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-06835919

Protocol Number: C1061013

Dates of Study: 21 January 2020 to 9 July 2021

Title of this Study: A Study to Compare the Pharmacokinetics of PF-06835919 in Participants With and Without Hepatic Impairment

[A Phase 1, Non-Randomized, Open-Label, Single-Dose Parallel-Cohort Study to Compare the Pharmacokinetics of PF-06835919 in Adult Participants With Varying Degrees of Hepatic Impairment Relative to Participants Without Hepatic Impairment]

Date(s) of this Report: 5 April 2022

– 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 hepatic impairment?

Hepatic impairment means that a person's liver is not functioning normally. The liver plays an important role in keeping the body healthy, including helping to digest food and helping to remove substances such as medicines or their byproducts from the body. People with hepatic impairment may not be able to remove some substances from the body as well as people with normal liver function.

What is PF-06835919?

PF-06835919 is an investigational drug being studied for the possible treatment of a type of liver disease. An investigational drug is one that has not been approved for use outside of research studies. PF-06835919 is a pill that is taken daily by mouth.

What was the purpose of this study?

The purpose of this study was to compare how PF-06835919 moved through the body and how long it stayed in the body in participants with varying levels of hepatic impairment and in participants with normal liver function. After PF-06835919 was swallowed, it entered the body (through the stomach and intestine) and moved through the body. PF-06835919 entered the blood and organs (for example liver) when it moved through the body. Afterwards, PF-06835919 was removed from the body through urine and feces.

This study did not test if PF-06835919 helps to treat liver disease.

Researchers wanted to know:

- **How did PF-06835919 act in the body of participants with varying levels of hepatic impairment, compared to participants with normal liver function?**

- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Researchers tested PF-06835919 on a group of participants with varying levels of hepatic impairment and on a group of participants with normal liver function and similar age, gender, and weight as the participants with hepatic impairment, to learn how hepatic impairment affected the way that PF-06835919 acted in the body.

In this study, participants received a single dose by mouth of PF-06835919 25 mg, taken after breakfast. This was an open-label study, which means that the participants and the researchers knew what treatment the participants received.

Researchers took samples of blood from participants during the study and measured the amount of PF-06835919. Researchers then compared the blood samples from participants with hepatic impairment and those with normal liver function. Researchers also checked the participants' health during the study and asked them how they were feeling. There was a 30-day follow-up visit at the end of the study.

Where did this study take place?

The Sponsor ran this study at 3 locations in Belgium, Czech Republic, and Slovakia.

When did this study take place?

It began 21 January 2020 and ended 9 July 2021.

Who participated in this study?

Participants between the ages of 18 and 75 years could join this study. Participants could not have another medical condition that might affect the way that medicines move through the body (for example, a past weight-loss surgery), and had to agree to certain lifestyle guidelines, such as avoiding alcohol during the study.

Participants with hepatic impairment were selected based on the severity of their disease (mild, moderate, or severe hepatic impairment). They had to have stable disease with no major change in hepatic impairment within the last 28 days, and a stable medication/treatment regimen. Participants with normal liver function were then selected for the study based on gender, age, and weight, so that they would have similar characteristics to the participants with hepatic impairment.

- A total of 16 men (70%) and 7 women (30%) participated
- All participants were between the ages of 38 and 73, with an average age of 61
- Six participants (26%) had mild hepatic impairment, 6 participants (26%) had moderate hepatic impairment, 5 participants (22%) had severe hepatic impairment, and 6 participants (26%) had normal liver function.

All 23 participants (100%) who started the study finished it.

How long did the study last?

Study participants were in the study for about 5 to 9 weeks. The entire study took about 1 ½ years to complete and was completed as planned.

When the study ended in July 2021, 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?

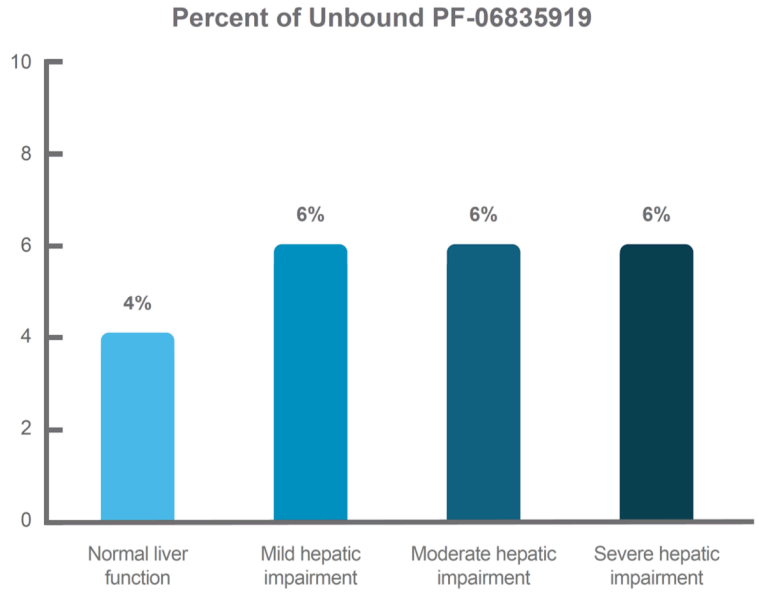
How did PF-06835919 act in the body of participants with varying levels of hepatic impairment, compared to participants with normal liver function?

To answer this question, the researchers compared blood tests from participants with varying levels of hepatic impairment and those with normal liver function.

How much of PF-06835919 was "unbound"?

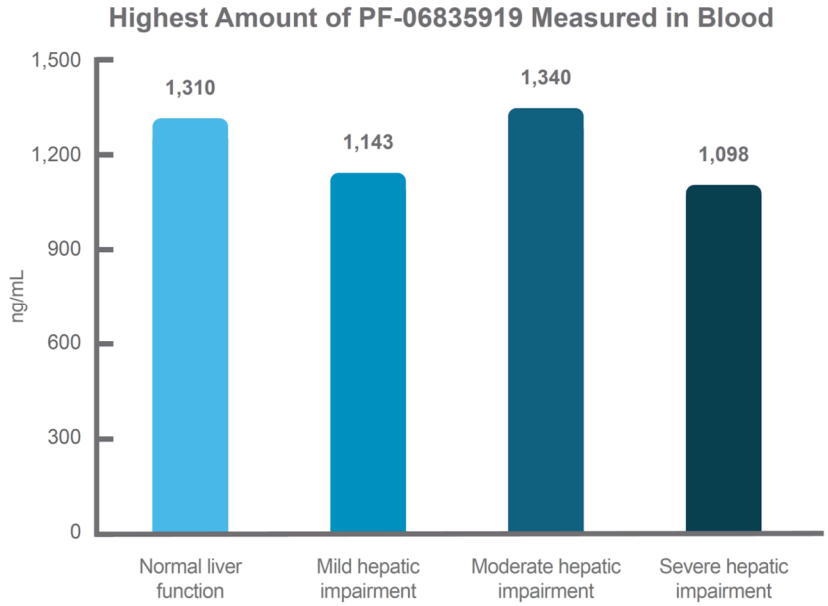
After a drug is swallowed and enters the blood, some of the drug attaches to proteins within the blood. This is known as drug "binding". When a new investigational drug is being developed, researchers are interested in learning how much of the drug does not bind to proteins, which is known as being "unbound". Only the amount of drug that remains unbound can have therapeutic effects on the body and then be removed by the liver.

In this study, about 4% of PF-06835919 was unbound in participants with normal liver function, and about 6% was unbound in participants with hepatic impairment. Figure 1 below shows this result in participants with varying levels of hepatic impairment compared to those with normal liver function.



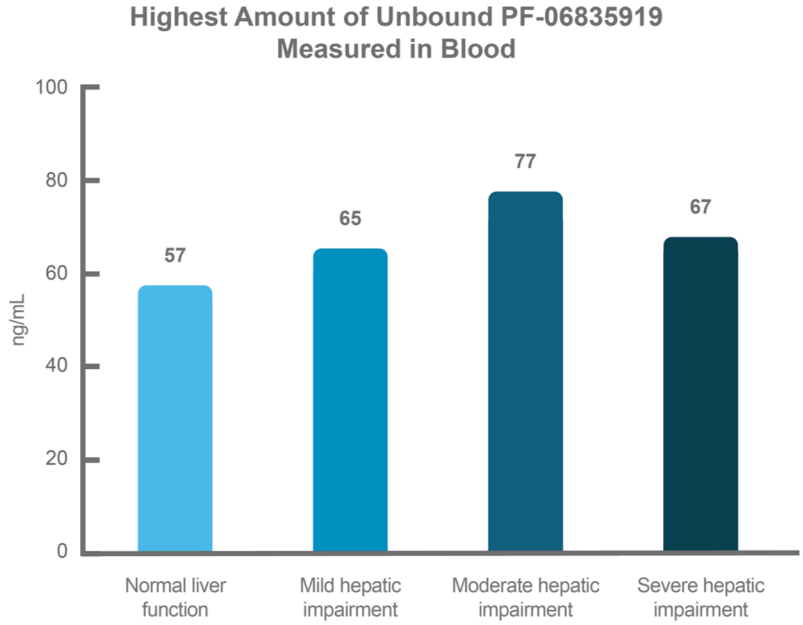
What was the highest amount of PF-06835919 measured in the blood after a single dose?

Figure 2 below shows the highest amount of PF-06835919 measured in the blood after a single dose in participants with varying levels of hepatic impairment compared to those with normal liver function. The amount of PF-06835919 in the blood was measured in nanograms per milliliter, also called ng/mL.



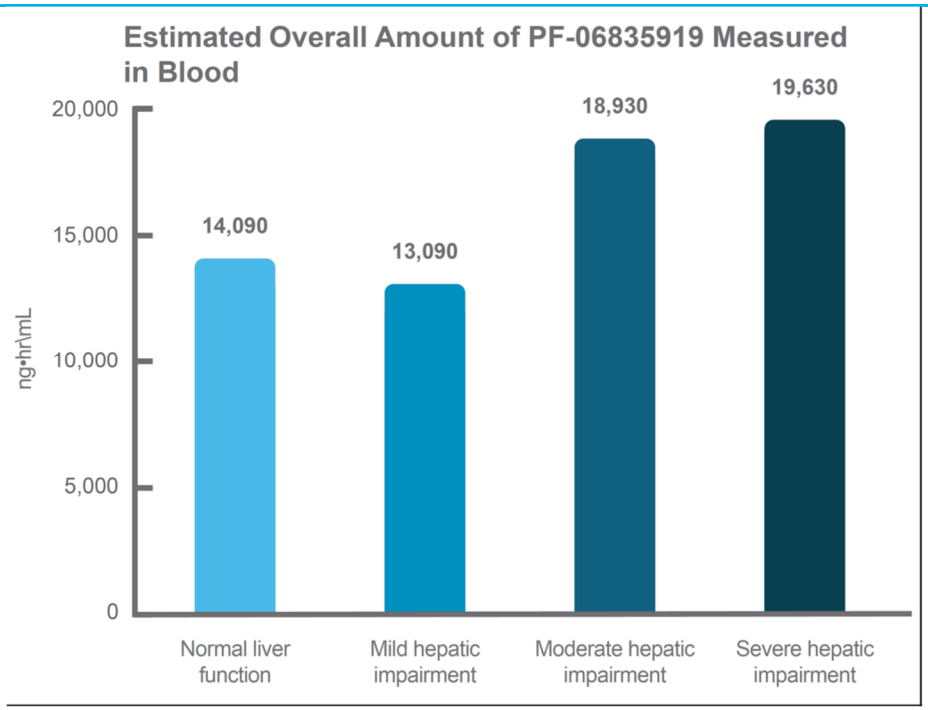
What was the highest amount of unbound PF-06835919 measured in the blood after a single dose?

Figure 3 below shows the highest amount of unbound PF-06835919 measured in the blood after a single dose in participants with varying levels of hepatic impairment compared to those with normal liver function. The amount of PF-06835919 in the blood was measured in nanograms per milliliter, also called ng/mL.



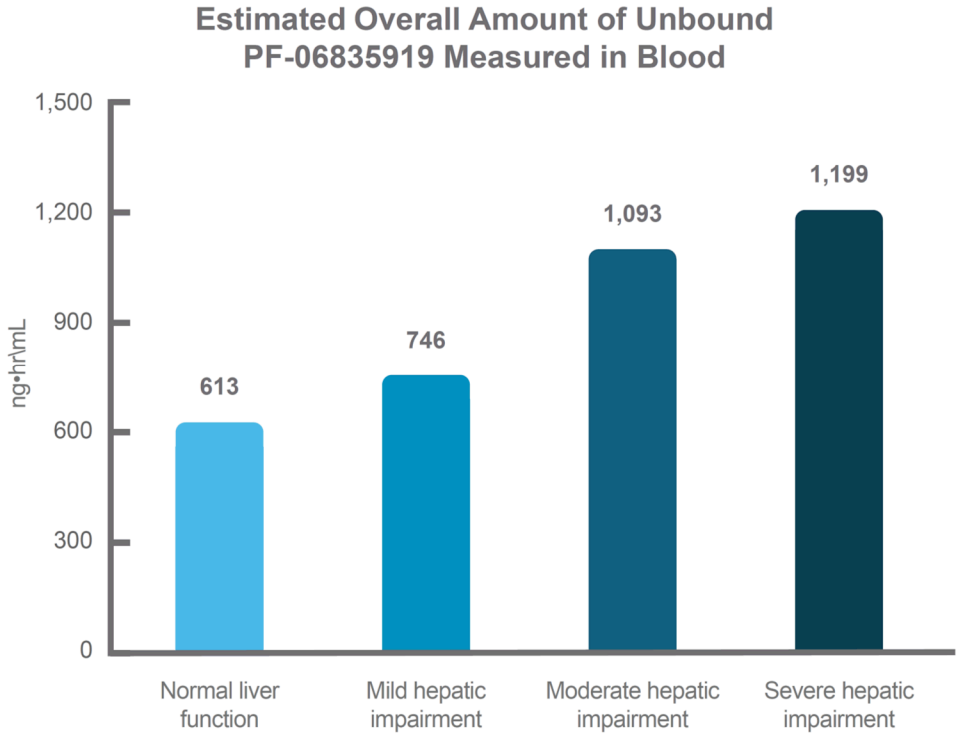
What was the estimated overall amount of PF-06835919 in the blood after a single dose?

The estimated overall amount of PF-06835919 in the blood after a single dose in participants with varying levels of hepatic impairment compared to those with normal liver function is shown in Figure 4 below. The estimated overall amount of PF-06835919 in the blood was measured in nanogram hours per milliliter, also called ng•hr/mL.



What was the estimated overall amount of unbound PF-06835919 in the blood after a single dose?

The estimated overall amount of unbound PF-06835919 in the blood after a single dose in participants with varying levels of hepatic impairment compared to those with normal liver function is shown in Figure 5 below. The estimated overall amount of unbound PF-06835919 in the blood was measured in nanogram hours per milliliter, also called ng•hr/mL.



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.

A total of 2 out of 23 participants (9%) in this study had at least 1 medical problem:

- 1 participant with moderate hepatic impairment had stomach discomfort, upper stomach pain, nausea, and nosebleed. The study doctor considered upper stomach pain and nausea to be related to PF-06835919.
- 1 participant with severe hepatic impairment had swelling caused by a blood clot in the vein, which was not considered to be related to PF-06835919.
- No participants left the study because of medical problems.

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. No participants in this study had serious medical problems, and no 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.clinicaltrials.gov Use the study identifier **NCT04193436**

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!