Efficacy and safety of durvalumab plus gemcitabine and cisplatin in Chinese participants with advanced biliary tract cancer: extension cohort of the Phase 3, randomised, double-blind, placebo-controlled, global TOPAZ-1 study

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Objective
• Durvalumab plus gemcitabine and cisplatin (GemCis) significantly improved overall survival (OS) versus placebo plus GemCis in participants with advanced biliary tract cancer (BTC) in the primary analysis of TOPAZ-1, an international, randomised, double-blind, Phase 3 study (NCT03875235, data cut-off [DCO]: 11 August 2021).

• The China Mainland cohort was randomised to receive either durvalumab plus GemCis or placebo plus GemCis in accordance with the primary analysis of TOPAZ-1.

Study population and characteristics
• In TOPAZ-1, OS benefit was observed in the China Mainland cohort with a median OS of 13.5 months (95% CI: 10.9–16.8) for durvalumab plus GemCis compared with 9.2 months (95% CI: 7.9–10.8) for placebo plus GemCis (HR 0.79, 95% CI: 0.67–0.94, p = 0.009).

• In the TOPAZ-1 China Mainland + Hong Kong + Taiwan (HK + TW) study, the durvalumab plus GemCis regimen was associated with a median overall survival of 14.0 months (95% CI: 12.3–15.8) for durvalumab plus GemCis compared with 10.6 months (95% CI: 8.8–12.6) for placebo plus GemCis (HR 0.73, 95% CI: 0.60–0.88, p = 0.004). The results of the TOPAZ-1 China Mainland + HK + TW study were consistent with the China Mainland cohort and the China Mainland + HK + TW pooled analysis (HR 0.73, 95% CI: 0.60–0.88, p = 0.001).

• All eligible participants with advanced BTC in the China Mainland cohort were randomised to receive either durvalumab plus GemCis or placebo plus GemCis in the TOPAZ-1 China Mainland study.

• In the primary analysis of TOPAZ-1, participants received durvalumab or placebo (NCT03875235, DCO: 11 August 2021), followed by treatment with durvalumab plus GemCis or placebo plus GemCis, respectively, every 2 weeks (Q2W) until disease progression, unacceptable toxicity or other specified reasons.

• Patients were randomised to receive durvalumab plus GemCis (200 mg/m²) or placebo until disease progression, unacceptable toxicity or other specified reasons.

• The primary endpoint was OS. Median OS and OS rates were estimated using the Kaplan-Meier method. OS hazard ratios (HRs) were calculated using a Cox proportional hazards model with the placebo plus GemCis group as the reference group. Secondary analyses included PFS, objective response rate (ORR) and safety.

• The China Mainland cohort included 152 evaluable patients (76% from China Mainland, 24% from Hong Kong and Taiwan). Among these, 65 participants were treated in the China Mainland (China Mainland + HK + TW study).

• Subgroup analyses should be interpreted with caution due to the lower number of patients with advanced BTC in the extension cohort compared with the main analysis.