ForPatients
by Roche

Unresectable Hepatocellular Carcinoma Hepatocellular Carcinoma (HCC)

A clinical trial to compare atezolizumab plus lenvatinib or sorafenib with lenvatinib or sorafenib alone in people with advanced and/or inoperable HCC (after previous treatment with atezolizumab plus bevacizumab)

A Study of Atezolizumab With Lenvatinib or Sorafenib Versus Lenvatinib or Sorafenib Alone in Hepatocellular Carcinoma Previously Treated With Atezolizumab and Bevacizumab

Trial Status	Trial Runs In	Trial Identifier
Recruiting	31 Countries	NCT04770896 MO42541

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 Phase III, open-label, multicenter, randomized, two-arm study designed to evaluate the efficacy and safety of atezolizumab plus either lenvatinib or sorafenib versus lenvatinib or sorafenib alone in participants with locally advanced or metastatic Hepatocellular Carcinoma (HCC) who have progressed on prior systemic treatment with atezolizumab plus bevacizumab combination.

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

NCT04770896 MO42541
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. How does the IMbrave251 clinical trial work?

This clinical trial is recruiting people who have a particular type of liver cancer called hepatocellular carcinoma (HCC). In order to take part, patients must have HCC that has spread within the liver or to other parts of the body and/or cannot be removed by surgery

(inoperable). Patients must have already received treatment with atezolizumab plus bevacizumab for their HCC.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus lenvatinib or sorafenib versus lenvatinib or sorafenib alone on patients with HCC. In this clinical trial, you will get either atezolizumab plus lenvatinib or sorafenib, or lenvatinib or sorafenib alone.

2. How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years of age and be diagnosed with inoperable HCC that has spread within the liver and/or to other parts of the body. You must have previously received atezolizumab plus bevacizumab as treatment for HCC and have good liver function. If you test positive for hepatitis B infection, you must take suitable anti-viral medication in order to participate in this clinical trial. If your cancer has spread to central nervous system, it must be well managed and not symptomatic.

If you have had previous treatment with certain medications or have certain medical conditions, you may not be able to take part.

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.

3. What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

Group A:

Atezolizumab, given as an infusion into the vein every three weeks, plus:

Lenvatinib, in the form of a pill to be swallowed once per day

Or sorafenib, in the form of a pill to be swallowed twice per day

Group B:

Lenvatinib or sorafenib alone, given as described above

You will have a 1 in 2 chance of being placed in either group. In both groups, whether you are given lenvatinib or sorafenib will depend on the study site, but all patients at each site will be given the same option.

4. How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment atezolizumab plus lenvatinib or sorafenib OR lenvatinib or sorafenib alone for as long as it can help you. You are free to stop this treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor. These hospital visits will include scans to see how you are responding to the treatment and checks for any side effects that you may be having. Scans happen every 6 weeks in the first 54 weeks of the trial and every 9 weeks in the time after that.

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.

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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