ForPatients
by Roche

Small Cell Lung Cancer

A clinical trial to compare atezolizumab plus lurbinectedin with atezolizumab alone after initial treatment with carboplatin, etoposide and atezolizumab in people with extensive-stage small-cell lung cancer (ES-SCLC)

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

NCT05091567 2023-503868-16-00 GO43104
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

The aim of this document is to give people interested in this trial the background, treatment plan, scope of participants who are able to take part, benefits and risks. We recommend that this should be read carefully by potential participants and shared with close family members and caregivers.

Why is the IMforte clinical trial needed?

ES-SCLC is an aggressive form of lung cancer that can quickly spread to other parts of the body. There are currently limited treatment options available and after initial treatment, the disease can worsen. Therefore, newer treatment options are needed to help people with this disease live longer.

This clinical trial aims to investigate whether combining atezolizumab (cancer immunotherapy) and lurbinectedin (a cytotoxic agent, similar to chemotherapy), can prolong people's lives compared with the current treatment option of atezolizumab alone, after their initial treatment for ES-SCLC.

How does the IMforte clinical trial work?

This clinical trial is recruiting people who have a type of lung cancer called extensive-stage small-cell lung cancer (ES-SCLC).

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus lurbinectedin versus atezolizumab alone in people with ES-SCLC, after induction (initial) treatment. Following induction treatment with carboplatin, etoposide and atezolizumab, people who are eligible to continue in this clinical trial will enter the 'maintenance phase', where treatment aims to prevent the cancer from worsening. To be eligible for the maintenance phase, the participants' disease must not have worsened and their clinical trial doctor will do additional assessments to see if they meet the other requirements needed to continue into the maintenance phase. In the maintenance phase, participants will be given either atezolizumab plus lurbinectedin or atezolizumab alone.

Participants will be given the clinical trial treatment atezolizumab plus lurbinectedin or atezolizumab alone for as long as it can help them. Participants will be seen by the clinical trial doctor around every three weeks when receiving treatment (these visits may last for 3–6 hours) and contacted approximately every three months (for as long as they agree to it) after their final treatment dose. This will include checks to see how the disease is responding to the treatment and any side effects participants may be having. Participants can remain on treatment as long as there is no worsening of the disease or unacceptable side effects, but are also free to stop trial treatment and leave the trial at any time.

What are the main outcome measures of the IMforte clinical trial?

The main clinical trial outcome measures (used to assess if the treatment is working) are how long participants live without their disease worsening (progression-free survival) and how long participants live in total (overall survival).

The other clinical trial outcome measures are how many participants have a reduction in the size of their tumours (a response) and how long this lasts. Both are assessed through imaging scans of various parts of the body. Participants will have imaging assessments around every six weeks for the first year and then every nine weeks thereafter (or as often as doctors feel it is necessary). The safety of the clinical trial treatment and its impact on quality of life will also be assessed regularly throughout the clinical trial.

Who can take part in this clinical trial?

People can take part in this trial if they are aged 18 years or over, if they have a confirmed diagnosis of ES-SCLC and have received no prior systemic treatment (any treatment that travels through the bloodstream) for ES-SCLC.

People may not be able to take part in this clinical trial if their cancer has spread to their central nervous system (the brain or spinal cord). Also, if someone has previously received certain treatments or has other health conditions, they may not be able to take part in this clinical trial. Another reason for not taking part is if someone is pregnant or breastfeeding, or if they plan on becoming pregnant during the clinical trial or within six months after the final dose of the clinical trial treatment.

What treatment will participants be given in this clinical trial?

Initially, everyone who joins the clinical trial will go through the induction phase, which is four cycles of standard initial treatment of carboplatin, etoposide and atezolizumab. Each cycle is approximately three weeks long.

Following the induction phase, participants whose cancer has not worsened will enter the maintenance phase and will be allocated into one of two groups randomly and given either:

- Atezolizumab plus lurbinectedin, each given as infusions (into the vein) every three weeks
  or
- Atezolizumab alone, as an infusion into the vein every three weeks

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

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

The safety and effectiveness of the experimental treatment (atezolizumab plus lurbinectedin) are not fully known at the time of the trial. Most trials involve some risks to

the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the disease. Potential participants will be told about any risks and potential benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need in order to make an informed decision as to whether they wish to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the 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 and even life-threatening, and can vary from person to person.

Clinical trial drugs

Potential participants will be told about the known side effects of atezolizumab, lurbinectedin, carboplatin and etoposide and, where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

Atezolizumab, lurbinectedin and carboplatin will each be given as infusions (into the vein). Etoposide can be given as an infusion or orally. Any known side effects from drug administration (infusion or oral dosing) will be shared with potential participants.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05091567