## Keytruda® (pembrolizumab) – Expanded indication

- On February 15, 2018, the FDA approved Merck's Keytruda (pembrolizumab), for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.
    - Keytruda was previously approved for the treatment of patients with unresectable or metastatic melanoma.
- Keytruda is also indicated for non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high or mismatch repair deficient solid tumors or colorectal cancer, gastric cancer, cervical cancer, hepatocellular cancer, and Merkel cell carcinoma.
- The expanded indication for Keytruda was based on data from KEYNOTE-054, a randomized study in 1,019 patients with completely resected stage IIIA, IIIB or IIIC melanoma. Patients were randomized to Keytruda or placebo for up to one year until disease recurrence or unacceptable toxicity. The major efficacy outcome measure was recurrence-free survival (RFS) in the whole population and in the population with PD-L1 positive tumors where RFS was defined as the time between the date of randomization and the date of first recurrence (local, regional, or distant metastasis) or death, whichever occurs first.
    - The RFS was 26% and 43% in patients receiving Keytruda and placebo, respectively. Median RFS was not reached with Keytruda vs. 20.4 months with placebo (95% CI: 16.2 months, not reached) (hazard ratio [HR] 0.57 [95% CI: 0.46, 0.70]; $p < 0.001$).
    - For patients with PD-L1 positive tumors, the HR was 0.54 (95% CI: 0.42, 0.69; $p < 0.001$). The RFS benefit for Keytruda vs. placebo was observed regardless of tumor PD-L1 expression.
- The recommended dose of Keytruda for the adjuvant treatment of adult patients with melanoma is 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease recurrence, unacceptable toxicity, or for up to 12 months in patients without disease recurrence.
- Refer to the Keytruda drug label for dosing for all other indications.