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
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Celesté Neuwirth Tel: 069 7601 4461 neuwirth.celeste@khnw.de
Sponsor	BeiGene, Ltd.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03419897 (primäres Register) EudraCT 2017-003983-10