## Keytruda® (pembrolizumab) – New indication

- On June 12, 2018, Merck announced the FDA approval of Keytruda (pembrolizumab) for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (combined positive score [CPS] ≥ 1) as determined by an FDA-approved test.
    - 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 indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, and gastric cancer.
- The American Cancer Society estimates that 13,240 new cases of cervical cancer will be diagnosed and 4,170 women will die from the disease in 2018.
- The new indication for Keytruda was based on a single cohort (cohort E) in the KEYNOTE-158 trial, involving 98 patients with recurrent or metastatic cervical cancer. The primary endpoints were objective response rate (ORR) and duration of response (DOR)
    - The ORR was 14.3% (95% CI: 7.4, 24.1).
    - The median DOR was not reached at the time of analysis, but 91% of patients achieved DOR ≥ 6 months.
- In patients with cervical cancer, the recommended dose of Keytruda is 200 mg administered as an intravenous infusion every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
    - Refer to the Keytruda drug label for dosage in other indications.