Keytruda® (pembrolizumab) – Expanded indication

- On November 16, 2023, Merck announced the FDA approval of Keytruda (pembrolizumab), in combination with fluoropyrimidine-and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma.

- Keytruda is also approved, in combination with trastuzumab, fluoropyrimidine-and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-positive gastric or GEJ adenocarcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.

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

- The approval of Keytruda for the expanded indication was based on KEYNOTE-859 a randomized, double-blind, placebo-controlled study in 1,579 patients with HER2-negative advanced gastric or GEJ adenocarcinoma who had not previously received systemic therapy for metastatic disease. Patients were randomized to receive Keytruda in combination with fluoropyrimidine- and platinum-containing chemotherapy, or placebo in combination with chemotherapy. All patients received investigator's choice of chemotherapy (5-fluorouracil plus cisplatin or capecitabine plus oxaliplatin). The major efficacy measure was overall survival (OS). Additional secondary efficacy measures included progression-free survival (PFS) and objective response rate (ORR).

    — Median OS was 12.9 months and 11.5 months for Keytruda plus chemotherapy vs. placebo plus chemotherapy, respectively (hazard ratio [HR] 0.78, 95% CI: 0.70, 0.87; $p < 0.0001$).
    — Median PFS was 6.9 months and 5.6 months, respectively (HR 0.76, 95% CI: 0.67, 0.85; $p < 0.0001$).
    — ORR was 51% (95% CI: 48, 55) and 42% (95% CI: 38, 45), respectively ($p < 0.0001$).

- The recommended dose of Keytruda for the treatment of HER2-negative gastric cancer 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.