ForPatients
by Roche

Hepatocellular Carcinoma (HCC)

A Study of Atezolizumab in Combination With Bevacizumab in Spanish Patients With Unresectable or Unsuitable for Locoregional Treatments Hepatocellular Carcinoma Not Previously Treated With Systemic Therapy

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Country	NCT04732286 2020-005268-71 ML42600

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 in Combination With Bevacizumab to Investigate Safety and Efficacy in Spanish Patients With Unresectable or Unsuitable for Locoregional Treatments Hepatocellular Carcinoma Not Previously Treated With Systemic Therapy

Trial Summary:

This is a Phase IIIb, one arm, multicenter, open-label study primarily designed to evaluate the safety of atezolizumab + bevacizumab in participants with unresectable or unsuitable for locoregional treatments for metastatic HCC not previously treated with systemic therapy. As part of its secondary objectives, this study is also designed to evaluate the efficacy of atezolizumab and bevacizumab in these participants.

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

NCT04732286 2020-005268-71 ML42600
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 or radiologically, following the AASLD criteria
- 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 (including systemic investigational agents) for HCC
- At least one measurable (per RECIST 1.1) untreated lesion detected by CT scan
- Patients who received prior local therapy such as radiofrequency ablation, percutaneous ethanol or acetic acid injection, cryoablation, high-intensity focused ultrasound, transarterial chemoembolization, transarterial embolization (excluding transarterial radioembolization.) 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

Exclusion Criteria:

- 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 fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC
- Co-infection of HBV and HCV