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-06439535

Protocol Number: B7391003

Dates of Trial: 20 April 2015 to 22 December 2017

Title of this Trial: A Phase 3 Randomized, Double-Blind Study of PF-06439535 Plus Paclitaxel-Carboplatin and Bevacizumab Plus Paclitaxel-Carboplatin for the First-Line Treatment of Patients With Advanced Non-Squamous Non-Small Cell Lung Cancer

Date of this Report: 19 February 2019

– 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?

Lung cancer is the name for cancer that starts in the lungs. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer.

Avastin® is one medicine that is currently used to treat NSCLC. Avastin may stop cancer tumors from growing. PF-06439535 is a medicine that is made to be similar to Avastin, and is being studied as a possible treatment for many cancers. In this specific study, Avastin was studied for NSCLC. The purpose of making a medicine similar to Avastin is to give patients another treatment option.

A committee of doctors have reviewed the data and recommended that PF-06439535 be approved for use in Europe. PF-06439535 is still being tested and has not been approved for use in other regions.

The main goal of this study was to determine if PF-06439535 works in a similar way to Avastin. Patients in this study also received 2 other medicines for NSCLC, called paclitaxel and carboplatin. Researchers wanted to know:

- At week 19 of the study, how many patients who took PF-06439535 would have a reduction in tumor size (tumor getting smaller), compared to patients who took Avastin?

WHAT HAPPENED DURING THE STUDY?

This study compared 2 groups of patients taking either PF-06439535 plus paclitaxel and carboplatin or Avastin plus paclitaxel and carboplatin, to determine if PF-06439535 works in a similar way to Avastin. The study included adult patients with either newly diagnosed or recurring NSCLC. For patients with recurring NSCLC, the last systemic treatment (a treatment that affects the whole body) should have been received at least 6 months ago. The patients and researchers did not know who took which medicines. This is known as a "blinded" study.

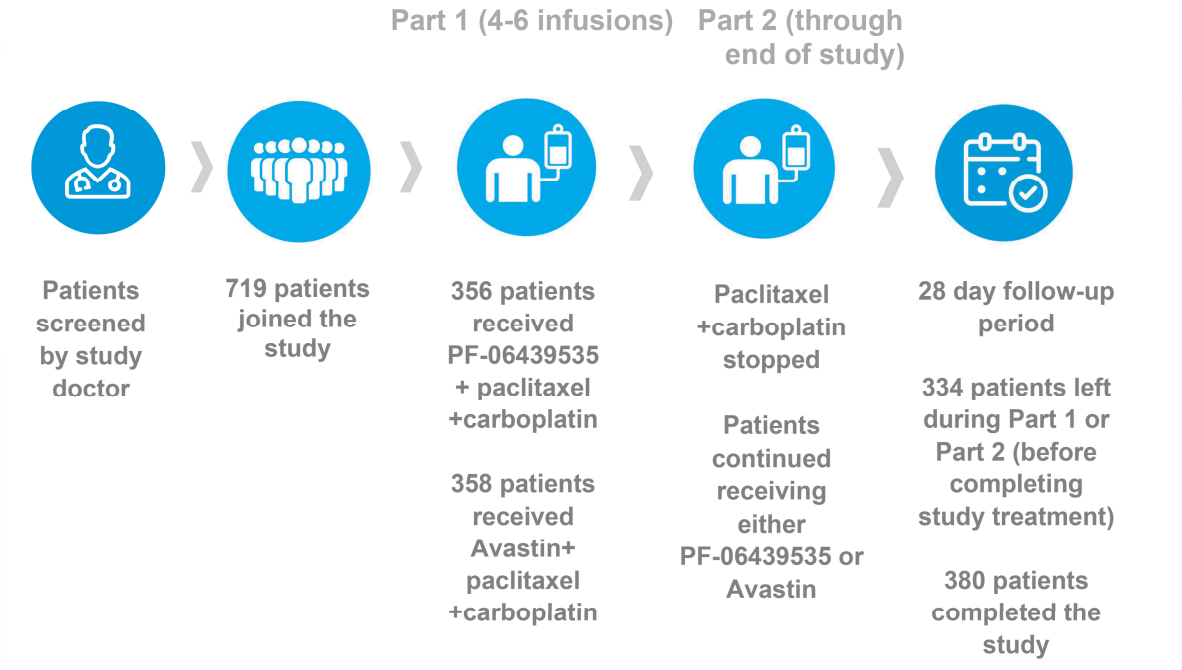
Patients were screened by the study doctor to make sure they were a good fit to join the study. This was known as the "screening period", which lasted up to 28 days. Next, patients were assigned to receive either PF-06439535 plus paclitaxel and

carboplatin or Avastin plus paclitaxel and carboplatin. Patients were assigned to each group by chance alone. Putting people into groups by chance helps to make the groups more even to compare.

The medicines were given by IV infusion (a needle into the vein). During the first part of this study, patients received 4 to 6 infusions of either PF-06439535 plus paclitaxel and carboplatin or Avastin plus paclitaxel and carboplatin. The infusions were given once every 21 days.

During the second part of this study, paclitaxel and carboplatin were stopped, and the infusions included only PF-06439535 or Avastin. This lasted until the end of the study. Finally, there was a follow-up period, which lasted for 28 days after the patients finished taking study treatment.

The figure below shows what happened during this study.



Patients were considered to have completed the study at 1 year, although some patients were in the study longer than 1 year. The entire study took more than 2 ½ years to complete. The sponsor ran this study at 216 locations in Africa, Asia,

Australia, Europe, North America, and South America (however, no patients joined the study at 57 of these locations). It began 20 April 2015 and ended 22 December 2017. 467 men (65%) and 252 women (35%) participated. All patients were between the ages of 25 and 87.

Patients were to be treated for 1 year and complete the 28 day follow-up period. A total of 719 patients joined the study, but only 714 received study treatment. Of these 714 patients, 380 (53%) finished the study. There were 334 patients who left before the study was over by their choice or a doctor decided it was best for a patient to stop the study, or because they passed away.

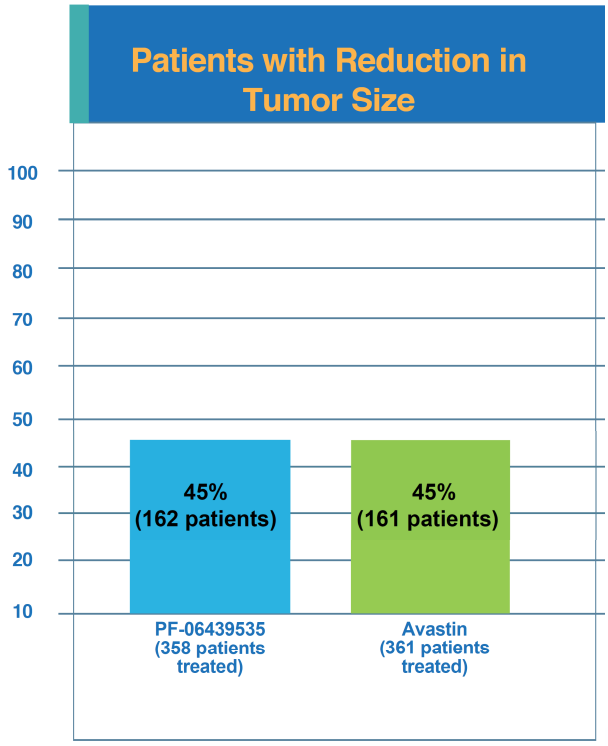
When the study ended in December 2017, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

At week 19 of the study, how many patients who took PF-06439535 had a reduction in tumor size, compared to patients who took Avastin?

At week 19 of the study, 162 patients (45%) in the PF-06439535 group had a reduction in tumor size. 161 patients (45%) in the Avastin group had a reduction in tumor size. The researchers have decided that these results are not likely based on chance. PF-06439535 may work in a similar way to Avastin, and may be an option for treating NSCLC.

The figure 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 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 714 patients who received study treatment, 661 (93%) patients had at least 1 medical problem. A total of 171 (24%) 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-06439535 (356 Patients treated)	Avastin (358 Patients treated)
Hair loss	166 (47%)	165 (46%)
Low number of red blood cells	102 (29%)	106 (30%)
Feeling tired	73 (21%)	71 (20%)
Nausea	71 (20%)	69 (19%)
High blood pressure	60 (17%)	62 (17%)
Low number of a certain type of white blood cells (neutrophils)	59 (17%)	66 (18%)
Low number of platelets in the blood	55 (15%)	66 (18%)
Muscle pain	54 (15%)	49 (14%)
Weakness, numbness, or pain caused by nerve damage	53 (15%)	65 (18%)
Low appetite	48 (14%)	46 (13%)
Diarrhea	46 (13%)	48 (13%)
Feeling weak	46 (13%)	43 (12%)
Vomiting	41 (12%)	33 (9%)
Cough	41 (12%)	47 (13%)
Joint pain	40 (11%)	43 (12%)
Burning or prickling feeling caused by nerve damage	40 (11%)	31 (9%)
Nosebleed	40 (11%)	32 (9%)

Most Common Medical Problems (Reported by More Than 5% of Patients)		
Medical Problem	PF-06439535 (356 Patients treated)	Avastin (358 Patients treated)
Constipation	39 (11%)	27 (8%)
Weakness, numbness, or pain caused by damage to the peripheral sensory nerves	34 (10%)	46 (13%)
Trouble breathing	32 (9%)	35 (10%)
Headache	30 (8%)	37 (10%)
Abnormal level of protein in urine	28 (8%)	34 (10%)
Low number of white blood cells	26 (7%)	30 (8%)
Bone pain	25 (7%)	23 (6%)
Fever	24 (7%)	23 (6%)
Damage to multiple nerves	23 (7%)	19 (5%)
Reaction to IV infusion	19 (5%)	22 (6%)
Pain in hands or feet	16 (5%)	23 (6%)
Rash	9 (3%)	21 (6%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

A total of 161 out of 714 patients (23%) who received study treatment had serious medical problems, including 81 patients (23%) in the PF-06439535 group and 80 patients (22%) in the Avastin group.

A total of 45 patients died during the study, including 21 patients (6%) in the PF-06439535 group and 24 patients (7%) in the Avastin group. Most of these deaths were due to NSCLC, but study doctors determined that 6 of these deaths were related to study treatment.

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 **NCT02364999**
www.clinicaltrialsregister.eu	Use the study identifier **2014-003878-16**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients. Future studies with PF-06439535 are being 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!