KURZPROTOKOLL
MS200647-0047

Öffentlicher Titel	Phase II Studie zu M7824 als Zweitlinientherapie bei metastasiertem Gallenwegskrebs
Wissenschaftl. Titel	A Phase II, Multicenter, Open-label Study to Investigate the Clinical Efficacy of M7824 Monotherapy in Participants With Locally Advanced or Metastatic Biliary Tract Cancer Who Fail or are Intolerant to First-line Platinum-Based Chemotherapy
Kurztitel	MS200647-0047
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase II
Erkrankung	Verdauung: Gallengangs-/Gallenblasenkrebs (maligne biliäre Tumoren): Zweitlinie oder höher

Einschlusskriterien

- Are participants with histologically or cytologically confirmed locally advanced or metastatic BTC.
- Availability of tumor (primary or metastatic) archival material or fresh biopsies (collected within 28 days before first administration) of study intervention is mandatory
- Participants with BTC must have failed or be intolerant to 1L systemic platinum-based chemotherapy
- Disease must be measurable with at least 1 unidimensionally measurable lesion by RECIST 1.1
- Eastern Cooperative Oncology Group (ECOG) PS of 0 to 1
- Life expectancy >= 12 weeks as judged by the Investigator
- Adequate hematological function defined by white blood cell (WBC) count >= 3 * 10^9/Litre with absolute neutrophil count (ANC) >= 1.5 * 109/Litre, lymphocyte count >= 0.5 * 10^9/Litre, platelet count >=75 * 10^9/Litre, and hemoglobin (Hgb) >= 9 grams/decilitre
- Adequate hepatic function defined by a total bilirubin level =< 1.5 * upper limit of normal (ULN), an aspartate aminotransferase (AST) level =< 2.5 * ULN, and an alanine aminotransferase (ALT) level =<2.5 * ULN. For participants with liver involvement in their tumor, AST =< 5.0 * ULN and ALT =< 5.0 * ULN is acceptable
- Adequate coagulation function defined as prothrombin time (PT) or international normalized ratio (INR) =< 1.5 * ULN unless the participant is receiving anticoagulant therapy
- Albumin >= 3.0 grams/decilitre
- Hepatitis B virus (HBV) deoxyribonucleic acid (DNA) positive participants must be treated and on a stable dose of antivirals
- Adequate renal function defined by either creatinine =< 1.5 * ULN or an estimated creatinine clearance (CCr) > 40 milliliter (mL) per minute (min) according to the Cockcroft-Gault formula or by measure of CCr from 24-hour urine collection
- Other protocol defined inclusion criteria could apply

Ausschlusskriterien

- Ampullary cancer is excluded
- Significant acute or chronic infections
- Active autoimmune disease that might deteriorate when receiving an immunostimulatory agent
- Interstitial lung disease or its history
- Participants who are not eligible for or have not been treated with 1L systemic chemotherapy
- Anticancer treatment within 21 days before the start of study intervention
- Concurrent treatment with nonpermitted drugs
- Prior participation in a M7824 clinical trial

	- Prior therapy with other immunotherapy or checkpoint inhibitors, such as anti-PD 1, anti PD L1, anti- cytotoxic T-cell lymphocyte-4 (CTLA-4) antibodies. - Pregnancy or breast feeding - Other protocol defined exclusion criteria could apply
Alter	18 Jahre und älter
Prüfzentren	**Universitätsklinikum Frankfurt** (Geschlossen) Medizinische Klinik I, Gastroenterologie/Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Lisa Weiss Tel: 069 6301-87769 Fax: 069 6301-6580 Lisa.Weiss@kgu.de
Sponsor	Merck KGaA
Registrierung in anderen Studienregistern	EudraCT 2018-003707-19 ClinicalTrials.gov NCT03833661 (primäres Register)