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News Release

Not intended for UK Media

Bayer initiates Phase II study of soluble guanylate cyclase activator (BAY3283142) in patients with chronic kidney disease

- Soluble guanylate cyclase (sGC) activator is being studied in patients with chronic kidney disease (CKD), with potential implications for cardiovascular disease treatment
- CKD is a progressive condition affecting more than 10% of the global population, totaling approximately 850 million individuals
- Phase II study aims to address the unmet medical needs of chronic kidney disease patients and has potential to improve outcomes in related cardiovascular conditions through innovative sGC modulation

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Berlin, Germany, August 22, 2024 – Bayer announced today the start of the ALPINE-1 study, a Phase II clinical trial with BAY3283142, an investigational soluble guanylate cyclase (sGC) activator, in patients with chronic kidney disease (CKD). The results of this study have the potential to provide evidence of the sGC activator as a viable treatment option for cardiovascular diseases.

CKD is a progressive condition that affects more than 10% of the global population, totaling approximately 850 million individuals. It is a common and potentially deadly condition that is widely underrecognized. It progresses silently and unpredictably, with many symptoms not appearing until the disease is well-advanced. CKD is one of the most frequent complications arising from diabetes and is also an independent risk factor of cardiovascular disease.

“This study marks a significant step forward in our commitment to addressing the high unmet medical need in this patient population and advancing our innovative approach to treat renal disease,” said Dr. Christian Rommel, Head of Research and Development at Bayer’s Pharmaceuticals Division. “In addition, this further strengthens our overall development portfolio. We are dedicated to advancing the development of BAY3283142

to improve outcomes for patients with chronic kidney disease and related cardiovascular conditions."

"The change in demography tells us that we are living longer in the future, and people want to spend this time in good health, with healthy kidneys," said Prof. Christoph Wanner, Senior Professor of Medicine in the Department of Clinical Studies and Epidemiology, University Hospital of Würzburg and Co-Chair of the ALPINE-1 study. "The prevalence of chronic kidney disease (CKD) as one of the top 10 leading causes of mortality underscores the pressing need for effective treatment options. The evaluation of the sGC activator in patients with CKD holds promise in addressing a critical unmet medical need in patient care."

Following the successful first-in-human trials, the goal of the randomized, double-blind, placebo-controlled, multi-center Phase II ALPINE-1 study is to assess the efficacy and safety of BAY3283142 in patients with chronic kidney disease. BAY3283142 is a soluble guanylate cyclase (sGC) activator that represents an innovative approach to modulating the nitric oxide (NO)-soluble guanylate cyclase (sGC)-cyclic guanosine monophosphate (cGMP) pathway with a broad treatment potential in cardiovascular diseases.

About Bayer's Commitment in Cardiovascular and Kidney Diseases
Bayer is an innovation leader in the area of cardiovascular diseases, with a long-standing commitment to delivering science for a better life by advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer is working in a wide range of therapeutic areas on new treatment approaches for cardiovascular and kidney diseases with high unmet medical needs. Together, this reflects the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cardiovascular diseases are treated.

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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