— NEW —
4-YEAR OS DATA

IMFINZI + GEM-CIS IS #1 PRESCRIBED IN 1L aBTCs BY GI ONCOLOGY SPECIALISTS[1*†]

>20,000 patients with aBTC treated since approval in September 2022[1‡]

*Data are based on total US aBTC patients treated with IMFINZI + gem-cis vs all other treatments in 1L from September 2022 to August 2025.[1]
†GI Oncology Specialists are defined as Medical Oncologists where patient volume is 50% or more GI.[1]
‡Data based on total number of US patients with aBTCs treated with 1L IMFINZI + gem-cis from September 2022 to August 2025.[1]

IMFINZI + gem-cis: The FIRST and ONLY FDA-approved 1L IO-based regimen to demonstrate statistical significance in both OS and PFS[2,3]

TOPAZ-1 PHASE III STUDY[2§]

IMFINZI + gem-cis vs gem-cis

mOS (primary endpoint)

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

HR=0.80 (95% CI, 0.66-0.97); *P*=0.021

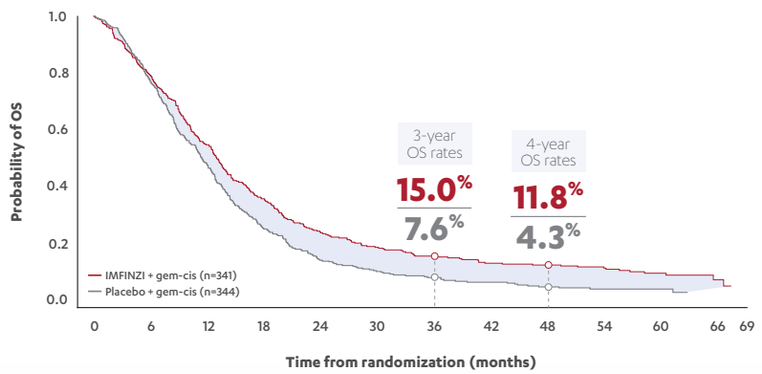
mPFS (secondary endpoint)

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

§The primary OS analysis was conducted after 424 deaths (198 in the IMFINZI + gem-cis arm and 226 in the gem-cis arm; OS maturity was 62%) with a median duration of follow-up of 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. HR based on Cox proportional hazards model stratified by disease status and primary tumor location. 2-sided *P* value based on a stratified log-rank test compared with alpha boundary of 0.030. Because superior OS was demonstrated at the prespecified interim analysis, PFS was formally evaluated at this time. The primary PFS analysis was conducted after 573 events (276 in the IMFINZI + gem-cis arm and 297 in the gem-cis arm; PFS maturity was 84%) with a median follow-up of 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. HR based on Cox proportional hazards model stratified by disease status and primary tumor location. 2-sided *P* value based on a stratified log-rank test compared with alpha boundary of 0.048. Data cutoff: August 11, 2021.[2,3]

NEW 4-YEAR OVERALL SURVIVAL (post-hoc analysis)[4]



Number at risk													
IMFINZI + gem-cis:	341	269	185	120	77	60	48	39	36	26	14	4	0
Placebo + gem-cis:	344	262	161	84	45	32	23	18	13	7	4	0	0

Nearly 3x more patients
were estimated to be alive at 4 years

25% REDUCTION IN RISK OF DEATH
with IMFINZI + gem-cis vs gem-cis (HR=0.75 [95% CI, 0.64-0.88])

- Median OS with IMFINZI + gem-cis was 13.0 months (95% CI, 11.6-14.1) and 11.4 months with gem-cis (95% CI, 10.1-12.5)
- **The 4-year OS analysis was conducted post hoc and not powered for statistical significance**
- In the post-hoc analysis, median duration of follow-up was 56.9 months (range: 1.7-67.2) for IMFINZI + gem-cis and 50.7 months (range: 0.9-62.6) for gem-cis. Data cutoff was February 28, 2025. At the 4-year OS analysis (post hoc), OS maturity was 90.3%

Study design: TOPAZ-1 was a randomized, double-blind, placebo-controlled, multicenter, Phase III study in patients with previously untreated locally advanced or metastatic intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, or gallbladder cancer. Patients who developed recurrent disease >6 months after surgery and/or completion of adjuvant therapy were eligible. Patients were randomized 1:1 to receive IMFINZI 1500 mg (n=341) or placebo (n=344) on Day 1 + gem-cis on Days 1 and 8 Q3W for up to 8 cycles followed by IMFINZI 1500 mg or placebo Q4W until disease progression or unacceptable toxicity.[2,3]

Standard-of-care IMFINZI + gem-cis: Longest follow-up of a 1L IO-based regimen in aBTCs with 4-year OS data[2,4]

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. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions.

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

1L=first line; aBTCs=advanced biliary tract cancers; CI=confidence interval; gem-cis=gemcitabine-cisplatin; GI=gastrointestinal; HR=hazard ratio; IO=immuno-oncology; mOS=median overall survival; mPFS=median progression-free survival; OS=overall survival; PFS=progression-free survival; Q3W=every 3 weeks; Q4W=every 4 weeks.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Real-world analysis: From **Clinical Trial** to **Clinical Practice**[2,5]

A global, multicenter, retrospective, real-world analysis was conducted to evaluate the use of 1L IMFINZI + gem-cis for the treatment of BTCs[5]

PATIENT CHARACTERISTICS IN THE REAL-WORLD ANALYSIS[5,6]

Patient characteristics	IMFINZI + gem-cis (n=666)[5]	Gem-cis (n=213)[6]
Gender, n (%)		
Male	355 (53.3)	98 (46.0)
Female	311 (46.7)	115 (54.0)
Primary tumor site, n (%)		
Intrahepatic	363 (54.5)	119 (56.0)
Extrahepatic	168 (25.2)	54 (24.5)
Gallbladder	135 (20.3)	38 (17.5)
Unknown	-	2 (1.0)
Previous surgery, n (%)		
Yes	178 (26.7)	77 (36.1)
No	488 (73.3)	136 (63.9)
Disease status, n (%)		
Locally advanced	157 (23.6)	32 (15.0)
Metastatic	509 (76.4)	181 (85.0)
ECOG PS, n (%)		
0	328 (49.2)	108 (50.5)
>0	338 (50.8)	101 (47.5)
Unknown	-	4 (2.0)

- In the IMFINZI + gem-cis group, age at 1L was 67 years (range: 29-89), while in the gem-cis group, 22.1% of patients were ≥70 years (77.9% of patients were <70 years)[5,6]

Study design: A real-world analysis was conducted to evaluate the use of 1L IMFINZI + gem-cis in patients with unresectable, locally advanced, or metastatic BTCs, including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer. Patients receiving IMFINZI 1500 mg Q3W for up to 8 cycles with gem-cis followed by IMFINZI 1500 mg Q4W until disease progression or unacceptable toxicity (n=666) were enrolled between 2022 and 2024 at study sites located in Italy, Germany, Austria, Spain, UK, US, South Korea, China, Hong Kong, Japan, and Belgium. Patients receiving gem-cis Q3W up to 8 cycles (n=213) were enrolled between 2016 and 2022 at study sites located in Italy.[5,6]

Study limitations: The real-world analysis of 1L IMFINZI + gem-cis has limitations and should be interpreted with caution

- The retrospective nature of the analysis cannot exclude potential selection bias. Despite adjustments, this study cannot replace level 1 evidence derived from a prospective, randomized trial. Some data may be missing[5,6]
- Patient characteristics are not fully balanced between the IMFINZI + gem-cis and gem-cis cohorts, and propensity score matching was not conducted for this analysis. In addition, some patient characteristics that may have influenced results (eg, race) are not reported[5,6]
- The median duration of follow-up was shorter for patients receiving IMFINZI + gem-cis (8.5 months [95% CI, 7.9-9.5]) than for patients receiving gem-cis alone (30.1 months [95% CI, 22.1-44.9]); as such, longer follow-up data are needed to support results[5,6]
- The results shown for the comparison between the IMFINZI + gem-cis and gem-cis cohorts are based on a univariate analysis, which is a statistical method that examines a single variable in a dataset to describe its distribution and patterns[5]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (continued)

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.

BTCs=biliary tract cancers; ECOG=Eastern Cooperative Oncology Group; PS=performance status.

REAL-WORLD ANALYSIS

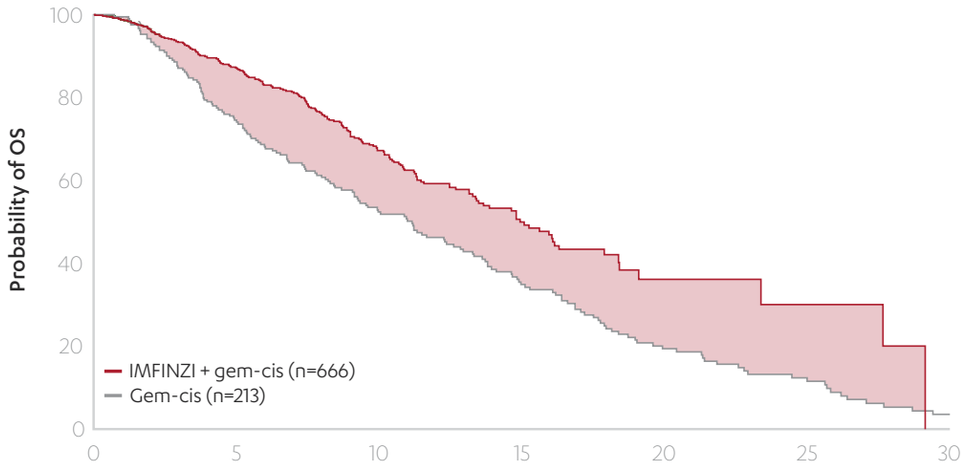
OS results observed in the **real-world analysis** were consistent with those observed in the **Phase III TOPAZ-1** study[3,5]

OVERALL SURVIVAL (coprimary endpoint)[5]

HR=0.59 (95% CI, 0.47-0.74)

15.1-month mOS with IMFINZI + gem-cis (95% CI, 13.4-29.1)

11.1-month mOS with gem-cis (not reported)



Number of patients at risk

IMFINZI + gem-cis	666	424	194	70	14	4	0
Gem-cis	213	151	98	56	27	13	4

- **This real-world analysis was retrospective and not part of TOPAZ-1; it cannot replace level 1 evidence nor be used to draw comparative conclusions**
- The median duration of follow-up at data cutoff (April 1, 2024) was 8.5 months (95% CI, 7.9-9.5) with IMFINZI + gem-cis and 30.1 months (95% CI, 22.1-44.9) with gem-cis (data cutoff: December 31, 2023)[5,6]

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. 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.

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.

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Hepatitis

IMFINZI can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 2.8% (52/1889) of patients receiving IMFINZI, including fatal (0.2%), Grade 4 (0.3%) and Grade 3 (1.4%) adverse reactions.

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.
- ***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.
- ***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.

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, other transplant (including corneal graft) 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 has not been established in pediatric patients.

You may report side effects related to AstraZeneca products.

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Durvalumab plus gemcitabine and cisplatin versus gemcitabine and cisplatin in biliary tract cancer: a real-world retrospective, multicenter study. *Target Oncol*. 2024;19(3):359-370. **7.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Biliary Tract Cancers V.2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed July 2, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. **8.** Oh DY, He AR, Qin S, et al. Durvalumab plus chemotherapy in advanced biliary tract cancer: 3-year overall survival update from the phase III TOPAZ-1 study. *J Hepatol*. Published online May 15, 2025. doi: 10.1016/j. 2025;83(5):1092-1101. **9.** Burris HA 3rd, Okusaka T, Vogel A, et al. 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Characterization of long-term survivors in the TOPAZ-1 study of durvalumab or placebo plus gemcitabine and cisplatin in advanced biliary tract cancer. Poster presented at: 2023 ASCO Gastrointestinal Cancers Symposium; January 19-21, 2023; San Francisco, CA. **23.** 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. **24.** Oh DY, He AR, Bouattour M, et al. Durvalumab or placebo plus gemcitabine and cisplatin in participants with advanced biliary tract cancer (TOPAZ-1): updated overall survival from a randomised phase 3 study. *Lancet Gastroenterol Hepatol*. 2024;9(8):694-704. **25.** Qin S, Chi J, Li E, et al. 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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 [7*†‡]

NCCN=National Comprehensive Cancer Network® (NCCN®).

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†See the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for detailed recommendations, including other treatment options.[7]

‡Biliary tract cancers: Gallbladder cancer, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma.[7]

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

IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

Treat advanced BTCs with standard-of-care **IMFINZI + GEM-CIS**

4

4-YEAR OS DATA (post-hoc analysis)[4]

4 REASONS to consider prescribing IMFINZI + gem-cis for your appropriate patients with 1L aBTCs

FIRST and ONLY 1L IO-based regimen to demonstrate statistically significant improvements in both OS and PFS[2,3]

- mOS: **12.8 months with IMFINZI + gem-cis** (95% CI, 11.1-14.0) vs 11.5 months with gem-cis (95% CI, 10.1-12.5) (HR=0.80 [95% CI, 0.66-0.97]; *P*=0.021)[2]
- mPFS: **7.2 months with IMFINZI + gem-cis** (95% CI, 6.7-7.4) vs 5.7 months with gem-cis (95% CI, 5.6-6.7) (HR=0.75 [95% CI, 0.63-0.89]; *P*=0.001)[2]

EXTENSIVELY STUDIED in a Phase III clinical trial, which includes 4 published papers and 16 exploratory analyses, and 1 global real-world analysis[3-6,8-26]

#1 PRESCRIBED by GI Oncology Specialists in 1L aBTCs since September 2022 approval[1*†]

>20,000 patients with aBTCs treated since approval[1‡]

*Data are based on total US aBTC patients treated with IMFINZI + gem-cis vs other treatments in 1L from September 2022 to August 2025.
†GI specialists are defined as Medical Oncologists where patient volume is 50% or more GI.
‡Data based on total number of US patients with aBTCs treated with 1L IMFINZI + gem-cis from September 2022 to August 2025.

CHEMOTHERAPY-FREE MAINTENANCE DOSING

- IMFINZI 1500 mg IV is given Q3W in combination with gem-cis for up to 8 cycles, followed by IMFINZI 1500 mg IV Q4W until disease progression or unacceptable toxicity[2§‖]
- Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for appropriate chemotherapy agent for dosing administration[2]

§IMFINZI is administered as a 60-minute IV infusion after dilution.
‖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.

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. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions.

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

IV=intravenous.

AstraZeneca

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL