Clinical Study 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 medication 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: Lorlatinib (PF-06463922)

Protocol Number: B7461030

Dates of Study: 27 August 2020 to 20 July 2022

Title of this Study: Lorlatinib in ALK Inhibitor Treated Unresectable Advanced/Recurrent ALK-Positive Non-Small Cell Lung Cancer Patients in India

[Single-Arm Study to Evaluate the Safety of Lorlatinib in ALK Inhibitor-Treated Unresectable Advanced and/or Recurrent ALK-Positive Non-Small Cell Lung Cancer Participants in India]

Date(s) of this Report: 17 May 2023

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is non-small cell lung cancer?

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. Some people have NSCLC that is referred to as “ALK-positive”. These people have changes in a gene that makes a protein called anaplastic lymphoma kinase (ALK). An abnormal form of ALK is produced that may cause the cancer cells to grow and to spread.

What is lorlatinib?

Lorlatinib (lor-la’-ti-nib) is a medicine that works by blocking the activity of ALK. Lorlatinib is known as an “ALK-inhibitor” medication. As cancer cells grow, they can form into a tumor and spread to other parts of the body, such as the brain. By blocking ALK, lorlatinib may help to slow down the growth or spread of ALK-positive tumors.

Lorlatinib is already approved for use in many countries to treat adults with advanced or recurrent NSCLC that is ALK-positive. Advanced means the cancer cells have spread outside the lung where the tumor started. Recurrent cancer is cancer that has come back after treatment. Lorlatinib is approved in the United States under the trade name Lorbrena®, in the European Union under Lorviqua®, and in India under Lorbriqua®. Lorlatinib is given in a tablet and is taken by mouth.

What was the purpose of this study?

Based on the results of a previous research study, lorlatinib is already approved in India for the treatment of ALK-positive NSCLC. As there was a lack of participants in India in the previous study, the Indian Ministry of Health asked the Sponsor to carry out this post-approval study. This was to allow more data to be obtained on lorlatinib from participants in India.

- The purpose of this study was to give people with ALK-positive NSCLC access to lorlatinib treatment in India.
- The researchers wanted to learn more about the safety and tolerability of lorlatinib in participants in India.

Researchers wanted to know:

What medical problems did participants have during the study?

What happened during the study?

How was the study done?

First, a study doctor checked each participant to make sure they were eligible to join the study. This is known as the screening period.

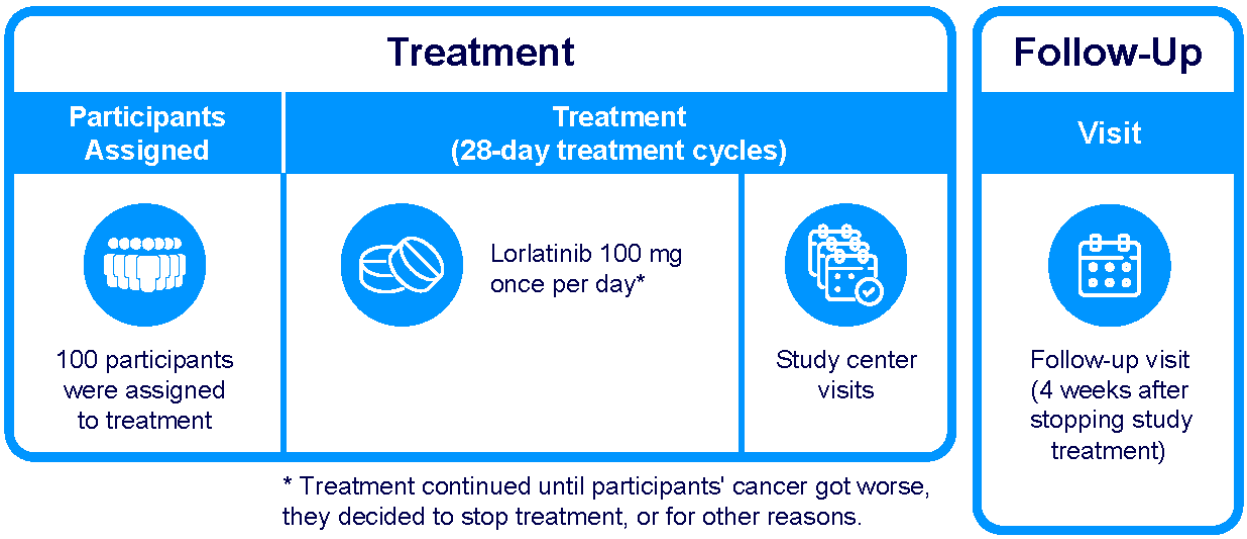
Participants then entered the treatment phase. All participants in this study took lorlatinib 100 milligram (mg), once per day by mouth.

Participants received study treatment in cycles that lasted 28 days. Participants attended visits at the study center on Day 1 of every cycle. They also attended an end of treatment visit within 1 week of stopping study treatment. A safety follow-up visit was done about 4 weeks after stopping study treatment.

Researchers took samples of blood from participants during the study. Researchers also checked the participants' health during the study and asked them how they were feeling.

Figure 1 on the next page shows what happened during the study.

Figure 1. Study Design



Where did this study take place?

The Sponsor ran this study at 11 locations in India.

When did this study take place?

It began 27 August 2020 and ended 20 July 2022.

Who participated in this study?

The study included adult participants who:

- Had a confirmed diagnosis of advanced or recurrent ALK-positive NSCLC and surgery was not a treatment option.
- Had previously received ALK-inhibitor treatment before joining the study, but the treatment was not effective or had stopped working.

Overall, 60 men and 40 women participated in the study. All participants were between the ages of 24 and 77.

Participants were to be treated until their cancer got worse, they left the study by their own choice, they experienced unacceptable medical problems, or the study ended. Of the 100 participants who started the study, 45 participants (45%) stopped taking the study treatment. The most common reason for participants stopping study treatment was because their cancer got worse (33 participants [33%]).

Overall, 92 participants (92%) entered follow-up. A total of 7 participants did not complete follow-up because they passed away (3 participants), they were lost to follow-up (2 participants), by their own choice (1 participant), or due to another unspecified reason (1 participant). Lost to follow-up means the participant stopped coming to study visits and could not be contacted by the study site staff.

How long did the study last?

The amount of time that participants were in the study varied. The entire study took almost 1 year and 11 months to complete. The study was completed as planned.

When the study ended in July 2022, 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?

How safe and well tolerated was lorlatinib?

The researchers assessed the safety and tolerability of lorlatinib by looking at the medical problems participants had during the study. Medical problems are discussed in full in the next 2 sections of this document.

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 effects a study medication might have on a participant.

A total of 94 out of 100 participants (94%) in this study had at least 1 medical problem, and 89 participants (89%) had a medical problem that researchers considered as related to the study treatment. A total of 7 participants (7%) left the study because of medical problems. The most common medical problems – those reported by at least 20% of participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by at least 20% of participants are listed.
- The **2nd** column tells how many of the 100 participants taking lorlatinib reported each medical problem. Next to this number is the percentage of participants taking lorlatinib who reported the medical problem.

- Using these instructions, you can see that 58 out of the 100 participants (58%) taking lorlatinib were reported with high levels of triglycerides in their blood.

Table 1. Most common medical problems in the study

Medical Problem	Lorlatinib (100 Participants)
High level of triglycerides (a type of fat) in blood	58 out of 100 participants (58%)
High level of cholesterol in blood	57 out of 100 participants (57%)
Weight increased	39 out of 100 participants (39%)
Limb swelling	29 out of 100 participants (29%)
Low numbers of red blood cells (anemia)	26 out of 100 participants (26%)
High level of lipids (fats) in blood	20 out of 100 participants (20%)

Did study participants have any serious medical problems?

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

Overall, 22 out of 100 participants (22%) had at least 1 serious medical problem. Serious medical problems that were reported in more than 1 participant included:

- Coronavirus disease (COVID-19): 4 out of 100 participants (4%)
- Shortness of breath: 3 out of 100 participants (3%)
- Serious lung condition causing low blood oxygen (acute respiratory distress syndrome): 2 out of 100 participants (2%)

All other serious medical problems were reported in 1 participant each. Researchers believe that 8 out of 100 participants (8%) had serious medical problems that were related to taking the study treatment. None of the treatment-related serious medical problems were reported in more than 1 participant.

A total of 8 participants (8%) died during the study. The most common causes of death were COVID-19 (including suspected COVID-19) and acute respiratory distress syndrome. The researchers did not believe any of the deaths were related to taking the 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.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results

Use the protocol number **B7461030**

The full scientific report of this study is available online at:

www.clinicaltrials.gov

Use the study identifier **NCT04541706**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

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