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: C5091001

Dates of Study: 17 October 2022 to 15 September 2023

Title of this Study: A Study to Learn About the Safety and Blood Levels of PF-07817883 in Healthy People

[COVID-19: A Multipart, Phase 1 Study With Randomized, Double-Blind, Sponsor-Open, Placebo-Controlled, Single- and Multiple-Dose Escalation to Evaluate the Safety, Tolerability and Pharmacokinetics of PF-07817883 and Optional Open-Label, Randomized Study to Evaluate Relative Bioavailability and Food Effect of Solid Oral Formulation and Optional Open-Label, Non-Randomized Study to Evaluate Metabolism and Excretion of PF-07817883 and Optional Randomized, Open-Label Study to Assess the Effect of PF-07817883 on Pharmacokinetics of Midazolam in Healthy Adult Participants]

Date of this Report: 29 October 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 **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 is the study medication also called **ibuzatrelvir**. Ibuzatrelvir was an investigational medicine, which means it is still being studied and health authorities have not approved it for use outside of research studies. In this study, ibuzatrelvir was taken by mouth as a liquid or tablet formulation.

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?

This study had 6 parts. The purpose of the study was to find out the following:

- If ibuzatrelvir is safe when given as a single dose (**Parts 1, 3, 4, and 6**) and multiple doses (**Parts 2 and 5**)
- How the body can affect ibuzatrelvir (**Parts 1 to 6**)
- How different formulations (tablet and liquid) of ibuzatrelvir behave in the body and how food can affect ibuzatrelvir blood levels (**Part 3**)
- How much of ibuzatrelvir leaves the body through the urine or feces (**Part 4**)
- If ibuzatrelvir affects the levels of another drug called midazolam in the blood when they were taken together (**Part 5**)

  Giving ibuzatrelvir and midazolam together helped researchers to understand if ibuzatrelvir can affect other drugs similar to midazolam.

Researchers wanted to know:

- **Are the tested doses of ibuzatrelvir safe and tolerable in this study? (Parts 1 through 6)**
- **How do the 2 different tablet formulations of ibuzatrelvir compare with the liquid formulation of ibuzatrelvir? (Part 3)**
- **How much of ibuzatrelvir leaves the body? (Part 4)**
- **Does ibuzatrelvir affect the level of midazolam in the body when they were taken together? (Part 5)**

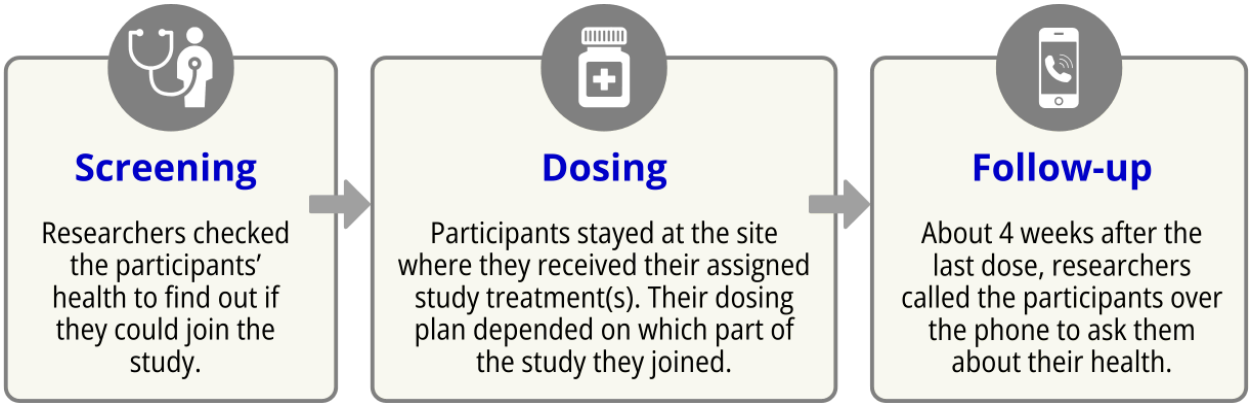
This study on healthy participants did not test if ibuzatrelvir helps to treat COVID-19.

What happened during the study?

How was the study done?

Participants joined at least 1 of 6 parts of the study. Figure 1 below shows how the study was done.

Figure 1. What happened in the study?



Ibuzatrelvir was given in **liquid** formulation in all 6 parts of the study. Ibuzatrelvir was also given as **tablet** formulations in **Part 3**.

Participants in **Parts 1, 2, and 6** were assigned to take ibuzatrelvir and/or a placebo. A **placebo** does not have any medicine in it, but it looks just like ibuzatrelvir. Comparing the results of ibuzatrelvir and placebo can help researchers find out if ibuzatrelvir works better than no treatment at all (placebo).

- In **Parts 1, 2, and 6**, the participants and researchers did not know who took ibuzatrelvir and who took the placebo. This is known as a "**blinded**" study. The Sponsor knew which treatment the participants got in these 3 parts of the study.

- In **Part 6**, participants also received a medicine called moxifloxacin so that researchers could check if the electrocardiogram (ECG) results were as expected. The participants, researchers, and Sponsor knew when participants were taking moxifloxacin.

  Moxifloxacin is known to cause changes in the electrical activity of the heart as seen on ECG tests.

All participants in **Parts 3, 4, and 5** were assigned to take ibuzatrelvir. The participants and researchers knew which treatments the participants got in these 3 parts of the study. This is known as an "**open-label**" study.

In **Parts 1 to 5**, ibuzatrelvir was given at standard doses (also called "**clinical doses"**). In **Part 6**, ibuzatrelvir was given at higher-than-standard doses (also called "**supratherapeutic doses"**).

Part 1:

Participants in Part 1 were divided into 2 groups: Group 1 or Group 2.

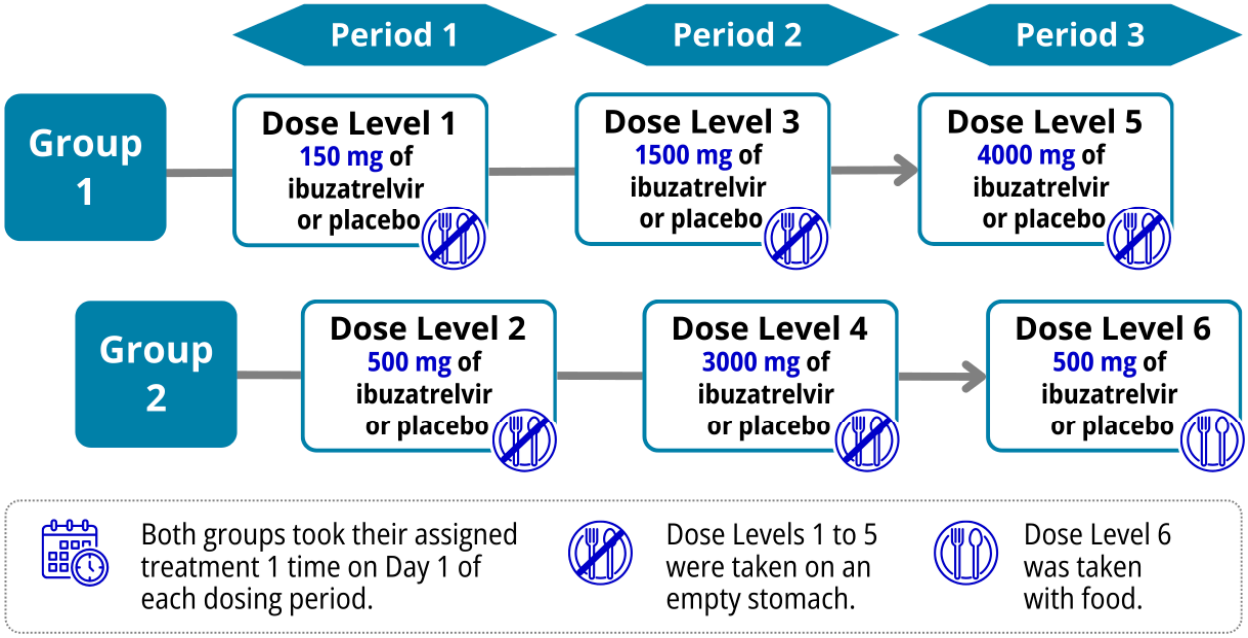
The study treatment (ibuzatrelvir or placebo) was taken in liquid formulation. Participants took their assigned dose level of study treatment as 1 dose (single dose) on Day 1 of each dosing period.

Part 1 had 3 dosing periods. Participants in each group were assigned to receive 1 dose of ibuzatrelvir or placebo by chance in each of the 3 periods. For every 8 participants, 6 had a chance to receive ibuzatrelvir and 2 had a chance to receive placebo.

The first group of participants (Group 1) was given the lowest dose (Dose Level 1) of ibuzatrelvir or placebo. After researchers made sure that there were no safety concerns seen with this dose, the next group of participants (Group 2) were then given the next higher dose (Dose Level 2). This process went on one step at a time until the highest dose level was given.

Figure 2 below shows how Part 1 was done. It also shows the dose levels tested in Part 1: 150 milligrams (mg), 500 mg, 1500 mg, 3000 mg, and 4000 mg.

Figure 2. What dose levels were given in Part 1?



Dose Levels 1 to 5 were taken on an empty stomach. Dose Level 6 was taken with food.

There was a **washout** of at least 5 days before starting the next dose level of study treatment. This was to allow the earlier dose to be cleared (or washed out) from the body before taking the next dose.

Participants stayed at the study site throughout these 3 periods up to 19 nights.

Part 2:

Part 2 signed up a total of 4 groups of participants: **Groups 3, 4, and 5,** and Chinese participants in **Group 8**. The optional **Groups 6 and 7** were not started.

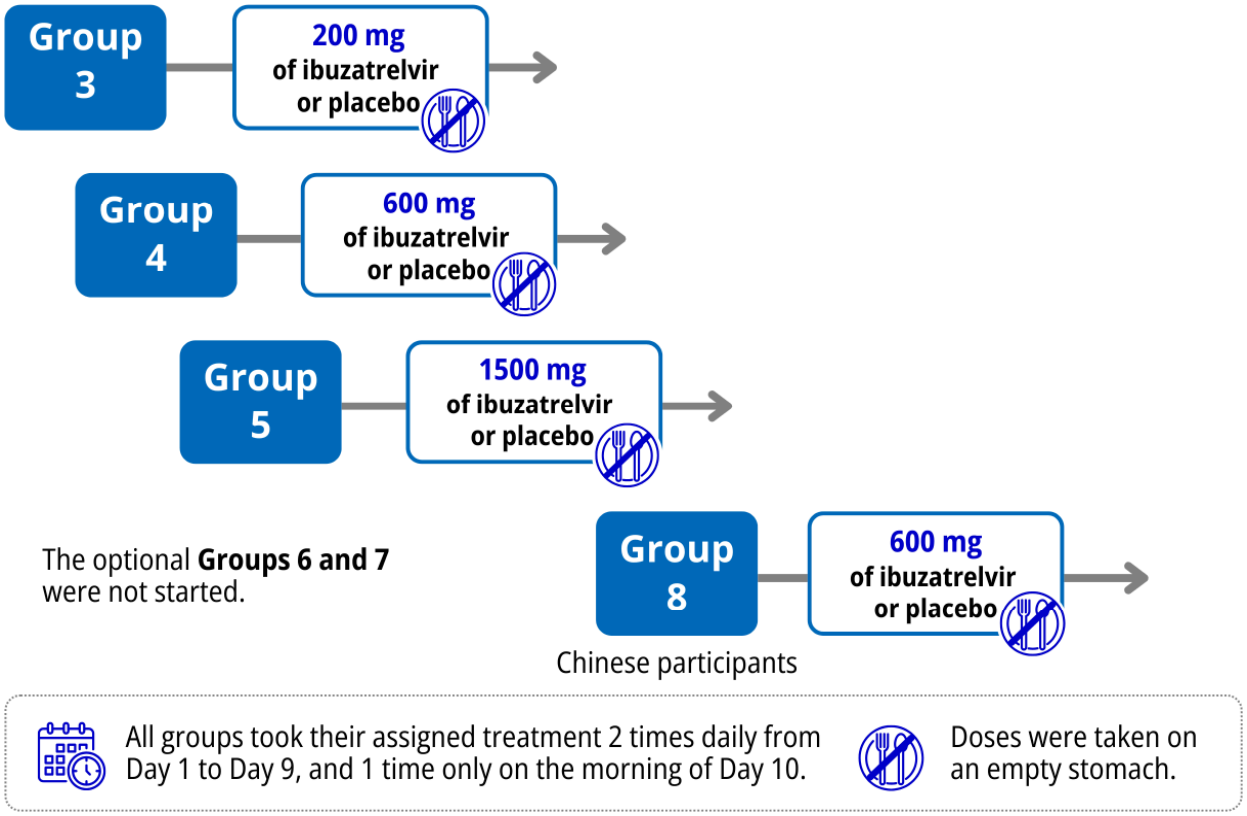
The study treatment (ibuzatrelvir or placebo) was taken in liquid formulation on an empty stomach. Participants took their assigned dose level of study treatment 2 times daily from Days 1 to 9 and 1 time only on the morning of Day 10.

Participants in each group were assigned to receive ibuzatrelvir or placebo by chance. For every 6 participants, 4 had a chance to receive ibuzatrelvir and 2 had a chance to receive placebo.

The first group of participants (Group 3) was given the lowest dose of ibuzatrelvir or placebo. After researchers made sure that there were no safety concerns seen with this dose, the next group of participants were then given the next higher dose. This went on one step at a time until the highest dose level was given.

Figure 3 below shows how Part 2 was done. It also shows the dose levels tested in Part 2: 200 mg, 600 mg, and 1500 mg.

Figure 3. What doses were given in Part 2?



Participants stayed at the study site throughout the dosing period up to 12 nights.

Part 3:

Part 3 signed up 1 group of participants (Group 9). Participants took 4 of 5 different treatments across 4 dosing periods in Part 3. The table below shows the 5 different treatments.

Treatment	Formulation of study medication
Treatment A	ibuzatrelvir (600 mg) **liquid formulation** taken on an **empty stomach**
Treatment B	ibuzatrelvir (600 mg) **crystalline tablet formulation** taken on an **empty stomach**
Treatment C	ibuzatrelvir (600 mg) **SDD tablet formulation** taken on an **empty stomach**
Treatment D	ibuzatrelvir (600 mg) **crystalline tablet formulation** taken **with food** (high-fat meal)
Treatment E	ibuzatrelvir (600 mg) **SDD tablet formulation** taken **with food** (high-fat meal)

- **Crystalline** means that the tablet formulation is like crystals.
- **SDD** tablet is a "spray-dried dispersed" formulation. This means that the study medication had a spray-drying process before it was pressed into a tablet form.

Participants took 1 of 4 different treatments as 1 dose on Day 1 of each dosing period. Which treatments were assigned to them and the order in which they took the treatments depended on which sequence they were assigned to. Participants were assigned to 1 of 6 sequences by chance. The table below shows the assigned treatments for each sequence.

Sequence	Period 1	Period 2	Period 3	Period 4
1	Treatment A	Treatment B	Treatment C	Treatment D
2	Treatment B	Treatment C	Treatment A	Treatment D
3	Treatment C	Treatment A	Treatment B	Treatment D
4	Treatment B	Treatment A	Treatment C	Treatment E
5	Treatment A	Treatment C	Treatment B	Treatment E
6	Treatment C	Treatment B	Treatment A	Treatment E

Treatments A, B, and C were given in Sequences 1 to 6. Treatment D was given in Sequences 1 to 3. Treatment E was given in Sequences 4 to 6.

There was a **washout** of at least 3 days between 2 treatments. This was to allow the earlier treatment to be cleared from the body before taking the next treatment.

Participants stayed at the study site throughout these 4 periods up to 12 nights.

Part 4:

Part 4 signed up a group of male participants (Group 10). Participants took 1 dose of ibuzatrelvir 600 mg in liquid formulation on an empty stomach on Day 1 of the dosing period.

Participants stayed at the study site up to 11 nights during the dosing period.

Part 5:

Part 5 signed up 1 group of participants (Group 11). An optional Group 12 was not started.

Participants took 2 different treatments across 2 dosing periods in Part 5. The table below shows the 2 different treatments.

Treatment	Study medications
Treatment A	**Midazolam** 5 mg tablet was taken 1 time.
Treatment B	**Ibuzatrelvir** 600 mg liquid formulation was taken as multiple doses for 10 days: 2 times daily from Days 1 to 9 and 1 time only on the morning of Day 10. **Midazolam** 5 mg tablet was taken 1 time on Day 10.

Participants were assigned to take 1 of 2 different treatments in each period. Which treatment they took first depended on which sequence they were assigned to. They were assigned to 1 of 2 sequences by chance. The table below shows the assigned treatments for each sequence.

Sequence	Period 1	Period 2
1	Treatment A	Treatment B
2	Treatment B	Treatment A

For Sequence 1, there was a washout of at least 2 days between the 2 treatments. For Sequence 2, the washout was at least 7 days between the 2 treatments. This was to allow the earlier treatment to be cleared from the body before taking the next treatment.

Participants stayed at the study site throughout these 2 periods up to 14 nights (Sequence 1) or 20 nights (Sequence 2).

Part 6:

Part 6 signed up 1 group of participants (Group 13). Participants took 3 different study treatments across 3 dosing periods in Part 6. Participants took their assigned study treatments as single doses on an empty stomach on Day 1 of the study. The table below shows the 3 different treatments.

Treatment	Study medications
Treatment A	**Ibuzatrelvir** 6000 mg liquid formulation was taken as 2 split doses (3000 mg for each dose, 1 hour apart).
Treatment B	**Placebo** was taken at first. Then, **placebo** was taken again 1 hour later.
Treatment C	**Moxifloxacin** 400 mg tablet was taken at first. Then, **placebo** was taken 1 hour later.

Participants were assigned to take 1 of 3 different treatments in each period. Which treatment they took first depended on which sequence they were assigned to. Participants were assigned to 1 of 6 sequences by chance. The table below shows the assigned treatments for each sequence.

Sequence	Period 1	Period 2	Period 3
1	Treatment A	Treatment B	Treatment C
2	Treatment B	Treatment C	Treatment A
3	Treatment C	Treatment A	Treatment B
4	Treatment B	Treatment A	Treatment C
5	Treatment A	Treatment C	Treatment B
6	Treatment C	Treatment B	Treatment A

There was a **washout** of at least 7 days between 2 treatments. This was to allow the earlier treatment to be cleared from the body before taking the next treatment.

Participants stayed at the study site throughout these 3 periods up to 20 nights.

Throughout the study: (Parts 1 to 6)

- Researchers checked the participants' health during the study and asked them how they were feeling.
- Researchers took samples of blood and urine from participants during the study. Samples of feces were also taken from participants in Part 1 and those in Part 4.

Follow-up period: (Parts 1 to 6)

About 4 weeks after the last dose, researchers called the participants over the phone to ask them how they were feeling and about any medicines they may have been taking.

Where did this study take place?

The study ran at 2 locations in 2 countries: Belgium and United States.

When did this study take place?

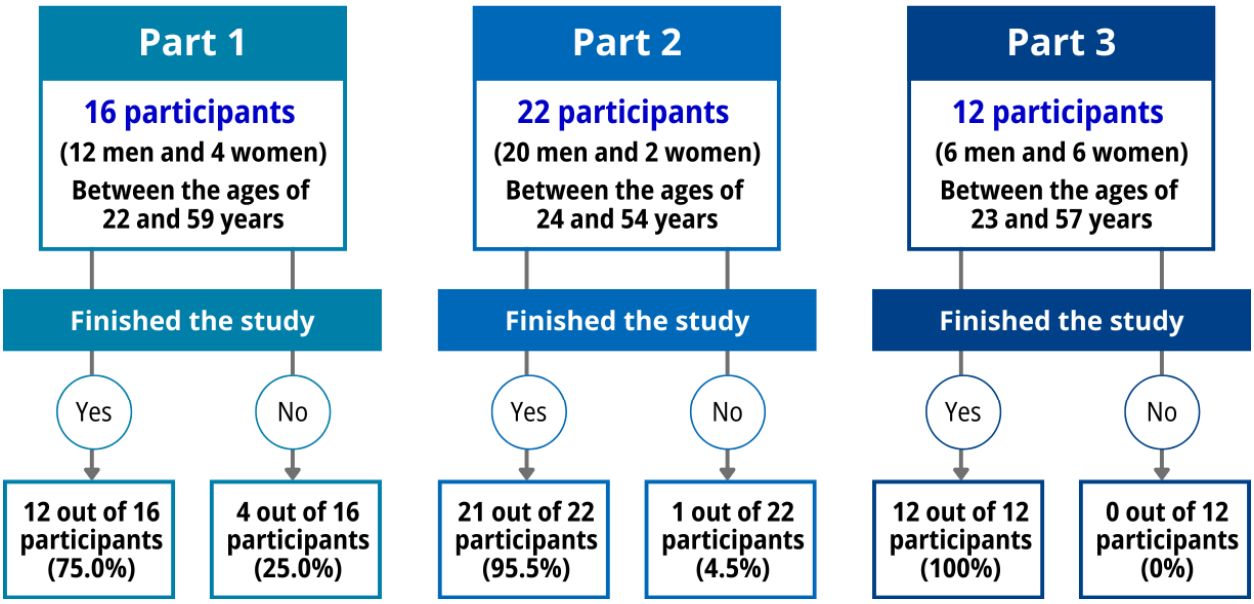
It began on 17 October 2022 and ended on 15 September 2023.

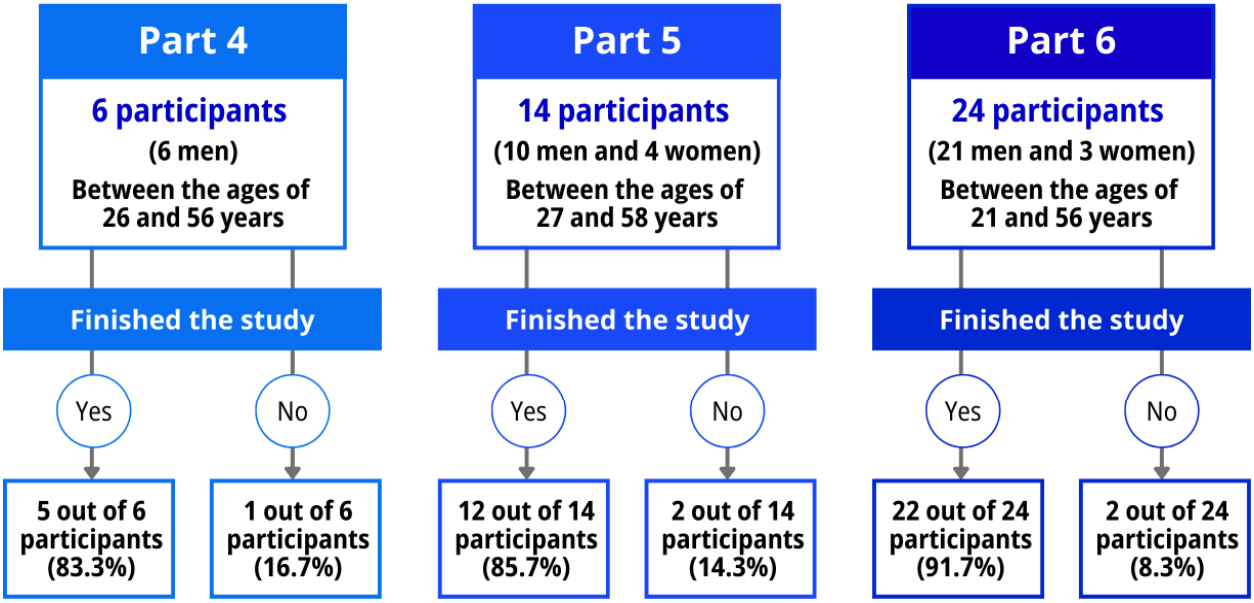
Who participated in this study?

In **Parts 1 to 6**, the study included healthy adults 18 to 60 years of age. In all parts of the study except Part 4, male and female adults could participate. In Part 4, only male adults could participate. Part 2 also signed up a group of Chinese participants. Part 5 also included a few Japanese participants.

The figure below shows how many participants were in Parts 1 to 6 of the study. All participants received at least 1 dose of the study treatment.

Figure 4. How many participants were in each part of the study?





Among those who did not finish the study as listed in Figure 4 above, it was due to the participant's or study doctor's decision to stop being in the study, a medical problem, or other reasons.

How long did the study last?

Each participant was in the study for about 30 to 47 days depending on which part they joined. The entire study took about 11 months to complete.

When the study ended in September 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?

Are the tested doses of ibuzatrelvir safe and tolerable in this study? (Parts 1 through 6)

To answer this question, researchers checked the health of participants in **Parts 1 through 6** throughout the study.

- Researchers reviewed the medical problems that participants had during the study.
- Researchers measured the participants' vital signs (heart rate, blood pressure, and breathing rate).
- Researchers also looked at the participants' blood test and ECG results. An ECG measures the electrical activity of the heart.

Study results:

Researchers found that the tested doses of ibuzatrelvir were generally safe and well tolerated when it was given in different formulations and doses:

- when participants took ibuzatrelvir liquid formulation as a **single dose** in **Part 1** and in **Part 4** (standard doses) and in **Part 6** (higher-than-standard doses),
- when participants took ibuzatrelvir liquid formulation as **multiple doses** in **Part 2** and in **Part 5** with or without midazolam.
- when participants took ibuzatrelvir **liquid** or **tablet** formulations as a **single dose** in **Part 3**

Researchers found that the results of participants' blood tests, vital signs, and ECG tests during the study did not have any medically important findings.

How do the 2 different tablet formulations of ibuzatrelvir compare with the liquid formulation of ibuzatrelvir? (Part 3)

To answer this question, researchers looked at how much of ibuzatrelvir was found in the blood during **Part 3**. Researchers compared the results of when ibuzatrelvir was taken as 2 different tablet formulations with the results of when ibuzatrelvir was taken as a liquid formulation.

Study results – **crystalline** tablet formulation compared with **liquid** formulation of ibuzatrelvir:

- The highest amount of ibuzatrelvir in the blood when it was taken as a **crystalline tablet** was about **67%** of the highest amount of ibuzatrelvir when it was taken as a **liquid**. This means that the highest amount of ibuzatrelvir in the blood reached by the **crystalline tablet formulation** was **lower** compared to the **liquid formulation**.
- The estimated total amount of ibuzatrelvir in the blood from when ibuzatrelvir **crystalline tablet** was taken until it was removed from the body was about **101%** of the estimated total amount of ibuzatrelvir when it was taken as a **liquid**. This means that the estimated total amount of ibuzatrelvir in the blood reached by the **crystalline tablet formulation** was **similar** to the **liquid formulation**.
- The total amount of ibuzatrelvir in the blood from when ibuzatrelvir **crystalline tablet** was taken until its lowest amount was detected in the blood about **98%** of the total amount of ibuzatrelvir when it was taken as a **liquid**. This means that the total amount of ibuzatrelvir in the blood reached by the **crystalline tablet formulation** was **similar** to the **liquid formulation**.

Study results – **SDD** tablet formulation compared with **liquid** formulation of ibuzatrelvir:

- The highest amount of ibuzatrelvir in the blood when it was taken as an **SDD tablet** was about **74%** of the highest amount of ibuzatrelvir when it was taken as a **liquid**. This means that the highest amount of ibuzatrelvir in the blood reached by the **SDD tablet formulation** was **lower** compared to the **liquid formulation**.
- The estimated total amount of ibuzatrelvir in the blood from when ibuzatrelvir **SDD tablet** was taken until it was removed from the body was about **103%** of the estimated total amount of ibuzatrelvir when it was taken as a **liquid**. This means that the estimated total amount of ibuzatrelvir in the blood reached by the **SDD tablet formulation** was **similar** to the **liquid formulation**.
- The total amount of ibuzatrelvir in the blood from when ibuzatrelvir **SDD tablet** was taken until its lowest amount was detected in the blood about **102%** of the total amount of ibuzatrelvir when it was taken as a **liquid**. This means that the total amount of ibuzatrelvir in the blood reached by the **SDD tablet formulation** was **similar** to the **liquid formulation**.

How much of ibuzatrelvir leaves the body? (Part 4)

To answer this question, researchers looked at the results of participants in **Part 4**. Researchers measured the total amount of ibuzatrelvir that left the body through the urine and feces.

Study results:

Almost all of ibuzatrelvir (calculated average of **102%**) left the body over 144 hours after taking 600 mg of ibuzatrelvir liquid formulation. Most of ibuzatrelvir left the body through the feces (**89%**), while the rest of it left the body through the urine (**13%**).

Does ibuzatrelvir affect the level of midazolam in the body when they were taken together? (Part 5)

To answer this question, researchers looked at the results of participants in **Part 5**. Researchers measured the amount of midazolam in the blood when participants took 5 mg of midazolam only and when they took 5 mg of midazolam with 600 mg of ibuzatrelvir liquid formulation.

Study results:

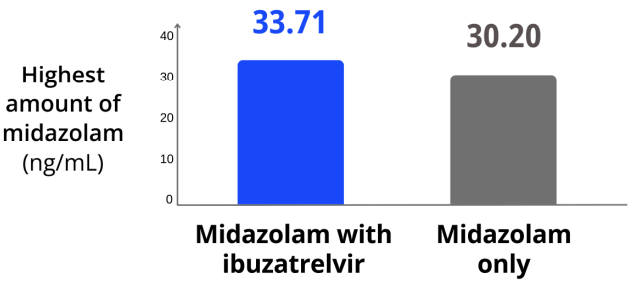
The amount of midazolam in the blood was **similar** when **midazolam only** was taken compared to when **midazolam and ibuzatrelvir** were taken together. The study results mean that ibuzatrelvir did not affect the level of midazolam in the body.

The results are described below.

The highest amounts of midazolam in the blood after participants took **midazolam** with or without **ibuzatrelvir** are shown in Figure 5.

The amount of drug in the blood was measured in nanograms per milliliter, also called ng/mL.

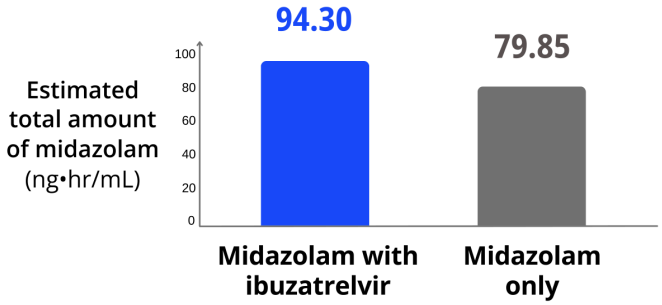
Figure 5. Highest amount of midazolam in the blood



The estimated total amounts of midazolam in the blood from when participants took **midazolam** with or without **ibuzatrelvir** until midazolam was removed from the body are shown in Figure 6.

The estimated total amount was measured in nanogram hours per milliliter, also called ng•hr/mL.

Figure 6. Estimated total amount of midazolam in the blood



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.

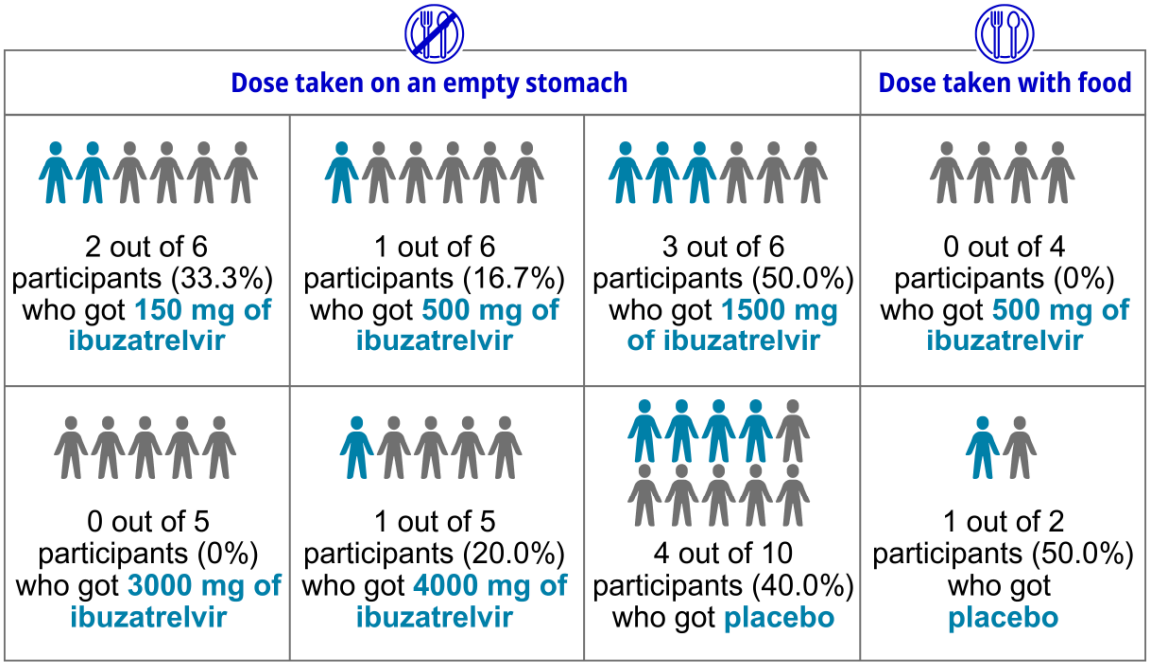
What medical problems did participants have during the study?

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.

Part 1:

Most of the participants in Part 1 who had at least 1 medical problem during the study were reported by those who got 1 dose of 1500 mg of ibuzatrelvir (empty stomach) or placebo (empty stomach). These results are shown in Figure 7 below.

Figure 7. How many participants had medical problems in Part 1?



The most common medical problems in Part 1 – those reported by more than 2 participants across the different dose levels – are listed below.

Constipation was reported by:

- 1 out of 6 participants (16.7%) who got 500 mg of ibuzatrelvir (empty stomach)
- 2 out of 6 participants (33.3%) who got 1500 mg of ibuzatrelvir (empty stomach)
- 2 out of 10 participants (20.0%) who got placebo (empty stomach)

Headache was reported by:

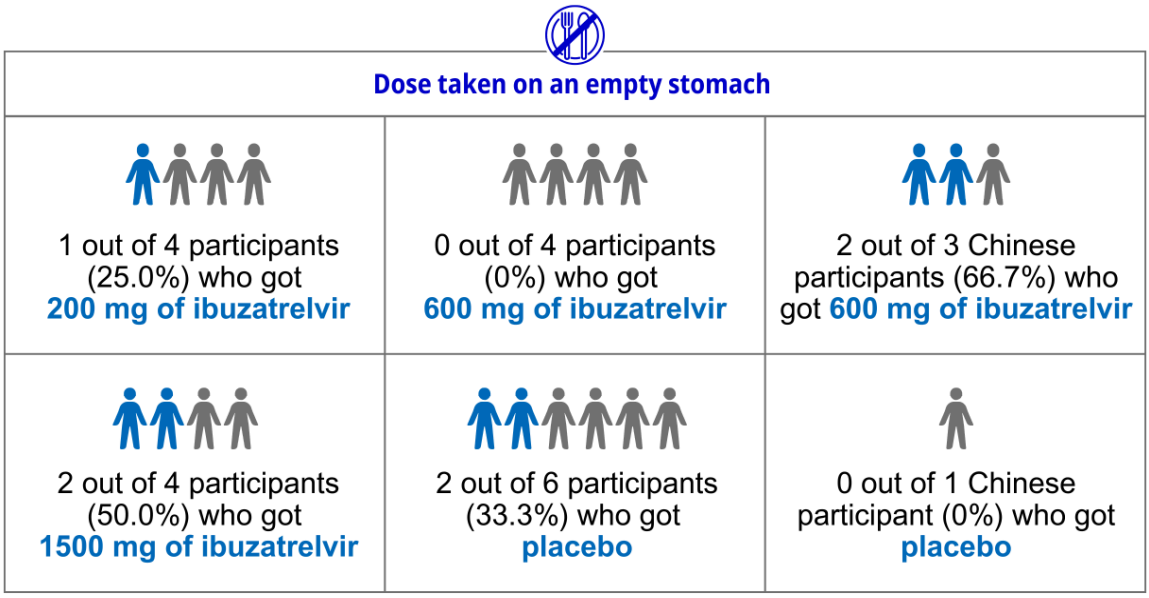
- 1 out of 6 participants (16.7%) who got 150 mg of ibuzatrelvir (empty stomach)
- 2 out of 10 participants (20.0%) who got placebo (empty stomach)

None of the participants in Part 1 left the study because of a medical problem.

Part 2:

Few participants in Part 2 had at least 1 medical problem during the study. These results are shown in Figure 8 below.

Figure 8. How many participants had medical problems in Part 2?



The most common medical problem in Part 2 – reported by at least 2 participants across the different dose levels – are listed below:

- **Bruising**: 2 out of 3 Chinese participants (66.7%) who got 600 mg of ibuzatrelvir
- **Runny nose**: 1 out of 6 participants (16.7%) who got placebo and 1 out of 4 participants (25.0%) who got 200 mg of ibuzatrelvir

None of the participants in Part 2 left the study because of a medical problem.

Part 3:

Figure 9 below shows how many participants in Part 3 had at least 1 medical problem during the study.

Figure 9. How many participants had medical problems in Part 3?

Dose taken on an empty stomach	 4 out of 12 participants (33.3%) after taking the **liquid** formulation of ibuzatrelvir	 4 out of 12 participants (33.3%) after taking the **crystalline tablet** formulation of ibuzatrelvir	 1 out of 12 participants (8.3%) after taking the **SDD tablet** formulation of ibuzatrelvir
Dose taken with food	**Liquid** formulation was not given with food in Part 3	 2 out of 6 participants (33.3%) after taking the **crystalline tablet** formulation of ibuzatrelvir	 1 out of 6 participants (16.7%) after taking the **SDD tablet** formulation of ibuzatrelvir

The most common medical problems in Part 3 – reported by at least 2 participants across the 5 different formulations – are listed below.

Constipation was reported by:

- 1 out 12 participants (8.3%) after taking the **crystalline tablet formulation** of ibuzatrelvir (empty stomach)
- 1 out of 12 participants (8.3%) after taking the **SDD tablet formulation** of ibuzatrelvir (empty stomach)

Headache was reported by:

- 1 out of 12 participants (8.3%) after taking the **liquid formulation** of ibuzatrelvir (empty stomach)
- 1 out 12 participants (8.3%) after taking the **crystalline tablet formulation** of ibuzatrelvir (empty stomach)

Tiredness (fatigue) was reported by:

- 1 out of 12 participants (8.3%) after taking the **liquid formulation** of ibuzatrelvir (empty stomach)
- 1 out 6 participants (16.7%) after taking the **crystalline tablet** of ibuzatrelvir (with food)

None of the participants in Part 3 left the study because of a medical problem.

Part 4:

Overall, 4 out of 6 participants (66.7%) in Part 4 had at least 1 medical problem during the study.

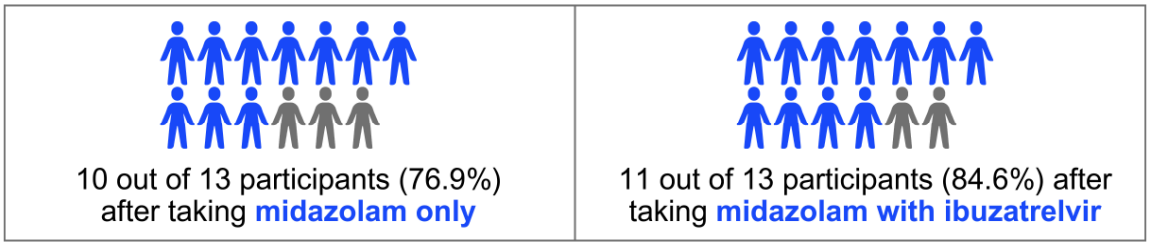
The most common medical problem in Part 4 – reported by at least 2 participants – was an **infection of the nose, throat, sinuses, or voice box**. This medical problem was seen in 2 out of 6 participants (33.3%) who got 1 dose of ibuzatrelvir.

Overall, 1 participant in Part 4 left the study because of a medical problem after dosing with ibuzatrelvir (empty stomach). This medical problem was **fainting**. Researchers believe that this medical problem was not related to ibuzatrelvir.

Part 5:

Most of the participants in Part 5 had at least 1 medical problem during the study. The results are shown in Figure 10 below.

Figure 10. How many participants had medical problems in Part 5?



The most common medical problem in Part 5 – reported by at least 5 participants across both dosing periods – was **sleepiness**. This medical problem was reported by:

- 9 out of 13 participants (69.2%) after taking **midazolam** only.
- 9 out of 13 participants (69.2%) after taking **midazolam with ibuzatrelvir**.

A total of 2 participants in Part 5 left the study because of a medical problem. These medical problems were:

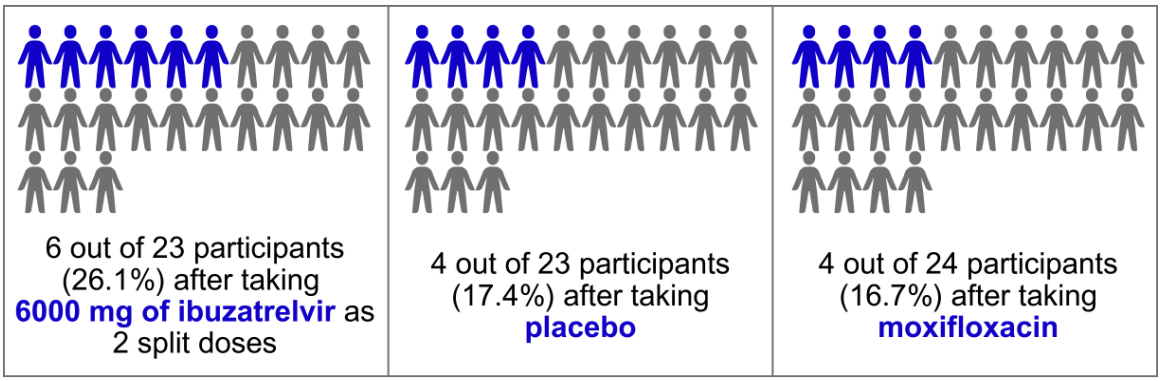
- **COVID-19** reported by 1 out of 13 participants (7.7%) after taking **midazolam** only.
- **Coughing up of blood** reported by 1 out of 13 participants (7.7%) after taking **midazolam with ibuzatrelvir**.

Researchers believe that these 2 medical problems were not related to the study treatments.

Part 6:

Some participants in Part 6 had at least 1 medical problem during the study. The results are shown in Figure 11 below.

Figure 11. How many participants had medical problems in Part 6?



None of the individual medical problems in Part 6 were reported by 2 or more participants after taking any of the 3 treatments during the study.

Overall, 1 participant in Part 6 left the study because of a medical problem after taking **placebo**. This participant had **extra heartbeats** that start in the lower chambers of the heart. Researchers believe that this medical problem may be related to the study treatment. The participant did not receive ibuzatrelvir during the study.

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 in any of the 6 parts of the study had serious medical problems or 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 **C5091001**

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

www.clinicaltrials.gov	Use the study identifier **NCT05580003**
www.clinicaltrialsregister.eu	Use the study identifier **2022-002871-12**

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!