ForPatients
by Roche

A Clinical Trial to Compare Atezolizumab plus Bevacizumab with Sorafenib in Patients with Untreated Advanced Hepatocellular Carcinoma (IMbrave150)

A Study of Atezolizumab in Combination With Bevacizumab Compared With Sorafenib in Patients With Untreated Locally Advanced or Metastatic Hepatocellular Carcinoma (IMbrave150) [IMbrave150]

Trial Status	Trial Runs In	Trial Identifier
Completed	17 Countries	NCT03434379 2017-003691-31 YO40245

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase III, Open-Label, Randomized Study of Atezolizumab in Combination With Bevacizumab Compared With Sorafenib in Patients With Untreated Locally Advanced or Metastatic Hepatocellular Carcinoma

Trial Summary:

This study will evaluate the efficacy and safety of atezolizumab in combination with bevacizumab compared with sorafenib in participants with locally advanced or metastatic Hepatocellular Carcinoma (HCC) who have received no prior systemic treatment.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03434379 2017-003691-31 YO40245
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

How does the IMbrave150 clinical trial work? This clinical trial is recruiting people who have a specific type of liver cancer called ‘hepatocellular carcinoma’ or HCC, which has begun to spread to surrounding tissues or lymph nodes (called ‘advanced’) or cannot be surgically removed (called ‘inoperable’).

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must not have already been given any medicine for your advanced or inoperable cancer.

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 who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of 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 and 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 and 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 split into two groups randomly (like flipping a coin) and given one of two different treatments:

- Either you will be given a combination of two new trial medicines, atezolizumab and bevacizumab, into your vein (called an ‘intravenous infusion’) once every 3 weeks.
- Or you will be given 2 tablets of sorafenib to swallow 2 times a day throughout the treatment period.

You will have a 2 out of 3 chance of being given atezolizumab and bevacizumab, and a 1 out of 3 chance of being given sorafenib.

How often will I be seen in follow-up appointments, and for how long? You will be given the trial treatment 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 every 3 weeks. These hospital visits will include a physical examination, blood tests (and a pregnancy test if you are a woman), surveys about how you are feeling and managing with day-to-day tasks, and to talk about how your cancer is responding to the treatment and any side effects that you may be having. You will also need to have tumour scans every 6 weeks for the first year, then every 9 weeks after that.

What happens if I'm unable to take part in this clinical trial? If your specific cancer type does not match what this clinical trial is looking at and/or the results of your blood tests are not in the range needed for the trial, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for your cancer that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

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

Trial-identifier: NCT03434379

Inclusion Criteria:

- Locally advanced or metastatic and/or unresectable Hepatocellular Carcinoma (HCC)
- No prior systemic therapy for HCC. Previous use of herbal therapies/traditional Chinese medicines with anti-cancer activity included in the label is allowed, provided that these medications are discontinued prior to randomization.
- At least one measurable untreated lesion
- ECOG Performance Status of 0 or 1
- Adequate hematologic and end-organ function
- For women of childbearing potential: agreement to remain abstinent
- For men: agreement to remain abstinent
- Child-Pugh class A

Exclusion Criteria:

- History of leptomeningeal disease
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography scan
- Known active tuberculosis
- History of malignancy other than HCC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within at least 5 months after the last dose of atezolizumab, 6 months after the last dose of bevacizumab, or 1 month after the last dose of sorafenib
- Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC
- Untreated or incompletely treated esophageal and/or gastric varices with bleeding or high-risk for bleeding
- A prior bleeding event due to esophageal and/or gastric varices within 6 months prior to initiation of study treatment.
- Moderate or severe ascites
- History of hepatic encephalopathy
- Co-infection of HBV and HCV
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Uncontrolled or symptomatic hypercalcemia

- Treatment with systemic immunostimulatory agents
- Inadequately controlled arterial hypertension
- Prior history of hypertensive crisis or hypertensive encephalopathy
- Evidence of bleeding diathesis or significant coagulopathy
- History of intestinal obstruction and/or clinical signs or symptoms of GI obstruction including sub-occlusive disease related to the underlying disease or requirement for routine parenteral hydration
- Serious, non-healing or dehiscing wound, active ulcer, or untreated bone fracture
- Metastatic disease that involves major airways or blood vessels, or centrally located mediastinal tumor masses
- Local therapy to liver within 28 days prior to initiation of study treatment or non-recovery from side effects of any such procedure
- Chronic daily treatment with a non-steroidal anti-inflammatory drug (NSAID)