Opdivo® (nivolumab) – New indication

- On March 7, 2024, Bristol Myers Squibb announced the FDA approval of Opdivo (nivolumab), in combination with cisplatin and gemcitabine, for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC).

- Opdivo is also approved for:

    - Adjuvant treatment of adult patients with UC who are at high risk of recurrence after undergoing radical resection of UC
    - Treatment of adult patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy
    - Treatment of adult patients with locally advanced or metastatic UC who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

- Refer to the Opdivo drug label for a complete list of its indications.

- The approval of Opdivo for the new indication was based on CHECKMATE-901, a randomized, open-label study in 608 patients with previously untreated unresectable or metastatic UC. Patients were randomized to Opdivo in combination with cisplatin and gemcitabine followed by Opdivo monotherapy vs. cisplatin-gemcitabine alone. The major outcome measures were overall survival (OS) and progression-free survival (PFS). Additional outcome measures were overall response rate (ORR) and duration of response (DOR).

    - Median OS was 21.7 months in the Opdivo group vs. 18.9 months in the comparator group (hazard ratio [HR] 0.78, 95% CI: 0.63, 0.96; p = 0.0171).
    - Median PFS was 7.9 months in the Opdivo group vs. 7.6 in the comparator group (HR 0.72, 95% CI: 0.59, 0.88; p = 0.0012).
    - The ORR was 57.6% (95% CI: 51.8, 63.2) in the Opdivo group vs. 43.1% (95% CI: 37.5, 48.9) in the comparator group.
    - The median DOR was 9.5 months (95% CI: 7.6, 15.1) in the Opdivo group vs. 7.3 months (95% CI: 5.7, 8.9) in the comparator group.

- For first-line unresectable or metastatic urothelial carcinoma, the recommended dose of Opdivo is 360 mg intravenously (IV) every 3 weeks, in combination with cisplatin and gemcitabine on the same day every 3 weeks, for up to 6 cycles. After completing up to 6 cycles of combination therapy, Opdivo as a single agent should be administered 240 mg every 2 weeks or 480 mg every 4 weeks until disease progression, unacceptable toxicity, or up to 2 years from first dose.

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