Keytruda® (pembrolizumab) – New indication

- On June 13, 2025, Merck announced the FDA approval of Keytruda (pembrolizumab), for the **treatment of adult patients with resectable locally advanced head and neck squamous cell cancer (HNSCC) whose tumors express PD-L1 (Combined Positive Score [CPS] ≥ 1) as determined by an FDA-approved test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy with or without cisplatin and then as a single agent**.

- 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-689, a randomized, open-label, active-controlled study in 714 patients with resectable locally advanced HNSCC. Patients were randomized to one of the following treatment arms: (1) neoadjuvant Keytruda for 2 cycles prior to surgical resection; within 6 weeks following surgery, 3 cycles of adjuvant Keytruda every 3 weeks in combination with radiotherapy with or without 3 cycles of cisplatin every 3 weeks; this was followed by Keytruda every 3 weeks for up to 12 cycles; or (2) no neoadjuvant treatment prior to surgery; within 6 weeks following surgery, adjuvant radiotherapy with or without 3 cycles of concurrent cisplatin every 3 weeks. The major outcome measure was event-free survival (EFS).

    — Median EFS was 59.7 months in the Keytruda arm vs. 29.6 months in the radiotherapy with or without cisplatin arm (hazard ratio 0.70, 95% CI: 0.55, 0.89; p = 0.00140).

- The recommended intravenous dose of Keytruda for the treatment of adult patients with locally advanced HNSCC is 200 mg every 3 weeks or 400 mg every 6 weeks.

    — For neoadjuvant treatment, Keytruda should be administered for 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity.
    — For adjuvant treatment, Keytruda should be administered in combination with radiotherapy with or without cisplatin. Keytruda as a single agent should be continued until disease recurrence or unacceptable toxicity or up to one year

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