ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A clinical trial to compare tiragolumab plus atezolizumab versus placebo plus atezolizumab in people with non-small cell lung cancer

A Study of Tiragolumab Plus Atezolizumab Compared With Placebo Plus Atezolizumab in Participants With Completely Resected Non-small Cell Lung Cancer Who Have Received Adjuvant Platinum-based Chemotherapy

Trial Status	Trial Runs In	Trial Identifier
Terminated	11 Countries	NCT06267001 2023-506696-10-00 GO45006

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

Trial Summary:

The purpose of this study was to evaluate the efficacy and safety of tiragolumab plus atezolizumab compared with placebo plus atezolizumab administered to participants with non-small cell lung cancer (NSCLC) following resection and adjuvant chemotherapy.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT06267001 2023-506696-10-00 GO45006
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the SKYSCRAPER-15 clinical trial needed?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. In ‘early-stage’ NSCLC, also known as stages I, II or III – the cancer may have grown in the lung or nearby lymph nodes but is not found anywhere else in the body. Standard treatment for early-stage NSCLC includes surgery - treatments can also be given before surgery to shrink the cancer, and after surgery to reduce the risk of cancer growing back.

Atezolizumab is approved for the treatment of early-stage NSCLC after surgery and chemotherapy. It is an immunotherapy – which means it helps the body’s immune system

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fight the cancer. Atezolizumab treatment is used when cancer cells have a protein called PD-L1 (known as a ‘biomarker’). PD-L1 positive cancer cells are more difficult for the immune system to find and destroy. Atezolizumab blocks the activity of PD-L1 to help the immune system fight cancer cells. Tiragolumab is another type of immunotherapy that may boost anti-cancer activity when given with atezolizumab. Tiragolumab plus atezolizumab is an experimental treatment – it has not been approved by health authorities for the treatment of NSCLC.

This clinical trial aims to compare the effects, good or bad, of tiragolumab plus atezolizumab versus a substance with no active ingredients (also known as a ‘placebo’) plus atezolizumab in people with early-stage NSCLC that has not spread beyond the lung or lymph nodes in the chest, that has been surgically removed and treated with chemotherapy.

2. How does the SKYSCRAPER-15 clinical trial work?

This clinical trial is recruiting people with early-stage NSCLC. People can take part if they have NSCLC that tests positive for the PD-L1 protein, and they have had surgery to remove NSCLC followed by chemotherapy. This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given atezolizumab plus a placebo that looks like tiragolumab but does not contain any real tiragolumab. Comparing results from the different groups helps the researchers know whether any changes seen result from the drugs or occur by chance.

People who take part in this clinical trial (participants) will be given either tiragolumab plus atezolizumab OR placebo plus atezolizumab for up to about 1 year (13 treatment cycles) unless their cancer comes back sooner. The clinical trial doctor will see them every month. These hospital visits will include a dose of treatment and checks to see how the participant responds to the treatment and any side effects they may have. After the final dose of treatment, the clinical trial doctor will follow up with participants one month later then about every 3 months for as long as they agree to it. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the SKYSCRAPER-15 clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the drug has worked) is the amount of time between the start of the trial and participants’ cancer coming back.

The other clinical trial endpoints include:

- How long participants live
- The number of participants whose cancer has not come back after 3, 5 or 7 years

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- The number of participants whose quality of life and ability to do daily activities has stayed the same or improved between the start and the end of treatment
- The number and seriousness of any side effects
- How the body breaks down and gets rid of tiragolumab and/or atezolizumab
- How tiragolumab and/or atezolizumab affect the immune system.

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old and were diagnosed with early-stage NSCLC that has the biomarker PD-L1 without other certain genetic changes (mutations). People who take part must have had surgery to remove NSCLC, followed by at least one dose of chemotherapy given within 3 months of their surgery. Participants must start the trial within approximately 10 weeks from their last dose of chemotherapy. People may not be able to take part in this trial if they have any NSCLC remaining after lung cancer surgery or chemotherapy, had a previous NSCLC diagnosis within 5 years, had any other type of cancer within 5 years (except for cancers that have a low risk of spreading in the body or causing loss of life), or if they have received certain treatments for NSCLC (such as immunotherapy, chemotherapy, or radiation) before. People with certain medical conditions, such as autoimmune diseases, lung or heart disease or women who are pregnant or breastfeeding, will not be able to take part.

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

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- **Tiragolumab** plus **atezolizumab**, given as an infusion (into the vein) once a month for up to 1 year,
  OR
- **Placebo** plus **atezolizumab**, given as an infusion (into the vein) once a month for up to 1 year

Participants will have an equal chance of being placed in either group.

This is a double-blinded trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This helps to prevent bias and expectations about what will happen. However, the participant's clinical trial doctor can find out which group the participant is in, if their safety is at risk.

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

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and

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benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly.

Tiragolumab and atezolizumab

Participants will be told about the known side effects of tiragolumab and atezolizumab and possible side effects based on human and laboratory studies or knowledge of similar drugs. Tiragolumab or placebo and atezolizumab will be given as a co-infusion - both drugs will be given into the vein at the same time (intravenous co-infusion). Participants will be told about any known side effects of intravenous co-infusions.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.

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