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: Brepocitinib (PF-06700841)

Protocol Number: B7931030

Dates of Study: 13 June 2019 to 15 January 2021

Title of this Study: A Study of PF-06700841 to Determine the Beneficial Effect at 16 Weeks and the Safety and Beneficial Effect up to 1 Year in Subjects with Active Psoriatic Arthritis

[A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study of PF-06700841 to Evaluate the Efficacy at 16 Weeks and to Evaluate the Safety and Efficacy up to 1 Year in Subjects with Active Psoriatic Arthritis]

Date(s) of this Report: 08 Aug 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 Psoriatic Arthritis?

Psoriatic Arthritis (PsA) is a type of arthritis that affects some people with the skin condition psoriasis. Psoriasis causes skin cells to multiply faster than normal which makes the skin build up into bumpy red patches covered with white scales. PsA typically causes affected joints to become swollen, stiff, and painful. PsA is thought to happen as a result of the immune system mistakenly attacking healthy tissue and causing lasting inflammation. Like psoriasis, PsA is a long-term condition that can get progressively worse.

What is PF-06700841?

PF-06700841 is a medicine that has shown potential in previous studies for the treatment of psoriasis. PF-06700841 stops the functioning of enzymes known as janus kinase 1 (JAK1) and tyrosine kinase 2 (TYK2). These enzymes control signals to the immune system cells that produce proteins known as cytokines which cause inflammation. This inflammation is used by the immune system to fight infections that may be caused by viruses or bacteria. In people with PsA, the body's immune system begins to attack healthy cells and tissue by causing inflammation. By stopping the function of JAK1 and TYK2, PF-06700841 may prevent the abnormal immune system response and inflammation in patients with PsA.

What was the purpose of this study?

The purpose of this study was to determine the effectiveness of PF-06700841 in participants with active (currently experiencing symptoms) PsA after 16 weeks of treatment in comparison with a placebo. After 16 weeks, the purpose of this study was to provide all participants with PF-06700841 to determine the safety and beneficial effect of this medicine after using it for 1 year.

- PF-06700841 is a new investigational medicine. A new investigational medicine is one that is currently not approved in a country.
- A placebo looks like the study medicine but does not contain any medicine. Researchers use a placebo to see if the study medicine works better or is safer than not taking anything.

Researchers wanted to know:

Did the participants taking PF-06700841 have better effectiveness in the treatment of PsA when compared to placebo?

- Researchers wanted to determine the American College of Rheumatology 20 (ACR20) score of participants taking PF-06700841 and compare it to the ACR20 score of participants taking placebo after 16 weeks of treatment.
- The ACR20 score was used to assess and establish the improvement by 20% in tender swollen joints of participants along with a 20% improvement in at least three of the following five factors:
    - Inflammation in joints.
    - Participants treatment response and progress.
    - Doctors' observations of participants treatment response and progress.
    - Daily pain in joints.
    - How much PsA interferes with the participants daily activities.

Whether PF-06700841 caused any medical problems in participants?

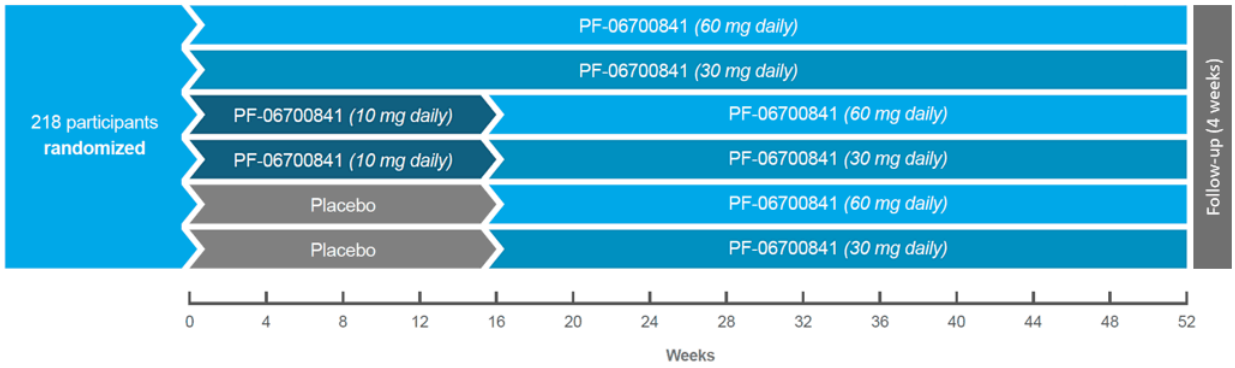
- Researchers also wanted to learn more about the safety of PF-06700841.
- They monitored the participants for any medical problems that happened while they were in the study.

What happened during the study?

How was the study done?

Researchers tested PF-06700841 on a group of study participants to find out if study participants with PsA taking PF-06700841 (the test medicine) had a higher ACR20 score than study participants with PsA taking placebo. A description of how the study was done can be seen in Figure 1 below.

Figure 1. A description of how the study was done. The ACR20 was determined at 16 weeks.



The study participants and researchers did not know who took PF-06700841 and who took the placebo. This is known as a "blinded" study. Study participants were assigned to each group by chance alone.

The study was only slightly affected by the COVID-19 pandemic as the study participants had already completed the treatment portion of the study.

Where did this study take place?

The Sponsor ran this study at 47 locations in 11 countries in Australia, Asia, and Europe.

When did this study take place?

It began 13 June 2019 and ended 15 January 2021.

Who participated in this study?

The study included participants who were between the ages of 18 and 75 years old, had symptoms of PsA for at least 6 months, and had active PsA despite taking anti-inflammatory medications for at least 4 weeks before the start of the study.

- A total of 102 men participated
- A total of 116 women participated
- All participants were between the ages of 21 and 73 years

Participants were to be treated until the ACR20 scores at the Week 16 and Week 52 study visits were determined. Of the 218 participants who started the study, 203 participants completed the study visit at Week 16. Of the 203 participants who completed the study visit at Week 16, 168 participants completed the study visit at Week 52.

Fifteen participants did not complete the Week 16 study visit because:

- The participants left the study by their own choice, and/or
- The participants did not experience an improvement in their PsA, and/or
- The participants experienced medical problems

After Week 16, an additional 35 participants left before the study was over by their choice or a doctor decided it was best for a participant to stop being in the study.

How long did the study last?

Study participants were in the study for about 12 months. The entire study took 19 months to complete.

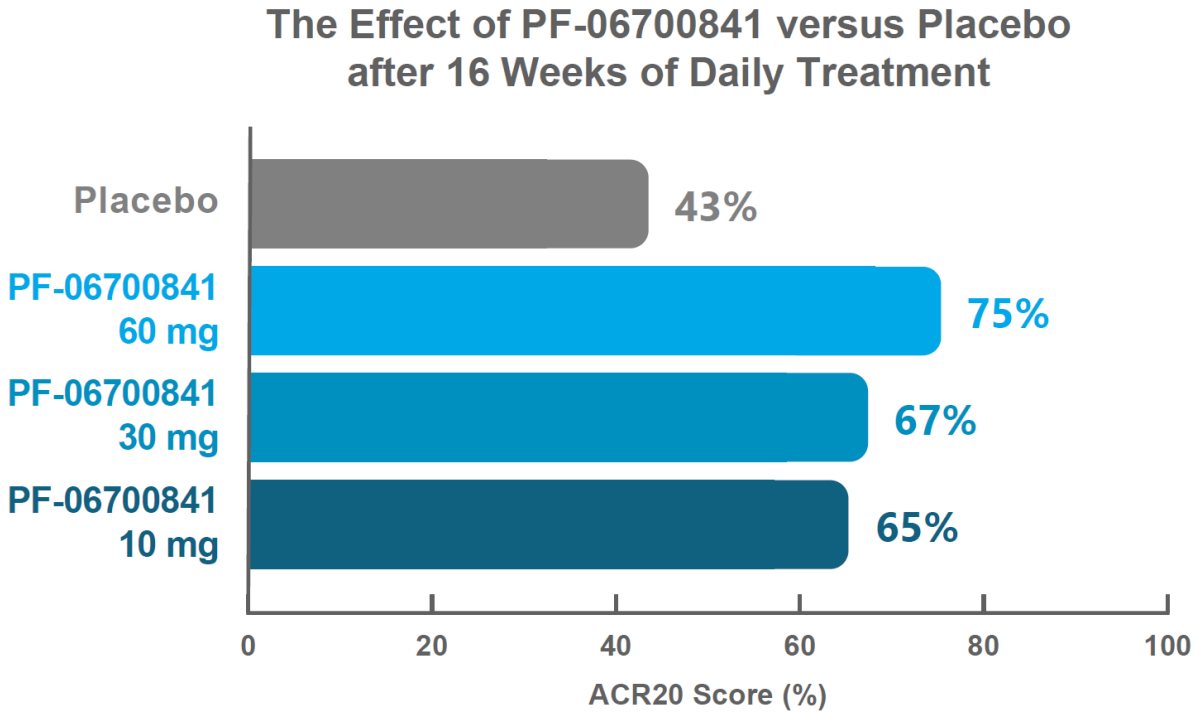
When the study ended in January 2021, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Did the participants taking PF-06700841 have a better ACR20 score in the treatment of PsA when compared to placebo?

Researchers determined the ACR20 score for participants with PsA taking PF-06700841 and for participants taking placebo at Week 16 (Figure 2).

Figure 2. The ACR20 score for participants with PsA taking PF-06700841 and placebo at week 16



Did the study medication have a better effect compared to placebo?

At Week 16, participants who took the study medication had an ACR20 score of:

- PF-06700841 10 mg group: 65%
- PF-06700841 30 mg group: 67%
- PF-06700841 60 mg group: 75%
- Placebo group: 43%

At Week 52, participants who took the study medication had an ACR20 score of:

- PF-06700841 10 mg to PF-06700841 60 mg group: 56%
- PF-06700841 10 mg to PF-06700841 30 mg group: 60%
- PF-06700841 30 mg group: 70%
- PF-06700841 60 mg group: 62%
- Placebo to PF-06700841 30 mg group: 67%
- Placebo to PF-06700841 60 mg group: 62%

Based on these results, the researchers have decided that the results are not likely the result of chance. The study medication may have a beneficial effect on participants with PsA.

This does not mean that everyone in this study had these results. These are just some of the main findings of this study.

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). Alternatively, 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.

One hundred and nineteen out of 218 (55%) participants in this study had at least 1 medical problem in the first 16 weeks of the study. One hundred and sixty out of 218 (73%) participants in this study had at least 1 medical problem by Week 52. A total of 3 participants left the study by Week 52 because of medical problems. The most common medical problems, those reported by more than 5% of participants, are described in Table 1 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 5% of participants are listed.
- The **2nd** to **7th** column tells us the number of participants in the groups below who reported each medical problem. Next to this number is the percentage of the participants taking the study medication who reported the medical problem.
    - PF-06700841 60 mg group
    - PF-06700841 30 mg group
    - PF-06700841 10 mg to PF-06700841 60 mg group
    - PF-06700841 10 mg to PF-06700841 30 mg group
    - Placebo to PF-06700841 30 mg group
    - Placebo to PF-06700841 60 mg group
- Using these instructions, you can see that 2 out of the 60 participants in the PF-06700841 60 mg group taking the study medication reported low red blood cell count.

Table 1. Commonly reported medical problems by participants by week 52

Medical Problem	PF-06700841 60 mg	PF-06700841 30 mg	PF-0670084 1 10 mg to 60 mg	PF-06700841 10 mg to 30 mg	Placebo to PF-06700841 60 mg	Placebo to PF-06700841 30 mg
Number of participants	**60**	**60**	**16**	**15**	**34**	**33**
Low red blood cell count	2 out of 60 participants (3%)	2 out of 60 participants (3%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	3 out of 34 participants (9%)	1 out of 33 participants (3%)
Low white blood cell count (neutrophils)	3 out of 60 participants (5%)	0 out of 60 participants (0%)	0 out of 16 participants (0%)	1 out of 15 participants (7%)	1 out of 34 participants (3%)	0 out of 33 participants (0%)
Low white blood cell count (leukocytes)	1 out of 60 participants (2%)	0 out of 60 participants (0%)	0 out of 16 participants (0%)	1 out of 15 participants (7%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Upper abdominal pain	4 out of 60 participants (7%)	0 out of 60 participants (0%)	0 out of 16 participants (0%)	1 out of 15 participants (7%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Sores in mouth	0 out of 60 participants (0%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Constipation	1 out of 60 participants (2%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (	0 out of 33 participants (0%)
Indigestion	1 out of 60 participants (2%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	1 out of 15 participants (7%)	0 out of 34 participants (	1 out of 33 participants (3%)
Inflamed stomach lining	3 out of 60 participants (5%)	0 out of 60 participants (0%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Nausea	4 out of 60 participants (7%)	1 out of 60 participants (2%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	3 out of 34 participants (9%)	1 out of 33 participants (3%)
Feeling tired	3 out of 60 participants (5%)	1 out of 60 participants (2%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	1 out of 34 participants (3%)	0 out of 33 participants (0%)
Liver disorder	0 out of 60 participants (0%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Infection affecting the smaller airways	4 out of 60 participants (7%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	2 out of 15 participants (13%)	1 out of 34 participants (3%)	1 out of 33 participants (3%)
COVID-19 infection	1 out of 60 participants (2%)	2 out of 60 participants (3%)	0 out of 16 participants (0%)	1 out of 15 participants (7%)	1 out of 34 participants (3%)	2 out of 33 participants (6%)
Infection of the bladder	1 out of 60 participants (2%)	0 out of 60 participants (0%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	2 out of 34 participants (6%)	0 out of 33 participants (0%)
Stomach flu	2 out of 60 participants (3%)	1 out of 60 participants (2%)	0 out of 16 participants (0%)	1 out of 15 participants (7%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Shingles	1 out of 60 participants (2%)	1 out of 60 participants (2%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Sensitive nose or hay fever	3 out of 60 participants (5%)	1 out of 60 participants (2%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Infection of nose, throat, voice box,	7 out of 60 participants	5 out of 60 participants (8%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	2 out of 34 participants (6%)	3 out of 33 participants (9%)

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Number of participants	**60**	**60**	**16**	**15**	**34**	**33**
windpipe and its branches, or lungs	(12%)					
Infection of nose and throat	8 out of 60 participants (13%)	5 out of 60 participants (8%)	0 out of 16 participants (0%)	2 out of 15 participants (13%)	1 out of 34 participants (3%)	4 out of 33 participants (12%)
Cold sores (oral herpes)	2 out of 60 participants (3%)	2 out of 60 participants (3%)	1 out of 16 participants (6%)	1 out of 15 participants (7%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Sore throat	2 out of 60 participants (3%)	2 out of 60 participants (3%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	2 out of 33 participants (6%)
Infection of the lung	2 out of 60 participants (3%)	2 out of 60 participants (3%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	1 out of 33 participants (3%)
Infection of the kidneys, bladder, or urethra	4 out of 60 participants (7%)	4 out of 60 participants (7%)	1 out of 16 participants (6%)	1 out of 15 participants (7%)	1 out of 34 participants (3%)	0 out of 33 participants (0%)
Liver test levels increased (alanine aminotransferase)	5 out of 60 participants (8%)	7 out of 60 participants (12%)	1 out of 16 participants (6%)	1 out of 15 participants (7%)	2 out of 34 participants (6%)	0 out of 33 participants (0%)
Liver test levels increased (aspartate aminotransferase)	3 out of 60 participants (5%)	3 out of 60 participants (5%)	0 out of 16 participants (0%)	1 out of 15 participants (7%)	2 out of 34 participants (6%)	1 out of 33 participants (3%)
Muscle protein (creatine phosphokinase) increased in the blood	4 out of 60 participants (7%)	4 out of 60 participants (7%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	1 out of 34 participants (3%)	2 out of 33 participants (6%)
Heart muscle took longer than normal to recharge between beats	1 out of 60 participants (2%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	2 out of 34 participants (6%)	0 out of 33 participants (0%)
Liver enzyme increased in the blood	2 out of 60 participants (3%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Positive SARS-CoV-2 test	3 out of 60 participants (5%)	0 out of 60 participants (0%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	1 out of 34 participants (3%)	1 out of 33 participants (3%)
PsA	1 out of 60 participants (2%)	1 out of 60 participants (2%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	1 out of 34 participants (3%)	2 out of 33 participants (6%)
Weight gain	1 out of 60 participants (2%)	1 out of 60 participants (2%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	2 out of 34 participants (6%)	0 out of 33 participants (0%)
Spinal pain	1 out of 60 participants (2%)	1 out of 60 participants (2%)	1 out of 16 participants (6%)	1 out of 15 participants (7%)	0 out of 34 participants (0%)	1 out of 33 participants (3%)

Table 1. Commonly reported medical problems by participants by week 52

Medical Problem	PF-06700841 60 mg	PF-06700841 30 mg	PF-06700841 10 mg to 60 mg	PF-06700841 10 mg to 30 mg	Placebo to PF-06700841 60 mg	Placebo to PF-06700841 30 mg
Number of participants	**60**	**60**	**16**	**15**	**34**	**33**
Headache	5 out of 60 participants (8%)	4 out of 60 participants (7%)	2 out of 16 participants (13%)	1 out of 15 participants (7%)	1 out of 34 participants (3%)	3 out of 33 participants (9%)
Nose, sinus, or throat inflammation	0 out of 60 participants (0%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Rash	2 out of 60 participants (3%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Skin lump	0 out of 60 participants (0%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	0 out of 33 participants (0%)
Acne	1 out of 60 participants (2%)	2 out of 60 participants (3%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	1 out of 34 participants (3%)	0 out of 33 participants (0%)
Psoriasis	1 out of 60 participants (2%)	0 out of 60 participants (0%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	1 out of 34 participants (3%)	2 out of 33 participants (6%)
Hives	0 out of 60 participants (0%)	0 out of 60 participants (0%)	0 out of 16 participants (0%)	0 out of 15 participants (0%)	0 out of 34 participants (0%)	2 out of 33 participants (6%)
High blood pressure	5 out of 60 participants (8%)	2 out of 60 participants (3%)	1 out of 16 participants (6%)	0 out of 15 participants (0%)	1 out of 34 participants (3%)	1 out of 33 participants (3%)

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.

Twelve out of 218 participants (6%) had serious medical problems. Of the serious medical problems, three events were considered to be related to study medication as follows:

- One participant in the PF-06700841 30 mg group had severe ear infection.
- One participant in the placebo to PF-06700841 30 mg treatment group had infection of the lung (viral pneumonia).
- One participant in the placebo to PF-06700841 60 mg treatment group had infection of the lung (pneumonia) and COVID-19 virus.
- 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 **NCT03963401**
www.clinicaltrialsregister.eu	Use the study identifier **2018-004241-16**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B7931030**

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!