Opdivo® (nivolumab) – New indication

- On August 17, 2018, Bristol-Myers Squibb announced the FDA approval of Opdivo (nivolumab) for the treatment of patients with metastatic small cell lung cancer (SCLC) with progression after platinum-based chemotherapy and at least one other line of therapy.
    - This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials
- Opdivo is also indicated as adjuvant treatment of melanoma, and as a single agent for the treatment of unresectable or metastatic melanoma, metastatic non-small cell lung cancer, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, microsatellite instability high or mismatch repair deficient metastatic colorectal cancer, renal cell carcinoma, and hepatocellular carcinoma.
- Approval for Opdivo's new indication was based on data from an open-label, ongoing clinical study evaluating Opdivo as a single agent or in combination with Yervoy® (ipilimumab) in patients with advanced or metastatic solid tumors. A total of 109 patients with metastatic SCLC, regardless of PD-L1 tumor status, with disease progression after platinum-based chemotherapy were enrolled to receive treatment with Opdivo every 2 weeks.
    - The ORR was 12% (95% CI: 6.5, 19.5).
    - Of 13 patients, 77% had a DOR ≥ 6 months, 62% with DOR ≥ 12 months and 39% with a DOR ≥ 18 months. The range in DOR was 3.0 - 42.1 months.
- The recommended dose of Opdivo for the treatment of SCLC is 240 mg administered as an intravenous infusion over 30 minutes every 2 weeks until disease progression or unacceptable toxicity.
    - Refer to the Opdivo drug label for dosing information for all other indications.