ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

MO43156: 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 (ASTRES)

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Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	2021-002695-40 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 (NSCLC) 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

2021-002695-40 MO43156
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>/=18	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.

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.