LOCALLY ADVANCED/METASTATIC BILIARY TRACT CANCER

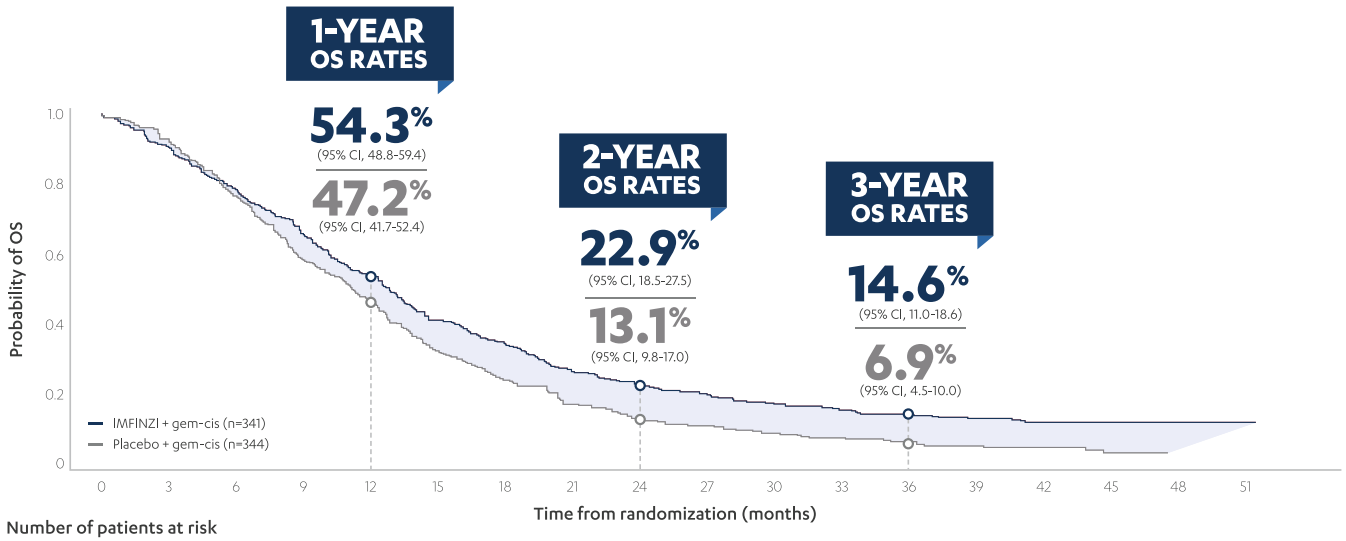
IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

IMFINZI® + gem-cis is the first IO combination in advanced BTC to demonstrate superior overall survival vs. gem-cis in the TOPAZ-1 study[2]

OVERALL SURVIVAL AT 3 YEARS (post-hoc analysis)[3]

26% REDUCTION IN THE RISK OF DEATH

with IMFINZI + gem-cis vs gem-cis[3]
HR=0.74 (95% CI, 0.63-0.87)



Number of patients at risk

IMFINZI + gem-cis	341	309	268	227	184	140	118	92	75	67	58	50	43	31	21	15	7	1
Placebo + gem-cis	344	316	260	199	159	110	82	59	43	37	30	25	18	11	8	4	0	0

Data cutoff was October 23, 2023. Median duration of follow-up: 42.9 months (95% CI, 39.8-44.3) with IMFINZI + gem-cis and 41.8 months (95% CI, 36.7-46.2) with gem-cis.

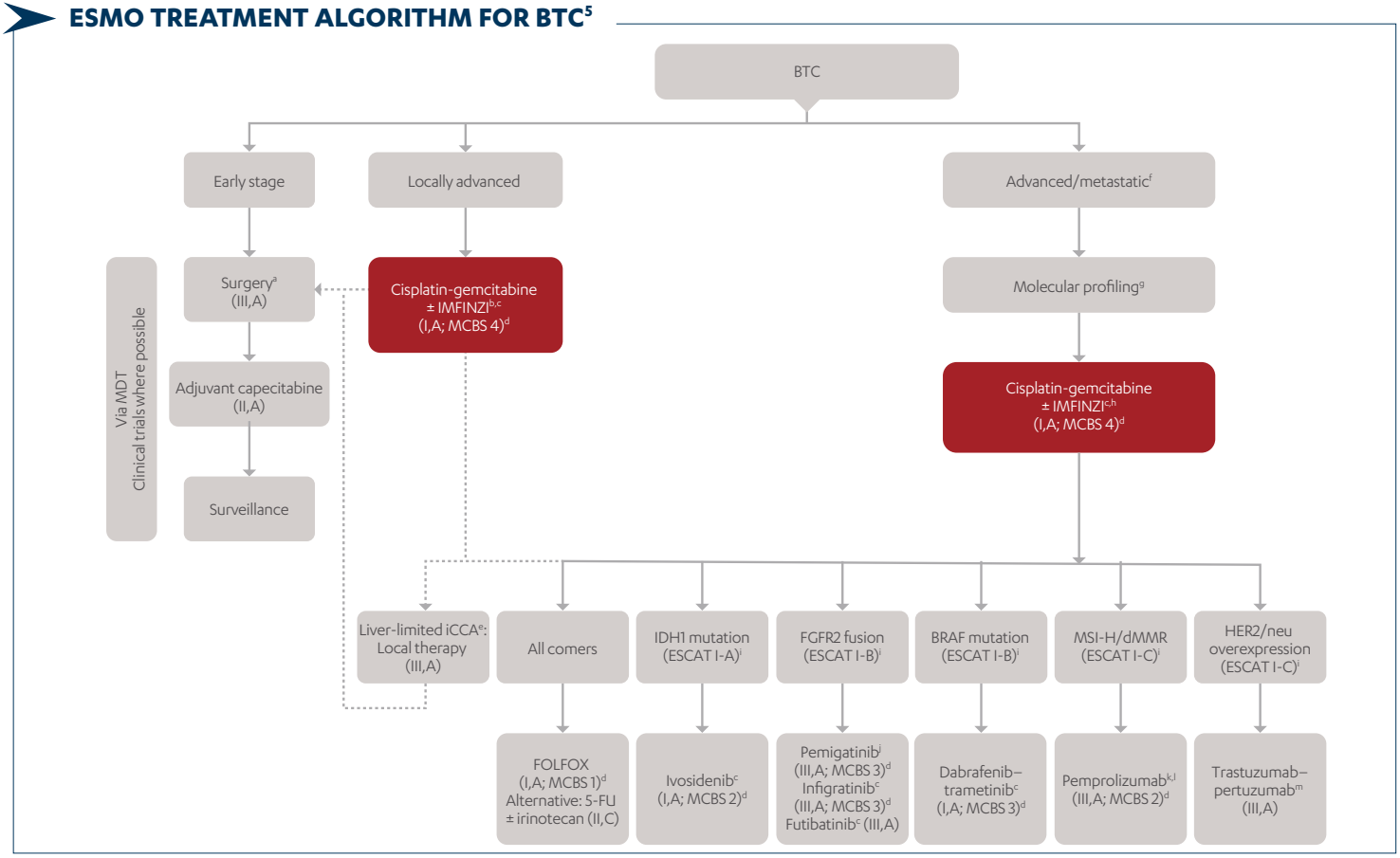
Adapted from Oh DY et al. 2024

- **~ 1 in 4 patients remained in response at 12 months: 26.1% vs. 15.0%[*,2]**
- **Similar rates of adverse events[*,2]**
- **Efficacy and safety confirmed in the first real-world evidence setting[4]**

IMFINZI® + gem-cis is recommended by ESMO and NCCN guidelines as first line treatment of advanced BTC[5,6]

Per ESMO-MCBS grading, the data from TOPAZ-1 meet the Grade 4 criteria, one of the highest levels in a non-curative setting which is indicative of a substantial magnitude of clinical benefit[*,5]

ESMO TREATMENT ALGORITHM FOR BTC[5]



Adapted from Vogel A et al. 2023

BTC=biliary tract cancer; cis=cisplatin; **dMMR**=mismatch repair deficiency; **EMA**=European Medicines Agency; **ESCAT**=ESMO Scale for Clinical Actionability of Molecular Targets; **ESMO**=European Society for Medical Oncology; **FDA**=Food and Drug Administration; **FGFR2**=fibroblast growth factor receptor 2; **FOLFOX**=5-fluorouracil–leucovorin–oxaliplatin; **GBC**=gallbladder cancer; **gem**=gemcitabine; **HER2**=human epidermal growth factor receptor 2; **iCCA**=intrahepatic cholangiocarcinoma; **IDH1**=isocitrate dehydrogenase 1; **MCBS**=Magnitude of Clinical Benefit Scale; **MDT**=multidisciplinary team; **MSI-H**=microsatellite instability-high; **NCCN**=National Comprehensive Cancer Network; **NTRK**=neurotrophic tyrosine receptor kinase; **pCCA**=perihilar cholangiocarcinoma; **PD-1**=programmed cell death protein 1; **PS**=performance status.

a Special considerations: (i) consider the need for preoperative drainage; (ii) avoid percutaneous biopsy in resectable d/pCCA; (iii) assess future liver remnant; (iv) neoadjuvant approach (selected cases);(v) completion surgery for incidental GBC stage ≥T1b. **b** Salvage surgery or local therapies should be considered in responding patients with initially inoperable disease. **c** FDA approved; not EMA approved. **d** ESMO-MCBS v1.1 was used to calculate scores for therapies/indications approved by the EMA or FDA. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee (https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluationforms). **e** Reconsider surgery in the event of dequate response to treatment. **f** Clinical trial recommended when available. **g** Molecular profiling should be performed before/during first-line therapy. Gene panel should include FGFR2, IDH1, HER2/neu and BRAF to test for hotspot mutations but may also include genes such as NTRK and c-MET. The rapidly evolving landscape of drug targets and predictive biomarkers may necessitate larger panels in the future. **h** Cisplatin–gemcitabine–durvalumab is recommended for first-line treatment [I, A]. Consider gemcitabine monotherapy in patients with a compromised PS or significant debility who are at risk of toxicity from platinum-containing ChT regimens. Was used to calculate scores for therapies/ indications approved by the EMA or FDA. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee (https://www.esmo.org/ guidelines/esmo-mcbs/esmomcbs-evaluation-forms). **i** ESCAT scores apply to genomic alterations only. These scores have been defined by the guideline authors and validated by the ESMO Translational Research and Precision Medicine Working Group. **j** EMA and FDA approved. **k** Anti-PD-1 therapy is ecommended for patients with MSI-H/dMMR who have not been treated with first-line immunotherapy. **l** EMA approved for MSI-H/dMMR BTC; FDA approved for all MSI-H/dMMR solid tumours. **m** Not EMA approved; not FDA approved.

BTC=biliary tract cancer; **CI**= confidence interval; **cis**=cisplatin; **ESMO**=European Society for Medical Oncology; **gem**=gemcitabine;**HR**=hazard ratio; **NCCN**=National Comprehensive Cancer Network; **OS**=overall survival.

References: 1. IMFINZI® Information for Healthcare Professionals. www.swissmedicinfo.ch. **2.** Oh DY, He AR, Qin S, et al. Durvalumab plus gemcitabine and cisplatin in advanced biliary tract cancer. NEJM Evidence. 2022;1(8). doi:10.1056/EVIDoa2200015 (including Supplementary Appendix and Protocol). **3.** Oh DY, He AR, Qin S, et al. Three-year survival and safety update from the phase 3 TOPAZ-1 study of durvalumab plus chemotherapy in biliary tract cancer. Poster presented at: 2024 CCF Conference; April 17-19, 2024; Salt Lake City, UT. **4.** Rimini M, et al. Durvalumab plus gemcitabine and cisplatin in advanced biliary tract cancer: An early exploratory analysis of real-world data. Liver international 2023. **5.** Vogel, A., et al. Biliary tract cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Annals of Oncology 34.2 (2023): 127-140. doi: 10.1016/j.annonc.2022.10.506. **6.** NCCN Guidelines Biliary Tract Cancers Version 1.2024; 9 April 2024, NCCN.org

Imfinzi® Comp: Durvalumab; concentrate for solution for infusion; 50 mg/mL; List A. **Ind:** For the treatment of adult patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) whose disease has not progressed following definitive platinum-based chemoradiation therapy. In combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). In combination with gemcitabine and cisplatin for the first line treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC). **Dos:** NSCLC: 10 mg/kg every 2 weeks or 1500 mg every 4 weeks. ES-SCLC: 1500 mg every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks. BTC: 1500 mg every 3 weeks (21 days) for up to 8 cycles, followed by 1500 mg every 4 weeks. **CI:** Hypersensitivity to the active substance or to any of the excipients. **W&P:** Immune-mediated ADRs (pneumonitis, hepatitis, colitis, nephritis, rash, myocarditis, haemophagocytic lymphohistiocytosis (HLH)), immune-mediated endocrinopathies (hypothyroidism, hyperthyroidism, thyroiditis, adrenal insufficiency, type 1 diabetes mellitus, hypophysitis/hypopituitarism), aseptic meningitis, haemolytic anaemia, immune thrombocytopenia, cystitis noninfective, myositis, rhabdomyolyses, encephalitis, pancreatitis, Guillain-Barré syndrome, arthritis, uveitis and ocular inflammatory toxicity, polymyositis, myasthenia gravis, infusion-related reactions, adverse reactions in transplant recipients, cerebrovascular events. **IA:** Corticosteroids and immunosuppressants before starting treatment. **ADRs:** Monotherapy: Very common: upper respiratory tract infections, hypothyroidism, cough/productive cough, diarrhoea, abdominal pain, rash, pruritus, pyrexia. Common: pneumonia, oral candidiasis, dental and oral soft tissue infections, influenza, hyperthyroidism, TSH increased, pneumonitis, dysphonia, aspartate aminotransferase increased or alanine aminotransferase increased, night sweats, myalgia, blood creatinine increased, dysuria, peripheral oedema, infusion related reaction. In combination with chemotherapy: Very common: neutropenia, anaemia, thrombocytopenia, leukopenia, decreased appetite, insomnia, cough/productive cough, nausea, constipation, vomiting, diarrhoea, abdominal pain, aspartate aminotransferase increased or alanine aminotransferase increase, alopecia, rash, fatigue, pyrexia. Common: upper respiratory tract infections, influenza, pneumonia, dental and oral soft tissue infections, sepsis, febrile neutropenia, pancytopenia, hypothyroidism, hyperthyroidism, adrenal insufficiency, hypomagnesaemia, hypokalaemia, hyponatraemia, dehydration, hypocalcaemia, cerebrovascular events, neuropathy peripheral, headache, tinnitus, tachycardia, hypotension, pneumonitis, dysphonia, dyspnoea, pulmonary embolism, hiccups, stomatitis, amylase increased, hepatitis, blood bilirubin increased, gamma-glutamyltransferase increased, blood creatinine increased, dysuria, acute kidney injury, proteinuria, pruritus, dermatitis, back pain, myalgia, muscle spasms, peripheral oedema, infusion related reaction, chills, oedema, malaise. Uncommon, rare, very rare, unknown: see www.swissmedicinfo.ch. Date of revision of the text: March 2024. Further information: www.swissmedicinfo.ch or AstraZeneca AG, Neuhofstrasse 34, 6340 Baar, Switzerland. www.astrazeneca.ch. Professionals can request the mentioned references to AstraZeneca AG.

AstraZeneca

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For more information about IMFINZI® in aBTC, please scan this QR code