ForPatients
by Roche

Small Cell Lung Cancer

A study of lurbinectedin in combination with atezolizumab compared with atezolizumab as maintenance therapy in participants with extensive-stage small-cell lung cancer (ES-SCLC) following first-line induction therapy with carboplatin, etoposide and atezolizumab

A Phase III, Open-Label Study of Maintenance Lurbinectedin in Combination With Atezolizumab Compared With Atezolizumab in Participants With Extensive-Stage Small-Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	13 Countries	NCT05091567 2023-503868-16-00 GO43104

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

Trial Summary:

Study GO43104 is a Phase III, randomized, open-label, multicenter study of lurbinectedin in combination with atezolizumab compared with atezolizumab alone administered as maintenance therapy in participants with extensive-stage small-cell lung cancer (ES-SCLC) after first-line induction therapy with carboplatin, etoposide, and atezolizumab. The study consists of 2 phases: an induction phase and a maintenance phase. Participants need to have an ongoing response or stable disease per the Response Evaluation Criteria in Solid Tumor (RECIST) v1.1 criteria after completion of 4 cycles of carboplatin, etoposide, and atezolizumab induction treatment in order to be considered for eligibility screening for the maintenance phase. Eligible participants will be randomized in a 1:1 ratio to receive either lurbinectedin plus atezolizumab or atezolizumab in the maintenance phase.

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?

Small cell lung cancer (SCLC) is a type of very fast-growing lung cancer. SCLC that has spread to both lungs or other parts of the body and cannot be removed with surgery is known as ‘extensive-stage SCLC’, or ‘ES-SCLC’. Initial treatment for ES-SCLC is called ‘induction therapy’. Induction therapy includes chemotherapy given with ‘immunotherapy’. Immunotherapy, such as atezolizumab, is a type of medicine that helps the body’s natural defense (immune system) attack cancer cells. After induction therapy, ‘maintenance’ treatment with immunotherapy is given to stop or slow the growth of cancer cells. Current treatments do not work well for everyone, so new combinations are needed.

This study is testing an experimental combination of medicines called lurbinectedin and atezolizumab. It is being developed to treat ES-SCLC. This means health authorities (like the U.S. Food and Drug Administration [FDA] and European Medicines Agency) have not approved lurbinectedin with atezolizumab for the treatment of ES-SCLC. Lurbinectedin alone is approved by the FDA for treating SCLC that has spread in the body and worsened during or after treatment with chemotherapy. This study aims to compare the effects of lurbinectedin plus atezolizumab versus atezolizumab as maintenance therapy in people with ES-SCLC.

2. Who can take part in the study?

People of at least 18 years of age with ES-SCLC can take part in the study if they have not been treated for ES-SCLC. People may not be able to take part in this study if they have cancer that has spread to the brain, certain medical conditions such as liver or heart disease, or have received certain treatments before, including lurbinectedin or certain medicines that affect the immune system. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 1 month before the start of treatment in each phase of the study. There are 2 treatment phases - induction and maintenance.

Everyone who joins this study will be given:

- Induction phase: chemotherapy (carboplatin and etoposide) and atezolizumab, as a drip into the vein (infusion) every 3 weeks
- Maintenance phase:
    - Lurbinectedin plus atezolizumab, as an infusion every 3 weeks, OR
    - Atezolizumab, as an infusion every 3 weeks

Participants who complete all treatment in the induction phase without having unacceptable unwanted effects or their cancer getting worse will be able to take part in the maintenance phase. They will have an equal chance of being placed in either group in the maintenance phase. 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 both phases of this study, the study doctor will see participants every 3 weeks, with extra visits during the first 6 weeks of the maintenance phase. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit 1 month after their last dose of the study treatment during which the study doctor will check on the participant's well being. Then, the study doctor will check on the participant through their medical records, hospital visits or telephone calls at least every 3 months for as long as they agree to it. Total time of participation in the study could be more than 2 years. 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 to assess if the medicine has worked are how long participants live, and how long participants live without their cancer getting worse.

Other key results measured in the study include:

- How many participants have a reduction of their cancer after treatment that lasts for at least 1 month
- How much time there is between participants' cancer first responding to treatment and the cancer getting worse
- The number of participants whose cancer has not worsened at 6 and 12 months after starting the study, or who are living 1 and 2 years after starting the study
- The number and seriousness of unwanted effects
- How atezolizumab affects the immune system
- The time it takes for a participant to have a significant worsening in certain measures (such as pain, quality of life, or being able to do daily activities)

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

Risks associated with atezolizumab and lurbinectedin Participants may have unwanted effects of the combinations of medicines 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 will have regular check-ups to see if there are any unwanted effects. Participants will be told about the known unwanted effects of atezolizumab and lurbinectedin and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects of atezolizumab include cough, pain or discomfort in the head, back pain, joint, muscle, or bone pain, loose watery stools, feeling tired or weak, fever, itching, rash, and difficulty breathing. Known unwanted effects of lurbinectedin include throwing up, wanting to throw up, feeling tired or weak, loose watery stools, and feeling less hungry than usual. Known unwanted effects of infusions include throwing up, wanting to throw up, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, pain or discomfort in the head, loose watery stools, shortness of breath, and cough.

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.