FDA Approves Ensacove for ALK-Positive Advanced Non-Small Cell Lung Cancer

Ensartinib, an oral targeted therapy, improved progression-free survival for patients with locally advanced or metastatic NSCLC.

December 18, 2024 By Food and Drug Administration (FDA)

On December 18, 2024, the Food and Drug Administration approved ensartinib (Ensacove, Xcovery Holdings, Inc.) for adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK-inhibitor.

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

Efficacy and Safety

Efficacy was evaluated in eXALT3 (NCT02767804), an open-label, randomized, active-controlled, multicenter trial in 290 patients with locally advanced or metastatic ALK-positive NSCLC who had not previously received an ALK-targeted therapy. Patients were randomized 1:1 to receive ensartinib or crizotinib.

The main efficacy outcome measure was progression-free survival (PFS) as evaluated by blinded independent central review. The key secondary efficacy outcome measure was overall survival (OS).

Ensartinib demonstrated a statistically significant PFS improvement compared to crizotinib with a hazard ratio (HR) of 0.56 (95% CI: 0.40, 0.79; p-value 0.0007). The median PFS was 25.8 months (95% CI: 21.8, not estimable) in the ensartinib arm and 12.7 months (95% CI: 9.2, 16.6) in the crizotinib arm. There was no statistically significant difference in OS (HR 0.88 [95% CI: 0.63, 1.23], p-value 0.4570).

The most common adverse reactions (≥20%) were rash, musculoskeletal pain, constipation, cough, pruritis, nausea, edema, pyrexia, and fatigue.

Recommended Dose

The recommended ensartinib dose is 225 mg orally once daily, with or without food, until disease progression or unacceptable toxicity.

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 at240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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