Opdivo® (nivolumab) – Expanded indication

- On December 20, 2017, Bristol-Myers Squibb announced the FDA approval of Opdivo (nivolumab) for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

- Opdivo is also approved for other oncological conditions, including unresectable or metastatic melanoma, metastatic non-small cell lung cancer, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or mismatch repair deficient metastatic colorectal cancer, and hepatocellular carcinoma.

- Approximately three in every 10 patients with stage III melanoma currently receive adjuvant therapy after surgery. Even with available treatment options, the majority of stage IIIB and IIIC melanoma patients (71% and 85%, respectively) experience disease recurrence within five years.

- Opdivo's approval for the adjuvant treatment of melanoma was based on a clinical study of 906 patients randomized to Opdivo or Yervoy® (ipilimumab). The major efficacy outcome measure was recurrence-free survival (RFS).

    — There was a statistically significant improvement in RFS for patients randomized to Opdivo vs. Yervoy (HR = 0.65; 95% CI: 0.53, 0.80; $p < 0.0001$).

- The recommended dose of Opdivo for the adjuvant treatment of melanoma is 240 mg administered as an IV infusion over 60 minutes every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year.

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

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.