Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

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Bayer's sevabertinib approved in Japan for patients with *HER2*-mutant non-small cell lung cancer

- First targeted therapy approved in Japan for this indication, with use across all lines of therapy, including first-line treatment
- 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, August 24, 2026 – The Ministry of Health, Labour, and Welfare (MHLW) in Japan has granted approval for Hyrnuo™ (sevabertinib) for the treatment of patients with *HER2 (ERBB2)* mutation-positive unresectable advanced or recurrent non-small cell lung cancer (NSCLC). In Japan, Hyrnuo is the first approved targeted therapy for this indication that can be used regardless of line of therapy, including as a first-line treatment. Sevabertinib is an oral, reversible, small molecule, tyrosine kinase inhibitor (TKI).

"*HER2*-mutant NSCLC remains an area of significant unmet medical need. Sevabertinib has demonstrated clinically meaningful efficacy together with a manageable safety profile and offers a promising new treatment option for these patients. The availability of sevabertinib in the first-line setting, without restriction by *HER2* mutation subtype, marks an important step forward in expanding treatment choices for both patients and healthcare professionals. We look forward to its potential as a new treatment option for patients," said Dr Koichi Goto, PhD, Chief of the Department of Thoracic Oncology at the National Cancer Center Hospital East in Japan.

The MHLW approval is supported by data from the global Phase I/II SOHO-01 trial (NCT05099172). In patients with unresectable advanced or recurrent HER2-mutant NSCLC who had not received prior systemic therapy following diagnosis of advanced or

recurrent disease, the primary endpoint of objective response rate (ORR) was 75.3% (95% CI: 63.9–84.7; N=73). Median duration of response (DOR) was 12.2 months (95% CI: 8.8–not estimable; N=73), and median progression-free survival (PFS) was 13.5 months (95% CI: 10.0–not estimable; N=73). The study also demonstrated a manageable safety profile, with the most frequently observed adverse events being diarrhea, rash, and paronychia. Adverse events leading to treatment discontinuation occurred in 3% of patients.[1]

“The approval of sevabertinib by Japan’s MHLW marks an important advancement for patients with advanced HER2-mutant NSCLC, a patient population that has historically faced limited treatment options,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “Supported by results from the ongoing SOHO-01 study, this latest approval advances our precision oncology strategy and builds on earlier approvals in both the U.S. and China. We continue to work with clinicians and diagnostic partners to support timely *HER2* testing and appropriate access in line with the approved indication, with the goal of improving outcomes for people living with this difficult-to-treat form of lung cancer.”

In November 2025, sevabertinib, under the brand name Hyrnuo™, received U.S. Food and Drug Administration (FDA) accelerated approval for patients with previously treated advanced *HER2*-mutant NSCLC. 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. These approvals follow on from the U.S. FDA and the Center for Drug Evaluation (CDE) in China granting sevabertinib Breakthrough Therapy Designation for both first- and second-line use in patients with advanced *HER2*-mutant NSCLC, highlighting its potential to provide substantial improvement over existing therapies. In May this year, the FDA granted sevabertinib Priority Review as a first-line treatment in this patient population recognizing its potential to address a critical unmet need.

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. 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.

Reference:

1. Herbert H. Loong, SOHO-01: Updated safety and efficacy of sevabertinib in patients with advanced HER2-mutant non-small cell lung cancer (NSCLC). ASCO Publications: https://ascopubs.org/doi/10.1200/JCO.2026.44.16_suppl.8622

Contact for media inquiries:

Silvia Grosso, phone +1 973 270 6828

Email: silvia.grosso@bayer.com

Contact for investor inquiries:

Bayer Investor Relations Team, phone +49 214 30-72704

Email: ir@bayer.com

www.bayer.com/de/investoren/ir-team

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