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News Release

Not intended for U.S. and UK Media

Data from Phase I/II SOHO-01 trial presented at 2024 World Conference on Lung Cancer

New results from the Investigational agent BAY 2927088 in HER2-mutant non-small cell lung cancer (NSCLC) presented at WCLC

- Investigational BAY 2927088 is an oral, small molecule, tyrosine kinase inhibitor as a potential new targeted therapy for patients with non-small cell lung cancer (NSCLC) harboring HER2 activating mutations
- The U.S. Food and Drug Administration and the Center for Drug Evaluation in China granted BAY 2927088 Breakthrough Therapy designation in 2024 for the treatment of adult patients with unresectable or metastatic NSCLC whose tumors have activating HER2 (ERBB2) mutations, and who have received a prior systemic therapy

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Berlin, September 9, 2024 – Bayer announced encouraging results from the expansion part of the ongoing Phase I/II SOHO-01 study evaluating the safety and preliminary efficacy of BAY 2927088 in advanced HER2-mutant non-small cell lung cancer (NSCLC). Data were presented during the Presidential Symposium at the IASLC 2024 World Conference on Lung Cancer (WCLC) hosted by the International Association for the Study of Lung Cancer, taking place in San Diego, United States, from September 7-10, 2024.

“The encouraging results from the expansion phase of the SOHO-01 trial demonstrate the potential of this targeted therapy to advance outcomes for patients with HER2-mutant NSCLC, a type of lung cancer with limited treatment options and poor prognosis,” said Christian Rommel, Ph.D., Head of Research and Development at Bayer’s Pharmaceuticals Division. “The development of BAY 2927088 underscores our ongoing commitment in lung cancer and our continued drive to develop precise and personalized healthcare solutions in disease areas with the highest unmet needs.”

“HER2-mutant NSCLC is a challenging disease that can predominantly affect individuals who are young and never smoked a cigarette. Given the current lack of therapeutic options, there is an immediate need for effective, manageable treatments,” said SOHO-01 lead trialist, Xiuning Le, MD, PhD, The University of Texas MD Anderson Cancer Center, Houston, TX. “BAY 2927088 showed promising preliminary efficacy in both response rate and duration, and a manageable safety profile, which emphasizes the importance of ongoing innovation to elevate the standard of care.”

The objective of the expansion phase of the study was to determine the safety, tolerability, and pharmacokinetics of BAY 2927088 in patients with HER2-mutant NSCLC. These data support the ongoing investigation of BAY 2927088 in patients with advanced NSCLC harboring HER2 mutations. Just recently Bayer announced that the first patient has been enrolled in the global Phase III SOHO-02 trial, an open-label, randomized, multicenter clinical trial, assessing the efficacy and safety of investigational agent BAY 2927088 as first-line therapy in patients with advanced non-small cell lung cancer, whose tumors have activating HER2 mutations.

Detailed Results from SOHO-01

SOHO-01 is an ongoing, open-label, multicenter Phase I/II study. Results from patients with advanced NSCLC harboring a HER2-activating mutation with disease progression after ≥1 systemic therapies for advanced disease, and who are naïve to HER2-targeted therapy were presented. In the trial, patients received oral BAY 2927088 20 mg twice daily. Forty-three out of forty-four patients enrolled were evaluable for efficacy, with a confirmed objective response rate (ORR) of 72.1% (n=31; 95% CI 56.3, 84.7) including 1 complete response (2.3%). Median duration of response (DOR) and progression-free survival (PFS) were 8.7 months (95% CI 4.5, not estimable) and 7.5 months (95% CI 4.4, 12.2), respectively. In patients with HER2 YVMA insertions, the most frequent mutation, ORR was 90.0%, DoR was 9.7 months, and PFS was 9.9 months.

The safety profile of BAY 2927088 was found to be manageable, and consistent with previous reports. Treatment-related adverse events (TRAEs) were reported in 95.5% of patients, with grade 3 TRAEs reported in 40.9%. Diarrhea was the most common TRAE (86.4%, 25.0% grade 3), followed by rash (43.2% grade 1 or 2) and paronychia (25.0% grade 1 or 2). Three patients (6.8%) discontinued due to TRAEs.

About BAY 2927088

BAY 2927088 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 HER2 activating mutations. BAY 2927088 is an oral, reversible tyrosine kinase inhibitor (TKI) that potently inhibits mutant human epidermal growth factor receptors 2 (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 BAY 2927088 is derived from Bayer's strategic research alliance with the Broad Institute of MIT and Harvard in Cambridge, MA, USA.

About Breakthrough Therapy Designation

This Breakthrough Therapy designation for BAY 2927088 is supported by preliminary clinical evidence from the Phase I/II, open-label, multicenter first-in-human study (NCT05099172) evaluating the safety, pharmacokinetics and preliminary efficacy of BAY 2927088 in adult patients with advanced NSCLC harboring HER2 or EGFR mutations. The Breakthrough Therapy designation is a process designed to expedite the development and review of novel medicines that are intended for the prevention or treatment of serious, life-threatening diseases or conditions that severely impact the quality of life for which there is no existing treatment, or where sufficient evidence indicates advantages of the novel drug over available treatment options.

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 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 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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