NEWS RELEASE

Merck to Present New Data from Its Innovative Cardio-Pulmonary Pipeline and Portfolio at AHA Scientific Sessions 2025

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Results from the Phase 3 CORALreef Lipids and HeFH trials of investigational oral PCSK9 inhibitor enlicitide decanoate will be presented for the first time

Presentations across hypercholesterolemia and pulmonary arterial hypertension (PAH) underscore Merck's continued commitment to research with the goal of helping address the cardiovascular (CV) epidemic and significant burden of cardio-pulmonary diseases on public health

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced plans to present new research from the company's cardio-pulmonary portfolio and pipeline at the American Heart Association (AHA) Scientific Sessions 2025 in New Orleans, La., from November 7–10. Data presented at AHA highlight Merck's continued dedication to advancing research across hypercholesterolemia and pulmonary arterial hypertension (PAH) to help address the global burden of cardio-pulmonary diseases.

Key data being presented:

- First presentation of detailed findings from the pivotal Phase 3 CORALreef Lipids trial, the largest study of enlicitide decanoate reported to date, evaluating the safety and efficacy of enlicitide, an investigational, once-daily oral proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor, in adults with hypercholesterolemia and a history of a major atherosclerotic cardiovascular disease (ASCVD) event or at increased risk for a first

event

- First presentation of detailed findings from the Phase 3 CORALreef HeFH trial evaluating the safety and efficacy of enlicitide in adults with heterozygous familial hypercholesterolemia (HeFH) who have a history of or were at risk for a major ASCVD event
- Pooled analysis of the PULSAR, STELLAR and ZENITH trials evaluating mortality and major morbidity outcomes in adults with PAH treated with WINREVAIR™ (sotatercept-csrk)

“AHA will be an important moment: for the first time, clinicians will see results from two pivotal trials from the Phase 3 clinical program for enlicitide and, if approved, the potential for an oral PCSK9 inhibitor to help address the significant burden of hypercholesterolemia,” said Dr. Joerg Koglin, senior vice president, head of general and specialty medicine, global clinical development, Merck Research Laboratories. “Cardiovascular disease continues to be the leading cause of death worldwide, and atherosclerotic cardiovascular disease accounts for the vast majority of those CV deaths. Merck continues to advance research to help address this CV epidemic and our work in LDL-C – one of the major modifiable risk factors for atherosclerosis – is an important part of our efforts.”

Merck investor event

Merck will hold an Investor Event to coincide with the AHA Scientific Sessions 2025 on Sunday, Nov. 9, 2025, 6:00 p.m. CT, during which senior management will provide an update on the company’s cardio-pulmonary strategy and program. The event will take place in New Orleans, La., and will be accessible via webcast. Investors, analysts, members of the media and the general public are invited to listen to a webcast of the presentation via this **weblink**. Participants may join the call by dialing (800) 369-2154 (U.S. and Canada Toll-Free) or (517) 308-9422 and using the access code 6979269.

Details on Merck abstracts at AHA Scientific Sessions:

Hypercholesterolemia	
Efficacy and safety of enlicitide, an oral PCSK9 inhibitor, for lowering LDL cholesterol in adults with or at-risk for ASCVD: the Phase 3 CORALreef Lipids trial. A. Navar.	Abstract #4391578, Oral abstract session: Saturday, Nov. 8, 2:30 p.m. ET/1:30 p.m. CT
Enlicitide decanoate, an oral PCSK9 inhibitor, in participants with heterozygous familial hypercholesterolemia: a Phase 3, double-blind, randomized placebo-controlled trial. C. Ballantyne.	Abstract #4391641 Moderated digital poster: Sunday, Nov. 9, 5:00 p.m. ET/4:00 p.m. CT
A 50% or greater reduction in LDL-cholesterol is associated with improved long-term outcomes and lower healthcare utilization after myocardial infarction – a SWEDEHEART study. A. Watanabe.	Abstract #4359798, Poster: Sunday, Nov. 9, 4:15 p.m. ET/3:15 p.m. CT
Excess cardiovascular events and healthcare resource utilization with lack of lipid lowering therapy in U.S. adults with or at risk of ASCVD. P. Muntner.	Abstract #4341629, Moderated digital poster: Monday, Nov. 10, 3:13 p.m. ET/2:13 p.m. CT
Healthcare resource use (HCRU) and costs differ between those with and without follow-up LDL-C monitoring after newly initiating lipid lowering therapy (LLT). L. Bash.	Abstract #4365782, Poster: Saturday, Nov. 8, 11:30 a.m. ET/10:30 a.m. CT

PAH	
Effect of sotatercept on mortality and major morbidity outcomes in patients with pulmonary arterial hypertension: pooled analysis of the PULSAR, STELLAR, and ZENITH trials. V. McLaughlin.	Abstract #4387511, Oral abstract session: Saturday, Nov. 8, 11:30 a.m. ET/10:30 a.m. CT

About enlicitide and PCSK9

Enlicitide has the potential to be the first FDA approved oral PCSK9 inhibitor. It is designed to lower LDL-C via the same biological mechanism as currently approved monoclonal antibody, injectable PCSK9 inhibitors but in a daily pill form. Enlicitide is a novel small molecule macrocyclic peptide candidate that binds to PCSK9 and inhibits the interaction of PCSK9 with LDL receptors.

PCSK9 plays a key role in cholesterol homeostasis by regulating levels of the LDL receptor, which is responsible for the uptake of cholesterol into cells. Inhibition of PCSK9 is designed to prevent the interaction of PCSK9 with LDL receptors. This results in greater numbers of LDL receptors available on the cell surface to remove LDL cholesterol from the blood.

The efficacy and safety profile of enlicitide are being evaluated through the comprehensive **CORALreef Clinical Trial program**.

About hypercholesterolemia

Hypercholesterolemia, a type of hyperlipidemia, is a disorder in which there are elevated low density lipoprotein (LDL) cholesterol levels in the blood. It affects approximately 86 million adults in the U.S. and is a major risk factor for ASCVD. Nearly 70% of people with ASCVD who are treated with lipid lowering therapies do not reach target LDL cholesterol levels. High LDL cholesterol, if left untreated, can lead to ASCVD events such as heart attacks and strokes.

About the CV epidemic and atherosclerotic cardiovascular disease

The silent CV epidemic is the leading cause of deaths globally, contributing to the majority of heart attacks and strokes, and deaths related to CV continue to rise. Atherosclerotic cardiovascular disease (ASCVD) accounts for 85% of CV deaths. It is a condition caused by the buildup of plaque within the arteries, leading to narrowed or blocked blood vessels that can result in serious CV events such as heart attacks and strokes. In addition to these serious events, ASCVD can also lead to coronary artery disease, peripheral artery disease and cerebrovascular disease.

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, WHO Group 1)

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

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/mm3. 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 (e.g., 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 have 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 (≥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 40,000 people in the U.S. 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%.

Merck's focus on cardiovascular disease

Merck has a long history of developing treatments for cardiovascular disease. Nearly 70 years ago, we introduced our first cardiovascular therapy—and our scientific efforts to understand and treat cardiovascular-related disorders have continued. Cardiovascular disease continues to be one of the most serious health challenges of the 21st century and is the leading cause of death worldwide. Approximately 18 million people across the globe die from cardiovascular disease every year; in the United States, one person dies every 36 seconds from cardiovascular disease.

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.

Information for other currently enrolling cardiovascular studies can be found by visiting: **https://www.merckclinicaltrials.com/cardiovascular**.

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.merck.com** and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

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**.

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