Keytruda® (pembrolizumab) – Expanded indication

- On April 11, 2019, the FDA approved Merck's Keytruda (pembrolizumab), as a single agent, for the first-line treatment of patients with stage III non-small cell lung cancer (NSCLC), who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (Tumor Proportion Score [TPS] ≥ 1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
    - Keytruda was previously approved as a single agent, for the first-line treatment of patients with metastatic NSCLC whose tumors have high PD-L1 expression (TPS ≥ 50%), with no EGFR or ALK genomic tumor aberrations.
- Keytruda is also indicated for 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, cervical cancer, hepatocellular cancer, and Merkel cell carcinoma.
- The expanded indication for Keytruda was based on data from KEYNOTE-042, an open-label study in 1,274 patients with stage III NSCLC, who were not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, whose tumors expressed PD-L1 (TPS ≥ 1%). Patients were randomized to receive Keytruda or investigator's choice of a platinum-containing chemotherapy regimen. The main efficacy outcome measure was overall survival (OS).
    - In the overall population (patients with TPS ≥ 1%), median OS was 16.7 months (95% CI: 13.9, 19.7) with Keytruda vs. 12.1 months (11.3, 13.3) with chemotherapy (Hazard Ratio [HR] 0.81; 95% CI: 0.71, 0.93; p = 0.0036).
    - Keytruda also demonstrated a statistically significant improvement in OS in the subgroup of patients with TPS ≥ 50% NSCLC and the subgroup of patients with TPS ≥ 20% NSCLC.
- The recommended dose of Keytruda for 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.
- Refer to the Keytruda drug label for dosing for all other indications.