

## Keytruda® (pembrolizumab) - Expanded indication

- On October 15, 2020, <u>Merck announced</u> the <u>FDA approval</u> of <u>Keytruda (pembrolizumab)</u>, 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.



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