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: Vizimpro® (dacomitinib)

Protocol Number: A7471058

Dates of Trial: 05 April 2019 to 24 October 2019

Title of this Trial: Study Looking at Safety of Dacomitinib and How it Works in the Body in People with Livers that Do Not Work Properly [A Phase 1, Open-Label, Single-Dose, Parallel-Group Study to Evaluate the Plasma Pharmacokinetics and Safety of Dacomitinib in Participants With Severely Impaired Hepatic Function Relative to Participants With Normal Hepatic Function]

Date(s) of this Report: 03 November 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?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. In some patients with NSCLC, the patient's liver may not work properly. Doctors often describe this as "hepatic impairment". Hepatic is a Latin word for things that are related to the liver and impairment means something that is not working properly. The liver is a large organ in the body that has many different jobs including cleaning the blood and making different proteins and chemicals, as well as acting as a store for other chemicals and energy. If the liver is not working properly, it can mean a patient is not able to take certain types of drugs. This is because the drug could build up in the body and cause medical problems or that not enough drug is able to get into the blood to treat the patient's disease.

Dacomitinib (Vizimpro®) is a medicine that has been approved in the United States, Japan and the European Union as treatment for patients with a certain type of advanced NSCLC that is known as epithelial growth factor receptor positive (EGFR+). Advanced NSCLC means the lung cancer has spread to other parts of the body. EGFR+ means the tumor has a mutation (or change) in the gene that makes EGFR proteins. These are proteins on the surface of cells that can stimulate cancer cells to grow and multiply. Dacomitinib works by blocking the activity of a group of proteins called the human epidermal growth factor receptor (HER) family that including EGFR (also known as HER1, HER2, and HER4) in patients who are EGFR+. By blocking the activity of these proteins dacomitinib may be able to help limit the growth and spread of cancer cells. Dacomitinib is given as a tablet once a day to be taken by mouth.

The researchers wanted to know what could happen to dacomitinib in the blood of participants with severe hepatic impairment (e.g., a liver that is hardly working). They also wanted to know if severe hepatic impairment altered how quickly dacomitinib got into the blood and if the amount of drug in the blood changed.

To answer this question, the researchers collected blood samples over several days from participants with severe hepatic impairment and from participants with no hepatic impairment (e.g., livers that were working properly). The researchers then measured the amount of dacomitinib in the samples to see if it was different in participants with severe hepatic impairment compared to participants with properly working livers. As food can change how long it takes a drug to reach the blood, this study looked at what happened to dacomitinib in the blood of participants who had not eaten for at least 10 hours. By doing this, the researchers knew that the food the participant had eaten previously was unlikely to change how much dacomitinib got into the blood and how quickly this happened.

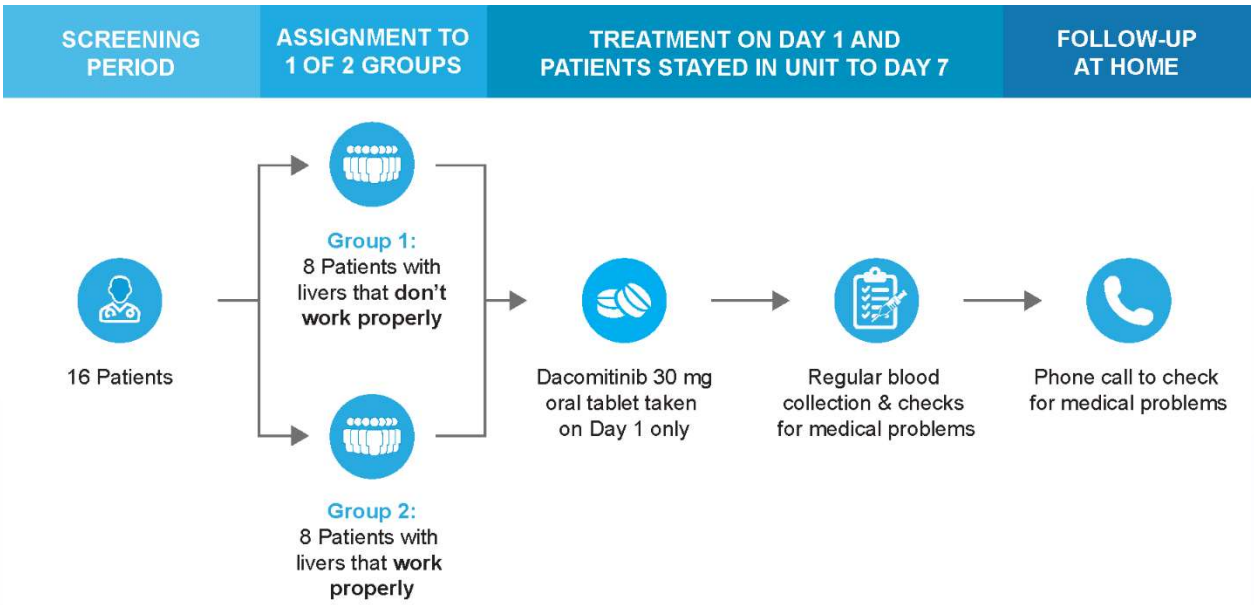
WHAT HAPPENED DURING THE STUDY?

This study compared 2 groups of participants to find out what happens to dacomitinib in the body of participants who have severe hepatic impairment compared to participants with no hepatic impairment.

The study included adult participants who weighed more than 50 kg (110 lb) with severe hepatic impairment or with no hepatic impairment.

Participants were put into 1 of 2 treatment groups according to how well their liver was working. Participants with severe hepatic impairment joined the study first and patients with no hepatic impairment joined afterwards. The researchers tried to match the 2 groups so that the average age and average body weight of each group were similar. This meant the 2 groups were similar except for how well their livers were working.

All participants in the study took dacomitinib.



While participants were only in the study for 8 days (i.e., from the day before treatment until 7 days after treatment), the entire study took just over 6 months to complete. The Sponsor ran this study at 2 locations in the US. It began 05 April 2019 and ended 24 October 2019. 16 men participated and all were between the ages of 52 and 68 years.

Participants were admitted to the study unit the day before they were treated and had to stay overnight and not to eat during this time. This meant that when they were treated with a single dose of 30 mg dacomitinib they had not eaten for more than 10 hours. Participants were then asked to stay in the study unit for 7 days. Blood samples were taken during this time and they were asked how they felt. Of the 16 patients who started the study, all finished the study.

When the study ended in October 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?

Does dacomitinib get into the blood differently in participants when they have severe hepatic impairment?

In participants with severe hepatic impairment, the highest levels of dacomitinib were seen in the blood around 7 hours after they took a single dose of dacomitinib. In participants with no hepatic impairment, dacomitinib levels were highest around 12 hours after dosing.

The highest level of dacomitinib in the blood was almost a third higher in participants with severe hepatic impairment compared to participants with no hepatic impairment. The overall amount of dacomitinib in the blood of participants with severe hepatic impairment was, however, similar to the overall amount of dacomitinib in the blood of participants with no hepatic impairment.

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 website 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.

None of the 16 participants in this study had any medical problems and none 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.

There were no serious medical problems in this study. No participants 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 your study protocol, please visit:

www.clinicaltrials.gov Use the study identifier **NCT03865446**

Clinical trials with dacomitinib are ongoing.

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!