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: Eucrisa®/Staquis®(Crisaborole/PF-06930164)

Protocol Number: C3291001

Dates of Trial: 31 July 2017 to 4 May 2018

Title of this Trial: Crisaborole Ointment 2% Skin Biomarker Biopsy Study in Atopic Dermatitis

[A Phase 2a, Randomized, Double-Blind, Vehicle-Controlled Study, to Characterize the Mechanism of Action of Crisaborole Ointment 2%, by Evaluation of Efficacy and Changes in Skin Biomarkers, in Adult Subjects With Mild to Moderate Atopic Dermatitis, With a 4 Week Open-Label Extension]

Date of this Report: 5 February 2020

– Thank You –

Pfizer, the Sponsor, would like to thank you 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 is a common skin condition that can cause many symptoms, such as itching, redness, and a rash that is scaling or oozing. The symptoms can look different on different people. Atopic dermatitis is also known as eczema. There is no known cure for this condition. People with atopic dermatitis often have this condition for many years, and may have "flare ups", when their symptoms worsen for a time.

Researchers are looking for treatments for atopic dermatitis. Crisaborole is a medicine that is used to treat atopic dermatitis. It is applied to the skin as an ointment. Crisaborole may improve symptoms of atopic dermatitis by decreasing inflammation in the skin. Inflammation is the body's immune system response, which can lead to symptoms such as redness.

The main goal of this study was to learn more about how crisaborole works by taking skin samples to analyze for "biomarkers", which are special substances in the skin related to inflammation. Researchers wanted to answer these main questions:

- Did atopic dermatitis "biomarkers" change in areas of skin that were treated with crisaborole, compared to areas of skin that were treated with plain ointment?
- Did symptoms of atopic dermatitis improve in areas of skin that were treated with crisaborole, compared to areas of skin that were treated with plain ointment?

WHAT HAPPENED DURING THE STUDY?

This study included patients who were treated with both crisaborole and plain ointment on 2 different areas of the skin. The areas of skin were then compared to see if atopic dermatitis symptoms would improve in the areas that were treated with crisaborole.

The study included adult patients with atopic dermatitis. To join the study, patients must have had at least 2 areas of atopic dermatitis that were 3 centimeters x 3 centimeters or larger, and at least 5 centimeters apart. Symptoms must have started

at least 6 months before the study began, and must have been stable for at least 1 month.

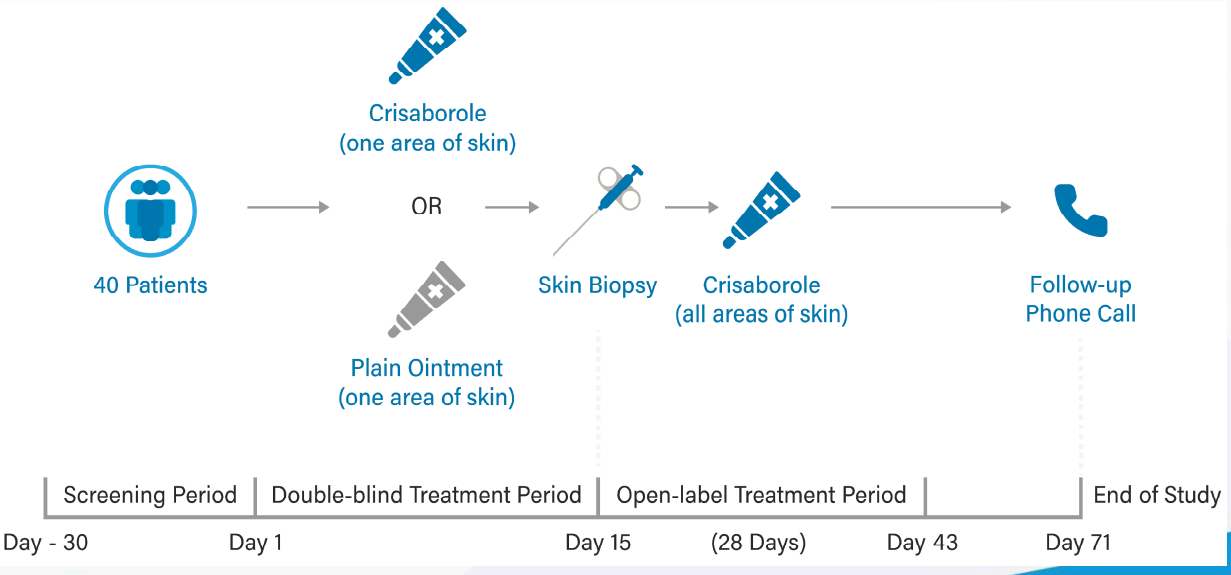
Patients were screened by the study doctor to make sure they were able to join the study. This was known as the "screening period", which lasted up to 30 days.

Patients then entered the "double-blind" treatment period, which lasted 15 days. Double-blind means that patients and doctors did not know which area of skin was treated with which medicine. This was done to make sure that the trial results were not influenced in any way. For each patient, 1 area of skin was treated with crisaborole, and 1 area of skin was treated with plain ointment. Patients came to the study center twice per day during this part of the study, so that they could receive treatment and be checked by the study doctor.

On day 15 of the study, samples of the treated skin were collected to be used for testing. Patients then entered the "open-label" treatment period, which lasted another 28 days until day 43 of the study. During this part of the study, patients stopped using the plain ointment and could use crisaborole to treat all areas of the skin affected by atopic dermatitis (except the scalp). Open-label means that patients and doctors knew which medicine was being used.

Patients received a follow-up phone call on day 71 to check for any medical problems. This was considered the end of the study.

The figure below shows what happened during this study.



While patients were only in the study for 71 days, the entire study lasted about 9 months from start to finish. The sponsor ran this study at 1 location in Canada. It began 31 July 2017 and ended 4 May 2018. A total of 13 men (33%) and 27 women (68%) participated. All patients were between the ages of 18 and 57.

Patients were expected to complete a 15-day double-blind treatment period followed by a 28-day open-label treatment period. Of the 40 patients who started the study, 38 (95%) completed the study. 2 patients (5%) did not finish the study because they had a medical problem that was not considered related to the study treatment.

When the study ended in May 2018, 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 atopic dermatitis biomarkers change in areas of skin that were treated with crisaborole, compared to areas of skin that were treated with plain ointment?

To answer this question, the researchers measured 7 skin biomarkers known to play a role in atopic dermatitis. They compared biomarkers from before patients started treatment and at day 15 of the study, after patients completed the double-blind treatment phase.

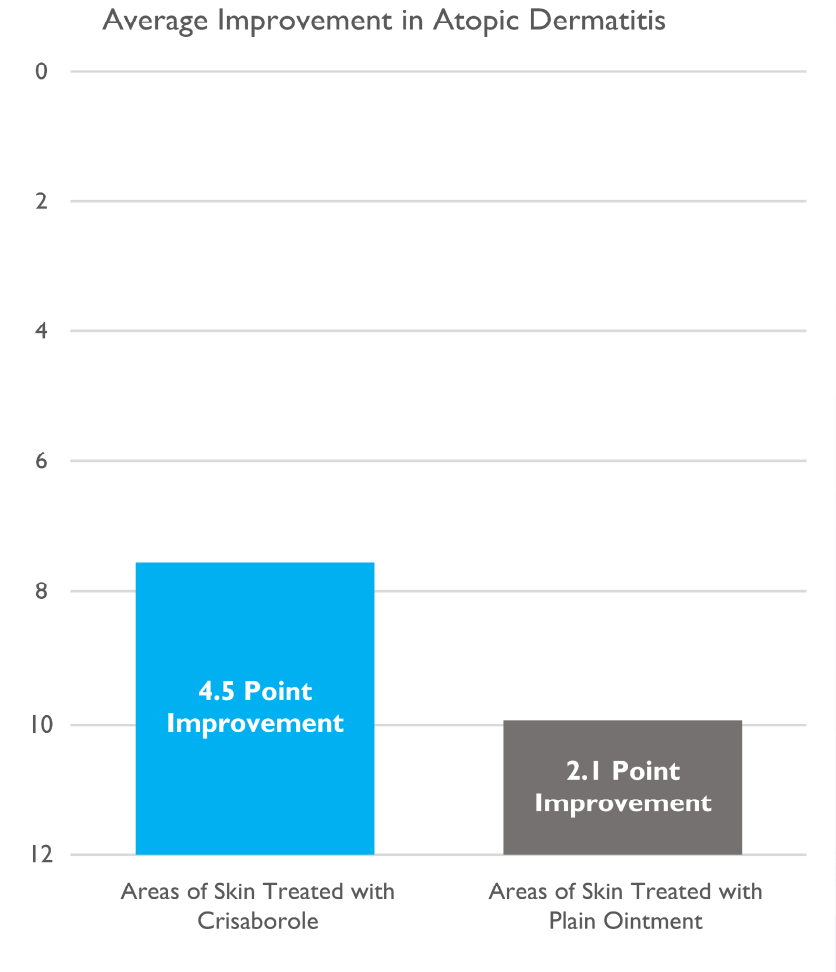
On average, all 7 biomarkers were reduced more in areas of skin treated with crisaborole compared to areas of skin treated with plain ointment. The researchers have decided that these results are not likely the result of chance. Crisaborole may reduce inflammation in skin with atopic dermatitis.

Did symptoms of atopic dermatitis improve in areas of skin that were treated with crisaborole, compared to areas of skin that were treated with plain ointment?

To answer this question, the researchers used a clinical tool to rate the severity of atopic dermatitis symptoms on a scale from 0 (no symptoms) to 12 points (most severe symptoms). They compared the severity of symptoms from before patients started treatment and at day 15 of the study, after patients completed the double-blind treatment phase.

On day 15 of the study, areas of skin treated with crisaborole improved an average of 4.5 points, and areas of skin treated with plain ointment improved an average of 2.1 points, on the scale from 0 to 12. The researchers have decided that these results are not likely the result of chance. Crisaborole may be an option for treating patients with atopic dermatitis.

The figure on the following page shows these study results.



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 PATIENTS HAVE DURING THE STUDY?

The researchers recorded any medical problems the patients had during the study. Patients 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 patient 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.

29 out of 40 (73%) patients in this study had at least 1 medical problem. A total of 2 (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 Patients)

Medical Problem	Double-Blind Treatment Period: Plain Ointment and Crisaborole (40 Patients Treated)	Open-Label Treatment Period: Crisaborole Throughout (39 Patients Treated)
Nausea	2 (5%)	0 (0%)
Pain at area of skin that study treatment was applied	4 (10%)	4 (10%)

Most Common Medical Problems (Reported by 2 or More Patients)		
Medical Problem	Double-Blind Treatment Period: Plain Ointment and Crisaborole (40 Patients Treated)	Open-Label Treatment Period: Crisaborole Throughout (39 Patients Treated)
Itching at area of skin that study treatment was applied	2 (5%)	0 (0%)
Stomach flu	0 (0%)	2 (5%)
Common cold	7 (18%)	5 (13%)
Pain from medical procedure	6 (15%)	1 (3%)
Problems related to sutures used to close a wound	4 (10%)	1 (3%)
Muscle pain	2 (5%)	0 (0%)
Headache	8 (20%)	1 (3%)
Throat pain	2 (5%)	0 (0%)
Worsening atopic dermatitis	1 (3%)	5 (13%)
Back pain	1 (3%)	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 (0%) had serious medical problems. No patients (0%) 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. The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT03233529**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **C3291001**

Findings from this trial will be used in other studies to learn whether patients are helped by crisaborole. Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

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!