KURZPROTOKOLL
MK3475-061

Öffentlicher Titel	Phase III Studie zu Pembrolizumab vs. Paclitaxel als Zweitlinien-Therapie bei Tumoren des Magens oder des gastroösophagealen Übergangs
Wissenschaftl. Titel	A Phase III, Randomized, Open-label Clinical Trial of Pembrolizumab (MK-3475) versus Paclitaxel in Subjects with Advanced Gastric or Gastroesophageal Junction Adenocarcinoma who progressed after First-Line Therapy with Platinum and Fluoropyrimide
Kurztitel	MK3475-061
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher
Einschlusskriterien	- Have histologically- or cytologically-confirmed diagnosis of gastric or gastroesophageal junction adenocarcinoma - Confirmed metastatic or locally advanced, unresectable disease (by CT scan or clinical evidence) - Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 - Progression on or after prior first-line therapy containing any platinum/fluoropyrimidine doublet - Willing to provide tumor tissue for PD-L1 biomarker analysis (new or archived specimens with agreement of Sponsor) - HER-2/neu status known and participants with HER2/neu positive tumors show documentation of disease progression on treatment containing trastuzumab - 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 pembrolizumab or through 180 days after the last dose of paclitaxel. - Male participants should agree to use an adequate method of contraception starting with the first dose of study therapy through 120 days after the last dose of pembrolizumab or through 180 days after the last dose of paclitaxel. - Adequate organ function
Ausschlusskriterien	- Currently participating and receiving study therapy, or participated in a study of an investigational agent and received study therapy or used an investigation device within 4 weeks of the first dose of medication - Squamous cell or undifferentiated gastric cancer - Active autoimmune disease that has required systemic treatment in past 2 years (replacement therapy is not considered a form of systemic treatment - 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 - Prior anti-cancer monoclonal antibody (mAb) within 4 weeks prior to study Day 1 or not recovered from adverse events due to agents administered more than 4 weeks earlier - Prior chemotherapy, targeted small molecule therapy, or radiation therapy within 2 weeks prior to study Day 1 or not recovered from adverse events due to a previously administered agent or surgery - Known additional malignancy that is progressing or requires active treatment (with the exception of basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or in situ cervical cancer that has undergone potentially curative therapy) - Known active central nervous system (CNS) metastases and/or carcinomatous meningitis

	- History or evidence of interstitial lung disease or active noninfectious 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 pembrolizumab or through 180 days after the last dose of paclitaxel. - Prior immunotherapy including anti-PD-1, anti-PD-L1, or anti-PD-L2 agent, or previously participated in Merck pembrolizumab (MK-3475) clinical trial - Known history of human immunodeficiency virus (HIV) - Known active Hepatitis B or Hepatitis C - Live vaccine within 30 days of planned start of study therapy - Known allergy or hypersensitivity to paclitaxel or any components used in the paclitaxel preparation or other contraindication for taxane therapy
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu neg.
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@khnw.de
Sponsor	MSD Sharp & Dohme
Registrierung in anderen Studienregistern	EudraCT 2014-005241-45