

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-07817883 (also called ibuzatrelvir)

Protocol Number: C5091008

Dates of Study: 13 April 2023 to 10 July 2023

Title of this Study: A Study to Learn About How Itraconazole Can Affect the Level of PF-07817883 in the Blood of Healthy Adults

[A Phase 1, Open-Label, 2-Period, Fixed Sequence Study to Estimate the Effect of Itraconazole on the Pharmacokinetics of PF-07817883 in Healthy Adults]

Date of this Report: 08 July 2024

– 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 COVID-19?

“Coronavirus disease 2019” (or COVID-19) is caused by a virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

COVID-19 spreads easily from person to person and can cause mild to severe illness. People with COVID-19 can have different symptoms, including fever, chills, cough, loss of taste or smell, or trouble breathing.

What is PF-07817883?

PF-07817883, also called ibuzatrelvir, is a tablet that is swallowed (oral). It is being studied as a possible oral treatment for people with COVID-19 infection.

PF-07817883 is an investigational medicine because it is not approved by the health authorities for use outside of research studies.

What was the purpose of this study?

The main purpose of this study was to see how a medicine called itraconazole may affect the amount of PF-07817883 in the blood of healthy adult participants.

Itraconazole is an approved medicine used to treat fungal infections. It was given in the study as a liquid that participants would drink.

Itraconazole is known to affect the amount of some medications in the blood if they are taken at the same time. Because of this, researchers chose itraconazole for this study to see if it affects PF-07817883 when they are taken together.

This study was not designed to test whether PF-07817883 helps treat COVID-19.

Researchers wanted to know:

- How did itraconazole affect the amount of PF-07817883 in the participants' blood?
 - What medical problems did participants have during the study?
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What happened during the study?

How was the study done?

Researchers tested PF-07817883 and itraconazole in a group of participants to learn how itraconazole may affect the amount of PF-07817883 in the blood of participants.

There were 2 dosing periods in the study:

- Period 1: Participants took **PF-07817883 only**. They took 1 dose of PF-07817883 300 milligrams (mg) on Day 1.
- Period 2: Participants took **PF-07817883 with itraconazole**. They took itraconazole 200 mg 1 time per day for 7 days (Days 5 to 11). On Day 8, participants took itraconazole 200 mg with 1 dose of PF-07817883 300 mg.

The participants took the study medications without meal.

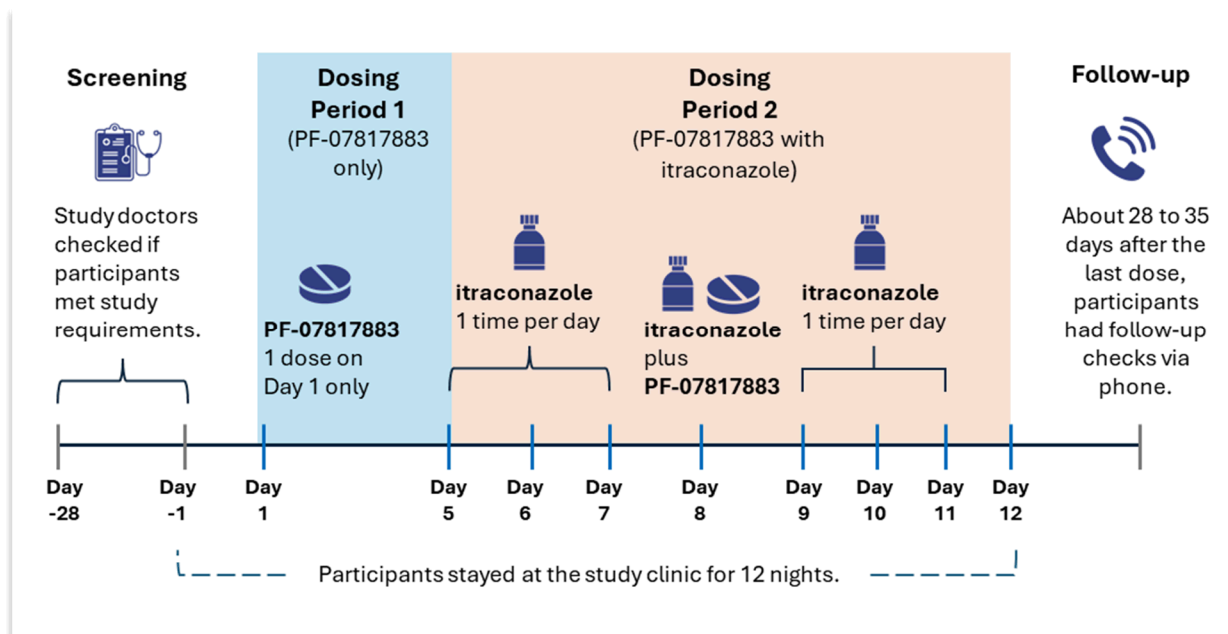
This was an open-label study. This means that the researchers and participants knew the study medications each participant was taking during each dosing period.

Participants stayed at the study clinic for 12 nights during the dosing periods. About 4 to 5 weeks after the last dose, study doctors called the participants on the phone for follow-up health checks.

Researchers took blood samples from participants throughout the study. Researchers also checked the participants' health and asked them how they were feeling.

Figure 1 below shows how the study was done.

Figure 1. How was this study done?



Where did this study take place?

The Sponsor ran this study at 1 study clinic in the United States.

When did this study take place?

It began on 13 April 2023 and ended on 10 July 2023.

Who participated in this study?

The study included healthy adult participants.

- A total of 8 men and 4 women participated.
- All participants were from 25 to 50 years old.

A total of 12 participants started the study and took the study medications. All 12 participants completed the study.

How long did the study last?

Each participant was in the study for about 2 and a half months. The entire study took about 3 months to complete.

When the study ended in April 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?

How did itraconazole affect the amount of PF-07817883 in the participants' blood?



To answer this question, study doctors took blood samples from participants throughout the study. Researchers measured the peak level and total amount of PF-07817883 in the participants' blood over time during Periods 1 and 2.

Researchers compared the amounts of PF-07817883 in the participants' blood during 2 periods:

- When participants took PF-07817883 only (Period 1), and
- When participants took PF-07817883 with itraconazole (Period 2).

Study results showed that the amount of PF-07817883 in healthy adult participants' blood was higher when PF-07817883 was taken with itraconazole than when it was taken without itraconazole.

- The peak level of PF-07817883 in the blood was about **24% higher when PF-07817883 was taken with itraconazole.**
- The total amount of PF-07817883 over time in the blood was about **2 times higher when PF-07817883 was taken with itraconazole.**

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.

Researchers also asked the participants to fill out a questionnaire about PF-07817883's appearance, feel, and taste. Researchers wanted to know how easy or difficult it was to take PF-07817883. Overall, most participants thought that PF-07817883's appearance, feel, and taste were acceptable.

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.

The list below shows how many participants had any medical problems during each dosing period of the study.

Period 1	Period 2
One (1) out of 12 participants (8%) had at least 1 medical problem while taking PF-07817883 only.	Three (3) out of 12 participants (25%) had at least 1 medical problem while taking itraconazole only.
	Two (2) out of 12 participants (17%) had at least 1 medical problem while taking PF-07817883 with itraconazole .

The most common medical problem reported across dosing periods was diarrhea, which was experienced by 2 participants overall. No other medical problems were experienced by more than 1 participant.

No participants left the study because of medical problems.

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 participants had a serious medical problem. None of the 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.pfizer.com/research/
research_clinical_trials/trial_results](http://www.pfizer.com/research/research_clinical_trials/trial_results)

Use the protocol number
C5091008

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

www.clinicaltrials.gov

Use the study identifier
NCT05822440

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!