KURZPROTOKOLL
Keynote 164

Öffentlicher Titel	Phase II Studie zu Pembrolizumab bei Patienten mit refraktär/rezidiviertem lokal fortgeschrittenem oder metastasiertem kolorektalem Karzinom
Wissenschaftl. Titel	A Phase II Study of Pembrolizumab (MK-3475) as Monotherapy in Subjects with previously treated locally advanced unresectable or metastatic (Stage IV) Microsatellite Instability-High Colorectal Carcinoma
Kurztitel	Keynote 164
Studienart	multizentrisch, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase II
Erkrankung	Verdauung: Darmkrebs (Kolorektales Karzinom): Zweitlinie oder höher
Einschlusskriterien	- Histologically-proven locally advanced unresectable or metastatic high colorectal carcinoma - Locally confirmed MMR deficient or MSI status - Previously treated with approved standard therapies, which must include fluoropyrimidine, oxaliplatin and irinotecan - Eastern Cooperative Oncology Group performance status of 0 or 1 - Life expectancy of greater than 3 months - At least one measureable lesion - Female participants of childbearing potential should be willing to use 2 methods of birth control or be surgically sterile, or abstain from heterosexual activity for the course of the study through 120 days after the last dose of study medication - Male participants should agree to use an adequate method of contraception starting with the first dose of study - Adequate organ function
Ausschlusskriterien	- Currently participating in another study and receiving trial treatment, participated in a study of an investigational agent and received trial treatment within 4 weeks of the first dose of medication in this study, or used an investigational device within 4 weeks of the first dose of medication in this study - Active autoimmune disease that has required systemic treatment in past 2 years - Diagnosis of immunodeficiency or receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study medication - Known active central nervous system (CNS) metastases and/or carcinomatous meningitis - Prior monoclonal antibody (mAb), chemotherapy, targeted small molecule therapy, or radiation therapy within 2 weeks prior to study Day 1 or not recovered (i.e., Grade 1 or at baseline) from adverse events due to a previously administered agent - Prior therapy with an anti-programmed cell death (PD)-1, anti-PD-L1, or anti-PD-L2 agent, or participant has previously participated in Merck pembrolizumab (MK-3475) clinical trial - Known additional malignancy that is progressing or requires active treatment with the exception of basal cell carcinoma of the skin or squamous cell carcinoma of the skin that has undergone potentially curative therapy, or in situ cervical cancer - Received a live vaccine within 30 days of planned start of study medication - Known history of human immunodeficiency virus (HIV) - Known active Hepatitis B or C - Known history or any evidence of interstitial lung disease or active, non-infectious pneumonitis - Active infection requiring systemic therapy

	- Known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial - Pregnant or breastfeeding, or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 120 days after the last dose of trial medication
Alter	18 Jahre und älter
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Prof. Dr. med. Salah-Eddin Al-Batran Tel: 069 7601 4420 albatran.salah@khnw.de
Sponsor	MSD Sharp & Dohme
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02460198 EudraCT 2015-001852-32