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News Release

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Bayer starts Phase II clinical study with BAY 2927088 in metastatic or unresectable HER2 mutant solid tumors

- First patient enrolled in the Phase II panSOHO basket trial; this is the third BAY 2927088 clinical trial in patients with HER2- activating mutations
 - Innovative drug development candidate with promising therapeutic potential across several tumor types further strengthens Bayer's precision oncology development portfolio
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Berlin, March 4, 2025 – Bayer announced today that the first patient has been enrolled in the global Phase II panSOHO study, an open-label clinical trial, assessing the efficacy and safety of investigational agent BAY 2927088 in adult patients with metastatic or unresectable solid tumors harboring HER2-activating mutations. These include tumors of the colon or rectum, the uterus and the cervix, the bladder, and the biliary tract (includes gall bladder and bile ducts) as well as other types of solid tumors, excluding advanced non-small cell lung cancer (NSCLC).

“We are excited to initiate the panSOHO trial, which represents our ongoing commitment to precision oncology research and the development of innovative targeted therapies,” said Christian Rommel, Ph.D., Head of Research and Development at Bayer's Pharmaceuticals Division. “This study is a critical step in evaluating a potential new treatment strategy for patients with a variety of solid tumors driven by HER2-activating mutations, who often have limited treatment options.”

Beyond the panSOHO trial, BAY 2927088 is also being investigated in patients with advanced NSCLC harboring 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. Additionally, BAY 2927088 is being studied in the Phase I/II SOHO-01 trial for patients with advanced NSCLC and HER2-activating mutations who have received prior

systemic therapy. In second-line NSCLC for patient with HER2-activating mutations, BAY 2927088 has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in China.

HER2-activating mutations can drive the growth of several types of solid tumors, and patients with these mutations often have limited treatment options. The panSOHO study, designed as a basket trial, aims to investigate whether targeting these mutations with BAY 2927088 can offer benefit to these patients. In oncology, basket trials provide the opportunity to test a new drug or treatment on patients with different cancer types that share a common genetic characteristic, like HER2-activating mutation, with the goal of identifying effective, personalized treatments.

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 the panSOHO Study

PanSOHO is a global Phase II, open-label basket trial evaluating the efficacy and safety of investigational agent BAY 2927088 in patients with metastatic or unresectable solid tumors harboring HER2-activating mutations, excluding advanced non-small cell lung cancer (NSCLC). The primary endpoint of the study is objective response rate (ORR) measured by a blinded, independent, central review. Secondary endpoints include duration of response (DOR), progression-free survival (PFS), and evaluating the safety of investigational agent BAY 2927088. More information can be found at <https://clinicaltrials.gov/study/NCT06760819>.

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 advanced 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.^{1,2}

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 Cell Intrinsic Pathways, Targeted Radionuclide Therapies, and selected 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

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.

References:

1. Siegel F, Karsli-Uzunbas G, Kotynkova K, et al, Preclinical activity of BAY 2927088 in HER2 mutant non-small cell lung cancer. [abstract]. In: Proceedings of the American Association for Cancer Research Annual Meeting 2023; Part 1 (Regular and Invited Abstracts); 2023 Apr 14-19; Orlando, FL. Philadelphia (PA): AACR; Cancer Res 2023;83(7_Suppl):Abstract nr 4035.
2. Siegel F, Siegel S, Graham K, et al. BAY 2927088: The first non-covalent, potent, and selective tyrosine kinase inhibitor targeting EGFR exon 20 insertions and C797S resistance mutations in NSCLC. European Journal of Cancer. 2022;174:S9-S10.