Opdivo® (nivolumab) – New indication

- On June 10, 2020, Bristol Myers Squibb announced the FDA approval of Opdivo (nivolumab), for the treatment of patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.

- Opdivo is also approved for the treatment of melanoma; non-small cell lung cancer; small cell lung cancer; 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; and hepatocellular carcinoma.

- In the U.S., it is estimated that approximately 18,440 new cases of esophageal cancer will be diagnosed and approximately 16,170 deaths will result from the disease this year alone. Esophageal cancer is a type of gastrointestinal cancer that starts in the inner layer of the esophagus. The mucosa is normally lined with squamous cells, and cancer starting in these cells is called squamous cell carcinoma, and accounts for less than 30% of esophageal cancers.

- The approval of Opdivo for the new indication was based on ATTRACTION-3, a randomized, active-controlled, open-label study in 419 patients with unresectable advanced, recurrent, or metastatic ESCC. Patients were randomized to receive Opdivo or investigator's choice of taxane chemotherapy consisting of docetaxel or paclitaxel. The major efficacy outcome measure was overall survival (OS). Additional efficacy outcome measures were overall response rate (ORR) and progression-free survival (PFS).

    — Median OS was 10.9 months for Opdivo vs. 8.4 months for taxane chemotherapy (hazard ratio [HR] 0.77; 95% CI: 0.62, 0.96; p = 0.0189).
    — There was no statistically significant difference between the two arms for ORR (19.3% vs. 21.5% for Opdivo and taxane chemotherapy, respectively; p = 0.6323).
    — The median PFS was 1.7 months for Opdivo vs. 3.4 months for taxane chemotherapy (HR 1.1; 95% CI: 0.9 to 1.3), however it was not tested due to the pre-specified hierarchical testing strategy.

- The recommended dose of Opdivo for the treatment of ESCC is 240 mg every 2 weeks (30-minute intravenous infusion) or 480 mg every 4 weeks (30-minute intravenous infusion) until disease progression or unacceptable toxicity.

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