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: Brepocitinib (PF-06700841)

Protocol Number: B7931022

Dates of Trial: 13 May 2019 to 07 May 2020

Title of this Trial: A Dose Ranging Study to Assess Efficacy, Safety, Tolerability and Pharmacokinetics of PF-06700841 Topical Cream in Participants With Mild or Moderate Atopic Dermatitis

[A Phase 2b, Randomized, Double Blind, Vehicle Controlled, Parallel Group, Dose Ranging Study to Assess the Efficacy, Safety, Tolerability and Pharmacokinetics of PF-06700841 Cream Applied Once or Twice Daily for 6 Weeks in Participants With Mild or Moderate Atopic Dermatitis]

Date(s) of this Report: 26 March 2021

– Thank You –

Pfizer, the Sponsor, would like to thank you for your participation and/or your child's 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?

Atopic dermatitis (or "AD"), which is also sometimes called atopic eczema, is a common skin condition that causes patches of dry, red, and very itchy skin. AD occurs in up to 36% of children and up to almost 23% of adults worldwide. Some of the current medicines available for AD can only be used for short time periods, or can cause other health problems. Researchers are looking for new treatments for AD that can be applied to the skin that can also be used for long periods of time.

Brepocitinib (also called PF-06700841) is an experimental medicine that has not been approved for sale yet. Brepocitinib blocks 2 enzymes (special proteins that cause chemical reactions in the body) called "Tyrosine Kinase 2" (TYK2) and "Janus kinase 1 (JAK1)". TYK2 and JAK1 act like a switch for the cells of the immune system (the body's defense against infection and inflammation). By turning off this switch, the cells of the immune system are expected to produce fewer chemical signals believed to cause AD. Brepocitinib was given in the form of a cream that is applied to areas of skin affected by AD.

The main purpose of this study was to explore the effect of multiple doses of brepocitinib on AD. The study also tested whether applying brepocitinib cream once-a-day or twice-a-day had a better effect in treating AD. The researchers asked,

- **Are patients who are treated with brepocitinib cream more likely to have their AD improve compared to patients treated with a vehicle cream?**

In this study, the "vehicle cream" was skin cream that looked just like the skin cream containing the study medicine (brepocitinib), but did not have any medicine in it.

To answer this question, the researchers used a tool called the EASI (Eczema Area and Severity Index). The EASI measures how severe a patient's AD is based on 4 different signs, as well as the total amount of a patient's skin affected by AD. The researchers also monitored the patients for any medical problems they had while in the study.

WHAT HAPPENED DURING THE STUDY?

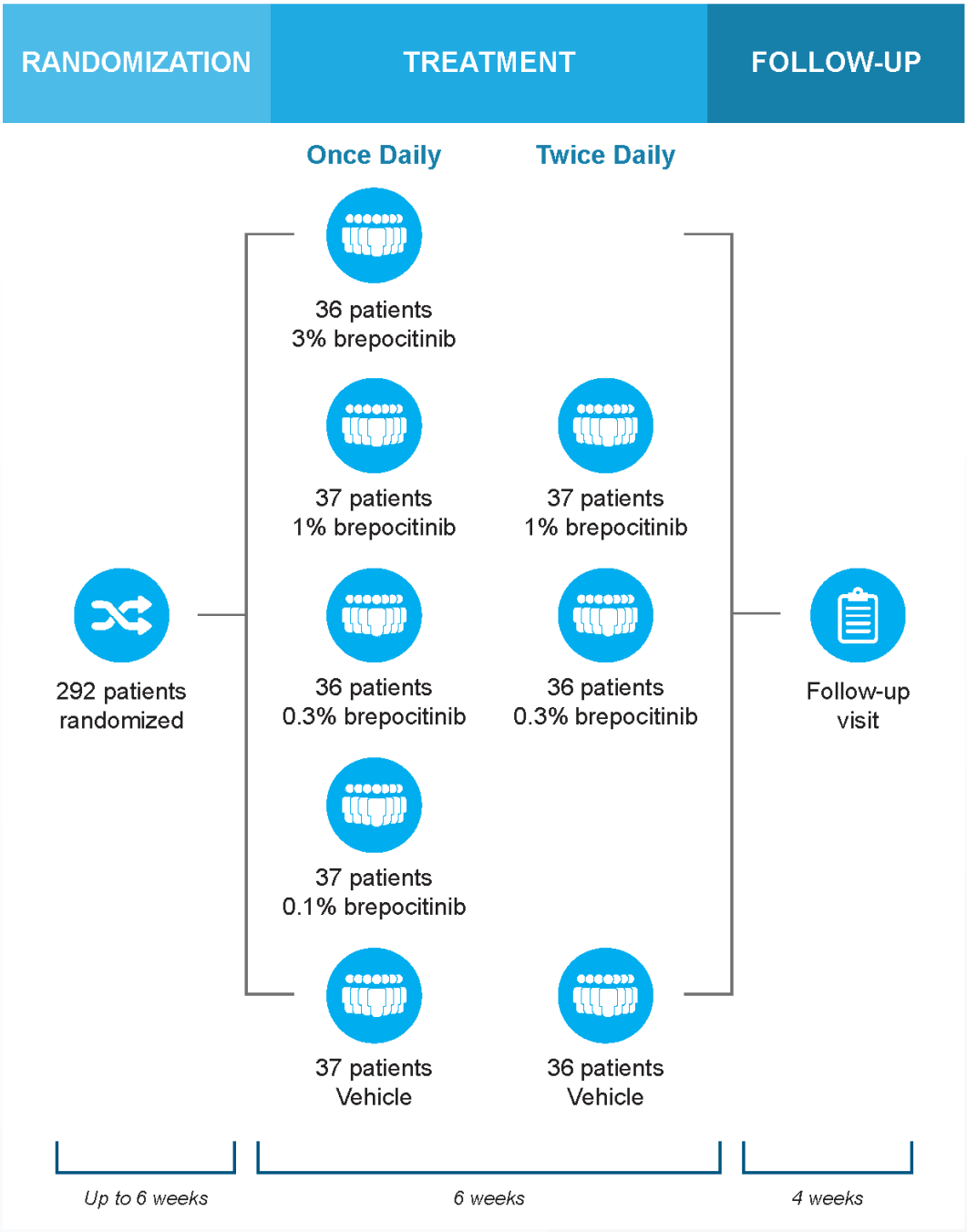
This study compared patients using different dose strengths and 2 application schedules to find out if patients who were treated with brepocitinib cream were more likely to have their AD improve compared to patients treated with a vehicle cream. The study included adults and children who were diagnosed with mild to moderate AD at least 3 months before enrolling in the study. Study participants must not have taken drugs like brepocitinib (called "TYK2 inhibitors" or "JAK inhibitors") in the 3 months before they were screened for the study.

The patients and doctors did not know who used brepocitinib cream and who used the vehicle cream. This is known as a "double-blinded" study. This is done to make sure the results of the research study cannot be unfairly influenced by anyone. Patients were assigned to 1 of the 8 treatment groups by chance (like the flip of a coin or drawing straws). This is known as a "randomized and vehicle-controlled" study.

While patients were only in the study for up to 16 weeks, the entire study took 12 months to complete. The Sponsor ran this study at 70 locations in 10 countries in North America, Australia, Europe, and Japan. It began on 13 May 2019 and ended on 07 May 2020. A total of 136 men/boys and 156 women participated. All patients were between the ages of 13 and 74.

Patients were to be treated until they completed the study treatment phase, until they chose to stop, or until they had certain medical problems. Of the 292 patients who started the study, 240 finished the treatment phase and 245 finished the follow-up phase of the study. A total of 52 patients did not finish the treatment phase and 47 patients did not finish the follow-up phase of the study. A total of 22 patients stopped treatment before the study was over by their choice, and 2 patients stopped treatment because a doctor decided it was best for a patient to stop being in the study.

The graphic on the next page shows what happened during the study.

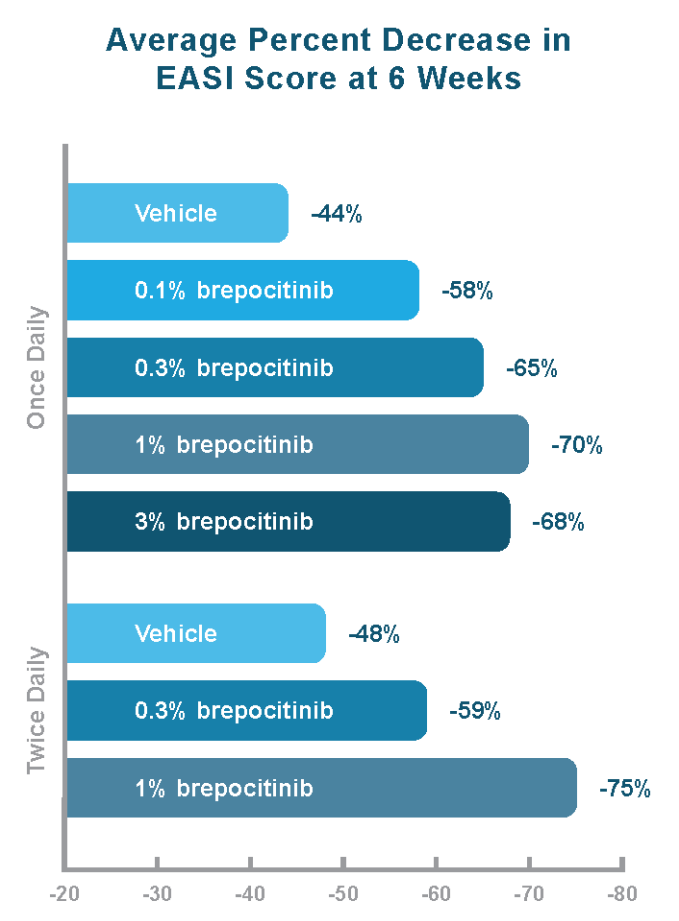


When the study ended in May 2020, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

Were patients who were treated with brepocitinib cream more likely to have their AD improve compared to patients treated with a vehicle cream?

Yes. Patients using 1% brepocitinib cream once daily had an average decrease in their EASI score of -70%, compared to -44% using vehicle cream. Patients using 1% brepocitinib cream twice daily had an average decrease in their EASI score of -75%, compared to -48% using vehicle cream. The researchers do not think these results are likely the result of chance. On average, all of the tested dose strengths and treatment schedules of brepocitinib cream decreased patients' EASI scores more than the vehicle cream.



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.

One hundred and eight (108) out of 292 patients in this study had at least 1 medical problem. A total of 16 patients left the study because of medical problems. The most common medical problems are listed on the next page.

Most Common Medical Problems Once Daily Application (Reported by 5% or More of Patients)					
Medical Problem	Vehicle Cream (37 patients)	Brepocitinib Cream			
		0.1% (37 patients)	0.3% (36 patients)	1% (37 patients)	3% (36 patients)
Influenza	0	1 (3%)	0	2 (5%)	1 (3%)
Infection of nose, mouth, and upper throat	1 (3%)	2 (5%)	2 (6%)	3 (8%)	4 (11%)
Urinary tract infection	1 (3%)	0	2 (6%)	2 (5%)	0
Cough	0	0	2 (6%)	0	0
Mouth or throat pain	1 (3%)	2 (5%)	1 (3%)	0	0
AD got worse	3 (8%)	3 (8%)	1 (3%)	0	1 (3%)
Itchiness	2 (5%)	1 (3%)	0	0	0

Most Common Medical Problems Twice Daily Application (Reported by 5% or More of Patients)			
Medical Problem	Vehicle Cream (36 patients)	Brepocitinib Cream	
		0.3% (36 patients)	1% (37 patients)
Redness at application site	2 (6%)	0	1 (3%)
Itching at application site	3 (8%)	0	0
Infection of nose, mouth, and upper throat	2 (6%)	2 (6%)	2 (5%)
AD got worse	3 (8%)	0	2 (5%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

No patients had serious medical problems that started after they began study treatment. No patients died during this 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.

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

www.clinicaltrials.gov	Use the study identifier **NCT03903822**
www.clinicaltrialsregister.eu	Use the study identifier **2018-003050-24**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B7931022**

Additional clinical trials of brepocitinib are ongoing.

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!