Opdivo® (nivolumab) – Updated indication

- On March 7, 2019, the FDA approved Bristol-Myers Squibb's Opdivo (nivolumab), for the treatment of patients with unresectable or metastatic melanoma, as a single agent or in combination with Yervoy® (ipilimumab).
    - Previously, this indication was listed as 3 separate indications: treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma, as a single agent; BRAF V600 mutation-positive unresectable or metastatic melanoma, as a single agent; and unresectable or metastatic melanoma, in combination with Yervoy.
    - In addition, the two indications, treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma, as a single agent; and unresectable or metastatic melanoma, in combination with Yervoy were originally approved under accelerated approval.
    - The accelerated approval for the two indications has now been converted to full approval.

- Opdivo is also indicated for adjuvant treatment of melanoma, metastatic non-small cell lung cancer, classical non-Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, microsatellite instability high or mismatch repair deficient colorectal cancer, advanced renal cell carcinoma, hepatocellular carcinoma, and metastatic small cell lung cancer.

- Approval for Opdivo's updated indication was based on overall survival (OS) data from the CHECKMATE-037 study in 405 patients with unresectable or metastatic melanoma treated with Opdivo or investigator's choice of chemotherapy and the CHECKMATE-067 study in 945 patients with previously untreated, unresectable or metastatic melanoma treated with Opdivo + Yervoy, Opdivo, or Yervoy.
    - In the CHECKMATE-037 study, the median duration of OS was 15.7 months (95% CI: 12.9, 19.9) in Opdivo-treated patients vs. 14.4 months in the investigator's choice of treatment patients (95% CI: 11.7, 18.2) (HR: 0.95; 95.54% CI: 0.73, 1.24).
    - In the CHECKMATE-067 study, based on 48-months of follow-up, the median OS was not reached (95% CI: 38.2, NR) in the Opdivo + Yervoy arm. The median OS was 36.9 months (95% CI: 28.3, NR) in the Opdivo arm and 19.9 months (95% CI: 16.9, 24.6) in the Yervoy arm.

- The recommended dose of Opdivo as a single agent for unresectable or metastatic melanoma is 240 mg every 2 weeks or 480 mg every 4 weeks administered as an intravenous (IV) infusion over 30 minutes until disease progression or unacceptable toxicity.

- The recommended dose of Opdivo in combination with Yervoy for unresectable or metastatic melanoma is 1 mg/kg administered as an IV infusion over 30 minutes, followed by Yervoy 3 mg/kg administered as an IV infusion over 90 minutes on the same day, every 3 weeks for a maximum of 4 doses or until unacceptable toxicity, whichever occurs earlier.
    - After completing 4 doses of the combination, administer Opdivo as a single agent, either: 240 mg every 2 weeks or 480 mg every 4 weeks as an IV infusion over 30 minutes until disease progression or unacceptable toxicity.
    - Refer to the Yervoy drug label for additional information prior to administration.

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- Refer to the Opdivo drug label for dosing recommendations for all other indications.

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