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: Abrocitinib (PF-04965842)

Protocol Number: B7451036

Dates of Trial: 18 February 2019 to 08 April 2020

Title of this Trial: JAK1 Inhibitor With Medicated Topical Therapy in Adolescents With Atopic Dermatitis (JADE TEEN)

[A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study Investigating the Efficacy and Safety of PF-04965842 Co-Administered With Background Medicated Topical Therapy in Adolescent Participants 12 to <18 Years of Age With Moderate-to-Severe Atopic Dermatitis]

Date(s) of this Report: 12 November 2020; Amended 02 February 2021

– Thank You –

Pfizer, the Sponsor, would like to thank you and/or your child for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you or your child 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 disorder that causes patches of flaky, red, and very itchy skin. AD occurs in 15%-30% of children in the United States. 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 taken for long periods of time.

While researchers think that many things cause AD, it is made worse by the body's immune system (the body's defense against infection) causing redness and swelling (inflammation). Cells in the immune system cause inflammation by making special proteins called "cytokines". Researchers think that medicines that lower the amount of cytokines that the body makes could help treat patients with AD.

The drug tested in this study was abrocitinib, which is an experimental drug that has not been approved for sale yet. Abrocitinib blocks the activity of a protein called "Janus kinase 1", or "JAK1", which acts like an on/off switch for the cells of the immune system. By turning off this switch, the cells of the immune system are expected to produce fewer cytokines, which may help AD improve. The researchers wanted to ask,

- **Are patients who are treated with medicated topical therapy more likely to have their AD improve when also taking abrocitinib compared to patients who are treated with a placebo?**

"Medicated topical therapy" was cream or ointment applied to the skin that contains medicine that is approved to treat AD. To see if the patients' AD got better during the study, the researchers used 2 standard methods to measure the severity of AD at the start of the study and throughout the 12 weeks of study treatment. The difference in severity was used to decide if a patient's AD had improved or not.

WHAT HAPPENED DURING THE STUDY?

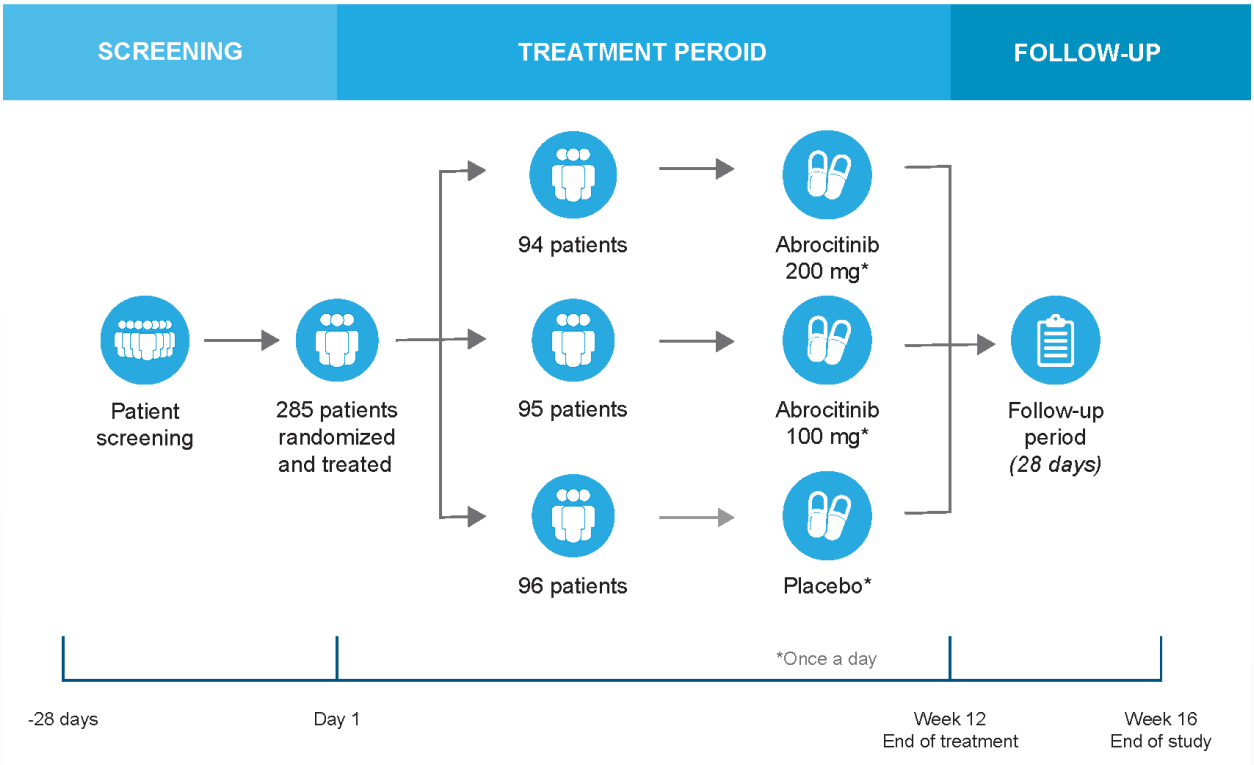
This study compared 3 groups of patients to find out if patients treated with 100 mg or 200 mg of abrocitinib once daily were more likely to have their AD improve compared to patients taking a placebo. A placebo does not have any medicine in it, but it looks just like the study medicine.

The study included adolescent boys and girls who were at least 12 years old and up to 18 years old. Patients included in the study:

- Had a confirmed diagnosis of moderate to severe AD when they entered the study.
- Also had one of the following:
  - Had been treated up to 6 months earlier for AD with medicines applied to the skin for at least 4 weeks, and their AD did not get better;
  - Had needed to use medicines that reach all parts of the body to control their AD in the last 6 months (for example, taking medicines by mouth), or were eligible to take these medicines.
- Had used moisturizing products on their skin (such as skin cream) that did not contain medicine at least twice daily for the 7 days before starting the study treatments.
- Were willing to use standard skin treatments for AD during the study (called 'topical background therapy').
- Had not taken medications like abrocitinib before (known as systemic JAK inhibitors).

The patients and doctors did not know who took abrocitinib and who took the placebo. 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 3 treatment groups by chance (like the flip of a coin or drawing straws) to receive either abrocitinib at a dose of 100 mg, abrocitinib at a dose of 200 mg, or placebo. This is known as a "randomized and placebo-controlled" study.

All of the patients in this study were treated with medicated topical therapy while taking abrocitinib or placebo.



The researchers in this study used 2 different tests to measure the severity of the patients' AD at the beginning of the study and throughout 12 weeks of treatment. The first test is called the Investigators Global Assessment (IGA) scale and measures the severity of AD on a 5-point scale (0 being the best and 4 being the worst). The second test is called the Eczema Area and Severity Index, and measures how severe a patient's AD is based on 4 different signs, as well as the amount of skin affected by AD. The difference in each patient's score between the start of the study and after 12 weeks of treatment was used to decide if their AD had improved.

While patients were only in the study for 12 to 16 weeks, the entire study took almost 14 months to complete. The Sponsor ran this study at 99 locations in 13 countries in Europe, Asia, Australia, and North America. It began on 18 February 2019 and ended on 08 April 2020. A total of 145 boys and 140 girls participated. All patients were between the ages of 11 and 18.

Patients were to be treated until the end of the 12 week treatment period. Of the 285 patients who started the study, 273 finished the study. Five (5) patients did not finish the study because of medical problems. Seven (7) patients left before the study

was over by their choice or their parent's choice, or because a doctor decided it was best for a patient to stop being in the study.

When the study ended in April 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?

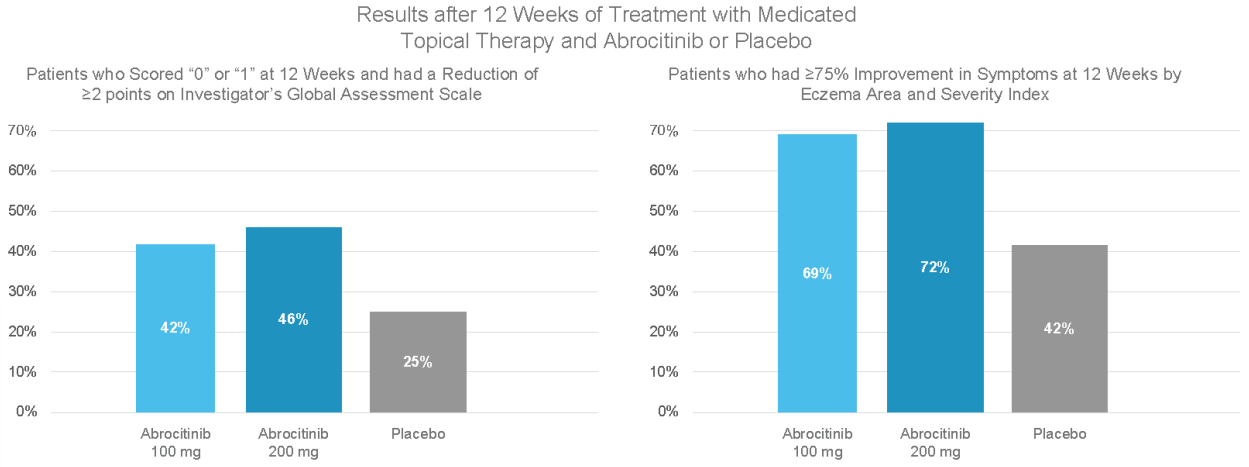
Were patients who were treated with medicated topical therapy more likely to have their AD improve when also taking abrocitinib compared to patients who were treated with a placebo?

Yes. In this study, more patients in the abrocitinib 100 mg or 200 mg treatment groups had their AD improve, compared to the placebo group.

When the change in severity of AD was measured using the IGA scale, 37 out of 89 patients (42%) in the abrocitinib 100 mg treatment group and 43 out of 93 patients (46%) in the abrocitinib 200 mg treatment group had their AD improve to 'clear' or 'almost clear' (score of 0 or 1) after 12 weeks. In comparison, 23 out of 94 patients (25%) in the placebo group had their AD improve to 'clear' or 'almost clear' after 12 weeks.

When the change in severity of AD was measured using the Eczema Area and Severity Index, 61 out of 89 patients (69%) in the abrocitinib 100 mg treatment group and 67 out of 93 patients (72%) in the abrocitinib 200 mg treatment group had their AD improve by at least 75% after 12 weeks. In comparison, 39 out of 94 patients (42%) in the placebo group had their AD improve by at least 75% after 12 weeks.

These results are also shown in graphs on the next page.



Based on these results, the researchers have decided that the results are not likely the result of chance. Abrocitinib may be an option for treating AD in adolescents who are 12 to 18 years of age.

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.

163 out of 285 patients in this study had at least 1 medical problem. A total of 5 patients left the study because of medical problems. The most common medical problems are listed below.

Most Common Medical Problems (Reported by 2% or More of Patients in Any Group)

Medical Problem	Placebo (96 Patients Treated)	Abrocitinib 100 mg (95 Patients Treated)	Abrocitinib 200 mg (94 Patients Treated)
Nausea	1 (1%)	7 (7%)	17 (18%)
Common cold	10 (10%)	9 (10%)	10 (11%)
Infection of nose, mouth, and upper throat	9 (9%)	8 (8%)	8 (9%)
Headache	7 (7%)	5 (5%)	8 (9%)
Dizziness	1 (1%)	0	6 (6%)
Vomiting	0	4 (4%)	5 (5%)
Acne	1 (1%)	3 (3%)	5 (5%)

Blood enzyme increased (CPK)	0	4 (4%)	4 (4%)
Upper abdominal pain	0	0	4 (4%)
Infection of mouth and upper throat	3 (3%)	5 (5%)	3 (3%)
Abdominal pain	1 (1%)	1 (1%)	3 (3%)
Sinus infection	0	0	3 (3%)
Infected hair follicle(s)	1 (1%)	7 (7%)	2 (2%)
Influenza	1 (1%)	4 (4%)	2 (2%)
Stomach flu	1 (1%)	2 (2%)	2 (2%)
Somnolence	2 (2%)	0	2 (2%)
Cold sores	0	1 (1%)	2 (2%)
Blood enzyme increased (lactate dehydrogenase)	0	1 (1%)	2 (2%)
Decreased hemoglobin	0	0	2 (2%)
Fever	4 (4%)	3 (3%)	1 (1%)
Cough	2 (2%)	4 (4%)	1 (1%)
Atopic dermatitis	3 (3%)	2 (2%)	1 (1%)
Asthma	2 (2%)	1 (1%)	1 (1%)
Diarrhea	0	2 (2%)	1 (1%)
Runny nose	3 (3%)	1 (1%)	0
Feeling tired	1 (1%)	2 (2%)	0
Blood uric acid increased	2 (2%)	1 (1%)	0
Protein in urine	2 (2%)	1 (1%)	0
Small painful bump on eyelid	0	2 (2%)	0
Strep throat	2 (2%)	0	0

Bruising	**0**	**2 (2%)**	**0**
Increased white blood cells (eosinophilia)	**2 (2%)**	**0**	**0**
Lip swelling	**2 (2%)**	**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.

Three (3) patients out of 285 patients (1%) had serious medical problems: 2 patients who took placebo and 1 patient that took abrocitinib 200 mg. No patients died during the study.

Serious Medical Problems			
Serious Medical Problem	**Placebo (96 Patients Treated)**	**Abrocitinib 100 mg (95 Patients Treated)**	**Abrocitinib 200 mg (94 Patients Treated)**
Anxiety	**0**	**0**	**1 (1%)**
Swelling under skin surface	**1 (1%)**	**0**	**0**
Atopic dermatitis	**1 (1%)**	**0**	**0**

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 **NCT03796676**
www.clinicaltrialsregister.eu	Use the study identifier **2018-003804-37**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B7451036**

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!