ForPatients
by Roche

A Study Evaluating Atezolizumab, With or Without Bevacizumab, in Participants With Unresectable Hepatocellular Carcinoma and Child-pugh B7 and B8 Cirrhosis

Trial Status	Trial Runs In	Trial Identifier
Recruiting	2 Countries	NCT06096779 ML44719

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 II, Open-label, Multi-cohort, Multicenter Study in Patients With Unresectable Hepatocellular Carcinoma and Child-pugh B7 and B8 Cirrhosis

Trial Summary:

The purpose of this study is to assess the safety of atezolizumab and bevacizumab, or atezolizumab alone, as first-line treatment in participants with unresectable, locally advanced or metastatic hepatocellular carcinoma (HCC) with Child-pugh B7 or B8 cirrhosis.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT06096779 ML44719
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Locally advanced or metastatic and/or unresectable HCC with diagnosis confirmed by histology/ cytology or clinically by American Association for the Study of Liver Diseases (AASLD) criteria in cirrhotic participants
- Disease that is not amenable to curative surgical and/or locoregional therapies
- No prior systemic treatment (including systemic investigational agents) for locally advanced or metastatic and/or unresectable HCC

- Measurable disease (at least one untreated target lesion) according to RECIST v1.1
- ECOG Performance Status of 0-2 within 7 days prior to initiation of study treatment
- Child-Pugh B7 or B8 cirrhosis at screening and within 7 days prior to study treatment
- Adequate hematologic and end-organ function
- Life expectancy of at least 12 weeks
- Female participants of childbearing potential must be willing to avoid pregnancy and egg donation
- Absolute neutrophil count #1.0 x 109/L (#1000/µL) without granulocyte colony-stimulating factor support
- Platelet count # 50 × 109/L (50,000/µL) without transfusion
- Hemoglobin # 80 g/L (8 g/dL) AST and ALT # 5 × upper limit of normal (ULN)
- Serum bilirubin # 3 × ULN
- Creatinine clearance # 50 mL/min (calculated using the Cockcroft-Gault formula)
- Serum albumin # 20 g/L (2.0 g/dL) without transfusion in the prior 3 months
- INR #2.3

Exclusion Criteria:

- Pregnancy or breastfeeding
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Treatment with locoregional therapy to liver within 28 days prior to initiation of study treatment, or non-recovery from side effects of any such procedure
- Treatment with systemic immunostimulatory agents
- Treatment with systemic immunosuppressive medication
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment
- Inadequately controlled hypertension
- 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
- Participants who have a known concurrent malignancy that is progressing or requires active treatment, who have not completely recovered from treatment, or who have a significant malignancy history that, in the opinion of the investigator, should preclude participation.
- Participants on preventative hormonal therapies (i.e., tamoxifen and other hormonal inhibitors) are not excluded.
- Known fibrolamellar HCC, sarcomatoid HCC, other rare HCC variant, or mixed cholangiocarcinoma and HCC
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Prior allogeneic stem cell or solid organ transplantation
- Actively listed for liver transplantation
- Co-infection with hepatitis B virus (HBV) and hepatitis C virus (HCV)
- Untreated or incompletely treated esophageal and/or gastric varices with bleeding or that are at high risk for bleeding
- A prior bleeding event due to esophageal and/or gastric varices within 6 months prior to initiation of study treatment
- Grade #3 hemorrhage or bleeding event within 6 months prior to initiation of study treatment
- Hepatic encephalopathy is allowed if no active symptoms or stable within 3 months of study treatment
- History, planned, or recommended placement of transjugular intrahepatic portosystemic shunt (TIPS) is excluded from Cohort A only. TIPS is acceptable in Cohort B.
- Diagnostic Paracentesis is allowed. Therapeutic Paracentesis within 3 months is an exclusion criteria
- Participants with ascites controlled on diuretics are allowed.
- History of spontaneous bacterial peritonitis within last 12 months