



## 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-06650833 (Zimlovisertib), PF-06700841 (Breprocitinib), and PF-06826647

**Protocol Number:** C2501007

**Dates of Study:** 02 December 2019 to 10 January 2022

**Title of this Study:** Safety and Efficacy of PF-06650833, PF-06700841, and PF-06826647 in Adults with Moderate to Severe Hidradenitis Suppurativa

A Phase 2a, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 16-Week Study Evaluating the Safety and Efficacy of PF-06650833, PF-06700841, and PF-06826647 in Adults with Moderate to Severe Hidradenitis Suppurativa

**Date(s) of this Report:** 16 January 2023

— 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?

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### What is Hidradenitis Suppurativa (HS)?

Hidradenitis suppurativa is a condition that causes small, painful lumps to form under the skin. The lumps usually develop in areas where your skin rubs together, such as the armpits, groin, buttocks, and breasts.

### What are PF-06650833 (Zimlovisertib), PF-06700841 (Brepocitinib), and PF-06826647?

Zimlovisertib, Brepocitinib, and PF-06826647 are study medications that researchers think may help with HS. Since the pathophysiology (the biological condition which causes this disease) of this disease is not clear yet, researchers decided to study these three medications to determine the most appropriate course of treatment for this disease.

Zimlovisertib blocks a small protein called interleukin-1 receptor-associated kinase 4 (IRAK4) and Brepocitinib blocks a complex of Janus kinase 1 (JAK1) and tyrosine kinase 2 (TYK2), and PF-06826647 blocks tyrosine kinase 2 (TYK2). Researchers believe excess presence of these proteins may cause the lumps in HS. Blocking these proteins with the study medications may help treat the disease.

### What was the purpose of this study?

The purpose of this study was to evaluate how effective and safe, Zimlovisertib, Brepocitinib and PF-06826647 were in treating HS compared to placebo. A placebo does not have any medicine in it, but it looks just like the study medicine. It is used as a comparator.

In this clinical trial, an assessment tool called hidradenitis suppurativa clinical response (HiSCR) is used to evaluate the efficacy of the medicines. Efficacy means how well the medicines work to help the patients.

HiSCR response means that the patient had at least 50% reduction in total number of modules/lumps, no increase in areas with pus (abscess) and no increase in abnormal

connections between the nodules/lumps, compared to baseline (Day 1 of the study i.e. before taking the study medication).

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### Researchers wanted to know:

**Did the participants taking Zimlovisertib, Brepocitinib, or PF-06826647 have better HiSCR score compared to placebo?**

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## What happened during the study?

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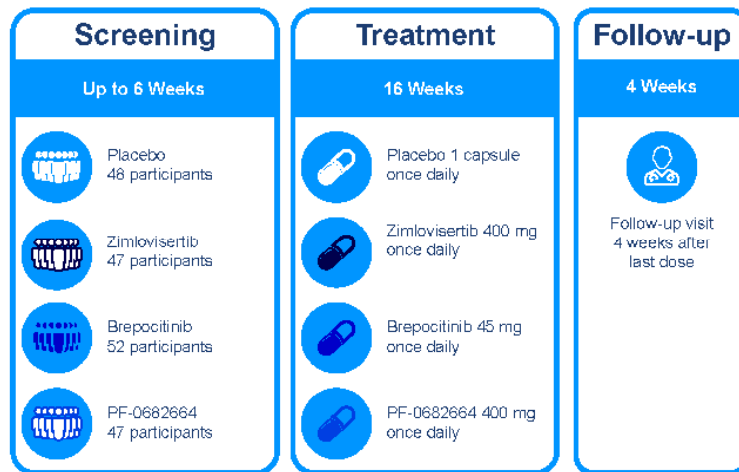
### How was the study done?

Researchers tested Zimlovisertib, Brepocitinib and PF-06826647 on a group of study participants to find out if study participants taking the study medications had better HiSCR score compared to participants taking placebo. Participants took either 400 mg Zimlovisertib or 45 mg Brepocitinib or 400 mg PF-0682664 once daily.

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

The study design is shown in figure 1.

## Figure 1 How was the study done?



## Where did this study take place?

The Sponsor ran this study at 60 locations in 3 countries; Australia, Canada, and United States.

## When did this study take place?

It began 02 December 2019 and ended 10 January 2022.

## Who participated in this study?

The study included participants who met the inclusion/exclusion criteria for things such as age, condition type etc.

A total of 43 men and 151 women participated in the study.

All participants were between the ages of 19 and 62

Participants were to be treated for 16 weeks. Of the 194 participants who started the study, 133 finished the Treatment Phase of the study and 5 finished Follow-Up Phase.

61 participants did not finish the study because either the participant chose to withdraw or due to medical problems or it was the physician's decision to stop treatment.

## How long did the study last?

Study participants were in the study for approximately 26 weeks. The entire study took approximately 2 years to complete.

When the study ended in January 2022, 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?

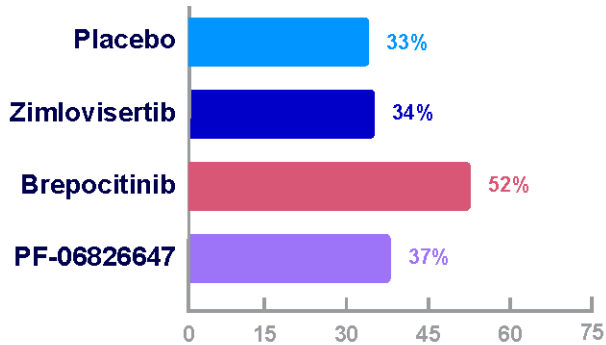
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### Did participants taking Zimlovisertib, Brepocitinib, or PF-06826647 have better HiSCR score compared to placebo?

Fifty two percent (52%) of participants who took Brepocitinib, 34% of participants who took Zimlovisertib, 37% of participants who took PF-06826647 and 33% of participants who took placebo showed HiSCR response compared to baseline. Researchers concluded that taking Brepocitinib showed a clear difference in the HiSCR score compared to placebo whereas Zimlovisertib and PF-06826647 did not show a clear difference from placebo.

These results are shown in Figure 2.

**Figure 2 Percentage of Participants Achieving HiSCR Response at Week 16**



### **Did the study medication help participants to have better HiSCR score compared to placebo?**

Overall, 16 out of 47 (34%) of participants who took Zimlovisertib, 27 out of 52 (52%) of participants who took Brepocitinib and 17 out of 46 (37%) of participants who took PF-06826647 achieved HiSCR response at Week 16, while 16 out 48 (33%) participants taking placebo achieved HiSCR response.

Based on these results, the researchers have decided that improvement with Brepocitinib is not likely the result of chance. Brepocitinib may help participants achieve HiSCR scores. There was insufficient evidence that PF-06826647 or Zimlovisertib were effective.

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?**

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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.

108 out of 194 (56%) participants in this study had at least 1 medical problem. Most of these problems were not related to the treatment based on doctor's assessment. Only 45 participants (23%) had treatment-related medical problems. A total of 8 participants left the study because of medical problems. The most common medical problems – those reported by more than or equal to 5% of participants – 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 or equal to 5% of participants are listed.
- The 2nd column tells how many of the 48 participants taking a placebo reported each medical problem. Next to this number is the percentage of the 48 participants taking the study medication who reported the medical problem.
- The 3rd column tells how many of the 47 participants taking Zimlovisertib reported each medical problem. Next to this number is the percentage of the 47 participants taking Zimlovisertib who reported the medical problem.
- The 4th column tells how many of the 52 participants taking Brepocitinib reported each medical problem. Next to this number is



the percentage of the 52 participants taking Brepocitinib who reported the medical problem.

- The 5th column tells how many of the 47 participants taking **PF-06826647** reported each medical problem. Next to this number is the percentage of the 47 participants taking PF-06826647 who reported the medical problem

Using these instructions, you can see that 4 out of the 47 (9%) participants taking Zimlovisertib, 5 out of 52 (10%) participants taking Brepocitinib and 4 out of the 47 (9%) taking PF-0682664 reported acne. A total of 1 out of the 48 (2%) participants taking a placebo reported acne.

**Table 1. Commonly reported medical problems by study participants**

Medical Problem	Placebo 48 Participants	Zimlovisertib 47 Participants	Brepocitinib 52 Participants	PF-06826647 47 Participants
Acne	1 out of 48 participants (2%)	4 out of 47 participants (9%)	5 out of 52 participants (10%)	4 out of 47 participants (9%)
Muscle protein increased in the blood (creatine phosphokinase)	0 out of 48 participants (0%)	0 out of 47 participants (0%)	4 out of 52 participants (8%)	6 out of 47 participants (13%)
Headache	3 out of 48 participants (6%)	5 out of 47 participants (11%)	4 out of 52 participants (8%)	3 out of 47 participants (6%)
Hidradenitis Suppurativa Worsening	2 out of 48 participants (4%)	1 out of 47 participants (2%)	1 out of 52 participants (2%)	6 out of 47 participants (13%)
Nausea	0 out of 48 participants (0%)	1 out of 47 participants (2%)	1 out of 52 participants (2%)	3 out of 47 participants (6%)
Urinary tract infection	1 out of 48 participants (2%)	3 out of 47 participants (6%)	2 out of 52 participants (4%)	0 out of 47 participants (0%)

## 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.

4 participants out of 194 participants had serious medical problems.

- 2 participants each in the Zimlovisertib and PF-06826647 groups had serious medical problem. In the Zimlovisertib group one participant had bacterial infection (cellulitis) and one participant had suicidal ideation and spontaneous miscarriage. In the PF-06826647 group one patient had COVID-19 and one participant had worsening of HS. Suicidal ideation, spontaneous miscarriage and worsening of HS were considered to be treatment related by the doctors.
- No participants in the placebo group had serious medical problem.

No participants died during the study.

## Where can I learn more about this study?

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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](http://www.clinicaltrials.gov)

Use the study identifier **NCT04092452**

[www.pfizer.com/research/](http://www.pfizer.com/research/)

Use the protocol number C2501007

[research\\_clinical\\_trials/trial\\_results](http://research_clinical_trials/trial_results)

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!