FDA Extends Approval of Keytruda for Classical Hodgkin Lymphoma

The checkpoint inhibitor is approved for adults and children with relapsed lymphoma.

October 16, 2020 By Food and Drug Administration (FDA)

On October 14, 2020, the Food and Drug Administration extended the approval of pembrolizumab (KEYTRUDA, Merck Sharp & Dohme Corp.) for the following indications:

- adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) and
- pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy.

Approval was based on KEYNOTE-204 (NCT02684292), a phase 3, randomized, open-label trial in 304 adult patients with relapsed or refractory cHL after at least one multiagent regimen. Patients were randomized (1:1) to receive either pembrolizumab 200 mg every 3 weeks or brentuximab vedotin (BV) 1.8 mg/kg every 3 weeks for up to 2 years.

Efficacy was based on progression-free survival (PFS) per blinded independent central review assessment. PFS was statistically significantly longer in the pembrolizumab arm. The median PFS was 13.2 months (95% CI: 10.9, 19.4) in the pembrolizumab arm and 8.3 months (95% CI: 5.7, 8.8) in the BV arm, with a hazard ratio of 0.65 (95% CI: 0.48, 0.88; p=0.0027).

Serious adverse reactions occurred in 30% of the patients who received pembrolizumab. Serious adverse reactions in ≥1% of patients included pneumonitis, pneumonia, pyrexia, myocarditis, acute kidney injury, febrile neutropenia, and sepsis.

Adverse reactions in ≥20% of pembrolizumab recipients included upper respiratory tract infection, musculoskeletal pain, diarrhea, cough, pyrexia, fatigue, and rash. Thirty-eight percent of patients had adverse reactions requiring systemic corticosteroids, including pneumonitis in 11%.

The recommended pembrolizumab dose for patients with lymphoma is 200 mg every 3 weeks or 400 mg every 6 weeks intravenously for adults, or 2 mg/kg (up to 200 mg) every 3 weeks intravenously for pediatric patients, for up to 2 years.

View full prescribing information for Keytruda.

The FDA collaborated with the Australian Therapeutics Goods Administration (TGA) and Health Canada (HC) as part of Project Orbis. The review of the application is ongoing for the TGA and HC. This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted orphan drug designation, breakthrough therapy designation, and priority review. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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