KURZPROTOKOLL
CA209-9DW

Öffentlicher Titel	Phase III Studie zu Nivolumab/Ipilimumab bei fortgeschrittenem Leberkrebs
Wissenschaftl. Titel	A Randomized, Multi-center, Phase 3 Study of Nivolumab in Combination With Ipilimumab Compared to Sorafenib or Lenvatinib as First-Line Treatment in Participants With Advanced Hepatocellular Carcinoma
Kurztitel	CA209-9DW
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Leberkrebs (Hepatozelluläres Karzinom): Erstlinie
Einschlusskriterien	- Participants must have a diagnosis of HCC based on histological confirmation - Participants must have an advanced HCC - Participants must have at least one Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 measurable previously untreated lesion - Child-Pugh score 5 or 6 - Eastern Cooperative Oncology Group (ECOG) performance status(PS) 0 or 1
Ausschlusskriterien	- Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC - Prior liver transplant - Episodes of hepatic encephalopathy (greater than or equal to [>=] Grade 2) within 12 months prior to randomization - Active brain metastases or leptomeningeal metastases
Alter	18 Jahre und älter
Prüfzentren	**Innere Medizin 1** (Nachbeobachtung) Gastroenterologie / Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Lisa Weiss Tel: 069 6301-87769 Fax: 069 6301-6580 Lisa.Weiss@kgu.de **Universitätsklinikum Frankfurt** (Nachbeobachtung) Medizinische Klinik I, Gastroenterologie/Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Lisa Weiss Tel: 069 6301-87769 Fax: 069 6301-6580 Lisa.Weiss@kgu.de
Sponsor	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04039607 (primäres Register) EudraCT 2019-000252-34