Opdivo® (nivolumab) – New Indication

- On February 2, 2017, the FDA announced the approval of Bristol-Myers Squibb's Opdivo (nivolumab) for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

- According to the National Cancer Institute, bladder cancer is the sixth most common cancer in the U.S. In 2017, it is estimated there will be 79,030 new cases and 16,870 deaths from bladder cancer. Urothelial carcinoma is the most common type of bladder cancer, comprising about 90% of cases.

- Opdivo is also FDA-approved for the following:

    - As a single agent for the treatment of patients with BRAF V600 wild-type or BRAF V600 mutation-positive unresectable or metastatic melanoma
    - In combination with Yervoy® (ipilimumab) for the treatment of patients with unresectable or metastatic melanoma
    - Treatment of patients with metastatic non-small cell lung cancer with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo.
    - Treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy
    - Treatment of patients with classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation Adcetris® (brentuximab vedotin)
    - Treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum-based therapy

- Opdivo's new indication approval was based on data from a clinical trial of 270 patients with locally advanced or metastatic urothelial carcinoma who received Opdivo. Patients were included in the trial regardless of their programmed death ligand-1 status. Major efficacy outcome measures included objective response rate (ORR) and duration of response (DOR).

    - The overall ORR was 19.6% (95% CI: 15.1, 24.9).
    - The median DOR was 10.3 months (range: 1.9+, 12.0+). Responses were ongoing at data cutoff.

- The recommended dose of Opdivo for the treatment of urothelial carcinoma is 240 mg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

    - Refer to the prescribing information for the recommended doses of Opdivo for all other labeled indications.