FDA Approves Keytruda for Cutaneous Squamous Cell Carcinoma

A third of people treated with the immunotherapy experienced remission.

June 26, 2020 By Food and Drug Administration (FDA)

On June 24, 2020, the Food and Drug Administration approved pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation.

Efficacy was investigated in KEYNOTE-629 (NCT03284424), a multicenter, multi-cohort, non-randomized, open-label trial. The trial excluded patients who had previously received therapy with an anti-PD-1, anti-PD-L1, or anti-CTLA-4 antibody and those with autoimmune disease or a medical condition that required immunosuppression. Patients received pembrolizumab 200 mg intravenously every 3 weeks until disease progression, unacceptable toxicity, or a maximum of 24 months. Assessment of tumor status was performed every 6 weeks during the first year and every 9 weeks during the second year.

The major efficacy outcome measures were objective response rate (ORR) and response duration as assessed by blinded independent central review according to RECIST 1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. The ORR was 34% (95% CI: 24, 44) and median response duration was not reached (range: 2.7, 13.1+ months).

Adverse reactions occurring in patients with cSCC enrolled in KEYNOTE-629 were similar to those occurring in patients who received pembrolizumab as a single agent in other clinical trials. The most common adverse reactions to pembrolizumab are fatigue, musculoskeletal pain, decreased appetite, pruritus, diarrhea, nausea, rash, pyrexia, cough, dyspnea, constipation, pain, and abdominal pain. Pembrolizumab is associated with immune-mediated side effects, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and skin adverse reactions.

Efficacy and safety of pembrolizumab using a dosage of 400 mg every 6 weeks for cSCC was primarily based on the modeling of dose/exposure efficacy and safety relationships and observed pharmacokinetic data in patients with melanoma.

The recommended pembrolizumab doses for cSCC are 200 mg every 3 weeks or 400 mg every 6 weeks.

View full prescribing information for KEYTRUDA.

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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