ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A study to look at how well atezolizumab works in people with non-small cell lung cancer that has spread to nearby tissues, cannot be removed with surgery and has not worsened after radiotherapy and chemotherapy given together

A clinical trial to look at how well atezolizumab works (and how safe the drug is) in people with inoperable locally advanced non-small cell lung cancer (NSCLC), whose cancer has not got worse after radiotherapy and platinum-based chemotherapy given together

Trial Status	Trial Runs In	Trial Identifier
Recruiting	13 Countries	2023-503756-27-00 MO43156

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

A clinical trial to look at how well atezolizumab works (and how safe the drug is) in people with inoperable locally advanced non-small cell lung cancer (NSCLC), whose cancer has not got worse after radiotherapy and platinum-based chemotherapy given together

F. Hoffmann-La Roche Ltd
Sponsor

Phase 2
Phase

2023-503756-27-00 MO43156
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is this study needed?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. NSCLC usually develops in the tissues lining the lungs and can spread to nearby lymph nodes and other organs. Cancer is known as ‘locally advanced’, or ‘Stage III’, if cancer cells have spread to nearby tissue.

This study is testing a medicine called atezolizumab. It is being developed to treat locally advanced/Stage III NSCLC that cannot be removed with surgery.

Atezolizumab is approved by health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) for treating ‘early-stage’ or ‘late-stage’ NSCLC. This is NSCLC that has not spread to nearby tissues (early-stage) or, it has spread to other parts of the body (late-stage or ‘metastatic’).

Atezolizumab is an experimental medicine in this study. It is not approved for treating some types of Stage III NSCLC. This includes Stage III NSCLC that cannot be removed with surgery and has not become worse after being treated with combined radiotherapy and platinum-based chemotherapy. Radiotherapy is a type of treatment where high energy rays are used to destroy cancer cells. Chemotherapy is a medicine that kills cancer cells.

This study aims to look at how well atezolizumab works in people with this type of NSCLC.

2. Who can take part in the study?

People of at least 18 years of age with NSCLC that has spread to nearby tissues and cannot be removed with surgery can take part in the study. NSCLC must have been treated with at least 2 rounds of radiotherapy and platinum-based chemotherapy. These must have been given together within 6 weeks of starting the study. Their cancer must not have worsened following this treatment.

People may not be able to take part in this study if their cancer has spread to other parts of the body or they have NSCLC known to have a certain change (‘mutation’). People with certain other medical conditions, such as autoimmune disease, lung, liver or heart disease may not be able to take part. Also, people who have received certain treatments are excluded. This includes treatments that help your immune system fight cancer. People who are pregnant, planning to become pregnant during the study, or are currently breastfeeding cannot take part.

3. How does this study work?

Participants will be screened to check if they are able to participate in the study. The screening period will take place from 1 month before the start of treatment.

Everyone who joins this study will be given atezolizumab as a drip into the vein once every month. This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants every month, and will telephone them once in between each visit. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit within 1 month of completing the study treatment, then every 3 months for as long as they agree to it or until their cancer gets worse. During follow-up visits, the study doctor will check on the participant's well being. Total time of participation in the study will be more than 1 year. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main result measured in the study to assess if the medicine has worked is the number of people whose cancer has not got worse after 12 months of starting atezolizumab treatment. This is called the 12-month progression-free survival rate.

Other key results measured in the study include:

- How long people live, and how long they live without their cancer getting worse
- How many people have a reduction of their cancer (also called a 'response') that lasts at least 1 month
- How much time there is between the person's cancer first responding to treatment and the cancer getting worse
- How many people live for 1 year and a half or 2 years without their cancer getting worse
- How many people live for 1 year and a half, 2 years or 3 years
- The duration between starting treatment and cancer spreading in the body or a person's life ending
- The number and seriousness of unwanted effects

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicine

Participants may have unwanted effects of the medicine used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Atezolizumab

Participants will be told about the known unwanted effects of atezolizumab and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include pain in the back, joints, muscles, bone or head, cough, fever, itching, wanting to throw up, throwing up, rash, difficulty breathing, infection in any part of the urinary tract, and feeling tired or weak.

Atezolizumab will be given as a drip into the vein. Known unwanted effects include a reaction to the drip into the vein. Symptoms of a reaction can include very low blood pressure, fever, shortness of breath, severe dizziness and cough.

The study medicine(s) may be harmful to an unborn baby. Women must take precautions to avoid exposing an unborn baby to the study treatment.