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News Release

Not intended for U.S. and UK Media

FDA grants sevabertinib Priority Review as a first-line treatment for patients with *HER2*-mutant non-small cell lung cancer

- The U.S. Food and Drug Administration (FDA) has granted sevabertinib Priority Review designation, recognizing its potential to address a critical unmet need. Priority Review specifically applies to the evaluation of medicines that, if approved, would provide significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition.[1]
- Regulatory submission for first-line use of sevabertinib is based on results from the ongoing Phase I/II SOHO-01 trial evaluating the efficacy and safety of sevabertinib in patients with advanced *HER2*-mutant non-small cell lung cancer (NSCLC)
- In December 2025, the U.S. FDA and the Center for Drug Evaluation (CDE) in China both granted sevabertinib Breakthrough Therapy to expedite the development of sevabertinib for first-line use in patients with *HER2*-mutant NSCLC given its potential to provide substantial benefit over available therapies in an area of high unmet need
- In November 2025, sevabertinib, under the brand name Hyrnuo™, received FDA accelerated approval for patients with previously treated advanced *HER2*-mutant NSCLC

Berlin, May 18, 2026 – Bayer today announced that sevabertinib has been granted Priority Review status by the US Food and Drug Administration (FDA) for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors have *HER2 (ERBB2)* tyrosine kinase domain (TKD) activating mutations.

“The FDA’s Priority Review decision for sevabertinib is an important milestone that underscores Bayer’s commitment to precision oncology, addressing critical unmet needs in patients with *HER2*-mutant NSCLC,” said Christian Rommel, Ph.D., Head of Research and Development at Bayer’s Pharmaceuticals Division. “Patients with *HER2*-mutant

NSCLC currently have limited treatment options, and there is an urgent need for more effective and better tolerated therapies that can be used early in the disease course to help improve survival outcomes."

The regulatory application for first-line use of sevabertinib is based on preliminary clinical evidence from cohort F (patients who had not previously received treatment) of the ongoing Phase I/II SOHO-01 Study (NCT05099172)[2] evaluating the efficacy and safety of sevabertinib in patients with locally advanced or metastatic *HER2*-mutant NSCLC.

In November 2025, sevabertinib, under the brand name Hyrnuo™, received FDA accelerated approval for patients with previously treated advanced *HER2*-mutant NSCLC based on objective response rate (ORR) and duration of response (DOR) data from the SOHO-01 trial (from cohort D - previously treated patients who had not received *HER2*-targeted therapy and cohort E - patients who had previously received *HER2*-directed antibody-drug conjugates). Sevabertinib has also recently been approved by the National Medical Products Administration (NMPA) in China as monotherapy in adult patients with unresectable, locally advanced or metastatic NSCLC whose tumors have *HER2* activating mutations, and who have received one prior systemic therapy.

About 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.

As part of its clinical development program, alongside the SOHO-01 trial, sevabertinib is also being studied in patients in the Phase III SOHO-02 trial (NCT 06452277) evaluating sevabertinib in treatment naïve patients with *HER2*-mutant NSCLC and in the panSOHO study (NCT06760819) in patients with metastatic or unresectable solid tumors with *HER2*-activating mutations, excluding advanced NSCLC.

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 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Bayer AG is a holding company with operating subsidiaries worldwide. References to "Bayer" or "the company" herein may refer to one or more subsidiaries as context requires.

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1 U.S. Food and Drug Administration. "Priority Review." https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review. Accessed April 2026.
2 N. Girard, H.H.F. Loong, B-C. Goh *et al.* 30: Phase I/II SOHO-01 study of BAY 2927088 in patients with previously treated HER2-mutant NSCLC: Safety and efficacy results from 2 expansion cohorts, *Journal of Thoracic Oncology*, Volume 20, Issue 3, Supplement 1,2025,Pages S5-S6,ISSN 1556-0864. Available at: https://www.sciencedirect.com/science/article/pii/S1556086425001984.