

Merck and Bayer's Investigational Drug Vericiguat Meets Primary Endpoint in Phase 3 Study of Patients with Worsening Chronic Heart Failure

Vericiguat Reduced the Risk of Heart Failure Hospitalization or Cardiovascular Death in Patients with Worsening Chronic Heart Failure with Reduced Ejection Fraction, Compared to Placebo When Added to Available Heart Failure Therapies

November 18, 2019 06:30 AM Eastern Standard Time

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the Phase 3 VICTORIA study evaluating the efficacy and safety of vericiguat, a soluble guanylate cyclase (sGC) stimulator being developed to treat patients with worsening chronic heart failure, has met the primary efficacy endpoint. Vericiguat reduced the risk of the composite endpoint of heart failure hospitalization or cardiovascular death in patients with worsening chronic heart failure with reduced ejection fraction (HFrEF) compared to placebo when given in combination with available heart failure therapies. Vericiguat is being jointly developed with Bayer AG.

“VICTORIA is the first large contemporary outcomes study to focus exclusively on a population with worsening chronic heart failure who have a high risk for cardiovascular mortality and repeated heart failure hospitalizations. We are pleased vericiguat met this primary endpoint and look forward to sharing the detailed findings of the study,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories.

“Heart failure affects more than 60 million patients worldwide. Despite advances in therapies and prevention efforts, the cardiovascular event rates remain high,” said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and head of Research and Development. “There is a high unmet need for new treatment options to reduce the risk of death and hospitalizations. We are pleased with the positive outcome with vericiguat as the first sGC stimulator evaluated in patients with worsening chronic heart failure with reduced ejection fraction.”

The results of the VICTORIA study will be presented at an upcoming medical meeting in 2020.

About the VICTORIA Trial (NCT02861534)

VICTORIA is a randomized, placebo-controlled, parallel-group, multi-center, double-blind, Phase 3 study of vericiguat versus placebo when given in combination with available heart failure therapies in patients with worsening chronic heart failure with reduced ejection fraction (HFrEF) following a decompensation 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. Secondary

endpoints include time to occurrence of cardiovascular death, time to first occurrence of heart failure hospitalization, time to total heart failure hospitalizations (including first and recurrent events), time to the composite of all-cause mortality or heart failure hospitalization, and time to all-cause mortality. The study enrolled 5,050 patients who were randomized to receive either vericiguat once daily (titrated up to 10 mg) or placebo when given in combination with available heart failure therapies. The study, which was co-sponsored by Merck 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.

About Heart Failure With Reduced Ejection Fraction

Heart failure with reduced ejection fraction (HFrEF), formerly known as systolic heart failure, is characterized by the compromised ability of the heart to eject blood sufficiently during its contraction phase. In the U.S., 6.5 million people have heart failure, and approximately 40-50% of these patients have HFrEF. Annually, approximately 30% of patients with symptomatic chronic heart failure will experience worsening of the disease, which is marked by progressive symptoms and/or a recent heart failure event. Approximately half of patients with worsening chronic HFrEF are rehospitalized within 30 days of the worsening event, and an estimated one in five patients with worsening chronic HFrEF will die within two years.

About the Worldwide Collaboration Between Bayer and Merck

Since October 2014, Bayer and Merck (known as MSD outside of the United States and Canada) 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 Merck.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions

of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2018 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).