Keytruda® (pembrolizumab) – New indication

- On June 18, 2019, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.
    - 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 confirmatory trials.
- Keytruda is also indicated for melanoma, non-small cell lung cancer, 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, hepatocellular cancer, Merkel cell carcinoma, and renal cell carcinoma.
- The new indication for Keytruda was based on data from KEYNOTE-028 and KEYNOTE-158, two open-label studies in 83 patients with SCLC. Patients received Keytruda until documented disease progression, unacceptable toxicity, or a maximum of 24 months. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR).
    - Keytruda demonstrated an ORR of 19% (95% CI: 11, 29).
    - Among the 16 responding patients, the DOR ranged from 4.1 to 35.8+ months; 94% had a DOR of six months or longer, 63% had a DOR of 12 months or longer and 56% had a DOR of 18 months or longer.
- The most common adverse reactions (≥ 20%) with Keytruda use as a single agent include fatigue, musculoskeletal pain, decreased appetite, pruritus, diarrhea, nausea, rash, pyrexia, cough, dyspnea, constipation, pain, and abdominal pain.
- The recommended dose of Keytruda for SCLC 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 its other indications.