NEWS RELEASE

Merck Announces Initiation of Phase 3 Study Evaluating VERQUVO® (vericiguat) in Patients with Chronic Heart Failure and Reduced Ejection Fraction Who Have Not Had a Recent Worsening Heart Failure Event

11/11/2021

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the initiation of VICTOR (VerICiguaT in adults withChrOnicheart failure and Reduced ejection fraction), a pivotal Phase 3 randomized, placebo-controlled cardiovascular clinical trial of VERQUVO® (vericiguat) in patients with chronic heart failure and reduced ejection fraction of 40% or less who have not had a recent worsening heart failure event.

Recruitment for the VICTOR trial has begun. The study is slated to enroll approximately 6,000 adults with chronic heart failure and reduced ejection fraction who have not been hospitalized for heart failure for 6 months or received outpatient IV diuretic use within 3 months prior to randomization. The primary efficacy endpoint is the time to first event of cardiovascular death or hospitalization for heart failure (**NCT05093933**).

Based on the VICTORIA study, VERQUVO (vericiguat) was approved by the U.S. Food and Drug Administration (FDA) in January 2021 to reduce the risk of cardiovascular death (CVD) and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient intravenous (IV) diuretics, in adults with symptomatic chronic heart failure and ejection fraction less than 45%. The VERQUVO label contains a boxed warning that indicates that VERQUVO should not be administered to pregnant females because it may cause fetal harm. For more information, see “Selected Safety Information” below.

“The VICTOR study will assess initiating vericiguat earlier in the heart failure journeys of certain patients,” said Dr. Javed Butler, the Patrick H. Lehan Chair in Cardiovascular Research, and professor and chairman of the department of medicine at the University of Mississippi Medical Center.

Like the VICTORIA trial, Merck and Bayer AG will serve as co-sponsors for the VICTOR trial. The study will be executed by Merck. VICTOR is expected to take 39 months to complete, and the trial will include patients from 34 countries at approximately 500 sites around the world. Every effort is being made to ensure that the patient population studied in the trial represents the diverse nature of people who may be diagnosed with chronic heart failure and reduced ejection fraction of less than 40% who have not had a recent worsening heart failure event.

“The initiation of the Phase 3 VICTOR study reflects our commitment to finding additional options for a chronic heart failure condition that affects more than 3 million people in the U.S. each year,” said Dr. Joerg Koglin, vice president, Global Clinical Development and Therapeutic Area Head, Cardiovascular for Merck Research Laboratories. “Along with our partners at Bayer, we look forward to studying vericiguat in a more stable chronic heart failure population than was studied in the Phase 3 VICTORIA study.”

Selected Safety Information for VERQUVO (vericiguat) tablets (2.5 mg, 5 mg, and 10 mg)

WARNING: EMBRYO-FETAL TOXICITY

Females of reproductive potential: Exclude pregnancy before the start of treatment. To prevent pregnancy, females of reproductive potential must use effective forms of contraception during treatment and for one month after stopping treatment. Do not administer VERQUVO to a pregnant female because it may cause fetal harm.

VERQUVO is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators. VERQUVO is contraindicated in pregnancy. Based on data from animal reproduction studies, VERQUVO may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to a fetus. Obtain a pregnancy test before the start of treatment. Advise females of reproductive potential to use effective contraception during treatment with VERQUVO and for at least one month after the final dose.

In a clinical trial, the most commonly observed adverse events with VERQUVO vs placebo, occurring at a frequency greater than or equal to 5%, were hypotension (16% vs 15%) and anemia (10% vs 7%).

Concomitant use of VERQUVO with PDE-5 inhibitors is not recommended because of the potential for hypotension.

There are no data on the presence of VERQUVO in human milk, the effects on the breastfed infant, or effects on milk production. Because of the potential for serious adverse reactions in breastfed infants from VERQUVO, advise

women not to breastfeed during treatment with VERQUVO.

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 pump blood sufficiently during its contraction phase. In the U.S., approximately 6.2 million adults (20 years of age and older) have heart failure, and approximately 50% of heart failure patients have HFrEF. An observational, cohort analysis of PINNACLE registry data showed that 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 Merck

For more than 130 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 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 2020 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**).

Please see Prescribing Information, including Boxed Warning, for VERQUVO (vericiguat) at **https://www.merck.com/product/usa/pi_circulars/v/verquvo/verquvo_pi.pdf** and Medication Guide at **https://www.merck.com/product/usa/pi_circulars/v/verquvo/verquvo_mg.pdf**.

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Source: Merck & Co., Inc.