Opdivo® (nivolumab) – Expanded indication

- On August 20, 2021, Bristol Myers Squibb announced the FDA approval of Opdivo (nivolumab), for the adjuvant treatment of patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC.

    — Opdivo is also approved for the treatment of patients with locally advanced or metastatic UC who: (1) have disease progression during or following platinum-containing chemotherapy and (2) have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

- In addition to UC, Opdivo is approved for unresectable or metastatic melanoma; adjuvant treatment of melanoma; metastatic non-small cell lung cancer; malignant pleural mesothelioma; advanced renal cell carcinoma; classical Hodgkin lymphoma; squamous cell carcinoma of the head and neck; microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer; hepatocellular carcinoma; esophageal cancer; and gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.

- The approval of Opdivo for the expanded indication was based on CHECKMATE-274, a randomized, double-blind, placebo-controlled study of adjuvant Opdivo in patients who were within 120 days of radical resection of UC of the bladder or upper urinary tract (renal pelvis or ureter) at high risk of recurrence. Patients were randomized to receive Opdivo or placebo until recurrence or until unacceptable toxicity for a maximum treatment duration of 1 year. The major efficacy outcome measures were disease-free survival (DFS) in all randomized patients (n = 709) and in patients with tumors expressing PD-L1 ≥ 1% (n = 282). DFS was defined as time to first recurrence or death.

    — In all randomized patients, median DFS was 20.8 months vs. 10.8 months for Opdivo and placebo, respectively (hazard ratio [HR] 0.70, 95% CI: 0.57, 0.86; p = 0.0008).
    — In patients with tumors expressing PD-L1 ≥ 1%, median DFS was not reached for Opdivo vs. 8.4 months with placebo (HR 0.55, 95% CI: 0.39, 0.77; p = 0.0005).
    — Overall survival data is immature with 33% of deaths in the overall randomized population.

- The recommended dose of Opdivo for adjuvant treatment of UC is 240 mg every 2 weeks or 480 mg every 4 weeks. Opdivo is administered via intravenous infusion and should be administered until disease recurrence or unacceptable toxicity, for up to 1 year.

- Refer to the Opdivo drug label for dosing for all its other indications.