FDA Approves Keytruda for Primary Mediastinal Large B Cell Lymphoma

Pembrolizumab approved for uncommon lymphoma mostly seen in young adults.

June 13, 2018 By Food and Drug Administration (FDA)

FDA approves pembrolizumab for treatment of relapsed or refractory PMBCL

On June 13, 2018, the Food and Drug Administration granted accelerated approval to pembrolizumab (Keytruda, Merck) for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy.

Approval was based on data from 53 patients with relapsed or refractory PMBCL enrolled in a multicenter, open-label, single-arm trial, KEYNOTE-170 (NCT02576990). Patients were treated with pembrolizumab 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression, or for up to 24 months for patients who did not progress. The overall response rate was 45% (95% CI: 32, 60), including 11% complete responses and 34% partial responses. The median duration of response was not reached within the follow-up period (median 9.7 months). The median time to first objective response was 2.8 months; pembrolizumab is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.

The most common adverse reactions in ≥10% of patients with PMBCL treated in KEYNOTE-170 were musculoskeletal pain, upper respiratory tract infection, pyrexia, fatigue, cough, dyspnea, diarrhea, abdominal pain, nausea, arrhythmia, and headache. Pembrolizumab was discontinued or interrupted due to adverse reactions in 8% and 15% of patients, respectively. Twenty-five percent of patients had an adverse reaction requiring systemic corticosteroid therapy. Serious adverse reactions occurred in 26% of patients.

The recommended pembrolizumab dose for treatment of adults with PMBCL is 200 mg every 3 weeks. The recommended dose in pediatric patients is 2 mg/kg (up to a maximum of 200 mg) every three weeks.

View full prescribing information for Keytruda.

FDA granted this application priority review. Pembrolizumab also received orphan product designation and breakthrough therapy designation for the PMBCL indication. 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. 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.

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