ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

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

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
Completed	5 Countries	NCT04832854 2020-002853-11 GO42501

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

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
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Phase 2
Phase

NCT04832854 2020-002853-11 GO42501
Trial Identifiers

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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 that usually develops in the tissues lining the lungs. Sometimes NSCLC presents at a stage that can be removed surgically (resectable). Treatments given before surgery to shrink or stop the cancer from spreading are called neoadjuvant treatments. Treatments given after surgery to stop the cancer from spreading are called adjuvant treatments. However, these treatments may not work for all patients, or at all times. Therefore, there is always a need to find new combinations of treatments.

This study is testing a combination of tiragolumab and atezolizumab. It is being developed as a combination treatment before and after surgery for lung cancers that can be removed surgically. Previous studies have shown that tiragolumab and atezolizumab can be given to treat advanced NSCLC. Atezolizumab alone is approved by health authorities (such as the U.S. Food and Drug Administration and European Medicines Agency) for the adjuvant treatment of surgically resected NSCLC. Additionally, it is also approved for use alone or in combination with platinum-based cancer medicines (chemotherapy) to treat advanced NSCLC. However, in this study, the combination of tiragolumab and atezolizumab is considered to be experimental. Health authorities have not approved the combination of tiragolumab and atezolizumab given prior to and after surgery for surgically removable lung cancers.

This study aims to compare the effects of tiragolumab plus atezolizumab with or without chemotherapy in people with lung cancers that can be removed by surgery. The study will also check the effects of tiragolumab plus atezolizumab after surgery.

2. Who could take part in the study?

People who were at least 18 years old with early-stage lung cancer that could be surgically removed are taking part in this study. People could not take part in this study if they had other types of lung cancer or had received any prior treatments for lung cancer. People who were pregnant or breastfeeding also could not participate in the study.

3. How does this study work?

People were screened before receiving any treatment or surgery to check if they could participate in the study. The screening period took place for about 42 days before the start of treatment.

Everyone who joined this study were split into two groups (Groups A and B). They received either atezolizumab plus tiragolumab alone (Group A) or with chemotherapy (Group B), as drip into the vein every 3 weeks for 12 weeks. Thereafter participants had a surgery to remove the cancer. After surgery, participants in Group A will continue to receive either atezolizumab plus tiragolumab for up to 48 weeks or chemotherapy for up to 12 weeks. Participants in Group B will continue to receive atezolizumab plus tiragolumab for up to 48 weeks after surgery. Treatment will continue until one of the following occurs: 12 weeks of treatment with chemotherapy or 48 weeks of treatment with atezolizumab plus tiragolumab, participants' cancer returns, they experience any unacceptable unwanted effects, withdraw from the study, or die due to any reason. 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 meet the participants every 3 weeks for 12 weeks before surgery and will continue checking on the participants every 3 weeks after surgery. This is to give the participants their treatment, see how well the treatment is working and also check for any unwanted effects participants may have. Participants will have follow-up visits every 3 months after completion of treatment to check on the participant's well-being. Total time of participation in the study will depend on how the cancer responds to treatment. 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 results measured in the study are to find out the number and length of surgical delays, cancellations, and complications during and after surgery.

- Number of participants with unwanted effects
- Number of participants with less than 10% of cancer cells left in the tumour sample removed during surgery

Other key results measured include:

- Number of participants who do not have active cancer cells in the tumour sample removed during surgery
- Approximate time from the start of treatment until the first incidence of cancer worsening that prevents surgery, cancer coming back, or participants dying due to any cause
- How well the body processes tiragolumab and atezolizumab
- Number of participants whose bodies produce proteins against tiragolumab and atezolizumab before treatment and during the treatment

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 may 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 were informed about the risks and benefits, as well as any additional procedures or tests they may have to undergo. All details of the study were described in an informed consent document. This included information about possible effects and other options of treatment.

Risks associated with the study drugs Participants may have unwanted effects of the drugs 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 are having regular check-ups to see if there are any unwanted effects.

Tiragolumab
Participants were told about the known unwanted effects of tiragolumab, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include inflammation of the liver (hepatitis) with symptoms of yellowing of skin, pain in the stomach area, nausea, vomiting, itching, fatigue (feeling tired or weak), bleeding or bruising under the skin, and dark urine.

Atezolizumab Participants were 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 back pain, cough, decreased appetite, fever, headache, itching of the skin (pruritus), rash, joint pain (arthralgia), lack of energy (asthenia), and shortness of breath (dyspnea).

Tiragolumab, atezolizumab and chemotherapy are given as a drip into a vein. Known unwanted effects with infusion include irritation where the injection is given, fever, chills, rash, redness, swelling, itching, or pain. The study medicines may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Histologically or cytologically confirmed Stage II, IIIA, or select IIIB (T3N2 only) NSCLC of squamous or non-squamous histology
- Eligible for R0 resection with curative intent at the time of screening
- Adequate pulmonary function to be eligible for surgical resection with curative intent
- Eligible to receive a platinum-based chemotherapy regimen
- Measurable disease, as assessed by the investigator per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
- Availability of a representative tumor specimen that is suitable for determination of PD-L1 status
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Normal life expectancy, excluding lung cancer mortality risk
- Adequate hematologic and end-organ function
- Negative human immunodeficiency virus (HIV) test at screening

- Negative serology for active hepatitis B virus (HBV) and active hepatitis C virus (HCV) at screening

Exclusion Criteria:

- NSCLC with histology of large cell neuroendocrine carcinoma, sarcomatoid carcinoma, or NSCLC not otherwise specified
- Small cell lung cancer (SCLC) histology or NSCLC with any component of SCLC
- Any prior therapy for lung cancer
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Active tuberculosis
- Significant cardiovascular disease
- NSCLC with an activating EGFR mutation or ALK fusion oncogene
- Known c-ros oncogene 1 (ROS1) rearrangement
- History of malignancy other than NSCLC within 5 years prior to screening, with the exception of malignancies with negligible risk of metastasis or death
- Severe infection within 4 weeks prior to initiation of study treatment or any active infection that, in the opinion of the investigator, could impact patient safety
- Prior treatment with CD127 agonists or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, anti-TIGIT, and anti-PD-L1 therapeutic antibodies
- Treatment with systemic immunostimulatory agents
- Treatment with systemic immunosuppressive medication
- Pregnancy or breastfeeding