

## Opdivo® (nivolumab) – Expanded indication

- On April 25, 2017, the <u>FDA approved</u> Bristol-Myers Squibb's <u>Opdivo (nivolumab)</u> 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 <u>Adcetris<sup>®</sup> (brentuximab vedotin)</u>.
- 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 <u>Yervoy<sup>®</sup> (ipilimumab)</u> 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 antiangiogenic 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 posttransplantation 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.



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