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: CIBINQO® (Abrocitinib)

Protocol Number: B7451094

Dates of Study: 16 July 2022 to 09 June 2023

Title of this Study: A Safety and Efficacy Study of Abrocitinib Tablets in Participants Aged 12 Years and Older With Atopic Dermatitis in India

[A Randomized, Open-Label, Parallel-Group Study to Evaluate the Safety and Efficacy of Abrocitinib 100 mg and 200 mg Tablets in Participants Aged 12 Years and Older With Moderate to Severe Atopic Dermatitis in India]

Date of this Report: 01 February 2024

– Thank You –

If you or your child participated in this study, Pfizer, the Sponsor, would like to thank you or your child 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 or your child's study site.

Why was this study done?

What is atopic dermatitis?

Atopic dermatitis (AD) is a common long-term skin disorder that causes patches of red, dry, and very itchy skin. These patches can occur anywhere on the body. AD most commonly starts in childhood, but anybody can get AD at any age. It is also called atopic eczema.

An overactive disease defense system (immune system) can play a role in causing AD and making it worse. Researchers think that medicines that reduce activity of certain parts of the immune system could be used to treat and improve AD.

What is abrocitinib?

Abrocitinib (sold as CIBINQO®) is a medicine that is approved in several countries (such as Great Britian, Japan, United States, and others) for the treatment of moderate to severe AD in adults. It is provided as a tablet and is taken by mouth.

Abrocitinib works by blocking the activity of a protein in the body called Janus kinase 1 (JAK1). JAK1 acts like an on/off switch for the cells of the immune system. Blocking JAK1 can reduce the high activity of the immune system in patients with AD. This can help improve AD.

What was the purpose of this study?

The purpose of this study was to collect more information on the safety of abrocitinib and how well it works in patients with moderate to severe AD in India.

Researchers wanted to know:

Did AD improve in participants with moderate to severe AD who took abrocitinib?

What medical problems did participants who took abrocitinib have?

What happened during the study?

How was the study done?

First, study doctors checked that potential study participants met the requirements to be in the study. This is known as a "screening period". Screening occurred within 28 days before starting treatment.

200 participants who met the study requirements were enrolled in the study. They were randomly put into 1 of 2 treatment groups by chance alone:

- Group 1: Abrocitinib 200 mg once daily – 99 participants were in this group.
- Group 2: Abrocitinib 100 mg once daily – 101 participants were in this group.

The participants and study doctors knew which treatment they were taking. This is known as an "open-label" study.

Participants received treatment for 12 weeks. They visited the study site on the first day of treatment (called "baseline"), Week 2, Week 4, Week 8, and Week 12. At these visits, study doctors checked the health of participants and asked if they had any medical problems.

Study doctors also measured the severity of AD during study visits by rating AD with different measurements. These included the Investigator's Global Assessment of AD (IGA), Eczema Area and Severity Index (EASI), and Scoring Atopic Dermatitis (SCORAD).

IGA Scale

The IGA scale is an evaluation of AD by the study doctor. Scores range from 0 to 4:

- Score of 0: This score means that there is no AD on the skin.
- Score of 1: This score means that AD is almost clear.
- Score of 2: This score means that AD is considered mild.
- Score of 3: This score means that AD is considered moderate.
- Score of 4: This score means that AD is considered severe.

EASI

The EASI is an evaluation of the severity of AD by location on the body. EASI scores range from 0.0 to 72.0, with higher scores meaning more severe AD.

SCORAD

The SCORAD is an evaluation of the severity and extent of AD. It also includes a measurement of how AD affects the patient personally. SCORAD scores range from 0 to 103.

Participants also completed 2 questionnaires during study visits. These included the Patient-oriented Eczema Measure (POEM) and the Atopic Dermatitis Control Tool (ADCT).

POEM

The POEM measures how much AD affects the day-to-day life of the participant over the past week. A higher score means that AD has a higher impact on day-to-day life.

ADCT

The Atopic Dermatitis Control Tool (ADCT) measures how much participants feel they have control over their AD. A higher score means less control over AD.

During the study, participants were allowed to continue using skin moisturizers and other topical medicines (medicine put on the skin) for AD.

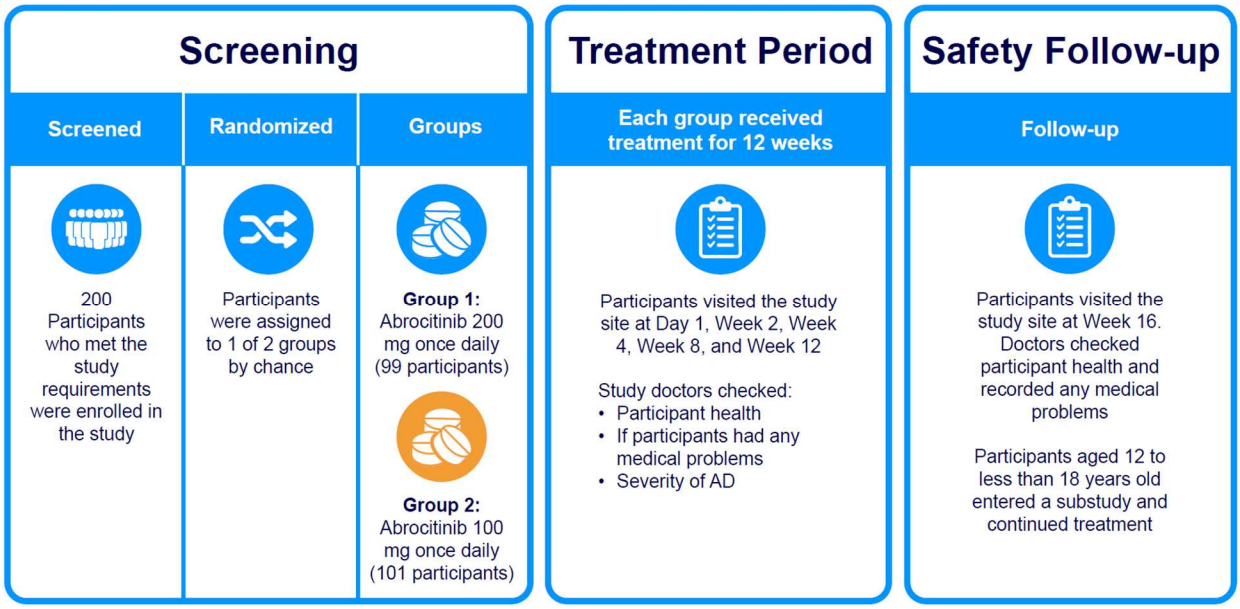
After the 12-week treatment period, all participants stopped treatment and visited the study site at Week 16 for a follow-up visit. At this visit, study doctors checked the health of participants and recorded any medical problems that they had.

Participants who were 12 to less than 18 years old entered a substudy after Week 12. In the substudy, they continued to receive treatment until 1 year after they started treatment in the main study. The substudy was ongoing at the time of this report.

When the study was completed, researchers compared the results of participants taking abrocitinib 200 mg to the results of participants taking abrocitinib 100 mg.

The study design is shown below in Figure 1.

Figure 1. Study Design



Where did this study take place?

The Sponsor ran this study at 15 locations in India.

When did this study take place?

It began 16 July 2022 and ended 09 June 2023. The substudy was ongoing at the time of this report.

Who participated in this study?

The study included participants who were 12 years of age or older and had moderate to severe AD.

- A total of 91 males participated.
- A total of 109 females participated.
- All participants were between the ages of 12 and 73 years old.

Participants were to be treated for 12 weeks. Of the 200 participants who started the study, 153 completed the study treatment. 32 adolescent participants entered the substudy and continued treatment.

15 participants did not finish the treatment phase because of 1 of the following reasons:

- They or their parent/guardian decided to not be in the study anymore and left by their or their parent/guardian's choice (12 participants).
- They had a medical problem (1 participant).
- They stopped showing up to visits and could not be reached by the study site (2 participants).

How long did the study last?

Participants 18 years or older were in the study for about 4 to 5 months. Participants that were 12 to less than 18 years old were expected to be in the study (including the substudy) for about 13 to 14 months. The substudy was not finished at the time of this report.

The main study took about 11 months to complete.

When the main study finished in June 2023 (not including the substudy), 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 AD improve in participants with moderate to severe AD who took abrocitinib?

To determine this, researchers measured the number of participants in each group that had "improvement" in their AD at Week 12.

For the IGA, “improvement” was defined as an AD severity score of 0 or 1 and 2 points or greater improvement from baseline at Week 12.

For the EASI and SCORAD, “improvement” was defined as a 75% or greater improvement in their scores from baseline at Week 12.

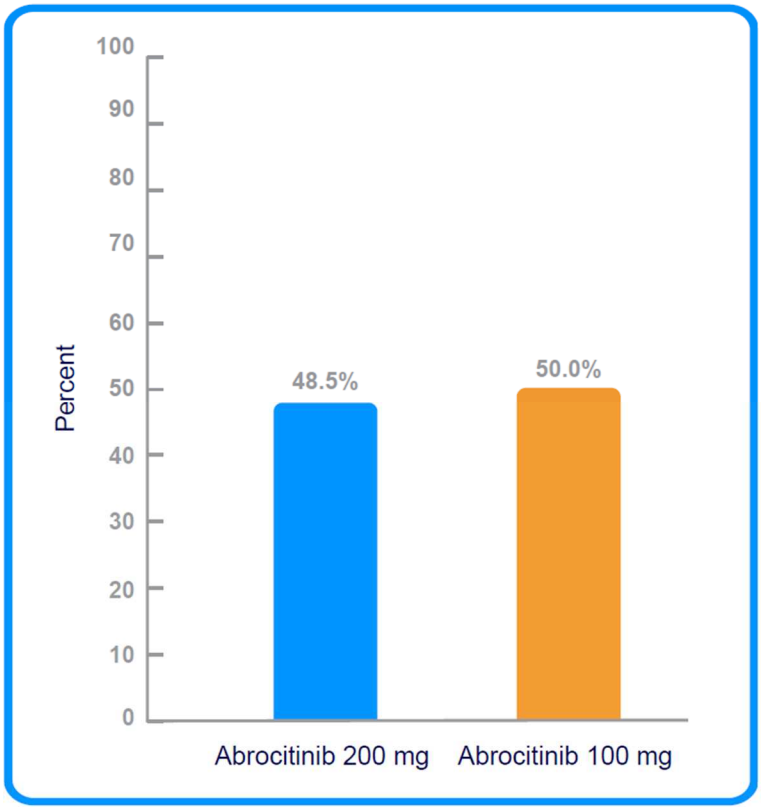
For POEM and ADCT, researchers measured how scores changed during the study. Decreases in scores indicated improvement.

Did AD improve in participants with moderate to severe AD who took abrocitinib?

IGA Scale

48 out of 99 (48.5%) participants who took abrocitinib 200 mg and 50 out of 100 (50.0%) participants who took abrocitinib 100 mg had improvement in their AD (score of 0 or 1 and 2 points or greater improvement from baseline at Week 12). These results are shown below in Figure 2.

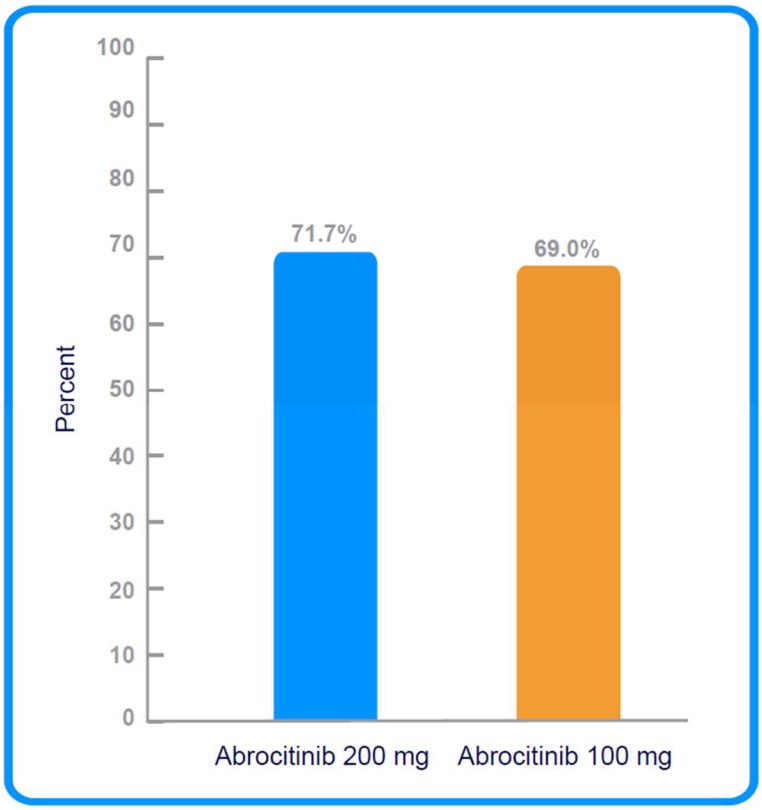
Figure 2. Percent of Participants With Improvement in Their AD at Week 12 Based on the IGA Scale



EASI

71 out of 99 (71.7%) participants who took abrocitinib 200 mg and 69 out of 100 (69.0%) participants who took abrocitinib 100 mg had an improvement in their AD (75% or greater improvement in EASI score from baseline). These results are shown below in Figure 3.

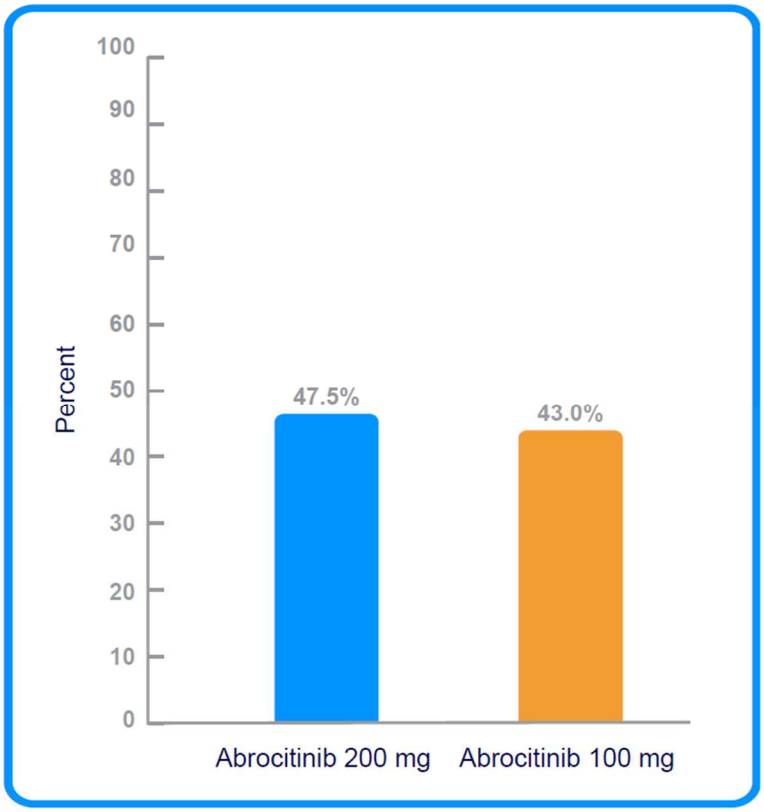
Figure 3. Percent of Participants With Improvement in Their AD at Week 12 Based on EASI Scores



SCORAD

47 out of 99 (47.5%) participants who took abrocitinib 200 mg and 43 out of 100 (43.0%) participants who took abrocitinib 100 mg had improvement in their AD (75% or greater improvement in SCORAD score from baseline). These results are shown below in Figure 4.

Figure 4. Percent of Participants With Improvement in Their AD at Week 12 Based on SCORAD Scores



POEM and ADCT

Participants in both groups had a reduction (improvement) in POEM and ADCT scores over the duration of the study. However, participants in the abrocitinib 200 mg group had a larger reduction in scores than participants in the abrocitinib 100 mg group.

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.

56 out of 200 (28%) participants in this study had at least 1 medical problem. A total of 1 participant left the study because of a medical problem. The most common medical problems – those reported by at least 2 participants in any group – 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 at least 2 participants in any group are listed.
- The **2nd** column tells how many of the 99 participants taking abrocitinib 200 mg reported each medical problem. Below this number is the percentage of the 99 participants taking the abrocitinib 200 mg who reported the medical problem.
- The **3rd** column tells how many of the 101 participants taking abrocitinib 100 mg reported each medical problem. Below this

number is the percentage of the 101 participants taking abrocitinib 100 mg who reported the medical problem.

- Using these instructions, you can see that 9 out of the 99 (9.1%) participants taking abrocitinib 200 mg reported feeling sick. A total of 5 out of the 101 (5.0%) participants taking abrocitinib 100 mg reported feeling sick.

Table 1. Commonly reported medical problems by study participants

Medical Problem	Abrocitinib 200 mg (99 Participants)	Abrocitinib 100 mg (101 participants)
Nausea	9 out of 99 participants (9.1%)	5 out of 101 participants (5.0%)
Stomach acid irritating the food pipe lining	4 out of 99 participants (4.0%)	2 out of 101 participants (2.0%)
Itching	4 out of 99 participants (4.0%)	2 out of 101 participants (2.0%)
Itchy patches of skin	1 out of 99 participants (1.0%)	4 out of 101 participants (4.0%)
Alanine aminotransferase (ALT) liver test increased	1 out of 99 participants (1.0%)	3 out of 101 participants (3.0%)

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Abrocitinib 200 mg (99 Participants)**	**Abrocitinib 100 mg (101 participants)**
Cough	1 out of 99 participants (1.0%)	3 out of 101 participants (3.0%)
Fever	1 out of 99 participants (1.0%)	3 out of 101 participants (3.0%)
Common cold	2 out of 99 participants (2.0%)	1 out of 101 participants (1.0%)
Vomiting	3 out of 99 participants (3.0%)	0 out of 101 participants (0%)
Dizziness	0 out of 99 participants (0%)	2 out of 101 participants (2.0%)
Headache	2 out of 99 participants (2.0%)	0 out of 101 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.

1 out of 200 (0.5%) participants had a serious medical problem. This participant was in the abrocitinib 100 mg group and had a serious medical problem of broken forearm during the study. Researchers determined that this serious medical problem was not related to taking the study medicine.

No participants died during the study.

Where can I learn more about this study?

If you have questions about the results of the study, please speak with the doctor or staff at your or your child's study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number B7451094

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

www.clinicaltrials.gov	Use the study identifier **NCT05375929**

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!