NEWS RELEASE

FDA Grants Priority Review to Merck's New Drug Application for Vericiguat

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Application Based on First Contemporary Outcomes Study Focused Exclusively on Chronic Heart Failure Patient Population Following a Worsening Event

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has accepted for priority review the New Drug Application (NDA) for vericiguat, an orally administered soluble guanylate cyclase (sGC) stimulator, to reduce the risk of cardiovascular death and heart failure hospitalization following a worsening heart failure event in patients with symptomatic chronic heart failure with reduced ejection fraction (HFrEF), in combination with other heart failure therapies. The FDA has set a Prescription Drug User Fee Act (PDUFA), or target action date, of Jan. 20, 2021. Vericiguat is being jointly developed with Bayer AG.

"This submission builds on Merck's commitment to patients with cardiovascular disease and long legacy of advancing cardiovascular research to meet unmet medical needs," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "We look forward to working with the FDA as they review this New Drug Application for vericiguat."

The application is based on results from the Phase 3 VICTORIA trial, which is the first contemporary outcomes study focused exclusively on a population with worsening chronic heart failure who are at high risk for cardiovascular mortality and repeated heart failure hospitalizations. Data from VICTORIA were presented at the virtual American College of Cardiology's 69th Annual Scientific Session together with World Congress of Cardiology (ACC.20/WCC) and published in The New England Journal of Medicine.

About the VICTORIA Trial

VICTORIA (**NCT02861534**) 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 (New York Heart Association class II-IV), a reduced left ventricular ejection fraction of <45% within 12 months prior to randomization following a decompensation event. The primary endpoint of the study was the composite of time to first occurrence of heart failure hospitalization or cardiovascular death. Secondary endpoints included 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 a total of 5,050 patients who were randomly selected to receive either vericiguat once daily (titrated up to 10 mg) or placebo when given in combination with available heart failure therapies. The study was co-sponsored by Merck and Bayer, conducted under the scientific oversight of the Canadian VIGOUR Centre and the Duke Clinical Research Institute, and executed by Merck in more than 600 centers in 42 countries including in Europe, Japan, China and the U.S.

About 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 a 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) 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 Merck.

About Merck

For more than 125 years, Merck, 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 in pursuit of our

mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

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 the recent global outbreak of novel coronavirus disease (COVID-19); 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 2019 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**).

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Media
Pamela Eisele, (267) 305-3558

Elizabeth Sell, (267) 305-3877

Investor
Peter Dannenbaum, (908) 740-1037
Michael DeCarbo, (908) 740-1807

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