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NEWS RELEASE

VERQUVO® (vericiguat) Approved in the European Union

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European Approval Granted to Bayer Marks Another Important Milestone for VERQUVO

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the European Commission (EC) has granted marketing authorization in the European Union (EU) for soluble guanylate cyclase (sGC) stimulator VERQUVO® (vericiguat). In the EU, VERQUVO (2.5 mg, 5 mg, and 10 mg) is indicated for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring intravenous (IV) therapy. VERQUVO is being jointly developed by Merck and Bayer AG. Merck has the commercial rights to VERQUVO in the United States and Bayer has the exclusive commercial rights in the rest of world. Bayer also issued a news release earlier today announcing the EC approval.

In January of this year, the U.S. Food and Drug Administration (FDA) approved VERQUVO in the U.S. to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics in adults with symptomatic chronic heart failure and ejection fraction less than 45%. In the U.S., the product label for VERQUVO 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. In June, the medicine was approved by the Ministry of Health, Labour, and Welfare (MHLW) in Japan. Bayer has also submitted applications for marketing authorization of the medicine in China as well as multiple other countries worldwide.

“This announcement reflects another important regulatory milestone in the development of this medicine,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research

Laboratories. “The approval of VERQUVO in the EU will provide doctors, health care professionals and patients with an important treatment option to complement currently available heart failure therapies.”

About VERQUVO® (vericiguat) tablets for once daily oral use (2.5 mg, 5 mg and 10 mg)

VERQUVO is a stimulator of soluble guanylate cyclase (sGC), an important enzyme in the nitric oxide (NO) signaling pathway. When NO binds to sGC, the enzyme catalyzes the synthesis of intracellular cyclic guanosine monophosphate (cGMP), a second messenger that plays a role in the regulation of vascular tone, cardiac contractility, and cardiac remodeling. Heart failure is associated with impaired synthesis of NO and decreased activity of sGC, which may contribute to myocardial and vascular dysfunction. By directly stimulating sGC, independently of and synergistically with NO, vericiguat augments levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation.

Selected Safety Information for VERQUVO in the United States

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 the Worldwide Collaboration Between Bayer and Merck

Since October 2014, Bayer and Merck 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. Merck has the commercial rights to vericiguat in the U.S. and Bayer has the exclusive commercial rights in the rest of world. The companies share equally the costs of the development of vericiguat.

About Merck

For 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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Media Contacts:
Melissa Moody
(215) 407-3536

Skip Irvine
(267) 305 0338

Investor Contact:
Peter Dannenbaum
(908) 740-1037

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