KURZPROTOKOLL
CA-209-9DX

Öffentlicher Titel	Phase III Studie zu Nivolumab als adjuvante Therapie bei Leberkrebs
Wissenschaftl. Titel	A Phase 3, Randomized, Double-blind Study of Adjuvant Nivolumab Versus Placebo for Participants With Hepatocellular Carcinoma Who Are at High Risk of Recurrence After Curative Hepatic Resection or Ablation
Kurztitel	CA-209-9DX
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Leberkrebs (Hepatozelluläres Karzinom): adjuvant
Einschlusskriterien	- Participants with a first diagnosis of HCC who have undergone a curative resection or ablation - Participants are eligible to enroll if they have non-viral related-HCC, or if they have HBV-HCC, or HCV-HCC - 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 - Any evidence of tumor metastasis or co-existing malignant disease - Participants previously receiving any prior therapy for HCC, including loco-regional therapies - Participants who have undergone a liver transplant or those who are in the waiting list for liver transplantation
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 NCT03383458 (primäres Register) EudraCT 2017-002755-29