



AMGEN'S REPATHA® REDUCES RISK OF DEATH IN PATIENTS AT HIGH RISK FOR A FIRST HEART ATTACK OR STROKE

August 31, 2026

Repatha is the First and Only PCSK9 Inhibitor Shown to Lower the Risk of Dying from All Causes, Including Cardiovascular Events, in High-Risk Primary Prevention Patients in a Phase 3 Trial

Separate Global Real-World Analyses Show Persistent Gaps in Lipid Management, With Many High-Risk Patients Undertreated and Not Achieving Recommended LDL-C Goals

THOUSAND OAKS, Calif., Aug. 31, 2026 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced new findings showing Repatha® (evolocumab) reduced the risk of death in high-risk adults without a prior heart attack or stroke when added to statins or other low-density lipoprotein cholesterol (LDL-C)-lowering treatments. The results are from a pre-specified analysis of the Phase 3 VESALIUS-CV trial and were presented in a late-breaking science session at the European Society of Cardiology (ESC) Congress 2026 in Munich, Germany. They were also simultaneously [published](#) in *Circulation*.

In a study of more than 12,000 high-risk patients, Repatha helped reduce the risk of dying by 20%. Treatment with Repatha led to meaningful reductions both in overall deaths and cardiovascular deaths in this pre-specified secondary analysis of VESALIUS-CV. By helping prevent major cardiovascular events, such as heart attacks and strokes, Repatha may extend life by helping patients avoid the serious health decline that can follow, contributing to fewer deaths overall. The reduction in deaths began to appear after approximately 1.5 years of treatment and continued through a median follow-up of 4.6 years.

"For people at high risk of a heart attack or stroke, lowering LDL-C or 'bad' cholesterol with Repatha may do more than help prevent these events; it may also reduce the risk of dying from heart disease and its serious consequences," said Jay Bradner, M.D., executive vice president, Research and Development, Artificial Intelligence and Data at Amgen. "This is especially significant given cardiovascular disease remains the leading cause of death worldwide. The totality of these data is practice-changing and reinforces the importance of identifying high-risk patients early and lowering LDL-C aggressively and consistently with Repatha."

Additional VESALIUS-CV and Real-World Analyses Reinforce the Need for Earlier, Intensive LDL-C Lowering in High-Risk Patients

The mortality findings were accompanied by two additional VESALIUS-CV analyses. One analysis showed that Repatha reduced the risk of first, subsequent and total CV events. The other analysis showed that the reduced risk of heart attack with Repatha was seen as early as six months after initiating treatment. The reduction in risk was primarily driven by a decrease in heart attacks caused by a rupture of atherosclerotic plaque (type 1) and larger infarctions. In both analyses, benefits were consistent across key patient subgroups, adding to the growing body of evidence supporting the importance of earlier LDL-C lowering with Repatha in high-risk patients.

"These analyses reinforce that a patient's first major cardiovascular event is not merely an isolated occurrence, but often a transition to a higher risk state," said Marc S. Sabatine, M.D., M.P.H., Chair of the TIMI Study Group and the Lewis Dexter, MD, Endowed Chair in Cardiovascular Medicine at Mass General Brigham Heart & Vascular Institute. "Evolocumab reduced not only first cardiovascular events, but also subsequent events during the course of the study, the latter of which almost doubled the number of events prevented. By preventing these events, evolocumab can alter the patient's trajectory, with lower rates of all-cause mortality and consistent effects for both cardiovascular and non-cardiovascular mortality. Together, these data support the large clinical benefit of intensive LDL-C lowering with evolocumab down to ~40 mg/dL to help prevent cardiovascular morbidity and mortality."

Amgen also presented results from two global real-world studies highlighting persistent gaps between guideline recommendations and everyday lipid management. One study found that patients with coronary artery disease and no prior heart attack or stroke were often undertreated and did not achieve recommended LDL-C levels, reflecting low rates of treatment initiation, intensification and monitoring.

The second study highlighted disparities observed in cardiovascular care between sexes, showing that women at high risk with no prior heart attack or stroke were less likely than men to receive intensive lipid-lowering treatment and achieve LDL-C goals across regions. These studies underscore an urgent need for timely, more intensive lipid-lowering treatment to help reduce the risk of a first major cardiovascular event.

For more information about the data presented at ESC, see below:

Amgen Abstracts

- **Effects of Evolocumab on Fatal Outcomes in Patients Without a Prior Myocardial Infarction or Stroke: Pre-specified Analysis of the VESALIUS-CV Trial**
Abstract #87624, Monday, August 31 from 9:15 - 9:30 a.m. CEST
- **Sex Differences in Lipid Management Among High-Risk Patients Without Prior Myocardial Infarction or Stroke: Results from the VESALIUS-REAL Global Study**
Abstract #83602, Monday, August 31 from 12:10 - 12:20 p.m. CEST
- **Real World Evaluation of Lipoprotein (a) Testing and Impact on Lipid Management in Atherosclerotic Cardiovascular Disease Patients: Findings from the CVMOBIOUS2 Registry**
Abstract #82835, Presented Sunday, August 30

- **Reduction in Total Cardiovascular Events with Evolocumab in Patients with No Prior Myocardial Infarction or Stroke: A Pre-Specified Analysis of VESALIUS-CV**
Abstract #85353, Presented Saturday, August 29
- **Lipid Management in Patients with Coronary Artery Disease at Risk of a First Major Atherosclerotic Cardiovascular Event: Findings from the VESALIUS-REAL Global Study**
Abstract #83605, Presented Saturday, August 29
- **Evolocumab and Risk of a First Myocardial Infarction: A Pre-Specified Analysis of the VESALIUS-CV Trial**
Abstract #87346, Presented Friday, August 28

Investigator-Sponsored Studies (ISS)

- **AMUNDSEN: Evolocumab Before Percutaneous Coronary Intervention for Acute Myocardial Infarction**
Abstract #7002, Presented Saturday, August 29

About the VESALIUS-CV Trial

VESALIUS-CV is a Phase 3, double-blind, randomized, placebo-controlled, global clinical trial designed to evaluate the impact of LDL-C lowering with evolocumab on MACE in adults at high CV risk without prior heart attack or stroke. Results were published in the [New England Journal of Medicine](#) in November 2025. Repatha demonstrated a 25% relative reduction in the risk of a composite of coronary heart disease (CHD) death, heart attack or ischemic stroke (3-P MACE), and 19% reduction in a broader composite that also included any ischemia-driven arterial revascularization (4-P MACE). Repatha also reduced the risk of heart attack by 36%. In a lipid sub-study, adding Repatha to a maximally tolerated dose of statin and/or ezetimibe substantially lowered LDL-C levels among observed patients, with a median level of 45 mg/dL compared to 109 mg/dL in the placebo group.

VESALIUS-CV enrolled more than 12,000 patients with known ASCVD or high-risk diabetes, who had no history of heart attack or stroke, an LDL-C $\geq$ 90 mg/dL, or non-high-density lipoprotein cholesterol (non-HDL-C) $\geq$ 120 mg/dL, or apolipoprotein B $\geq$ 80 mg/dL; and treated with highest tolerated dose of statin and/or ezetimibe. The median baseline LDL-C was 122 mg/dL (IQR, 104-149 mg/dL) on local lab testing. Participants were randomized to receive Repatha or placebo in addition to optimized lipid-lowering therapy and were followed for a median of approximately 4.6 years.

Amgen's Commitment to Cardiometabolic Innovation

Amgen is redefining cardiometabolic care with cutting-edge science rooted in human biology that addresses closely connected cardiovascular and metabolic diseases that lead to serious outcomes or death.

Cardiometabolic conditions commonly coexist and can lead to serious outcomes or death, even though they are treatable.¹ Despite advances in lipid-lowering and metabolic therapies, substantial residual cardiovascular risk remains, driven by persistent LDL-C elevation, genetically mediated Lp(a) and obesity-related cardiometabolic dysfunction.²

Leveraging 40+ years of cutting-edge science and human genetics, Amgen is redefining cardiometabolic care and risk management. With years of success in cardiovascular disease with Repatha, Amgen is well positioned to deliver potential breakthrough medicines like maridebart cafraglutide (MariTide) and olpasiran to help address patient needs in cardiometabolic care and multiple interconnected drivers of cardiovascular and metabolic disease.

About Repatha

Repatha is a human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9). Repatha binds to PCSK9 and inhibits circulating PCSK9 from binding to the low-density lipoprotein (LDL) receptor (LDLR), preventing PCSK9-mediated LDLR degradation and permitting LDLR to recycle back to the liver cell surface. By inhibiting the binding of PCSK9 to LDLR, Repatha increases the number of LDLRs available to clear LDL from the blood, thereby lowering LDL-C levels.

Repatha is one of the most extensively studied PCSK9 inhibitors, with clinical and real-world evidence across diverse populations and CV risk profiles.³ The clinical benefits and safety of Repatha have been studied for 15 years in 51 clinical trials with over 57,000 patients.⁴ Repatha is the only PCSK9 inhibitor to demonstrate a significant reduction of cardiovascular events as both high-risk primary and secondary prevention, with patients achieving and maintaining dramatic LDL-C reductions using Repatha once every two weeks.^{5,6}

Repatha was first approved in 2015 and has since been used by approximately 9 million patients globally.⁷ In August 2025, the U.S. Food and Drug Administration [broadened](#) the approved use of Repatha to include adults at increased risk for major adverse CV events due to uncontrolled LDL-C. In August 2026, the European Commission approved an expanded indication for the use of Repatha in adults with established or high risk for ASCVD to reduce CV risk by lowering LDL-C levels, as an adjunct to correction of other risk factors, based on results from the Phase 3 VESALIUS-CV trial. Repatha is approved in 75 countries, including the U.S., Japan, Canada and in all 28 countries that are members of the European Union.⁸ Applications in other countries are pending.

Important EU Product Information

In Europe Repatha is approved for use in:

Hypercholesterolemia and mixed dyslipidemia

Repatha is indicated in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or,

- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Homozygous familial hypercholesterolemia

Repatha is indicated in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolemia in combination with other lipid-lowering therapies.

Atherosclerotic cardiovascular disease

Repatha is indicated in adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

- in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Posology

Primary hypercholesterolemia and mixed dyslipidemia in adults

The recommended dose of Repatha is either 140 mg every two weeks or 420 mg once monthly; both doses are clinically equivalent.

Homozygous familial hypercholesterolemia in adults and adolescents aged 12 years and over

The initial recommended dose is 420 mg once monthly. After 12 weeks of treatment, dose frequency can be up-titrated to 420 mg once every 2 weeks if a clinically meaningful response is not achieved. Patients on apheresis may initiate treatment with 420 mg every two weeks to correspond with their apheresis schedule.

Important Safety Information

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special Warnings and Precautions: Renal impairment: Patients with severe renal impairment (defined as eGFR < 30 mL/min/1.73 m²) have not been studied. Repatha should be used with caution in patients with severe renal impairment. Hepatic impairment: In patients with moderate hepatic impairment, a reduction in total evolocumab exposure was observed that may lead to a reduced effect on LDL-C reduction. Therefore, close monitoring may be warranted in these patients. Patients with severe hepatic impairment (Child-Pugh C) have not been studied. Repatha should be used with caution in patients with severe hepatic impairment. Dry natural rubber: The needle cover of the glass pre-filled syringe and of the pre-filled pen is made from dry natural rubber (a derivative of latex), which may cause allergic reactions. Sodium content: Repatha contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially 'sodium-free'.

Interactions: No formal drug-drug interaction studies have been conducted for Repatha. No studies on pharmacokinetic and pharmacodynamics interaction between Repatha and lipid-lowering drugs other than statins and ezetimibe have been conducted.

Fertility, Pregnancy and Lactation: There are no or limited amount of data from the use of Repatha in pregnant women. Repatha should not be used during pregnancy unless the clinical condition of the woman requires treatment with evolocumab. It is unknown whether evolocumab is excreted in human milk. A risk to breastfed newborns/infants cannot be excluded. No data on the effect of evolocumab on human fertility are available.

Undesirable Effects: The following common (> 1/100 to < 1/10) adverse reactions have been reported in pivotal, controlled clinical studies: influenza, nasopharyngitis, upper respiratory tract infection, rash, nausea, back pain, arthralgia, injection site reactions. Please consult the SmPC for a full description of undesirable effects.

Pharmaceutical Precautions: Store in a refrigerator (2 degrees C – 8 degrees C). Do not freeze. Keep the pre-filled syringe or the pre-filled pen in the original carton in order to protect from light. If removed from the refrigerator, Repatha may be stored at room temperature (up to 25 degrees C) in the original carton and must be used within 1 month.

US INDICATIONS

Repatha® is a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor indicated:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events.
- As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in:
 - adults with hypercholesterolemia.
 - adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH).
 - adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH).

The safety and effectiveness of Repatha® have not been established in pediatric patients with HeFH or HoFH who are younger than 10 years old or in pediatric patients with other types of hypercholesterolemia. For full prescribing information, visit www.Repatha.com.

IMPORTANT SAFETY INFORMATION

- **Contraindication:** Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to evolocumab or any of the excipients in Repatha®. Serious hypersensitivity reactions including angioedema have occurred

in patients treated with Repatha®.

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, have been reported in patients treated with Repatha®. If signs or symptoms of serious hypersensitivity reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.
- **Adverse Reactions in Adults with Primary Hypercholesterolemia:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

From a pool of the 52-week trial and seven 12-week trials: Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. Hypersensitivity reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common hypersensitivity reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

- **Adverse Reactions in the FOURIER Cardiovascular Outcomes Trial:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: diabetes mellitus (8.8% Repatha®, 8.2% placebo), nasopharyngitis (7.8% Repatha®, 7.4% placebo), and upper respiratory tract infection (5.1% Repatha®, 4.8% placebo).

Among the 16,676 patients without diabetes mellitus at baseline, the incidence of new-onset diabetes mellitus during the trial was 8.1% in patients treated with Repatha® compared with 7.7% in patients that received placebo.

- **Adverse Reactions in Pediatric Patients with HeFH:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, headache, oropharyngeal pain, influenza, and upper respiratory tract infection.
- **Adverse Reactions in Adults and Pediatric Patients with HoFH:** In a 12-week study in 49 patients, the adverse reactions that occurred in at least two patients treated with Repatha® and more frequently than placebo were: upper respiratory tract infection, influenza, gastroenteritis, and nasopharyngitis. In an open-label extension study in 106 patients, including 14 pediatric patients, no new adverse reactions were observed.
- **Immunogenicity:** Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity with Repatha®.

Please [see](#) full Prescribing Information.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative medicines to fight some of the world's toughest diseases. Harnessing the best of biology and technology, Amgen reaches millions of patients with its medicines.

More than 45 years ago, Amgen helped establish the biotechnology industry at its U.S. headquarters in Thousand Oaks, California, and it remains at the cutting edge of innovation, using technology and human genetic data to push beyond what is known today. Amgen is advancing a broad and deep pipeline and portfolio of medicines to treat cancer, heart disease, inflammatory conditions, rare diseases and obesity and obesity-related conditions.

Amgen has been [consistently recognized](#) for innovation and workplace culture, including honors from Fast Company and Forbes. Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average®, and it is also part of the Nasdaq-100 Index®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

For more information, visit [Amgen.com](https://www.amgen.com) and follow Amgen on [X](#), [LinkedIn](#), [Instagram](#), [YouTube](#), [Facebook](#), [TikTok](#) and [Threads](#).

Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeOne Medicines Ltd.), the performance of Otezla® (apremilast), our acquisitions of ChemoCentryx, Inc., Dark Blue Therapeutics, Ltd. or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems on our business, outcomes, progress, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or

otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions, including those resulting from geopolitical relations and government actions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions. A breakdown, cyberattack or information security breach of our information technology systems could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our sustainability objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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