

# Trastuzumab in Combination With Serplulimab and Chemotherapy for the Treatment of HER2-overexpressing Unresectable Locally Advanced or Metastatic Biliary Tract Cancer or Urothelial Carcinoma After Failure of Standard Therapy

NCT07506057

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Status	RECRUITING
Phase	Phase 2
Sponsor	Xiujian Qu
Enrollment	20 participants

## Key Eligibility Criteria

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### Inclusion (13)

- Age 18 to 75 years, male or female.
  - Histologically or cytologically confirmed recurrent and/or metastatic advanced biliary tract cancer or urothelial carcinoma.
  - Disease progression after at least one prior line of systemic antitumor therapy. For patients who received systemic antitumor therapy during adjuvant therapy or concurrent chemoradiotherapy, progression occurring within 6 months after completion of therapy is considered as one prior line of therapy.
  - HER2 overexpression confirmed by immunohistochemistry (IHC) 3+ or IHC 2+ with in situ hybridization (ISH)+.
  - Left ventricular ejection fraction (LVEF)  $\geq$  50%.
- ... and 8 more (see full listing online)

### Exclusion (13)

- Known HER2-negative or HER2-low expression.
  - Active autoimmune disease or history of autoimmune disease with potential for relapse. Patients with the following conditions are not excluded and may proceed to further screening
  - Presence of other malignancies within the past 2 years or currently, except for cured cervical carcinoma in situ, non-melanoma skin cancer, and superficial bladder tumors (Ta, Tis, and T1).
  - Uncontrolled pleural effusion, pericardial effusion, or ascites requiring repeated drainage (at least once per month) within 14 days prior to enrollment.
  - Weight loss  $\geq$  20% within 2 months prior to enrollment.
- ... and 8 more (see full listing online)

## Locations (1 total)

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The First Affiliated Hospital of China Medical University, Shenyang, Liaoning, China