Keytruda® (pembrolizumab) – New indication

- On June 24, 2020, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation.

- Keytruda is also approved for melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, and tumor mutational burden-high cancer.

- The approval of Keytruda for the new indication was based on KEYNOTE-629, a multi-cohort, non-randomized, open-label study. The study enrolled 105 patients with recurrent or metastatic cSCC. Patients received Keytruda every 3 weeks until documented disease progression, unacceptable toxicity, or a maximum of 24 months. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR).

    — The ORR was 34% (95% CI: 25, 44).
    — The median DOR was not reached (range: 2.7 months, 13.1+ months).

- The recommended dose of Keytruda for the treatment of cSCC is 200 mg intravenously every 3 weeks or 400 mg every 6 weeks. Keytruda is administered until disease progression, unacceptable toxicity, or up to 24 months.

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