FDA Approves Zynyz for Merkel Cell Carcinoma

Half of patients with this rare skin cancer experienced tumor shrinkage when treated with the new checkpoint inhibitor.

March 23, 2023 By Food and Drug Administration (FDA)

FDA grants accelerated approval to retifanlimab-dlwr for metastatic or recurrent locally advanced Merkel cell carcinoma

On March 22, 2023, the Food and Drug Administration granted accelerated approval to retifanlimab-dlwr (Zynyz, Incyte Corporation) for adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).

Safety and efficacy were evaluated in PODIUM-201 (NCT03599713), an open-label, multiregional, single-arm study evaluating 65 patients with metastatic or recurrent locally advanced MCC who had not received prior systemic therapy for advanced disease.

The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR) assessed by an independent central review committee according to RECIST v1.1. The ORR was 52% (95% CI: 40, 65) with complete response rate of 18%. Twenty-six patients (76%) had a DOR ≥ 6 months and 21 (62%) had a DOR ≥ 12 months.

The safety population consisted of 105 patients with MCC. The most common (≥10%) adverse reactions were fatigue, musculoskeletal pain, pruritus, diarrhea, rash, pyrexia, and nausea. Serious adverse reactions occurred in 22% of patients receiving retifanlimab-dlwr.

The recommended retifanlimab-dlwr dose is 500 mg administered as an intravenous infusion over 30 minutes every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months.

View full prescribing information for Zynyz.

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

This application was granted priority review, fast track, and orphan drug designation. FDA expedited programs are described 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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