Bavencio® (avelumab) – Expanded indication

- On June 30, 2020, Pfizer and EMD Serono announced the FDA approval of Bavencio (avelumab), for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy.
    - Bavencio is also approved for treatment of patients with locally advanced or metastatic UC who: (1) have disease progression during or following platinum-containing chemotherapy, or (2) have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- In addition to UC, Bavencio is approved for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma and in combination with axitinib (Inlyta®) for the first-line treatment of patients with advanced renal cell carcinoma.
- The approval of Bavencio for the expanded indication was based on a randomized, open-label study in 700 patients with unresectable, locally advanced or metastatic urothelial carcinoma that did not progress with first-line platinum-containing chemotherapy. Patients were randomized to receive either Bavencio plus best supportive care (BSC) or BSC alone. The major efficacy outcome measure was overall survival (OS) in all randomized patients and patients with PD-L1-positive tumors.
    - Median OS was 21.4 months for Bavencio plus BSC vs. 14.3 months with BSC (Hazard ratio [HR] 0.69; 95% CI: 0.56, 0.86; p = 0.001).
    - In the prespecified endpoint of OS among patients with PD-L1-positive tumors, the HR was 0.56 (95% CI: 0.40, 0.79; p < 0.001) for patients randomized to Bavencio plus BSC vs. BSC alone.
- The most common adverse reactions (≥ 20%) with Bavencio use in maintenance treatment of UC were fatigue, musculoskeletal pain, urinary tract infection, and rash.
- The recommended dose of Bavencio for treatment of UC is 800 mg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.
    - Patients should be premeditated with an antihistamine and with acetaminophen prior to the first 4 infusions of Bavencio. Premedication should be administered for subsequent Bavencio doses based upon clinical judgment and presence/severity of prior infusion reactions.
    - Refer to the Bavencio drug label for dosing for its other indications.