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# Phase III VICTORIA study with vericiguat in patients with worsening chronic heart failure meets primary endpoint

- Vericiguat reduced the risk of cardiovascular death or heart failure hospitalization versus placebo when given in combination with available heart failure therapies
- Vericiguat is the first-in-class soluble guanylate cyclase stimulator being developed to treat patients with worsening chronic heart failure

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**Leverkusen, Germany, November 18, 2019** – Bayer announced today that the Phase III study VICTORIA (**V**er**IC**igua**T** gl**O**bal study in patients with heart failure with **R**educed eject**I**on fr**A**ction) evaluating the efficacy and safety of investigational vericiguat versus placebo, in combination with available heart failure therapies in patients with worsening chronic heart failure with reduced ejection fraction (HFrEF), has met the primary endpoint. The findings demonstrate superiority of vericiguat in prolonging the time to first occurrence of the composite endpoint of cardiovascular death or heart failure hospitalization. Vericiguat is being jointly developed with MSD (known as Merck & Co., Inc. in the U.S. and Canada).

“Heart failure affects more than 60 million patients worldwide. Despite advances in therapies and prevention efforts, the cardiovascular event rates remain high,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “There is a high unmet need for new treatment options to reduce the risk of death and hospitalizations. We are pleased with the positive outcome with vericiguat as the first sGC stimulator evaluated in patients with worsening chronic heart failure with reduced ejection fraction.”

“VICTORIA is the first large contemporary outcomes study to focus exclusively on a population with worsening chronic heart failure who have a high risk for cardiovascular mortality and repeated heart failure hospitalizations. We are pleased vericiguat met this primary endpoint and look forward to sharing the detailed findings of the study,” said Dr.

Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories, Merck & Co., Inc., Kenilworth, NJ, USA.

VICTORIA is a randomized, placebo-controlled, parallel-group, multi-center, double-blind Phase III study investigating vericiguat versus placebo in combination with available heart failure therapies in patients with worsening chronic heart failure with reduced ejection fraction (HFrEF) following a decompensation event, defined as HF hospitalization or receiving an intravenous diuretic for HF without hospitalization. The primary endpoint of the study is the composite of time to first occurrence of cardiovascular death or heart failure hospitalization. Secondary endpoints include time to occurrence of cardiovascular death, time to first occurrence of heart failure hospitalization, time to total heart failure hospitalizations (including first and recurrent events), time to the composite of all-cause mortality or heart failure hospitalization, and time to all-cause mortality.

The study enrolled 5,050 patients with HFrEF who were randomized to receive either vericiguat once daily (titrated up to 10mg) or placebo in combination with available heart failure therapies. The study, which was co-sponsored by Merck and Bayer, was conducted in collaboration with the Canadian VIGOUR Centre and the Duke Clinical Research Institute in more than 600 centers in 42 countries including in Europe, Japan, China and the U.S.

The clinical data from VICTORIA will be presented at an upcoming scientific meeting in 2020.

**About Vericiguat**

Vericiguat (BAY 1021189 / MK-1242) is an investigational, oral, once-daily, direct stimulator of the soluble guanylate cyclase (sGC) enzyme. While sGC is important for the function of both the blood vessels and the heart, it is insufficiently stimulated in heart failure patients due to impaired nitric oxide (NO) availability resulting in myocardial and vascular dysfunction. Vericiguat is the first-in-class sGC-stimulator in late-stage clinical development in this indication.

**About Heart Failure**

Heart failure is a highly prevalent chronic condition, affecting more than 60 million people worldwide, characterized by the progressive decline in the heart’s ability to pump enough blood to meet the body’s needs for blood and oxygen. Risk factors include hypertension,

diabetes mellitus, smoking, a past myocardial infarction, and coronary artery disease. Despite advances in therapy and prevention efforts, heart failure remains as malignant as some common cancers. In the U.S. and Europe, 50-60% of hospitalized heart failure patients can be classified as HFrEF. Annually, approximately 30% of patients with symptomatic chronic heart failure will experience worsening of the disease, which is marked by progressive symptoms and/or a recent heart failure event. More than half of patients with worsening chronic HFrEF are rehospitalized within 30 days of the worsening event, and 1 in 5 patients with worsening chronic HFrEF will die within 2 years.

**About Worldwide Collaboration between Bayer and MSD**

Since October 2014, Bayer and MSD (known as Merck & Co., Inc. in the U.S. and Canada) are in 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.

**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 benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2018, the Group employed around 117,000 people and had sales of 39.6

billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 billion euros. For more information, go to 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. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.