Keytruda® (pembrolizumab) – New indication

- On June 17, 2024, Merck announced the FDA approval of Keytruda (pembrolizumab), in combination with carboplatin and paclitaxel, followed by Keytruda as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.

- This is the 3rd indication for Keytruda for endometrial cancer and the 40th indication overall. Refer to the Keytruda drug label for a complete listing of all its indications and uses.

- The approval of Keytruda for the new indication was based on KEYNOTE-868, a randomized, double-blind, placebo-controlled study in 810 patients with advanced or recurrent endometrial carcinoma. The study design included two separate cohorts based on mismatch repair (MMR) status; 27% of patients were in the mismatch repair deficient (dMMR) cohort and 73% of patients were in the mismatch repair proficient (pMMR) cohort. Patients were randomized to one of the following groups: (1) Keytruda plus carboplatin and paclitaxel for 6 cycles, followed by Keytruda as a single-agent for up to 14 cycles, or (2) placebo plus carboplatin and paclitaxel for 6 cycles, followed by placebo for up to 14 cycles. The major outcome measure was progression-free survival (PFS). An additional outcome measure was overall survival (OS).

    - In the dMMR cohort, median PFS was not reached in the Keytruda arm vs. 6.5 months in the chemotherapy arm (hazard ratio [HR] 0.30, 95% CI: 0.19, 0.48; $p < 0.0001$).
    - In the pMMR cohort, median PFS was 11.1 months in the Keytruda arm vs. 8.5 months in the chemotherapy arm (HR 0.60, 95% CI: 0.46, 0.78; $p < 0.0001$).
    - At the time of the PFS analysis, OS data were not mature with 12% deaths in the dMMR population and 17% deaths in the pMMR population.

- When used in combination with carboplatin and paclitaxel for endometrial cancer, the recommended dose of Keytruda is 200 mg every 3 weeks or 400 mg every 6 weeks via intravenous (IV) infusion, until disease progression, unacceptable toxicity, or for Keytruda, up to 24 months. Keytruda should be administered prior to carboplatin and paclitaxel when given on the same day.

- Refer to the Keytruda drug label for dosing for all its other indications.