Keytruda® (pembrolizumab) – New indication

- On November 1, 2023, Merck announced the FDA approval of Keytruda (pembrolizumab), in combination with gemcitabine and cisplatin, for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer (BTC).

- Refer to the Keytruda drug label for a complete listing of its other indications and uses.

- The approval of Keytruda for the new indication was based on KEYNOTE-966, a randomized, double-blind, placebo-controlled study in 1,069 patients with locally advanced unresectable or metastatic BTC. Patients were randomized to Keytruda plus gemcitabine and cisplatin or placebo plus gemcitabine and cisplatin. The major outcome measure was overall survival (OS). Additional outcome measures were progression-free survival (PFS), objective response rate (ORR), and duration of response (DOR).

    - Median OS was 12.7 months in the Keytruda arm vs. 10.9 months in the placebo arm (hazard ratio [HR] 0.83, 95% CI: 0.72, 0.95; p = 0.0034).
    - Median PFS was 6.5 months in the Keytruda arm vs. 5.6 months in the placebo arm (HR 0.86, 95% CI: 0.75, 1.00; no significant difference).
    - The ORR was 29% (95% CI: 25, 33) in the Keytruda arm vs. 29% (95% CI: 25, 33) in the placebo arm (no significant difference).
    - Median DOR was 8.3 months (95% CI: 6.9, 10.2) in the Keytruda arm vs. 6.8 months (95% CI: 5.7, 7.1) in the placebo arm.

- The recommended dose of Keytruda for the treatment of BTC is 200 mg every 3 weeks or 400 mg every 6 weeks via intravenous infusion, until disease progression, unacceptable toxicity, or up to 24 months. Keytruda should be administered prior to chemotherapy when given on the same day.

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