FDA Approves HER2-Targeted Therapy for Advanced Lung Cancer

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November 20, 2025 By Liz Highleyman

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On November 19, the Food and Drug Administration (FDA) granted accelerated approval of Hyrnuo (sevabertinib), a new targeted therapy for non-small-cell lung cancer (NSCLC) with specific HER2 mutations, based on promising results from a Phase I/II study of previously treated patients.

Hyrnuo, from Bayer, is an oral kinase inhibitor that interferes with HER2, a protein that plays a role in malignant cell growth. It is indicated for the treatment of adults with locally advanced or metastatic non-squamous NSCLC whose tumors have HER2 tyrosine kinase domain activating mutations, as detected by an FDA-approved companion test, and who have received prior systemic therapy.

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. Another kinase inhibitor, Hernexeos (zongertinib), from Boehringer Ingelheim, was approved in August for the same indication.

Hyrnuo approval is supported by results from the open-label Phase I/II SOHO-01 (NCT05099172), which evaluated the safety and efficacy of Hyrnuo in previously treated patients with unresectable or metastatic NSCLC with HER2 activating mutations. Participants received Hyrnuo tablets twice daily.

Among 70 people who had received some prior systemic therapy but not other HER2-targeted drugs, the objective response rate, indicating tumor shrinkage, was 71%, with a median response duration of 9.2 months. Just over half had a duration of response lasting at least six months.

Among 52 patients who had previously received HER2-targeted antibody drug conjugates, the

objective response rate fell to 38%, with a response duration of 7.0 month and 60% responding for six months or more.

More detailed findings were presented at the European Society for Medical Oncology Congress in October and published in The New England Journal of Medicine.

The most common adverse reactions include diarrhea, rash, nail inflammation, mouth sores and nausea. The most common Grade severe (Grade 3 or 4) laboratory abnormalities included decreased white blood cell count, decreased potassium and sodium, increased lipase and amylase and elevated ALT and AST liver enzymes. The Hyrnuo prescribing information includes warnings and precautions about severe diarrhea, liver toxicity, interstitial lung disease or pneumonitis, eye problems and pancreatic enzyme elevation.

Therapies that receive accelerated approval based on response rates are expected undergo further testing to determine if they offer clinical benefits, such as improved survival, and the FDA can pull drugs that fail to measure up.

Hyrnuo is being further evaluated in the randomized Phase 3 SOHO-02 trial (NCT06452277), which is comparing it against standard-of-care systemic therapy for patients with previously untreated advanced HER2-mutated NSCLC.

Click here for full prescribing information for Hyrnuo.
Click here for more news about lung cancer.
