Opdivo® (nivolumab), Yervoy® (ipilimumab) – New indication

- On October 2, 2020, the FDA announced the approval of Bristol-Myers Squibb's Opdivo (nivolumab) in combination with Yervoy (ipilimumab), for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM).

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

- Yervoy is also approved for unresectable or metastatic melanoma, adjuvant treatment of melanoma, advanced renal cell carcinoma, microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer, hepatocellular carcinoma, and metastatic non-small cell lung cancer.

- MPM is a life-threatening cancer of the lungs' lining caused by inhaling asbestos fibers that about 20,000 Americans are diagnosed with each year. MPM accounts for most mesothelioma diagnoses, and most patients have an unresectable tumor at time of diagnosis. With currently available therapy, overall survival is generally poor.

- The approval of Opdivo plus Yervoy for the new indication was based on CHECKMATE-743, a randomized, open-label study in 605 patients with unresectable MPM. Patients received intravenous (IV) infusions of Opdivo every two weeks with IV infusions of Yervoy every six weeks for up to two years, or platinum-doublet chemotherapy for up to six cycles. The primary efficacy outcome measure was overall survival (OS). Additional efficacy outcome measures included progression-free survival (PFS), overall response rate (ORR), and duration of response (DOR).

    - Median OS was 18.1 months and 14.1 months for Opdivo plus Yervoy vs. chemotherapy, respectively (hazard ratio [HR] 0.74, 95% CI: 0.61, 0.89; p = 0.002).
    - Median PFS was 6.8 months vs. 7.2 months for Opdivo plus Yervoy vs. chemotherapy, respectively (HR 1.0, 95% CI: 0.82, 1.21).
    - The ORR was 40% (95% CI: 34, 45) vs. 43% (95% CI: 37, 49) for Opdivo plus Yervoy vs. chemotherapy, respectively.
    - Median DOR was 11.0 months (95% CI: 8.1, 16.5) vs. 6.7 (95% CI: 5.3, 7.1) for Opdivo plus Yervoy vs. chemotherapy, respectively.

- The recommended dose of Opdivo for the treatment of MPM is 360 mg every 3 weeks (30-minute IV infusion). The recommended dose of Yervoy is 1 mg/kg every 6 weeks (30-minute IV infusion). Treatment should be continued until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression.

- Refer to the Opdivo and Yervoy drug labels for dosing for their other indications.