Safety and tolerability profile from TOPAZ-1**††

- Most frequent grade 3-4 AEs were fatigue (34% vs 32%), diarrhea (33% vs 26%), and increased ALT (27% vs 23%), and decreased AST (27% vs 21%)
- Infusion-related reactions occurred in 4% of patients receiving IMFINZI + gem-cis, and included Grade 3 haematologic adverse events in 1% of patients receiving IMFINZI and 1% of patients receiving gem-cis
- The most common treatment-related infections were upper respiratory tract infection (7% vs 6%), urinary tract infection (6% vs 6%), and candidemia (2% vs 2%

TOPAZ-1: A randomized, double-blind, placebo-controlled, multicenter, global Phase III study††

Keyeligibilities:

- Advanced or metastatic BTCs*

- ECOG PS 0 or 1

- No prior treatments for advanced or metastatic BTCs

- No prior treatment with PD-1/PD-L1 inhibitors and no anti-CTLA-4 therapy within 8 weeks of the first dose of IMFINZI

- Eligibility criteria.

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