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

- On April 11, 2025, Bristol Myers Squibb announced the FDA approval of Opdivo (nivolumab) plus Yervoy (ipilimumab), for the **first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC)**.

- In addition to the approval for first-line use, the FDA also granted full approval for Opdivo plus Yervoy for treatment of adult patients with unresectable or metastatic HCC who have been previously treated with sorafenib.

    - This combination was previously granted accelerated approval for treatment of adult patients with HCC who have been previously treated with sorafenib.

- 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 expanded indication was based on CheckMate-9DW, a randomized, open-label study in 668 adults with unresectable or metastatic HCC. Patients were randomized to Opdivo plus Yervoy vs. investigator's choice of lenvatinib or sorafenib monotherapy. The primary outcome measure was overall survival (OS) in all randomized patients. Additional efficacy measures included overall response rate (ORR) and duration of response (DOR).

    - Median OS was 23.7 months with Opdivo plus Yervoy vs. 20.6 months with the comparator arm (hazard ratio 0.79, 95% CI: 0.65, 0.96; p = 0.0180).
    - The ORR was 36.1% (95% CI: 31.0, 41.5) with Opdivo plus Yervoy vs. 13.2% (95% CI: 9.8, 17.3) with the comparator arm (p < 0.0001).
    - The median DOR was 30.4 months (95% CI: 21.2, not reached) with Opdivo plus Yervoy vs. 12.9 months (95% CI: 10.2, 31.2) with the comparator arm.

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