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News Release

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U.S. FDA grants accelerated approval to Bayer's targeted therapy sevabertinib as a first-line treatment option for adults with *HER2*-mutant non-small cell lung cancer

- Accelerated approval of sevabertinib for patients with advanced *HER2*-mutant non-small cell lung cancer (NSCLC) follows FDA Priority Review and Breakthrough Therapy Designations, and reflects the potential for sevabertinib to provide substantial benefit over available therapies in an area of high unmet need
- Approval 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 NSCLC
- *HER2*-mutant NSCLC typically has a poor prognosis and limited treatment options

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Berlin, September 9, 2026 – Following Priority Review and Breakthrough Therapy Designation, the U.S. Food and Drug Administration (FDA) has granted accelerated approval for sevabertinib as a first-line treatment option for 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/ERBB2)* tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-authorized test. Sevabertinib is an oral, reversible, small molecule, tyrosine kinase inhibitor (TKI).

"The FDA's accelerated approval of sevabertinib marks an important advance for treatment-naïve patients with *HER2*-mutated NSCLC who historically have a poor prognosis," said SOHO-01 lead investigator, Xiuning Le, MD, PhD, associate professor of Thoracic/Head and Neck Medical Oncology at The University of Texas MD Anderson Cancer Center, Houston, Texas. "This milestone also underscores the critical importance of comprehensive molecular testing at diagnosis, including for activating *HER2* mutations, to ensure patients receive the most appropriate treatment as early as possible."

The FDA approved this indication for sevabertinib under accelerated approval based on objective response rate (ORR) and duration of response (DOR) demonstrated in a cohort of treatment-naïve patients (N=69) in the ongoing Phase I/II SOHO-01 trial (NCT05099172), evaluating the efficacy and safety of sevabertinib in patients with locally advanced or metastatic HER2-mutant NSCLC. In this cohort, the ORR was 75% including complete responses in 6% of patients and partial responses in 70% of patients, with 73% of responders maintaining response for at least six months. The safety profile of sevabertinib was consistent with previous findings. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the ongoing Phase III SOHO-02 confirmatory trial (NCT06452277), which is evaluating sevabertinib versus standard of care in treatment-naïve patients with advanced HER2-mutant NSCLC.

"Today's FDA approval of sevabertinib as an initial treatment option for locally advanced or metastatic non-squamous *HER2*-mutated NSCLC is an important milestone for patients and a powerful validation of Bayer's commitment to advancing precision oncology in areas with the highest unmet needs," said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. "Lung cancer remains the leading cause of cancer-related deaths worldwide and for patients with *HER2*-mutated NSCLC, a distinct subtype that often affects people who have never smoked, there remains a critical need for additional treatment options. This approval underscores the potential of precision medicine to transform outcomes by matching the right patients to the right therapy at the right time."

In November 2025, sevabertinib 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). Earlier this year, sevabertinib was also 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. The approval follows the Center for Drug Evaluation (CDE) in China granting sevabertinib Breakthrough Therapy Designation for this patient population. The CDE has also granted sevabertinib Breakthrough Therapy Designation to expedite its development for first-line use in patients with advanced HER2-mutant NSCLC. Sevabertinib has also recently been approved as the first approved

targeted therapy for this indication that can be used regardless of line of therapy, including as a first-line treatment, by the Ministry of Health, Labour, and Welfare in Japan.

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. 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 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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