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-07104091
Protocol Number:	C4161007
Dates of Study:	10 June 2022 to 17 October 2022
Title of this Study:	A Study to Test the Effects of Different Tablet Formulations of PF-07104091 and Food on Blood Levels of PF-07104091 in Healthy Participants [A Phase 1, Randomized, Open-Label, 4-Period, 5-Treatment, 6-Sequence, Crossover, Single-Dose Study in Healthy Participants to Investigate the Effect of Tablet Formulation and Food on the Bioavailability of PF-07104091]
Date of this Report:	09 October 2023

– 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 advanced or metastatic cancer?

Cancer is a disease in which cells in the body grow without control. Cancer can start in almost any part of the body. Sometimes cancer can spread to other parts of the body from where it originated. This is called metastatic cancer. Most metastatic cancers can be managed but cannot be cured.

When a cancer is unlikely to be cured it is called advanced cancer. The goal of treating advanced cancer is to help slow the growth of advanced cancers or relieve symptoms.

What is PF-07104091?

PF-07104091 is an investigational cancer medicine that is being tested as a treatment for people with advanced or metastatic lung, ovarian, or breast cancer. It is taken as a tablet by mouth. At the time of this study, it was not approved by the government (Food and Drug Administration [FDA]) to treat any disease or medical problem. It works by stopping or preventing the action of a protein called Cyclin-Dependent Kinase 2 (CDK2). This helps prevent the growth of cancer cells. This study was the first time it was given to healthy participants. The participants in this study did not have cancer.

What was the purpose of this study?

The purpose of this study was to:

- Measure and compare the amount of PF-07104091 in the blood after single 300 mg doses of 4 different tablet formulations (mixtures) of PF-07104091 with and without food.
- See how PF-07104091 is tolerated and if participants have side effects after taking it.

Researchers wanted to know:

- **How did 4 different tablet formulations of PF-07104091 affect the amount of PF-07104091 in the blood?**
- **What side effects, if any, did participants have during the study?**

What happened during the study?

How was the study done?

Researchers tested 4 different tablet formulations of PF-07104091 in healthy participants to learn how they affect the amount of PF-07104091 in the blood. All 4 tablet formulations were given without food. Researchers also wanted to know if taking PF-07104091 with food had different effects on the amount of PF-0710491 in the blood. To test this, some participants took 1 tablet formulation with food.

The 4 tablet formulations are referred to as Tablet A, Tablet B, Tablet C, and Tablet D.

There were 5 treatments in this study:

- Treatment A: Single 300 mg dose of Tablet A without food.
- Treatment B: Single 300 mg dose of Tablet B without food.
- Treatment C: Single 300 mg dose of Tablet C without food.
- Treatment D: Single 300 mg dose of Tablet D without food.
- Treatment E: Single 300 mg dose of Tablet C with food.

Participants received 4 of the 5 treatments during this study on different days (referred to as study periods). To do this, researchers organized the

5 treatments into 6 different sequences (See Table 1). Each sequence had 4 treatments. The order of treatments in each sequence was different. Five participants were assigned to each sequence by chance alone.

Each study period was 4 days long. Each treatment was taken on Day 1 of each study period. There was a minimum of 5 days between each PF-07104091 dose.

Table 1 shows the sequence number and the order of treatments for that sequence. For example, a participant in Sequence 1 received Treatment A at Study Period 1, Treatment B at Study Period 2, Treatment C at Study Period 3, and Treatment D at Study Period 4.

Table 1. Sequence of Treatments

Sequence Number	Study Period 1	Study Period 2	Study Period 3	Study 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 A	Treatment B	Treatment C	Treatment E
5	Treatment B	Treatment C	Treatment A	Treatment E
6	Treatment C	Treatment A	Treatment B	Treatment E

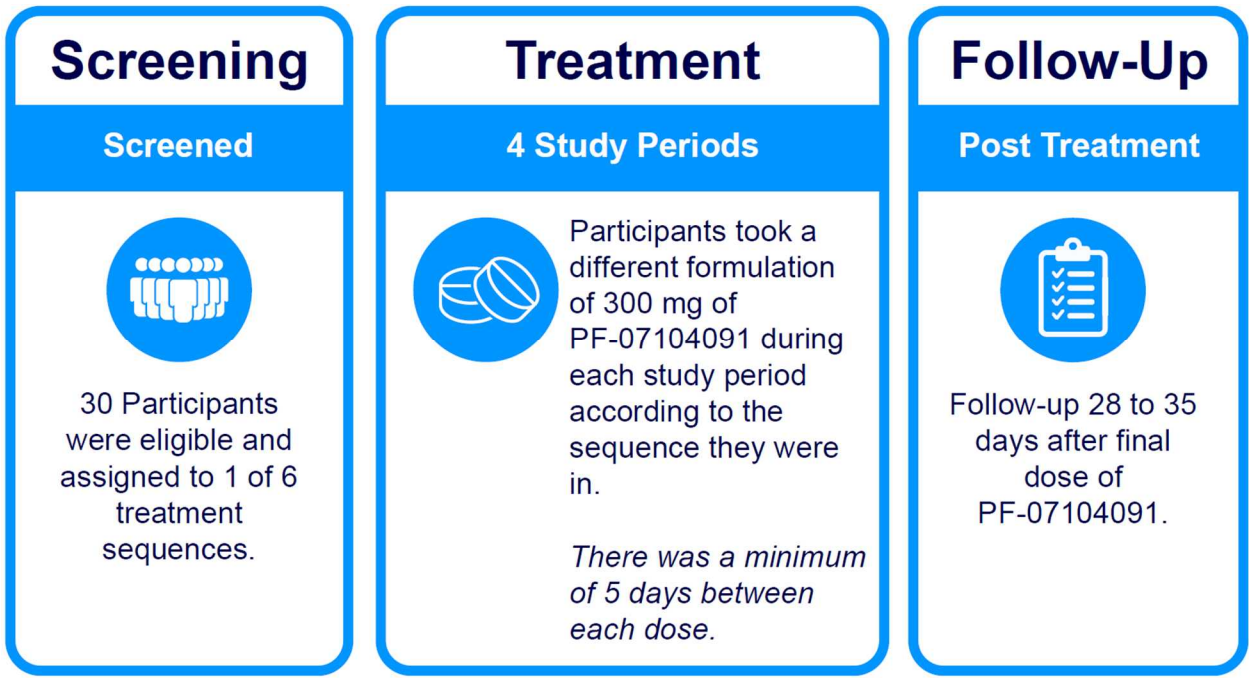
Researchers took samples of blood from participants during each study period and measured the amount of PF-07104091 in their blood. Researchers also checked the participants' health during the study and asked them how they were feeling.

The participants and researchers knew who took the different formulations of PF-07104091 at each study period. This is known as an "open-label" study.

For each treatment, researchers combined the results from all the participants that received that treatment. They then compared the results of each treatment to see how the different tablet formulations affected the amount of PF-07104091 in the blood.

Figure 1 shows the design of the study.

Figure 1



Where did this study take place?

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

When did this study take place?

It began 10 June 2022 and ended 17 October 2022.

Who participated in this study?

The study included healthy participants.

- A total of 30 men participated
- All participants were between the ages of 23 and 60

Of the 30 participants who started the study, 29 finished. One participant did not finish the study because they left the study due to personal reasons.

How long did the study last?

Study participants were in the study for up to 11 weeks. The entire study took 4 months to complete.

When the study ended in October 2022, 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 different tablet formulations of PF-07104091 act in the body?

To answer this question, the researchers compared the amount of PF-07104091 in the blood of participants after they took the different tablet formulations.

For each tablet formulation, researchers looked at:

- The highest amount of PF-07104091 in the blood after it was taken
- Total amount of PF-07104091 in the blood from when it was taken until it was removed from the body

This study found that all tablet formulations of PF-07104091 had similar effects on the amount of PF-07104091 in the blood when taken without food. When Tablet C was taken with food (Treatment E), it also had similar effects on the amount of PF-07104091 in the blood compared to when it was taken without food (Treatment C).

This is a summary of just some of the main results of this study. Other studies may have different results.

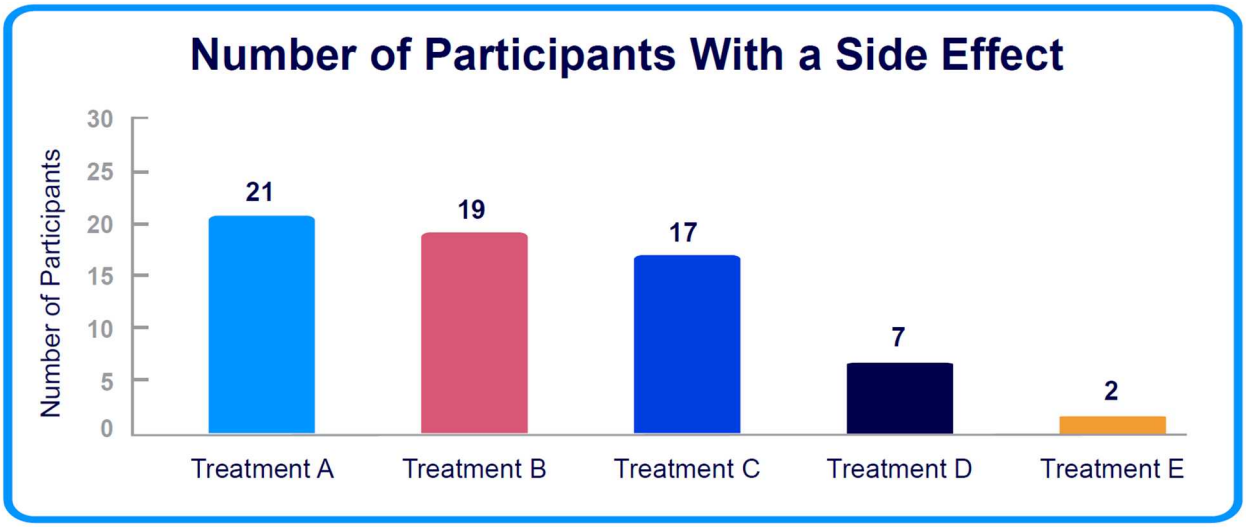
What side effects did participants have during the study?

The researchers recorded any side effects the participants had during the study. Participants could have had side effects for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, side effects could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a side effect is unknown.

By comparing side effects across many treatment groups in many studies, doctors try to understand what side effects a study medication might have on a participant.

Researchers recorded side effects in each treatment. The number of participants that had at least 1 side effect for each treatment is shown in Figure 2.

Figure 2



No participant left the study because of side effects. The most common side effects – those reported by more than 5 participants – are described below.

Below are instructions on how to read Table 2.

Instructions for Understanding Table 2.

- The **1st** column of Table 2 lists side effects that were commonly reported during the study. All side effects reported by more than 5 participants are listed.
- The **2nd** column tells how many of the 29 participants reported each side effect when taking Treatment A. Below this number is the percentage of the 29 participants who reported the side effect when taking Treatment A.
- The **3rd** column tells how many of the 30 participants reported each side effect when taking Treatment B. Below to this

number is the percentage of the 30 participants who reported the side effect when taking Treatment B.

- The **4th** column tells how many of the 29 participants reported each side effect when taking Treatment C. Below to this number is the percentage of the 29 participants who reported the side effect when taking Treatment C.
- The **5th** column tells how many of the 15 participants reported each side effect when taking Treatment D. Below to this number is the percentage of the 15 participants who reported the side effect when taking Treatment D.
- The **6th** column tells how many of the 14 participants reported each side effect when taking Treatment E. Below to this number is the percentage of the 14 participants who reported the side effect when taking Treatment E.

Using these instructions, you can see that:

- 18 out of the 29 (62.1%) participants reported feeling sick when taking Treatment A.
- 14 out of the 30 (46.7%) participants reported feeling sick when taking Treatment B.
- 13 out of the 29 (44.8%) participants reported feeling sick when taking Treatment C.
- 4 out of 15 (26.7%) participants reported feeling sick when taking Treatment D.
- 1 out of 14 (7.1%) participants reported feeling sick when taking Treatment E.

Table 2. Commonly reported side effects by study participants

Side Effect	Treatment A 29 Participants	Treatment B 30 Participants	Treatment C 29 Participants	Treatment D 15 Participants	Treatment E 14 Participants
Feeling Sick	18 (62.1%)	14 (46.7%)	13 (44.8%)	4 (26.7%)	1 (7.1%)
Vomiting	6 (20.7%)	7 (23.3%)	3 (10.3%)	3 (20.0%)	0 (0%)
Diarrhea	5 (17.2%)	4 (13.3%)	5 (17.2%)	1 (6.7%)	0 (0%)
Headache	3 (10.3%)	5 (16.7%)	3 (10.3%)	2 (13.3%)	0 (0%)
Dizziness	3 (10.3%)	1 (3.3%)	3 (10.3%)	1 (6.7%)	1 (7.1%)
Feeling Tired	1 (3.4%)	1 (3.3%)	3 (10.3%)	1 (6.7%)	0 (0%)

Did study participants have any serious side effects?

A side effect is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

No participants had serious side effects in 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.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **C4161007**

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

www.clinicaltrials.gov	Use the study identifier **NCT05431153**

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!