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News Release

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Bayer and Puhe BioPharma enter into global license agreement for clinical phase I PRMT5 inhibitor

- Bayer obtains exclusive worldwide license for MTA-cooperative PRMT5 inhibitor for selective targeting of MTAP-deleted tumors
- Clinical phase I study under development name BAY 3713372 initiated and first participant enrolled
- MTAP deletions occur in approximately 10 to 30 percent of all cancers[1]
- Highly strategic fit strengthens Bayer´s diversified early precision oncology pipeline

Berlin, Germany and Beijing, China, March 26, 2025 – Bayer and Suzhou Puhe BioPharma Co.,Ltd., a clinical-stage biotechnology company, today announced that they have entered into a global license agreement for Puhe BioPharma's oral, small molecule PRMT5 inhibitor that selectively targets MTAP-deleted tumors. Under the agreement, Bayer obtains an exclusive worldwide license to develop, manufacture and commercialize the MTA-cooperative PRMT5 inhibitor. Bayer has enrolled the first participant in a Phase I first-in-human dose escalation study investigating MTA-cooperative PRMT5 inhibitor under the development name BAY 3713372 for the treatment of MTAP-deleted solid tumors.

"We are looking forward to explore the potential of the PRMT5 inhibitor, which could improve outcomes for patients with MTAP-deleted tumors who often have a poor prognosis," said Juergen Eckhardt, M.D., Head of Business Development and Licensing at Bayer's Pharmaceuticals Division. "The highly selective targeting of cancer cells while sparing healthy cells, based on the innovative mechanism of action is very promising. This will support our mission to build one of the most transformative and differentiated precision oncology pipelines in the industry."

“We see great potential in MTA-cooperative PRMT5 inhibitors in treating MTAP-deleted tumors. Our MTA-cooperative PRMT5 inhibitor, PH020, now named BAY 3713372, has demonstrated competitive selectivity for PRMT5 bound to MTA and activity in preclinical studies, as well as brain penetration capabilities,” said Yongqi Guo, CEO of Puhe BioPharma. “We are excited to partner with Bayer, a global leader in the field of life sciences, to advance our PRMT5 inhibitor into the clinic. Together with Bayer, we look forward to bringing this therapeutic option to patients worldwide.”

PRMT5 (protein arginine methyltransferase 5) and a specific gene called MTAP (metabolic enzyme 5’-deoxy-5'-methylthioadenosine phosphorylase) play important roles in cell metabolism and are critical for cell survival. MTAP deletions, which occur in approximately 10 to 30 percent of all cancers[1], lead to elevated levels of MTA in tumor cells and BAY 3713372 is designed to bind the PRMT5-MTA complex thus specifically exploiting tumor vulnerability.

“Loss of the MTAP gene occurs in a variety of tumor types, including those with few treatment options and poor prognosis, such as pancreatic cancer and glioblastoma,” said Dominik Ruettinger, M.D., Ph.D., Global Head of Research and Early Development for Oncology at Bayer’s Pharmaceuticals Division. “We look forward to advancing this program as we are driven by our ambition to develop innovative medicines that improve and extend the lives of cancer patients we serve, focusing on areas of high unmet medical need.”

Financial terms are not disclosed.

About BAY 3713372 (MTA-cooperative PRMT5 inhibitor)
BAY 3713372 is an investigational agent and has not been approved by any health authority for use in any country, for any indication. It is an oral, potent selective MTA-cooperative PRMT5 inhibitor being evaluated as a potential new targeted treatment option for patients with MTAP-deleted solid tumors. BAY 3713372 has unique characteristics including brain penetrance, which allows targeting of central nervous system (CNS) metastases and primary brain tumors.

Protein arginine N-methyltransferase 5 (PRMT5) plays a crucial role in modifying proteins that control the cell cycle. The metabolic enzyme 5’-deoxy-5'-methylthioadenosine phosphorylase (MTAP) is involved in the methionine salvage pathway which recycles

methionine from methylthioadenosine (MTA).This targeted approach takes advantage of the unique relationship between MTA and PRMT5, creating a specific vulnerability that can be exploited to effectively treat MTAP deficient cancer cells.

About the clinical phase I study

BAY 3713372 is investigated in a global Phase I first-in-human dose escalation study in patients with MTAP-deleted solid tumors. The clinical program aims to evaluate the safety, tolerability and pharmacokinetics, pharmacodynamics and preliminary clinical activity of BAY 3713372, a novel cancer cell specific PRMT5 inhibitor.

About Puhe BioPharma

Suzhou Puhe BioPharma Co., Ltd. is a biotechnology company dedicated to the research and development of innovative small-molecule precision therapeutics. Adhering to a strategy that addresses differentiated clinical needs, the company focuses on high-incidence, high-mortality cancers and other chronic diseases. By leveraging scientific and industrial insights, Puhe combines various advanced technologies such as next-generation kinase inhibitors, synthetic lethality, and molecular glue approaches to address complex medical challenges. For more information, go to www.puhebiopharma.com.

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 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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References

1. TCGA Research Network. Available at: https://www.cancer.gov/ccg/research/genome-sequencing/tcga