Keytruda® (pembrolizumab) – New indication

- On November 9, 2018, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar® (sorafenib).
    - 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 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, and cervical cancer.
- HCC is a rare disorder in the U.S., but it accounts for about 85 – 90% of all primary liver cancers. According to the National Organization for Rare Disorders, there are approximately six new cases of HCC per every 100,000 people in the general population of the U.S. Most people who develop HCC have an underlying liver disease such as infection with hepatitis B or C virus, and alcoholic or non-alcoholic fatty liver disease.
- The new indication for Keytruda was based on data from KEYNOTE-224, a single-arm, open-label study evaluating Keytruda in 104 patients with HCC who had disease progression on or after Nexavar or were intolerant to Nexavar. Patients received Keytruda every three weeks until unacceptable toxicity or confirmed disease progression. Patients without disease progression were treated for up to 24 months. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR).
    - The ORR was 17% (95% CI: 11, 26), with a complete response rate of 1% and a partial response rate of 16%.
    - Among the responding patients (n = 18), 89% experienced a DOR for 6 months or longer and 56% experienced a DOR for 12 months or longer.
- 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 patients with HCC is 200 mg 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.