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## News Release

**Not intended for UK Media**

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### **Bayer receives U.S. FDA Breakthrough Therapy designation for BAY 2927088 for non-small cell lung cancer harboring HER2 activating mutations**

- BAY 2927088 is an oral, small molecule tyrosine kinase inhibitor under development as a potential new targeted therapy for patients with NSCLC harboring HER2 activating mutations
  - Breakthrough Therapy designation is a process designed to expedite the development and review of investigational drugs that have potential to provide substantial improvement over available therapy in areas of high unmet medical need
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**Berlin, Germany, February 26, 2024** – Bayer announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for BAY 2927088 for the treatment of 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. 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.<sup>1,2</sup>

Lung cancer is the leading cause of cancer-related deaths worldwide.<sup>3</sup> NSCLC is the most common type of lung cancer, accounting for more than 85% of cases.<sup>4</sup> Activating HER2 mutations are found in 2% to 4% of advanced NSCLC.<sup>5</sup> Currently there are no available therapies that have received full approval in the U.S. for patients with NSCLC in the metastatic or advanced setting harboring HER2 activating mutations.

The Breakthrough Therapy designation is supported by preliminary clinical evidence from the Phase I, 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.

“Early clinical evidence suggests that BAY 2927088, our investigational novel oral tyrosine kinase inhibitor, has the potential to benefit patients with NSCLC harboring a HER2 mutation that have progressed on a prior systemic therapy and currently have no other approved treatment available,” said Dominik Ruettinger, M.D., Ph.D., Head of Research and Early Development for Oncology at Bayer’s Pharmaceuticals Division. “This Breakthrough Therapy designation is a significant milestone in our relentless efforts to develop innovative therapies for the treatment of lung cancer characterized by specific genomic markers. We will continue working closely with the FDA to advance BAY 2927088 through the clinic and look forward to providing these patients with lung cancer and their physicians with a targeted, effective treatment option.”

The FDA's Breakthrough Therapy designation is intended to expedite the development and review of drug candidates that treat serious or life-threatening diseases or conditions, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies.<sup>6</sup>

BAY 2927088 was derived from Bayer’s long-standing strategic research alliance with the Broad Institute of MIT and Harvard in Cambridge, MA, USA.

### **About Bayer**

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its 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 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to [www.bayer.com](http://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](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Sung, H. et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J. Clin. 71, 209–249 (2021).

<sup>4</sup> Leiter, A., Veluswamy, R.R. & Wisnivesky, J.P. The global burden of lung cancer: current status and future trends. Nat Rev Clin Oncol 20, 624–639 (2023).

<sup>5</sup> Stephens P, Hunter C, Bignell G, et al. Lung cancer: intragenic ERBB2 kinase mutations in tumours. Nature 2004;431:525-526.

<sup>6</sup> <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy>