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-06700841

Protocol Number: B7931004

Dates of Trial: 01 December 2016 to 19 March 2018

Title of this Trial: Study to Evaluate Safety and Efficacy of PF-06700841 in Subjects with Moderate to Severe Plaque Psoriasis

[A Phase 2a, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety and Efficacy of PF-06700841 in Subjects with Moderate to Severe Plaque Psoriasis]

Date of this Report: 13 April 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?

Plaque psoriasis is a disease that can cause a red, scaly rash to form on the skin. The rash may be painful or itchy. Plaque psoriasis can also affect other parts of the body, such as the joints or nails. These problems are because the immune system, whose job is to attack foreign invaders like viruses and other germs, mistakenly attacks the body instead.

There is no cure for plaque psoriasis at this time, but common treatments include medicines that may control pain, reduce inflammation, and help prevent the immune system from attacking the body.

PF-06700841 is a medicine that is being studied as a possible treatment for moderate to severe plaque psoriasis. PF-06700841 may help to stop the immune system from attacking the body, and reduce inflammation. Because it is still being tested, PF-06700841 has not been approved for use in patients.

The main purpose of this study was to find out how PF-06700841 works to treat moderate to severe plaque psoriasis, compared to a placebo. A placebo looks just like the medicine, but doesn't have any medicine in it.

Researchers wanted to know:

- At week 12 of the study, did patients who took PF-06700841 have an improvement in psoriasis symptoms, compared to patients who took placebo?

To answer this question, the researchers used a tool called the PASI (Psoriasis Area and Severity Index) to measure plaque psoriasis symptoms. The PASI looks at the redness, thickness, and scaling of the rash, as well as how much of the body is covered by the rash.

WHAT HAPPENED DURING THE STUDY?

This study compared patients taking different dose strengths of PF-06700841 to patients taking placebo, to find out if they would have an improvement in psoriasis symptoms. The study included adult patients with moderate to severe plaque

psoriasis. The patients and researchers did not know who took PF-06700841 and who took the placebo. This is known as a "blinded" study. Patients were assigned to each group by chance alone. Putting people into groups by chance helps to make the groups easier to compare.

First, patients were checked by the study doctor to make sure they were a good fit to join the study. This was known as the "screening period", which could last up to 6 weeks.

During the first part of the treatment period, which lasted 4 weeks, patients received 1 of 3 possible treatments:

- 30 mg PF-06700841, taken once per day ("QD")
- 60 mg PF-06700841, QD
- Placebo, QD

During the second part of the treatment period, which lasted 8 weeks, patients were switched to 1 of 4 possible treatments:

- 10 mg PF-06700841, QD
- 30 mg PF-06700841, QD
- 100 mg PF-06700841, taken once per week ("QW"). These patients also received a placebo medicine on the days that they did not take PF-06700841, so that the study would stay blinded.
- Placebo, QD

The last part of the study was a follow-up period, which lasted for 8 weeks after the patients finished taking study treatment.

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

While patients were only in the study for up to 26 weeks, the entire study took more than 15 months to complete, because patients joined the study at different times. The sponsor ran this study at 34 locations in Canada, Poland, and the United States. It began 01 December 2016 and ended 19 March 2018. 148 men (70%) and 64 women (30%) participated. All patients were between the ages of 18 and 75.

Patients were to be treated for 12 weeks and complete the 8-week follow-up period. Of the 212 patients who started the study, 164 finished the study. A total of 48 patients left before the study was over by their choice, because they had a medical problem, or because a doctor decided it was best for a patient to stop the study.

When the study ended in March 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?

At week 12 of the study, did patients who took PF-06700841 have an improvement in psoriasis symptoms, compared to patients who took placebo?

On average, patients who took PF-06700841 in this study had a greater improvement in psoriasis symptoms, compared to those who only took placebo. On average, patients who took the following treatments had a "statistically significant" improvement in psoriasis symptoms, which means that the researchers decided the improvement in symptoms is not likely a result of chance:

Study Part 1	Study Part 2
60 mg PF-06700841, QD	30 mg PF-06700841, QD
60 mg PF-06700841, QD	100 mg PF-06700841, QW
30 mg PF-06700841, QD	30 mg PF-06700841, QD
30 mg PF-06700841, QD	10 mg PF-06700841, QD
30 mg PF-06700841, QD	100 mg PF-06700841, QW

On average, patients who took the following treatments did not have a "statistically significant" difference in their symptoms, compared to patients who took placebo. This means although these patients may have seen an improvement in their symptoms, the differences seen could have been due to chance.

Study Part 1	Study Part 2
60 mg PF-06700841, QD	10 mg PF-06700841, QD
60 mg PF-06700841, QD	Placebo, QD

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 PATIENTS HAVE DURING THE STUDY?

The researchers recorded any medical problems the patients had during the study. Patients 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 patient 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.

149 out of 212 (70%) patients in this study had at least 1 medical problem. A total of 14 (7%) patients stopped taking study treatment because of medical problems. Nine (9) of these patients (4%) had medical problems that were considered related to study treatment, including 1 patient who became pregnant and the fetus had a condition in which the lip did not develop properly.

The most common medical problems are listed below.

Most Common Medical Problems (Reported by More Than 5% of Patients)

Medical Problem	60 mg to 30 mg PF-06700841 (25 patients)	60 mg to 10 mg PF-06700841 (29 patients)	60 mg to 100 mg PF-06700841 (26 patients)	60 mg PF-06700841 to placebo (25 patients)	30 mg PF-06700841 (29 patients)	30 mg to 10 mg PF-06700841 (25 patients)	30 mg to 100 mg PF-06700841 (30 patients)	Placebo Only (23 patients)
Acne	0 (0%)	2 (7%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)	2 (7%)	0 (0%)
Back pain	1 (4%)	2 (7%)	0 (0%)	0 (0%)	2 (7%)	2 (8%)	1 (3%)	2 (9%)
Bronchitis	0 (0%)	2 (7%)	0 (0%)	0 (0%)	2 (7%)	0 (0%)	0 (0%)	0 (0%)

Diarrhea	0 (0%)	1 (3%)	0 (0%)	1 (4%)	0 (0%)	1 (4%)	3 (10%)	1 (4%)
Feeling irritable	0 (0%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Feeling tired	1 (4%)	1 (3%)	1 (4%)	2 (8%)	0 (0%)	1 (4%)	0 (0%)	1 (4%)
Headache	1 (4%)	2 (7%)	3 (12%)	3 (12%)	4 (14%)	1 (4%)	0 (0%)	1 (4%)
Hot flush	0 (0%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Infection of the nose, throat, and airways	2 (8%)	1 (3%)	5 (19%)	1 (4%)	2 (7%)	0 (0%)	3 (10%)	1 (4%)
Itching	0 (0%)	0 (0%)	1 (4%)	3 (12%)	1 (3%)	0 (0%)	1 (3%)	0 (0%)
Joint pain	1 (4%)	2 (7%)	0 (0%)	0 (0%)	1 (3%)	1 (4%)	1 (3%)	1 (4%)
Low number of a type of white blood cell	0 (0%)	0 (0%)	1 (4%)	0 (0%)	2 (7%)	0 (0%)	1 (3%)	0 (0%)
Nausea	1 (4%)	1 (3%)	1 (4%)	2 (8%)	0 (0%)	0 (0%)	1 (3%)	2 (9%)
Sinus infection	1 (4%)	0 (0%)	1 (4%)	2 (8%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)
Sore throat	4 (16%)	3 (10%)	3 (12%)	3 (12%)	5 (17%)	6 (24%)	4 (13%)	3 (13%)
Sore, dry, cracked lips	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (7%)	0 (0%)	0 (0%)	0 (0%)
Sprain in the tissue that connects the bones and joints	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)
Throat pain	0 (0%)	0 (0%)	1 (4%)	0 (0%)	2 (7%)	0 (0%)	0 (0%)	0 (0%)

Urinary tract infection	0 (0%)	1 (3%)	1 (4%)	0 (0%)	0 (0%)	1 (4%)	2 (7%)	0 (0%)
Vomiting	0 (0%)	1 (3%)	1 (4%)	1 (4%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)
Worsening psoriasis	0 (0%)	1 (3%)	3 (12%)	1 (4%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

A total of 5 out of 212 patients (2%) had serious medical problems. These 5 patients received PF-06700841 during the study. Two (2) of the patients (1%) had serious medical problems that were determined to be related to study treatment. The serious medical problems are listed below.

Serious Medical Problems								
Serious Medical Problem	60 mg to 30 mg PF-06700841 (25 patients)	60 mg to 10 mg PF-06700841 (29 patients)	60 mg to 100 mg PF-06700841 (26 patients)	60 mg PF-06700841 to placebo (25 patients)	30 mg PF-06700841 (29 patients)	30 mg to 10 mg PF-06700841 (25 patients)	30 mg to 100 mg PF-06700841 (30 patients)	Placebo Only (23 patients)
Low number of red blood cells	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Chest pain caused by reduced blood flow to heart	1 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Chest pain	**0 (0%)**	**0 (0%)**	**0 (0%)**	**1 (4%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**
Pneumonia	**0 (0%)**	**0 (0%)**	**1 (4%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**
Extreme response to infection (sepsis)	**0 (0%)**	**0 (0%)**	**1 (4%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**
Gunshot wound	**1 (4%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**

One (1) patient died after leaving the study early. This death was not related to study treatment.

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.

www.clinicaltrials.gov Use the study identifier **NCT02969018**

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!