A Phase 3, randomized study of adjuvant rilvegostomig plus chemotherapy in resected biliary tract cancer: ARTEMIDE-Biliary01

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ARTEMIDE biliary01

Plain language summary

Why are we performing this research?

- Some people with biliary tract cancer (BTC) that is diagnosed in the early stages of the disease undergo surgery to remove the tumor, followed by treatment with chemotherapy. However, the cancer often comes back and new treatment options are needed
- ARTEMIDE-Biliary01 is a study that is aiming to find out if a new treatment called rilvegostomig can stop cancer from coming back in patients with early stage BTC when given with chemotherapy after surgery

How are we performing this research?

- Patients who have previously undergone surgery to remove their tumor will be randomly allocated to one of two treatment groups: rilvegostomig plus chemotherapy or placebo (an inactive substance) plus chemotherapy
- The study will measure the length of time after being randomly allocated to treatment that patients are alive without their cancer coming back, comparing patients in the group treated with rilvegostomig with the group not treated with rilvegostomig

Who will participate in this study?

- Approximately 750 people with early stage BTC will be enrolled from 21 countries across the globe

Where can I access more information?

- This study is ongoing and no results are available yet; expected completion is September 2030
- More information about this study can be found here: https://clinicaltrials.gov/study/NCT06109779. You may also speak to your doctor about clinical studies

This study is funded by AstraZeneca
Poster presented at the AMMF 2025 European Cholangiocarcinoma Conference by John Bridgewater

Background

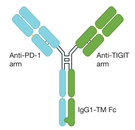
- BTC is a rare but aggressive heterogenous group of gastrointestinal cancers that arise from the intrahepatic or extrahepatic bile ducts (cholangiocarcinoma) or the gallbladder[1,2]
- While resection is a potentially curative treatment option for BTC, less than 35% of patients are diagnosed in the early stages of disease and are eligible for curative therapy[3,4]
- Adjuvant treatments have been used in patients with early stage BTC but, until recently, data were limited to non-randomized, non-controlled retrospective studies[3]
- Capecitabine and tegafur/oteracil/gimeracil (S-1) are commonly used for the adjuvant treatment of BTC, based on the BILCAP and ASCOT studies.[5,6] Gemcitabine plus cisplatin is the preferred chemotherapy in advanced BTC and may also be used in the adjuvant setting[7]
- Recurrence rates remain high with current adjuvant treatments in early stage BTC.[5,6] New adjuvant treatments are needed to reduce disease recurrence and improve outcomes in patients with BTC

Rationale

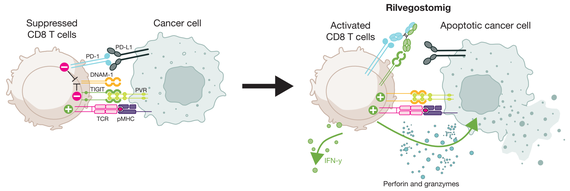
- Immunotherapy is efficacious as adjuvant therapy in other cancer types[8]
- Results from the TOPAZ-1 and KEYNOTE-966 studies support combining immunotherapy and chemotherapy in advanced BTC, including in locally advanced non-metastatic disease[9,10]
- Dual inhibition of programmed cell death-1 (PD-1) or programmed cell death ligand-1 (PD-L1) and the novel immune checkpoint, T-cell immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domain (TIGIT), has shown promising results across multiple tumor types, including BTC, with an acceptable tolerability profile, either in single-arm studies or compared with PD-1 or PD-L1 inhibition alone[11–14]
- Rilvegostomig is an anti-PD-1/anti-TIGIT bi-specific monoclonal antibody that appears active and well tolerated in non-small-cell lung cancer[15]
- Combining rilvegostomig with standard of care adjuvant chemotherapy may improve outcomes in patients with early stage BTC after curative intent resection when compared with adjuvant chemotherapy alone

Rilvegostomig is a monovalent, bi-specific, humanized IgG1 antibody targeting PD-1 and TIGIT[15]

Rilvegostomig structure



Rilvegostomig enhances CD8 T cell-mediated killing*,†



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CD8, cluster of differentiation 8; DNAM-1, deoxyribonucleic acid polymerase III subunit tau (DNAX) accessory molecule-1; IFN-γ, interferon-gamma; IgG1, immunoglobulin gamma 1; PD-1, programmed cell death-1; PD-L1, programmed cell death ligand-1; pMHC, peptide major histocompatibility complex; PVR, poliovirus receptor; TCR, T-cell receptor; TIGIT, T-cell immunoglobulin and immunoreceptor tyrosine-based inhibitor motif domain.

ARTEMIDE-Biliary01 (NCT06109779) study design

A Phase 3, randomized, double-blind, placebo-controlled, multicenter, global study to assess the efficacy and tolerability of rilvegostomig plus adjuvant chemotherapy versus placebo plus adjuvant chemotherapy in patients with BTC at risk of recurrence after resection with curative intent

Patients with BTC at risk of recurrence after resection with curative intent

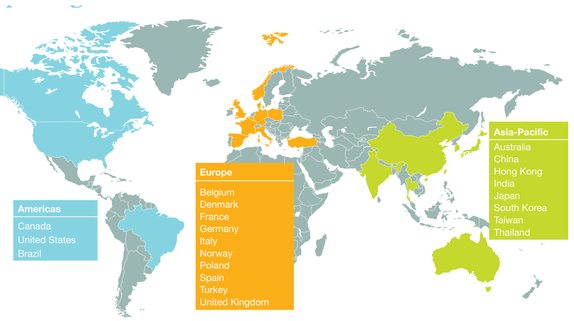
Approximately 750 patients randomized 1:1

Arm A: Rilvegostomig IV Q3W plus investigator's choice of chemotherapy	Arm B: Placebo IV Q3W plus investigator's choice of chemotherapy

Investigator's choice of chemotherapy:
- Capecitabine 1250 mg/m^2 PO BID, 2 weeks on/1 week off, 21-day cycles or per local practice
- S-1 40–60 mg PO BID (based on body surface area), 4 weeks on/2 weeks off, 42-day cycles
- Gemcitabine 1000 mg/m^2 IV plus cisplatin 25 mg/m^2 IV, Days 1 and 8 of each 21-day cycle

BID, twice daily; BTC, biliary tract cancer; IV, intravenous; PO, oral; Q3W, every 3 weeks; S-1, tegafur/oteracil/gimeracil.

Enrollment start: December 2023 | Expected study end: September 2030



Study enrollment is ongoing; enrollment is intended at approximately 200 sites across 21 countries

Key inclusion criteria

- Adults aged ≥18 years
- Histologically confirmed BTC (intrahepatic or extrahepatic cholangiocarcinoma or muscle-invasive gallbladder cancer) after macroscopically complete resection (R0 or R1)
- Provision of a tumor sample collected at surgical resection
- Randomization within 12 weeks after resection with adequate healing and removal of drains
- Confirmed to be disease-free by imaging within 28 days prior to randomization
- Eastern Cooperative Oncology Group performance status of 0 or 1

Key exclusion criteria

- Locally advanced, unresectable, or metastatic BTC at initial diagnosis
- Ampullary cancer, neuroendocrine, mixed neuroendocrine, and non-neuroendocrine neoplasms, and non-epithelial tumors
- Any anti-cancer therapy for BTC prior to surgery
- Active or prior documented autoimmune or inflammatory disorders, or any severe or uncontrolled systemic disease
- Current or prior use of immunosuppressive medication within 14 days before the first dose of study drug
- Thromboembolic event within 3 months before the first dose of study drug
- Active hepatitis B or C infection (unless treated)

Study endpoints

1° Recurrence-free survival

2° Overall survival

\+
- Patient-reported tolerability
- Progression-free survival following recurrence
- Safety and tolerability

Poster

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https://bit.ly/42Ktesf

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Disclosures

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