



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

Protocol Number: B7981006

Dates of Trial: 20 December 2016 to 12 December 2017

Title of this Trial: Study to Assess the Efficacy and Safety of PF-06651600 in Subjects with Rheumatoid Arthritis with an Inadequate Response to Methotrexate

[A Phase 2a, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety Profile of PF-06651600 in Subjects With Moderate to Severe Active Rheumatoid Arthritis With an Inadequate Response to Methotrexate]

Date of this Report: 27 April 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?

Rheumatoid arthritis, or RA, is a disease that causes swelling, pain, and stiffness in the joints. RA is an autoimmune disease, which means that patients with RA have an overactive immune system that mistakenly attacks healthy parts of the body, such as the joints. RA can cause permanent damage to the joints if it goes unchecked, so researchers are looking for new treatment options for RA.

PF-06651600 is a medicine that is being studied as a possible treatment for RA. Because it is still being tested, PF-06651600 has not been approved for use outside of research studies.

The main goal of this study was to learn more about the use of PF-06651600 in patients with RA. Researchers wanted to know:

- At week 8 of the study, did patients who received PF-06651600 show an improvement in RA, compared to patients who received placebo?

A placebo does not have any medicine in it, but looks just like the medicine. To answer this question, the researchers used a tool called the Simple Disease Activity Index (SDAI) to assess RA signs and symptoms.

WHAT HAPPENED DURING THE STUDY?

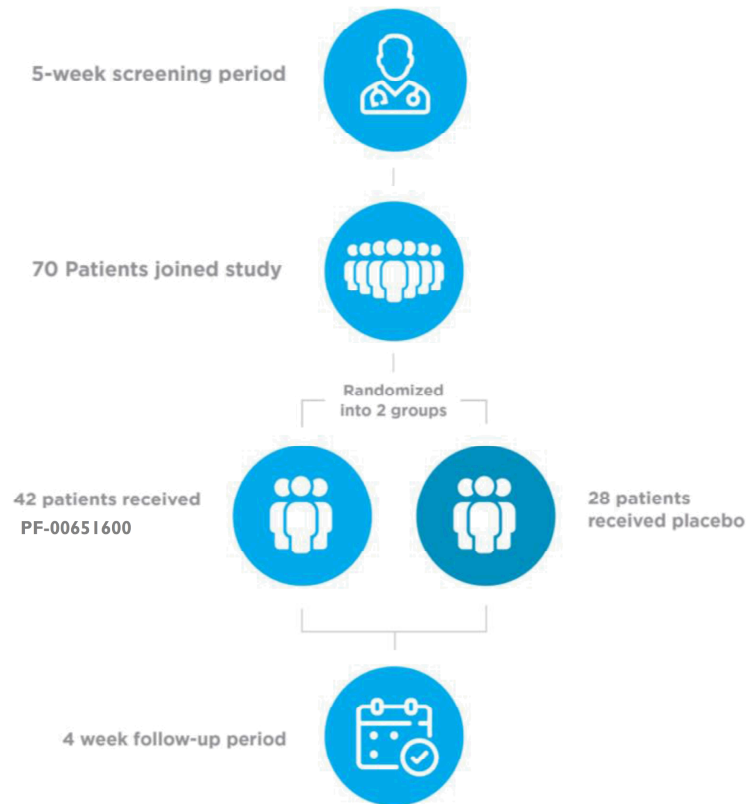
This study compared 2 groups of patients taking either PF-06651600 or placebo, to find out if they would have an improvement in RA. The study included adult patients with RA who had tried certain other RA medicines, such as methotrexate, but did not get adequate relief. The patients and researchers did not know who took PF-06651600 and who took the placebo. This is known as a “blinded” study. Patients were assigned to each group by chance alone.

First, patients were screened by the study doctor to make sure they were a good fit to join the study. This was known as the “screening period”, which lasted up to 5 weeks.

Next, patients were assigned to receive either PF-06651600 200 milligrams (mg) or placebo. The medicines were taken by mouth every day for 8 weeks. During this time, patients were to continue taking methotrexate and certain other medicines, as

prescribed by their doctor. Patients were assigned to each group by chance alone. Putting people into groups by chance helps make the groups more even to compare.

After patients completed study treatment, there was a follow-up period that lasted for 4 weeks. The figure below shows what happened during this study.



While patients were only in the study for about 12 weeks (treatment plus follow-up), the entire study took about 1 year to complete. The sponsor ran this study at 32 locations in 9 countries in Europe and North America. It began 20 December 2016 and ended 12 December 2017. 13 men (19%) and 57 women (81%) participated. All patients were between the ages of 24 and 74.

Patients were to be treated for 8 weeks then complete the 4 week follow-up period. Of the 70 patients who started the study, 59 (84%) finished it. 11 patients (16%) left

before the study was over by their choice or a doctor decided it was best for a patient to stop the study.

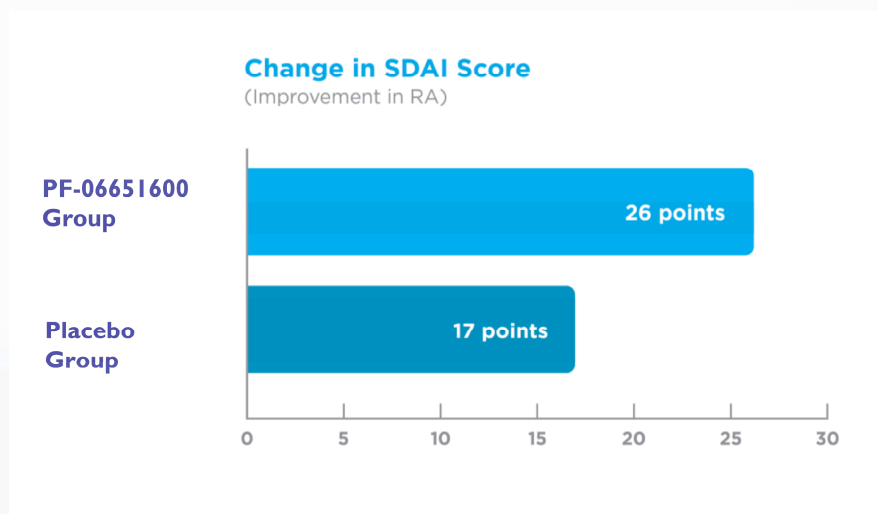
When the study ended in December 2017, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

At week 8 of the study, did patients who received PF-06651600 show an improvement in RA, compared to patients who received placebo?

To answer this question, the researchers used the SDAI to assess the patients' RA signs and symptoms. They compared the SDAI scores from before patients started treatment to after they finished treatment (week 8). On average, patients who received PF-06651600 had a change in SDAI score (improvement in RA) of about 26 points. On average, patients who received placebo had a change in SDAI score (improvement in RA) of about 17 points. The researchers have decided that these results are not likely based on chance. PF-06651600 may be an option for treating RA.

The figure below shows the results of the study.



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.

Of the 70 patients who joined the study, 25 (36%) patients had at least 1 medical problem. A total of 3 (4%) patients left the study because of medical problems. The most common medical problems are listed below.

Most Common Medical Problems (Reported by More Than 5% of Patients)		
Medical Problem	PF-06651600 (42 Patients treated)	Placebo (28 Patients treated)
Low number of a type of white blood cell (lymphopenia)	3 (7%)	0 (0%)
Flu	3 (7%)	0 (0%)
Itching	2 (5%)	1 (4%)
Headache	0 (0%)	3 (11%)

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 in this study had serious medical problems. 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 **NCT02969044**

www.clinicaltrialsregister.eu

Use the study identifier **2016-002862-30**

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!