tell how severe their AD or PsO was. IGA and PGA scores range from 0 to 4. A higher score means more severe AD or PsO.

Understanding IGA and PGA scores:

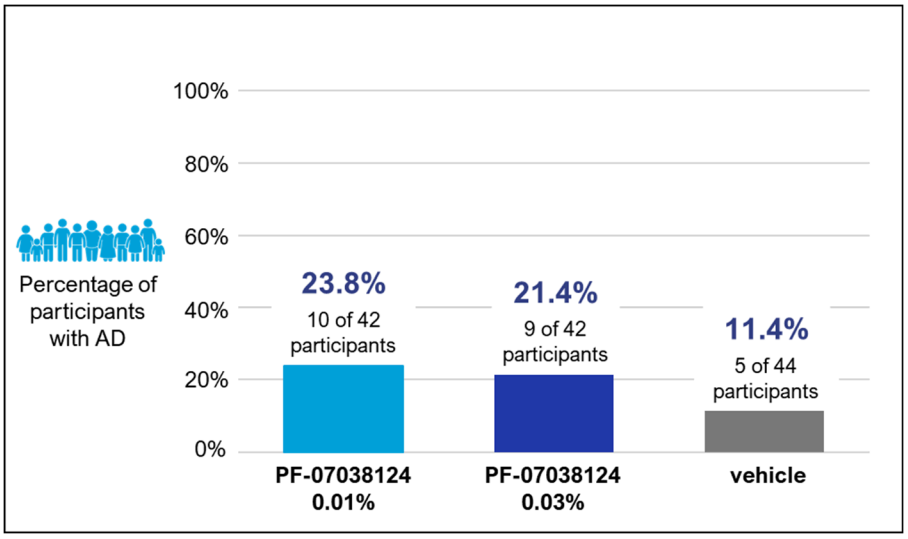
After 12 weeks of treatment, researchers checked how many participants had little to no AD or PsO symptoms, and a drop in score by 2 points or more since the start of treatment.

Participants with AD:

Figure 2 below shows that more participants who used PF-07038124 0.01% (23.8%) and 0.03% (21.4%) had little to no AD symptoms after treatment compared to those who used a vehicle ointment (11.4%). But, the difference in results between the PF-07038124 and vehicle ointment treatment groups was too small and was likely due to chance.

This means that **PF-07038124 0.01%** or **0.03%** may not help children and adults with mild to moderate AD with their symptoms.

Figure 2. How many participants had little to no AD symptoms after 12 weeks of treatment?



Participants with PsO:

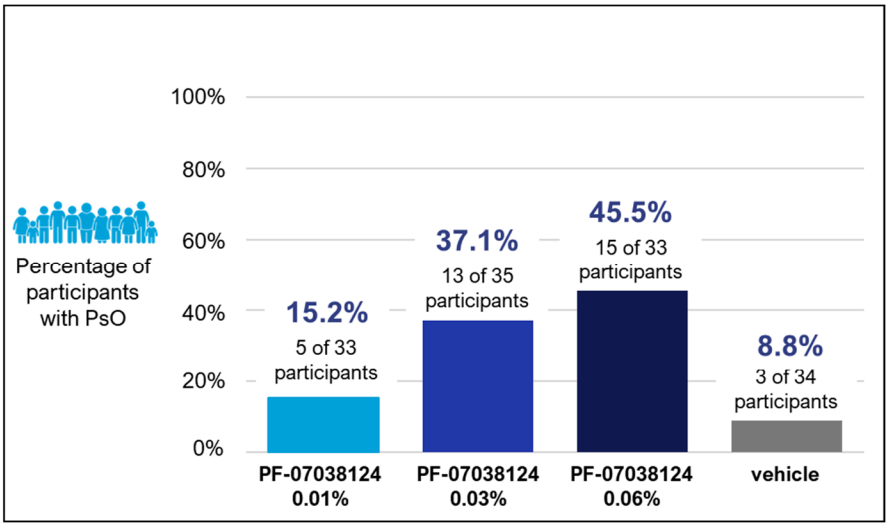
- Figure 3 below shows that more participants who used PF-07038124 0.01% (15.2%) had little to no PsO symptoms compared to those who used a vehicle ointment (8.8%). But, the difference in results between these treatment groups was too small and was likely due to chance.

  This means that **PF-07038124 0.01%** may not help children and adults with mild to severe PsO with their symptoms.

- Figure 3 also shows that more participants who used PF-07038124 0.03% (37.1%) and 0.06% (45.5%) had little to no PsO symptoms after treatment compared to those who used a vehicle ointment (8.8%). The difference in results between the PF-07038124 (0.03% and 0.06%) and vehicle ointment treatment groups was big enough for researchers to say that these results are not likely due to chance.

  This means that **PF-07038124 0.03%** or **0.06%** may help children and adults with mild to severe PsO with their symptoms.

Figure 3. How many participants had little to no PsO symptoms after 12 weeks of treatment?



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.

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 medication might have on a participant.

The list below shows how many participants using PF-07038124 or a vehicle ointment had at least 1 medical problem during the study:

- 67 out of 128 participants (52.3%) with AD.
- 52 out of 135 participants (38.5%) with PsO.

No participant left the study because of medical problems.

Participants with AD:

The most common medical problems that participants with AD had in the study are described in Table 1 below. These common medical problems are those reported by more than 2% of total participants with AD.

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 by participants with AD during the study. All medical problems reported by more than 2% of total participants with AD are listed.
- The **2nd** column tells how many of the 42 participants who used PF-07038124 0.01% reported each medical problem. Next to this number is the percentage of these 42 participants who reported the medical problem.
- The **3rd** column tells how many of the 42 participants who used PF-07038124 0.03% reported each medical problem. Next to this number is the percentage of these 42 participants who reported the medical problem.
- The **4th** column tells how many of the 44 participants who used a vehicle ointment reported each medical problem. Next to this number is the percentage of these 44 participants who reported the medical problem.
- For example, using these instructions, you can see how many participants were reported with COVID-19:
    - 1 out of 42 participants (2.4%) in the **PF-07038124 0.01%** group.
    - 0 out of 42 participants (0%) in the **PF-07038124 0.03%** group.
    - 2 out of 44 participants (4.5%) in the **vehicle** group.

Table 1. Commonly reported medical problems by study participants with AD

Medical Problem	PF-07038124 0.01% (42 Participants)	PF-07038124 0.03% (42 Participants)	Vehicle (44 Participants)
COVID-19	1 out of 42 participants (2.4%)	0 out of 42 participants (0%)	2 out of 44 participants (4.5%)
Flu	2 out of 42 participants (4.8%)	1 out of 42 participants (2.4%)	0 out of 44 participants (0%)
Common cold	1 out of 42 participants (2.4%)	2 out of 42 participants (4.8%)	1 out of 44 participants (2.3%)
Infection of the upper lung airways	5 out of 42 participants (11.9%)	2 out of 42 participants (4.8%)	0 out of 44 participants (0%)
Worsening of AD	0 out of 42 participants (0%)	2 out of 42 participants (4.8%)	1 out of 44 participants (2.3%)
Skin allergy	0 out of 42 participants (0%)	1 out of 42 participants (2.4%)	2 out of 44 participants (4.5%)

Table 1. Commonly reported medical problems by study participants with AD			
Medical Problem	**PF-07038124 0.01% (42 Participants)**	**PF-07038124 0.03% (42 Participants)**	**Vehicle (44 Participants)**
Itchy skin	2 out of 42 participants (4.8%)	1 out of 42 participants (2.4%)	1 out of 44 participants (2.3%)
Skin discoloration	1 out of 42 participants (2.4%)	2 out of 42 participants (4.8%)	0 out of 44 participants (0%)

Participants with PsO:

The most common medical problems that participants with PsO had in the study are described in Table 2 below. These common medical problems are those reported by more than 2% of total participants with PsO.

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 by participants with PsO during the study. All medical problems reported by more than 2% of total participants with PsO are listed.

- Like in Table 1, the **2nd** to **5th** columns tell how many of the participants in each treatment group reported each medical problem.
- For example, using these instructions, you can see how many participants were reported with common cold:
    - 2 out of 33 participants (6.1%) in the **PF-07038124 0.01%** group.
    - 2 out of 35 participants (5.7%) in the **PF-07038124 0.03%** group.
    - 3 out of 33 participants (9.1%) in the **PF-07038124 0.06%** group.
    - 0 out of 34 participants (0%) in the **vehicle** group.

Table 2. Commonly reported medical problems by study participants with PsO

Medical Problem	PF-07038124 0.01% (33 Participants)	PF-07038124 0.03% (35 Participants)	PF-07038124 0.06% (33 Participants)	Vehicle (34 Participants)
Common cold	2 out of 33 participants (6.1%)	2 out of 35 participants (5.7%)	3 out of 33 participants (9.1%)	0 out of 34 participants (0%)

Table 2. Commonly reported medical problems by study participants with PsO				
Medical Problem	**PF-07038124 0.01% (33 Participants)**	**PF-07038124 0.03% (35 Participants)**	**PF-07038124 0.06% (33 Participants)**	**Vehicle (34 Participants)**
Infection of the upper lung airways	1 out of 33 participants (3.0%)	0 out of 35 participants (0%)	2 out of 33 participants (6.1%)	1 out of 34 participants (2.9%)
High level of blood sugar	1 out of 33 participants (3.0%)	0 out of 35 participants (0%)	1 out of 33 participants (3.0%)	1 out of 34 participants (2.9%)
Headache	1 out of 33 participants (3.0%)	1 out of 35 participants (2.9%)	1 out of 33 participants 3.0%)	0 out of 34 participants (0%)

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.

A total of 3 out of 263 participants (1.1%) had serious medical problems during the study. The serious medical problems reported by the participants in the AD and PsO groups are described below.

Participants with AD:

- 1 participant from the **PF-07038124 0.01%** group had a mental disorder.
- 1 participant from the **PF-07038124 0.03%** group had a tumor in the pancreas.

Participants with PsO:

- 1 participant from the **PF-07038124 0.06%** group had a high level of fats in the blood.

Researchers do not think that any of these serious medical problems were caused by PF-07038124.

No participants died during the study.

Where can I learn more about this study?

If you or your child have questions about the results of your or your child's 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 **C3941005**

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

www.clinicaltrials.gov	Use the study identifier **NCT05375955**

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 or your child 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!