Imfinzi™ (durvalumab) – New drug approval

- On May 1, 2017, AstraZeneca and its global biologics research and development arm, MedImmune, announced the FDA approval of Imfinzi (durvalumab), for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
    - This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Urothelial carcinomas arise from the bladder epithelium and are the 6th most common form of cancer in the U.S. According to the National Cancer Institute, it is estimated there will be 79,030 new cases of bladder cancer and 16,870 deaths from the disease in 2017.
- Imfinzi contains a human immunoglobulin G1 kappa monoclonal antibody that blocks the interaction of programmed death-ligand 1 (PD-L1) with PD-1 and CD80.
    - Other related biologic agents with an FDA-approved use in bladder cancer include Tecentriq® (atezolizumab) and Opdivo® (nivolumab).
- The efficacy and safety of Imfinzi were based on an early phase, single-arm trial in 182 patients with locally advanced or metastatic urothelial carcinoma who had progressed while on or after a platinum-based therapy.
    - Across all patients, the objective response rate (ORR) was 17% (95% CI: 11.9, 23.3). Moreover, among the responders, 45% of patients had ongoing responses of 6 months or longer and 16% of patients had ongoing responses of 12 months or longer.
    - Among patients with high PD-L1 expression, the ORR was 26.3% (95% CI: 17.8, 36.4).
    - Among patients with low PD-L1 expression, the ORR was 4.1% (95% CI: 0.9, 11.5).
- Warnings and precautions of Imfinzi include immune-mediated pneumonitis, immune-mediated hepatitis, immune-mediated colitis, immune-mediated endocrinopathies, other immune-mediated adverse reactions, infection, infusion-related reactions, and embryo-fetal toxicity.
- The most common adverse events (≥ 15%) with Imfinzi use were fatigue, musculoskeletal pain, constipation, decreased appetite, nausea, peripheral edema, and urinary tract infection.
- The recommended dose of Imfinzi is 10 mg/kg administered as an intravenous (IV) infusion every 2 weeks until disease progression or unacceptable toxicity.
    - Administer Imfinzi through an IV line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter.

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- The average wholesale acquisition cost of Imfinzi is $15,000 per month.
- AstraZeneca's launch plans for Imfinzi are pending. Imfinzi will be available as 120 mg/2.4 mL and 500 mg/10 mL solutions in single-dose vials for injection.