Universitäres Centrum für Tumorerkrankungen Frankfurt
University Cancer Center

KURZPROTOKOLL
MK7902-005

Öffentlicher Titel	Phase II Studie zu Lenvatinib und Pembrolizumab bei vorbehandelten soliden Tumoren
Wissenschaftl. Titel	A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors
Kurztitel	MK7902-005
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase II
Erkrankung	NEURO: Glioblastom (WHO Grad IV): Zweitlinie oder höher
Einschlusskriterien	- Have a histologically or cytologically-documented, advanced (metastatic and/or unresectable) solid tumor that is incurable and for which prior standard systemic therapy has failed in one of the following cohorts: Cohort E: Glioblastoma - Participants must have progressed on or since the last treatment - Have measurable disease per RANO for the GBM - Life expectancy of 12 weeks or more - (ECOG) performance status of 0 to 1 within 7 days of treatment initiation - Adequately controlled blood pressure (BP) with or without antihypertensive medications, defined as BP <=150/90 mm Hg
Ausschlusskriterien	- Prolongation of QTc interval (calculated using Fridericia's formula) to >480 ms. - Has left ventricular ejection fraction (LVEF) <55 as determined by multigated acquisition scan (MUGA) or echocardiogram (ECHO). - Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior the first dose of study drug. - HIV, Hep B, Hep C, Tuberculosis - Has carcinomatous meningitis - Has recurrent tumor greater than 6cm in maximum diameter. - The GBM participant will not be excluded from the study for systemic steroid therapy, as long as dexamethasone or its steroid equipotent dosing equivalent is administered at a constant dose for at least 2 weeks prior to study treatment start where the dexamethasone dose (or its equivalent) is <= 2 mg daily.
Alter	18 Jahre und älter
Status	Aktiv
Beginn der Rekrutierung	05.04.2019
Prüfzentren	**Universitätsklinikum Frankfurt** Klinik und Poliklinik für Neurochirurgie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Martin Voß Tel: 069 6301 - 87711 martin.voss@kgu.de
Sponsoren	MSD
Registrierung in anderen Studienregistern	ClinicalTrials NCT03797326 (primäres Register) EUDRACT 2018-003747-37