Opdivo ® (nivolumab) and Yervoy ® (ipilimumab) – Expanded indication

- On July 11, 2018, Bristol-Myers Squibb announced the FDA approval of Opdivo (nivolumab) plus Yervoy (ipilimumab), for the treatment of adult and pediatric patients 12 years and older with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
    - Opdivo was previously approved as a single agent this indication.
    - This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Combination treatment with Opdivo plus Yervoy is also indicated for unresectable or metastatic melanoma and for advanced renal cell carcinoma.
- Opdivo is also indicated as adjuvant treatment of melanoma, and as a single agent for the treatment of unresectable or metastatic melanoma, metastatic non-small cell lung cancer, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, renal cell carcinoma, and hepatocellular carcinoma.
- Yervoy is also indicated as a single agent for the treatment of unresectable or metastatic melanoma and as adjuvant treatment of melanoma.
- The expanded indication is based on safety and efficacy data from the CheckMate-142 trial evaluating Opdivo in combination with Yervoy in 82 patients with MSI-H or dMMR mCRC previously treated with fluoropyrimidine-, oxiliplatin-, or irinotecan-based chemotherapy. Efficacy outcome measures included ORR and DOR.
    - The ORR was 46% (95% CI: 35, 58).
    - For the DOR, 89% of patients had responses of 6 months or longer, and 21% had responses of 12 months or longer.
- Yervoy carries a boxed warning regarding the risk of immune-mediated adverse reactions.
- The most common adverse reactions (≥ 20%) with Opdivo in combination with Yervoy were fatigue, rash, diarrhea, nausea, pyrexia, musculoskeletal pain, pruritus, abdominal pain, vomiting, cough, arthralgia, decreased appetite, and dyspnea.
- In patients with MSI-H or dMMR mCRC that has progressed following treatment with a fluoropyrimidine, oxiliplatin, and irinotecan, the recommended dose of Opdivo is 3 mg/kg administered as an intravenous (IV) infusion followed by Yervoy 1 mg/kg administered as an IV infusion on the same day, every 3 weeks for 4 doses.
    - After completing 4 doses of the combination, administer Opdivo 240 mg as a single agent every 2 weeks as an IV infusion, until disease progression or unacceptable toxicity.
- Refer to the Opdivo and Yervoy drug labels for dosing information for all other indications.