Keytruda® (pembrolizumab) – Expanded indication

- On October 16, 2023, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer (NSCLC) in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
    - With this approval, Keytruda has six indications in NSCLC, across both metastatic and earlier stages of NSCLC.
- Refer to the Keytruda drug label for a complete list of Keytruda's other indications and uses.
- The approval of Keytruda for the expanded indication was based on KEYNOTE-671, a randomized, double-blind, placebo-controlled study in 797 patients with previously untreated and resectable Stage II, IIIA, or IIIB (N2) NSCLC. Patients were randomized to: (1) neoadjuvant Keytruda in combination with chemotherapy followed by single agent Keytruda, or (2) neoadjuvant chemotherapy followed by placebo. The major efficacy measures were overall survival (OS) and event-free survival (EFS).
    - Median OS was not reached in the Keytruda arm vs. 52.4 months in the placebo arm (hazard ratio [HR] 0.72, 95% CI: 0.56, 0.93; p = 0.0103).
    - Median EFS was not reached in the Keytruda arm vs. 17.0 months in the placebo arm (HR 0.58, 95% CI: 0.46, 0.72; p < 0.0001).
- The recommended dose of Keytruda for adult patients with NSCLC is 200 mg every 3 weeks or 400 mg every 6 weeks via intravenous infusion.
    - Neoadjuvant treatment should be given in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with Keytruda as a single agent after surgery for 39 weeks or until disease recurrence or unacceptable toxicity.
    - Refer to the Keytruda drug label for dosing for all its other uses.