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News Release

Not intended for UK Media

Bayer starts Phase III trial in non-small cell lung cancer (NSCLC)

- First patient enrolled in the Phase III SOHO-02 trial of investigational agent BAY 2927088 in treatment-naïve patients with advanced NSCLC with HER2-activating mutations
 - Data from the phase I/II SOHO-01 trial selected for a presidential symposium at the World Conference on Lung Cancer
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Berlin, August 29, 2024 – Bayer announced today 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 (NSCLC), whose tumors have activating HER2 mutations.

Beyond the SOHO-02 trial, investigational agent BAY 2927088 is also being assessed for its potential as a second-line therapy in adult patients with unresectable or metastatic NSCLC whose tumors have activating HER2 (ERBB2) mutations, and who have received a prior systemic therapy. Late-breaking results from the phase I/II SOHO-01 trial will be presented in the presidential symposium at the World Conference on Lung Cancer (WCLC) in San Diego on Monday, September 9th, 2024.

“Our commitment to precision medicine is not just a promise but a mission to address the critical unmet needs of individuals battling HER2-mutant NSCLC, a variant of the most prevalent form of lung cancer,” said Christian Rommel, Ph.D., Head of Research and Development at Bayer’s Pharmaceuticals Division. “By advancing innovative research, we are dedicated to improving survival rates for those affected by this devastating disease. This endeavor underscores our commitment to pioneering precise and personalized healthcare solutions for those in direct need.”

Investigational agent BAY 2927088 is derived from Bayer's strategic research alliance with the Broad Institute of MIT and Harvard in Cambridge, MA, USA.

Lung cancer is the leading cause of cancer-related deaths worldwide. Currently there are no approved targeted first-line therapies for patients with NSCLC harboring HER2 activating mutations.

BAY 2927088 has received Breakthrough Therapy designation in the second-line setting from the U.S. Food and Drug Administration (FDA) in February 2024. In June 2024, the Center for Drug Evaluation (CDE) in China also granted investigational agent BAY 2927088 Breakthrough Therapy designation for the same patient population.

About the SOHO-02 Study

SOHO-02 is a global Phase III, open-label, randomized, multicenter clinical trial, assessing the efficacy and safety of investigational agent BAY 2927088 as first-line therapy for adult patients with advanced non-small cell lung cancer (NSCLC), whose tumors have activating HER2 mutations. Participants will be randomized to either investigational agent BAY 2927088 or the current standard of care (cisplatin/carboplatin + pemetrexed + pembrolizumab). The primary endpoint of the study is progression free survival (PFS) measured by a blinded, independent, central review. Additional endpoints include overall response rate (ORR), duration of response (DoR) and evaluating the safety of investigational agent BAY 2927088. More information can be found at <https://clinicaltrials.gov/study/NCT06452277>.

About Investigational Agent 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.

About Non-Small Cell Lung Cancer (NSCLC)

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.

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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