Keytruda® (pembrolizumab) – Expanded indication

- On October 30, 2018, Merck announced the FDA approval of Keytruda (pembrolizumab), in combination with carboplatin and either paclitaxel or Abraxane® (nab-paclitaxel), as first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC).
    - Keytruda is the first anti-programmed T-cell death 1 (PD-1) approved for first-line treatment of squamous NSCLC regardless of PD-L1 expression.
- Keytruda is also indicated for the treatment of melanoma, as a single agent for NSCLC with PD-L1 expression, in combination with other agents for nonsquamous 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.
    - About 25% – 30% of all lung cancers are squamous cell carcinomas.
- The expanded indication for Keytruda was based on the KEYNOTE-047 study enrolling 559 patients with metastatic squamous NSCLC, regardless of PD-L1 tumor expression status, who had not previously received systemic therapy for metastatic disease. Patients received Keytruda plus carboplatin and either paclitaxel or Abraxane (chemotherapy) or placebo plus chemotherapy. The main efficacy outcome measures were progression free survival (PFS), overall response rate (ORR), and overall survival (OS).
    - The PFS was 6.4 vs. 4.8 months for Keytruda plus chemotherapy vs. placebo plus chemotherapy (hazard ration [HR] = 0.56, 95% CI: 0.45, 0.70; $p < 0.0001$).
    - The ORR was 58% for Keytruda plus chemotherapy vs. 35% for placebo plus chemotherapy (difference = 23.6%, 95% CI: 9.9, 36.4; $p = 0.0008$).
    - The OS for Keytruda plus chemotherapy was 15.9 months (95% CI: 13.2, not estimable) vs. 11.3 months (95% CI: 9.5, 14.8) for placebo plus chemotherapy (HR = 0.64, 95% CI: 0.49, 0.85; $p = 0.0017$).
    - In addition, the median duration of response in months was 7.2 (95% CI: 2.4, 12.4+) for Keytruda plus chemotherapy vs. 4.9 (95% CI: 2.0, 12.4+) for placebo plus chemotherapy.
- The most common adverse reactions (≥ 20%) with Keytruda use in combination with chemotherapy were fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, pyrexia, alopecia, and peripheral neuropathy.
- 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.

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

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