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 study participants. 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-06687234

Protocol Number: B7581002

Dates of Study: 20 December 2017 to 07 January 2021

Title of this Study: Study on Use of PF-06687234 in Participants with Active Ulcerative Colitis Already Treated with Infliximab Compared with Infliximab Alone

[A Phase 2a, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, Tolerability and Pharmacokinetics of PF-06687234 as Add-On Therapy to Infliximab in Active Ulcerative Colitis Subjects Who Are Not in Remission (Build UC)]

Date(s) of this Report: 01 September 2021

– 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 ulcerative colitis?

Ulcerative colitis (UC) is a long-term inflammatory bowel disease that causes inflammation (swelling) and ulcers (sores) in the digestive tract. UC affects the mucosa (inner lining) of the large intestine (colon) and rectum. People with UC experience occasional periods of increased inflammation, known as active disease or flares. These periods of active disease are characterized by diarrhea (loose stools) and presence of blood in the stools, as well as sense of urgency. Active disease is often followed by periods of remission (time with no symptoms) that vary in length from weeks to years.

There is no known cure for UC. Treatment can greatly reduce signs and symptoms of UC and can even lead to long-term remission. Medication is the most common treatment for UC and biologic therapies like infliximab, adalimumab, and golimumab are often used. A biologic therapy is a treatment that has been developed from a natural source, such as a component found in the body, but then updated in the laboratory so that it can be used to treat a disease. Biologics are usually produced using biotechnology methods. Some people do not respond to these biologics or the treatment can stop working after a while. Other medicines that can be used with the biologic therapy are needed.

What is PF-06687234?

At the time this study started, PF-06687234 was an experimental treatment being developed for people with UC that could be used with infliximab. PF-06687234 is given by a subcutaneous injection weekly. Subcutaneous means the injection is given under the skin.

This study was the first time PF-06687234 was used in participants with UC. This study was stopped early after the researchers looked at data and saw that PF-06687234 was not working as well as they hoped.

What was the purpose of this study?

Researchers did this study to learn if PF-06687234 could help participants with UC achieve remission as well as if this treatment was safe.

Researchers wanted to know:

- **Did the participants taking PF-06687234 and infliximab achieve remission?**
- **Is treatment with PF-06687234 safe and well tolerated?**

What happened during the study?

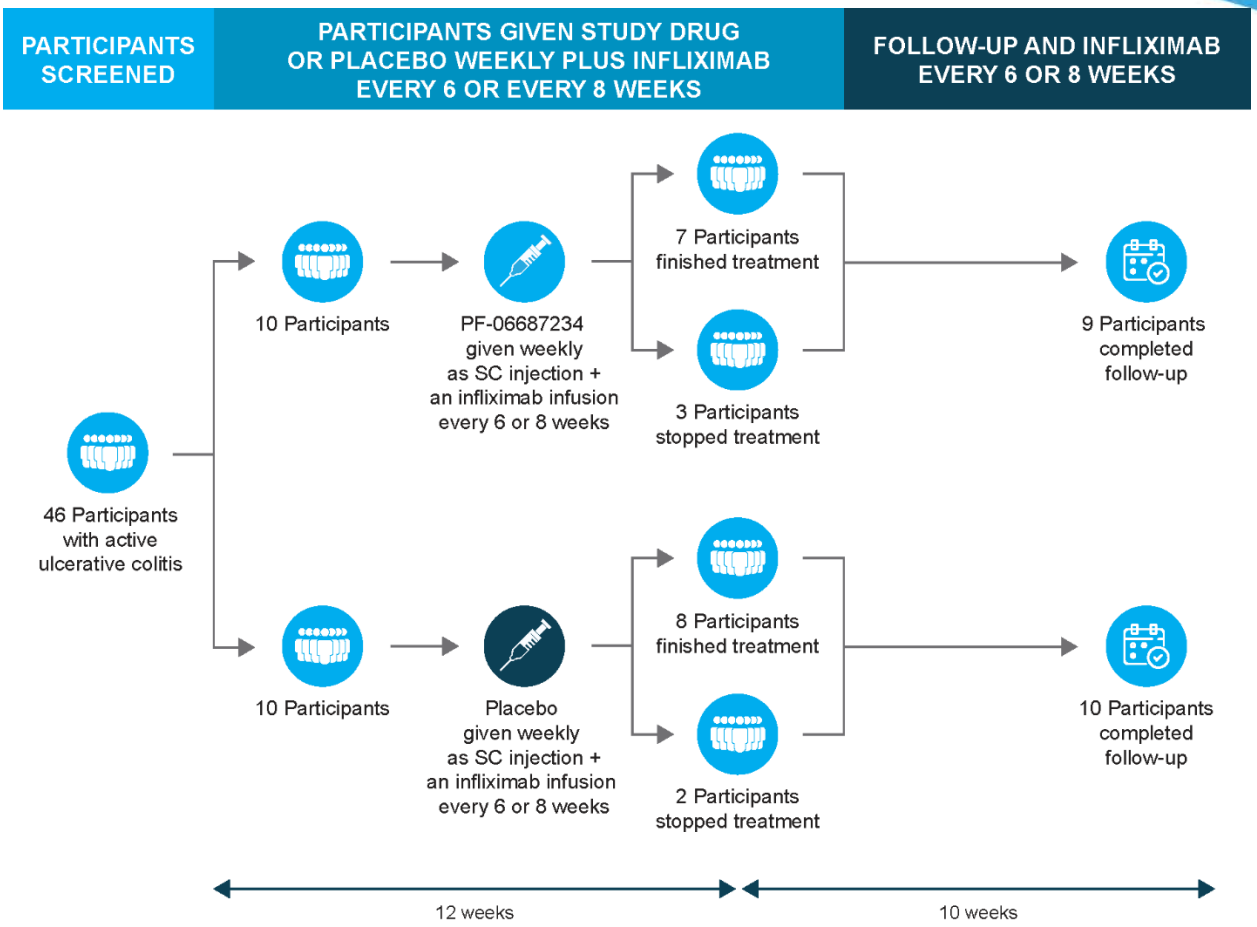
How was the study done?

Researchers tested PF-06687234 in a group of study participants to find out if study participants taking this treatment could achieve remission of their UC when also given infliximab. Infliximab is a licensed treatment for UC.

Researchers then compared the results of study participants taking the study medication to the results of study participants taking placebo and infliximab. A placebo does not have any medicine in it, but it looks just like the study medication.

The study participants and researchers did not know who took PF-06687234 and who took the placebo. This is known as a "blinded" study. Study participants were assigned to each group by chance alone.

The figure on the next page shows what happened during this study.



SC = subcutaneous.
Note: All participants were to remain in the study for 22 weeks even if they stopped the study treatment before they had completed 12 weeks of treatment so that they could be monitored for safety.

Where did this study take place?

The Sponsor ran this study at 27 locations in 11 countries in the United States, Europe, the Middle East, Asia, and Australia.

When did this study take place?

It began 20 December 2017 and ended 07 January 2021.

Who participated in this study?

The study included participants who had active UC and who had partially responded to treatment with infliximab, but who had not achieved remission. Participants did not have other bowel diseases, such as Crohn's disease, infectious colitis, or colon cancer.

- A total of 13 men participated
- A total of 7 women participated
- All participants were between the ages of 20 and 73 years.

Participants were to be treated for 12 weeks with PF-06687234 and infliximab and a further 10 weeks when PF-06687234 was to be stopped but infliximab was continued. Of the 20 participants who started the study, 19 participants finished the study and completed the safety follow-up. There were 15 participants who finished the 12 weeks of treatment (7 in the PF-06687234 group and 8 in the placebo group) and 5 participants did not finish treatment. The participants who did not finish treatment included:

- 3 participants in the PF-06687234 group
  - 1 participant because of medical problems
  - 1 participant because of lack of treatment effect
  - 1 participant by their own choice
- 2 participants in the placebo group
  - both because of medical problems.

How long did the study last?

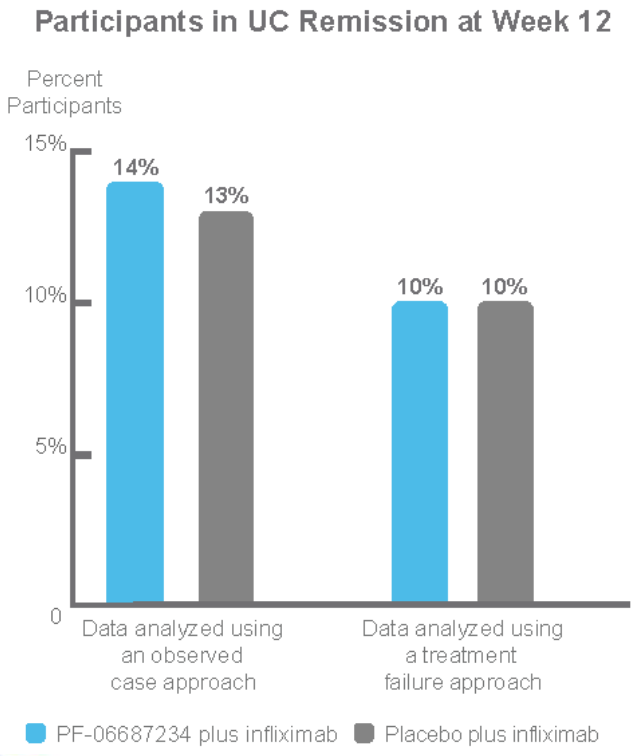
Study participants were in the study for 22 weeks. The entire study ran for just over 3 years. This study was stopped because PF-06687234 was not working as well as the researchers hoped.

When the study ended in January 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?

Did participants taking PF-06687234 and infliximab achieve remission?

In this study, the researchers used remission to measure treatment effect for participants treated with PF-06687234 plus infliximab or placebo plus infliximab. Remission happens when the participant responds to treatment and the signs and symptoms of UC are no longer present. The remission involved resolving UC symptoms as well as looking at what was happening in the large bowel using an endoscope to see if UC was present. An endoscope is a thin flexible tube that has a light and camera on the end that can be used to display images from inside the body on a television screen. The results were then analyzed for remission for each treatment group.



In general, there was no difference between participants who took PF-06687234 plus infliximab and participants who took placebo plus infliximab.

Did the study medication help participants achieve remission compared to placebo?

On average, 10% to 14% of participants who took PF-096687234 plus infliximab achieved remission at Week 12, while about 10% to 13% of the participants taking placebo plus infliximab achieved remission.

Based on these results, the researchers have decided that the results are likely the result of chance. This means the study results did not show that one treatment was better than another at helping participants achieve remission.

This does not mean that everyone in this study had these results. These are just some of the main findings 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 17 out of 20 (85%) participants in this study had at least 1 medical problem. The most common medical problems – those reported by more than 1 participant – 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 1 participant are listed.
- The **2nd** column tells how many of the 10 participants taking PF-06687234 plus infliximab reported each medical problem. Next to this number is the percentage of the 10 participants taking PF-06687234 plus infliximab who reported the medical problem.
- The **3rd** column tells how many of the 10 participants taking a placebo plus infliximab reported each medical problem. Next to this number is the percentage of the 10 participants taking a placebo plus infliximab who reported the medical problem.
- Using these instructions, you can see that none of the 10 participants taking PF-06687234 plus infliximab reported worsening UC. A total of 3 out of the 10 (30%) participants taking a placebo reported worsening UC.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**PF-06687234 Plus Infliximab (10 Participants Treated)**	**Placebo Plus Infliximab (10 Participants Treated)**
Worsening ulcerative colitis (UC)	0 out of 10 participants (0%)	3 out of 10 participants (30%)
Chest pain	2 out of 10 participants (20%)	0 out of 10 participants (0%)
Injection site reaction	3 out of 10 participants (30%)	0 out of 10 participants (0%)
Nose, sinus, or throat infection	2 out of 10 participants (20%)	1 out of 10 participants (10%)
Headache	2 out of 10 participants (20%)	2 out of 10 participants (20%)

There were 3 participants (15%, or 3 out of 20 participants) who left the study because of medical problems; 1 in the PF-06687234 plus infliximab group and 2 in the placebo plus infliximab group.

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.

There was 1 participant (5%, or 1 out of 20 participants) who had a serious medical problem. This was a serious case of worsening UC in a participant in the placebo plus

infliximab group. None of the participants in the PF-06687234 plus infliximab had serious medical problems.

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:

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

www.clinicaltrials.gov	Use the study identifier **NCT03269695**
www.clinicaltrialsregister.eu	Use the study identifier **2017-002108-28**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for study participants.

Again, if you participated in this study,
thank you for volunteering.
We do research to try to find the
best ways to help study participants, and you
helped us to do that!