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

News Release

Not intended for U.S. and UK Media

Sevabertinib (BAY 2927088) granted FDA Priority Review for the treatment of patients with HER2-mutant non-small cell lung cancer

- The U.S. FDA granted sevabertinib Priority Review designation. This is specifically for the evaluation of medicines that, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition[1]
- Regulatory submission for sevabertinib is based on results from the ongoing Phase I/II SOHO-01 trial in patients with advanced HER2-mutant non-small cell lung cancer (NSCLC). Latest data showed an objective response rate of 70.5 % in pre-treated patients, and a manageable safety profile consistent with previous reports
- In 2024, the U.S. FDA and the CDE in China both granted sevabertinib Breakthrough Therapy designation signifying that the compound may provide substantial improvement over existing therapies in NSCLC with HER2-activating mutations
- Patients with HER2-mutant NSCLC currently have limited treatment options, highlighting an urgent need for more effective therapies

Berlin, May 28, 2025 – Bayer today announced that the investigational compound sevabertinib (BAY 2927088) has been granted Priority Review status by the US Food and Drug Administration (FDA) for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) whose tumors have activating human epidermal growth factor receptor 2 (HER2/ERBB2) mutations and who have received a prior systemic therapy. Sevabertinib is an oral, small molecule, tyrosine kinase inhibitor (TKI).

“Patients with HER2-mutant NSCLC are predominantly women, may be of younger age and non-smokers. The FDA’s decision to grant Priority Review designation to our application for sevabertinib is a significant milestone that validates both the unmet need and the potential for sevabertinib to fulfill that need,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the

Pharmaceuticals Leadership Team at Bayer. “If approved, sevabertinib will help address critical unmet needs and improve outcomes for these patients, who currently have a poor prognosis and limited treatment options.”

The regulatory application for sevabertinib is based on positive results from the ongoing Phase I/II SOHO-01 trial in patients with advanced NSCLC harboring a HER2-activating mutation, with disease progression after ≥1 systemic therapies for advanced disease, and who were naïve to treatment with a HER2-targeted TKI.

The Breakthrough Therapy designation for sevabertinib was supported by preliminary clinical evidence from the SOHO-01 trial. A Breakthrough Therapy designation is specifically designed to expedite the development and review of investigational medicines that have the potential to provide substantial improvement over available therapies in areas of high unmet medical need. By expediting the development and review process via a Breakthrough Therapy designation, promising therapies can be made available to patients as quickly and as safely as possible.

Results from SOHO-01 (NCT05099172)[2]

SOHO-01 is an ongoing, open-label, multicenter Phase I/II study. The latest results are from two expansion cohorts; patients with advanced NSCLC with HER2-activating mutations who had disease progression after ≥1 systemic therapies and were either naïve to HER2-targeted therapy (Cohort D) or previously treated with HER2-targeted antibody-drug conjugates (Cohort E). Both cohorts received oral sevabertinib 20 mg twice daily.

As of October 14, 2024, 44 patients from cohort D and 34 patients from cohort E were treated. The investigator-assessed objective response rate was 70.5% (95% CI 54.8, 83.2) in D and 35.3% (95% CI 19.7, 53.5) in E. The disease control rates (response or stable disease for ≥12 weeks) were 81.8% (D) and 52.9% (E). Median duration of response (DOR) was 8.7 months (95% CI 4.5, not estimable [NE]) in D and 9.5 months (95% CI 4.1, NE) in E.

The safety profile of sevabertinib was found to be manageable, and consistent with previous reports. Treatment-related adverse events (TRAEs) were reported in 97.4% of patients; diarrhea was the most common TRAE leading to dose reduction, but no patients discontinued treatment due to diarrhea. There were no cases of interstitial lung disease.

About sevabertinib (BAY 2927088)

Sevabertinib is an investigational agent and has not been approved by any health authority for use in any country, for any indication. It is currently being evaluated as a potential new targeted treatment option for patients with NSCLC harboring human epidermal growth factor receptors 2 (HER2) activating mutations. The ongoing Phase III SOHO-02 trial (NCT 06452277) is evaluating BAY 2927088 as a first-line treatment option for these patients. Sevabertinib is also being studied in patients with metastatic or unresectable solid tumors harboring HER2-activating mutations (panSOHO), excluding advanced non-small cell lung cancer (NSCLC). Sevabertinib is an oral, reversible tyrosine kinase inhibitor (TKI) that potently inhibits mutant 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. Investigational agent sevabertinib is derived from Bayer's strategic research alliance with the Broad Institute of MIT and Harvard in Cambridge, MA, USA.

About Non-Small Cell Lung Cancer (NSCLC)

Lung cancer is the leading cause of cancer-related deaths worldwide. Non-Small Cell Lung Cancer (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 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.

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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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.

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 23, 2025.
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