

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	<ul style="list-style-type: none">- 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 \geq 12 weeks as judged by the Investigator- Adequate hematological function defined by white blood cell (WBC) count $\geq 3 * 10^9$/Litre with absolute neutrophil count (ANC) $\geq 1.5 * 10^9$/Litre, lymphocyte count $\geq 0.5 * 10^9$/Litre, platelet count $\geq 75 * 10^9$/Litre, and hemoglobin (Hgb) ≥ 9 grams/decilitre- Adequate hepatic function defined by a total bilirubin level $\leq 1.5 * \text{upper limit of normal (ULN)}$, an aspartate aminotransferase (AST) level $\leq 2.5 * \text{ULN}$, and an alanine aminotransferase (ALT) level $\leq 2.5 * \text{ULN}$. For participants with liver involvement in their tumor, AST $\leq 5.0 * \text{ULN}$ and ALT $\leq 5.0 * \text{ULN}$ is acceptable- Adequate coagulation function defined as prothrombin time (PT) or international normalized ratio (INR) $\leq 1.5 * \text{ULN}$ 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 $\leq 1.5 * \text{ULN}$ 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	<ul style="list-style-type: none">- 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

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- 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

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Sponsor

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**Registrierung in anderen
Studienregistern**

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ClinicalTrials.gov NCT03833661 (primäres Register)