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: PF-06651600 and PF-06700841

Protocol Number: B7931005

Dates of Trial: 15 December 2016 to 15 May 2019

Title of this Trial: Study to Evaluate the Efficacy and Safety of PF-06651600 and PF-06700841 to Treat Moderate to Severe Alopecia Areata in Adults

[A Phase 2a Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety Profile of PF-06651600 and PF-06700841 in Subjects With Moderate to Severe Alopecia Areata With a Single-Blind Extension Period and a Cross-Over Open Label Extension Period]

Date(s) of this Report: 22 December 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?

Alopecia areata (AA) is an autoimmune skin disease that causes hair loss ranging from small patches to a loss of all hair on the head and body. AA occurs when the immune system mistakes normal cells in the body as foreign invaders and attacks these cells. There is no cure for AA and most countries do not have an approved treatment for AA. Treatments that reduce the activity of parts of the immune system are often used to treat AA, but some of these treatments can cause other health problems or can only be used for short periods of time. Researchers are looking for new treatments for AA that can be taken safely for longer periods of time.

Two (2) drugs were tested in this study: PF-06651600 and PF-06700841. PF-06651600 and PF-06700841 are both experimental drugs that have not been approved for sale yet. PF-06651600 blocks the activity of proteins called "Janus kinase 3" and the "TEC family kinases". PF-06700841 blocks the activity of 2 other enzymes called "Janus kinase 1" and "Tyrosine-protein kinase 2". These enzymes act like on/off switches for the cells of the immune system. By turning off these switches, the cells of the immune system are expected to produce fewer cytokines, a different type of protein, that are believed to make AA worse.

The researchers wanted to know,

- **Were patients who took PF-06651600 or PF-06700841 more likely to have their AA improve compared to patients who were treated with a placebo?**

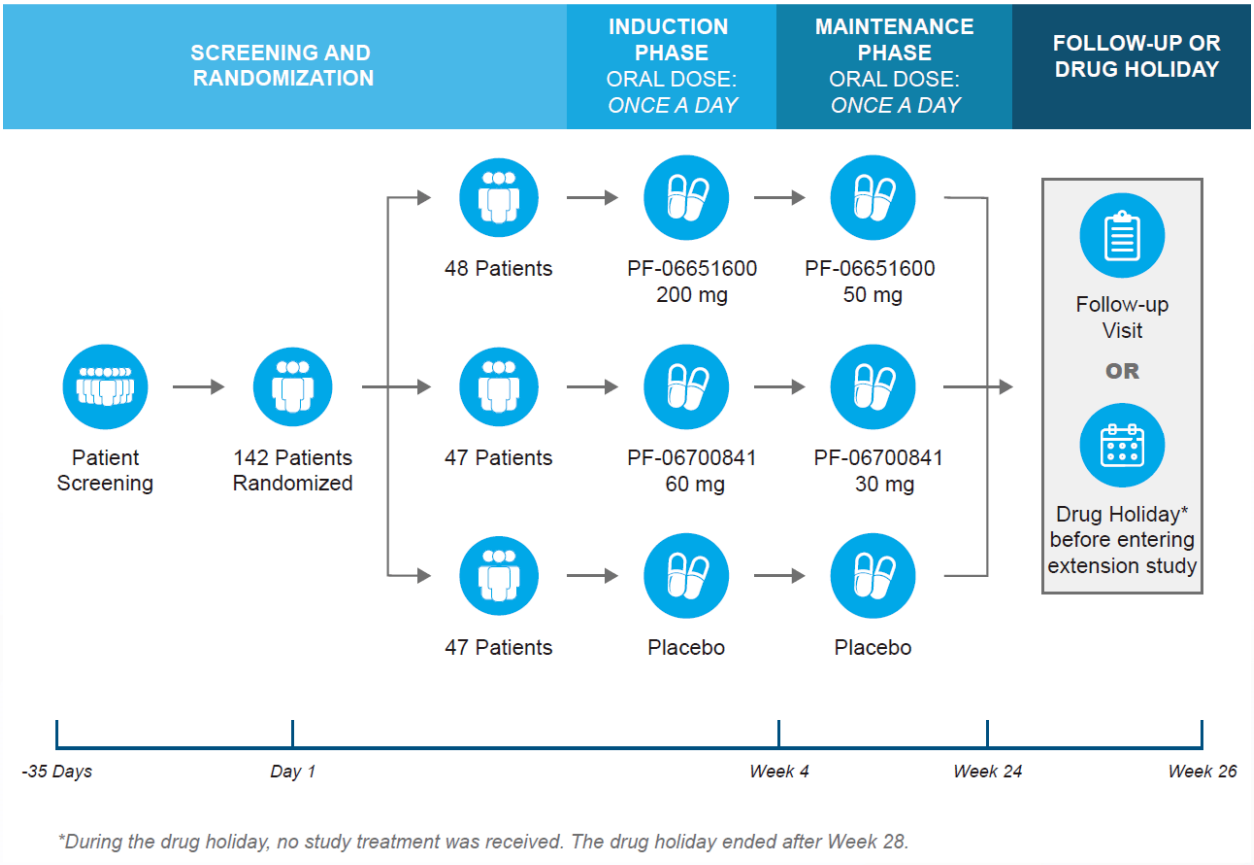
To do this, researchers measured the severity of each patient's AA at the beginning of the study. The researchers measured the severity of AA after 24 weeks of treatment. The difference in severity was used to decide if a patient's AA had improved or not.

WHAT HAPPENED DURING THE STUDY?

This study compared 3 groups of patients to find out if patients taking PF-06651600 or PF-06700841 had their AA improved compared to patients taking placebo. A placebo does not have any medicine in it, but looks just like the medicine.

The study included adult men and women who were aged 18 to 75 years. Patients included in the study had moderate to severe AA with:

- At least 50% hair loss on the scalp and no hair growing back within 6 monthsCurrent episode of hair loss started less than 7 years ago.The patients and researchers did not know who took PF-06651600, who took PF-06700841 and who took the placebo. This was done to make sure that the trial results were not influenced in any way. This is known as a "double-blinded" study. Patients were put into 1 of 3 treatment groups by chance alone (like the flip of a coin or drawing straws) to receive either PF-06651600, PF-06700841, or placebo. Patients had a 33% (1 in 3) chance of receiving PF-06651600, a 33% (1 in 3) chance of receiving PF-06700841, and a 33% (1 in 3) chance of receiving placebo in the initial 24 weeks of the treatment period. This is known as a "randomized" study. This is done to make the groups more similar. Reducing differences between the groups (like age or the number of men and women), makes the groups more even to compare.



While patients were only in the study for 24 weeks for the first part of the study, the entire study took 29 months to complete. The Sponsor ran this study at 55 locations in 3 countries in Australia and North America. It began 15 December 2016 and ended 15 May 2019. Forty-four (44) men and 98 women participated. All patients were between the ages of 18 and 68 years old.

Patients were to be treated until the end of week 24. Of the 142 patients who started the study, 114 finished the initial 24-week treatment period. 8 patients did not finish the initial 24-week treatment period because of medical problems. Twenty (20) patients stopped taking the study medication by their choice or a doctor decided it was best for a patient to stop being in the study.

When the study ended in May 2019, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

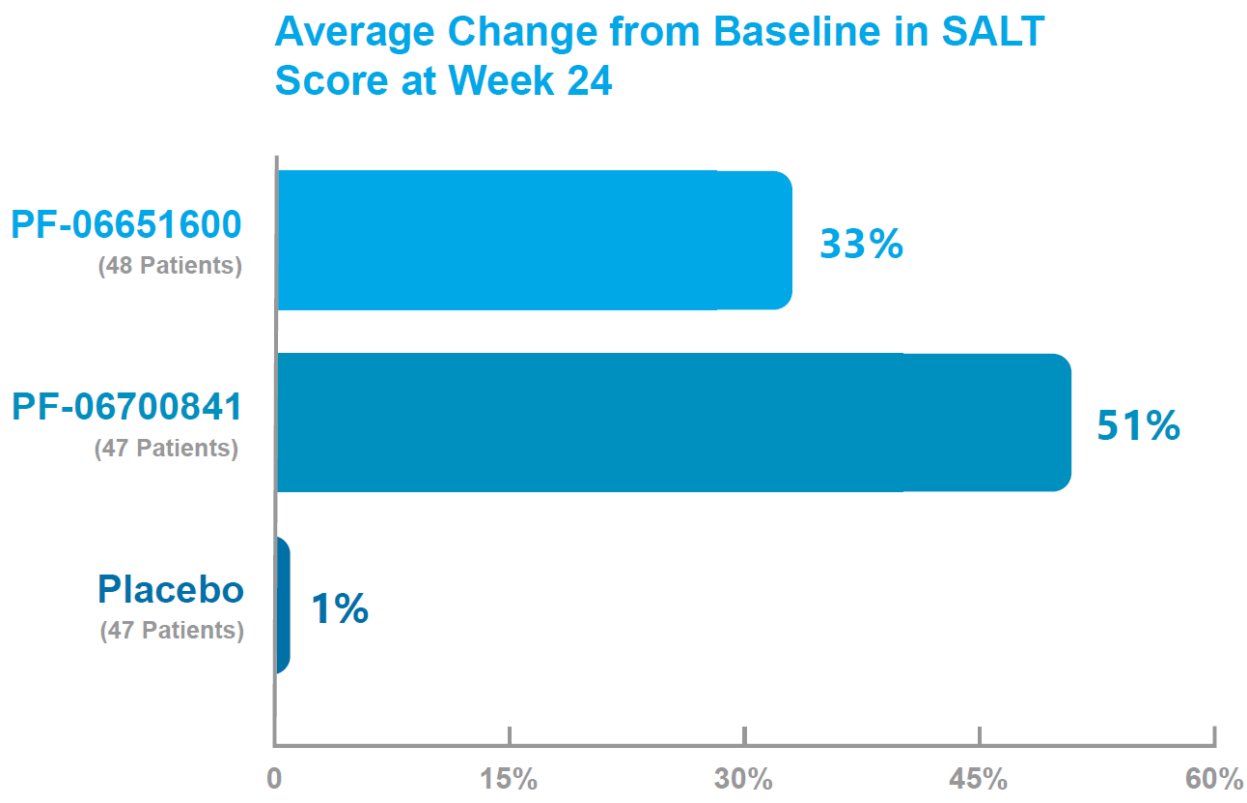
WHAT WERE THE RESULTS OF THE STUDY?

Were patients who took PF-06651600 or PF-06700841 more likely to have their AA improve compared to patients who are treated with a placebo?

In this study, change in AA severity was measured using the Severity of Alopecia Tool (SALT) Score. This score is based on how much of the hair on the scalp is missing. Researchers recorded how much hair patients were missing at the end of the study compared with how much they had right before the study. The amount of hair patients entered the study with was called the "baseline".

At the end of the 24-week treatment period, more patients both in the PF-06651600 and PF-06700841 treatment groups had their AA improved compared to patients in the placebo group.

When the change in severity of AA was measured using the Severity of Alopecia Tool (SALT) Score, patients in the PF-06651600 treatment group had an average improvement of 33% from baseline, patients in the PF-06700841 treatment group had an average improvement of 51% from baseline, and patients in the placebo group had an average improvement of 1% from baseline.



Based on these results, the researchers have decided that the results are not likely the result of chance. The test medicine may be an option for treating patient population with AA.

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 three (103) out of 142 patients in this study had at least 1 medical problem deemed related to experimental drug or placebo by doctors. A total of 4 patients left the study because of medical problems. The most common medical problems are listed below.

Most Common Medical Problems (Reported by At Least 5% of Patients)			
Medical Problem	PF-06651600 (48 Patients Treated)	PF-06700841 (47 Patients Treated)	Placebo (47 Patients Treated)
Abdominal discomfort	0	1 (2%)	4 (9%)
Abdominal pain	0	3 (6%)	0
Loose stools	4 (8%)	1 (2%)	3 (6%)
Nausea	3 (6%)	3 (6%)	5 (11%)
Feeling tired	0	0	3 (6%)
Infection of one or more of the pockets from which hair grows (follicles)	3 (6%)	1 (2%)	1 (2%)
Common cold	6 (13%)	4 (9%)	6 (13%)
Swelling of the tissues in the sinuses	0	3 (6%)	2 (4%)
Nose and throat infection	4 (8%)	11 (23%)	5 (11%)
Nose and throat infection caused by a virus	2 (4%)	3 (6%)	0
Low levels of white blood cells	0	3 (6%)	1 (2%)
Headache	6 (13%)	4 (9%)	5 (11%)

Most Common Medical Problems (Reported by At Least 5% of Patients)			
Medical Problem	PF-06651600 (48 Patients Treated)	PF-06700841 (47 Patients Treated)	Placebo (47 Patients Treated)
Throat pain	0	3 (6%)	0
Acne	5 (10%)	5 (11%)	2 (4%)
Patches of itchy skin	3 (6%)	1 (2%)	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.

Two (2) patients (1%, or 1 out of 100 patients) had serious medical problems. Both patients experienced rhabdomyolysis, or the breakdown of muscle tissue that releases a damaging protein into the blood. Both patients were in the PF-06700841 treatment group and both cases of rhabdomyolysis were considered by the doctors as not related to study medicines. No patients 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 **NCT02974868**

www.pfizer.com/research/research_clinical_trials/trial_results Use the protocol number **B7931005**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients. Further clinical trials with both PF-06651600 and PF-06700841 are planned.

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!