KURZPROTOKOLL
MSD 7339-006

Öffentlicher Titel	Phase III Studie zu Pembrolizumab als Erstlinientherapie beim metastasierten NSCLC Adenokarzinom
Wissenschaftl. Titel	A Phase 3 Study of Pembrolizumab in Combination with Pemetrexed/Platinum (Carboplatin or Cisplatin) followed by Pembrolizumab and Maintenance Olaparib vs Maintenance Pemetrexed in the First-Line Treatment for Participants with Metastatic Nonsquamous Non-Small-Cell Lung Cancer
Kurztitel	MSD 7339-006
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
Einschlusskriterien	- Have a histologically or cytologically confirmed diagnosis nonsquamous NSCLC - Have stage IV nonsquamous NSCLC - Have confirmation that epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or Proto-oncogene tyrosine-protein kinase (ROS1)-directed therapy is not indicated - Have measurable disease based on RECIST 1.1 - Have provided archival tumor tissue sample or newly obtained core or incisional biopsy of a tumor lesion not previously irradiated - Have a life expectancy of at least 3 months - Have a performance status of 0 or 1 on the Eastern Cooperative Oncology Group (ECOG) Performance Status assessed within 7 days prior to the administration of study intervention - Have not received prior systemic treatment for their advanced/metastatic NSCLC - Have adequate organ function. - Male and female participants who are not pregnant and of childbearing potential must follow contraceptive guidance during the treatment period and for 180 days afterwards - Male participants must refrain from donating sperm during the treatment period and for 180 days afterwards.
Ausschlusskriterien	- Has predominantly squamous cell histology NSCLC - Has a known additional malignancy that is progressing or has progressed within the past 3 years requiring active treatment - Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis - Has a severe hypersensitivity (Grade 3) to pembrolizumab and/or any of its excipients - Has a known hypersensitivity to any components or excipients of cisplatin, carboplatin, pemetrexed, or olaparib - Has an active autoimmune disease that has required systemic treatment in past 2 years - Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy. - Has a known history of human immunodeficiency virus (HIV) infection, a known history of hepatitis B infection, or known active hepatitis C virus infection - Has interstitial lung disease, or history of pneumonitis requiring systemic steroids for treatment. - Has received prior therapy with olaparib or with any other polyadenosine 5' diphosphoribose (polyADP ribose) polymerization (PARP) inhibitor

	- Has received prior therapy with an agent directed to programmed cell death ligand 1 (PD-L1), anti PD-L2, or directed to a stimulatory or co-inhibitory T-cell receptor (e.g., cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), OX-40, CD137). - Has myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML) or with features suggestive of MDS/AML. - Has not completed palliative radiotherapy within 7 days of the first dose. Participants must have recovered from all radiation-related toxicities and not require corticosteroids
Alter	18 Jahre und älter
Prüfzentren	**Universitätsklinikum Frankfurt** (Geschlossen) Medizinische Klinik I, Pneumologie/Allergologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Inge Wortmann Tel: 069 6301-6337 pneumo.studien@kgu.de
Sponsor	MSD Sharp & Dohme
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03976323 EudraCT 2018-004720-11