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News Release

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Vericiguat approved in Japan to treat patients with chronic heart failure

Heart failure affects approximately 1.2 million people in Japan

Berlin, Germany, June 23, 2021 – Bayer announced today that the Ministry of Health, Labour, and Welfare (MHLW) in Japan has approved soluble guanylate cyclase (sGC) stimulator vericiguat under the brand name Verquvo™. Verquvo (vericiguat) 2.5 mg, 5 mg, and 10 mg is approved for the treatment of patients with chronic heart failure who are receiving standard treatment for chronic heart failure. The approval is based on the results of the pivotal Phase III VICTORIA trial, published in The [New England Journal of Medicine](#) (NEJM) in March 2020.

“Heart failure is a life-altering disease which affects approximately 1.2 million people in Japan, a number that continues to rise. It has a serious impact on the lives of patients, their families and loved ones,” said Dr. Michael Devoy, Chief Medical Officer and Head of Medical Affairs and Pharmacovigilance at Bayer’s Pharmaceuticals Division. “Bayer is proud of the approval of vericiguat in Japan and the contribution it has shown in clinical trials.”

Vericiguat is the first sGC stimulator to be approved for the treatment of chronic heart failure. It was studied specifically in patients who have experienced a recent worsening heart failure event, meaning a recent hospitalization for heart failure or the use of intravenous diuretics, in order to reduce the risk of further worsening events. Verquvo (vericiguat) was approved by the U.S. Food and Drug Administration (FDA) in January 2021 and was recommended for marketing authorization by the Committee for Medicinal Products for Human Use (CHMP) in the EU in May 2021. Additionally, it has been

submitted for marketing authorization in China, as well as multiple other countries worldwide.

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 catalyzes 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, which counteracts the impaired function of the heart and blood vessels.

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.

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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