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:	Abrocitinib (PF-04965842)
Protocol Number:	B7451050
Dates of Study:	11 June 2020 to 13 July 2021
Title of this Study:	Study of Abrocitinib Compared With Dupilumab in Adults With Moderate to Severe Atopic Dermatitis on Background Topical Therapy [A Phase 3b Randomized, Double-Blind, Double-Dummy, Active-Controlled Multi-Center Study Assessing the Efficacy and Safety of Abrocitinib Compared With Dupilumab in Adult Participants on Background Topical Therapy With Moderate to Severe Atopic Dermatitis]
Date(s) of this Report:	17 January 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?

Atopic dermatitis (or "AD"), which is also sometimes called atopic eczema, is a common skin disorder that causes patches of flaky, red, and very itchy skin. Some of the current medicines available for AD are not suitable for everyone and therefore researchers are looking for new treatments that are both safe and effective (over the longer term).

While researchers think that many things cause AD, it is made worse by the body's immune system (the body's defense against infection) causing redness and swelling (inflammation). Cells in the immune system trigger inflammation by making special proteins called "cytokines". Researchers think that medicines that modify the way these cytokines work could help treat patients with AD.

What is abrocitinib?

The treatment tested in this study was PF-04965842, which now has the generic name abrocitinib. Abrocitinib may block the activity of a protein called "Janus kinase 1", which acts like an on/off switch for the cells of the immune system. By blocking Janus kinase 1 activity, the signal to the cells that triggers inflammation is modified.

What was the purpose of this study?

The purpose of this study was to learn about the safety and efficacy of abrocitinib in participants with moderate to severe AD who were also using skin therapy (treatments applied to the skin), compared to another treatment for AD called dupilumab.

Researchers wanted to know:

How many participants who took abrocitinib had an improvement in itching after 2 weeks of treatment, compared to participants who took dupilumab?

How many participants who took abrocitinib had a 90% or greater improvement in amount and severity of AD after 4 weeks of treatment, compared to participants who took dupilumab?

What happened during the study?

How was the study done?

Researchers studied 2 groups of study participants. One group received abrocitinib 200 mg every day by mouth, plus skin therapy. The other group received dupilumab 600 mg loading dose followed by 300 mg every 2 weeks by injection under the skin, plus skin therapy.

A placebo does not have any medicine in it, but it looks just like the study treatment. Because abrocitinib and dupilumab look different, the participants also received placebo so that they did not know which treatment group they were in. This is known as a "blinded" study. Study participants were assigned to each group by chance alone.

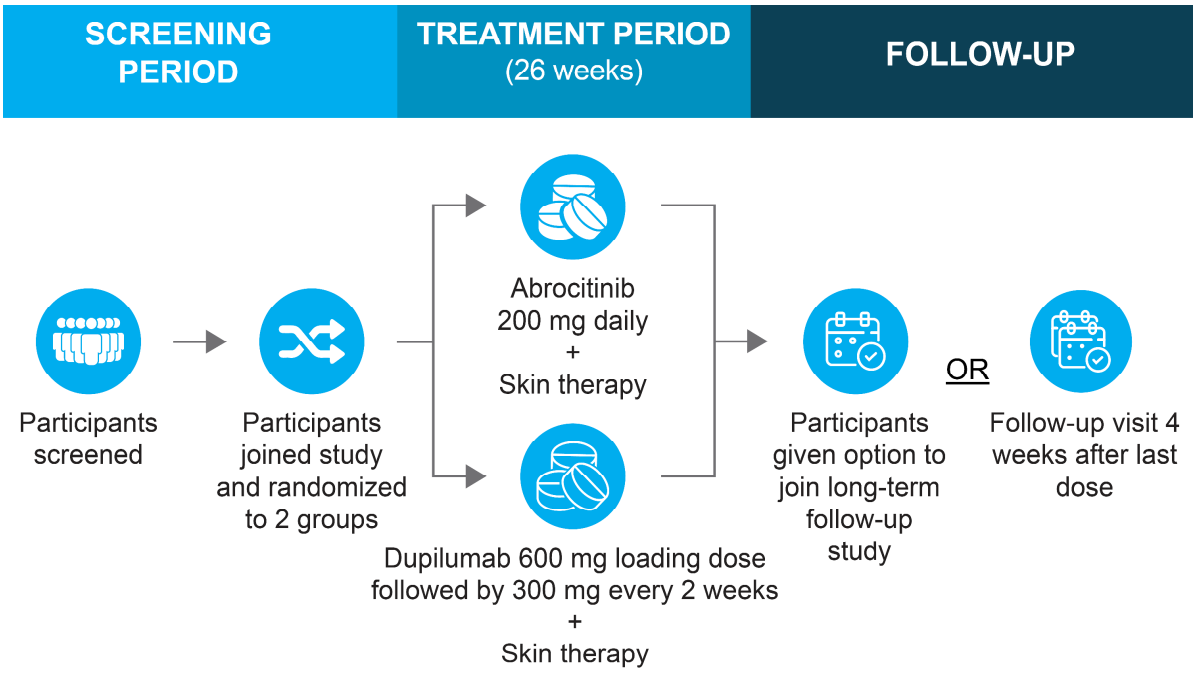
- Abrocitinib group: 362 participants
- Dupilumab group: 365 participants

Participants were screened by a doctor to make sure they met the requirements to join the study. This was known as the screening period, which lasted up to 4 weeks. The

treatment period lasted 26 weeks, and participants were expected to attend 8 on-site visits and 2 phone visits during this time. During the first visit, participants received their first injection at the study site, and the study nurse taught them how to give themselves injections at home.

At the end of the study, participants were given the option to join a long-term follow-up study of abrocitinib. Participants who stopped study treatment early or who were otherwise not eligible to join the long-term follow-up study were expected to attend a follow-up visit 4 weeks after their last dose of study treatment.

The figure below shows what happened during the study.



Where did this study take place?

The Sponsor ran this study at 143 locations in 15 countries in North America, South America, Europe, Asia, and Australia.

When did this study take place?

It began 11 June 2020 and ended 13 July 2021.

Who participated in this study?

The study included adult men and women with moderate to severe AD. Study participants:

- Had AD for at least 6 months
- Had either an unsatisfactory response to skin therapies for at least 4 weeks, or required systemic therapies (AD treatment taken by mouth or by injection) within the past year
- Were examined by the study doctor and determined to be appropriate for study participation
- Agreed to avoid sun and ultraviolet (UV) light exposure during the study

- A total of 397 men (55%) participated
- A total of 330 women (45%) participated
- All participants were between the ages of 18 and 83 years.

A total of 727 participants joined the study. 66 participants (9%) stopped study treatment early by their choice, because they had a medical problem, because a doctor decided it was best for a participant to stop being in the study, or because they passed away (2 participants). 661 participants (91%) completed study treatment.

How long did the study last?

Study participants were in the study for up to 30 weeks (treatment period plus follow-up). The entire study took a little more than a year to complete. Upon completion of the treatment period, eligible participants had the option to continue into a long-term follow-up study.

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

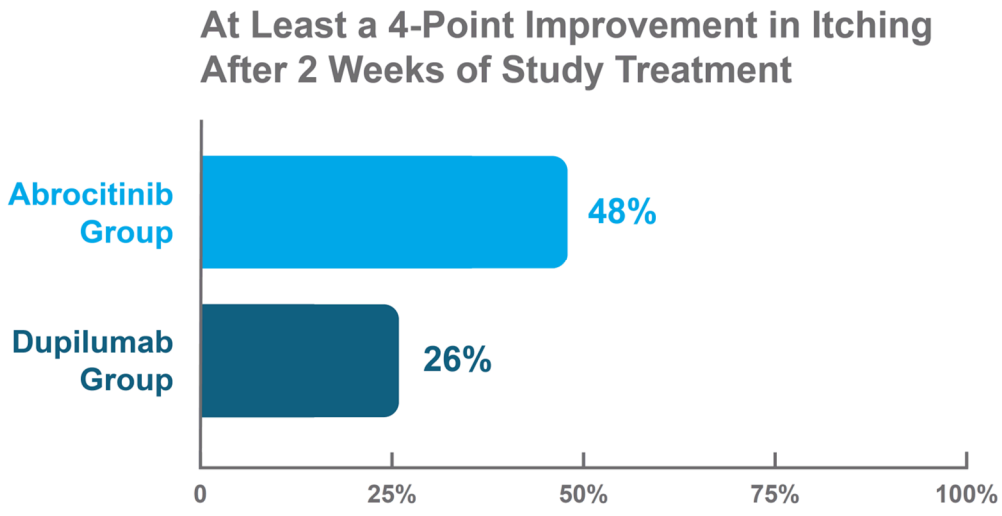
What were the results of the study?

How many participants who took abrocitinib had an improvement in itching after 2 weeks of treatment, compared to participants who took dupilumab?

To answer this question, participants were asked to rate how severe their worst itch was over the previous 24 hours, on a scale of 1 to 10. The researchers looked at the number of participants in each group who had at least a 4-point improvement in itching after 2 weeks of study treatment, compared to before they started study treatment.

48% (172 of 357) of participants from the abrocitinib group had at least a 4-point improvement in itching after 2 weeks of study treatment. 26% (93 of 364) of participants from the dupilumab group had at least a 4-point improvement in itching after 2 weeks of study treatment. Based on these results, the researchers have decided that the results are not likely the result of chance. Abrocitinib may help to improve itching in participants with moderate to severe AD.

The figure below shows this result.

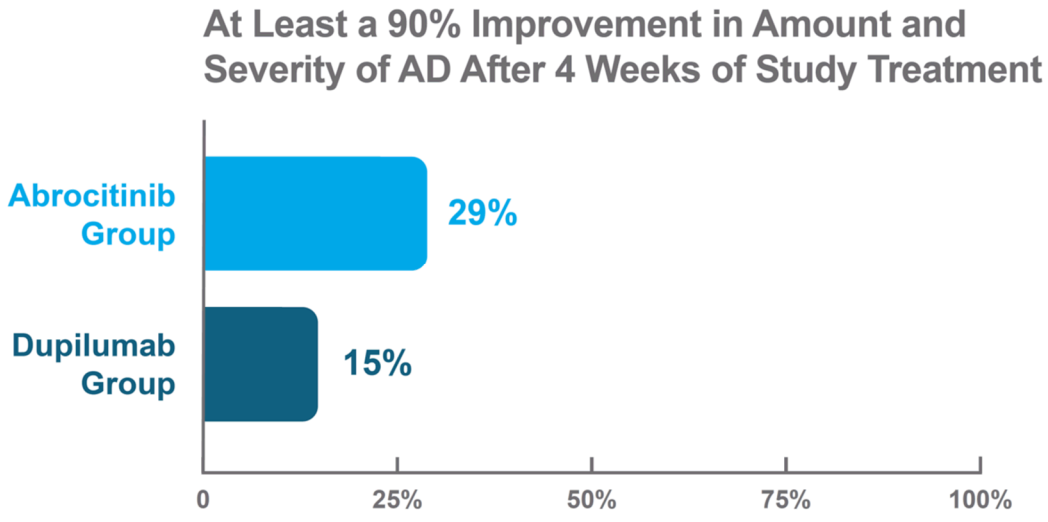


How many participants who took abrocitinib had a 90% or greater improvement in amount and severity of AD after 4 weeks of treatment, compared to participants who took dupilumab?

To answer this question, study doctors examined the amount and severity of each participants' AD. The researchers looked at the number of participants in each group who had at least a 90% improvement in amount and severity of AD after 4 weeks of study treatment, compared to before they started study treatment.

29% (101 of 354) of participants from the abrocitinib group had at least a 90% improvement in amount and severity of AD after 4 weeks of study treatment. 15% (53 of 364) of participants from the dupilumab group had at least a 90% improvement in amount and severity of AD after 4 weeks of study treatment. Based on these results, the researchers have decided that the results are not likely the result of chance. Abrocitinib may help to improve amount and severity of AD in participants with moderate to severe disease.

The figure below shows this result.



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.

507 out of 727 (70%) participants had at least 1 medical problem. A total of 21 (3%) participants left the study because of medical problems, including 12 (3%) participants in the abrocitinib group and 9 (3%) participants in the dupilumab group. The most common medical problems – those reported by at least 10% of participants in any group – are described below.

Below are instructions for understanding 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 at least 10% of participants in any group are listed.
- The **2nd** column tells how many of the 362 participants taking abrocitinib reported each medical problem. Next to this number is the percentage of the 362 participants taking abrocitinib who reported the medical problem.
- The **3rd** column tells how many of the 365 participants taking dupilumab reported each medical problem. Next to this number is the percentage of the 365 participants taking dupilumab who reported the medical problem.
- Using these instructions, you can see that 70 out of the 362 (19%) participants taking abrocitinib reported nausea. A total of 8 out of the 365 (2%) participants taking dupilumab reported nausea.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Group 1 Abrocitinib 200 mg (362 Treated)**	**Group 2 Dupilumab 300 mg (365 Treated)**
Nausea	70 out of 362 treated (19%)	8 out of 365 treated (2%)
Headache	47 out of 362 treated (13%)	24 out of 365 treated (7%)
Acne	46 out of 362 treated (13%)	10 out of 365 treated (3%)
Eye inflammation/disorder	8 out of 362 treated (2%)	35 out of 365 treated (10%)

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.

Six out of 362 (2%) participants in the abrocitinib group and 6 out of 365 (2%) participants in the dupilumab group had serious medical problems. No serious medical problem happened in more than 1 study participant. One serious medical problem, rhabdomyolysis (serious condition caused by harmful substances being released from injured muscles into the bloodstream), was considered by the study doctors to be related to study treatment. This medical problem happened in a participant from the dupilumab group.

A total of 2 participants (less than 1%) died during this study. Both participants were in the abrocitinib group. Neither death was considered by the study doctors to be related to study treatment.

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	Use the study identifier **NCT04345367**
www.clinicaltrialsregister.eu	Use the study identifier **2019-004013-13**

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!