Keytruda® (pembrolizumab) – New Indication

- On August 8, 2016, Merck announced the FDA approval of Keytruda (pembrolizumab) for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy.
    - 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 approved for the following:
    - Treatment of patients with unresectable or metastatic melanoma.
    - Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.
- The new indication is based on data from a clinical study of 174 patients with recurrent or metastatic HNSCC who had disease progression on or after platinum-containing chemotherapy or following platinum-containing chemotherapy. The major efficacy outcome measures were objective response rate (ORR) and duration of response.
    - The ORR was 16% (95% CI: 11, 22) with a complete response rate of 5%. The median follow-up time was 8.9 months.
    - Among the 28 responding patients, the median duration of response had not been reached (range 2.4+ to 27.7+ months), with 23 patients having responses of 6 months or longer.
- The recommended dose of Keytruda for HNSCC is 200 mg administered intravenously over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
- The recommended dose of Keytruda for melanoma and NSCLC is 2 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.