FDA Approves Keytruda For Merkel Cell Carcinoma

Pembrolizumab led to 56 percent overall response rate for rare skin cancer.

December 21, 2018 By Food and Drug Administration (FDA)

On December 19, 2018, the Food and Drug Administration granted accelerated approval to pembrolizumab (KEYTRUDA, Merck & Co. Inc.) for adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC).

Approval was based on Cancer Immunotherapy Trials Network protocol 9 (CITN-09), also known as KEYNOTE-017 (NCT02267603), a multicenter, non-randomized, open-label trial that enrolled 50 patients with recurrent locally advanced or metastatic MCC who had not received prior systemic therapy for their advanced disease. Patients received pembrolizumab 2 mg/kg every 3 weeks.

The major efficacy outcome measures were overall response rate (ORR) and response duration assessed by blinded independent central review per RECIST 1.1. The ORR was 56% (95% CI: 41, 70) with a complete response rate of 24%. The median response duration was not reached. Among the 28 patients with responses, 96% had response durations of greater than 6 months and 54% had response durations of greater than 12 months.

The most common adverse reactions of pembrolizumab reported in at least 20% of patients who received pembrolizumab as a single agent were fatigue, musculoskeletal pain, decreased appetite, pruritus, diarrhea, nausea, rash, pyrexia, cough, dyspnea, constipation, pain, and abdominal pain.

The recommended pembrolizumab dose for MCC is 200 mg administered as a 30-minute intravenous infusion every 3 weeks for adults; 2 mg/kg (to a maximum of 200 mg) administered as a 30-minute intravenous infusion every 3 weeks for patients less than 18 years of age (pediatric patients).

View full prescribing information for KEYTRUDA.

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 the confirmatory trials.

FDA granted this application priority review and Breakthrough Therapy designation. 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.

This announcement was originally published on the Food and Drug Administration website on December 20, 2018.
