ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Phase II, single-arm study of tiragolumab plus atezolizumab and bevacizumab in patients with previously untreated locally advanced unresectable or metastatic PD-L1-positive non-squamous non-small cell lung cancer

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	1 Countries	ML43138

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 study to assess the effect of tiragolumab in presence of atezolizumab and bevacizumab in participants detected with lung cancer

F. Hoffmann-La Roche Ltd (USA) Sponsor	**Phase 2** Phase

ML43138
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 years and above	No

Background and study aims:

Non-squamous non-small cell lung cancer (nsq NSCLC) is the most common type of lung cancer. It usually grows and spreads more slowly than small cell lung cancer. Tiragolumab (formerly MTIG7192A) is a human antibody that is being studied as a potential therapy against various cancer types. An antibody is a protein in the blood that helps the body's defences by identifying and attaching to specific foreign substances including germs.

The aim of this study is to compare the effects, good or bad, of tiragolumab plus atezolizumab and bevacizumab in participants with nsq NSCLC.

Tiragolumab plus atezolizumab and bevacizumab are experimental drugs, which means health authorities have yet not approved the combination for the treatment of nsq NSCLC.

Who can participate?

Participants aged 18 years and above with previously untreated, locally advanced nsq NSCLC that has grown or spread and cannot be removed by surgery.

What does the study involve?

Participants will need to be a part of this study for about 3-5 years. This study will have three parts:

1. A screening visit, wherein certain tests would be done to determine if the participant is eligible to take part in the study.

2. The treatment period, when eligible participants will be given a single dose of tiragolumab plus atezolizumab and bevacizumab combination into the vein (infusion) every 3 weeks for a cycle of 21 days on a regular basis unless their cancer condition worsens. Participants will have to visit the clinic about every 3 weeks while they are receiving treatment and each visit may last 6 to 72 hours.

3. A follow-up period during which participants will have check-up visits every 3 months or more frequently till the end of the study. The participant will have to visit the clinic or will be contacted telephonically for the follow-up procedures

What are the possible benefits and risks of participating?

Participants will not receive any direct medical benefit, but the information gained from this study may help other people with non-squamous non-small cell lung cancer in the future. Participants will be paid renminbi (RMB) 100 as a transportation reimbursement for every clinic visit including the screening procedures.

Participants may have side effects from the drugs or procedures used in this study. These can be mild to severe and even life-threatening, and they can vary from person to person.

Tiragolumab has had limited testing in humans. Known potential side effects include fever, chills, shortness of breath, nausea, and changes in blood pressure. Participants may experience inflammation in the tumour but also in the healthy parts (normal tissue) of the body due to increased activity of the immune system. The affected parts of the body could be (but not limited to) the skin, eyes, nerves, gut, hormone system, kidneys, lungs, liver, muscles, blood vessels, and blood cells. Tiragolumab could also lower the number of certain white blood cells (lymphocytes).

Very common side effects of atezolizumab include back pain, cough, decreased appetite, loose stools, fatigue, fever, headache, itching of the skin (pruritus), joint pain (arthralgia), lack of energy (asthenia), muscle and bone pain (myalgia, musculoskeletal pain and bone pain), nausea, rash, shortness of breath (dyspnea), urinary tract infection, vomiting

Common side effects of atezolizumab include allergic reaction or intolerance to medication (hypersensitivity), chills, decreased level of potassium in the blood (hypokalemia), decreased level of sodium in the blood (hyponatremia), decreased oxygen supply in the body resulting in shortness of breath (hypoxia), difficulty swallowing (dysphagia), dry skin, flu-like illness, increased blood level of creatinine, a substance normally eliminated by the kidneys into the urine, increased blood sugar level (hyperglycemia), inflammation of the intestines (colitis), inflammation of the liver (hepatitis), inflammation of the lungs (pneumonitis), infusion-related reaction, low blood pressure (hypotension), a low platelet count in the blood, which may make you more likely to bruise or bleed (thrombocytopenia), mouth and throat pain (oropharyngeal pain), inflammation of the nose and throat (nasopharyngitis), stomach-area pain (abdominal pain), underactive thyroid gland (hypothyroidism)

Less common side effects of atezolizumab include decreased production of hormones by the adrenal glands (adrenal insufficiency), diabetes mellitus, inflammation of the brain and membrane surrounding the brain and spinal cord (meningoencephalitis), inflammation of the heart muscle (myocarditis), inflammation of the kidneys (nephritis), inflammation of the pancreas (pancreatitis), inflammation of the pituitary gland (hypophysitis), inflammation or damage of the muscles (myositis), nerve damage resulting in muscle weakness (myasthenic syndrome/myasthenia gravis), nerve damage that may cause muscle weakness and/or paralysis (Guillain-Barré syndrome), overactive thyroid gland (hyperthyroidism), red, dry, scaly patches of thickened skin (psoriasis), severe high levels of sugar and acids in the blood or urine (diabetic ketoacidosis), severe skin or mucosal reactions (severe cutaneous adverse reactions)

Very common serious side effects of bevacizumab include high blood pressure, numbness or loss of feeling in the fingers or toes, low numbers of white blood cells potentially associated with fever, low numbers of platelets, weakness, loss of energy, loose stools, with nausea, vomiting, and abdominal pain.

Very common non-serious side effects of bevacizumab include nausea and vomiting, pain, including headache and joint pain, constipation, mucosal inflammation or inflammation of the mouth, protein in the urine, bleeding in the moist lining of the digestive, respiratory, reproductive, or urinary tracts, loss of appetite, fever, runny nose, dry skin, flaking and inflammation of the skin, change in skin color, change in the sense of taste, problems with the eyes and tearing, cough.

Common serious side effects of bevacizumab include infection, presence of bacteria in the blood, collection of pus in tissue or organs, a tear or hole in the gut, an abnormal

tube-like connection between the gastrointestinal tract and skin or other tissues that are not normally connected, low number of red blood cells, bleeding, including bleeding associated with the tumour and nose bleeds, clogging of a vessel in the lung, blocking of the blood vessels (arteries) by a blood clot, including stroke or heart attack, heart failure, especially in participants who have taken certain chemotherapy, blood clots in the veins, abdominal pain, blockage in the intestine, body water loss, pain, tenderness, or blistering on the fingers or feet, reduced consciousness, sleepiness, feeling tired, fainting, allergic reaction, including allergic reaction to the drug during infusion, shortness of breath, low levels of oxygen in the blood, wound-healing problems.

Common non-serious side effects of bevacizumab include digestive system disorder, voice changes, hoarseness, muscular pain or muscular weakness.

Less common serious side effects of bevacizumab include an abnormal connection between internal organs (other than the digestive tract) and skin or other tissues not normally connected.

Other rare but potentially serious side effects of bevacizumab include reversible posterior leukoencephalopathy syndrome, which may include symptoms of impaired brain function (headaches, vision changes, confusion, or fit [seizures]), and, often, high blood pressure, hypertensive encephalopathy, which may include symptoms of impaired brain function (headaches, vision changes, confusion, or fit [seizures]) and, often, high blood pressure.

During tumour tissue sampling (biopsy) participants might experience pain, redness, swelling, excessive bleeding, bruising, or draining at the needle site. Abnormal wound healing, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site can also occur

Blood sampling: Drawing blood can cause pain, bruising, or infection where the needle is inserted. Some participants might experience dizziness, fainting, or an upset stomach when their blood is drawn.

Tumour assessment scanning procedures including computed tomography (CT) scan, positron emission tomography (PET)/CT scan, magnetic resonance imaging (MRI) scan, and Bone scan might include potential risks such as allergic reaction, nausea, constipation, diarrhoea, abdominal bloating, headaches, hives, temporary low blood pressure, chest pain, back pain, fever, weakness, and seizures to a tracer or a contrast agent. Although there are no known long-term harmful effects from the radiation of a single scan, the risk of harmful effects from multiple scans over a period is not known.

There may be a risk in exposing an unborn child to the study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to the study drug. Participants who are pregnant, become pregnant or are currently breastfeeding cannot take part in this study.

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Where is the study run from?

F. Hoffmann-La Roche Ltd (USA)

When is the study starting and how long is it expected to run for?

January 2022 to December 2026

Who is funding the study?

F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?

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