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News Release

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New Phase III study to investigate expanded use of vericiguat in patients with chronic heart failure with reduced ejection fraction

- New Phase III study VICTOR will assess vericiguat efficacy and safety in patients who have not had a recent worsening heart failure event
- VICTOR expands upon the Phase III VICTORIA study, providing further insight into the use of vericiguat in a broader range of patients with chronic heart failure with reduced ejection fraction

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Berlin, Germany, November 11, 2021 – Bayer and its development partner MSD (a tradename of Merck & Co., Inc., Kenilworth, NJ, USA) today announced the start of VICTOR (VerICiguaT in adults with ChrOnic heart failure and Reduced ejection fraction), a new Phase III cardiovascular study investigating the expanded use of heart failure (HF) treatment vericiguat. The VICTOR study will explore the efficacy of vericiguat in chronic heart failure patients and reduced ejection fraction of 40 percent or less who have not had a recent worsening HF event, a population comparable to those of several other recent heart failure studies.

Based on the VICTORIA study, vericiguat was recently approved in the U.S., Japan, the EU and other countries under the brand name Verquvo™. In the EU it is indicated for symptomatic chronic HF in adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring IV therapy.

“Vericiguat is currently approved in several countries for heart failure patients who have recently experienced a worsening event. This is an area where we recognize a large unmet medical need,” said Dr. Javed Butler, the Patrick H. Lehan Chair in Cardiovascular Research, and professor and chairman of the department of medicine at the University of

Mississippi Medical Center. “With VICTOR, we look forward to assessing the use of vericiguat earlier in the progression of heart failure and evaluating its potential benefit for a broader heart failure population.”

“We are pleased to see the difference that vericiguat has started to make for those living with heart failure. This new Phase III study, VICTOR, reflects our mission to bring that potential benefit to even more patients,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Head of Research and Development. “In addition to this key study, we are committed to gathering further evidence regarding the use of vericiguat.”

Recruitment for the VICTOR trial has begun and is expected to enroll approximately 6,000 adults with chronic HF and reduced ejection fraction of 40 percent or less who have not had a recent worsening HF event, complementary to the VICTORIA study patient population. The primary efficacy endpoint is the time to first event of cardiovascular death or hospitalization for HF (NCT05093933).

Vericiguat is being jointly developed with MSD (a tradename of Merck & Co., Inc., Kenilworth, NJ, USA).

About Vericiguat

Vericiguat 2.5 mg, 5 mg, and 10 mg is an oral once daily stimulator of soluble guanylate cyclase (sGC), an important enzyme in the nitric oxide (NO) signaling pathway. When NO binds to sGC, the enzyme catalyses the synthesis of intracellular cyclic guanosine monophosphate (cGMP), a second messenger that plays a role in the regulation of vascular tone, cardiac contractility, and cardiac remodeling. Heart failure is associated with impaired synthesis of NO and decreased activity of sGC, which may contribute to myocardial and vascular dysfunction. By directly stimulating sGC, independently of and synergistically with NO, vericiguat augments levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation.

About the Worldwide Collaboration between Bayer and MSD

Since October 2014, Bayer and MSD have pursued a worldwide collaboration in the field of sGC modulators. The collaboration brings together two leading companies that have stated their intent to fully evaluate this therapeutic class in areas of unmet medical need. The vericiguat program is being co-developed by Bayer and MSD. MSD has the

commercial rights to vericiguat in the U.S. and Bayer has the exclusive commercial rights in the rest of world. The companies share equally the costs of the development of vericiguat.

About Cardiology at Bayer
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. The cardiology franchise at Bayer already includes a number of products and several other compounds are in various stages of preclinical and clinical development. Together, these products reflect 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. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate 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 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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