Protocol Title: A Randomized, Open-label, Multi-center Phase III Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma (HIMALAYA)

Target Population: Hepatocellular Carcinoma (HCC)

Summary: This is a randomized, open-label, multi-center, global, Phase III study to assess the efficacy and safety of Durvalumab + Tremelimumab combination therapy and Durvalumab monotherapy VS Sorafenib in the treatment of patients with no prior systemic therapy for unresectable HCC. The patients cannot be eligible for locoregional therapy.

Key Inclusion Criteria:
- Unresectable Hepatocellular Carcinoma (HCC) histopathological diagnosis confirmation based on tumor tissue.
- No prior systemic therapy for HCC.
- Barcelona Clinic Liver Cancer (BCLC) Stage B (that is not eligible for locoregional therapy) or Stage C.
- Child-Pugh Score Class A.
- ECOG Performance Status of 0 or 1 at enrollment.

Key Exclusion Criteria:
- Hepatic encephalopathy within past 12 Months or requirement for medication to prevent or control encephalopathy.
- Ascites that your doctor will manage by increasing your medications or by performing non-invasive methods (e.g., paracentesis) to control, within 6 Months prior to the first scheduled dose.
- Main Portal Vein tumor thrombosis.
- Active or prior documented GI bleeding (e.g., esophageal varices or ulcer bleeding) within 12 Months.
- HBV and HVC co-infection, or HBV and Hep D co-infection.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03298451