Keytruda® (pembrolizumab) – Expanded indication

- On October 15, 2020, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) and for the treatment of pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy.

    — Keytruda was previously approved for treatment of adult and pediatric patients with refractory cHL, or who have relapsed after 3 or more prior lines of therapy.

- Keytruda is also approved for melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell cancer, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, MSI-H or dMMR colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, and cutaneous squamous cell carcinoma.

- The approval of Keytruda for the expanded indication was based on KEYNOTE-204, a randomized, open-label, active-controlled study in 304 patients with relapsed or refractory cHL. Patients were randomized to Keytruda or Adcetris® (brentuximab vedotin). Treatment was continued until unacceptable toxicity, disease progression, or a maximum of 35 cycles. The main efficacy measure was progression free survival (PFS).

    — Median PFS was 13.2 months for Keytruda vs. 8.3 months with Adcetris (hazard ratio 0.65, 95% CI: 0.48, 0.88; p = 0.0027).
    — The objective response rate was 66% (95% CI: 57, 73) with Keytruda vs. 54% (95% CI: 46, 62) with Adcetris.
    — The median duration of response was 20.7 months (range: 0.0+, 33.2+) for Keytruda vs. 13.8 months (range: 0.0+, 33.9+) for Adcetris.

- Keytruda was previously approved under the FDA's accelerated approval process for the treatment of adult and pediatric patients with refractory cHL based on data from the KEYNOTE-087 trial. In accordance with accelerated approval regulations, continued approval was contingent upon verification and description of clinical benefit; these accelerated approval requirements have been fulfilled with the data from KEYNOTE-204.

- The recommended dose of Keytruda for the treatment of cHL in adults is 200 mg intravenously (IV) every 3 weeks or 400 mg every 6 weeks. The recommended dose in pediatric patients is 2 mg/kg IV every 3 weeks (up to a maximum of 200 mg). Keytruda is administered until disease progression, unacceptable toxicity, or up to 24 months.

    — Refer to the Keytruda drug label for dosing for all its other indications.