



# 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:** Dacomitinib (Vizimpro<sup>®</sup>)

**Protocol Number:** A7471055

**Dates of Trial:** 10 July 2015 to 30 May 2019

**Title of this Trial:** Study for continued access to dacomitinib for patients previously treated with dacomitinib in clinical studies in Japan

[Treatment Access Protocol for Patients Previously Treated With Dacomitinib on a Clinical Trial in Japan]

**Date(s) of this Report:** 26 August 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, their cancer cells have changes (mutations) in the gene that makes a protein called epidermal growth factor receptor, or “EGFR”. These mutations in EGFR help stimulate cancer cells to grow and multiply. Researchers are looking for better treatments for patients with NSCLC whose cancer cells have mutations in the EGFR gene.

Dacomitinib (Vizimpro®) is a medicine that has been approved in the United States, Japan and European Union as treatment for patients with NSCLC. At the time of this study, dacomitinib was not yet approved for treatment of patients with NSCLC. Dacomitinib works by blocking the activity of a group of proteins called the human epidermal growth factor receptor (HER) family (including EGFR [also known as HER1], HER2, and HER4). These are proteins on the surface of cells that can stimulate cancer cells to grow and multiply. 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 purpose of this study was to provide continued access to dacomitinib for patients who participated in other dacomitinib studies in Japan and would be deemed to derive benefit from continued dacomitinib treatment.

Researchers also wanted to learn more about the safety of dacomitinib. They monitored the patients for any medical problems that happened while they were in the study.

## WHAT HAPPENED DURING THE STUDY?

---

This study evaluated a group of patients who received dacomitinib in previous studies for advanced NSCLC, to have them continue treatment with dacomitinib.

The study included patients who had advanced NSCLC and who received dacomitinib in a previous study in Japan (Study A7471009 or Study A7471050) without unpleasant side effects based on the researcher’s evaluation. For this study, 3 different dose

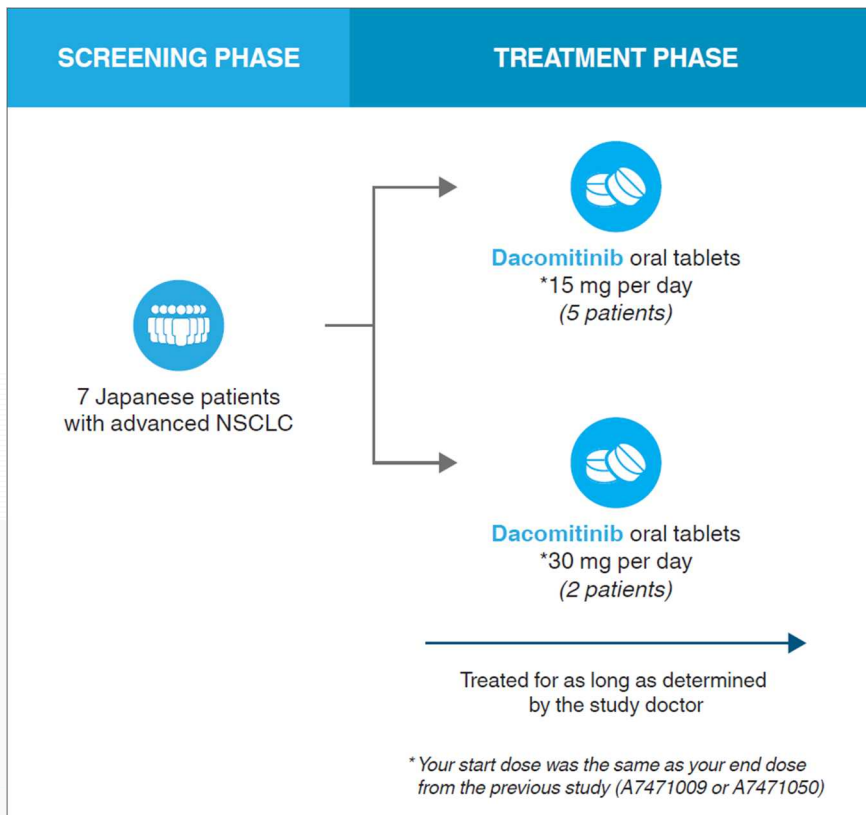
strengths of dacomitinib oral tablets were planned:

- 45 mg per day
- 30 mg per day
- 15 mg per day

The dose strength patients started on in this study, was the same as the dose the patient ended on in the previous study. There were 7 patients included in this study; 5 patients started at a dose of 15 mg once a day and 2 patients started at a dose of 30 mg once a day.

This was an “open-label” study, which means that the patients and the researchers knew which medicine the patients received.

The figure below shows what happened during the study.



The Sponsor ran this study in Japan. It began 10 July 2015 and ended 30 May 2019.

Three (3) men and 4 women participated. All patients were between the ages of 68 and 76 and had an average weight of 56 kg. The study doctor was allowed to change the strength of the dacomitinib dose during the study, depending on how the treatment made the patients feel.

Patients were to be treated until there was evidence of the study drug helping to relieve NSCLC symptoms, as determined by the study doctor. All 7 patients 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, of which 3 patients left as dacomitinib became available on the market.

When the study ended in May 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?**

---

The main purpose of the study was to allow patients with NSCLC who received dacomitinib in a previous study, to continue treatment with dacomitinib while their health was monitored. The medical problems that the patients had during this study, is summarized below.

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 7 patients in this study had at least 1 medical problem. None of the patients left the study because of medical problems. The most common medical problems are listed below.

<b>Most Common Medical Problems (Reported by More Than 1 Patient)</b>	
<b>Medical Problem</b>	<b>Dacomitinib (7 Patients Treated)</b>
Diarrhea	2 (29%)
Lung infection	2 (29%)
Nail inflammation	2 (29%)
Bruise (contusion)	2 (29%)
Headache	2 (29%)
Dry skin	2 (29%)
Hives (red itchy bumps on the skin)	2 (29%)

## **WERE THERE ANY SERIOUS MEDICAL PROBLEMS?**

---

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

Two (2) out of 7 patients (29%) had a total of 3 serious medical problems. No patients died during the study. All serious side effects were considered by the researchers as not related to study medicine.

The 3 serious side effects were as follows:

- Obstruction (blockage) in the digestive system and lung infection by a patient that received 15 mg dacomitinib.
- A tumor in the pancreas (gland organ that forms part of the digestive system) by a patient that received 15 mg dacomitinib.

## **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](http://www.clinicaltrials.gov)

Use the study identifier **NCT02382796**

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!**