

Phase 3 Study of T-DXd and Rilvegostomig Versus SoC in Advanced HER2-expressing Biliary Tract Cancer

NCT06467357

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| Status | RECRUITING |
| Phase | Phase 3 |
| Sponsor | AstraZeneca |
| Enrollment | 620 participants |

Key Eligibility Criteria

Inclusion (9)

- Male and female patients must be at least 18 years of age at the time of signing the informed consent. Other age restrictions may apply as per local regulations.
 - Unresectable, previously untreated, locally advanced or metastatic biliary tract adenocarcinoma. Prior treatment in the perioperative and/or adjuvant setting is permissible provided there is > 3 months (90 days) between the end of adjuvant treatment and the diagnosis of locally advanced or metastatic disease.
 - Histologically confirmed HER2-expressing (IHC 3+ or IHC 2+) BTC.
 - Patients must provide an FFPE tumor sample that is no older than 3 years for tissue-based IHC staining to centrally determine HER2 expression, PD-L1 status, and other correlatives.
 - Has at least one target lesion assessed by the Investigator based on RECIST v1.1. (Randomized portion only)
- ... and 4 more (see full listing online)

Exclusion (17)

- Prior exposure to other HER2 targeting therapies, ADCs, immune checkpoint inhibitors and therapeutic anticancer vaccines.
 - Histologically confirmed ampullary carcinoma.
 - Any other medical conditions such as clinically significant cardiac or psychological conditions, that may, in the opinion of the Investigator, interfere with the patient's participation in the clinical study or evaluation of the clinical study results.
 - Spinal cord compression or clinically active central nervous system metastases, defined as untreated and symptomatic, or requiring therapy with corticosteroids or anticonvulsants to control associated symptoms.
 - Medical history of myocardial infarction within 6 months before randomization/enrollment, symptomatic congestive heart failure (New York Heart Association Class II to IV), unstable angina pectoris, clinically important cardiac arrhythmias, or a recent (< 6 months) cardiovascular event including stroke.
- ... and 12 more (see full listing online)

Locations (263 total)

Research Site, Scottsdale, Arizona, United States
Research Site, Tucson, Arizona, United States
Research Site, Tucson, Arizona, United States
... and 260 more locations