Keytruda® (pembrolizumab) – New indication

- On January 27, 2023, Merck announced the FDA approval of Keytruda (pembrolizumab), as a single agent, as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIA non-small cell lung cancer (NSCLC).

- This approval marks the fifth indication for Keytruda-based regimens in NSCLC and overall, this is the 34th indication for Keytruda. Refer to the Keytruda drug label for a complete list of indications and uses.

- The approval of Keytruda for the new indication was based on KEYNOTE-091, a randomized, triple-blind, placebo-controlled study in 1177 patients with completely resected stage IB (T2a ≥4 cm), II, or IIIA NSCLC. Adjuvant chemotherapy up to 4 cycles was optional. Patients were randomized to receive Keytruda or placebo every 3 weeks. Treatment continued until disease recurrence as determined by the investigator, unacceptable toxicity, or up to one year. The major outcome measure was disease-free survival (DFS).

    - The trial met its primary endpoint, demonstrating a statistically significant improvement in DFS in the overall population for patients randomized to the Keytruda arm compared to patients randomized to the placebo arm.
    - In an exploratory subgroup analysis of the 167 patients (14%) who did not receive adjuvant chemotherapy, the DFS hazard ratio (HR) was 1.25 (95% CI: 0.76, 2.05).
    - In patients who did receive adjuvant chemotherapy, median DFS was 58.7 months and 34.9 months for Keytruda and placebo, respectively (HR 0.73, 95% CI: 0.60, 0.89).

- The recommended dose of Keytruda for the adjuvant treatment of NSCLC is 200 mg every 3 weeks or 400 mg every 6 weeks, until disease recurrence, unacceptable toxicity, or up to 12 months.

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