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News Release

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U.S. FDA grants accelerated approval to Bayer's HYRNUO™ (sevabertinib) for patients with previously treated advanced HER2-mutant non-small cell lung cancer

- Accelerated approval is based on an objective response rate of 71% (N=70) for patients naïve to *HER2* targeted therapy, as demonstrated in the Phase I/II SOHO-01 trial
- In SOHO-01, sevabertinib demonstrated robust and durable anti-tumor responses and a manageable safety profile
- *HER2*-mutant NSCLC typically has a poor prognosis and limited treatment options

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Berlin, November 20, 2025 – Following Priority Review and Breakthrough Therapy Designation, the U.S. Food and Drug Administration (FDA) has granted accelerated approval for HYRNUO™ (sevabertinib), for the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have human epidermal growth factor receptor 2 (*HER2*) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy. Sevabertinib is an oral, reversible, small molecule, tyrosine kinase inhibitor (TKI).

"The FDA's approval of sevabertinib elevates the standard of care and provides a new treatment option for patients living with *HER2*-mutant NSCLC, which is a challenging disease with limited therapies available," said SOHO-01 lead trialist, Xiuning Le, MD, PhD, The University of Texas MD Anderson Cancer Center, Houston, Texas. "Clinical results from the SOHO-01 trial showed that sevabertinib is effective with a manageable safety profile."

The FDA approved this indication for sevabertinib under accelerated approval based on objective response rate (ORR) and duration of response (DOR) data from the ongoing

Phase I/II SOHO-01 trial (NCT05099172) in patients with advanced NSCLC harboring a *HER2*-activating mutation, with disease progression after ≥1 systemic therapies for advanced disease. Continued approval of sevabertinib for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Results from the Phase I/II SOHO-01 trial demonstrated for patients naïve to *HER2* targeted therapy an ORR of 71% (95% CI: 59%-82%, N=70); 2.9% of patients had a complete response and 69% of patients had a partial response. Median DOR was 9.2 months (95% CI, 6.3–15.0, N=50). Sevabertinib demonstrated a manageable safety profile with a 3.7% discontinuation rate. In the pooled safety population, the most common (> 20%) adverse reactions were diarrhea (87%), rash (66%), paronychia (33%), stomatitis (29%) and nausea (21%).

Positive results from the Phase I/II SOHO-01 trial were presented at the European Society for Medical Oncology (ESMO) Congress 2025 and simultaneously published in the *New England Journal of Medicine.*[1]

“Globally, it is estimated that up to 84,000 people are diagnosed with NSCLC harboring a *HER2* mutation each year,” said Christian Rommel, Ph.D., Head of Research and Development at Bayer’s Pharmaceuticals Division. “At Bayer our oncology R&D strategy is centered on precision drug development which is designed to help us address critical unmet medical needs through the advancement of innovative therapies. Today's FDA approval of sevabertinib exemplifies this approach, delivering a targeted treatment specifically for patients with advanced *HER2*-mutant NSCLC. This significant milestone underscores our unwavering commitment to transforming cancer care by delivering meaningful therapies that have the potential to improve outcomes and extend survival for people living with cancer.”

In 2024, both the U.S. FDA and the CDE in China granted sevabertinib Breakthrough Therapy designation indicating that the compound has the potential to provide substantial improvement over existing therapies in NSCLC with *HER2*-activating mutations. China accepted a new drug application (NDA) for sevabertinib in July 2025.

About HYRNUO™ (sevabertinib)
Sevabertinib is a new, oral, reversible, small molecule, tyrosine kinase inhibitor (TKI) that potently inhibits mutant human *HER2*, including *HER2* exon 20 insertions and *HER2* point

mutations, as well as epidermal growth factor receptors (EGFR), with high selectivity for mutant vs wild-type *EGFR*. Sevabertinib works by blocking certain enzymes called tyrosine kinases, which are involved in the growth of cancer cells. Reversible TKIs can temporarily block their targets, allowing for more precise control over treatment and potentially reducing long-term side effects compared to irreversible TKIs.

Sevabertinib is derived from Bayer's strategic research alliance with the Broad Institute of MIT and Harvard in Cambridge, MA, USA.

The ongoing Phase III SOHO-02 trial (NCT06452277) is evaluating sevabertinib as a first-line treatment option for patients with advanced NSCLC whose tumors have *HER2* mutations. Sevabertinib is also being studied in patients with metastatic or unresectable solid tumors harboring *HER2*-activating mutations, excluding advanced NSCLC, in the panSOHO study (NCT06760819).

About Non-Small Cell Lung Cancer (NSCLC)

Lung cancer is the leading cause of cancer-related deaths worldwide. NSCLC is the most common type of lung cancer, accounting for more than 85% of cases. Activating *HER2* mutations are found in 2% to 4% of patients with advanced NSCLC. 80% of people diagnosed with NSCLC have already progressed to advanced stages, which makes it more difficult to treat. Patients with *HER2*-mutant NSCLC currently face limited treatment options, highlighting an urgent need for more effective therapies.

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The company has the passion and determination to develop new medicines that help improve and extend the lives of people living with cancer. The oncology franchise at Bayer includes several marketed products across diverse indications and multiple compounds in different stages of clinical development. We have a wealth of expertise in areas including: Tumor Intrinsic Pathways, Targeted Radionuclide Therapies, and Next-Generation Immuno-Oncology. We are advancing prostate cancer treatment from early to metastatic stage, with the goal of extending survival while limiting side effects. Part of Bayer's focus on innovative precision oncology treatments, includes an approved TRK inhibitor exclusively designed to treat tumors that have an NTRK gene fusion, the oncogenic driver of tumor growth and spread.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, “Health for all, Hunger for none,” the company’s products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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1 X Le, M.D., Ph.D., TM Kim, M.D., Ph.D. H.H.Loong, M.B., B.S. et al. Sevabertinib in Advanced *HER2*-Mutant Non–Small-Cell Lung Cancer. New England Journal of Medicine. 2025/10/21. Available at: https://www.nejm.org/doi/abs/10.1056/NEJMoa2511065. Last accessed November 2025.