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News Release

Not intended for U.S. and UK Media

U.S. FDA grants priority review to New Drug Application for vericiguat to treat chronic heart failure

Berlin, Germany, July 16, 2020 – Bayer, in collaboration with MSD (a tradename of Merck & Co., Inc., Kenilworth, NJ, USA), announced today that the U.S. Food and Drug Administration (FDA) has accepted for priority review the New Drug Application (NDA) for vericiguat, being developed to treat patients with symptomatic chronic heart failure with an ejection fraction less than 45% following a worsening heart failure event. Vericiguat is being jointly developed with MSD.

This regulatory submission was based on positive data from the Phase III VICTORIA study published in the New England Journal of Medicine in March[1]. A priority review designation means that the FDA´s goal is to take action on an application within 6 months of acceptance (compared to 10 months under standard review). The FDA has set a Prescription Drug User Fee Act (PDUFA) date, or target action date, of January 20, 2021.

“Heart failure is the number one cause of hospitalization for those over the age of 65 and affects more than 60 million people worldwide. Repetitive hospitalization, or sadly even death, is common for heart failure patients as many still experience worsening events despite being treated with existing therapies,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “With this regulatory filing now underway for vericiguat, Bayer and MSD are making strides towards the shared goal of tackling this life-altering disease so that heart failure patients could stay out of hospital and remain healthier for longer.”

The Phase III VICTORIA data were presented at ACC.20/WCC Virtual and published in the New England Journal of Medicine. Vericiguat 10 mg once daily significantly reduced the combined risk of first heart failure hospitalization or cardiovascular death. Based on

these data Bayer submitted vericiguat for marketing authorization in the EU and Japan earlier this year.

About Vericiguat

Vericiguat (BAY 1021189 / MK-1242) is an investigational, oral, once-daily, direct stimulator of the soluble guanylate cyclase (sGC) enzyme. Vericiguat actively restores the functioning of a critical pathway (NO-sGC-cGMP) not addressed by current therapies. While sGC is important for the function of both the blood vessels and the heart, it is insufficiently stimulated in heart failure patients resulting in myocardial and vascular dysfunction. Vericiguat is the first-in-class sGC-stimulator under development in this indication.

About Worldwide Collaboration between Bayer and MSD

Since October 2014, Bayer and MSD (a tradename of Merck & Co., Inc., Kenilworth, NJ, USA) 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 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 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.

Refences
1) Armstrong, P, et al. *Vericiguat in Patients with Heart Failure and Reduced Ejection Fraction*. NEJM, 28 March 2020. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1915928