Keytruda® (pembrolizumab) – Expanded indication

- On August 20, 2018, the FDA announced the approval of Merck's Keytruda (pembrolizumab), in combination with Alimta® (pemetrexed) and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.

  — Previously, Keytruda was approved under accelerated approval in combination with pemetrexed and carboplatin, as first-line treatment of patients with metastatic nonsquamous NSCLC.
  — The accelerated approval has now been converted to full approval.

- Keytruda is also indicated for the treatment of melanoma, as a single agent for NSCLC, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high or mismatch repair deficient solid tumors or colorectal cancer, gastric cancer and cervical cancer.

- The American Cancer Society estimates that 234,030 new cases of lung cancer will be diagnosed and 154,050 will die from the disease in 2018.

- The expanded indication for Keytruda was demonstrated in the KEYNOTE-189 study of 616 patients with metastatic nonsquamous NSCLC, who had not previously received systemic therapy for metastatic disease and in whom there were no EGFR or ALK genomic tumor aberrations. Patients received Keytruda + Alimta + platinum chemotherapy or placebo + Alimta + platinum chemotherapy. The primary efficacy outcome measures were overall survival (OS) and progression-free survival (PFS).

  — OS was not reached in the Keytruda group vs. 11.3 months in the placebo group (HR = 0.49 [95% CI: 0.38, 0.64], $p < 0.00001$).
  — The PFS was 8.8 months in the Keytruda group vs. 4.9 months in the placebo group (HR = 0.52 [95% CI: 0.43, 0.64], $p < 0.00001$).

- The most common adverse reactions ($\geq$ 20%) with Keytruda in combination with pemetrexed and platinum chemotherapy use were fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, and pyrexia.

- The recommended dosage of Keytruda in patients with NSCLC is 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

  — When administering Keytruda in combination with chemotherapy, Keytruda should be administered prior to chemotherapy when given on the same day.
  — Refer to the permetrexed and platinum chemotherapy drug labels for dosing information.
  — Refer to the Keytruda drug label for dosing for all other indications.