Opdivo® (nivolumab) – New indication

- On April 16, 2021, Bristol Myers Squibb announced the FDA approval of Opdivo (nivolumab), in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.

- Opdivo is also 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; urothelial carcinoma; microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer; hepatocellular carcinoma; and esophageal squamous cell carcinoma.

- The approval of Opdivo for the new indication was based on a randomized, open-label study in 1,581 patients with previously untreated advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma. Patients were randomized to receive Opdivo in combination with chemotherapy or chemotherapy alone. The major efficacy outcome measures, assessed in patients with PD-L1 combined positive score (CPS) ≥ 5, were progression-free survival (PFS) and overall survival (OS). Additional efficacy outcome measures included OS and PFS in patients with PD-L1 CPS ≥ 1 and in all randomized patients.

    — In patients with PD-L1 CPS ≥ 5, median PFS was 7.7 months for Opdivo plus chemotherapy vs. 6.0 months for chemotherapy alone (hazard ratio [HR] 0.68, 95% CI: 0.58, 0.79; p < 0.0001). Median OS was 14.4 months vs. 11.1 months, respectfully (HR 0.71, 95% CI: 0.61, 0.83; p < 0.0001).
    — In all randomized patients, median PFS was 7.7 months for Opdivo plus chemotherapy vs. 6.9 months for chemotherapy alone (HR 0.77, 95% CI: 0.68, 0.87; not evaluated for statistical significance). Median OS was 13.8 months vs. 11.6 months, respectfully (HR 0.80, 95% CI: 0.71, 0.90; p = 0.0002).

- The most common adverse reactions (≥ 20%) with Opdivo use in combination with fluoropyrimidine- and platinum-containing chemotherapy were peripheral neuropathy, nausea, fatigue, diarrhea, vomiting, decreased appetite, abdominal pain, constipation, and musculoskeletal pain.

- The recommended dose of Opdivo for the treatment of gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma is 240 mg with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks or 360 mg with fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks. Opdivo is administered via intravenous infusion and should be administered until disease progression, unacceptable toxicity, or up to 2 years.

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