Opdivo™ (nivolumab) – New Indication

- On November 8, 2016, the FDA approved Opdivo (nivolumab) for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.

- 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 classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation Adcetris® (brentuximab vedotin)

- Opdivo's new indication is based on data from a clinical trial of 361 patients with recurrent or metastatic SCCHN randomized to Opdivo or investigator's choice of chemotherapy (cetuximab, methotrexate, or docetaxel). The major efficacy outcome measure was overall survival (OS). Additional measures were progression free survival (PFS) and objective response rate (ORR).

    - At a pre-specified interim analysis, there was a statistically significant improvement in OS for patients randomized to Opdivo vs. chemotherapy (HR: 0.70; 95% CI: 0.53, 0.92; p = 0.0101). The estimated median OS was 7.5 months in the Opdivo arm vs. 5.1 months in the chemotherapy arm.
    - There were no statistically significant differences between the two arms for PFS (HR: 0.89; 95% CI: 0.70, 1.13) or ORR (13.3% [95% CI: 9.3, 18.3] vs. 5.8% [95% CI: 2.4, 11.6] for Opdivo and chemotherapy arms, respectively).

- The recommended dose of Opdivo for the treatment of SCCHN is 3 mg/kg 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.