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-07062119

Protocol Number: C3861001

Dates of Study: 19 November 2019 to 28 November 2023

Title of this Study: A Study to Find and Test a Safe Dose of PF-07062119 in People with Advanced Stomach and Gut Cancer

[A Phase 1 Dose Escalation and Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Anti Tumor Activity of PF-07062119 in Patients With Advanced Gastrointestinal Tumors]

Date of this Report: 07 November 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 advanced stomach and gut cancer?

Stomach and gut cancers can affect the parts of the body which helps in digestion, such as the food pipe, stomach and intestines. Advanced cancer means that the cancer has spread from where it started and is more difficult to treat.

What is PF-07062119?

The study medication PF-07062119 works by directing “immune cells” to the cancer cells, to kill them. Immune cells are body’s natural defense to protect it from bacteria and diseases. PF-07062119 is made up of 2 parts, and targets two different things at once. One part attaches to the immune cell and the other part attaches to a specific substance on the cancer cell. In this way, PF-07062119 helps the immune cell to directly recognize and kill the cancer cell. PF-07062119 is not yet approved for use.

In this study, it was given as an injection under the skin. PF-07062119 was given alone or in combination with two other medications, which were sasanlimab and bevacizumab-Pfizer. These two medications are used to treat different cancers but work differently than the study medication. Sasanlimab was given as an injection under the skin. Bevacizumab-Pfizer was given as a drip into the vein.

What was the purpose of this study?

This was the first study where PF-07062119 was given to humans. The purpose of this study was to:

- find the highest dose of PF-07062119 that people with advanced stomach and gut cancer could tolerate.

- learn about the safety of PF-07062119 when given alone or in combination with other study treatments.

To find the highest dose, researchers look for “dose-limiting toxicities or DLTs”. DLTs are medical problems that prevent the increase in the dose of medication.

Researchers wanted to know:

- **What was the highest dose of PF-07062119 given alone that participants could tolerate?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Researchers tested different doses of PF-07062119 on a group of study participants with advanced stomach and gut cancers to find out the safety of increasing doses of PF-07062119 when given alone or with other study treatments.

This was an “open label” study, in which both the researchers and the study participants knew the treatment being given.

The study had three parts: Screening, Treatment and Follow-up.

Screening:

For up to a month before the start of treatment, the researchers checked who could take part in this study.

Treatment:

Treatment was divided into two parts, Part A (Figure 1) and Part B (Figure 2).

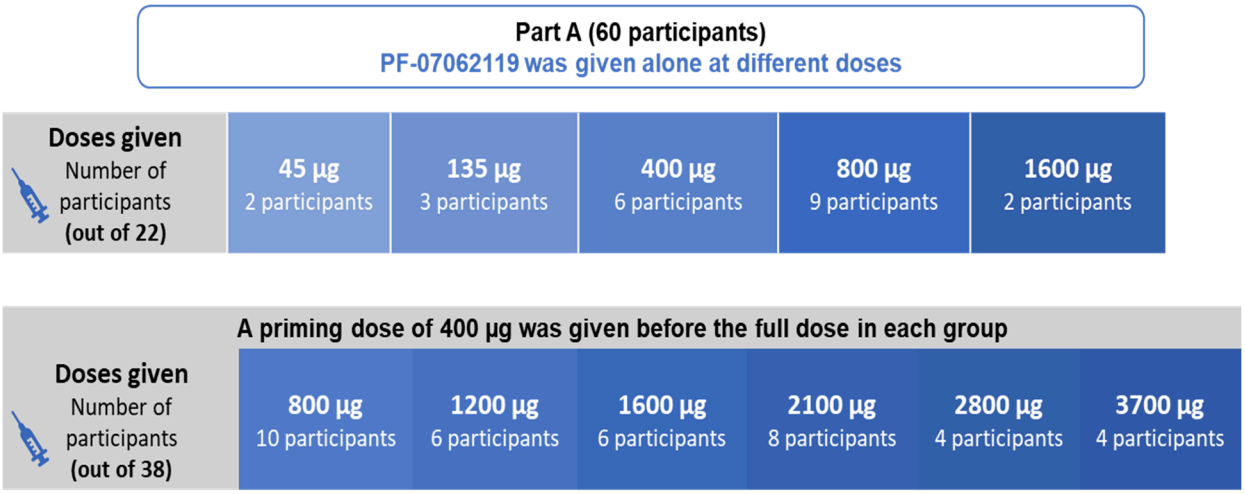
In **Part A**, researchers wanted to find the highest dose of PF-07062119 given alone, that participants could tolerate.

Sixty (60) participants received PF-07062119 alone. Of these, 22 participants received PF-07062119 at doses, which ranged from lowest 45 micrograms (µg) to highest 1600 µg. PF-07062119 was given on Day 1 and Day 15 of each treatment cycle. Each treatment cycle was 28 days.

For the remaining 38 participants, the researchers further tested different doses of PF-07062119 using a "priming dose". A priming dose is generally a small starter dose of a medication given before the main actual dose. This smaller dose helps the body to prepare for the actual dose and may also help to lower the intensity of some side effects.

The priming dose was decided as 400 µg, followed by full actual doses which ranged from 800 µg to 3700 µg. For the first treatment cycle, the priming dose was given on Day 1 and the full dose was given on Day 15. For further cycles, the full dose was given every 2 weeks.

Figure 1: Treatment during Part A



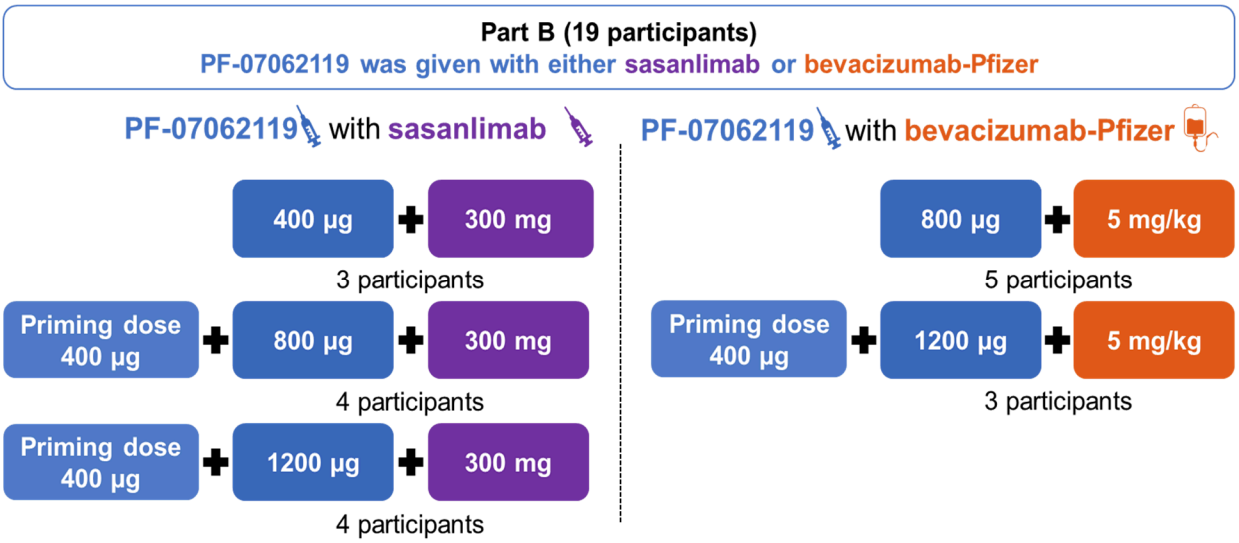
In **Part B**, PF-07062119 was given in combination with either sasanlimab or bevacizumab-Pfizer. Researchers wanted to learn about the safety of PF-07062119 when given with other study treatments and to find a safe dose of PF-07062119 that could be used in future studies.

Nineteen (19) participants received treatment in this part.
Eleven (11) participants received PF-07062119 with sasanlimab and 8 participants received PF-07062119 with bevacizumab-Pfizer.

The doses of PF-07062119 in combination ranged from 400 µg to 1200 µg. PF-07062119 was given with or without a priming dose. For the first treatment cycle, the priming dose was given on Day 1 and full dose was given on Day 15. For further cycles, full dose was given every 2 weeks.

The dose of sasanlimab was 300 milligrams (mg). The dose of bevacizumab-Pfizer was 5 mg for every kilogram (kg) of body weight (mg/kg).

Figure 2: Treatment during Part B



In both parts, for each dose given, researchers checked if participants had any medical problems.

The participants continued to receive PF-07062119 until their cancer got worse, they had side effects which led to discontinuation from the treatment, or either the study doctor or the participant decided to stop the treatment.

Follow-up:

A month after the treatment ended for the participants, the participants visited the trial site. During this visit, the researchers monitored the health of the participants and checked for any medical problems.

The study was stopped early by the Sponsor following business decision. The study was not stopped due to any safety issue.

Where did this study take place?

The Sponsor ran this study at 10 locations in 3 countries in North America, Australia and Asia.

When did this study take place?

It began on 19 November 2019 and ended on 23 November 2023.

Who participated in this study?

The study included participants who were diagnosed with advanced cancers of stomach, food pipe and large bowel and rectum, for whom the standard treatment did not work or there was no standard treatment. The participants were either fully active, or unable to do hard physical activity but were able to walk and do light work.

- A total of 49 men participated.
- A total of 30 women participated.

All participants were between the ages of 29 and 81 years.

Of the 79 participants who started the study, all were treated with PF-07062119.

Fifty-six (56) out of 79 participants did not finish the study follow-up because of

- worsening of cancer, worsening health or death,
- loss of contact with study team or either the study doctor's or the participants' decision to discontinue,
- sponsors' decision to stop the study, and
- other reasons, not provided.

How long did the study last?

Study participants were in the study treatment for around 2 months. The entire study took about 4 years. The study was stopped early by the Sponsor following business decision. The study was not stopped due to any safety issue.

When the study ended in November 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?

What was the highest dose of PF-07062119 given alone that participants could tolerate?

The highest dose of PF-07062119 given alone without the priming dose that participants could tolerate was found to be 800 µg. The recommended highest dose with priming was found to be 2100 µg.

Did participants who were treated with PF-07062119 during the first cycle of treatment had DLTs?

Of the 79 participants, 63 were available to be evaluated for DLTs.

Six out of 63 participants (10%) had DLTs. These were immune system response presented with fever combined with vomiting, shortness of breath, headache and low blood pressure; inflammation in the large bowel; diarrhea; rash and rash with raised red bumps on the skin.

All DLTs were observed when PF-07062119 was given alone, without the other study treatments.

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 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.

All (100%) participants in this study had at least 1 medical problem. A total of 7 participants left the study because of medical problems. For Part A, the most common medical problems – those reported by more than 20% of participants– are described below in Table 1. For Part B, the most common medical problems – those reported by more than 30% of participants – are described below in Table 2.

Below are instructions on how to read tables.

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 20% of participants are listed.
- The **2nd** column tells how many of the 60 participants taking the study medication in Part A reported each medical problem. Next to this number is the percentage of the 60 participants taking the study medication who reported the medical problem.
- Using these instructions, you can see that 44 out of the 60 (73%) participants taking the study medication reported diarrhea.

Table 1. Commonly reported medical problems by study participants for Part A

Medical Problem	PF-07062119 (60 Participants)
Diarrhea	44 out of 60 participants (73%)
Immune system response presented with fever combined with vomiting, shortness of breath, headache and low blood pressure	29 out of 60 participants (48%)

Table 1. Commonly reported medical problems by study participants for Part A	
Medical Problem	**PF-07062119 (60 Participants)**
Reddening of the skin at injection site	28 out of 60 participants (47%)
Feeling sick	25 out of 60 participants (42%)
Vomiting	23 out of 60 participants (38%)
Tiredness	22 out of 60 participants (37%)
Decreased appetite	16 out of 60 participants (27%)
Itching at injection site	15 out of 60 participants (25%)
Reaction at injection site	15 out of 60 participants (25%)
Rash with raised red bumps on the skin	13 out of 60 participants (22%)

Table 2. Commonly reported medical problems by study participants for Part B	
Medical Problem	**PF-07062119 (19 Participants)**
Diarrhea	14 out of 19 participants (74%)
Feeling sick	9 out of 19 participants (47%)
Immune system response presented with fever combined with vomiting, shortness of breath, headache and low blood pressure	9 out of 19 participants (47%)
Reddening of the skin at injection site	9 out of 19 participants (47%)
Reaction at injection site	8 out of 19 participants (42%)
Tiredness	8 out of 19 participants (42%)
Chills	7 out of 19 participants (37%)
Vomiting	7 out of 19 participants (37%)

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.

Thirty (30) out of 79 (38%) participants had serious medical problems.

- In Part A, 24 out of 60 (40%) participants had at least 1 serious medical problem. The most common serious medical problems were diarrhea; immune system response presented with fever combined with vomiting, shortness of breath, headache and low blood pressure; worsening of cancer and partial or complete blockage of the small bowel.
- In Part B, 6 out of 19 (32%) participants had at least 1 serious medical problem. The serious medical problems were immune system response presented with fever combined with vomiting, shortness of breath, headache and low blood pressure; blockage of the path of “bile” (bile helps in digestion of food); blockage of the airways in the lungs; inflammation of the tubes that carry bile; delay in the movement of food from stomach to the small bowel; stomach issues that affect the movement of food from the stomach to the small bowel; blockage of the rectum (large bowel) and bleeding in the small bowel.

Four (4) out of 79 (5%) participants died during the study treatment including the follow-up, all due to worsening of disease. All 4 deaths happened in Part A. Researchers do not believe any of the deaths were related to the study medication.

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 **C3861001**

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

www.clinicaltrials.gov	Use the study identifier **NCT04171141**

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!