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Protocol Title: An open-label randomized trial of the efficacy and safety of zanidatamab with standard-of-care therapy against standard-of-care therapy alone for advanced HER2-positive biliary tract cancer

Key Inclusion criteria

1. Histologically- or cytologically-confirmed BTC, including GBC, ICC, or ECC. Locally advanced unresectable or metastatic BTC and not eligible for curative resection, transplantation, or ablative therapies.
2. Received no more than 2 cycles of systemic therapy with gemcitabine and a platinum agent (eg, CisGem or GEMOX) 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. Participants who have received prior adjuvant or neoadjuvant treatment (including investigational products) for earlier stage disease are permitted as long as therapy was completed more than 6 months prior to expected date of C1D1.
4. HER2-positive disease (defined as IHC 3+; or IHC 2+/ ISH+) by IHC and 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. Male or female ≥ 18 years or age (or the legal age of adulthood per country-specific regulations).
6. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

Exclusion Criteria

1. Prior treatment with a HER2-targeted agent, with the exception of participants who completed HER2-targeted treatment for breast cancer > 5 years prior to their diagnosis of BTC.
2. Prior treatment with checkpoint inhibitors, other than durvalumab or pembrolizumab as part of the up to 2 cycles of systemic therapy allowed prior to expected date of C1D1 per Inclusion Criterion 3. Exclusionary checkpoint inhibitors include but are not limited to other anti-PD-1, anti-PD-L1, anti-cytotoxic T lymphocyte-associated antigen (CTLA)-4 antibodies.
4. Brain metastases: Untreated central nervous system (CNS) metastases, symptomatic CNS metastases, or radiation treatment for CNS metastases within 4 weeks of expected date of C1D1. Stable, treated brain metastases are allowed (defined as participants who are off steroids and anticonvulsants and are neurologically stable with no evidence of radiographic progression for at least 4 weeks at the time of screening).
5. QTc Fridericia (QTcF) > 470 ms. Note: For participants with longer QTcF on initial electrocardiogram (ECG), follow-up ECG may be performed in triplicate to determine eligibility.
6. History of interstitial lung disease or non-infectious pneumonitis.
7. Acute or chronic uncontrolled pancreatitis or Child-Pugh Class C liver disease

For further more information please contact

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