Opdivo® (nivolumab) – Expanded indication

- On April 25, 2017, the FDA approved Bristol-Myers Squibb's Opdivo (nivolumab) for the treatment of adult patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after 3 or more lines of systemic therapy that includes autologous hematopoietic stem cell transplantation (HSCT).
    - Previously Opdivo was only approved for the treatment of cHL that has relapsed or progressed after autologous HSCT and Adcetris® (brentuximab vedotin).
- Opdivo is also 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 recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum-based therapy
    - 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
- Opdivo's expanded indication was based on data from two clinical studies of patients with cHL after failure of autologous HSCT and post-transplantation Adcetris and in patients with relapsed or progressive cHL after autologous HSCT. Most of these patients had a history of prior systemic regimens. Patients with cHL after failure of autologous HSCT and Adcetris received Opdivo therapy for a median of 14 months while patients who had relapsed or progressive cHL after autologous HSCT received Opdivo therapy for a median of 10 months. The major efficacy outcome measure was objective response rate (ORR).
    - The ORRs were 66% (95% CI: 56, 76) in patients with cHL after autologous HSCT and post-transplantation Adcetris and 69% (95% CI: 63, 75) in patients with cHL after autologous HSCT.
- The recommended dose of Opdivo for cHL is 3 mg/kg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.
- Refer to the Opdivo drug label for the dosing recommendations for all other indications.