Keytruda® (pembrolizumab) – New indication

- On December 19, 2018, Merck announced the FDA approval of Keytruda (pembrolizumab) for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC).
    - This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
- Keytruda is also indicated for the treatment of melanoma, as a single agent for non-small cell lung cancer (NSCLC) with PD-L1 expression, in combination with other agents for nonsquamous or squamous NSCLC, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high or mismatch repair deficient solid tumors or colorectal cancer, gastric cancer, cervical cancer, and hepatocellular carcinoma.
- According to the American Cancer Society, MCC is a rare and dangerous type of skin cancer that is likely to spread to other parts of the body. About 2,000 cases of MCC are diagnosed in the U.S. each year.
- The new indication of Keytruda was based on the KEYNOTE-017 study enrolling 50 adult patients with recurrent locally advanced or metastatic MCC who had not received prior systemic therapy for their advanced disease. Patients received Keytruda 2 mg/kg every 3 weeks until unacceptable toxicity, disease progression, or up to 24 months if no disease progression. The major efficacy outcome measures were objective response rate (ORR) and duration of response.
    - The ORR was 56% (95% CI: 41, 70).
    - The duration of response was 5.9 to 34.5+ months.
    - Efficacy for pediatric patients with MCC is extrapolated from the results in the adult population.
- The most common adverse reactions (≥ 20%) with single-agent Keytruda use were fatigue, musculoskeletal pain, decreased appetite, pruritus, diarrhea, nausea, rash, pyrexia, cough, dyspnea, constipation, pain, and abdominal pain.
- The recommended dosage of Keytruda in adult and pediatric patients with MCC is 200 mg and 2 mg/kg (up to a maximum of 200 mg), respectively, administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
    - Refer to the Keytruda drug label for dosing for all other indications.