FDA Grants Accelerated Approval to Zegfrovy for Metastatic Lung Cancer

Nearly half of patients treated with sunvozertinib experienced tumor shrinkage, with a response duration of 11 months.

July 8, 2025 By Food and Drug Administration (FDA)

FDA grants accelerated approval to sunvozertinib for metastatic non-small cell lung cancer with EGFR exon 20 insertion mutations

On July 2, 2025, the Food and Drug Administration granted accelerated approval to sunvozertinib (Zegfrovy, Dizal (Jiangsu) Pharmaceutical Co., Ltd.) for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Today, FDA also approved the Oncomine Dx Express Test (Life Technologies Corporation) as a companion diagnostic device to aid in detecting EGFR exon 20 insertion mutations in patients with NSCLC who may be eligible for treatment with Zegfrovy.

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

Efficacy was evaluated in WU-KONG1B (NCT03974022), a multinational, open-label, dose randomization trial. Eligible patients had locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations with disease progression on or after platinum-based chemotherapy. The primary efficacy population was 85 patients who received sunvozertinib 200 mg orally once daily with food until disease progression or intolerable toxicity.

The major efficacy outcome measure was confirmed overall response rate (ORR) according to RECIST v1.1 as evaluated by a blinded independent review committee (BIRC). An additional efficacy outcome measure was duration of response (DOR) by BIRC. The ORR was 46% (95% CI: 35, 57) and DOR was 11.1 months (95% CI: 8.2, not evaluable).

The sunvozertinib prescribing information includes warnings and precautions for interstitial lung disease/pneumonitis, gastrointestinal adverse reactions, dermatologic adverse reactions, ocular toxicity, and embryo-fetal toxicity.

The recommended sunvozertinib dose is 200 mg orally once daily with food until disease

progression or unacceptable toxicity.

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

This application was granted priority review. Sunvozertinib received breakthrough therapy 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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