Bavencio® (avelumab) – New indication

- On May 9, 2017, EMD Serono announced the FDA approval of Bavencio (avelumab) injection, for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC) 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 and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Bavencio is also approved for the treatment of adults and pediatric patients ≥ 12 years old with metastatic Merkel cell carcinoma (MCC).
- Bavencio's new indication was approved based on an open-label, single-arm trial involving 242 patients with mUC. The primary endpoints were confirmed overall response rate (ORR) and duration of response (DOR).
    - Patients who were followed for ≥ 13 weeks achieved an ORR of 13.3% (95% CI: 9.1, 18.4). Patients who were followed for ≥ 6 months achieved an ORR of 16.1% (95% CI: 10.8, 22.8).
    - The median DOR had not been reached in patients followed for ≥13 weeks or ≥ 6 months, but ranged from 1.4+ to 17.4+ months in both groups.
    - The median time to response was 2.0 months (range: 1.3 – 11.0 months) among patients followed for either ≥ 13 weeks or ≥ 6 months.
- Deaths due to an adverse reaction occurred in 6% of patients. Serious adverse reactions were reported in 41% of patients.
    - The most frequent serious adverse reactions (≥ 2%) with Bavencio use were urinary tract infection/urosepsis, abdominal pain, musculoskeletal pain, increased creatinine/renal failure, dehydration, hematuria/urinary tract hemorrhage, intestinal obstruction/small intestinal obstruction, and pyrexia.
- In patients with locally advanced or mUC, the most common adverse reactions (≥ 20%) with Bavencio use were fatigue, infusion-related reaction, musculoskeletal pain, nausea, decreased appetite, and urinary tract infection.

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- For both mUC and MCC, the recommended dose of Bavencio is 10 mg/kg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.
    - Patients should be treated with an antihistamine and 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.