

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	Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Zweitlinie oder höher
Einschlusskriterien	<ul style="list-style-type: none">- 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 \leq150/90 mm Hg
Ausschlusskriterien	<ul style="list-style-type: none">- 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 \leq 2 mg daily.
Alter	18 Jahre und älter
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Sponsor	MSD Sharp & Dohme
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03797326 (primäres Register) EudraCT 2018-003747-37