CLINICAL TRIAL 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 medicine 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-06480605

Protocol Number: B7541002

Dates of Trial: 26 October 2016 to 22 August 2018

Title of this Trial: A Study to Measure Whether PF-06480605 is Safe and Effective in the Treatment of Moderate to Severe Ulcerative Colitis.

[A Phase 2a, Multicenter, Single Arm, Open-Label, Two-Stage, Study to Evaluate the Efficacy, Safety, Tolerability and Pharmacokinetics of PF-06480605 in Subjects With Moderate to Severe Ulcerative Colitis]

Date(s) of this Report: 31 January 2020

– Thank You –

Pfizer, the Sponsor, would like to thank you for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

WHY WAS THIS STUDY DONE?

Ulcerative Colitis (or "UC") is a long-term inflammatory medical condition that affects the large intestines (also known as the colon). The exact cause of UC is not known. It is thought that UC is caused by an overactive immune system, which is normally responsible for fighting infections. Medicines are available that lower the activity of the immune system, but some patients with UC do not get better when taking these medicines. Some patients who do get better when taking these medicines still have their UC get worse over time. Researchers are looking for new treatments that can help treat patients with UC.

PF-06480605 is an investigational medicine, and is a type of medicine that is called a "monoclonal antibody". Monoclonal antibodies are special proteins made by cells of the immune system that bind to and block the activity of other proteins. PF-06480605 blocks the activity of an inflammatory protein called "TL1A", which is thought to make UC worse. By blocking this protein, researchers hope to lower inflammation in the large intestines and help patients with UC get better.

Researchers are studying PF-06480605 to see if it can safely treat moderate to severe UC. To test the effectiveness of this medicine, the researchers asked:

- **Do patients treated with PF-06480605 have their UC improve after 14 weeks?**

  To measure improvement, the researchers used a test called the Mayo endoscopic subscore to measure how severe each patient's UC was.

- **What medical problems do patients with UC have when they are treated with PF-06480605?**

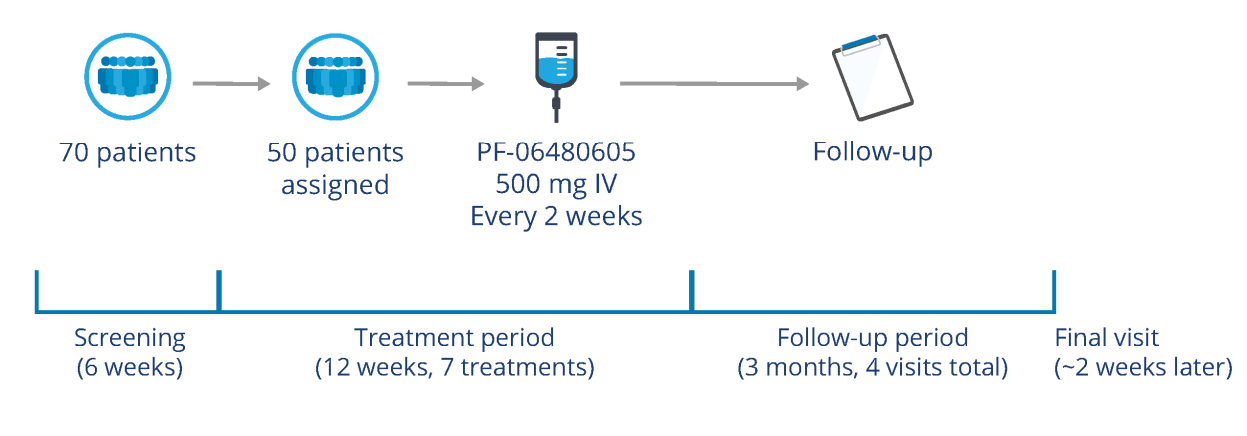
WHAT HAPPENED DURING THE STUDY?

All 50 patients who were enrolled in this study received the investigational medicine.

The study included men and women with moderate to severe UC who:

- Were between the ages of 18 and 75
- Were diagnosed with UC 4 or more months before entering the study
- Had active disease above the rectum (the lowest part of the large intestines)
- Were unable to tolerate, did not respond to, or lost response to at least 1 conventional therapy for UC (such as steroids, medications that suppress the immune system, or anti-TNF/anti-integrin inhibitors)
- Did not have another medical condition that could be made worse by treatment with the study medication

This study consisted of a screening period, a treatment period, and a follow-up period. A diagram of the study is shown below.



In this study, "improvement" in a patient's UC was measured using a test called the Mayo endoscopic subscore. This test measures how severe a patient's UC is on a scale of 0 to 3 (0 being the best and 3 being the worst). Improvement was defined as reaching a Mayo endoscopic subscore of "0" or "1".

While patients were only in the study for 8 months, the entire study took 2 years to complete. The Sponsor ran this study at 13 locations in 6 countries in North

America, Europe, and Asia. It began on 26 October 2016 and ended 22 August 2018. 28 men and 22 women participated. All patients were between the ages of 20 and 68.

Patients were to be treated until 14 weeks after their last dose of the investigational medicine, or until 2 or more patients developed the same serious medical problem or an abnormal heartbeat. Of the 50 patients who started the study, 42 finished the follow-up period. 1 patient did not finish the study because the study medication wasn't working, and 1 patient did not finish the study because of a medical problem. 6 patients left before the study was over by their choice or a doctor decided it was best for a patient to stop being in the study.

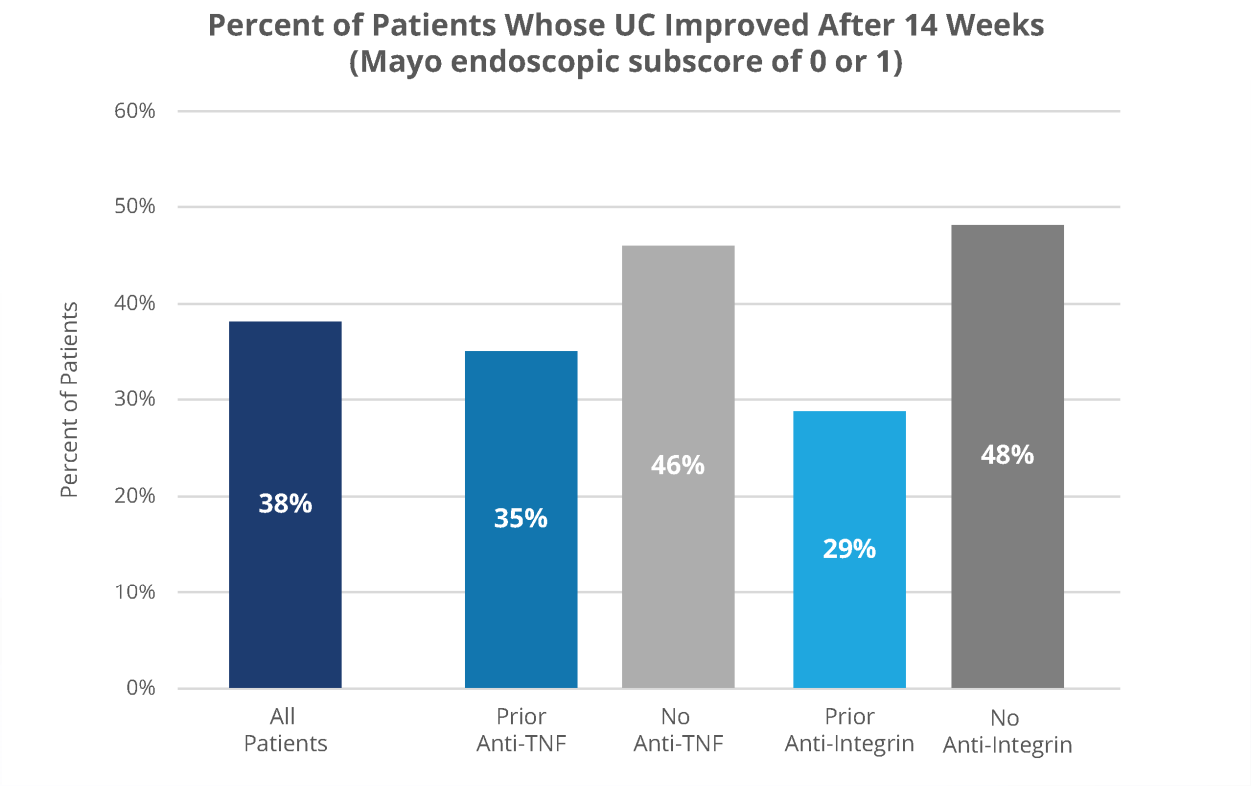
When the study ended in August 2018, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

Did patients treated with PF-06480605 have their UC improve after 14 weeks?

On average, 38% of patients in this study who took the test medicine saw their condition improve after 14 weeks of treatment. The researchers expected about 6% of patients to improve by chance after 14 weeks of treatment. Based on these results, the researchers have decided that the results are not likely the result of chance. The test medicine may be an option for treating patients with moderate to severe UC.

The researchers also looked at whether the patients had received certain types of medications before to treat their UC, called "anti-TNF" or "anti-integrin" inhibitors. 46% of patients who had not received anti-TNF inhibitors before saw their UC improve, compared to 35% of patients who had received anti-TNF inhibitors. 48% of patients who had not received anti-integrin inhibitors before saw their UC improve, compared to 29% of patients who had received anti-integrin inhibitors before.



This does not mean that everyone in this study had these results. Other studies may produce different results, as well. These are just some of the main findings of the study, and more information may be available at the websites listed at the end of this summary.

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 the side effects of an experimental drug might be.

33 out of 50 patients in this study had at least 1 medical problem. 1 patient left the study because of medical problems. The most common medical problems are listed below.

Most Common Medical Problems (Reported by 3 or More Patients)	
Medical Problem	**PF-06480605 (50 Patients Treated)**
Ulcerative colitis got worse	**6 (12%)**
Joint pain	**6 (12%)**
Abdominal pain	**3 (6%)**
Nausea	**3 (6%)**
Common cold	**3 (6%)**
Sore throat	**3 (6%)**
Back pain	**3 (6%)**
Hair loss	**3 (6%)**

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

3 patients (6%, or 3 out of 50 patients) had serious medical problems that started during this study. 2 patients reported that their UC got worse, and 1 patient reported a serious abdominal infection (peritonitis). 1 patient reported serious hair loss, which might have been related to the study medicine. No patients died during the study.

Serious Medical Problems	
Serious Medical Problem	**PF-06480605 (50 Patients Treated)**
Ulcerative colitis got worse	**2 (4%)**
Abdominal infection (peritonitis)	**1 (2%)**
Hair loss	**1 (2%)**

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

www.clinicaltrials.gov	Use the study identifier **NCT02840721**
www.clinicaltrialsregister.eu	Use the study identifier **2016-001158-16**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B7541002**

Findings from this trial will be used in other studies to learn whether patients with UC are helped by this drug. Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again ,**thank you** for volunteering.
We do research to try to find the best ways to help patients ,and you helped us to do that!