ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

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	2021-002695-40 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

2021-002695-40 MO43156
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the ASTRES clinical trial needed?

People with inoperable locally advanced non-small cell lung cancer (NSCLC) have a poor prognosis. Previous clinical trials have shown how treatments that support the immune system in fighting cancer, such as atezolizumab, can help people with locally advanced NSCLC live longer. The ASTRES clinical trial will help doctors understand more about the benefit of atezolizumab in patients with locally advanced NSCLC that cannot be removed with surgery, has been treated with radiotherapy and platinum-based chemotherapy given together, and has not progressed further.

2. How does the ASTRES clinical trial work?

This clinical trial is recruiting people who have a health condition called non-small cell lung cancer or NSCLC. People can take part if they have inoperable NSCLC that has spread within the chest (stage III), and they have already received radiotherapy and platinum-based chemotherapy given together.

The purpose of this clinical trial is to investigate the effects, good or bad, of atezolizumab in people with NSCLC. People who take part in this clinical trial (participants) will receive intravenous infusions of atezolizumab. This means the treatment is given directly into a vein via a drip. This takes approximately 30 to 60 minutes.

Participants will be given atezolizumab once every four weeks for up to 12 months. Participants will be seen by the clinical trial doctor every four weeks. These hospital visits will include checks to see how they are responding to the treatment, blood tests, and discussions about any side effects they may be having.

Participants' total time in the clinical trial will be roughly 12 months, although there will be a follow-up visit within 30 days after the participant’s final dose of atezolizumab, and subsequent follow-up appointments every 12 weeks for as long as the participant agrees or until the cancer gets worse. Participants are free to stop their participation in the clinical trial and stop receiving clinical trial treatment at any time.

3. What are the main endpoints of the ASTRES clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the medicine has worked) is the proportion of participants in the clinical trial whose cancer has not got worse after 12 months of atezolizumab. This is called the 12-month progression-free survival rate.

Additional clinical trial endpoints that also measure how well a patient has responded to treatment include the number of patients in the clinical trial who survive, and how long atezolizumab prevents the spread of cancer to other parts of the body. The safety of atezolizumab will also be assessed.

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old, have inoperable stage III NSCLC, and they have received radiotherapy and platinum-based chemotherapy given together (within 42 days before joining the trial) without their cancer getting worse.

People may not be able to take part in this trial if they have a known mutation (change) in specific genes called *EGFR* or *ALK*, or their cancer has spread to other distant parts of the body. People may not be able to take part in this trial if they have certain other medical conditions, such as autoimmune disease, immune deficiency or significant heart disease,

or have received certain medications, such as other treatments that help your immune system fight cancer.

5. What treatment will participants be given in this clinical trial?

All participants will receive intravenous infusions of atezolizumab directly into a vein via a drip, every four weeks for up to 12 months (up to 13 infusions in total, each taking 30 to 60 minutes).

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the investigated treatment may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe and even life-threatening, and can vary from person to person.

Atezolizumab

Potential participants will be told about the known side effects of atezolizumab, and where relevant, the potential side effects based on human and laboratory studies or knowledge of similar drugs.

Atezolizumab will be given by intravenous infusion. Participants will be told about any known side effects of intravenous infusion.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.