Keytruda® (pembrolizumab) – Expanded indication

- On March 21, 2022, Merck announced the FDA approval of Keytruda (pembrolizumab), as a single agent, for the treatment of patients with advanced endometrial carcinoma that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
    - Keytruda is also approved in combination with Lenvima® (lenvatinib), for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
- In addition to endometrial carcinoma, Keytruda is approved for melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial cancer, MSI-H or dMMR cancer, MSI-H or dMMR colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, tumor mutational burden-high cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.
- The approval of Keytruda for the expanded indication was based on KEYNOTE-158, a non-randomized, open-label, multi-cohort study. The study included 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma who received at least one dose of Keytruda. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR).
    - The ORR was 46% (95% CI: 35, 56).
    - The median DOR was not reached (range: 2.9, 55.7+).
- The recommended dose of Keytruda for the treatment of MSI-H or dMMR endometrial carcinoma is 200 mg intravenously every 3 weeks or 400 mg every 6 weeks. Keytruda should be administered until disease progression, unacceptable toxicity, or up to 24 months.
    - Refer to the Keytruda drug label for dosing for all its other indications.