Opdivo® (nivolumab), Yervoy® (ipilimumab) – Updated indication, accelerated approval converted to traditional approval

- On April 8, 2025, the FDA announced the approval of Bristol Myers Squibb's Opdivo (nivolumab) plus Yervoy (ipilimumab), for the **treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC)**.

- The FDA also converted the accelerated approval to traditional approval for single agent Opdivo for the treatment of adult and pediatric patients 12 years and older with MSI-H or dMMR CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

- Opdivo and Yervoy are approved across multiple cancers. Refer to the individual drug labels for a complete listing of their indications.

- The approval of Opdivo plus Yervoy for the updated indication was based on CHECKMATE-8HW, a randomized, open-label study in immunotherapy-naïve patients with unresectable or metastatic CRC with known MSI-H or dMMR status. Patients were randomized to receive one of the following treatments: Opdivo every 3 weeks and Yervoy every 3 weeks for a maximum of 4 doses, then Opdivo every 4 weeks; Opdivo every 2 weeks for 6 doses, then Opdivo every 4 weeks; or investigator's choice chemotherapy. The major outcome measure was progression-free survival (PFS) in the following pre-specified settings: first-line setting: Opdivo plus Yervoy vs. chemotherapy; all lines: Opdivo plus Yervoy vs. Opdivo alone.

    — In the first line setting (n = 255), median PFS was not reached in the Opdivo plus Yervoy arm vs. 5.8 months in the chemotherapy arm (hazard ratio [HR] 0.21, 95% CI: 0.14, 0.32; $p < 0.0001$).
    — In all lines (n = 582), median PFS was not reached in the Opdivo plus Yervoy arm avs. 39.3 months in the Opdivo alone arm (HR 0.62, 95% CI: 0.48, 0.81; $p = 0.0003$).

- Refer to the Opdivo and Yervoy drug labels for complete dosing and administration recommendations.