Keytruda® (pembrolizumab) – Expanded indication

- On May 10, 2017, Merck announced the FDA approval of Keytruda (pembrolizumab) in combination with Alimta® (pemetrexed) and carboplatin, as first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC).

- Keytruda is also approved to treat the following:

    - Treatment of patients with unresectable or metastatic melanoma.
    - As a single agent for the first-line treatment of patients with metastatic NSCLC whose tumors have high PD-L1 expression [(Tumor Proportion Score (TPS) ≥ 50%)] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
    - As a single agent for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥ 1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.
    - Treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy.
    - Treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma, or who have relapsed after 3 or more prior lines of therapy.

- The expanded indication for Keytruda was approved based on the KEYNOTE-021, Cohort G1, study of 123 patients who were previously untreated with metastatic nonsquamous NSCLC with no EGFR or ALK genomic tumor aberrations and irrespective of PD-L1 expression. Patients received Keytruda and pemetrexed + carboplatin (pem/carbo) or pem/carbo alone. The major efficacy outcome was objective response rate (ORR). Additional efficacy outcome measures were progression-free survival (PFS) and duration of response.

    - The ORR was significantly improved in the Keytruda + pem/carbo group vs. the pem/carbo group (55% [95% CI: 42, 68] vs. 29% [95% CI: 18, 41]; p = 0.0032).
    - There was significantly greater improvement in PFS for Keytruda + pem/carbo patients (13.0 months [95% CI: 8.3, not estimable]) vs. pem/carbo patients (8.9 months [95% CI: 4.4, 10.3]) (HR 0.53 [95% CI: 0.31, 0.91; p = 0.0205]).
    - Duration of response for > 6 months was seen in 93% (range:1.4+ – 13+ months) of Keytruda + pem/carbo patients vs. 81% (range: 1.4+ – 15.2+ months) of pem/carbo patients.

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- 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.
    - When administering Keytruda in combination with chemotherapy, Keytruda should be administered prior to chemotherapy when given on the same day.
    - Consult drug labels for pemetrexed and carboplatin dosing recommendations.
- Consult Keytruda's drug label for dosing recommendations for other indications.