ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A study evaluating the efficacy and safety of neoadjuvant treatment with atezolizumab or placebo in combination with platinum-based chemotherapy in patients with resectable stage II, IIIA, or select IIIB non-small cell lung cancer

A Study of Neoadjuvant Atezolizumab Plus Chemotherapy Versus Placebo Plus Chemotherapy in Patients With Resectable Stage II, IIIA, or Select IIIB Non-Small Cell Lung Cancer (IMpower030)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	24 Countries	NCT03456063 2023-504209-35-00 GO40241

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 is a randomized, double-blinded study designed to evaluate the efficacy, safety, pharmacokinetics, and immunogenicity of neoadjuvant treatment with atezolizumab (MPDL3280A) or placebo in combination with platinum-based chemotherapy in participants with resectable Stage II, IIIA, or select IIIB non-small cell lung cancer (NSCLC) followed by open-label adjuvant/postoperative atezolizumab or best supportive care and monitoring.

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

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Trial Identifiers

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 is present at a stage that can

be removed surgically (resectable). Treatments given prior to surgery to shrink or stop the cancer from spreading are called neoadjuvant 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 medicine called atezolizumab. It is being developed as a treatment to be given prior to surgery for lung cancers that can be removed surgically. Atezolizumab alone and in combination with platinum-based cancer medicines (chemotherapy) is approved by health authorities for treating advanced NSCLC and other cancer types. However, in this study, it is considered to be an experimental drug. Health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved the combination of atezolizumab with chemotherapy prior to surgery treatment for surgically removable lung cancers.

This study aims to compare the effects of atezolizumab plus chemotherapy versus placebo plus chemotherapy in people with lung cancers that can be removed by surgery. The study will check the effects of the combination treatment before surgery followed by atezolizumab given alone after surgery. Placebo is a medicine without any active ingredients.

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 took part in this study. People could not take part in this study if they had a major surgery within 28 days before they started the study or had planned a surgery or procedure during this study.

People who were pregnant, or breastfeeding also could not participate in the study.

3. How does this study work?

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

Everyone who joined this study was split into two groups (Groups A and B). They received either atezolizumab (Group A) or placebo (Group B), with chemotherapy, as a drip into the vein every 3 weeks for 12 weeks. Participants underwent surgery to remove the cancer after 12 weeks of prior to surgery treatment. After surgery, participants continued to receive atezolizumab (Group A) for up to 16 treatments or 48 weeks, or best supportive care (Group B). Treatment continued until one of the following occurred: 48 weeks of treatment (Group A), completion of observation visit (Group B), participants' cancer returned, they experienced any unacceptable side effects, they withdrew from the study, or death due to any reason.

This first part of this study (i.e., prior to surgery) was double-blind. This means that neither the participants in the study nor the team running it knew which treatment was being given before the surgery. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment. However, the study doctor could find out which group the participant was in, if the participants' safety was at risk. After the surgery, the study was open-label. This means everyone involved, including the participant and the study doctor, knew the study treatment the participant was given.

During this study, the study doctor met the participants every 3 weeks for 12 weeks before surgery and continued checking the participants every 3 or 6 weeks after surgery for up to 48 weeks. This is to see how well the treatment is working and any unwanted effects participants may have. Participants will have follow-up visits every 3 months after completion of treatment or observation visits 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 is to find out the 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.

Other key results measured include:

- Number of participants who are cancer free or have less than 10% of their cancer cells left in the tumour sample removed during surgery after 12 weeks of treatment
- Number of participants who die from any cause during the study
- Time taken for the cancer to come back in a participant who was previously cancer free after undergoing surgery
- Change in participant’s physical and mental health over time assessed using a questionnaire from the start of the study until the completion of treatment
- Number of participants with unwanted effects
- How well the body processes atezolizumab
- Number of participants whose bodies produce proteins against atezolizumab

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 can help other people with similar health conditions in the future.

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.

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, dry mouth, weakness, fever, headache, itching of the skin (pruritus), rash, joint pain (arthralgia), lack of energy (asthenia), and shortness of breath (dyspnoea).

Nab-Paclitaxel

Known unwanted effects include difficulty in passing stools (constipation), decrease in red blood cells (anaemia), decreased appetite, weakness, muscle aches, decrease in white blood cells (leukopenia), and rash.

Atezolizumab, chemotherapy, and placebo were given as a drip into the vein. Known unwanted effects with infusion include irritation where the drip is given, fever, chills, swelling, rash, redness, 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.