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-06647020

Protocol Number: B7661001

Dates of Trial: 17 October 2014 to 05 November 2019

Title of this Trial: A Study Of PF-06647020 For Adult Patients With Advanced Solid Tumors
[A First-in-Human Phase 1, Dose Escalation, Safety and Pharmacokinetic Study of PF-06647020 in Adult Patients With Advanced Solid Tumors]

Date(s) of this Report: 27 Oct 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?

Chemotherapy is often used to treat cancer, but not all patients' cancer gets better with treatment. The drugs used for chemotherapy can kill healthy cells in a patient's body along with the cancer cells, which can cause serious medical problems. Researchers are looking for new ways to treat cancer by directing chemotherapy drugs to cancer cells while leaving healthy cells alone.

PF-06647020 is a new investigational drug being studied to treat patients with cancer. An investigational drug is one that is currently not approved for sale in this country. PF-06647020 is a type of medicine called an "antibody-drug conjugate". An antibody-drug conjugate is made up of an antibody with a toxic agent chemically attached to it. Antibodies are special proteins made by the immune system that recognize and stick to specific proteins on the surface of germs or cells. The antibody part of PF-06647020 recognizes a protein called PTK7, which is found in larger amounts on certain cancer cells when compared to healthy tissue. Researchers think that PF-06647020 will deliver the toxic agent directly to cancer cells, slowing their growth and causing the cells to die.

The main purpose of this Phase 1 study was to learn more about the safety of PF 06647020, and to find the best dose of PF-06647020 to use to treat cancer in Phase 2 trials. To do this, the researchers asked,

- **What medical problems did patients have while taking PF-06647020?**
- **What dose-limiting toxicities, or "DLTs", did patients have when taking PF-06647020?**

  DLTs are certain medical problems caused by taking PF-06647020 which require the patient to lower the dose or stop taking the medicine temporarily or permanently.

The researchers also wanted to know if any of the patients' cancer got better during the study. To do this, they measured many things, including the "Clinical Response Rate". This was the percentage of patients whose cancer stayed the same or got better during 6 or more cycles of treatment.

WHAT HAPPENED DURING THE STUDY?

In the beginning of the study, patients were treated with PF-06647020 once every 3 weeks (or the "Q3W regimen"). Later on in the study, patients were treated with PF-06647020 once every 2 weeks (or the "Q2W regimen"). This was an "open-label" study, which means that the patients and doctors knew what the patients were being treated with.

The study included patients ≥ 18 years old who met the following conditions:

For all study patients:

- Had adequate kidney, liver, and bone marrow function

For the Q3W regimen:

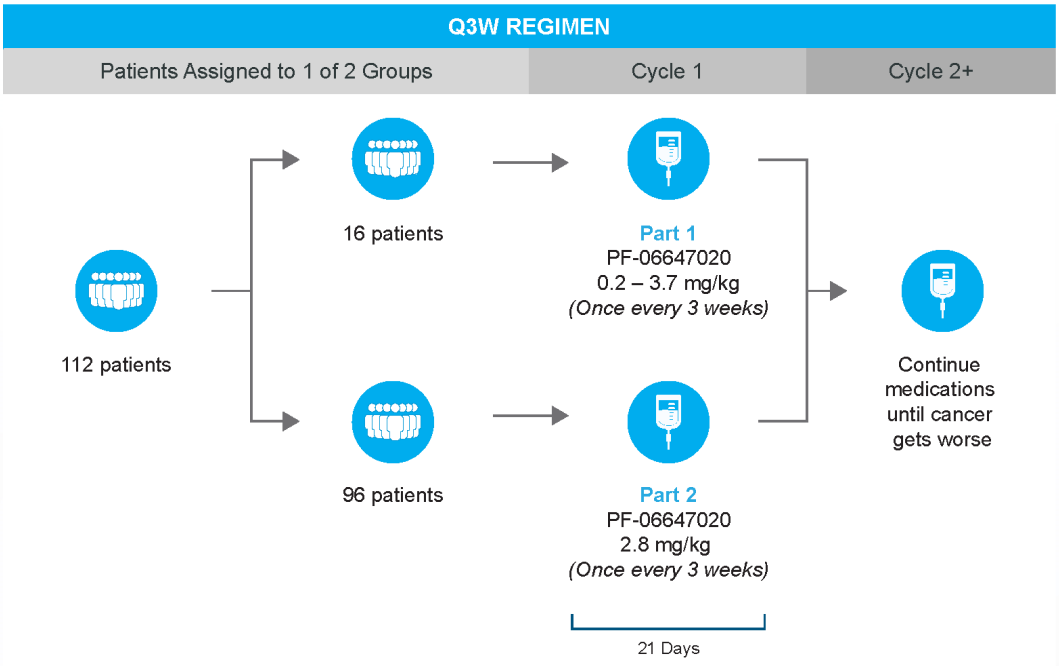
- Part 1: Patients with solid tumor(s) whose cancer was advanced/metastatic (spread to other parts of the body). The patient's cancer either did not respond to standard therapy, or there was no standard therapy available for their cancer.
- Part 2: Patients with one of the following types of cancer:
    1. Ovarian cancer (or "OVCA")
    2. A type of lung cancer called non-small cell lung cancer (or "NSCLC"), whose cancer made medium to high amounts of the protein PTK7
    3. A type of breast cancer called triple negative breast cancer (or "TNBC"), whose cancer made medium-high to high amounts of the protein PTK7
- Able to walk around, take care of themselves, and do light house work or office work.

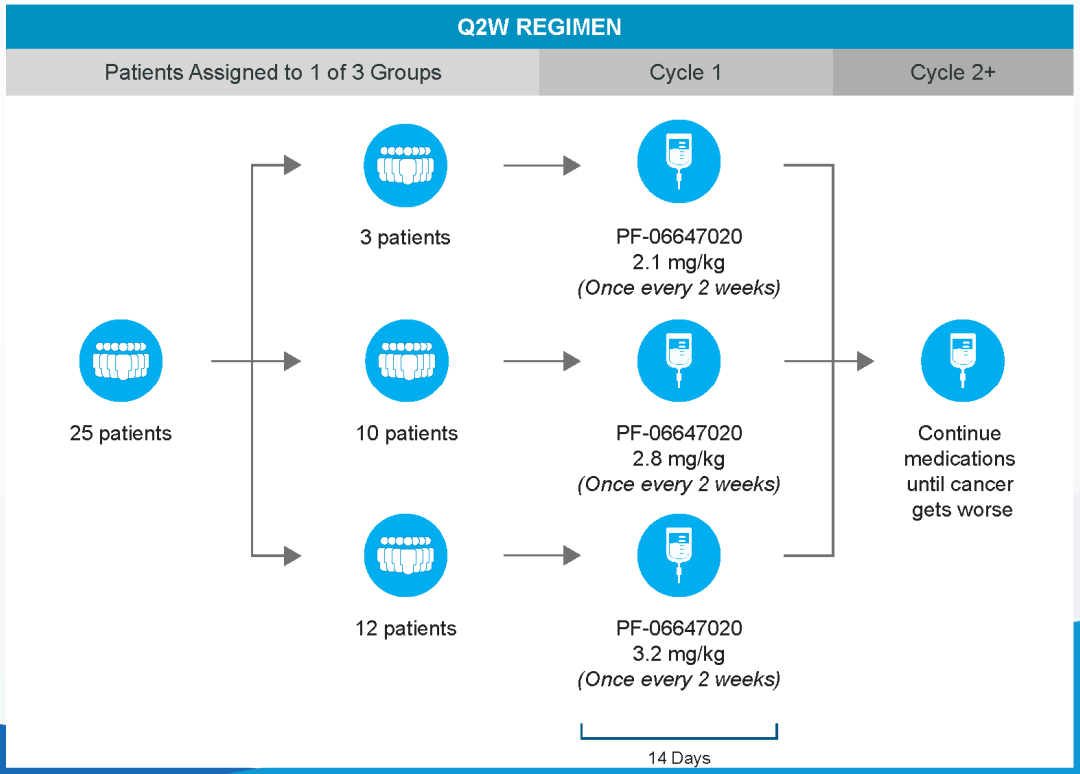
For the Q2W regimen:

- Patients with ovarian cancer (OVCA) that did not respond well to platinum-based chemotherapy, and who had received 2 or fewer regimens of systemic anti-cancer therapy (meaning that medicines were taken by mouth or intravenously [IV])
- Patients with NSCLC whose cancer had gotten worse after treatment, who had received 3 or fewer regimens of systemic anti-cancer therapy, and whose cancer made medium to high amounts of the protein PTK7.

- Able to walk around, take care of themselves, and be active for more than 50% of the day, but may not be able to do light work.

The graphs below show what happened during the study:





While patients were treated for up to 30 months, the entire study took 5 years to complete. The Sponsor ran this study at 10 locations in Spain and the United States of America. It began 17 October 2014 and ended 05 November 2019. A total of 22 men and 126 women participated in the study. All patients were between the ages of 31 and 80.

Patients were to be treated until their cancer got worse, their general health got worse, they had too many medical problems, the patient wanted to stop, or until the patient had passed away. A total of 67 of the 113 patients (59%) who started the Q3W regimen finished the study. A total of 13 of the 25 patients (52%) who started the Q2W regimen finished the study. Forty six (46) patients in the Q3W regimen part and 12 patients in the Q2W regimen part of the study stopped taking the study medicine, mostly due to their cancer getting worse. Thirteen (13) patients who started the Q3W regimen and 2 patients who started the Q2W regimen passed away during the study. Thirty three (33) patients who started the Q3W regimen and 10 patients who started the Q2W regimen left before the study was over by their choice or a doctor decided it was best for a patient to stop being in the study.

When the study ended in November 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?

What dose-limiting toxicities (DLT) were reported when taking PF-06647020?

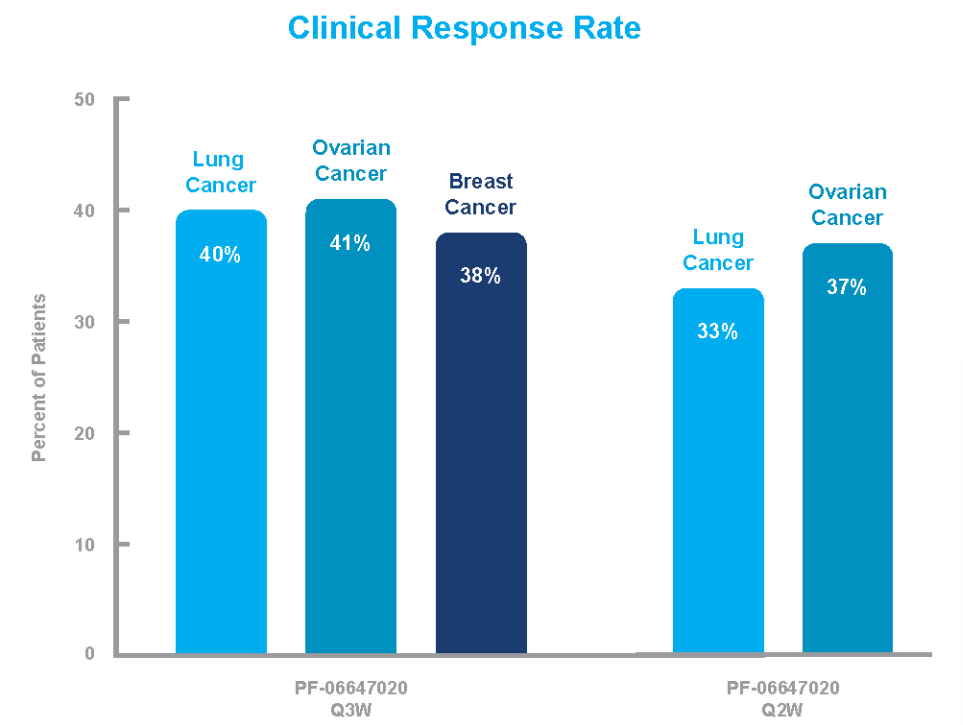
During the first part of the Q3W regimen and the Q2W regimen, the researchers wanted to find the correct dose of PF-06647020 for treating patients with cancer. To find the correct dose, the researchers needed to know how many patients in each dose group had a DLT during their first 21-day treatment cycle (Q3W) or 14-day treatment cycle (Q2W).

Two (2) out of 31 patients (6%) enrolled in the Q3W regimen dose-escalation period and 3 out of 25 patients (12%) in the Q2W regimen dose-escalation period had a DLT. Since the 2 patients with DLT in the Q3W regimen were treated with 3.7 mg/kg and 2 of 3 patients with DLT in the Q2W regimen were treated with 3.2 mg/kg, the researchers decided that the dose of 2.8 mg/kg PF-06647020 was the best dose to use to treat cancer.

What percentage of patients had their cancer stay the same or get better?

To do this, the researchers measured the "Clinical Response Rate" for the patients treated every 3 weeks (Q3W) and every 2 weeks (Q2W). The Clinical Response Rate was the percentage of patients in the study whose cancer stayed the same or got better during 6 or more cycles of treatment.

For patients treated Q3W, 40% of patients with lung cancer (NSCLC), 41% of patients with ovarian cancer, and 38% of patients with breast cancer (TNBC) had their cancer stay the same or get better when treated with PF-06647020. For patients treated Q2W, 33% of patients with lung cancer (NSCLC) and 37% of patients with ovarian cancer had their cancer stay the same or get better when treated with PF-06647020.



This study was not designed to test if one medicine was better than another, so the results could be due to chance. 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 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.

All of the patients in this study had at least 1 medical problem. A total of 11 patients treated with the Q3W regimen and 1 patient treated with the Q2W regimen stopped taking the study medication because of medical problems. The most common medical problems are listed below.

Most Common Medical Problems (Reported by 40% or More of Patients in Q3W or Q2W)

Medical Problem	Q3W Regimen (112 Patients Treated)	Q2W Regimen (25 Patients Treated)
Hair loss	46 (41%)	18 (72%)
Tiredness	60 (54%)	12 (48%)
Constipation	38 (34%)	13 (52%)
Nausea	56 (50%)	11 (44%)
Low appetite	36 (32%)	12 (48%)
Headache	41 (37%)	11 (44%)
Abdominal pain	17 (15%)	11 (44%)
Joint pain	23 (21%)	10 (40%)
Diarrhea	31 (28%)	10 (40%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

Thirty six (36) out of 112 patients (32%) who were treated with the Q3W regimen had serious medical problems. Twelve (12) out of 25 patients (48%) who were treated with the Q2W regimen had serious medical problems. A total of 21 patients passed away during the study, mostly due to their cancer getting worse. The most common serious medical problems reported during the study are shown in the table below.

Serious Medical Problems (Reported by More Than 2 Patients in Q3W or Q2W)

Serious Medical Problem	Q3W Regimen (112 Patients Treated)	Q2W Regimen (25 Patients Treated)
Abdominal pain	1 (1%)	4 (16%)
Cancerous tumor	5 (5%)	0
Constipation	4 (4%)	1 (4%)
Nausea	3 (3%)	2 (8%)
Low white blood cell count with fever	3 (3%)	0
Vomiting	3 (3%)	2 (8%)
Fever	3 (3%)	1 (4%)
Pneumonia	3 (3%)	0
Buildup of fluid around lungs	3 (3%)	1 (4%)
Blood clot in lung	3 (3%)	1 (4%)

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 **NCT02222922**
www.clinicaltrialsregister.eu	Use the study identifier **2014-003296-36**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B7661001**

Findings from this trial will be used in other studies to learn whether patients with cancer are helped by this drug.

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!