**IMFINZI plus Gemcitabine and Cisplatin in Locally Advanced or Metastatic BTCs**

**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. 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.

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

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Costs of IMFINZI® (durvalumab) plus gemcitabine-cisplatin (gem-cis) and pembrolizumab plus gem-cis in locally advanced or metastatic Biliary Tract Cancers (BTCs)1-5

Estimated Monthly Average Sales Price (ASP) by Month of Treatment1-5

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<tr>
<th>Monthly ASP Cost (USD)</th>
<th>Months 1-6 of Treatment</th>
<th>Months 7+ of Treatment</th>
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IMFINZI® (durvalumab) + gem-cis

Pembrolizumab + gem-cis

Pricing comparisons do not imply comparable efficacy, safety or FDA-approved indications.

Total annual ASP costs of locally advanced or metastatic BTCs treatment with IMFINZI plus gem-cis are $175k and with pembrolizumab plus gem-cis are $189k*†‡§¶

Dosing & Assumptions:
* IMFINZI 1500 mg on Day 1 plus gemcitabine 1000 mg/m² and cisplatin 25 mg/m² on Days 1 and 8 of each 21-day cycle up to 8 cycles, followed by IMFINZI 1500 mg every 4 weeks.1
† Patients with a body weight of <30 kg must receive weight-based dosing, equivalent to IMFINZI 20 mg/kg until body weight is ≥30 kg.1
‡ Average BTCs patient Body Surface Area (BSA) of 1.79m² for gemcitabine and cisplatin dosing.3
§ Pembrolizumab 200 mg on Day 1 plus gemcitabine 1000 mg/m² and cisplatin 25 mg/m² on Day 1 and Day 8 every 3 weeks.2
¶ In the Keynote-966 study, pembrolizumab treatment continued for a maximum of 35 cycles, or approximately 24 months. For gemcitabine, treatment could be continued beyond 8 cycles while for cisplatin, treatment could be administered for a maximum of 8 cycles.2

IMPORTANT SAFETY INFORMATION (Cont’d)

**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.

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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, 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.