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 information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A phase II, single-arm study of atezolizumab in patients with locally advanced, unresectable stage III non-small cell lung cancer who have not progressed after platinum-based concurrent chemoradiation

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.

Inclusion Criteria:

• Age >=18 years at time of signing the Informed Consent Form

• Histologically or cytologically documented NSCLC with locally advanced, unresectable Stage III NSCLC of either squamous or non-squamous histology

• Whole-body positron emission tomography–computed tomography (PET-CT) scan (from the base of skull to mid-thighs) for the purposes of staging, performed prior and within 42 days of the first dose of cCRT

• At least two prior cycles of platinum-based chemotherapy administered cCRT completed within 1 to 42 days prior to baseline (one cycle of cCRT is defined as 21 or 28 days)

• The radiotherapy (RT) component in the cCRT must have been at a total radiation dose of 60 (±10%) gray (Gy) (54 Gy to 66 Gy), administered either as intensity-modulated radiotherapy (IMRT) or by 3D-conforming technique

• No progression during or following platinum-based cCRT

• Tumor Programmed Cell Death 1–Ligand 1 (PD-L1) expression, as determined by the investigational Ventana PD-L1 (SP263) CDx Assay and documented by means of central testing of a representative tumor tissue sample, in either a previously obtained archival tumor tissue sample or a fresh tissue sample obtained from a biopsy collected prior to the first dose of cCRT

• Submission of representative formalin-fixed, paraffin-embedded (FFPE) tumor specimens in blocks (preferred) or at least 10 unstained serial slides, along with an associated pathology report to a central laboratory for PD-L1 testing

• Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1

• Life expectancy >=12 weeks

• Adequate hematologic and end-organ function.

Exclusion Criteria:

• Any history of prior NSCLC and/or any history of prior treatment for NSCLC (patients must be newly diagnosed with unresectable Stage III disease)

• NSCLC known to have a mutation in the epidermal growth factor (EGFR) gene or an anaplastic lymphoma kinase (ALK) fusion oncogene

• Any evidence of Stage IV disease

• Treatment with sequential CRT for locally advanced NSCLC

• Patients with locally advanced NSCLC who have progressed during or after definitive cCRT prior to baseline

• Any Grade > 2 unresolved toxicity from previous cCRT

• Grade # 2 pneumonitis from prior cCRT

• Concurrent enrolment in another clinical study, unless it is an observational clinical study or the follow-up period of an interventional study

• Any concurrent chemotherapy, immunotherapy, biologic, or hormonal therapy for cancer

• Active or history of autoimmune disease or immune deficiency

• History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on the screening chest CT scan

• History of malignancy other than NSCLC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death

• Severe infection within 4 weeks prior to initiation of study treatment

• Treatment with therapeutic oral or intravenous (IV) antibiotics within 2 weeks prior to initiation of study treatment

• Prior allogeneic stem cell or solid organ transplantation

• Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications

• Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during study treatment or within 5 months after the final dose of study treatment

• Current treatment with anti-viral therapy for HBV or HCV

• Treatment with investigational therapy within 28 days prior to initiation of study treatment

• Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-cytotoxic T lymphocyte–associated protein 4, anti-TIGIT, anti-PD-1, and anti-PD-L1 therapeutic antibodies

• Treatment with systemic immunostimulatory agents (including, but not limited to, IFN and IL-2) within 4 weeks or 5 drug-elimination half-lives (whichever is longer) prior to initiation of study treatment

• Treatment with systemic immunosuppressive medication (including, but not limited to, corticosteroids, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor– [anti-TNF–agents) within 2 weeks prior to initiation of study treatment, or anticipation of need for systemic immunosuppressive medication during study treatment.