

FDA Approves New Targeted Therapy for Advanced Lung Cancer

Three quarters of patients treated with Hernexeos, an oral HER2 inhibitor, experienced tumor regression.

August 14, 2025 By [Liz Highlyman](#)

On August 8, the Food and Drug Administration (FDA) [granted accelerated approval](#) of Hernexeos (zongertinib), a new targeted therapy for previously treated people with inoperable or metastatic [non-small cell lung cancer \(NSCLC\)](#) that carries specific HER2 mutations. Hernexeos is the first oral targeted medication for such patients.

“With the approval of zongertinib, we have an effective, targeted, orally administered treatment option for patients with HER2 (ERBB2)-mutant non-small cell lung cancer in the U.S. that not only elicits a durable response but, importantly, has a manageable safety profile,” John Heymach, MD, PhD, of the University of Texas MD Anderson Cancer Center, said in a [Boehringer Ingelheim news release](#). “In a patient population where there are currently limited treatment options, this approval represents a significant advancement in cancer care.”

Hernexeos is a novel tyrosine kinase inhibitor that selectively targets HER2 (human epidermal growth factor receptor 2), a protein that promotes malignant cell growth and spread. Though best known as a target for breast cancer treatment, up to 4% of NSCLC tumors are driven by HER2 mutations, which are associated with resistance to standard therapies and poor prognosis. Unlike some other HER2 inhibitors, Hernexeos does not interfere with EGFR (epidermal growth factor receptor), which should lessen side effects.

The accelerated approval is supported by findings from the Phase Ib Beamion LUNG-1 trial ([NCT04886804](#)), which included previously treated people with advanced or metastatic NSCLC with HER2 mutations. Patients were enrolled in different cohorts depending on their type of mutation and treatment history.

[As previously reported](#), Heymach presented primary results at this year’s American Association for Cancer Research annual meeting; they were also published in [The New England Journal of Medicine](#).

Participants in Cohort 1 had lung tumors with HER2 activating mutations in the tyrosine kinase domain and less extensive prior treatment. Among 71 patients who had received platinum-based

chemotherapy but not a HER2-targeted tyrosine kinase inhibitor or antibody-drug conjugate, the objective response rate—indicating substantial tumor shrinkage—was 75%, including 6% with a complete response. Among 34 patients in Cohort 5 who had the same type of mutation but had previously received both chemotherapy and a HER2-targeted antibody-drug conjugate, the objective response rate was 44%. What’s more, Hernexeos showed activity in the brain in people with metastatic cancer.

The most common adverse reactions and Grade 3-4 laboratory abnormalities among people taking Hernexeos are diarrhea, nausea, skin rash, fatigue, decreased lymphocyte count, low potassium and elevated liver enzymes. The drug’s prescribing information includes warnings about liver toxicity, heart dysfunction and interstitial lung disease (lung inflammation).

The recommended dose of Hernexeos is either 120 or 180 milligrams, depending on body weight. The tablets can be taken with or without food and may be continued until patients experience disease progression or unacceptable side effects.

Therapies that receive FDA accelerated approval based on overall response rate are expected to undergo further testing in larger trials to confirm clinical benefits, such as overall survival, and the agency can rescind approval if they fail to measure up.

Hernexeos is also being evaluated for first-line treatment of people with inoperable locally advanced or metastatic NSCLC with HER2 mutations in the Phase III Beamion LUNG-2 trial ([NCT06151574](#)). It is also being studied for other solid tumors with HER2 mutations.

“The advocacy community is thrilled about the approval of zongertinib, as it is another testament to the importance of personalized options for lung cancer that allow for a much more targeted approach for a subgroup of patients who have been waiting many years for innovative treatments,” said Marcia Horn, president of the International Cancer Advocacy Network and executive director of the Exon 20 Group/HER2 Warriors. “Understanding your cancer’s unique biomarkers, including HER2, through comprehensive testing is critical for all patients with NSCLC, as it can unlock targeted treatment options.”

Click here for [full prescribing information for Hernexeos](#).

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