Imfinzi® (durvalumab) – New orphan indication

- On September 5, 2022, AstraZeneca announced the FDA approval of Imfinzi (durvalumab), in combination with gemcitabine and cisplatin, for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).
- Imfinzi is also approved for the treatment of non-small cell lung cancer and small cell lung cancer.
- The approval of Imfinzi for the new indication was based on TOPAZ-1, a randomized, double-blind, placebo-controlled study in 685 patients with locally advanced unresectable or metastatic BTC who have not previously received systemic therapy. Patients were randomized to Imfinzi in combination with chemotherapy (gemcitabine plus cisplatin) or placebo in combination with chemotherapy. The major efficacy outcome measure was overall survival (OS). Additional outcome measures were progression-free survival (PFS), and objective response rate (ORR).
    - Median OS was 12.8 months and 11.5 months for Imfinzi plus chemotherapy vs. chemotherapy alone, respectively (hazard ratio [HR] 0.80, 95% CI: 0.66, 0.97; p = 0.021).
    - Median PFS was 7.2 months and 5.7 months for Imfinzi plus chemotherapy vs. chemotherapy alone, respectively (HR 0.75, 95% CI: 0.63, 0.89; p = 0.001).
    - The ORR was 27% (95% CI: 22, 32) in the Imfinzi plus chemotherapy arm and 19% (95% CI: 15, 23) in the chemotherapy alone arm.
- The recommended dose of Imfinzi for the treatment of BTC for patients with a body weight of 30 kg and more is 1,500 mg via intravenous (IV) infusion in combination with chemotherapy every 3 weeks (21 days) up to 8 cycles followed by 1,500 mg every 4 weeks as a single agent. Treatment with Imfinzi should be continued until disease progression or until unacceptable toxicity.
- The recommended dose of Imfinzi for the treatment of BTC for patients with a body weight of less than 30 kg is 20 mg/kg via IV infusion in combination with chemotherapy every 3 weeks (21 days) up to 8 cycles followed by 20 mg/kg every 4 weeks as a single agent. Treatment with Imfinzi should be continued until disease progression or until unacceptable toxicity.
- Refer to the Imfinzi drug label for dosing for its other indications.