ForPatients
by Roche

Small Cell Lung Cancer

A Study of Atezolizumab Plus Carboplatin and Etoposide With or Without Tiragolumab in Patients With Untreated Extensive-Stage Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	4 Countries	NCT04256421 2019-003301-97 GO41767

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 efficacy of tiragolumab plus atezolizumab and carboplatin and etoposide (CE) compared with placebo plus atezolizumab and CE in participants with chemotherapy-naive extensive-stage small cell lung cancer (ES-SCLC). Eligible participants will be stratified by Eastern Cooperative Oncology Group (ECOG) Performance Status (0 vs. 1), LDH (</= upper limit of normal [ULN] vs. > ULN), and presence or history of brain metastasis (yes vs. no) and randomly assigned in a 1:1 ratio to receive one of the following treatment regimens during induction phase: * Arm A: Tiragolumab plus atezolizumab plus CE * Arm B: Placebo plus atezolizumab plus CE Following the induction phase, participants will continue maintenance therapy with either atezolizumab plus tiragolumab (Arm A) or atezolizumab plus placebo (Arm B).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04256421 2019-003301-97 GO41767
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. HOW DOES THE GO41767 CLINICAL TRIAL WORK?

This clinical trial is recruiting people who have a type of disease called small cell lung cancer (SCLC) that has spread to other parts of the body (called ‘extensive stage’ or ES-SCLC).

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus platinum-based chemotherapy (the current standard of care) against atezolizumab plus platinum-based chemotherapy plus tiragolumab (the study drug). If you take part in this clinical trial, you will receive either atezolizumab plus platinum-based chemotherapy plus a placebo OR atezolizumab plus platinum-based chemotherapy plus tiragolumab.

2. HOW DO I TAKE PART IN THIS CLINICAL TRIAL?

To be able to take part in this clinical trial, you must have ES-SCLC that has spread to other parts of the body. You must not have previously received any treatment for your ES-SCLC.

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 the information you need to make a 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 and for up to 6 months after your final treatment, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or must take contraceptive medication for safety reasons.

3. WHAT TREATMENT WILL I BE GIVEN IF I JOIN THIS CLINICAL TRIAL?

Everyone who joins this clinical trial will be split into 2 groups randomly (like flipping a coin) and receive the standard treatment (atezolizumab plus chemotherapy) with or without tiragolumab.

Treatment will be given in 2 parts or ‘phases’: the induction phase and then the maintenance phase.

Induction phase

- Atezolizumab, given as an infusion into the vein once every 3 weeks for 4 treatment cycles
- Tiragolumab (Group 1) OR placebo (Group 2), given as an infusion into the vein once every 3 weeks for 4 treatment cycles Chemotherapy
- Carboplatin given as an infusion into the vein once every 3 weeks for 4 treatment cycles
- Etoposide given as an infusion into the vein on Day 1, 2 and 3 every 3 weeks for 4 treatment cycles

Maintenance phase

- Atezolizumab plus tiragolumab, given as an infusion into the vein once every 3 weeks (Group 1)
- OR atezolizumab plus placebo, given as an infusion into the vein once every 3 weeks (Group 2)

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

This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a 'placebo') along with the current standard of care of atezolizumab plus platinum-based chemotherapy. A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

4. HOW OFTEN WILL I BE SEEN IN FOLLOW-UP APPOINTMENTS AND FOR HOW LONG?

During this study, you will come in for visits approximately every 3 weeks while you are receiving treatment.

You will continue to receive study treatment on a regular basis unless your cancer worsens or if your doctor determines there is no benefit of continuing treatment. After your final dose, your study doctor will follow up with you about every 3 months for as long as you agree to it. Your total time in the study will depend on how your SCLC responds to treatment. This could range from 1 day to more than 12 months.

5. WHAT HAPPENS IF I AM UNABLE TO TAKE PART IN THIS CLINICAL TRIAL?

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.

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For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

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