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News Release

Not intended for U.S. and UK Media

Bayer receives Breakthrough Therapy designation in China for BAY 2927088 in high unmet need patients with HER2-mutant non-small cell lung cancer

- BAY 2927088 is an oral, small molecule, tyrosine kinase inhibitor under development as a potential new targeted therapy for patients with non-small cell lung cancer (NSCLC) harboring HER2 activating mutations
- The Center for Drug Evaluation in China has granted Breakthrough Therapy designation to expedite the development and review of BAY 2927088, given its potential to provide substantial benefit over available therapies in an area of high unmet need
- In February 2024, the U.S. Food and Drug Administration (FDA) also granted BAY 2927088 Breakthrough Therapy designation

Berlin, June 11, 2024 – Bayer announced today that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in China has granted Breakthrough Therapy designation for BAY 2927088, a potential new targeted therapy for adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC), whose tumors have activating HER2 (ERBB2) mutations, and who have received a prior systemic therapy. The CDE's designation for BAY 2927088 follows the Breakthrough Therapy designation granted by the U.S. Food and Drug Administration (FDA) in February 2024 for the same patient population.

"The Breakthrough Therapy designations granted for BAY 2927088 by China's CDE and the U.S. FDA underscore the potential of this targeted therapy to transform the lives of patients with HER2-mutant NSCLC, a type of lung cancer with limited treatment options and often poor prognosis," said Christian Rommel, Ph.D., Head of Research and Development at Bayer's Pharmaceuticals Division. "This recognition, backed by promising clinical evidence, strengthens our commitment to addressing critical unmet needs in

cancer care. It reinforces our mission to be a leader in oncology by accelerating the development of targeted therapies, one of our key focus areas."

This Breakthrough Therapy designation 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. 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 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.[1,2]

About Non-Small Cell Lung Cancer (NSCLC)

Lung cancer is the leading cause of cancer-related deaths worldwide.[3] NSCLC is the most common type of lung cancer, accounting for more than 85% of cases.[4] Activating HER2 mutations are found in 2% to 4% of advanced NSCLC.[5] 80% of people diagnosed with NSCLC have already progressed to advanced stages, which makes it more difficult to treat.[6] Currently there are no available therapies that have received full approval for patients with NSCLC harboring HER2 activating mutations.

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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