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News Release

Not intended for U.S. and UK Media

Bayer's new symptomatic chronic heart failure treatment Verquvo™ (vericiguat) approved in EU

- Approved for adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring intravenous therapy
- Studied in a population with a high risk of cardiovascular death or heart failure hospitalization
- The sGC-stimulator Verquvo provides a specific approach to managing chronic heart failure following a decompensation event

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Berlin, Germany, July 21, 2021 – The European Commission has granted marketing authorization in the European Union (EU) for vericiguat under the brand name Verquvo™. Verquvo (2.5 mg, 5 mg, and 10 mg), a soluble guanylate cyclase (sGC) stimulator, is indicated for symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring intravenous (IV) therapy. It works differently to existing heart failure treatments, providing a specific approach to managing chronic heart failure patients following a decompensation event, also known as a worsening event.

"With this latest approval, we have the potential to bring new hope to patients living with heart failure, by breaking the cycle of decompensation events, also known as worsening events, and reducing the risk of re-hospitalization," said Dr. Burkert Pieske, professor of internal medicine and cardiology at Charité and principal investigator of the Phase III VICTORIA trial. "Re-hospitalization has a significant impact on both patients and their families, and even when taking guideline-based therapy, many will still experience progressive worsening of symptoms. Therefore, access to a new treatment that has been developed with these patients specifically in mind, is extremely welcome news."

Current therapies block the harmful effects of the natural neurohormonal systems that are activated by the myocardial and vascular dysfunction present in heart failure. Vericiguat works in conjunction with existing approaches through a different mode of action. It specifically restores the deficient NO-sGC-cGMP pathway, which plays a critical role in the progression of heart failure and aggravating its symptoms.

“The approval of Verquvo in the EU represents a significant breakthrough for those living with this condition,” said Dr. Michael Devoy, Chief Medical Officer and Head of Medical Affairs and Pharmacovigilance at Bayer’s Pharmaceuticals Division. “As the leading cause of hospitalization in Europe, it is vital we continue to make such advances to improve patients’ quality of life. Currently half of patients with heart failure are readmitted within 30 days of hospitalization or initiation of intravenous diuretics. We believe availability of Verquvo provides clinicians with a much-needed new option to help alleviate the huge burden of chronic heart failure.”

Verquvo (vericiguat) has been approved by the U.S. Food and Drug Administration (FDA) and the Ministry of Health, Labour, and Welfare (MHLW) in Japan. Vericiguat has also 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 Verquvo™ (vericiguat)

Verquvo 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, 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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