**Introduction**

- In the primary analysis of TOPAZ-1 (November 15, 2021; data cut-off 11 August 2021; NCT=03875235), durvalumab plus GemCis significantly improved OS in patients with locally advanced or metastatic BTC treated with chemotherapy (HR, 0.57; 95% CI, 0.49-0.67; p<0.0001).
- The OS improvement persisted after 6 months of follow-up (HR, 0.76; 95% CI, 0.64-0.93; data cut-off 25 February 2022).

**Methods**

- TOPAZ-1 is a randomised, double-blind, global, Phase 3 study (2019–February 2022) aimed at evaluating durvalumab plus GemCis versus placebo plus GemCis in patients with advanced BTC.

**Study population**

- Patients were treated with durvalumab and chemotherapy or placebo and chemotherapy.

**Prognostic analysis**

- NLR and CA 19-9 were found to be prognostic factors.

**Key secondary endpoints**

- ORR and PFS for patients with advanced BTC (HR, 0.80; 95% CI, 0.62-1.00; p=0.021).

**Results and interpretation**

**Study population**

- Baseline demographics and disease characteristics (Table 1) and clinical and laboratory factors (presented here) were generally balanced between the two treatment groups (Table 1).

**Disclosures**

- No conflicts of interest have been reported by the authors of this poster.