

NOW RECOMMENDED BY NCCN & ESMO GUIDELINES<sup>1-3\*</sup>

In first-line advanced BTC<sup>4</sup>

**REACH**

**BEYOND**

with IMFINZI + gem-cis

The first and only approved IO combination to extend overall survival vs gem-cis<sup>4,5\*\*</sup>

**SAFETY:**

Similar rates of adverse reactions with IMFINZI + gem-cis and gem-cis.<sup>3</sup> Rates of Grades 3-4 adverse reactions were 76% with IMFINZI + gem-cis vs 78% with gem-cis.

**Therapeutic Indication**

IMFINZI in combination with cisplatin and gemcitabine, is indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer<sup>3</sup>

BTC=biliary tract cancer; CI=confidence interval; DCO=data cutoff; ESMO=European Society of Medical Oncology; gem-cis=gemcitabine-cisplatin; HR=hazard ratio; IO=immuno-oncology; MCBS=magnitude of clinical benefit score; NCCN=National Comprehensive Network Cancer; OS=overall survival.

\*NCCN category 1 evidence<sup>1</sup> and ESMO (IA, MCBS 4).<sup>2</sup>#Locally advanced or metastatic biliary tract cancer.<sup>3</sup>

^The primary endpoint of TOPAZ-1 was overall survival. At the prespecified interim analysis (DCO: August 11, 2021), 198 patients (58.1%) in the IMFINZI group and 226 patients (65.7%) in the placebo group had died. Overall survival was significantly longer with IMFINZI + gem-cis vs gem-cis (HR=0.80 [95% CI, 0.66-0.97]; P=0.021). With 62% OS maturity (424 events), the interim analysis of OS met the prespecified O'Brien-Fleming-type boundary for declaring statistical significance with a 2-sided P value of <0.03. Median OS was 12.8 months (95% CI, 11.1-14.0) with IMFINZI + gem-cis vs 11.5 months (95% CI, 10.1-12.5) with gem-cis. Median duration of follow-up was 16.8 months (95% CI, 14.8-17.7) with IMFINZI + gem-cis and 15.9 months (95% CI, 14.9-16.9) with gem-cis.<sup>3,5</sup>

The updated OS exploratory analysis (DCO: February 25, 2022) was conducted after 6.5 months of additional follow-up. With 77% OS maturity (527 events), overall survival continued to improve with IMFINZI + gem-cis vs gem-cis

(HR=0.76 [95% CI, 0.64-0.91]). OS was not formally tested for statistical significance at this time. Median duration of follow-up was 23.4 months (95% CI, 20.6-25.2) with IMFINZI + gem-cis and 22.4 months (95% CI, 21.4-23.8) with gem-cis.<sup>3,4</sup>

References: 1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Biliary Tract Cancers. Version 2.2023 – May 10, 2023. Retrieved from: [https://www.nccn.org/professionals/physician\\_gls/pdf/btc.pdf](https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf) [Accessed as of 2023, June 12] 2. Vogel A, Bridgewater J, Edeline J et al. Biliary tract cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. *Annals of Oncology*. 2023;34(2):127-140. 3. ESMO-MCBS Scorecards, Durvalumab (TOPAZ-1). Retrieved from: <https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards/scorecard-350-1> [Access as of 2023, June 12] 4. IMFINZI Singapore Prescribing Information 12/BB/SG/Doc ID-003724020 v16.0 (December 2022).

5. Oh DY, He AR, Qin S, et al. Updated overall survival from the Phase 3 TOPAZ-1 study of durvalumab or placebo plus gemcitabine and cisplatin in patients with advanced biliary tract cancer. Poster presented at: 2022 ESMO Congress; September 9-13, 2022; Paris, France.



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