Keytruda® (pembrolizumab) – New indication

- On September 18, 2024, Merck announced the FDA approval of Keytruda (pembrolizumab), in combination with pemetrexed and platinum chemotherapy, for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM).

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

- The approval of Keytruda for the new indication was based on KEYNOTE-483, a randomized, open-label, active-controlled study in 440 patients with unresectable advanced or metastatic MPM and no prior systemic therapy for advanced/metastatic disease. Patients were randomized to one of the following regimens: (1) Keytruda with pemetrexed and cisplatin or carboplatin on day 1 of each 21-day cycle for up to 6 cycles, followed by Keytruda every 3 weeks; or (2) pemetrexed and cisplatin or carboplatin on day 1 of each 21-day cycle for up to 6 cycles. The main outcome measure was overall survival (OS). Additional efficacy outcome measures were progression-free survival (PFS) and overall response rate (ORR).

    — Median OS was 17.3 months in the Keytruda arm vs. 16.1 months in the comparator arm (hazard ratio [HR] 0.79, 95% CI: 0.64, 0.98; p = 0.0162).
    — Median PFS was 7.1 months in the Keytruda arm vs. 7.1 months in the comparator arm (HR 0.80, 95% CI: 0.65, 0.99; p = 0.0194).
    — The ORR was 52% in the Keytruda arm vs. 29% in the comparator arm (p < 0.00001).

- The recommended dose of Keytruda for the treatment of MPM is 200 mg every 3 weeks or 400 mg every 6 weeks administered as an intravenous infusion. Keytruda should be given until disease progression, unacceptable toxicity, or up to 24 months.

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