

**KURZPROTOKOLL**  
**MSD 7339-006**

<b>Öffentlicher Titel</b>	Phase III Studie zu Pembrolizumab als Erstlinientherapie beim metastasierten NSCLC Adenokarzinom
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	MSD 7339-006
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Have a histologically or cytologically confirmed diagnosis nonsquamous NSCLC</li><li>- Have stage IV nonsquamous NSCLC</li><li>- Have confirmation that epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or Proto-oncogene tyrosine-protein kinase (ROS1)-directed therapy is not indicated</li><li>- Have measurable disease based on RECIST 1.1</li><li>- Have provided archival tumor tissue sample or newly obtained core or incisional biopsy of a tumor lesion not previously irradiated</li><li>- Have a life expectancy of at least 3 months</li><li>- 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</li><li>- Have not received prior systemic treatment for their advanced/metastatic NSCLC</li><li>- Have adequate organ function.</li><li>- 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</li><li>- Male participants must refrain from donating sperm during the treatment period and for 180 days afterwards.</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Has predominantly squamous cell histology NSCLC</li><li>- Has a known additional malignancy that is progressing or has progressed within the past 3 years requiring active treatment</li><li>- Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis</li><li>- Has a severe hypersensitivity (Grade 3) to pembrolizumab and/or any of its excipients</li><li>- Has a known hypersensitivity to any components or excipients of cisplatin, carboplatin, pemetrexed, or olaparib</li><li>- Has an active autoimmune disease that has required systemic treatment in past 2 years</li><li>- Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy.</li><li>- Has a known history of human immunodeficiency virus (HIV) infection, a known history of hepatitis B infection, or known active hepatitis C virus infection</li><li>- Has interstitial lung disease, or history of pneumonitis requiring systemic steroids for treatment.</li><li>- Has received prior therapy with olaparib or with any other polyadenosine 5' diphosphoribose (polyADP ribose) polymerization (PARP) inhibitor</li></ul>

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- 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

<b>Alter</b>	18 Jahre und älter
<b>Sponsor</b>	MSD Sharp & Dohme
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT03976323 EudraCT 2018-004720-11