

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: PF-07263689

Protocol Number: C4651001

Dates of Study: 20 October 2021 to 14 October 2022

Title of this Study: Study of PF-07263689 in Participants With Selected Advanced Solid Tumors
[A Phase 1, Open-Label, Dose Escalation and Expansion Study Evaluating the Safety and Pharmacodynamics of PF-07263689, Either Alone or in Combination With an Anti-PD-1 Antibody, in Previously Treated Participants With Selected Locally Advanced or Metastatic Solid Tumors]

Date(s) of this Report: 21 September 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 are solid tumors?

Solid tumors are abnormal masses of tissues in different parts of the body that may be cancerous or non-cancerous. Solid tumors can affect different parts of body such as the lungs, bladder, ovaries, colon etc. Participants in this study had solid tumor cancer that was “advanced” or “metastatic”. This means that the original cancer has spread from where it originally started to other parts of the body and has become more difficult to cure.

What is PF-07263689?

PF-07263689 is a new investigational drug that is a genetically modified virus that specifically grows in and kills cancer cells. It also helps increase bodies’ own capabilities to fight against cancer. This drug could bring this response in cancer patients whether they have had previous anti-cancer therapies or not.

What was the purpose of this study?

The purpose of this study was to determine the safety and tolerability of PF-07263689 in patients with advanced solid tumors. Tolerability means how well the patient can tolerate the drug.

This was the first time PF-07263689 was given to people. Researchers wanted to find the best and safest (optimal) dose of the drug to decide what dose to give to people in future studies.

Researchers did this by giving participants increasing doses of PF-07263689. At each dose level, researchers checked if participants had any dose limiting toxicities (DLTs), before deciding if a higher dose could be given. They also looked at the general safety of different doses. DLTs

are medical problems which usually prevent further increases in the dose of the study medication.

This study was planned to be conducted in 3 parts. In Part 1A participants were to be given PF-07263689 alone to find the best dose. In Part 1B participants were to be given the selected “best dose” of PF-07263689 along with another anti-cancer drug called sasanlimab, which also boosts the immune response against cancer. In Part 2 a combination of PF-07263689 and sasanlimab was to be given to a larger group of participants with specific solid tumors.

However, on 07 September 2022, the study was ended early due to sponsor’s business decision and not due to any safety concerns with PF-07263689. Therefore, only Part 1A enrolled participants and Part 1B and Part 2 were not conducted.

Researchers wanted to know:

- What medical problems did participants have during the study?
 - What was the optimal dose of PF-07263689?
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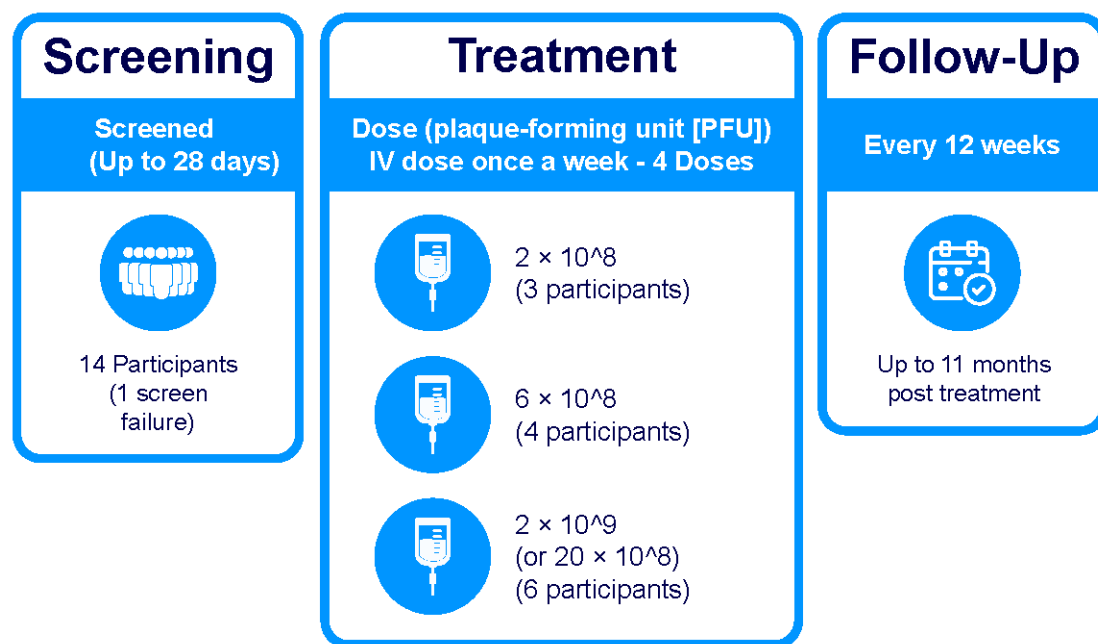
What happened during the study?

How was the study done?

In Part 1A researchers tested increasing doses of PF-07263689 as a single agent on groups of participants with solid tumor cancers to find the “best- dose” based on the side effects they experienced.

Participants were given doses of PF-7263689 of either 2×10^8 (Cohort 1), or 6×10^8 (Cohort 2), or 2×10^9 (or 20×10^8) (Cohort 3), via injection through the vein once a week for 4 weeks. as shown in Figure 1:

Figure 1 How was the Study done?



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

Researchers then looked the safety results of participants taking PF-07263689 at a given dose level to see if it was considered safe and tolerable, before starting treatment for the next group of participants at the next dose level of PF-07263689.

Where did this study take place?

The Sponsor ran this study at 2 locations in the United States.

When did this study take place?

It began 20 October 2021 and ended 14 October 2022.

Who participated in this study?

The study included adult participants with solid tumors that had spread around or throughout the body, and who were already treated with available standard treatments.

- A total of 7 men participated
- A total of 6 women participated
- All participants were between the ages of 38 and 66.

All participants who started the study, finished Part 1A and did not finish Part 1B and Part 2 of the study because the study was ended by the sponsor.

No participants left before the study was ended by the sponsor.

How long did the study last?

The entire study lasted for about 1 year before it was ended early due to sponsor's business decision.

When the study ended in October 2022 including the follow-up, 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?

What dose of PF-07263689 was determined to have DLTs?

PF-07263689 when given alone was in general safe and tolerable across the 3 dose levels tested. DLTs were not identified during the study at any dose level.

Based on the early results, the researchers did not find determine a "best dose" or a dose that was intolerable to 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.

In this study, all (100%) participants had at least 1 medical problem (regardless of the cause or relationship to study drug). 2 participants left

the treatment because of their medical problems. The most common issues reported by more than 25% of total participants are described below.

Below are instructions on how to read Table 1.

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 25% of the total participants are listed.
- The **2nd** column tells how many of the 3 participants taking PF-07263689 2×10^8 PFU reported each medical problem. Next to this number is the percentage of the 3 participants taking PF-07263689 2×10^8 PFU who reported the medical problem.
- The **3rd** column tells how many of the 4 participants taking PF-07263689 6×10^8 PFU reported each medical problem. Next to this number is the percentage of the 4 participants taking PF-07263689 6×10^8 PFU who reported the medical problem.
- The **4th** column tells how many of the 6 participants taking PF-07263689 20×10^8 PFU reported each medical problem. Next to this number is the percentage of the 6 participants taking PF-07263689 20×10^8 PFU who reported the medical problem.
- Using these instructions, you can see that 1 out of the 3 (33.3%) participants taking PF-07263689 2×10^8 PFU reported headache. A total of 2 out of the 4 (50.0%) participants taking PF-07263689 6×10^8 PFU and a total of 5

out of 6 (83.3%) participants taking PF-07263689 20×10^8 PFU reported headache.

Table 1. Commonly reported medical problems by study participants

Medical Problem	PF-07263689 2×10^8 (3 Participants)	PF-07263689 6×10^8 PFU (4 Participants)	PF-07263689 20×10^8 PFU (6 Participants)
Headache	1 out of 3 participants (33.3%)	2 out of 4 participants (50.0%)	5 out of 6 participants (83.3%)
Fever	1 out of 3 participants (33.3%)	2 out of 4 participants (50.0%)	5 out of 6 participants (83.3%)
Chills	1 out of 3 participants (33.3%)	2 out of 4 participants (50.0%)	3 out of 6 participants (50.0%)
Tiredness	2 out of 3 participants (66.7%)	2 out of 4 participants (50.0%)	1 out of 6 participants (16.7%)

Table 1. Commonly reported medical problems by study participants

Medical Problem	PF-07263689 2 x 10 ⁸ (3 Participants)	PF-07263689 6 x 10 ⁸ PFU (4 Participants)	PF-07263689 20 x 10 ⁸ PFU (6 Participants)
Low Magnesium Levels	1 out of 3 participants (33.3%)	2 out of 4 participants (50.0%)	2 out of 6 participants (33.3%)
Low Phosphate Levels	1 out of 3 participants (33.3%)	1 out of 4 participants (25.0%)	2 out of 6 participants (33.3%)
Abnormal Heartbeat	0 out of 3 participants (0%)	0 out of 4 participants (0%)	5 out of 6 participants (83.3%)
Aggressive Immune Response	1 out of 3 participants (33.3%)	2 out of 4 participants (50.0%)	1 out of 6 participants (16.7%)
Difficulty Breathing	1 out of 3 participants (33.3%)	2 out of 4 participants (50.0%)	1 out of 6 participants (16.7%)
Nausea	0 out of 3 participants (0%)	1 out of 4 participants (25.0%)	3 out of 6 participants (50.0%)

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.

3 participants (23.1%) had serious medical problems, all of which were not considered related to study drug. 1 participant was in Cohort 2, and two participants were in Cohort 3.

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 C4651001
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The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier NCT05061537
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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!