Keytruda® (pembrolizumab) – Expanded indication

- On July 6, 2021, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or **locally advanced** cSCC that is not curable by surgery or radiation.
    - Keytruda was previously approved in this indication in the recurrent or metastatic setting only.
- Keytruda is also approved for melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, MSI-H or dMMR colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, and triple-negative breast cancer.
- The approval of Keytruda for the expanded indication was based on KEYNOTE-629, a multi-cohort, non-randomized, open-label study in patients with cSCC. The study included 54 patients with locally advanced cSCC. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR).
    - The ORR was 50% (95% CI: 36, 64).
    - The median DOR was not reached (range: 1.0+, 17.2+).
- 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.