Investor News

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Bayer submits vericiguat for marketing authorization in the EU and Japan for the treatment of chronic heart failure

Regulatory submissions based on positive data from Phase III VICTORIA study recently published in the New England Journal of Medicine[1]

Leverkusen, Germany, June 5, 2020 – Bayer today announced the submission of two regulatory applications seeking the approval of vericiguat in the EU and Japan. Vericiguat is an investigational oral, once-daily, first-in-class soluble guanylate cyclase (sGC)-stimulator being developed to treat patients with symptomatic chronic heart failure with an ejection fraction less than 45% who have had a previous worsening heart failure event (defined as heart failure hospitalization or receiving an intravenous diuretic for heart failure without hospitalization) in combination with available heart failure therapies. Vericiguat is being jointly developed with MSD (a tradename of Merck & Co., Inc., Kenilworth, NJ, USA).

“Despite significant advances in treatment, many patients with heart failure and reduced ejection fraction still experience worsening events – even when taking guideline-based therapy. This reality puts them at an increased risk for frequent heart failure hospitalizations or the need for urgent treatment,” said Paul W. Armstrong, M.D., cardiologist and Distinguished University Professor of Medicine at the Canadian VIGOUR Centre, University of Alberta. “Vericiguat has a specific mechanism of action that distinguishes it from other current heart failure treatments. The absolute risk reduction in heart failure hospitalization and cardiovascular mortality of 4.2 per 100 patient years observed in the VICTORIA data recently presented at ACC.20/WCC Virtual and published in the New England Journal of Medicine is a gratifying result for these heart failure patients. If approved, vericiguat will give clinicians an important and welcome new option to augment existing treatment.”

“For many heart failure patients, worsening events can lead to a downward spiral where prognosis is poor and around 50% sadly die within five years of diagnosis,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “VICTORIA was the first positive contemporary outcomes trial focusing exclusively on a patient population living with symptomatic chronic heart failure with reduced ejection fraction who have had a previous worsening heart failure event. Its findings open the door for new possibilities in the management of chronic heart failure. We look forward to working with the regulatory bodies to make this treatment available in the market as soon as possible.”

The marketing authorization application (MAA) submitted to the European Medicines Agency (EMA) and the new drug application (NDA) submitted to the Ministry of Health, Labor and Welfare (MHLW) in Japan were based on positive Phase III data from the VICTORIA study.

About VICTORIA

VICTORIA is a randomized, placebo-controlled, multi-center, double-blind Phase III study investigating vericiguat compared to placebo when added to currently available heart failure therapies in symptomatic chronic heart failure patients with an ejection fraction less than 45% with a prior worsening event, defined as heart failure hospitalization or receiving an intravenous diuretic for heart failure without hospitalization. The primary endpoint of the study is the composite of time to first occurrence of cardiovascular death or heart failure hospitalization. A greater than two-fold higher annual placebo event rate for the primary endpoint and twice the baseline levels of a clinical marker of disease prognosis (NT-proBNP) put these patients at higher risk for hospitalization or death compared to recent heart failure outcomes trials.

Vericiguat 10 mg once daily significantly reduced the combined risk of heart failure hospitalization and cardiovascular death by 10% (relative risk reduction; HR 0.90; 95% CI (0.82-0.98; p=0.019) compared to placebo; absolute risk reduction (ARR) 4.2 per 100 patient years. In a pre-specified baseline NT-proBNP analysis, patients were divided into four quartiles. The overall treatment benefit was driven by the patients within the lower three quartiles, where relative risk reduction of the primary composite endpoint ranged between 18-27%. Vericiguat was well-tolerated, which is consistent with the safety profile seen in previous studies with vericiguat.

The Phase III VICTORIA study enrolled 5,050 patients with an ejection fraction of <45% 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 MSD 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.

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.

References

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

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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