Opdivo® (nivolumab) – New indication

- On October 3, 2024, Bristol-Myers Squibb announced the FDA approval of Opdivo (nivolumab), for the neoadjuvant treatment of adult patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, in combination with platinum-doublet chemotherapy followed by single-agent Opdivo as adjuvant treatment after surgery.
    - Neoadjuvant therapy is a type of treatment administered before primary cancer treatment (such as surgery) to shrink the tumor before the main treatment.
    - Adjuvant therapy is administered after the primary treatment to lower the chance of the cancer coming back.
    - Opdivo is approved for four other NSCLC indications in the neoadjuvant setting, as first-line therapy and in cases that have progressed after other therapies.

- Opdivo is also approved for the treatment of multiple other cancers including: melanoma, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal cancer, and gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.

- The approval of Opdivo for the new indication was based on a randomized, double-blind study (CHECKMATE-77T) in 461 patients with resectable NSCLC. Patients were randomized to Opdivo plus platinum-doublet chemotherapy followed by Opdivo given 90 days after surgery or to placebo plus platinum-doublet chemotherapy followed by placebo given 90 days after surgery. The major efficacy outcome measure was event-free survival (EFS).
    - The median EFS was not reached in the Opdivo arm vs. 18.4 months in the placebo arm (Hazard ratio 0.58; 95% CI: 0.43, 0.78; p = 0.00025).
    - At the time of the EFS analysis, overall survival (OS) data were immature.

- The recommended dose of Opdivo during the neoadjuvant period is 360 mg intravenously (IV) every 3 weeks with platinum-doublet chemotherapy on the same day every 3 weeks. During the adjuvant period, the dose of Opdivo is 480 mg IV every 4 weeks.
    - Neoadjuvant treatment in combination with chemotherapy should be continued for up to 4 cycles or until disease progression or unacceptable toxicity, followed by adjuvant treatment with Opdivo as a single agent after surgery for up to 13 cycles (approximately 1 year) or until disease recurrence or unacceptable toxicity.
    - Refer to the Opdivo drug label for dosing for all its other indications.