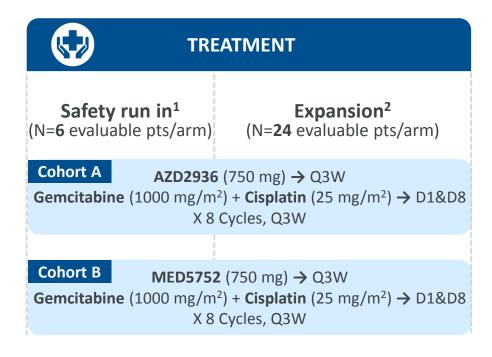
GEMINI Platform Study Design---BTC substudy



POPULATION

1L BTC Patient Population:

- Patients aged ≥ 18 years with histologically confirmed adenocarcinoma BTC
- Not ampullary carcinoma
- Unresectable advanced or metastatic stage
- No prior immunotherapy and locoregional therapy for BTC
- ECOG performance score 0–1





ENDPOINTS

Primary Endpoint: PFS6 and Safety by Inv (per RECIST1.1)

Secondary Endpoint:

ORR, DOR, DCR at 12w/24w, mPFS & PFS9 & PFS12, mOS & OS rate at 12m / 18m), PK, ADA

Exploratory Endpoint:

Efficacy (e.g ORR) by BICR (per RECIST 1.1), PD biomarker, predictive biomarker, ctDNA related to efficacy

Considerations

- 1. Study will have **SRC** for the first **6** evaluable pts / cohort.
- 2. Expansion to enroll **24** additional pts in each cohort to have a total of **30** evaluable pts / cohort
- 3. Provision of tumor samples 1) mandatory baseline tissue-archival or fresh biopsy, 2) optional on-treatment and progression biopsy

