Bavencio® (avelumab) – New orphan drug approval

- On March 23, 2017, the FDA announced the approval of EMD Serono's Bavencio (avelumab) for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC).

    - This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

- MCC is a rare, aggressive form of skin cancer. In the U.S., approximately 1,600 people are diagnosed with MCC every year. The majority of patients present with localized tumors that can be treated with surgical resection; however, approximately half of all patients will experience recurrence, and > 30% will develop metastatic disease.

- Bavencio is the first treatment approved for metastatic MCC and targets the programmed cell death protein 1 (PD-1)/ programmed cell death ligand-1 (PD-L1) pathway. By blocking these interactions, Bavencio may help the body's immune system attack cancer cells.

- There are other PD-1/PD-L1 pathway inhibitors approved: Keytruda® (pembrolizumab), Opdivo® (nivolumab), Tecentriq™ (atezolizumab), and Yervoy® (ipilimumab). Refer to drug labels for indications for each agent.

- The efficacy and safety of Bavencio were demonstrated in the JAVELIN Merkel 200 trial, an open-label study that enrolled 88 patients with metastatic MCC. The major efficacy outcome measures were overall response rate (ORR) and duration of response (DOR).

    - The ORR was 33.0% (95% CI: 23.3, 43.8) and the DOR (range in months) was 2.8 - 23.3+.
    - The response lasted for > 6 months in 86% of responding patients and > 12 months in 45% of responding patients.

- Warnings and precautions of Bavencio include immune-mediated pneumonitis, immune-mediated hepatitis, immune-mediated colitis, immune-mediated endocrinopathies, immune-mediated nephritis and renal dysfunction, other immune-mediated adverse reactions, infusion-related reactions, and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%) with Bavencio use were fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, rash, decreased appetite, and peripheral edema.

- The recommended starting 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.

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- EMD Serono's launch plans for Bavencio are pending. Bavencio will be available as a 200 mg/10 mL (20 mg/mL) solution in a single-dose vial.