FDA Approves Unloxcyt for Cutaneous Squamous Cell Carcinoma

New PD-L1 checkpoint inhibitor is indicated for people with metastatic or locally advanced cancer who are not eligible for curative therapy.

October 16, 2023 By Food and Drug Administration (FDA)

On December 13, 2024, the Food and Drug Administration approved cosibelimab-ipdl (Unloxcyt, Checkpoint Therapeutics, Inc.), a programmed death ligand-1 (PD-L1) blocking antibody, for adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

Full prescribing information for Unloxcyt will be posted on Drugs@FDA.

Efficacy and Safety

Efficacy was evaluated in Study CK-301-101 (NCT03212404), a multicenter, multicohort, open-label trial in 109 patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation. Patients were excluded if they had any of the following: active or suspected autoimmune disease, allogeneic transplant within 6 months prior to treatment, prior treatment with anti-PD-1/PD-L1 blocking antibodies or other immune checkpoint inhibitor therapy, uncontrolled or significant cardiovascular disease, ECOG PS ≥ 2, or infection with HIV, hepatitis B, or hepatitis C.

The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR) as assessed by an independent central review committee (IRC) according to RECIST version 1.1. For patients with laCSCC with externally visible target lesions not assessable by radiologic imaging, ORR was determined by ICR assessments of digital photography (WHO criteria). ORR was 47% (95% CI: 36, 59) for patients with mCSCC (n=78) and 48% (95% CI: 30, 67) for patients with laCSCC (n=31). Median DOR was not reached (range: 1.4+, 34.1+) in patients with mCSCC and 17.7 months (range: 3.7+, 17.7) in patients with laCSCC.

Adverse Reactions

The most common adverse reactions (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritis, edema, localized infection, and urinary tract infection.

The recommended cosibelimab-ipdl dose is 1,200 mg administered as an intravenous infusion over

60 minutes every 3 weeks until disease progression or unacceptable toxicity.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

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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