KURZPROTOKOLL
BGB-A317-301

Öffentlicher Titel	Phase III Studie zu BGB-A317 vs. Sorafenib bei nicht resektablem Leberkrebs
Wissenschaftl. Titel	A Randomized, Open-label, Multicenter Phase 3 Study to Compare the Efficacy and Safety of BGB-A317 versus Sorafenib as First-Line Treatment in Patients with Unresectable Hepatocellular Carcinoma
Kurztitel	BGB-A317-301
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Leberkrebs (Hepatozelluläres Karzinom): Erstlinie
Einschlusskriterien	- Histologically confirmed diagnosis of HCC - Barcelona Clinic Liver Cancer (BCLC) Stage B or C disease not amenable to or progressing after loco-regional therapy and not amenable to a curative treatment approach - No prior systemic therapy for HCC (with the exception of HCC patients enrolled in the safety run-in substudy [Japan only]) - Measurable disease - Child-Pugh score A - Easter Cooperative Oncology Group (ECOG) Performance Status <= 1 - Adequate organ function
Ausschlusskriterien	- Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC histology - Tumor thrombus involving main trunk of portal vein or inferior vena cava - Loco-regional therapy to the liver within 28 days before randomization - Clinical evidence of portal hypertension with bleeding esophageal or gastric varices at Screening, or within 6 months before randomization - Bleeding or thrombotic disorder or any prescribed anticoagulant requiring therapeutic international normalized ratio monitoring (eg, warfarin or similar agents) at Screening, or within 6 months before randomization/enrollment - Presence at Screening of active immune deficiency or autoimmune disease and/or prior history of any immune deficiency or autoimmune disease that may relapse - Patient with any condition requiring systemic treatment with either corticosteroids (> 10 mg daily of prednisone or equivalent) or other immunosuppressive medication within 14 days before randomization - History of interstitial lung disease or non-infectious pneumonitis, unless induced by radiation therapy - QT interval corrected for heart rate (QTc) (corrected by Fridericia's method) > 450 msec at Screening
Alter	18 Jahre und älter
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) Klinik für Onkologie und Hämatologie Steinbacher Hohl 2-26 60488 Frankfurt am Main Manuela Padberg Tel: 069 7601-4558 Fax: 069 7601-3655 padberg.manuela@khnw.de
Sponsor	BeiGene, Ltd.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03412773 (primäres Register) EudraCT 2017-002423-19