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

Einschlusskriterien

Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie

- 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

KURZPROTOKOLL MSD 7339-006

- 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
Sponsor MSD Sharp & Dohme

Registrierung in anderen ClinicalTrials.gov NCT03976323 **Studienregistern** ClinicalTrials.gov NCT03976323