



NEWS RELEASE

Merck Demonstrates Ongoing Commitment to Advancing Cardiovascular Disease Management and Patient Care with New Data at the European Society of Cardiology Congress 2025

2025-08-25

New real-world evidence and clinical trial data provide insights into treatment patterns for several serious cardiovascular diseases, including ASCVD, PH, and HFrEF

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced that new clinical trial and outcomes research data will be presented at the European Society of Cardiology Congress (ESC) 2025 in Madrid, Spain from August 29 – September 1. Data presented at ESC include Merck's latest research focusing on atherosclerotic cardiovascular disease (ASCVD), pulmonary hypertension (PH), and heart failure with reduced ejection fraction (HFrEF).

"Cardiovascular disease remains the leading cause of death worldwide, and Merck is committed to addressing this urgent public health challenge through research and innovative science," said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. "At this year's congress, the data we are presenting reflect our continued commitment to advancing cardiovascular research with the goal of improving outcomes for patients at risk around the world."

Merck will share two oral presentations focused on the treatment patterns and burdens for patients living with ASCVD. The first presentation evaluates the clinical and economic burden on patients with and without myocardial infarction using a nationwide 10-year registry; the second explores temporal trends in lipid-lowering therapy utilization in a large-scale patient population with ASCVD. These data demonstrate Merck's commitment to

advancing research focused on patients living with ASCVD and highlight opportunities for improved disease management in a real-world setting.

Key details on clinical trial research for WINREVAIR™ (sotatercept-csrk) in PH will be shared. The rationale and design of the Phase 2 study CADENCE in adults with combined post- and precapillary pulmonary hypertension (Cpc-PH) associated with heart failure with preserved ejection fraction (HFpEF) will be featured. Additionally, results from the ZENITH trial describing the effect of WINREVAIR on hemodynamics in high-risk pulmonary arterial hypertension (PAH) will also be presented.

Merck will also share two hot line oral presentations and two supplementary poster presentations evaluating VERQUVO® (vericiguat) in adult patients with HFpEF from the VICTOR trial and a pooled-analysis of the VICTOR and VICTORIA trials, along with real-world analyses.

Details on Merck-sponsored symposia at ESC in Madrid:

Merck will host three symposia throughout the congress. A symposium on Sunday, August 31 from 9:15 – 10:00 a.m. ET/15:15 – 16:00 p.m. CEST (Room Yerevan, North Convention Center) will focus on how learnings from LDL-C cumulative exposure and ASCVD risk continuum perspective could impact clinical practice in hyperlipidemia management. The importance of early and lower LDL-C goal attainment in ASCVD to prevent CV outcomes will also be discussed. Other Merck-hosted symposia focus on treating PAH by reverse remodeling and RV function improvement (Sunday, August 31 from 9:15 – 10:00 a.m. ET/15:15 – 16:00 p.m. CEST in Room Algiers, Hall 7) and a patient advocacy event discussing barriers and challenges in CVD (Friday, August 29 from 4:00 – 4:45 a.m. ET/10:00 – 10:45 a.m. CEST in Room Nicosia, North Convention Center).

In addition to the three symposia, Merck is one of the sponsors of the ESC Cardiovascular Health Check, an opportunity for on-site attendees to participate in a free cardiovascular risk screening via comprehensive blood testing including total cholesterol, LDL-cholesterol, Lp(a), triglycerides, HbA1c as well as BMI, blood pressure and more.

Details on Merck abstracts at ESC:

ASCVD	
Temporal trends in lipid-lowering therapy utilization among ASCVD patients: a large-scale database analysis. M. Goldberg	Abstract #83219, Oral abstract session: Friday, August 29, 3:30 a.m. ET/9:30 a.m. CEST
Clinical and economic burden of patients with and without myocardial infarction: a contemporary nationwide 10-year registry comparison. C. Reitan	Abstract #82314, Oral abstract session: Sunday, August 31, 7:15 a.m. ET/13:15 p.m. CEST



PH	
Rationale and design of the CADENCE trial: Evaluating sotatercept in Cpc-PH secondary to HFpEF. A. Urbinati	Abstract #83974, Poster session: Monday, September 1, 4:15 – 4:45 a.m. ET/10:00 – 10:45 a.m. CEST
Sotatercept Improves Hemodynamics in High-Risk Pulmonary Arterial Hypertension (PAH): Results from ZENITH Trial. V. McLaughlin	Abstract #7382, Poster session: Saturday, August 30, 6:30 – 7:15 a.m. ET; 12:30 – 13:15 p.m. CEST

Heart Failure	
Residual risk of hospitalization & all-cause mortality among patients with heart failure with reduced ejection fraction without worsening heart failure who received guideline-directed medical therapy. A. Stevenson	Abstract #85697, Moderated ePoster session: Friday, August 29, 3:15 – 4:00 a.m. ET/9:15 – 10:00 a.m. CEST
Dose titration among patients receiving vericiguat in real-world clinical practice and association with clinical outcomes and health care resource use. A. Ambrosy	Abstract #85842, Moderated ePoster session: Friday, August 29, 3:15 – 4:00 a.m. ET/9:15 – 10:00 a.m. CEST
Guideline-directed medication therapy use among patients with HFrEF receiving vericiguat: comparing findings from a real-world study to clinical trials. A. Ambrosy	Abstract #85837, Moderated ePoster session: Friday, August 29, 3:15 – 4:00 a.m. ET/9:15 – 10:00 a.m. CEST
VICTOR: Vericiguat Global Study in Participants with Chronic Heart Failure. F. Zannad	Abstract #7316, Hot line oral session: Saturday, August 30, 2:33 a.m. ET/8:33 a.m. CEST
VICTOR: Vericiguat Global Study in Participants with Chronic Heart Failure and VICTORIA: Vericiguat Global Study in Subjects with Heart Failure with Reduced Ejection Fraction. J. Butler	Abstract #7319, Hot line oral session: Saturday, August 30, 2:43 a.m. ET/8:43 a.m. CEST
Effect of vericiguat on mortality in ambulatory patients with heart failure and reduced ejection fraction: VICTOR Trial Prespecified Analysis. J. Butler	Abstract #7315, Moderated ePoster session: Monday, September 1, 5:15 – 6:00 a.m. ET/11:15 a.m. – 12:00 p.m. CEST
Effect of vericiguat on heart failure hospitalisation events in ambulatory patients with heart failure and reduced ejection fraction: VICTOR Trial Prespecified Analysis. F. Zannad	Abstract #7314, Moderated ePoster session: Monday, September 1, 5:15 – 6:00 a.m. ET/11:15 a.m. – 12:00 p.m. CEST

Merck's focus on cardiovascular disease

Merck has a long history of making an impact in cardiovascular disease. More than 60 years ago, we introduced our first cardiovascular therapy – and our scientific efforts to understand cardiovascular-related disorders have continued. Cardiovascular disease continues to be one of the most serious health challenges, and approximately 19 million people across the globe die every year.

At Merck, we strive for scientific excellence and innovation in all stages of research, from discovery through approval and life cycle management. We work with experts throughout the cardiovascular and pulmonary community to advance research that can help improve the lives of patients globally.

About atherosclerotic cardiovascular disease

Atherosclerotic cardiovascular disease (ASCVD) is a condition caused by the buildup of plaque within the arteries, leading to narrowed or blocked blood vessels that can result in serious cardiovascular events. ASCVD includes conditions such as coronary artery disease, peripheral artery disease, and cerebrovascular disease. It is a leading cause of death worldwide, contributing to the majority of heart attacks and strokes. Despite advances in prevention and treatment, ASCVD continues to pose a significant public health burden, underscoring the need for early identification, lifestyle modification, and medical management.

About WINREVAIR™ (sotatercept-csrk) for injection, for subcutaneous use, 45 mg, 60 mg

WINREVAIR is FDA-approved for the treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1 PH) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events. WINREVAIR is the first activin signaling inhibitor therapy approved to treat PAH. WINREVAIR improves the balance between pro-proliferative and anti-proliferative signaling to modulate vascular proliferation. In preclinical models, WINREVAIR induced cellular changes that were associated with thinner vessel walls, partial reversal of right ventricular remodeling, and improved hemodynamics.

WINREVAIR is the subject of a licensing agreement with Bristol Myers Squibb.

Selected Safety Information for WINREVAIR in the U.S.

WINREVAIR may increase hemoglobin (Hgb). Severe erythrocytosis may increase the risk of thromboembolic events or hyperviscosity syndrome. Monitor Hgb before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter, to determine if dose adjustments are required.

WINREVAIR may decrease platelet count. Severe thrombocytopenia may increase the risk of bleeding. Thrombocytopenia occurred more frequently in patients also receiving prostacyclin infusion. Do not initiate treatment if platelet count is $<50,000/\text{mm}^3$. Monitor platelets before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter to determine whether dose adjustments are required.

In clinical studies, serious bleeding (eg, gastrointestinal, intracranial hemorrhage) was reported in 4% of patients taking WINREVAIR and 1% of patients taking placebo. Patients with serious bleeding were more likely to be on prostacyclin background therapy and/or antithrombotic agents, or with low platelet counts. Advise patients about signs and symptoms of blood loss. Do not administer WINREVAIR if the patient is experiencing serious bleeding.

WINREVAIR may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use an effective method of contraception during treatment with WINREVAIR and for at least 4 months after the final dose. Pregnancy testing is recommended for females of reproductive potential before starting WINREVAIR treatment.

Based on findings in animals, WINREVAIR may impair female and male fertility. Advise patients on the potential effects on fertility.

The most common adverse reactions occurring in the phase 3 clinical trial ($\geq 10\%$ for WINREVAIR and at least 5% more than placebo) were headache (24.5% vs 17.5%), epistaxis (22.1% vs 1.9%), rash (20.2% vs 8.1%), telangiectasia

(16.6% vs 4.4%), diarrhea (15.3% vs 10.0%), dizziness (14.7% vs 6.2%), and erythema (13.5% vs 3.1%).

Because of the potential for serious adverse reactions in the breastfed child, advise patients that breastfeeding is not recommended during treatment with WINREVAIR, and for 4 months after the final dose.

About PAH

Pulmonary arterial hypertension (PAH) is a rare, progressive and life-threatening blood vessel disorder characterized by the constriction of small pulmonary arteries and elevated blood pressure in the pulmonary circulation. Approximately 90,000 people worldwide are living with PAH. The disease progresses rapidly for many patients. PAH results in significant strain on the heart, leading to limited physical activity, heart failure and reduced life expectancy. The five-year mortality rate for patients with PAH is approximately 43%.

About VERQUVO® (vericiguat)

VERQUVO is an oral once daily 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, VERQUVO augments levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation.

VERQUVO is FDA-approved to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for HF or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

Selected Safety Information for VERQUVO 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 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. 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

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of

research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.msd.com and connect with us on **X (formerly Twitter)**, **LinkedIn** and **YouTube**.

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

This news release of Merck & Co., Inc., Rahway, 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 candidates that the candidates 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 Annual Report on Form 10-K for the year ended December 31, 2024 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 for WINREVAIR (sotatercept-csrk) at http://www.merck.com/product/usa/pi_circulars/w/winrevair/winrevair_pi.pdf, Patient Information for WINREVAIR at http://www.merck.com/product/usa/pi_circulars/w/winrevair/winrevair_ppi.pdf, and Instructions for Use for WINREVAIR (1-vial kit, 2-vial kit) at https://www.merck.com/product/usa/pi_circulars/w/winrevair/winrevair_ifu_1-vial_2-vial_kits.pdf.

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.

Media Contacts:

Julie Cunningham
(617) 519-6264

Elizabeth Sell
(484) 698-9978

Investor Contacts:

Peter Dannenbaum
(732) 594-1579

Steven Graziano
(732) 594-1583

Source: Merck & Co., Inc.