# 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:** Cibinqo® (abrocitinib) Commercial Tablets and Abrocitinib Liquid Formulation

**Protocol Number:** B7451061

**Dates of Study:** 04 June 2021 to 26 October 2021

**Title of this Study:** Study Comparing Single Doses of Abrocitinib Tablets and Abrocitinib Liquid Medicine Taken Alone and After Famotidine Antacids

[A Phase 1, Randomized, Crossover Study to Evaluate Relative Bioavailability of Abrocitinib Oral Suspension and Effect of an Acid-Reducing Agent on the Bioavailability of Abrocitinib Commercial Tablet and to Assess the Taste of Abrocitinib Oral Formulations in Healthy Adult Participants Aged 18 to 55 Years of Age]

**Date(s) of this Report:** 22 March 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. AD occurs in 5% to 10% of adults and 15% to 20% of children worldwide. Some of the current medicines available for AD can only be used for short time periods or can cause other health problems. Researchers are looking for new treatments for AD that can be taken safely for long periods of time.

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 cause inflammation by making special proteins called "cytokines". Researchers think that medicines that lower the amount of cytokines that the body makes could help treat patients with AD.

## What is abrocitinib?

The drug tested in this study was abrocitinib. Abrocitinib has been approved for sale and can be used by adults in some countries around the world. Abrocitinib blocks the activity of a protein called "Janus kinase 1", which acts like a switch for the cells of the immune system. By turning off this switch, the cells of the immune system are expected to produce fewer cytokines that are believed to make AD worse.

## What was the purpose of this study?

The purpose of this study was to compare the levels of abrocitinib seen in the blood after participants had taken abrocitinib tablets, abrocitinib liquid, and abrocitinib tablets taken 2 hours after the medicine famotidine. Famotidine is an antacid. It is used to treat and prevent heartburn, indigestion, and other symptoms caused by too much stomach acid such as stomach ulcers and reflux disease. The researchers did this study as they wanted to develop a new liquid preparation or formulation of abrocitinib as an alternative to taking tablets.

**Researchers wanted to know:**

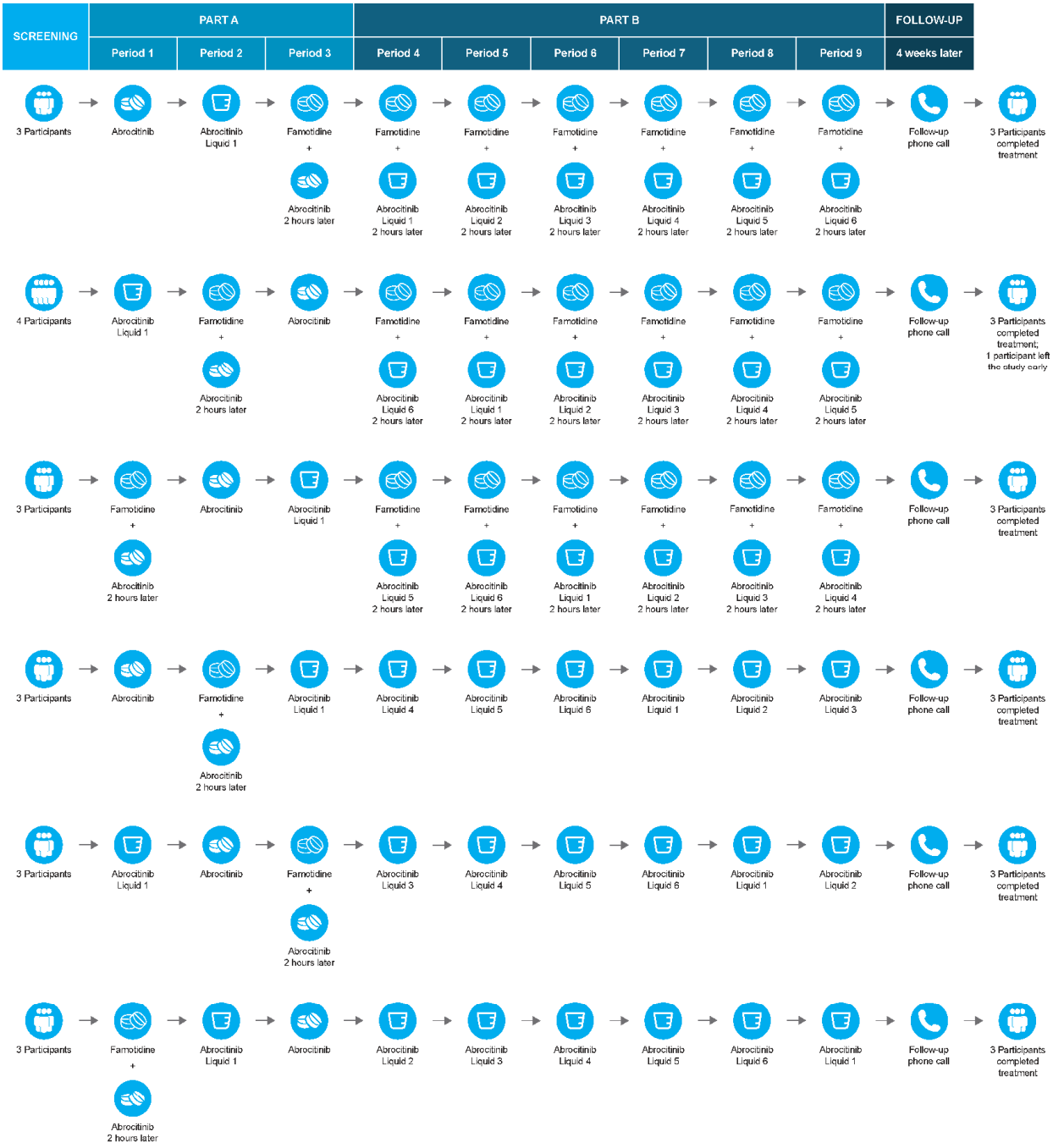
- **Part A: How did the amount of abrocitinib in the blood change when this treatment was given as a tablet or as a liquid or when abrocitinib tablets were taken after the antacid famotidine?**
- **Part B: What did participants think of the taste of the abrocitinib liquid?**
- **What medical problems did participants have during the study?**

# What happened during the study?

## How was the study done?

Researchers tested the study treatments of abrocitinib tablets, abrocitinib liquid (Liquid 1), and abrocitinib tablets when taken 2 hours after famotidine on groups of healthy participants to learn how abrocitinib acted in the body in Part A. The researchers also wanted to know what the participants thought about the taste of different abrocitinib liquids in Part B.

Participants had to stay at the study center for the entire study (Part A and Part B). Participants were assigned to each group by chance alone and the treatments in Part A and in Part B were given in a random order as shown in the following figure.




*There was at least 3 days between each dose period in Part A and between Part A and Part B, and at least 1 day between each dose period in Part B*

In Part A, participants were to take abrocitinib tablets, abrocitinib liquid (Liquid 1), and abrocitinib tablets 2 hours after having taken famotidine tablets. The dose of abrocitinib was 200 milligram or mg and this was taken after an overnight fast

(nothing to eat or drink except water). The participants took the study treatments in a random order. The participants and the researchers knew who was taking what treatment and this is known as an "open-label study". There was to be at least 3 days between each dose in Part A, and also 3 days between Period 3 of Part A and Period 4 of Part B.

In Part B, participants were to take all 6 different liquid formulations of 200 mg abrocitinib and were asked about the taste. The 6 liquids were to be taken a random order with at least 1 day between each dose. Some participants also took famotidine. The participants did not know what was in each formulation of abrocitinib, but the researchers knew what was in the liquids. This is known as a "single-blind study". The results of this taste testing are not included in this report.

Researchers took samples of blood and urine from participants during the study for safety tests and for testing for abrocitinib. Researchers then compared the levels of abrocitinib in the blood of the participants.

Researchers also checked the participants' health during the study and asked them how they were feeling.

## Where did this study take place?

The Sponsor ran this study at 1 location in the United States of America.

## When did this study take place?

It began 04 June 2021 and ended 26 October 2021.

## Who participated in this study?

The study included healthy adult participants.

- A total of 14 men participated
- A total of 5 women participated
- All participants were between the ages of 22 and 55 years

Of the 19 participants who started the study, 18 finished the study. One (1) participant did not finish the study because they wanted to leave the study.

### How long did the study last?

Study participants were in the study for about 52 days. The entire study took almost 5 months to complete.

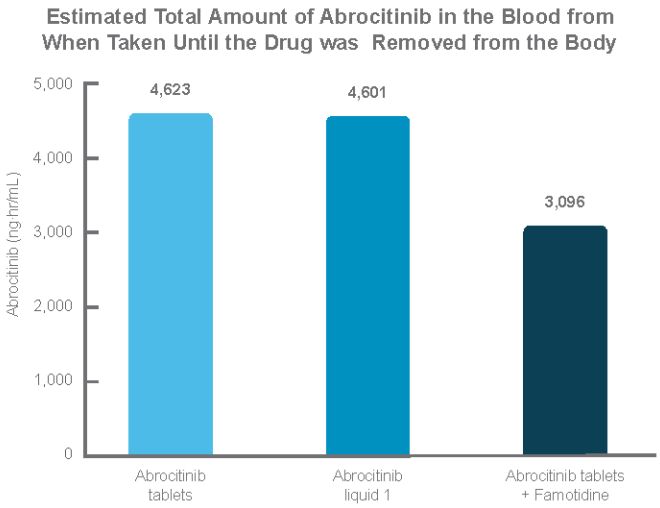
When the study ended in October 2021, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

## What were the results of the study?

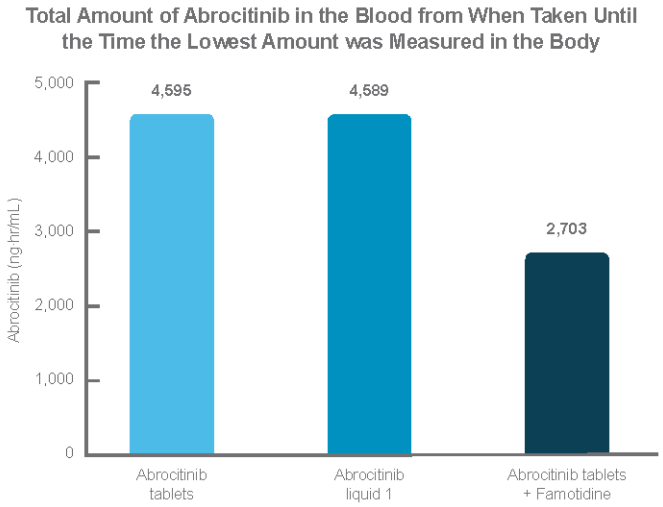
### Part A: How did the amount of abrocitinib in the blood change when this treatment was given as a tablet or as a liquid or when abrocitinib tablets were taken after the antacid famotidine?

#### What was the estimated total amount of abrocitinib in the blood after participants took the study treatments?

- The estimated total amount of abrocitinib in the blood from when 200 mg abrocitinib tablets were taken until abrocitinib was removed from the body was 4,623 nanogram hours per milliliter, also called ng•hr/mL. The ng•hr/mL is a unit used to measure total amount of drug over time in the blood. When 200 mg abrocitinib liquid was taken, the estimated total amount of abrocitinib in the blood was similar at 4,601 ng•hr/mL.
- When 200 mg abrocitinib tablets were taken after famotidine, the estimated total amount of abrocitinib in the blood from when the abrocitinib tablets were taken until abrocitinib was removed from the body was 3,096 ng•hr/mL. This a third (or 33%) lower than when abrocitinib was taken by itself.

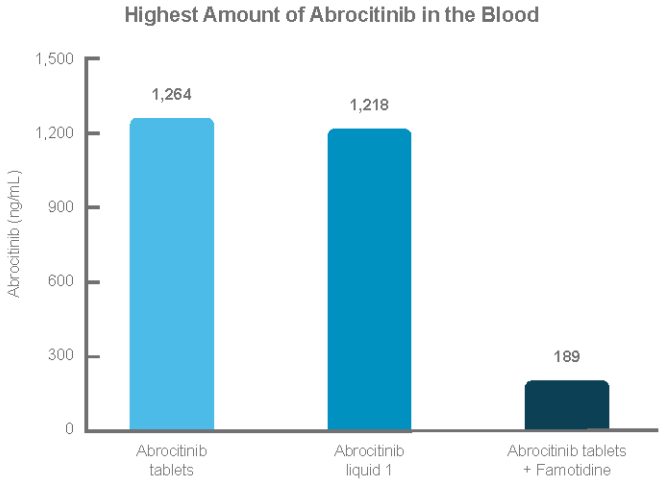



- The total amount of abrocitinib in the blood from when 200 mg abrocitinib tablets were taken to the time when the lowest amount was detected in the blood was 4,595 nanogram ng•hr/mL. When 200 mg abrocitinib liquid was taken, the total amount of abrocitinib in the blood was similar at 4,589 ng•hr/mL.
- When 200 mg abrocitinib tablets were taken after famotidine, the total amount of abrocitinib in the blood from when the abrocitinib tablets were taken to the time when the lowest amount was detected in the blood was 2,703 ng•hr/mL. This is around two-fifths (2/5$^{th}$ or 40%) lower than when abrocitinib was taken by itself.




## What was the highest amount of abrocitinib in the blood after participants took the study treatments?

- The highest amount of abrocitinib in the blood after participants took 200 mg abrocitinib tablets was 1,264 nanogram per milliliter, also called ng/mL. The ng/mL is a unit used to measure the amount of drug in the blood. When 200 mg abrocitinib liquid was taken, the highest amount of abrocitinib was 1,218 ng/mL.
- When 200 mg abrocitinib tablets were taken after famotidine, the highest amount of abrocitinib in the blood was 189 ng/mL. This was a reduction of over four-fifths (80%).




Based on these results, the researchers have decided that the results are not likely the result of chance. The researchers considered the tablet and liquid versions of abrocitinib gave comparable or similar results. The researchers also found that taking famotidine and abrocitinib together changes how abrocitinib behaves in the body.

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 unknown 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.

In Part A, 6 out of the 18 (33%) participants had at least 1 medical problem after taking abrocitinib tablets, 8 out of the 18 (44%) participants had at least 1 medical problem after taking abrocitinib liquid, and 6 out of out of the 18 (33%) participants had at least 1 medical problem after taking abrocitinib after famotidine tablets.

In Part B, 5 out of the 9 (56%) participants had at least 1 medical problem after taking the 6 abrocitinib liquids and 2 out of the 10 (20%) participants had at least 1 medical problem after taking abrocitinib after famotidine tablets.

Note: Information on medical problems experienced by participants was not available for all the participants who were treated in Part B.

No participants left the study because of medical problems. The most common medical problems – those reported by more than 1 participant in any group – are described in Table 1 for Part A and in Table 2 for Part B.

Below are instructions on how to read Table 1, which shows the medical problems reported in Part A. These instructions can also be used to help explain Table 2, which shows the medical problems in Part B.

### 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 more than 1 participant in any group are listed.
- The **2nd** column tells how many of the 18 participants taking abrocitinib tablets reported each medical problem. Next to this number is the percentage of the 18 participants taking abrocitinib tablets who reported the medical problem.
- The 3rd column tells how many of the 18 participants taking abrocitinib liquid (Liquid 1) reported each medical problem. Next to this number is the percentage of the 18 participants taking abrocitinib liquid (Liquid 1) who reported the medical problem.
- The 4th column tells how many of the 18 participants taking abrocitinib tablets after famotidine tablets reported each medical problem. Next to this number is the percentage of the 18 participants taking abrocitinib tablets after famotidine tablets who reported the medical problem.
- Using these instructions, you can see that 3 out of the 18 (17%) participants taking abrocitinib tablets and 5 out of the 18 (28%) participants taking abrocitinib liquid (Liquid 1) reported nausea. A total of 0 out of the 18 (0%) participants taking abrocitinib tablets after famotidine tablets reported nausea.

| Table 1. Commonly reported medical problems by study participants in Part A | | | |
|---|---|---|---|
| **Medical Problem** | **200 mg Abrocitinib Tablets (18 Participants)** | **200 mg Abrocitinib Liquid (Liquid 1) (18 Participants)** | **200 mg Abrocitinib Tablets After Famotidine Tablets (18 Participants)** |
| **Nausea** | 3 out of 18 participants (17%) | 5 out of 18 participants (28%) | 0 out of 18 participants (0%) |
| **Complication around operation site** | 2 out of 18 participants (11%) | 2 out of 18 participants (11%) | 4 out of 18 participants (22%) |
| **Headache** | 2 out of 18 participants (11%) | 3 out of 18 participants (17%) | 0 out of 18 participants (0%) |

| Table 2. Commonly reported medical problems by study participants in Part B | | |
|---|---|---|
| **Medical Problem** | **200 mg Abrocitinib Liquid (Liquid 1, 2, 3, 4, 5, and 6) (9 Participants)** | **200 mg Abrocitinib Liquid (Liquid 1, 2, 3, 4, 5, and 6) After Famotidine Tablets (10 Participants)** |
| **Nausea** | 4 out of 9 participants (44%) | 0 out of 10 participants (0%) |
| **Hunger** | 2 out of 9 participants (22%) | 0 out of 10 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.

There were 0 participants (0%, or 0 out of 18 participants) who had serious medical problems. No participants died during this 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 Use the study identifier **NCT04903093**

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!