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-06372865

Protocol Number: B7431005

Dates of Trial: 16 December 2015 to 07 February 2017

Title of this Trial: A Double Blind, Randomized, Cross-Over Study Examining Efficacy of PF-06372865 in a Photosensitivity Epilepsy Study Using Lorazepam as a Positive Control

Date of this Report: 15 April 2018

– 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?

A seizure is a sudden increase in electrical activity in the brain. Seizures can cause many different symptoms, such as shaking, feeling confused, or losing control of your body. In some patients, seizures can be triggered by bright lights or patterns. The name for this is "photosensitive epilepsy".

More than 2 million people in the United States have had a seizure. Seizure medications can cause unwanted side effects, and they may not work well for all patients. Therefore, researchers are interested in finding new treatment options for epilepsy (seizures). PF-06372865 is a new drug that is being tested in patients with photosensitive epilepsy. It has not been approved for sale.

Doctors use a machine called an "EEG" to look at electrical activity in the brain. Patients with photosensitive epilepsy may have changes on their EEG when they are shown flashing lights, and these changes are known as "epileptic activity". For this study, researchers wanted to answer the question:

- Would PF-06372865 reduce epileptic activity on EEG in patients with photosensitive epilepsy, compared to Lorazepam or placebo?

Lorazepam is a drug that has already been shown to reduce epileptic activity. A placebo does not have any medicine in it, but looks just like the medicine. Researchers use a placebo to decide if the study drug works better than no treatment at all.

WHAT HAPPENED DURING THE STUDY?

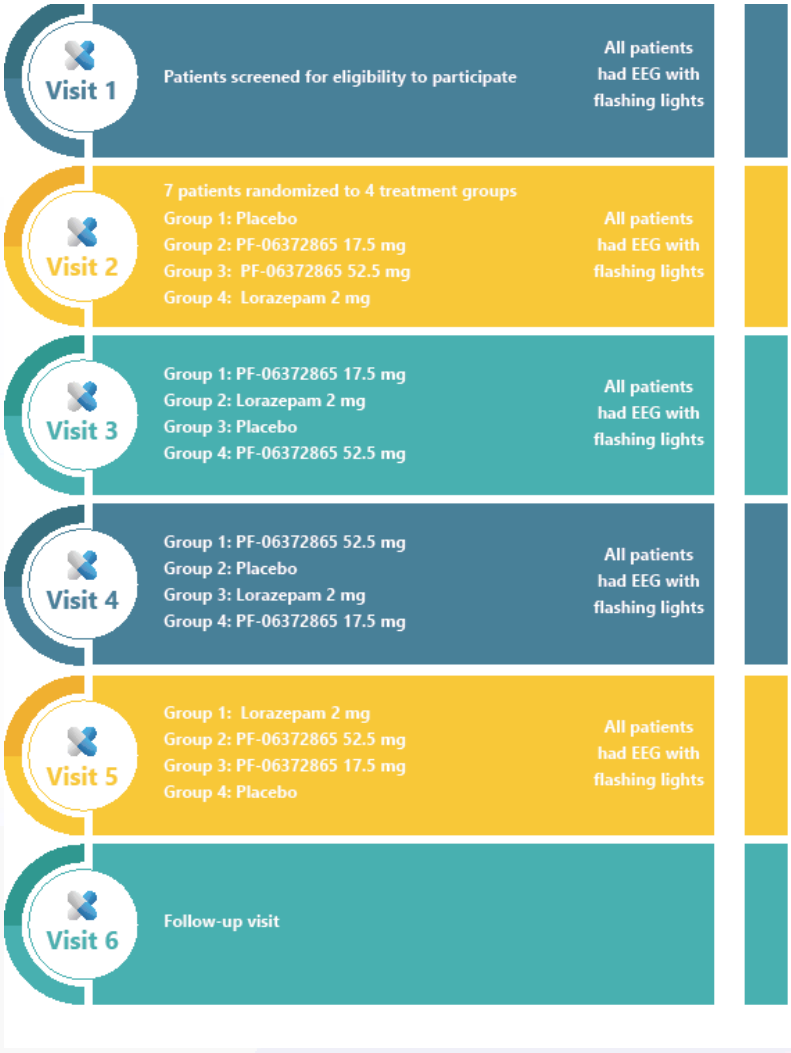
Each patient took 4 different medications over the course of the study. The medications were PF-06372865 17.5 milligrams (mg), PF-06372865 52.5 mg, Lorazepam 2 mg, and placebo. The medications were all taken by the mouth.

The study included 7 patients who had already been diagnosed with photosensitive epilepsy. The patients and researchers did not know the order in which each patient took the medications. This is called a "double-blind study", and it is used to make sure that the results are not influenced by knowing the order in which each patient received the medications. The order in which patients took the medications was

picked by chance alone, which is known as a "randomized study". Researchers use this type of study to make the groups more even to compare.

While patients were only in the study for about 19 weeks, the entire study took more than 2 years to complete. Patients joined the study at 5 locations in the United States. It began 16 December 2015 and ended 07 February 2017. A total of 2 men and 5 women participated. All patients were between the ages of 18 and 39 years old.

Patients were supposed to come to the study center for 6 visits. On visits 1 through 5, patients had EEG electrodes (pads) placed on their head. They were given an EEG and shown flashing lights for about 20 minutes. On visits 2 through 5, patients took study medications and had the EEG with flashing lights 4 more times. Flashing lights have the risk of causing a seizure, so researchers tried to stop the test before a seizure happened. No patients had a seizure during the test.



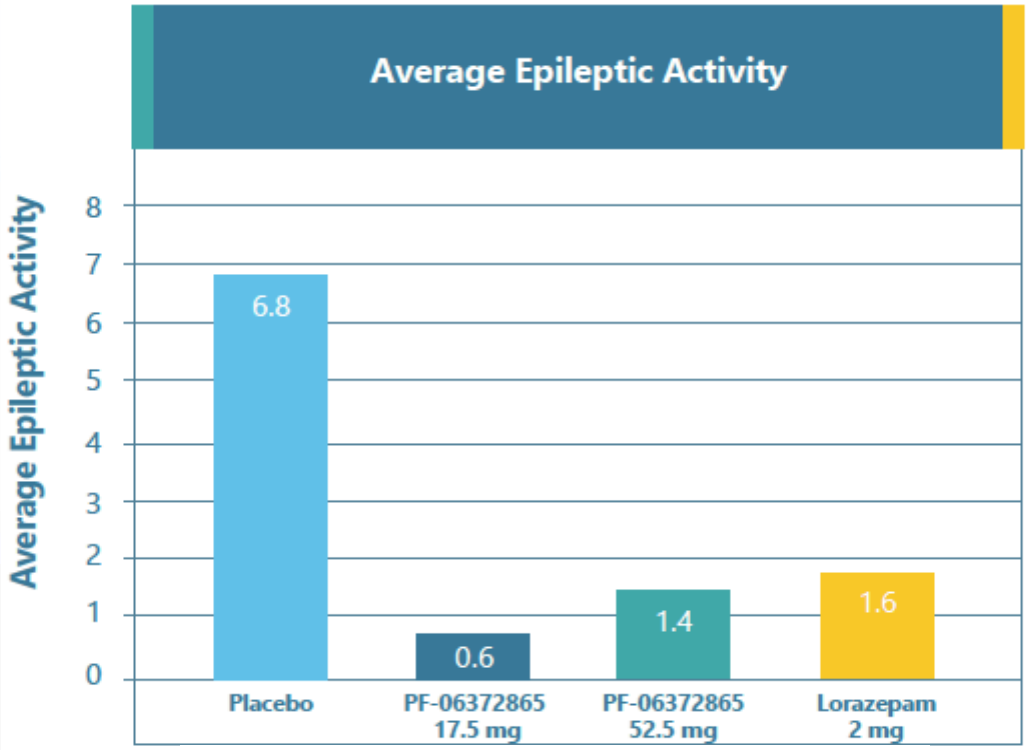
All 7 patients who started the study finished it. When the study ended in February 2017, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

Did PF-06372865 reduce epileptic activity on EEG?

Yes. Both PF-06372865 17.5 mg and PF-06372865 52.5 mg reduced epileptic activity on EEG. In this study, both doses were shown to have a greater reduction on epileptic activity than placebo. Lorazepam 2 mg also had a greater reduction on epileptic activity than placebo. The researchers concluded that these results were not likely due to chance.

While the results of the study showed that PF-06372865 17.5 mg, PF-06372865 52.5 mg, and Lorazepam 2 mg all reduced epileptic activity on EEG, the results did not show that any one of these medications worked better than the others. The graph below shows the results of this study. In this graph, the smaller the number, the better the epileptic activity.



*In this graph, the smaller the number, the better the epileptic activity

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, 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.

No patients left the study due to medical problems. Most of the patients in this study had at least 1 non-serious medical problem. Four (4) patients had a medical problem after taking placebo, 6 patients had a medical problem after taking PF-06372865 17.5 mg, 6 patients had a medical problem after taking PF-06372865 52.5 mg, and 5 patients had a medical problem after taking Lorazepam. The non-serious medical problems are listed below.

Non-Serious Medical Problems (Reported by More Than 5% of Patients)

Medical Problem	PF-06372865 17.5 mg (7 Patients Treated)	PF-06372865 52.5 mg (7 Patients Treated)	Lorazepam 2 mg (7 Patients Treated)	Placebo (7 Patients Treated)
Blurred vision	0 (0%)	1 (14%)	0 (0%)	0 (0%)
Stomach pain	0 (0%)	0 (0%)	0 (0%)	1 (14%)
Nausea	0 (0%)	1 (14%)	0 (0%)	1 (14%)
Vomiting	1 (14%)	1 (14%)	0 (0%)	1 (14%)
Feeling tired	0 (0%)	0 (0%)	1 (14%)	0 (0%)
Feeling hot	1 (14%)	0 (0%)	0 (0%)	0 (0%)

General pain	0 (0%)	1 (14%)	0 (0%)	0 (0%)
Sore throat	1 (14%)	1 (14%)	0 (0%)	0 (0%)
Nose and throat infection	0 (0%)	0 (0%)	1 (14%)	1 (14%)
Muscle weakness	0 (0%)	1 (14%)	0 (0%)	0 (0%)
Feeling unsteady	0 (0%)	1 (14%)	0 (0%)	0 (0%)
Trouble paying attention	1 (14%)	1 (14%)	0 (0%)	1 (14%)
Feeling dizzy	3 (43%)	3 (43%)	1 (14%)	0 (0%)
Trouble speaking	1 (14%)	0 (0%)	0 (0%)	0 (0%)
Bad taste in mouth	1 (14%)	0 (0%)	0 (0%)	0 (0%)
Headache	1 (14%)	1 (14%)	0 (0%)	0 (0%)
No energy	1 (14%)	0 (0%)	0 (0%)	0 (0%)
Feeling drowsy	3 (43%)	4 (57%)	3 (43%)	3 (43%)
Feeling unusually happy	0 (0%)	1 (14%)	1 (14%)	0 (0%)
Feeling irritable	1 (14%)	0 (0%)	0 (0%)	0 (0%)
Throat pain	0 (0%)	0 (0%)	1 (14%)	0 (0%)
Runny nose	0 (0%)	0 (0%)	1 (14%)	0 (0%)
Itchy rash	0 (0%)	1 (14%)	0 (0%)	0 (0%)

*The numbers in this chart indicate the number and percentage of patients who had a non-serious medical problem.

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

A medical problem is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care. No patients in this study had a serious medical problem. 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.

For more details on this study protocol, please visit:

www.clinicaltrials.gov Use the study identifier **NCT02564029**

Please remember that researchers look at the results of many studies to find out which medicines work best and are safest for patients. There are no further studies planned for this study drug.

Again, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us do that!