KURZPROTOKOLL
BGB-A317-208

Öffentlicher Titel	Phase III Studie zu BGB-A317 bei vorbehandeltem, nicht resektablem Leberkrebs
Wissenschaftl. Titel	A Phase 2, Open-label, Multicenter Study to Investigate the Efficacy, Safety, and Pharmacokinetics of the Anti-PD-1 Monoclonal Antibody BGB-A317 in Patients with Previously Treated Hepatocellular Unresectable Carcinoma
Kurztitel	BGB-A317-208
Studienart	prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase II
Erkrankung	Verdauung: Leberkrebs (Hepatozelluläres Karzinom): Zweitlinie oder höher
Einschlusskriterien	- Histologically confirmed HCC - Patients with Barcelona Clinic Liver Cancer (BCLC) Stage C, or BCLC stage B not amenable to locoregional therapy or relapsed after locoregional therapy, and not amenable to a curative treatment approach - Has received at least 1 line of systemic therapy for unresectable HCC - Has at least 1 measurable lesion as defined per RECIST v1.1 - 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 - Prior therapies targeting PD-1 or PD-L1 - Has Known brain or leptomeningeal metastasis - Tumor thrombus involving main trunk of portal vein or inferior vena cava - Medical history of interstitial lung disease, non-infectious pneumonitis or uncontrolled systemic diseases, including diabetes, hypertension, pulmonary fibrosis, acute lung diseases, etc - Has received: - -> Within 28 days or 5 half-lives (whichever is shorter) of the first study drug administration: any chemotherapy, immunotherapy (eg, interleukin, interferon, thymoxin) or any investigational therapies - -> Within 14 days of the first study drug administration: sorafenib, regorafenib, or any Chinese herbal medicine or Chinese patent medicines used to control cancer - -> Active autoimmune diseases or history of autoimmune diseases 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 study drug administration
Alter	18 Jahre und älter
Sponsor	BeiGene, Ltd.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03419897 (primäres Register) EudraCT 2017-003983-10