ForPatients
by Roche

Small Cell Lung Cancer

A clinical trial to look at how well venetoclax plus atezolizumab, carboplatin and etoposide work to reduce certain signs of extensive-stage small cell lung cancer and how safe venetoclax is at different doses.

A Study Evaluating The Safety, Tolerability, Pharmacokinetics, And Efficacy Of Venetoclax In Combination With Atezolizumab, Carboplatin, And Etoposide In Participants With Untreated Extensive-Stage Small Cell Lung Cancer (ES-SCLC).

Trial Status	Trial Runs In	Trial Identifier
Terminated	4 Countries	NCT04422210 2019-004487-22 GO41864

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

Trial Summary:

A study consisting of a dose-escalation phase and a dose-expansion phase to evaluate the safety, tolerability, pharmacokinetics, and efficacy of venetoclax in combination with atezolizumab, carboplatin, and etoposide.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT04422210 2019-004487-22 GO41864
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the GO41864 clinical trial work? This clinical trial is recruiting people who have a type of disease called small cell lung cancer (SCLC). In order to take part, patients must have extensive-stage small cell lung cancer (ES-SCLC).

The purpose of this clinical trial is to find the best dose of venetoclax and to test the safety of venetoclax in combination with atezolizumab, carboplatin and etoposide.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have been diagnosed with ES-SCLC. You cannot join the trial if you are pregnant or breastfeeding.

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 all the information you need to make your 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, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be enrolled into one of two parts; these parts are called the Dose-Escalation Phase and the Dose-Expansion Phase.

Dose-Escalation Phase
If you are enrolled into this Phase you will then be placed into one of two groups: Group A or Group B. Group A will be tested first. If patients in Group A are able to take the treatment without any serious side effects, Group B will be opened.

Group A – venetoclax plus atezolizumab

- Patients who have completed 4-6 rounds of chemotherapy with carboplatin and etoposide will be placed in Group A.
    - Venetoclax given as a tablet to take each day for a 3-week cycle
        - If patients are able to take venetoclax without serious side effects, the dose of venetoclax will be increased for the next set of patients
    - Atezolizumab given as an infusion into the vein every 3 weeks

OR

Group B – venetoclax, atezolizumab, carboplatin and etoposide

- Patients who have not received any previous treatment for ES-SCLC will be placed in Group B.
    - 4 rounds of treatment with venetoclax, atezolizumab, carboplatin and etoposide
        - Venetoclax is given as a tablet to take each day for 7 days of a 3-week cycle
            - If patients are able to take venetoclax without serious side effects, the dose of venetoclax will be increased for the next set of patients
        - Atezolizumab and carboplatin are given as infusions into the vein every 3 weeks
        - Etoposide is given as an infusion into the vein for the first 3 days
    - You will then receive venetoclax plus atezolizumab
        - Venetoclax is given as a tablet to take each day based on the safe dose that was found in Group A
        - Atezolizumab is given as an infusion into the vein every 3 weeks

Dose-Expansion Phase
Once the Dose-Escalation Phase has established the most effective and safe dose of venetoclax, more patients will be included in the study in the Dose-Expansion Phase. New patients will be added to Group A or Group B, depending on what the results from the Dose-Escalation Phase showed.

How often will I be seen in follow-up appointments and for how long? You will be given the clinical trial treatment venetoclax, atezolizumab, carboplatin and etoposide OR venetoclax plus atezolizumab for as long as it can help you. During treatment, you will be seen by the clinical trial doctor every 3 weeks to see how you are responding to the treatment and any side effects that you may be having. You are free to stop this treatment at any time. After stopping treatment, you will still be seen in clinic or contacted via telephone regularly by the clinical trial doctor every 3 months.

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.

For more information about this clinical trial see the For Expert tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04422210?term=NCT04422210&draw=2&rank=1