Generic Name:
Pembrolizumab
Trade Name:
Keytruda
Company:
Merck
Notes:

FDA granted accelerated approval to pembrolizumab 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, a multicenter, nonrandomized, 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, 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 dose for MCC is 200 mg administered as a 30-minute I.V. infusion every 3 weeks for adults; 2 mg/kg (to a maximum of 200 mg) administered as a 30-minute I.V. infusion every 3 weeks for patients younger than 18 years (pediatric patients).

Medication Monitor Categories:
Supplemental Approvals