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News Release

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Data from Phase III VICTOR clinical trial of vericiguat presented at ESC Congress 2025

- In VICTOR, vericiguat did not meet the primary endpoint of the combined risk of heart failure hospitalization or cardiovascular death in a well-controlled patient population with heart failure with reduced ejection fraction (HFrEF) without a recent heart failure event
- Fewer events of cardiovascular death, a key secondary endpoint, were observed in the vericiguat group
- In a pre-specified pooled analysis of VICTORIA and VICTOR, vericiguat showed a statistically significant risk reduction in cardiovascular death or heart failure hospitalization across the broad spectrum of patients with HFrEF
- The positive benefit-risk profile of vericiguat in its approved indication in patients with HFrEF following a recent heart failure event based on the pivotal Phase III VICTORIA trial remains unchanged

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Berlin, August 30, 2025 – Today, results from the VICTOR Phase III clinical trial with vericiguat (Verquvo™) in patients with chronic heart failure with reduced ejection fraction (HFrEF) without a recent heart failure event were presented at the European Society of Cardiology (ESC) Congress 2025 and simultaneously published in *The Lancet*. Vericiguat when added to guideline-directed medical therapy (GDMT) did not reduce the risk of the primary composite endpoint of heart failure hospitalization or cardiovascular death compared to placebo plus GDMT. Secondary endpoints indicated fewer events of cardiovascular death and all-cause mortality in the vericiguat group compared to placebo on top of GDMT. The overall safety profile of vericiguat in the VICTOR trial was consistent with previous clinical trials.

The positive benefit-risk profile of vericiguat in its approved indication in patients with HFrEF following a recent heart failure event based on the pivotal Phase III VICTORIA trial remains unchanged.

“The VICTOR trial enrolled a very well-treated HFrEF population in a Phase III heart failure trial. 83% of patients were on three or more heart failure therapies and 47.5% of patients had no prior heart failure hospitalization. In this stable patient population, we did see less events in the primary endpoint with vericiguat versus placebo, although this did not reach statistical significance. Secondary endpoints indicated fewer events for vericiguat in cardiovascular death and all-cause mortality compared to the placebo group. Although these results are descriptive, the data on mortality in a well-controlled HFrEF patient population is a positive sign”, said Professor Faiez Zannad, Principal Investigator of VICTOR, cardiologist and clinical pharmacologist, France.

In a pre-specified pooled analysis of VICTORIA and VICTOR with 11,155 HFrEF patients, vericiguat showed a statistically significant risk reduction which was consistent across the primary composite of cardiovascular death or heart failure hospitalization and its components, in a broad spectrum of patients with HFrEF.

About the VICTOR study

VICTOR was a randomized, double-blind, placebo-controlled, multicenter, event-driven phase III study investigating the efficacy and safety of vericiguat (Verquvo™) in adult patients with symptomatic chronic heart failure with reduced ejection fraction (with a left ventricular ejection fraction of ≤40%) without a recent heart failure event during the last six months. Patients (New York Heart Association, NYHA class II-IV) received contemporary guideline-directed medical therapy (GDMT), including SGLT2-inhibitors (59%) and angiotensin receptor-neprilysin inhibitor (ARNI, 56%), at baseline. 6,105 patients were randomized.[1,2]

About Verquvo™ (vericiguat)

Vericiguat is an oral once daily stimulator of soluble guanylate cyclase (sGC), an important enzyme in the NO-sGC-cGMP signaling pathway.[3] Heart failure is associated with impaired synthesis of nitric oxide (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 cyclic guanosine monophosphate (cGMP), leading to smooth muscle relaxation and

vasodilation. In the EU Verquvo (vericiguat) is indicated for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring intravenous therapy.

About the Worldwide Collaboration between Bayer and MSD
Since October 2014, Bayer and MSD (known as Merck & Co., Inc. in the U.S. and Canada) 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. MSD and Bayer AG are co-developers of the VICTOR trial.

About Heart Failure
Heart failure (HF) is characterized by a progressive decline in the heart's ability to pump enough blood to meet the body's needs for blood and oxygen. Heart failure affects more than 64 million people worldwide. This number is projected to increase drastically over the next decade, partly as a consequence of the ageing population. One in five people will develop heart failure. Patients with heart failure face a poor prognosis with mortality rates similar or worse than the most common cancers. Symptoms of HF may include dizziness, shortness of breath, fatigue and sleep disturbance, chest discomfort, edema (swelling of feet and legs), and chronic coughing or wheezing.

Risk factors are hypertension, diabetes mellitus, smoking, a past myocardial infarction, and coronary artery disease. Despite advances in treatment, around 30% of people diagnosed with heart failure will die within a year, increasing to around 40% after five years.

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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[3] Ezekowitz JA *et al. JACC Heart Fail.* 2020;8:931-939