

KURZPROTOKOLL
MK-3475-966

Öffentlicher Titel	Phase III Studie zu Pembrolizumab als Erstlinientherapie bei bösartigen biliären Tumoren
Wissenschaftl. Titel	A Phase 3 Randomized, Double Blind Study of Pembrolizumab Plus Gemcitabine/Cisplatin versus Placebo Plus Gemcitabine/Cisplatin as First-Line Therapy in Participants with Advanced and/or Unresectable Biliary Tract Carcinoma
Kurztitel	MK-3475-966
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Gallengangs-/Gallenblasenkrebs (maligne biliäre Tumoren): Erstlinie
Einschlusskriterien	<ul style="list-style-type: none">- Has histologically confirmed diagnosis of advanced (metastatic) and/or unresectable (locally advanced) biliary tract cancer (intra-or extrahepatic cholangiocarcinoma or gallbladder cancer)- Have measurable disease based on Response Evaluation Criteria in Solid Tumors (RECIST 1.1), as determined by the site investigator- Participants with a history of hepatitis B or hepatitis C can be enrolled if they meet study criteria- Provide archival tumor tissue sample or newly obtained core or excisional biopsy of a tumor lesion- Have a life expectancy of greater than 3 months- Have adequate organ function
Ausschlusskriterien	<ul style="list-style-type: none">- Has had previous systemic therapy for advanced (metastatic) or unresectable (locally advanced) biliary tract cancer (intra-or extra hepatic cholangiocarcinoma or gallbladder cancer), with the exception of adjuvant therapy which is allowed.- Has ampullary cancer- Has small cell cancer, neuroendocrine tumors, lymphoma, sarcoma and/or Mucinous cystic neoplasms- Has received prior therapy with an anti-programmed cell death 1 (anti-PD-1), anti-programmed cell death ligand 1 or 2 (anti-PD-L1, anti-PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g., CTLA-4, OX-40, CD137)- Has a known history of, or any evidence of, central nervous system (CNS) metastases and/or carcinomatous meningitis, as assessed by local site investigator- Has had an allogenic tissue/solid organ transplant
Alter	18 - 99 Jahre
Status	Aktiv
Prüfzentren	Krankenhaus Nordwest GmbH Klinik für Onkologie und Hämatologie Steinbacher Hohl 2-26 60488 Frankfurt am Main Dr. med Thorsten Götze Tel: 069 7601-4187 Fax: 069 069-7601-3655 goetze.thorsten@khnw.de
Sponsor	Merck Sharp & Dohme GmbH