

# Efficacy and Safety of Zanidatamab With Standard-of-care Therapy Against Standard-of-care Therapy for Advanced HER2-positive Biliary Tract Cancer

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

**Inclusion Criteria** 1. Histologically- or cytologically-confirmed Biliary Tract Cancer (BTC), including Gallbladder Cancer (GBC), Intrahepatic Cholangiocarcinoma (ICC), or Extrahepatic Cholangiocarcinoma (ECC). 2. Locally advanced unresectable or metastatic BTC and not eligible for curative resection, transplantation, or ablative therapies. 3. Received no more than 2 cycles of systemic therapy which is limited to Cisplatin and Gemcitabine (CisGem) with or without a PD-1/L1 inhibitor (physician's choice of durvalumab or pembrolizumab, where approved under local regulations) for advanced unresectable or metastatic disease. 4. HER2-positive disease (defined as IHC 3+; or IHC 2+ / ISH+) by IHC and in situ Hybridization (ISH) assay (in participants with IHC 2+ tumors) at a central laboratory on new biopsy tissue or archival tissue from the most recent biopsy. 5. Assessable (measurable or non-measurable) disease as defined by Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1), per investigator assessment. 6. Male or female  $\geq$  18 years or age (or the legal age of adulthood per country-specific regulations). 7. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. 8. Adequate organ function 9. Females of childbearing potential must have a negative pregnancy test result. 10. Females of childbearing potential and males with a partner of childbearing potential must be willing to use 2 methods of birth control. **Exclusion Criteria** 1. Prior treatment with a HER2-targeted agent 2. Prior treatment with checkpoint inhibitors, other than durvalumab or pembrolizumab 3. The following BTC histologic subtypes are excluded: small cell cancer, neuroendocrine tumors, lymphoma, sarcoma, mixed tumor histology, and mucinous cystic neoplasms detected in the biliary tract region. 4. Use of systemic corticosteroids. 5. Brain metastases 6. Severe chronic or active infections 7. History of allogeneic organ transplantation. 8. Active or prior autoimmune inflammatory conditions 9. History of interstitial lung disease or non-infectious pneumonitis. 10. Participation in another clinical trial with an investigational medicinal product within the last 3 months. 11. Females who are breastfeeding 12. Any other medical, social, or psychosocial factors that, in the opinion of the investigator, could impact safety or compliance with study procedures. 13. Use of phenytoin

## Conditions & Interventions

**Interventions:**

DRUG: Zanidatamab, DRUG: Cisplatin, DRUG: Gemcitabine, DRUG: Pembrolizumab, DRUG: Durvalumab

**Conditions:**

Biliary Tract Cancer

**Keywords:**

JZP598, ZW25, HER-2 positive Biliary Tract cancer, Gallbladder Cancer, Intrahepatic Cholangiocarcinoma (ICC), Extrahepatic Cholangiocarcinoma (ECC), Zanidatamab, HER-2 overexpression, HER-2 amplification

## More Information

**Contact(s):** Clinical Trial Disclosure & Transparency - [ClinicalTrialDisclosure@JazzPharma.com](mailto:ClinicalTrialDisclosure@JazzPharma.com)

**Principal Investigator:**

**Phase:** PHASE3

**IRB**

**Number:**

**System ID:** NCT06282575

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