ForPatients
by Roche

A Study of Atezolizumab (Tecentriq) in Combination With Bevacizumab to Investigate Safety and Efficacy in Patients With Unresectable Hepatocellular Carcinoma Not Previously Treated With Systemic Therapy-Amethista

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04487067 ML42243

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 IIIB, Single Arm, Multicenter Study of Atezolizumab (Tecentriq) in Combination With Bevacizumab to Investigate Safety and Efficacy in Patients With Unresectable Hepatocellular Carcinoma Not Previously Treated With Systemic Therapy-Amethista

Trial Summary:

This is a Phase IIIb, one arm, multicenter, open-label study designed to evaluate the safety and efficacy of atezolizumab + bevacizumab in patients with unresectable HCC who have received no prior systemic treatment.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT04487067 ML42243
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Unresectable HCC with diagnosis confirmed by histology, with a biopsy within 6 months from recruitment;
- Disease that is not amenable to curative surgical and/or locoregional therapies, or progressive disease after surgical and /or locoregional therapies;

- No prior systemic therapy for HCC;
- At least one measurable untreated lesion;
- Patients who received prior local therapy are eligible provided the target lesion(s) have not been previously treated with local therapy or the target lesion(s) within the field of local therapy have subsequently progressed in accordance with RECIST version 1.1;
- ECOG Performance Status of 0 or 1 within 7 days prior to recruitment;
- Child-Pugh class A within 7 days prior to recruitment;
- Patients must undergo an esophagogastroduodenoscopy (EGD), and all size of varices (small to large) must be assessed. In case of varices at high risk of bleeding (corresponding to medium (F2) or large (F3) varices, or F1 varices with cherry red spots or red wale marking) prophylatic treatment per local standard of care must be adopted prior to enrollment. Patients who have undergone an EGD within 6 months of prior to initiation of study treatment do not need to repeat the procedure provided they had no varices at high risk of bleeding;
- Adequate hematologic and end-organ function
- Resolution of any acute, clinically significant treatment-related toxicity from prior therapy to Grade <= 1 prior to study entry, with the exception of alopecia
- Negative HIV test at screening with the following exception: patients with a positive HIV test at screening are eligible provided they are stable on anti-retroviral therapy, have a CD4 count #200µL, and have an undetectable viral load;
- In patients with viral HCC, documented virology status of hepatitis, as confirmed by screening HBV and HCV serology test;
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating eggs.
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm.

Exclusion Criteria:

- History of leptomeningeal disease or brain metastases;
- 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 (CT) scan;
- Known active tuberculosis;
- Significant cardiovascular disease within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina;
- 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;
- Prior allogeneic stem cell or solid organ transplantation;
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within at least 5 months after the last dose of atezolizumab and 6 months after the last dose of bevacizumab;
- 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 oesophageal and/or gastric varices within 6 months prior to initiation of study treatment;
- Clinically evident ascites;
- Co-infection of HBV and HCV;
- Co-infection with HBV and hepatitis D viral infection;
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases;
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures;
- Clinically significant uncontrolled or symptomatic hypercalcemia;
- Inadequately controlled arterial hypertension;

- Significant vascular disease within 6 months prior to initiation of study treatment;
- History of haemoptysis;
- Evidence of bleeding diathesis or significant coagulopathy;
- History of gastrointestinal (GI) fistula, GI perforation, or intra-abdominal abscess within 6 months prior to initiation of study treatment;
- 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, parenteral nutrition, or tube feeding prior to initiation of study treatment;
- Metastatic disease that involves major airways or blood vessels, or centrally located mediastinal tumor masses of large volume;
- Local therapy to liver within 28 days prior to initiation of study treatment or non-recovery from side effects of any such procedure.