Keytruda® (pembrolizumab) – New indication

- On September 22, 2017, Merck announced the FDA approval of Keytruda (pembrolizumab) injection, for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted 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 the confirmatory trials.
- Concurrent with the approval of Keytruda's new indication, the FDA has also granted expanded approved to Agilent Technologies' Dako PD-L1 IHC 22C3 pharmDx assay, for use as an aid in identifying gastric or GEJ adenocarcinoma patients for treatment with Keytruda.
- Keytruda is also approved for other oncological conditions, including melanoma, non-small cell lung cancer (NSCLC), head and neck squamous cell cancer, classical Hodgkin lymphoma, urothelial cancer, and microsatellite instability-high (MSI-H) cancer.
- The American Cancer Society estimates that 28,000 cases of gastric cancer will be diagnosed by the end of 2017, with approximately 10,960 deaths from the disease.
    - Gastric cancer primarily affects older individuals. The average age at diagnosis is 69.
- The approval of Keytruda in gastric and GEJ cancer was based on an open-label trial in 259 patients who had progressed on at least 2 prior systemic treatments for advanced disease. Among the 259 patients, only 55% (N = 143) had tumors that expressed PD-L1 with a CPS ≥ 1 and microsatellite stable tumor status or undetermined MSI or MMR status.
    - For the 143 patients who had PD-L1 expressing tumors, the objective response rate was 13.3% (95% CI: 8.2, 20.0).
    - In addition, among the responders, the duration of response ranged from 2.8+ months to 19.4+ months.
    - Among the 259 patients, 7 patients (3%) had tumors that were determined to be MSI-H. An objective response was observed in 4 patients, including 1 complete response. The duration of response ranged from 5.3+ months to 14.1+ months.
- The recommended dosage of Keytruda in gastric or GEJ cancer is 200 mg administered intravenously every 3 weeks until disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression.
    - Refer to the Keytruda drug label for dosing in other FDA approved indications.