



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 study participants. 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: C3941002

Dates of Study: 21 December 2020 to 18 August 2021

Title of this Study: Study of PF-07038124 Ointment Compared With Plain Ointment in the Treatment of Participants With Mild to Moderate Atopic Dermatitis or Plaque Psoriasis
[A Phase 2a, Randomized, Double Blind, Vehicle Controlled, Parallel Group Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of PF-07038124 Ointment for 6 Weeks in Participants With Mild to Moderate Atopic Dermatitis or Plaque Psoriasis]

Date(s) of this Report: 17 February 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?

What is atopic dermatitis and plaque psoriasis?

Atopic dermatitis is a common skin condition that can cause many symptoms, such as itching, redness, and a rash that is scaling or oozing. The symptoms can look different on different people. Atopic dermatitis is also known as eczema. People with atopic dermatitis often have this condition for many years, and may have “flare ups”, when their symptoms worsen for a time.

Plaque psoriasis is a common type of psoriasis seen by doctors. People with this disease, also have flare ups where their symptoms worsen. The skin, during a flare up, is usually red and scaly with raised plaques or patches on the skin.

What is PF-07038124?

The study drug (PF-07038124) is an investigational drug because it is not approved for use in people with atopic dermatitis or plaque psoriasis. It is applied to the skin as an ointment once a day. The researchers wanted to know if treatment with PF-07038124 ointment was able to improve symptoms of atopic dermatitis and plaque psoriasis by decreasing inflammation in the skin. Inflammation is the body’s immune system response, which can lead to the symptoms seen in atopic dermatitis and plaque psoriasis.

What was the purpose of this study?

The purpose of this study is to compare the effects of PF-07038124 ointment with a plain ointment to see if there are any differences between these ointments when used to treat atopic dermatitis or plaque psoriasis. The plain ointment looks and feels like the PF-07038124 ointment but does not contain any medicine.

The researchers compared PF-07038124 ointment with plain ointment by measuring the amount and severity of atopic dermatitis or plaque psoriasis. They did this by calculating the Eczema Area and Severity Index (EASI) score or the Psoriasis Area and Severity Index (PASI) score. These measures are used to estimate how much of a

person's body is affected by atopic dermatitis (EASI score) or plaque psoriasis (PASI score) and also the severity of the atopic dermatitis or plaque psoriasis. The researchers also wanted to find out about the safety of PF-07038124.

Researchers wanted to know:

Did participants using PF-07038124 ointment have less severe atopic dermatitis or plaque psoriasis and/or the area affected was reduced compared to participants using plain ointment?

What happened during the study?

How was the study done?

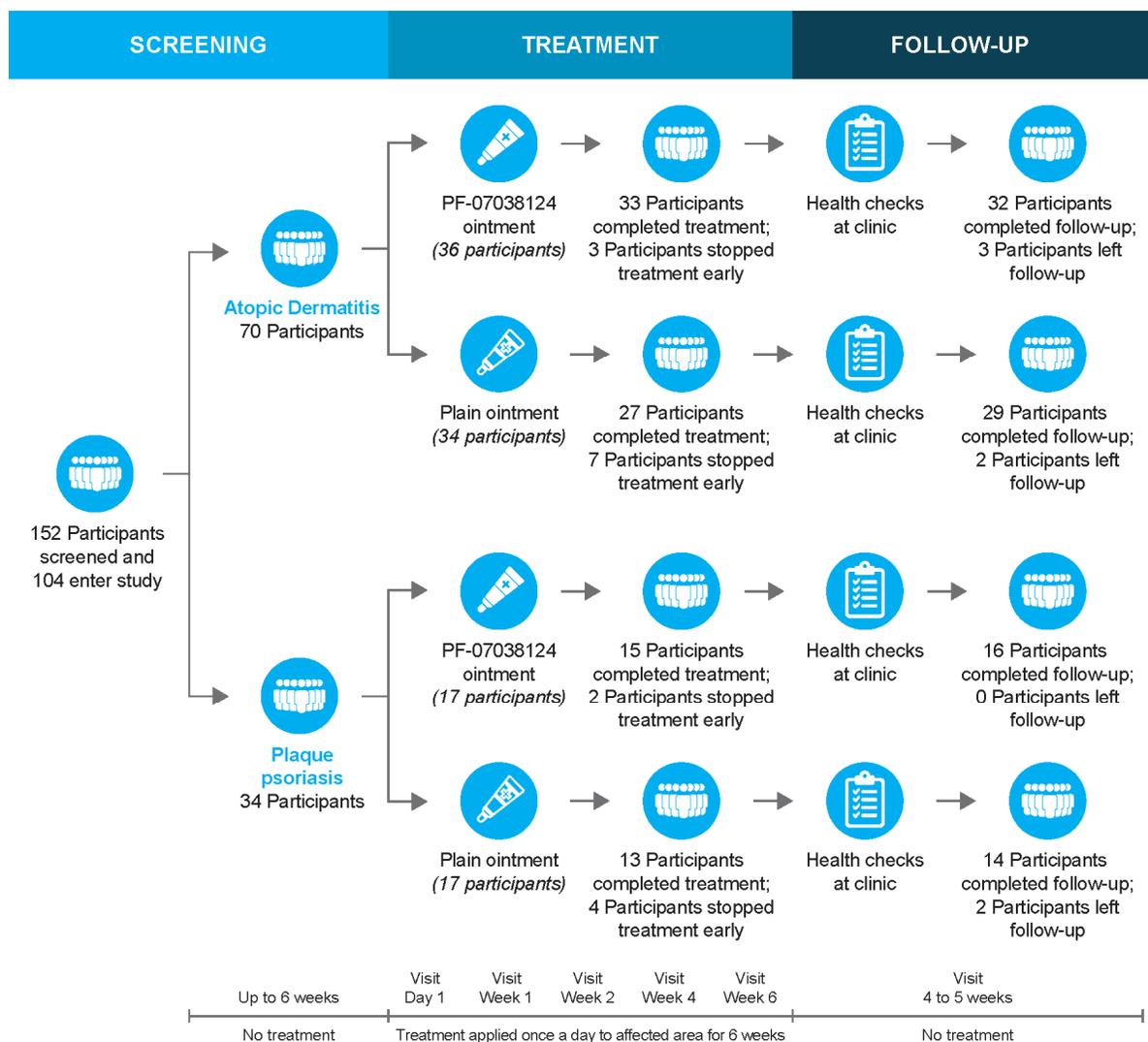
Researchers tested PF-07038124 ointment on a group of study participants to find out if study participants treated with this ointment had fewer symptoms of atopic dermatitis or plaque psoriasis than participants who used a plain ointment.

Participants went to the study center to be screened by the study doctor to make sure they were able to join the study and to see if they had mild to moderate atopic dermatitis or plaque psoriasis. This was known as the “screening period” and this lasted up to 6 weeks. Participants then entered the treatment period, which started on Day 1 and lasted 6 weeks. During the treatment period, participants were to apply the ointment once a day to an area or areas of skin affected by their atopic dermatitis or plaque psoriasis.

The study participants and researchers did not know who used PF-07038124 ointment and who used the plain ointment. This is known as a “blinded” study. Study participants were assigned to each group by chance alone.

Each participant visited the study center on Day 1, and then on Week 1, Week 2, Week 4, and Week 6. During these visits, the study doctors assessed the participant's atopic dermatitis or plaque psoriasis and general health. Participants were also asked to provide blood and urine samples for testing. Participants were not treated after Week 6 but were to remain in the study for the next 4 to 5 weeks for safety monitoring and questioning about their health. Participants then returned to the study center for the final study assessments.

The following figure shows what happened during this study:



Note: Not all participants were available to attend the follow-up visit.

Where did this study take place?

The Sponsor ran this study at 34 locations in 4 countries in North America, Australia, and Europe.

When did this study take place?

It began 21 December 2020 and ended 18 August 2021.

Who participated in this study?

The study included adult participants who had mild or moderate atopic dermatitis or mild or moderate plaque psoriasis.

- A total of 49 men participated
- A total of 55 women participated
- All participants were between the ages of 19 and 70 years

Participants were to be treated for 6 weeks. Of the 152 participants who were screened, 104 participants (70 [67%] with atopic dermatitis and 34 [33%] with plaque psoriasis) started the study, 88 participants (60 [58%] with atopic dermatitis and 28 [27%] with plaque psoriasis) completed treatment, and 91 participants (61 [59%] with atopic dermatitis and 30 [29%] with plaque psoriasis) finished the safety follow up phase of the study.

There were 16 participants (10 [10%] with atopic dermatitis and 6 [6%] with plaque psoriasis) who did not finish treatment, and 7 participants (5 [5%] with atopic dermatitis and 2 [2%] with plaque psoriasis) who did not finish the safety follow up part of the study. Most participants stopped study treatment because of medical problems or because they no longer wanted to continue in the study.

How long did the study last?

Study participants were in the study for 16 to 17 weeks. The entire study took just over 34 weeks to complete.

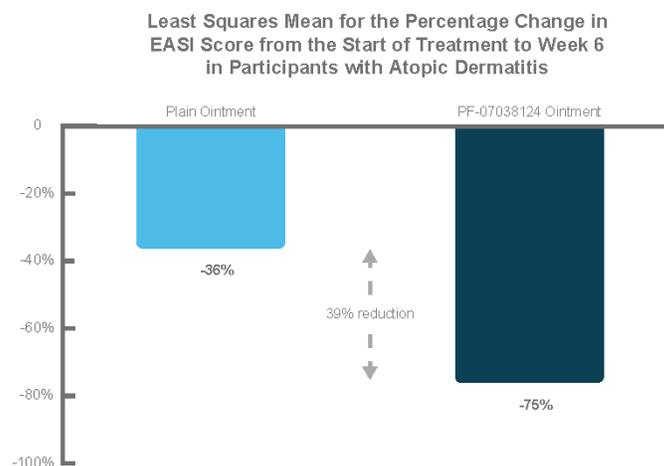
When the study ended in August 2021, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Did participants using PF-07038124 ointment have less severe atopic dermatitis or plaque psoriasis and/or the area was affected was reduced compared to participants using plain ointment?

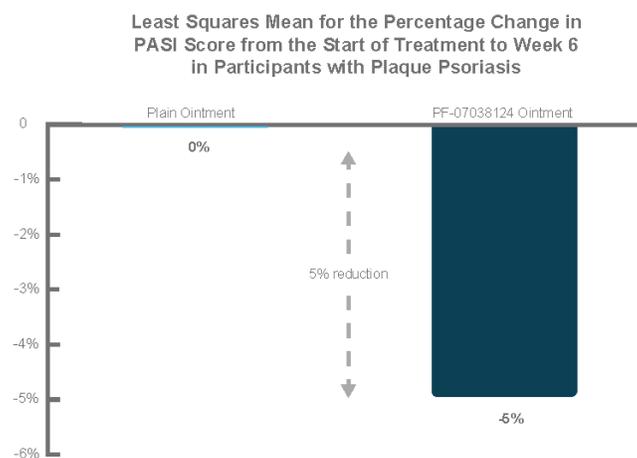
Did the PF-07038124 ointment help reduce the symptoms of atopic dermatitis compared to plain ointment?

On average, the least squares mean (LSM) for the percentage change in EASI score from the start of treatment to Week 6 in participants with atopic dermatitis was reduced by 75% with PF-07038124 compared to 36% with plain ointment (see figure below). A lower EASI score means the atopic dermatitis affects a smaller area or it is less severe. The difference between the treatment groups was 39%. An LSM is a special way of calculating the average in certain types of statistical analysis.



Did the PF-07038124 ointment help reduce the symptoms of plaque psoriasis compared to plain ointment?

On average, the LSM for the percentage change in PASI score from the start of treatment to Week 6 in participants with plaque psoriasis was reduced by 5% with PF-07038124 compared to no change with plain ointment (see figure below). A lower PASI score means the plaque psoriasis affects a smaller area or it is less severe. The difference between the treatment groups was 5%.



Based on these results, the researchers have decided that the results are not likely the result of chance. The study medication may help reduce some symptoms of atopic dermatitis and plaque psoriasis.

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.

Twenty-seven (27) out of 104 (26%) participants in this study had at least 1 medical problem. There were no participants who stopped using PF-07038124 ointment because of medical problems. There were 5 (10%) participants who stopped using the plain ointment because of medical problems. The most common medical problems – those reported by 2 or more participants – are described below.

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 2 or more participants are listed.
- The **2nd** column tells how many of the 53 participants in the PF-07038124 ointment group with atopic dermatitis or plaque psoriasis reported each medical problem. Next to this number is the percentage of the 53 participants in the PF-07038124 ointment with atopic dermatitis or plaque psoriasis who reported the medical problem.
- The **3rd** column tells how many of the 51 participants in the plain ointment group with atopic dermatitis or plaque psoriasis reported each medical problem. Next to this number is the percentage of the

51 participants in the plain ointment group with atopic dermatitis or plaque psoriasis who reported the medical problem.

- Using these instructions, you can see that none of the 53 participants in the PF-07038124 group with atopic dermatitis or plaque psoriasis reported itching where the ointment was applied. A total of 2 out of the 51 (4%) participants in the plain ointment with atopic dermatitis or plaque psoriasis reported itching where the ointment was applied.

Table 1. Commonly reported medical problems by study participants with atopic dermatitis or plaque psoriasis

Medical Problem	PF-07038124 ointment (53 Participants)	Plain ointment (51 Participants)
Itching where the ointment was applied	0 out of 53 participants (0%)	2 out of 51 participants (4%)
Positive COVID-19 test	0 out of 53 participants (0%)	2 out of 51 participants (4%)
Atopic dermatitis	1 out of 53 participants (2%)	3 out of 51 participants (6%)
Itching	0 out of 53 participants (0%)	2 out of 51 participants (4%)
Psoriasis	0 out of 53 participants (0%)	2 out of 51 participants (4%)

COVID-19: Coronavirus disease 2019.

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 104 participants had serious medical problems.

No participants 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.clinicaltrials.gov
www.clinicaltrialsregister.eu

Use the study identifier NCT04664153
Use the study identifier 2020-003977-23

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

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