Keytruda® (pembrolizumab) – New indication

- On June 13, 2018, Merck announced the FDA approval of Keytruda (pembrolizumab) for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after ≥ 2 prior lines of therapy.
    - Keytruda is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.
    - This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Keytruda is also indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, and cervical cancer.
- PMBCL is a rare, diffuse large B-cell non-Hodgkin lymphoma that arises in the thymus.
    - PMBCL affects adults in their 30s or 40s and is slightly more prevalent among females. It accounts for 5% – 7% of all aggressive lymphomas and 2% – 3% of all non-Hodgkin lymphomas.
- The new indication for Keytruda was based on an open-label, single-arm trial involving 53 patients with relapsed or refractory PMBCL. The primary endpoints were overall response rate (ORR) and duration of response (DOR).
    - The ORR was 45% (95% CI: 32, 60).
    - The DOR was not reached at the time of analysis (range: 1.1+, 19.2+).
- In patients with PMBCL, the recommended dose of Keytruda in adults is 200 mg (or 2 mg/kg in pediatric patients up to a maximum of 200 mg) administered as an intravenous infusion 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 dosage in other indications.