Keytruda® (pembrolizumab) – Expanded indication

- On January 12, 2024, Merck announced the FDA approval of Keytruda (pembrolizumab), in combination with chemoradiotherapy (CRT), for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer.

- Keytruda is also approved for use for cervical cancer:
    - In combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.
    - As a single agent, for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.

- In addition to cervical cancer, Keytruda is approved for 36 other uses or indications. Refer to the Keytruda drug label for complete details.

- The approval of Keytruda for the expanded indication was based on KEYNOTE-A18, a randomized, double-blind, placebo-controlled study in 1,060 patients with cervical cancer who had not previously received any definitive surgery, radiation, or systemic therapy for cervical cancer. There were 596 patients with FIGO 2014 Stage III-IVA. Patients received Keytruda or placebo, in combination with CRT. The major efficacy outcome measures were progression-free survival (PFS) and overall survival (OS).
    - The study demonstrated a statistically significant improvement in PFS in the overall population. In an exploratory subgroup analysis for the 462 patients (44%) with FIGO 2014 Stage IB2-IIB disease, the PFS hazard ratio (HR) estimate was 0.91 (95% CI: 0.63, 1.31), indicating that the PFS improvement in the overall population was primarily attributed to the results seen in the subgroup of patients with FIGO 2014 Stage III-IVA disease.
    - In the FIGO 2014 Stage III-IVA disease subgroup, the HR was 0.59 (95% CI: 0.43, 0.82).
    - OS data were not mature at the time of PFS analysis, with 10% deaths in the overall population.

- When used in combination with CRT, the recommended dose of Keytruda for the treatment of cervical cancer is 200 mg every 3 weeks or 400 mg every 6 weeks via intravenous (IV) infusion. Keytruda should be administered prior to CRT when given on the same day. Keytruda treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
    - Refer to the Keytruda drug label for dosing for all its other uses.