ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A clinical trial to look at the safety and effectiveness of tiragolumab plus atezolizumab (with or without platinum-based chemotherapy) in patients with untreated locally advanced non-small cell lung cancer (NSCLC) that can be removed by surgery

A Study Evaluating the Safety and Efficacy of Neoadjuvant and Adjuvant Tiragolumab Plus Atezolizumab, With or Without Platinum-Based Chemotherapy, in Participants With Previously Untreated Locally Advanced Resectable Stage II, IIIA, or Select IIIB Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	5 Countries	NCT04832854 2020-002853-11 GO42501

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

Trial Summary:

This study will evaluate the surgical safety and feasibility of atezolizumab plus tiragolumab alone or in combination with platinum-based chemotherapy as neoadjuvant treatment for participants with previously untreated locally advanced non-small cell lung cancer (NSCLC). The study will also evaluate the efficacy, pharmacokinetics, immunogenicity, and safety of atezolizumab plus tiragolumab alone or in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by adjuvant atezolizumab plus tiragolumab or adjuvant platinum-based chemotherapy.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04832854 2020-002853-11 GO42501
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the GO42501 clinical trial work?

This clinical trial is recruiting people who have a type of disease called non-small cell lung cancer (NSCLC). In order to take part, patients must have locally advanced NSCLC (in the lung and lymph nodes in the middle of the chest) that can be removed by surgery (known as resectable). Patients must not have received any previous treatment for their NSCLC.

The purpose of this clinical trial is to find out the effects, good or bad, of tiragolumab plus atezolizumab, with or without chemotherapy in patients with locally advanced, resectable NSCLC. If you take part in this clinical trial, you will receive either tiragolumab plus atezolizumab, or tiragolumab plus atezolizumab plus chemotherapy.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and diagnosed with locally advanced NSCLC (stage II, IIIA or select IIIB) that is suitable for surgery.

You must not have had any previous treatment for NSCLC. Your NSCLC will be tested for genetic mutations and abnormalities – if your NSCLC is found to have mutations in the EGFR or ALK genes, or a known ROS1 genetic abnormality you will not be able to take part. You also may not be able to take part if you have certain other medical conditions or have previously received certain treatments.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into 2 groups. Which group you join will depend on the level of a protein called PD-L1 that is present in your NSCLC:

Group A (high levels of PD-L1):

- tiragolumab plus atezolizumab as infusions into the vein every 3 weeks for 4 cycles of treatment, THEN
- surgery to remove the NSCLC, THEN
- tiragolumab plus atezolizumab as infusions into the vein every 3 weeks for 16 cycles, or chemotherapy for 4 cycles (based on a decision by the clinical trial doctor)

Group B (all levels of PD-L1):

- tiragolumab plus atezolizumab plus chemotherapy as infusions into the vein every 3 weeks for 4 cycles of treatment, THEN
- surgery to remove the NSCLC, THEN
- tiragolumab plus atezolizumab for another 16 cycles

If you receive chemotherapy, your clinical trial doctor will decide which type to give you depending on how a sample of your NSCLC cells looks under a microscope:

- If your NSCLC is classified as **non-squamous NSCLC**, you may be given cisplatin plus pemetrexed, carboplatin plus pemetrexed or carboplatin plus paclitaxel
- If your NSCLC is classified as **squamous NSCLC**, you may be given cisplatin plus gemcitabine, carboplatin plus gemcitabine or carboplatin plus paclitaxel

How often will I be seen in follow-up appointments and for how long?

After your first 4 cycles of tiragolumab plus atezolizumab, you will have a pre-surgery visit about 30 days before your surgery to remove your NSCLC. You will then see your clinical trial doctor about 2 to 3 weeks after this surgery, so they can check how you are feeling, before you restart treatment with tiragolumab plus atezolizumab or chemotherapy. After surgery and during the post-surgery treatment period, you will have CT scans every 4 months for the first year and every 6 months for the second year. If there are no signs that your cancer has come back, you will continue to have CT scans every 6 months during Years 3–5. You are free to stop this treatment at any time. After your last dose of treatment, the clinical trial doctor will follow up with you via telephone calls, medical records and/or clinic visits every 3 months so that the trial team can collect information about any new cancer treatments you are receiving and check whether you have had any side effects.

What happens if I am unable to take part in this clinical trial?

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If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/record/NCT04832854

Trial identifier: NCT04832854