Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Pivotal Phase III Study Started With Vericiguat in Patients With Chronic Heart Failure

Leverkusen, September 28, 2016 – Bayer announced today that the first patient was enrolled in VICTORIA, a pivotal Phase III clinical study led by Bayer's collaboration partner MSD, which will investigate vericiguat in patients suffering from chronic heart failure with reduced ejection fraction (HFrEF). Vericiguat, discovered at Bayer, is the first soluble guanylate cyclase (sGC) stimulator to be evaluated in patients with deteriorating chronic heart failure. The development and commercialization of vericiguat is part of the worldwide strategic collaboration between Bayer and MSD (through a subsidiary) in the field of sGC modulation. MSD is known under the name of Merck in the U.S. and Canada.

Heart failure (HF) is a serious debilitating condition that is characterized by the progressive decline in the heart's ability to pump enough blood through the body. The global burden of HF is increasing, and the mortality rate remains high. In fact, HF mortality is worse than some cancers, with between 17% and 45% of patients dying within one year of hospitalization for an acute HF event.

"Despite available treatment options, the prognosis for HFrEF patients remains poor, and we need new treatment options," said Paul W. Armstrong, M.D., Founding Director of the Canadian VIGOUR Centre and Distinguished Professor at the University of Alberta, and Chair of the study's Executive Committee. "The VICTORIA study is designed to assess whether the addition of vericiguat on top of best standard of care HF therapy can help restore a vital cardiovascular pathway, thereby improving heart and vascular function and reducing the risk of cardiovascular death or HF hospitalization in patients with deteriorating chronic HF with reduced ejection fraction."

"Currently, one in five people worldwide are expected to develop HF in their lifetime. With the novel compound vericiguat, Bayer and MSD are pursuing a new research approach in this field," said Dr. Jörg Möller, member of the Executive Committee of Bayer AG's

Pharmaceutical Division and Head of Development. “We are excited about vericiguat being the first sGC stimulator to be evaluated in patients with chronic HF.”

“There is a critical need for new treatments, especially for patients with deteriorating HFrEF that slow the progression of disease and improve the standard of care,” said Dan Bloomfield, M.D., Vice President, Cardiovascular Diseases, The research labs of Merck & Co., Inc., Kenilworth, NJ, USA. “The VICTORIA Phase III program will help us determine if vericiguat could have a role in the future of HF treatment in this high-risk population.”

The event-driven Phase III VICTORIA study will assess the efficacy and safety of vericiguat up to 10 mg once daily compared to placebo (on background standard of care treatment) in reducing the risk of cardiovascular death or HF hospitalization in patients with HFrEF following HF hospitalization or receiving an intravenous diuretic without hospitalization. The primary efficacy outcome is the time to first occurrence of the composite endpoint of cardiovascular mortality or HF hospitalization. VICTORIA will enroll approximately 4,900 patients at 530 centres in 39 countries and it is anticipated that the study will take 39 months to complete. VICTORIA is conducted in partnership with the Canadian VIGOUR Centre (CVC) at the University of Alberta and the Duke Clinical Research Institute (DCRI).

The design and dosing of the Phase III VICTORIA study was informed by results from the SOCRATES-REDUCED Phase II trial in 456 patients with HFrEF, which were presented at the 2015 annual meeting of the American Heart Association (AHA) in Orlando, Florida and published in the Journal of the American Medical Association (JAMA).

About Heart Failure

The prevalence of heart failure (HF) has increased progressively over the past several decades owing primarily to a reduction in myocardial infarction mortality and the aging of the world’s population.When categorized by ejection fraction, HF is divided into two different forms, each accounting for approximately 50% of HF patients: heart failure with reduced ejection fraction (HFrEF), also known as systolic heart failure, is characterized by the compromised ability of the heart to eject oxygen rich blood sufficiently during its contraction phase. HFrEF is a final common pathway for many cardiovascular diseases, notably coronary artery disease. Once established, HFrEF progresses through activation of a variety of pathways that adversely affect cardiac structure and function. Currently, the most effective pharmacological therapies for HFrEF target the over-activation of the

renin–angiotensin–aldosterone system and the adrenergic sympathetic nervous system that occurs in HF. However, even with the current treatment options, morbidity and mortality remain high and increase further after episodes of acute decompensation or HF hospitalization. The other form of HF is heart failure with preserved ejection fraction (HFpEF), also known as diastolic heart failure, a condition characterized by stiffness of the heart leading to filling abnormalities and increased pressure in the heart. There is no treatment currently approved for HFpEF.

About Vericiguat

Vericiguat (BAY 1021189 / MK-1242) is an investigational, oral once-daily stimulator of the soluble guanylate cyclase (sGC) enzyme. While sGC is important for the function of both the blood vessels and the heart, it is insufficiently stimulated in heart failure patients due to impaired nitric oxide (NO) availability resulting in systemic vascular and coronary dysfunction. The sGC pathway is being investigated as a potential therapeutic target for the treatment of heart failure, with vericiguat being the first sGC-stimulator under development in this indication.

About Worldwide Collaboration between Bayer and MSD

Since October 2014, the worldwide strategic collaboration with the U.S.-based company MSD (known as Merck in the U.S. and Canada) in the field of sGC modulators brings together the two leading companies in this field, who both have the stated intent to make full use of this investigational class of compounds and the potential it may hold for the benefit of patients. As part of the collaboration, the vericiguat program is being co-developed by Bayer and MSD. While MSD is taking the lead on the Phase III VICTORIA study, the companies are equal partners and funders in the development and commercialization of vericiguat. For vericiguat, MSD has the commercial rights for the Americas and Bayer has the commercial rights to the rest of the world.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of

sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

Bayer AG, Investor Relations contacts:

Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Prof. Dr. Olaf Weber (+49-214-30-33567)