KURZPROTOKOLL
MSD 7339-008

Öffentlicher Titel	Phase III Studie zu Pembrolizumab als Erstlinientherapie beim metastasierten NSCLC Plattenepithelkarzinom
Wissenschaftl. Titel	A Phase 3 Study of Pembrolizumab in Combination with Carboplatin/Taxane (Paclitaxel or Nab-paclitaxel) followed by Pembrolizumab with or without Maintenance Olaparib in the First-line Treatment of metastatic squamous Non-small Cell Lung cancer (NSCLC)
Kurztitel	MSD 7339-008
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
Einschlusskriterien	- Have a histologically or cytologically confirmed diagnosis squamous NSCLC - Have stage IV squamous NSCLC - Have measurable disease based on RECIST 1.1 - Have not received prior systemic treatment for their advanced/metastatic NSCLC - Have provided archival tumor tissue sample or newly obtained core or incisional biopsy of a tumor lesion not previously irradiated. Note: Adequacy of biopsy specimen for the above analyses must be confirmed by the central laboratory before the participant can receive study intervention(s). Submission of another tumor specimen may be required prior to enrolling the participant, if adequate tumor tissue was not provided the first time. - 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 a life expectancy of at least 3 months - Has 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 non-squamous 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 known hypersensitivity to any components or excipients of carboplatin, paclitaxel or nab-paclitaxel, or olaparib - Has a severe hypersensitivity (Grade 3) to pembrolizumab and/or any of its excipients - 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 - as 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
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 **Innere Medizin 1** (Geschlossen) 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 NCT03976362 (primäres Register) EudraCT 2018-004721-88