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-06410293

Protocol Number: B5381002

Dates of Trial: 25 June 2015 to 06 December 2017

Title of this Trial: A Phase 3 Randomized, Double-Blind Study Assessing the Efficacy and Safety of PF-06410293 and Adalimumab in Combination With Methotrexate in Subjects With Moderately to Severely Active Rheumatoid Arthritis Who Have Had an Inadequate Response to Methotrexate

Date of this Report: 25 November 2019

– Thank You –

Pfizer, the Sponsor, would like to thank you for participating 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.

There are medicines that can be used to treat RA. One medicine that is approved for treatment of RA is called HUMIRA® (in this document HUMIRA® is also called adalimumab). Adalimumab may help calm the activity of the immune system and decrease RA symptoms.

PF-06410293 is a new medicine being studied for RA. PF-06410293 was made to be similar to adalimumab. The reason for making a drug that is similar to adalimumab is to help give patients access to another treatment option.

This main purpose of this study was to learn more about using PF-06410293 to treat RA, compared to adalimumab, and to determine if the 2 medicines are similar. The researchers wanted to answer this question:

- **How many patients who took PF-06410293 had at least 20% improvement in RA symptoms at week 12 of the study, compared to patients who took adalimumab?**

WHAT HAPPENED DURING THE STUDY?

This study compared 2 groups of patients to learn more about using PF-06410293 to treat RA, compared to adalimumab.

The study included adult patients with moderate to severe RA. All the patients in this study were already taking another medicine for RA called methotrexate (MTX), but still had RA symptoms.

First, the patients were screened by the study doctor to make sure they were a good fit to join the study. Next, patients were assigned to 1 of 2 treatment groups:

- 297 patients were assigned to receive PF-06410293 plus MTX
- 300 patients were assigned to receive adalimumab plus MTX

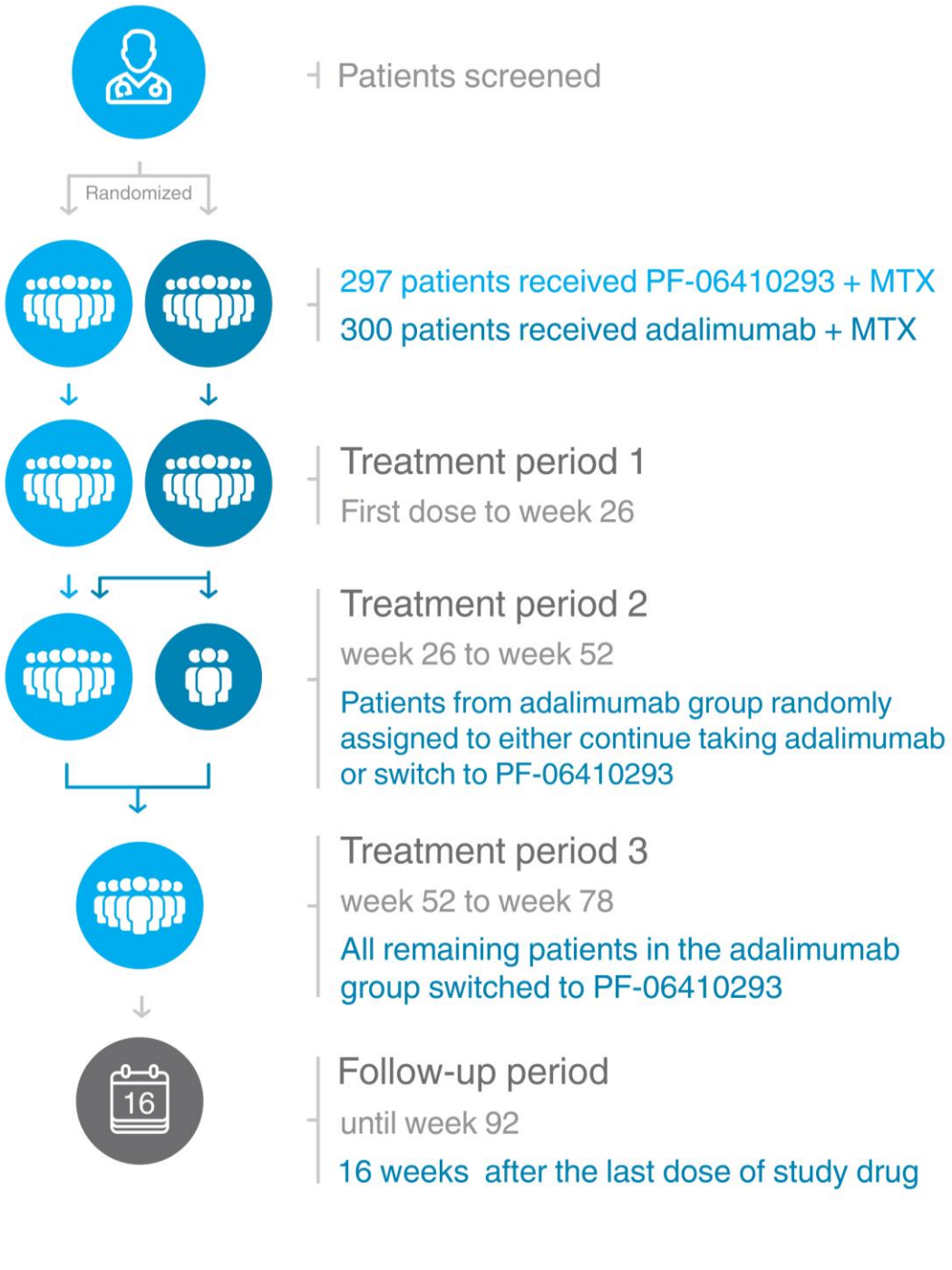
PF-06410293 and adalimumab were given as an injection under the skin. The study doctor or nurse showed the patients how to do the injection, then the patients were to give themselves the injections at home. The dose was 40 milligrams (mg) every other week. In addition, the patients were required to continue taking MTX as prescribed by the doctor.

The patients and researchers did not know who took PF-06410293 and who took adalimumab. This is known as a "blinded" study. Patients were picked for each treatment by chance alone.

There were 4 parts to this study:

- Treatment period 1 started with the first dose of study drug and ended during week 26.
- Treatment period 2 started during week 26 and ended during week 52. At the beginning of this treatment period, patients from the adalimumab group were randomly assigned to either continue taking adalimumab or switch to PF-06410293.
- Treatment period 3 started during week 52 and ended during week 78. At the beginning of this treatment period, all the remaining patients in the adalimumab group were switched to PF-06410293.
- Follow-up period for 16 weeks after the last dose of study drug.

The figure on the following page shows what happened during this study.



While patients were only in the study for up to 92 weeks (treatment plus follow-up), the entire study took about 2 ½ years to complete. Patients joined the study at 1 of 151 locations in 24 countries in Africa, Asia, Australia/New Zealand, Europe, North America, and South America. The first patient joined the study on 25 June 2015 and

the last patient finished the study on 06 December 2017. A total of 470 women and 127 men joined the study.

Patients were supposed to receive study treatment for 76 weeks and come to a follow-up visit 16 weeks later. A total of 597 patients started the study, but 1 patient did not receive study treatment. Of the 596 remaining patients, 474 (80%) completed all 3 treatment periods. 122 patients (20%) did not finish the study by their choice or because a doctor decided it was best that they leave the study.

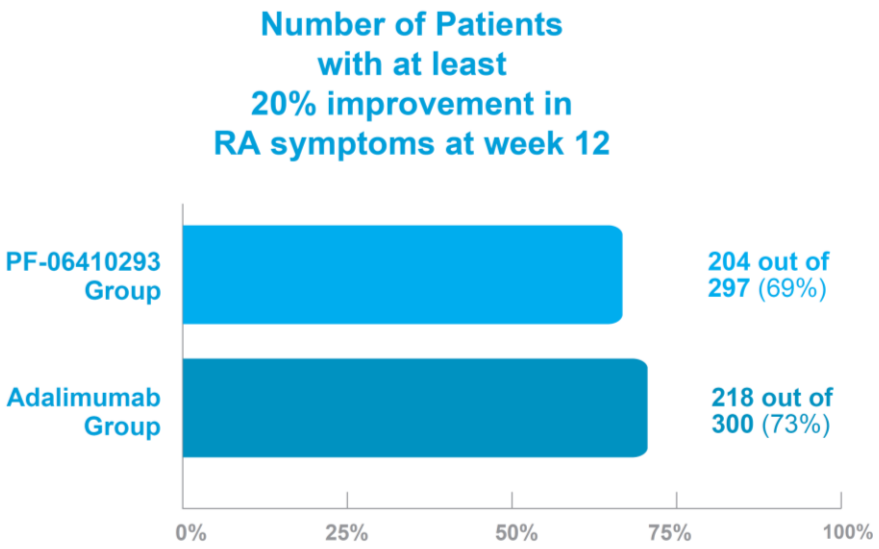
When the study ended in December 2017, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

How many patients who took PF-06410293 had at least 20% improvement in RA symptoms at week 12 of the study, compared to patients who took adalimumab?

At week 12 of the study, 204 out of 297 (69%) patients in the PF-06410293 group had at least 20% improvement in RA symptoms. At week 12 of the study, 218 out of 300 (73%) patients in the adalimumab group had at least 20% improvement in RA symptoms. These results were comparable for patients in both groups.

The chart on the following page 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 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). Medical problems could have also 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.

During treatment period 1, which included 596 patients, 279 patients (47%) had at least 1 non-serious medical problem (that means a medical problem that is not life-threatening, does not cause lasting problems, or does not need hospital care). Viral infection of the nose, throat, and upper airways happened in 39 participants (7%) during treatment period 1.

During treatment period 2, which included 551 patients, 233 patients (42%) had at least 1 non-serious medical problem (that means a medical problem that is not life-threatening, does not cause lasting problems, or does not need hospital care). Viral infection of the nose, throat, and upper airways happened in 26 patients (5%) during treatment period 2.

During treatment period 3, which included 505 patients, 215 patients (43%) had at least 1 non-serious medical problem (that means a medical problem that is not life-threatening, does not cause lasting problems, or does not need hospital care). Common cold happened in 26 patients (5%) and worsening RA happened in 28 patients (6%) during treatment period 3.

Over the 3 treatment periods, a total of 31 patients (5%) left the study because of medical problems.

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

During treatment period 1, 25 patients (4%) had a serious medical problem. During treatment period 2, 13 patients (2%) had a serious medical problem. During treatment period 3, 21 patients (4%) had a serious medical problem.

2 participants passed away during this study. The study doctors determined that one of deaths was related to the study drug, and one of the deaths was not related to the study drug.

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 **NCT02480153**
www.clinicaltrialsregister.eu	Use the study identifier **2014-000352-29**

Please remember that researchers look at the results of many studies to find out which medicines work best and are safest 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!