NEW 3-YEAR OS DATA

IMFINZI + gem-cis: Standard of care in 1L advanced biliary tract cancers (BTCs)[1-3]

The first and only FDA-approved regimen to demonstrate **significant improvement in OS and PFS vs gem-cis** in locally advanced or metastatic BTCs, including cholangiocarcinoma and gallbladder cancer[1-3]

OVERALL SURVIVAL (primary endpoint)[1,2]

20% REDUCTION IN THE RISK OF DEATH with IMFINZI + gem-cis vs gem-cis
HR=0.80 (95% CI, 0.66-0.97); *P*=0.021*

12.8-month mOS (95% CI, 11.1-14.0) **vs** 11.5-month mOS (95% CI, 10.1-12.5)

PROGRESSION-FREE SURVIVAL (secondary endpoint)[1,2]

25% REDUCTION IN THE RISK OF DISEASE PROGRESSION OR DEATH
with IMFINZI + gem-cis vs gem-cis
HR=0.75 (95% CI, 0.63-0.89); *P*=0.001*

7.2-month mPFS (95% CI, 6.7-7.4) **vs** 5.7-month mPFS (95% CI, 5.6-6.7)

Data cutoff was August 11, 2021. Because superior OS was demonstrated at the prespecified interim analysis, PFS was formally evaluated at this time. 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.[1,2]

*HR based on Cox proportional hazards model stratified by disease status and primary tumor location. Two-sided *P* value based on a stratified log-rank test compared with alpha boundary of 0.030 for OS and 0.048 for PFS.[1]

NCCN CATEGORY 1, PREFERRED

National Comprehensive Cancer Network® (NCCN®)—Category 1, Preferred
Durvalumab (IMFINZI®) + gemcitabine and cisplatin is an **NCCN Category 1, preferred** primary systemic therapy option for unresectable or metastatic biliary tract cancers[4†‡§]

1L=first line; CI=confidence interval; gem-cis=gemcitabine-cisplatin; HR=hazard ratio; mOS=median overall survival; mPFS=median progression-free survival; NCCN=National Comprehensive Cancer Network® (NCCN®); OS=overall survival; PFS=progression-free survival.

†Preferred intervention=intervention that is based on superior efficacy, safety, and evidence, and, when appropriate, affordability. Category 1=based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. To view the most recent and complete version of the guideline, go online to NCCN.org.[4]

‡See the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for detailed recommendations, including other treatment options.[4]

§Biliary tract cancers: Gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma.[4]

Indication

IMFINZI, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

Immune-Mediated Adverse Reactions
Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment or after discontinuation.

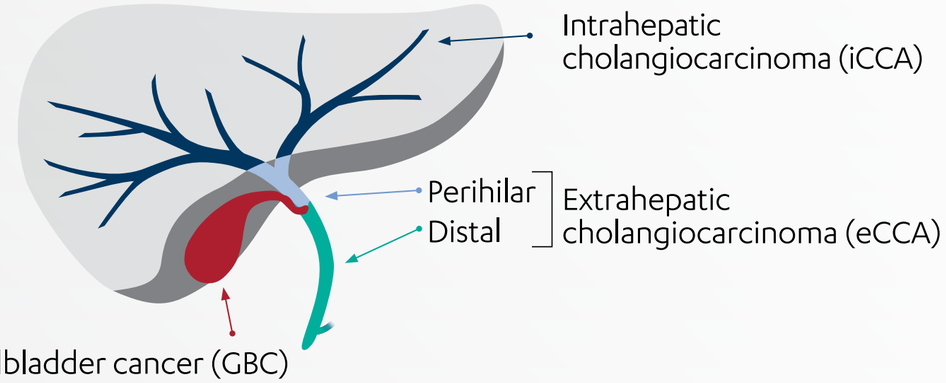
Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

BTCs are a heterogeneous group of aggressive malignancies with a historically poor prognosis[5,6]

These rare cancers emerge along the epithelium of the biliary tree and are characterized by anatomical site of origin[7,8]

BTCs by anatomical site of origin[7]



Adapted from: Valle JW et al. *Lancet*. 2021;397(10272):428-444.

>12,350* **new cases of BTCs are estimated to occur in the United States in 2024, with BTCs accounting for <1% of new cancer cases annually[9-11]**

*Per the American Cancer Society, the actual number of cases is likely to be higher, because these cancers can be hard to diagnose, and some might be misclassified as other types of cancer.[9]

BTCs often go undetected until advanced stages, with metastatic BTCs having low survival rates across subtypes[12-15]

of patients with BTCs **experience recurrence post resection[12]**

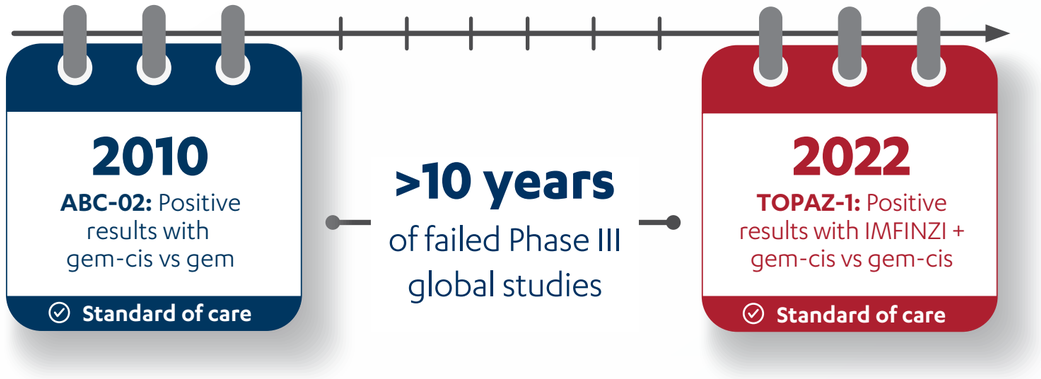
~80% of patients are diagnosed with advanced, unresectable disease[13,16]

The 5-year survival rate (SEER) is 2% to 3% for patients with metastatic BTCs, including iCCA, eCCA, and GBC[14,15]

SEER=Surveillance, Epidemiology, and End Results Program.

IMFINZI + gem-cis: standard of care option in 1L treatment of advanced BTCs[1-3]

Over the past decade, no treatment for advanced BTCs had demonstrated positive results in a global Phase III study vs gem-cis—until TOPAZ-1[2,5-7]



IMFINZI + gem-cis: 3 key takeaways

#1 **Prescribed** in first-line, with **>10,000 patients** treated to date[17*]

The only FDA-approved 1L IO regimen to demonstrate both superior OS and PFS[1-3]

- Median OS was 12.8 months with IMFINZI + gem-cis vs 11.5 months with gem-cis: HR=0.80 (95% CI, 0.66-0.97); *P*=0.021
- Median PFS was 7.2 months with IMFINZI + gem-cis vs 5.7 months with gem-cis: HR=0.75 (95% CI, 0.63-0.89); *P*=0.001

The only FDA-approved 1L IO regimen with a 3-year OS analysis[18]

- Median OS was 12.9 months with IMFINZI + gem-cis and 11.3 months with gem-cis; HR=0.74 (95% CI, 0.63-0.87)†
- The 3-year OS analysis was conducted post hoc and not powered for statistical significance

gem=gemcitabine; IO=immuno-oncology.
*Data are based on total US patients treated with IMFINZI vs non-IMFINZI in 1L from September 2022 to January 2024.
†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.

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (continued)
Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate. Withhold or permanently discontinue IMFINZI depending on severity. See USPI Dosing and Administration for specific details. In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

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IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

TOPAZ-1: The first positive global Phase III study in 1L locally advanced or metastatic BTCs in >10 years[1,2,5-7]

A randomized, double-blind, placebo-controlled, global Phase III study[1,2]

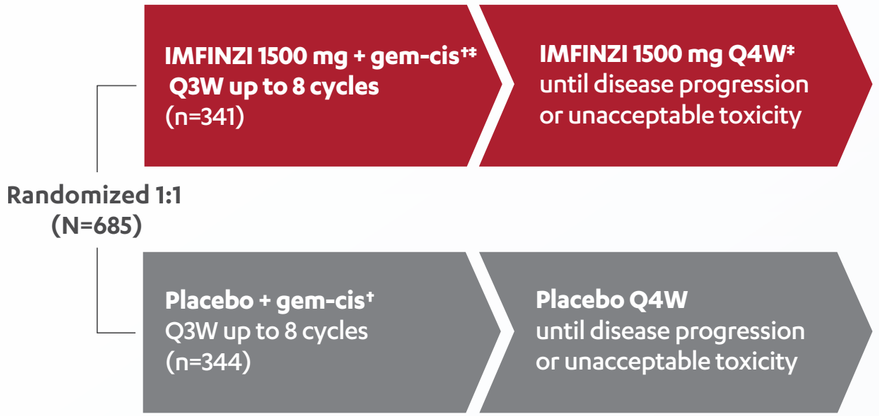
TOPAZ-1 STUDY DESIGN[1,2]

Key eligibility criteria

- Histologically confirmed locally advanced or metastatic BTCs
  - iCCA
  - eCCA
  - GBC
- Previously untreated if unresectable or metastatic at initial diagnosis*
- ECOG PS 0 or 1
- ≥1 target lesion by RECIST v1.1

Stratification factors

- Disease status (initially unresectable vs recurrent)
- Primary tumor location (iCCA vs eCCA vs GBC)



Primary endpoint

- Overall survival (OS)

Key secondary endpoints

- Progression-free survival (PFS)§
- Objective response rate (ORR)§
- Duration of response (DoR)§
- Safety

Patients with ampullary carcinoma, active or prior documented autoimmune or inflammatory disorders, HIV infection or active infections, or current or prior use of immunosuppressive medications within 14 days before the first dose of IMFINZI were ineligible to participate in the TOPAZ-1 study[1]

ECOG=Eastern Cooperative Oncology Group; HIV=human immunodeficiency virus; PS=performance status; Q3W=every 3 weeks; Q4W=every 4 weeks; RECIST=Response Evaluation Criteria in Solid Tumors.

Tumor assessments were conducted every 6 weeks for the first 24 weeks after the date of randomization, and then every 8 weeks until confirmed objective disease progression.[1]

*Patients who developed recurrent disease >6 months after surgery and/or completion of adjuvant therapy were eligible.[1]

†IMFINZI 1500 mg or placebo administered on Day 1 + gemcitabine 1000 mg/m^2 and cisplatin 25 mg/m^2 (each administered on Days 1 and 8) every 3 weeks (21 days) for up to 8 cycles, followed by IMFINZI 1500 mg or placebo every 4 weeks until disease progression or unacceptable toxicity. Treatment was permitted beyond disease progression if the patient was clinically stable and deriving clinical benefit as determined by the investigator.[1]

‡In patients weighing <30 kg, IMFINZI was administered using weight-based dosing at 20 mg/kg.[1]

§Investigator assessed according to RECIST v1.1.[2]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Pneumonitis

IMFINZI can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation. In patients who did not receive recent prior radiation, the incidence of immune-mediated pneumonitis was 2.4% (34/1414), including fatal (<0.1%), and Grade 3-4 (0.4%) adverse reactions. In patients who received recent prior radiation, the incidence of pneumonitis (including radiation pneumonitis) in patients with unresectable Stage III NSCLC following definitive chemoradiation within 42 days prior to initiation of IMFINZI in PACIFIC was 18.3% (87/475) in patients receiving IMFINZI and 12.8% (30/234) in patients receiving placebo. Of the patients who received IMFINZI (475), 1.1% were fatal and 2.7% were Grade 3 adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

TOPAZ-1 enrolled a diverse, all-comers population with no biomarker requirements[1,2]

KEY BASELINE CHARACTERISTICS[2]

Patient characteristics	IMFINZI + gem-cis (n=341)	Placebo + gem-cis (n=344)	Total (N=685)
Median age (range), years	64 (20-84)	64 (31-85)	64 (20-85)
Female	50%	49%	50%
ECOG PS 0	51%	47%	49%
ECOG PS 1	49%	53%	51%
Race			
Asian	54%	58%	56%
White	38%	36%	37%
Black or African American	2%	2%	2%
American Indian or Alaskan Native	0%	0.3%	0.1%
Other	5%	4%	4%
Primary tumor type			
iCCA	56%	56%	56%
eCCA	19%	19%	19%
GBC	25%	25%	25%
Disease status at randomization*			
Initially unresectable	80%	81%	81%
Recurrent	20%	19%	19%

Patient characteristics	IMFINZI + gem-cis (n=341)	Placebo + gem-cis (n=344)	Total (N=685)
Disease classification at diagnosis*			
Locally advanced†	11%	17%	14%
Metastatic	89%	83%	86%
MSI status			
High	0.9%	0.6%	0.7%
Stable	47%	49%	48%
Missing‡	52%	51%	51%
Virology status			
No viral hepatitis	55%	51%	53%
Any viral hepatitis B	20%	24%	22%
Active viral hepatitis B	2%	4%	3%
Prior hepatitis C	2%	3%	3%
Missing	24%	24%	24%
PD-L1 expression			
TAP ≥1%	58%	60%	59%
TAP <1%	30%	30%	30%
Missing	12%	11%	11%

Patient demographics and disease characteristics were well balanced between treatment arms[2]

MSI=microsatellite instability; PD-L1=programmed death-ligand 1; TAP=tumor area positivity.

*Disease status and disease classification missing for 1 patient.[2]
†Patients have only locally advanced sites of disease.[2]
‡MSI status was missing for approximately 50% of patients in each treatment group due to either an insufficient tissue sample or a test result of MSI status unknown.[2]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Pneumonitis (continued)

The frequency and severity of immune-mediated pneumonitis in patients who did not receive definitive chemoradiation prior to IMFINZI were similar in patients who received IMFINZI as a single agent or with ES-SCLC or BTC when given in combination with chemotherapy.

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In the treatment of locally advanced or metastatic biliary tract cancers,

IMFINZI + gem-cis demonstrated superior overall survival vs gem-cis[1]

OVERALL SURVIVAL (primary endpoint)[1,2]

20% REDUCTION IN THE RISK OF DEATH with IMFINZI + gem-cis vs gem-cis
HR=0.80 (95% CI, 0.66-0.97); *P*=0.021*

12.8-month mOS	vs	11.5-month mOS
(95% CI, 11.1-14.0)		(95% CI, 10.1-12.5)

- Data cutoff was August 11, 2021. At the prespecified interim analysis, 424 events (198 in the IMFINZI group and 226 in the placebo group) had occurred. OS maturity was 62%[1,2]

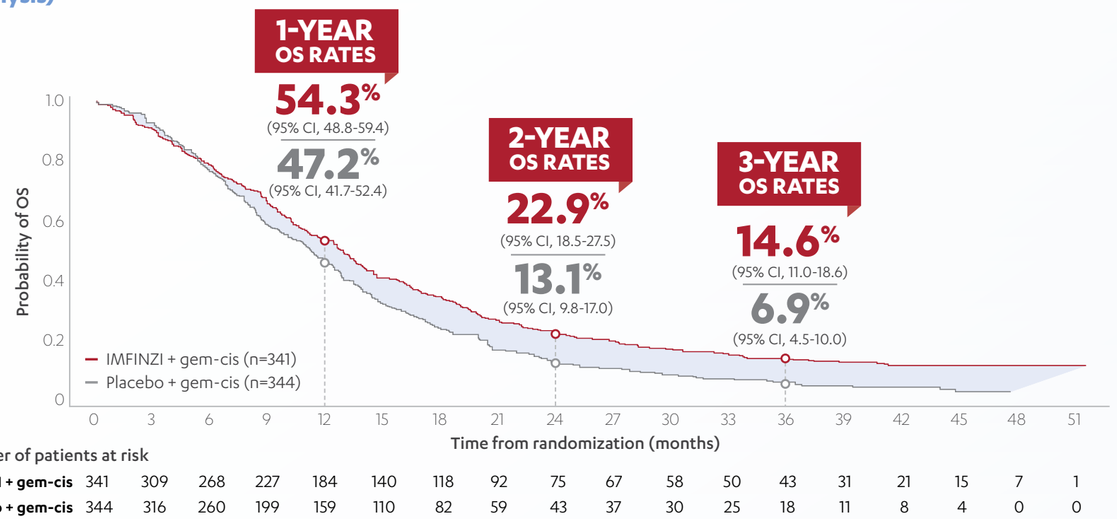
Median duration of follow-up: 16.8 months (95% CI, 14.8-17.7) with IMFINZI + gem-cis and 15.9 months (95% CI, 14.9-16.9) with gem-cis.[2]
*HR based on Cox proportional hazards model stratified by disease status and primary tumor location. Two-sided *P* value based on a stratified log-rank test compared with alpha boundary of 0.030.[1]

OVERALL SURVIVAL AT 3 YEARS (post-hoc analysis)[18]

26% REDUCTION IN THE RISK OF DEATH
with IMFINZI + gem-cis vs gem-cis
HR=0.74 (95% CI, 0.63-0.87)

12.9-month mOS
(95% CI, 11.6-14.1)

11.3-month mOS
(95% CI, 10.1-12.5)



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

- **The 3-year OS analysis was conducted post hoc and not powered for statistical significance**
- Data cutoff was October 23, 2023. At the 3-year OS analysis, OS maturity was 89%

IMFINZI + gem-cis is the ONLY FDA-approved 1L regimen to set the 3-year benchmark for OS analyses in advanced BTCs[18]

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.

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Colitis
IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 2% (37/1889) of patients receiving IMFINZI, including Grade 4 (<0.1%) and Grade 3 (0.4%) adverse reactions.

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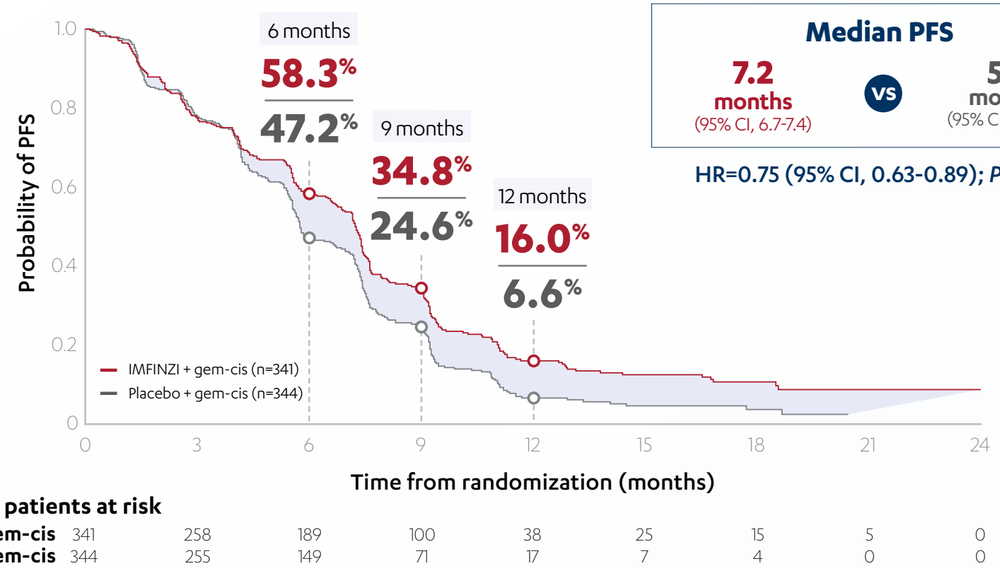
durvalumab
Injection for Intravenous Use 50 mg/mL

In the treatment of locally advanced or metastatic biliary tract cancers,

IMFINZI + gem-cis is the first and only FDA-approved regimen to demonstrate significant improvement in PFS vs gem-cis[1]

25% reduction in the risk of disease progression or death with IMFINZI + gem-cis vs gem-cis[1,2,19]

PROGRESSION-FREE SURVIVAL (secondary endpoint)[1,2,18]



Median PFS

7.2 months (95% CI, 6.7-7.4) **vs** **5.7 months** (95% CI, 5.6-6.7)

HR=0.75 (95% CI, 0.63-0.89); *P*=0.001*

Number of patients at risk

IMFINZI + gem-cis	341	258	189	100	38	25	15	5	0
Placebo + gem-cis	344	255	149	71	17	7	4	0	0

- Data cutoff was August 11, 2021. Because superior OS was demonstrated at the prespecified interim analysis, PFS was formally evaluated at this time. At the interim analysis, 573 events (276 in the IMFINZI group and 297 in the placebo group) had occurred. PFS maturity was 84%[1,2]
- PFS rates at 6, 9, and 12 months were descriptive endpoints and were not powered to determine statistical significance[19]

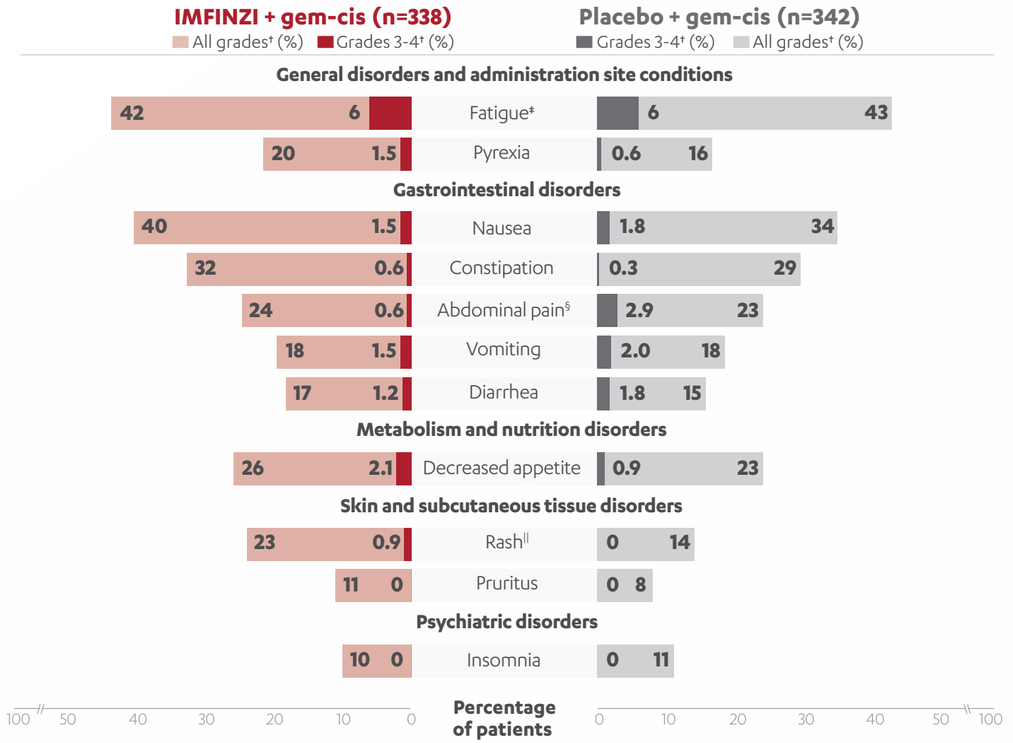
Median duration of follow-up: 16.8 months (95% CI, 14.8-17.7) with IMFINZI + gem-cis and 15.9 months (95% CI, 14.9-16.9) with gem-cis.[2]

*HR based on Cox proportional hazards model stratified by disease status and primary tumor location. Two-sided *P* value based on a stratified log-rank test compared with alpha boundary of 0.048.[1]

Safety and tolerability profile for IMFINZI + gem-cis in locally advanced or metastatic BTCs

Similar rates of Grades 3-4 adverse reactions were reported for IMFINZI + gem-cis (75.7%) and gem-cis (77.8%)[2]

ADVERSE REACTIONS OCCURRING IN ≥10% OF PATIENTS[1]*



DISCONTINUATION RATES DUE TO TREATMENT-RELATED ARs[2]

8.9% of patients discontinued IMFINZI + gem-cis

11.4% of patients discontinued placebo + gem-cis

- Safety data are available for the 680 patients who received at least 1 dose of IMFINZI + gem-cis (n=338) or placebo + gem-cis (n=342)[1,2]
- Serious ARs occurred in 47% of patients receiving IMFINZI + gem-cis. The most frequent serious ARs (≥2% of patients) were cholangitis (7%), pyrexia (3.8%), anemia (3.6%), sepsis (3.3%), and acute kidney injury (2.4%)[1]
- Fatal ARs occurred in 3.6% of patients receiving IMFINZI + gem-cis. These include ischemic or hemorrhagic stroke (4 patients), sepsis (2 patients), and upper gastrointestinal hemorrhage (2 patients)[1]
- The most common ARs (occurring in ≥20% of patients) with IMFINZI + gem-cis were fatigue, nausea, constipation, decreased appetite, abdominal pain, rash, and pyrexia[1]
- The safety profile observed at the 3-year analysis (post-hoc analysis; data cutoff: October 23, 2023) was consistent with the safety profile observed at the primary analysis[18]

ARs=adverse reactions; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

*Table summarizes the ARs that occurred in ≥10% of patients treated with IMFINZI + gem-cis.
†Graded according to NCI CTCAE version 5.0.
‡Includes fatigue, malaise, cancer fatigue, and asthenia.
§Includes abdominal pain, abdominal pain lower, abdominal pain upper, and flank pain.
‖Includes rash macular, rash maculopapular, rash morbilliform, rash papular, rash pruritic, rash pustular, rash erythematous, dermatitis acneiform, dermatitis bullous, drug eruption, eczema, erythema, dermatitis, and rash.

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Endocrinopathies

- ***Adrenal Insufficiency***: IMFINZI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Immune-mediated adrenal insufficiency occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

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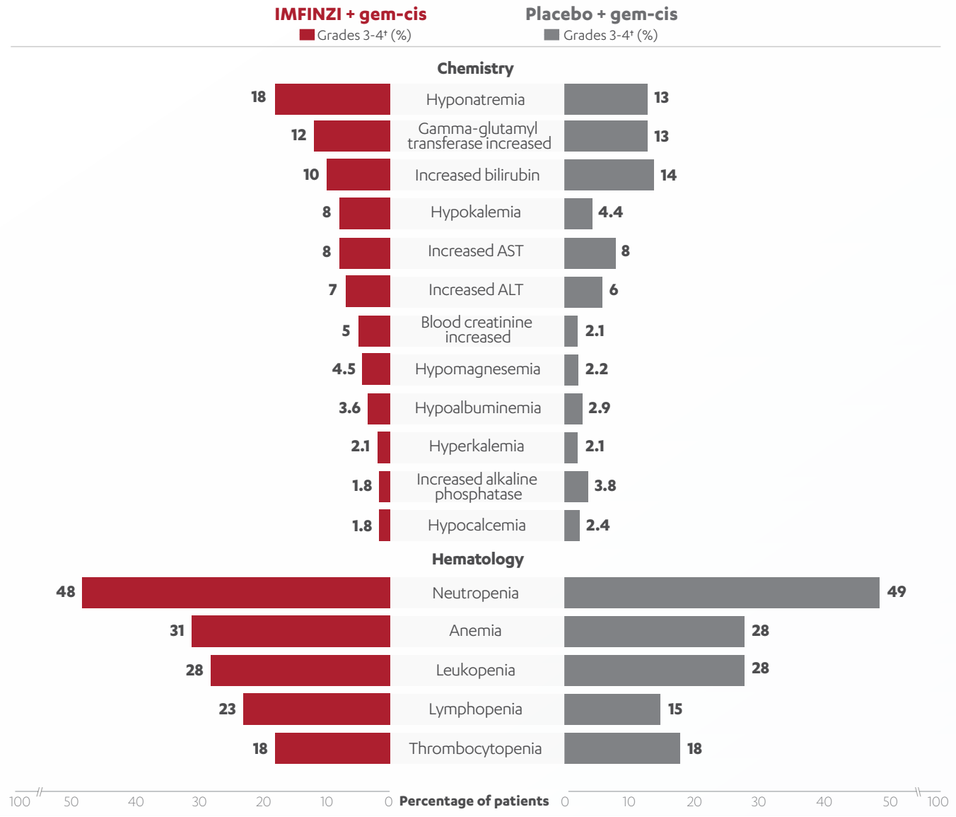
Injection for Intravenous Use 50 mg/mL

Safety and tolerability profile for IMFINZI + gem-cis in locally advanced or metastatic BTCs (cont'd)

GRADES 3-4 LABORATORY ABNORMALITIES WORSENING FROM BASELINE IN ≥20% OF PATIENTS[1]*



- Median relative dose intensity was 100% for IMFINZI or placebo, and 94% for gemcitabine and cisplatin in both treatment groups[2]
- Most immune-mediated adverse reactions were Grade 1 or 2[2‡]
  - Any-grade imARs: 12.7% with IMFINZI + gem-cis and 4.7% with gem-cis
  - Grade 3 or 4 imARs: 2.4% with IMFINZI + gem-cis and 1.5% with gem-cis

ALT=alanine aminotransferase; AST=aspartate aminotransferase; imARs=immune-mediated adverse reactions.

*Table summarizes the laboratory abnormalities that occurred in ≥20% of patients treated with IMFINZI + gem-cis. The frequency cutoff is based on any grade change from baseline.

†Graded according to NCI CTCAE version 5.0. Each test incidence is based on the number of patients who had both baseline and at least 1 on-study laboratory measurement available: IMFINZI + gem-cis (range: 312 to 335) and placebo + gem-cis (range: 319 to 341).

‡An immune-mediated adverse reaction is defined as a reaction that is associated with drug exposure and consistent with an immune-mediated mechanism of action and where there is no clear alternate etiology.[2]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Endocrinopathies (continued)

- ***Hypophysitis***: IMFINZI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate symptomatic treatment including hormone replacement as clinically indicated. Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) of patients who received IMFINZI.

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Injection for Intravenous Use 50 mg/mL

In the treatment of locally advanced or metastatic biliary tract cancers,

Patients start with IMFINZI and chemotherapy, then continue with IMFINZI monotherapy[1]

For patients with a body weight of ≥30 kg

START

IMFINZI + gem-cis Q3W

Up to 8 cycles

IMFINZI 1500-mg fixed dose* + GEMCITABINE + CISPLATIN

CONTINUE

IMFINZI Q4W

Until disease progression or unacceptable toxicity

IMFINZI 1500-mg fixed dose*

NO CHEMOTHERAPY NEEDED WITH IMFINZI Q4W

Biomarker testing is not required to start IMFINZI + gem-cis[1]

- IMFINZI is administered as a 60-minute IV infusion after dilution
- IMFINZI is administered prior to chemotherapy on the same day. Refer to the Prescribing Information for appropriate chemotherapeutic agent for dosage information

IV=intravenous.

In the TOPAZ-1 study, IMFINZI 1500 mg was administered on Day 1 of each cycle in combination with gemcitabine 1000 mg/m^2 and cisplatin 25 mg/m^2 on Days 1 and 8 of each 21-day cycle for up to 8 cycles, followed by IMFINZI 1500 mg every 4 weeks until disease progression or unacceptable toxicity.[1]

*Patients with a body weight of <30 kg: 20 mg/kg in combination with gemcitabine and cisplatin every 3 weeks (21 days) for up to 8 cycles, followed by 20 mg/kg every 4 weeks as a single agent.[1]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Endocrinopathies (continued)

- ***Thyroid Disorders***: IMFINZI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement therapy for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated.
- ***Thyroiditis***: Immune-mediated thyroiditis occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Hyperthyroidism***: Immune-mediated hyperthyroidism occurred in 2.1% (39/1889) of patients receiving IMFINZI.
- ***Hypothyroidism***: Immune-mediated hypothyroidism occurred in 8.3% (156/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Type 1 Diabetes Mellitus, which can present with diabetic ketoacidosis***: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Grade 3 immune-mediated Type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI.

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.5% (10/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

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AstraZeneca strives to make treatment with IMFINZI accessible and affordable

AstraZeneca Access 360™

Helping patients access the care they need

The AstraZeneca Access 360™ program provides personal support to connect patients to affordability programs and streamline access and reimbursement for IMFINZI.*

Access 360 provides:

- Assistance with understanding patient insurance coverage and pharmacy options
- Prior authorization support
- Claims and appeal process support
- Eligibility requirements and enrollment assistance with AstraZeneca's Co-pay Savings Programs
- Referrals to patient assistance programs

To learn more about the Access 360 program, please call **1-844-ASK-A360 (1-844-275-2360)** Monday through Friday, 8 AM - 6 PM ET, or visit **www.MyAccess360.com**.

*This description of the Access 360 program is for informational purposes only. Access 360 does not file claims or appeals on behalf of healthcare professionals or patients and makes no representation or guarantee concerning reimbursement or coverage for any service or item.

$0 CO-PAY

IMFINZI Patient Savings Programs

The IMFINZI Patient Savings Programs† are available to assist eligible, commercially insured patients with their out-of-pocket costs for IMFINZI.

- The IMFINZI Patient Savings Programs cover out-of-pocket costs for both the medication and administration
  - Eligible patients with commercial insurance may pay as little as $0 per infusion for IMFINZI
  - Eligible patients can receive up to $100 per infusion of IMFINZI to help cover the costs of administration‡§
- There are no income requirements to participate

For more information, including full Eligibility Requirements for the program and Terms of Use, visit **www.AstraZenecaSpecialtySavings.com** or call Access 360 at **1-844-ASK-A360 (1-844-275-2360)** for more information.

†To be eligible, patients must be a resident of the United States or Puerto Rico and have commercial health insurance that covers medication costs for IMFINZI, but not the full cost to the patient. Patients are ineligible if prescriptions are paid by any state or other federally funded programs, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA or TRICARE, or where prohibited by law. Additional restrictions may apply. The IMFINZI Patient Savings Programs cover the cost of IMFINZI and up to $100 administration cost per infusion, per drug, and does not cover costs for office visits, or any other associated costs. Offer is invalid for claims and transactions more than 365 days from the date of service. Individual costs and benefit design may vary by plan. Costs to patients may vary by plan. Please consult with individual plan for specific information.

‡Patients who are residents of Massachusetts and Rhode Island are not eligible for infusion administration assistance.

§Patients are responsible for any cost associated with the infusion above the $100 per infusion assistance provided by the program.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Important Safety Information (continued)

Immune-Mediated Dermatology Reactions
IMFINZI can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/L-1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Immune-mediated rash or dermatitis occurred in 1.8% (34/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) adverse reactions.

Other Immune-Mediated Adverse Reactions
The following clinically significant, immune-mediated adverse reactions occurred at an incidence of less than 1% each in patients who received IMFINZI or were reported with the use of other PD-1/PD-L1 blocking antibodies.

- ***Cardiac/vascular***: Myocarditis, pericarditis, vasculitis.
- ***Nervous system***: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.
- ***Ocular***: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.
- ***Gastrointestinal***: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis.
- ***Musculoskeletal and connective tissue disorders***: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic.
- ***Endocrine***: Hypoparathyroidism.
- ***Other (hematologic/immune)***: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection.

Infusion-Related Reactions
IMFINZI can cause severe or life-threatening infusion-related reactions. Monitor for signs and symptoms of infusion-related reactions. Interrupt, slow the rate of, or permanently discontinue IMFINZI based on the severity. See USPI Dosing and Administration for specific details. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses. Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, including Grade 3 (0.3%) adverse reactions.

Complications of Allogeneic HSCT after IMFINZI
Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/L-1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/L-1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/L-1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity
Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. In females of reproductive potential, verify pregnancy status prior to initiating IMFINZI and advise them to use effective contraception during treatment with IMFINZI and for 3 months after the last dose of IMFINZI.

Lactation
There is no information regarding the presence of IMFINZI in human milk; however, because of the potential for adverse reactions in breastfed infants from IMFINZI, advise women not to breastfeed during treatment and for 3 months after the last dose.

Adverse Reactions

- In patients with locally advanced or metastatic BTC in the TOPAZ-1 study receiving IMFINZI (n=338), the most common adverse reactions (occurring in ≥20% of patients) were fatigue (42%), nausea (40%), constipation (32%), decreased appetite (26%), abdominal pain (24%), rash (23%), and pyrexia (20%).
- In patients with locally advanced or metastatic BTC in the TOPAZ-1 study receiving IMFINZI (n=338), discontinuation due to adverse reactions occurred in 6% of the patients receiving IMFINZI plus chemotherapy. Serious adverse reactions occurred in 47% of patients receiving IMFINZI plus chemotherapy. The most frequent serious adverse reactions reported in at least 2% of patients were cholangitis (7%), pyrexia (3.8%), anemia (3.6%), sepsis (3.3%) and acute kidney injury (2.4%). Fatal adverse reactions occurred in 3.6% of patients receiving IMFINZI plus chemotherapy. These include ischemic or hemorrhagic stroke (4 patients), sepsis (2 patients), and upper gastrointestinal hemorrhage (2 patients).

The safety and effectiveness of IMFINZI have not been established in pediatric patients.

You may report side effects related to AstraZeneca products.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

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1. IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023. **2.** Oh DY, He AR, Qin S, et al. Durvalumab plus gemcitabine and cisplatin in advanced biliary tract cancer [article and supplementary materials]. *NEJM Evid*. 2022;1(8). doi: 10.1056/EVIDoa2200015 **3.** Oncology (cancer)/hematologic malignancies approval notifications. US Food and Drug Administration. Updated March 21, 2024. Accessed April 5, 2024. https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancer-hematologic-malignancies-approval-notifications **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Biliary Tract Cancers V.1.2024. ©National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed April 5, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. **5.** Rizzo A, Brandi G. First-line chemotherapy in advanced biliary tract cancer ten years after the ABC-02 trial: "And yet it moves!" *Cancer Treat Res Commun*. 2021;27:100335. doi: 10.1016/j.ctarc.2021.100335 **6.** Valle J, Wasan H, Palmer DH, et al. Cisplatin plus gemcitabine versus gemcitabine for biliary tract cancer. *N Engl J Med*. 2010;362(14):1273-1281. doi: 10.1056/NEJMoa0908721 **7.** Valle JW, Kelley RK, Nervi B, Oh DY, Zhu AX. Biliary tract cancer. *Lancet*. 2021;397(10272):428-444. doi: 10.1016/S0140-6736(21)00153-7 **8.** Oneda E, Hilal MA, Zaniboni A. Biliary tract cancer: current medical treatment strategies. *Cancers (Basel)*. 2020;12(5):1237. doi: 10.3390/cancers12051237 **9.** American Cancer Society. Key statistics for bile duct cancer. Revised January 12, 2023. Accessed April 5, 2024. https://www.cancer.org/cancer/types/bile-duct-cancer/about/key-statistics.html **10.** American Cancer Society. Key statistics for gallbladder cancer. Revised January 17, 2024. Accessed April 5, 2024. https://www.cancer.org/cancer/types/gallbladder-cancer/about/key-statistics.html **11.** American Cancer Society. Cancer facts and figures 2024. Accessed April 5, 2024. https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2024-cancer-facts-figures.html **12.** Primrose JN, Fox RP, Palmer DH, et al. Capecitabine compared with observation in resected biliary tract cancer (BILCAP): a randomised, controlled, multicentre, phase 3 study. *Lancet Oncol*. 2019;20(5):663-673. doi: 10.1016/S1470-2045(18)30915-X **13.** Shroff RT, Kennedy EB, Bachini M, et al. Adjuvant therapy for resected biliary tract cancer: ASCO Clinical Practice Guideline. *J Clin Oncol*. 2019;37(12):1015-1027. doi: 10.1200/JCO.18.02178 **14.** American Cancer Society. Survival rates for bile duct cancer. Revised March 1, 2023. Accessed April 5, 2024. https://www.cancer.org/cancer/bile-duct-cancer/detection-diagnosis-staging/survival-by-stage.html **15.** American Cancer Society. Survival rates for gallbladder cancer. Revised March 1, 2023. Accessed April 5, 2024. https://www.cancer.org/cancer/gallbladder-cancer/detection-diagnosis-staging/survival-rates.html **16.** Wu L, Tsilimigras DI, Paredes AZ, et al. Trends in the incidence, treatment and outcomes of patients with intrahepatic cholangiocarcinoma in the USA: facility type is associated with margin status, use of lymphadenectomy and overall survival. *World J Surg*. 2019;43(7):1777-1787. **17.** Data on File, US-88164, AstraZeneca Pharmaceuticals LP; 2024. **18.** Oh DY, He AR, Qin S, et al. Three-year survival and safety update from 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. **19.** Oh DY, He AR, Qin S, et al. A phase 3 randomized, double-blind, placebo-controlled study of durvalumab in combination with gemcitabine plus cisplatin in patients with advanced biliary tract cancer: TOPAZ-1. Abstract presented at: 2022 ASCO Gastrointestinal Cancers Symposium; January 20-22; San Francisco, CA.

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