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: B7451012

Dates of Trial: 07 December 2017 to 26 March 2019

Title of this Trial: Study to Measure the Efficacy and Safety of Abrocitinib (PF-04965842) in Subjects Aged 12 Years And Older With Moderate to Severe Atopic Dermatitis (JADE Mono-1)

[A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Evaluate the Efficacy and Safety of PF-04965842 Monotherapy in Subjects Aged 12 Years and Older, With Moderate to Severe Atopic Dermatitis]

Date(s) of this Report: 31 December 2019

– 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 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 and 10% of adults 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 PF-04965842, which now has the generic name abrocitinib. PF-04965842 is an experimental drug that has not been approved for sale yet. PF-04965842 blocks the activity of a protein called "Janus kinase 1", 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 that are believed to make AD worse. The researchers wanted to ask,

- **Are patients who take PF-04965842 more likely to have their AD improve compared to patients who are treated with a placebo?**

To do this, researchers used 2 different tests to measure the severity of each patient's AD at the beginning of the study. The researchers measured the severity of AD during 12 weeks of study treatment. The difference in severity was used to decide if a patient's AD had improved or not.

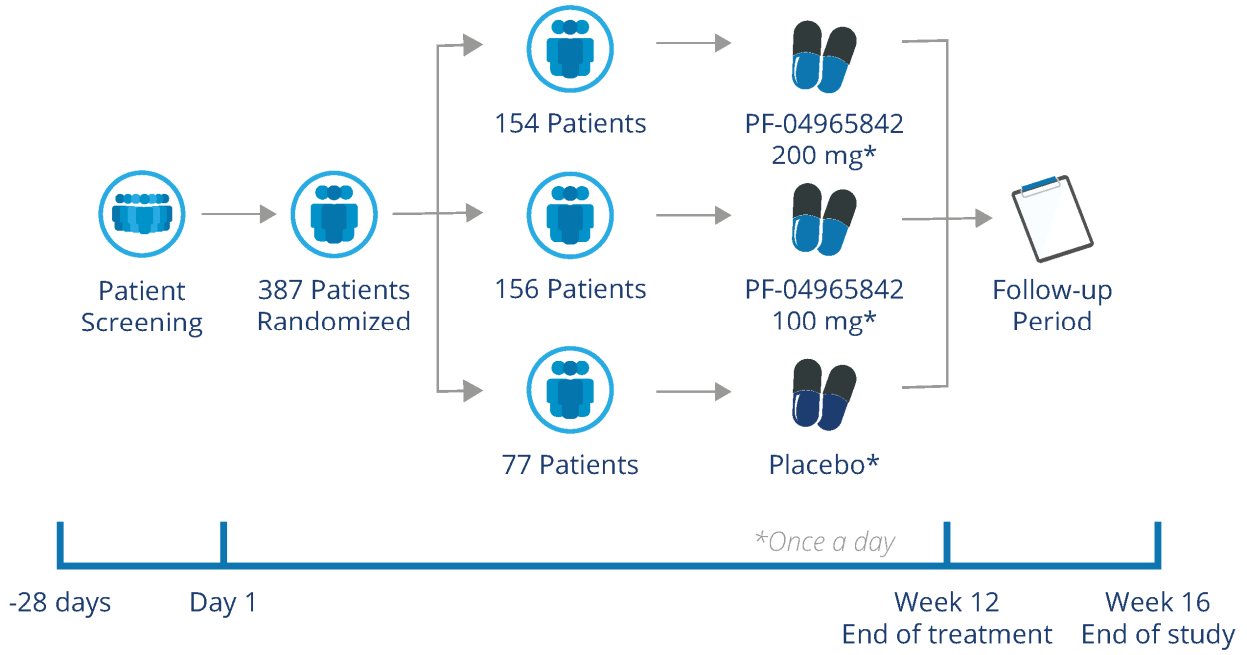
WHAT HAPPENED DURING THE STUDY?

This study compared 3 groups of patients to find out if more patients taking PF-04965842 had 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 adult men and women, and boys and girls who were aged 12 years and older. Patients included in the study:

- Had chronic (long-term) AD for at least 1 year, and had 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, and their AD did not get better;
  - Were unable to use medicines on the skin because of a medical problem;
  - Needed to use medicines that reach all parts of the body to control their AD (for example, taking medicines by mouth).

The patients and doctors did not know who took PF-04965842 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 PF-04965842 at a dose of 100 mg, PF-04965842 at a dose of 200 mg or placebo. Patients had an 80% (4 out of 5) chance of receiving PF-04965842 and a 20% (1 out of 5) chance of receiving placebo. This is known as a "randomized" study.



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 15 months to complete. The Sponsor ran this study at 69 locations in 8 countries in North America, Europe, and Australia. It began 07 December 2017 and ended 26 March 2019. A total of 167 women or girls and 220 men or boys participated. All patients were between the ages of 12 and 84.

Patients were to be treated until the end of the 12 week treatment period. Of the 387 patients who started the study, 333 finished the study. 25 patients did not finish the study because of medical problems. 13 patients left before the study was over by

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

When the study ended in March 2019 as planned, 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?

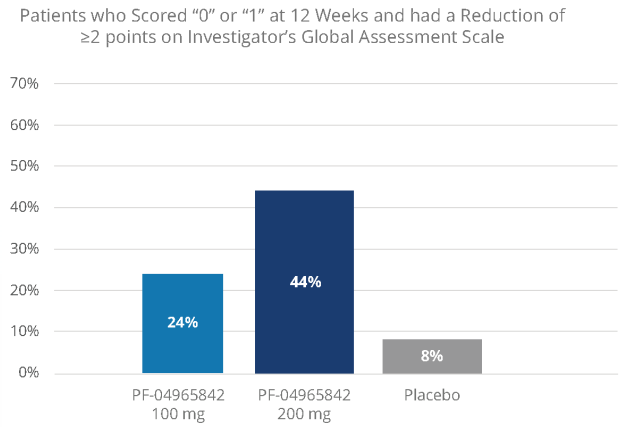
Were patients who took PF-04965842 more likely to have their AD improve compared to patients who took a placebo?

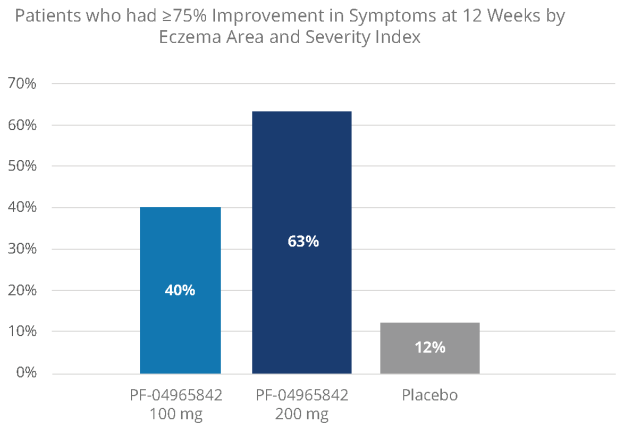
In this study, more patients in the PF-04965842 100 mg or 200 mg treatment groups had their AD improve, compared to the placebo group.

When the change in severity of AD was measured using the IGA scale, 37 out of 156 patients (24%) in the PF-04965842 100 mg treatment group and 67 out of 153 patients (44%) in the PF-04965842 200 mg treatment group had their AD improve to 'clear' or 'almost clear' (score of 0 or 1) after 12 weeks. In comparison, 6 out of 76 patients (8%) 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, 62 out of 156 patients (40%) in the PF-04965842 100 mg treatment group and 96 out of 153 patients (63%) in the PF-04965842 200 mg treatment group had their AD improve by at least 75% after 12 weeks. In comparison, 9 out of 76 patients (12%) 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. PF-04965842 may be an option for treating AD in adults and children 12 years and older.

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.

272 out of 387 patients in this study had at least 1 medical problem. A total of 25 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)

Medical Problem	PF-04965842 100 mg (156 Patients Treated)	PF-04965842 200 mg (154 Patients Treated)	Placebo (77 Patients Treated)
Common cold	23 (15%)	18 (12%)	8 (10%)
Atopic dermatitis	22 (14%)	8 (5%)	13 (17%)
Nausea	14 (9%)	31 (20%)	2 (3%)
Headache	12 (8%)	15 (10%)	2 (3%)
Nose, sinus or throat infection	11 (7%)	11 (7%)	5 (7%)
Feeling tired	6 (4%)	2 (1%)	0
Dizziness	5 (3%)	6 (4%)	1 (1%)

Throat pain	**5 (3%)**	**6 (4%)**	**0**
Stomach flu	**5 (3%)**	**3 (2%)**	**0**
Eye infection	**4 (3%)**	**4 (3%)**	**0**
Infected eczema	**4 (3%)**	**0**	**2 (3%)**
Vomiting	**4 (3%)**	**6 (4%)**	**1 (1%)**
Diarrhea	**3 (2%)**	**4 (3%)**	**2 (3%)**
Muscle protein (creatine phosphokinase) increased in the blood	**3 (2%)**	**5 (3%)**	**0**
Acne	**1 (1%)**	**4 (3%)**	**0**
Lung infection	**0**	**4 (3%)**	**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 13 patients (3%, or 3 out of 100 patients) had serious medical problems during this study. Of these, 2 patients had at least 1 serious medical problem that was possibly related to taking the medicines in the study. The serious medical problems that were reported for more than 1 patient were 2 patients who developed appendicitis (1 patient in the PF-04965842 100 mg group, and 1 patient in the placebo group) and 2 patients in the PF-04965842 200 mg group who experienced asthma. No patients died during the study.

Serious Medical Problems (Reported by More Than 1 Patient)			
Serious Medical Problem	**PF-04965842 100 mg (156 Patients Treated)**	**PF-04965842 200 mg (154 Patients Treated)**	**Placebo (77 Patients Treated)**
Appendicitis	**1 (1%)**	**0**	**1 (1%)**
Asthma	**0**	**2 (1%)**	**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 **NCT03349060**
www.clinicaltrialsregister.eu	Use the study identifier **2017-003651-29**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B7451012**

Findings from this trial, along with other trials, will be used to seek approval for using PF-04965842 to treat patients with moderate to severe AD.

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!