Keytruda® (pembrolizumab) – Indication withdrawal

- On July 1, 2021, Merck announced that the company plans to voluntarily withdraw the accelerated approval indication for Keytruda (pembrolizumab) for the treatment of patients with:
    - Recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 [combined positive score (CPS ≥1)] as determined by a 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, human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy.
- The decision was made in consultation with the FDA following the April Oncologic Drugs Advisory Committee evaluation of this third-line gastric cancer indication for Keytruda as a monotherapy because it failed to meet its post-marketing requirement of demonstrating an overall survival benefit in a Phase 3 study.
    - As agreed with the FDA, Merck will initiate the withdrawal in 6 months.
- Patients being treated with Keytruda for metastatic gastric cancer in the third- or further-line setting should discuss their care with their health care provider.
- This decision does not affect other indications for Keytruda, including its other uses in gastric cancer.
    - Refer to the Keytruda drug label for information regarding Keytruda's other FDA approved indications.