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:	C5091013
Dates of Study:	23 November 2023 to 12 January 2024
Title of this Study:	A Study to Learn How PF-07817883 Is Taken Up Into the Blood of Healthy Adults After Taking Tablets of Study Drug With Different Formulations [A Phase 1, Open-Label, Randomized, Single Dose, Crossover Study to Estimate the Relative Bioavailability of PF-07817883 Following Oral Administration of New Formulations Relative to the Reference Formulation in Healthy Adult Participants Under Fasted Condition]
Date of this Report:	09 January 2025

– 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 **s**evere **a**cute **r**espiratory **s**yndrome **co**rona**v**irus 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). Ibuzatrelvir is an investigational medicine, which means it is still being studied and health authorities have not approved it for use outside of research studies.

Researchers think that ibuzatrelvir can be a possible treatment for COVID-19. Ibuzatrelvir was designed to block an enzyme that the COVID-19 virus needs to spread within a person's body. An enzyme is a protein that helps speed up chemical reactions in the body.

What was the purpose of this study?

The main aim of this study was to find out how much of ibuzatrelvir enters the blood when healthy adult participants took ibuzatrelvir as different formulations by mouth. Three (3) different **test** tablet formulations were compared to the **reference** ("original") tablet formulation.

This study also wanted to learn if ibuzatrelvir is safe when given as single doses of the test and reference formulations.

Researchers wanted to know:

- **How did the 3 test formulations of ibuzatrelvir compare with the reference formulation of ibuzatrelvir?**
- **What medical problems did participants have during the study?**

This study on healthy participants did not test if ibuzatrelvir helps to treat COVID-19.

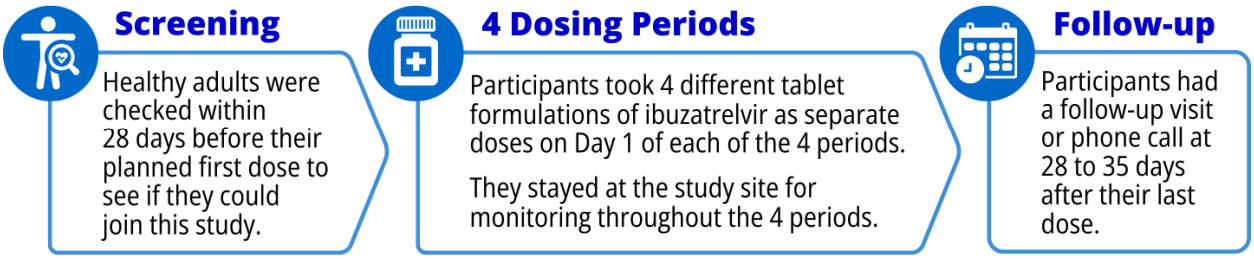
What happened during the study?

How was the study done?

Researchers tested 3 different **test** tablet formulations of ibuzatrelvir and compared them to the **reference** tablet formulation of ibuzatrelvir in a group of healthy participants. This was done to learn how much of ibuzatrelvir entered the blood when taken as different formulations.

Figure 1 below shows what happened in the study.

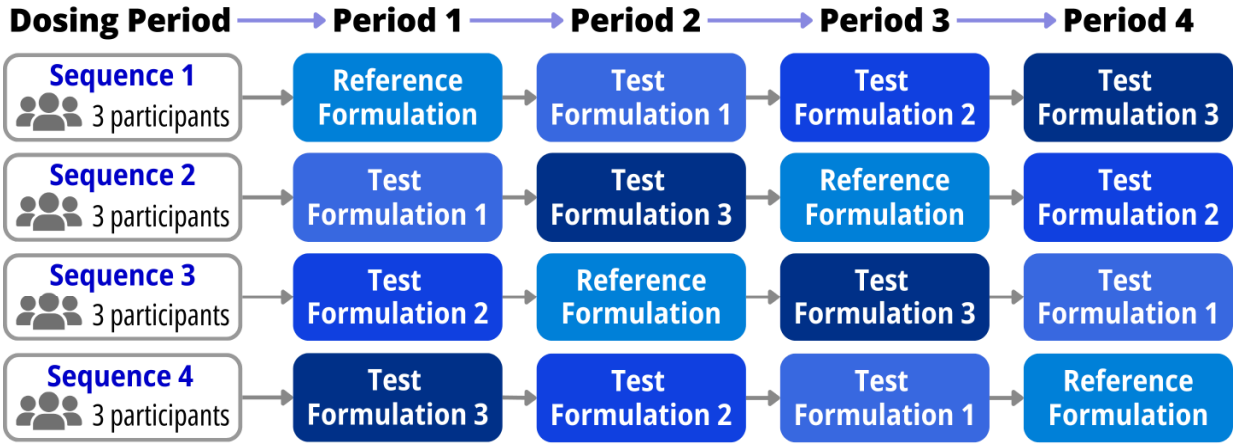
Figure 1. Study plan



Participants received all 4 formulations of ibuzatrelvir in this study. They took 1 dose of each formulation of ibuzatrelvir 300 milligrams (mg) on Day 1 of each of the 4 consecutive (one after another) dosing periods. They took each dose after "fasting" (no eating) overnight. Each dosing period lasted up to 48 hours. Participants stayed at the study site from 1 day before the start of Period 1 through Day 3 of Period 4 for monitoring.

The order in which they took the 4 different formulations depended on which sequence they were assigned to by chance. Figure 2 below shows the order in which they took the 4 different formulations of ibuzatrelvir across the 4 dosing periods.

Figure 2. Assignment to 1 of 4 sequences



This was an open-label study, meaning that the participants and researchers knew which formulation of ibuzatrelvir was taken during each dosing period.

Researchers took samples of blood from participants during the study and measured the amount of ibuzatrelvir during each dosing period. 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 Belgium.

When did this study take place?

The study began on 23 November 2023 and ended on 12 January 2024.

Who participated in this study?

The study included healthy adults 18 years of age or older.

A total of 12 participants received ibuzatrelvir in the study.

- 9 men (75.0%) and 3 women (25.0%) participated.
- Participants were between the ages of 28 and 70 years.

Of the 12 participants who started the study, 11 participants (91.7%) finished all 4 dosing periods. One (1) participant (8.3%) left the study on Day 2 of Period 1 due to symptoms of flu.

How long did the study last?

After the screening period, participants were in the study for up to 45 days (10 days in the 4 dosing periods and through 28 to 35 days after their last dose). The entire study took about 7 weeks to complete.

When the study ended in January 2024, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

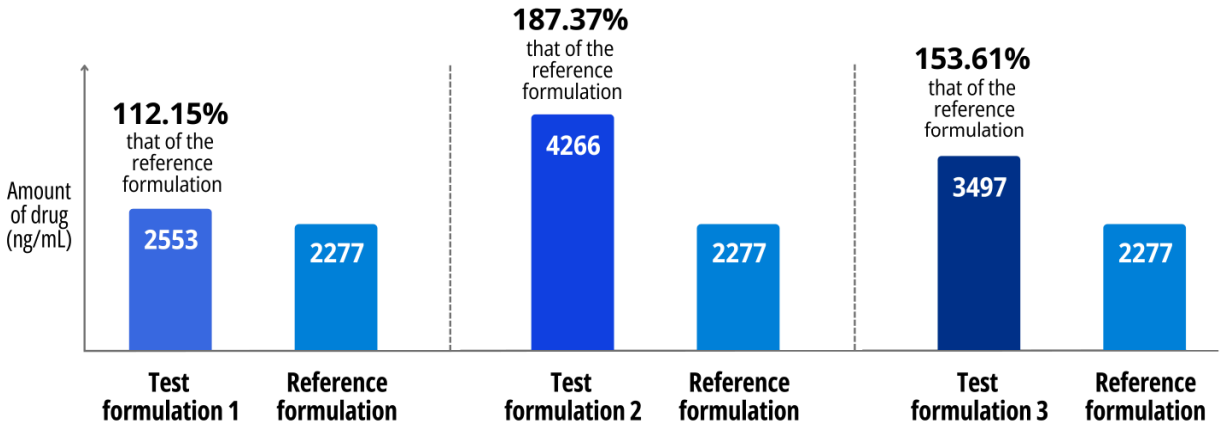
What were the results of the study?

How did the 3 test formulations of ibuzatrelvir compare with the reference formulation of ibuzatrelvir?

To answer this question, researchers measured the amount of ibuzatrelvir in the blood when participants took the 3 test formulations compared to when they took the reference formulation.

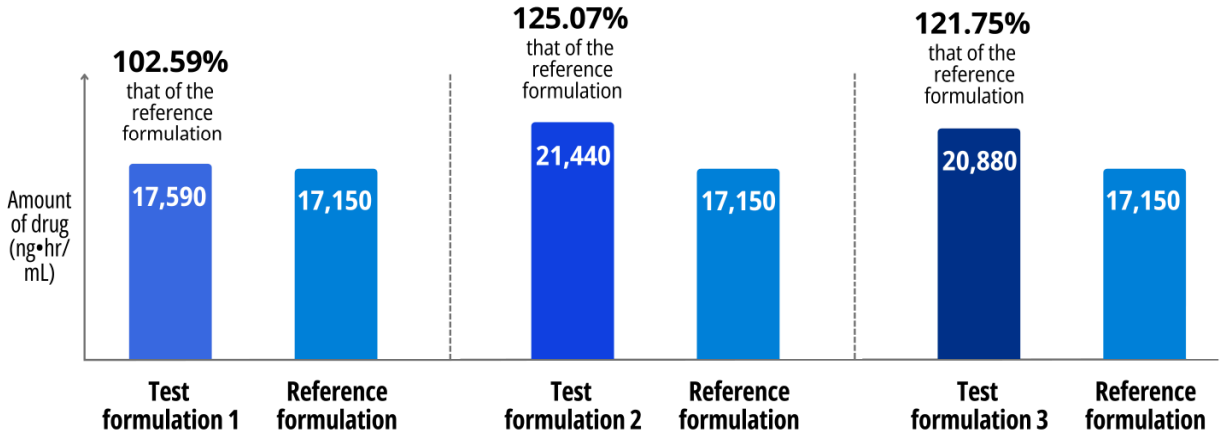
Although the highest amount of ibuzatrelvir in the blood when it was taken as **test formulation 1 to 3** was **higher** than that of the **reference formulation**, these observed amounts were considered safe. Figure 3 below shows these results. The amount of drug in the blood was measured in nanograms per milliliter, also called ng/mL.

Figure 3. Highest amount of ibuzatrelvir in the blood



The estimated total amount of ibuzatrelvir in the blood from when ibuzatrelvir was taken as **test formulation 1 to 3** until it was removed from the body was **comparable** to that of the **reference formulation**. Figure 4 below shows these results. The total amount of drug in the blood was measured in nanogram hours per milliliter, also called ng•hr/mL.

Figure 4. Estimated total amount of ibuzatrelvir in the blood



Overall results:

Researchers found that the test and reference formulations of ibuzatrelvir (300 mg) were generally safe and well tolerated in healthy participants.

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.

A total of 6 out of 12 participants (50.0%) had at least 1 medical problem across the 4 dosing periods in the study. The most common medical problem across the 4 dosing periods in the study was headache – reported by 2 out of 12 participants (16.7%). One (1) participant left the study because they had symptoms of flu at the start of the study. Researchers believe that the flu was not caused by ibuzatrelvir.

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 12 participants had serious medical problems during the study. 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	Use the protocol number **C5091013**

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

www.clinicaltrials.gov	Use the study identifier **NCT06122194**
euclinicaltrials.eu	Use the study identifier **2023-506442-24-00**

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!