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

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

General

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 General

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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

Conditions & Interventions

Interventions:

DRUG: Atezolizumab, DRUG: Bevacizumab

Conditions:

Hepatocellular Carcinoma

Keywords:

Cirrhosis, liver cancer, liver tumor, Child-Pugh B, hepatocellular carcinoma, atezolizumab, bevacizumab, Immune Checkpoint Inhibitor, Digestive System Neoplasms, Kirros, ML44719, liver disease, Genentech, Immunotherapy, CPB, CPB 7, CPB 8, Tecentriq, Avastin, HCC, Cirrhotic Liver, Fatty Liver

More Information

Contact(s): Reference Study ID Number: ML44719 https://forpatients.roche.com/ - global-roche-genentech-trials@gene.com

Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT06096779
