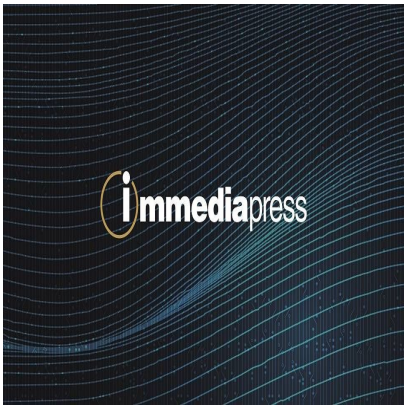

POSITIVE CHMP OPINION SUPPORTS BROADER USE OF AMGENâ??S REPATHAÂ® BEFORE A FIRST HEART ATTACK OR STROKE

Descrizione

default watermark

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

Repatha is the Only PCSK9 Inhibitor Proven to Significantly Reduce Risk of First Heart Attack and Stroke in Phase 3 Clinical Trial, Setting a New Benchmark in Cardiovascular Risk Reduction

Recommendation Based on the Landmark Phase 3 Global VESALIUS-Cardiovascular Trial of More Than 12,000 Patients

THOUSAND OAKS, Calif., July 29, 2026 /PRNewswire/ â?? Amgen (NASDAQ: AMGN) today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for RepathaÂ® (evolocumab) for 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. The recommendation is based on results from the Phase 3 VESALIUS-CV trial, which demonstrated that Repatha significantly reduced the risk of major adverse cardiovascular events (MACE) in high-risk adults without a prior heart attack or stroke, when added to statins or other LDL-C-lowering treatments.

â??There remains a significant unmet need in Europe, where many patients at high cardiovascular risk are unable to achieve recommended LDL-C levels despite available lipid-lowering therapies,â?• said Paul Burton, M.D., Ph.D., chief medical officer at Amgen. â??The CHMPâ??s positive opinion reflects the strength of Repathaâ??s clinical evidence and brings us one step closer to making Repatha available to more patients who may benefit from it. Repatha is the only PCSK9 inhibitor proven in a Phase 3 clinical trial to reduce the risk of a first major cardiovascular event. If approved by the European Commission, this expanded indication has the potential to redefine cardiovascular care for appropriate patients in Europe.â?•

Cardiovascular disease is the leading cause of death worldwide.1 Recent research shows that more than 99% of people who experience a first-time cardiovascular event have at least one traditional risk factor, including high LDL-C, which is one of the most modifiable risk factors for heart attack or stroke.2

While the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS) guidelines recommend intensive LDL-C lowering based on cardiovascular risk, many high-risk patients remain above recommended LDL-C targets despite available lipid-lowering therapies.3

Repatha was initially approved in the European Union in 2015 for the treatment of adults and pediatric patients with primary hypercholesterolemia or mixed dyslipidemia, as well as to reduce cardiovascular risk in adults with established ASCVD. The European Commission is expected to make a final decision on the application in the coming months.

About the VESALIUS-CV TrialVESALIUS-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). Evolocumab also reduced the risk of heart attack by 36%. A consistent benefit was seen with evolocumab vs. placebo across all three endpoints, including the reduced risk of heart attack by 36%. In a lipid sub-study, adding evolocumab 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.

default watermark

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 â?¥ 90 mg/dL, or non-high-density lipoprotein cholesterol (non-HDL-C) â?¥ 120 mg/dL, or apolipoprotein B â?¥ 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 evolocumab or placebo in addition to optimized lipid-lowering therapy and were followed for a median of approximately 4.6 years.

Amgenâ??s Commitment to Cardiovascular InnovationAmgen 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.4 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.5

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 MariTide and olpasiran to help address patient needs in cardiometabolic care and multiple interconnected drivers of cardiovascular and metabolic disease.

About RepathaRepatha 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.6 The clinical benefits and safety of Repatha have been studied for 15 years in 51 clinical trials with over 57,000 patients.7 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 only once every two weeks.8,9

Repatha was first approved in 2015 and has since been used by more than 10 million patients globally.10 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. Repatha is approved in 74 countries, including the U.S., Japan, Canada and in all 28 countries that are members of the European Union.11 Applications in other countries are pending.

default watermark

Important EU Product Information

In Europe Repatha is approved for use in:

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

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

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

PosologyPrimary 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 InformationThis 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 LDLâ??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.

default watermark

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

The safety and effectiveness of RepathaÂ® 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

Please see full Prescribing Information.

About Amgen Amgen discovers, develops, manufactures and delivers innovative medicines to fight some of the worldâ??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 AverageÂ®, and it is also part of the Nasdaq-100 IndexÂ®, 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 and follow Amgen on X, LinkedIn, Instagram, YouTube, Facebook, TikTok and Threads.

Forward-Looking StatementsThis 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. or Kyowa Kirin Co., Ltd.), the performance of OtezlaÂ® (apremilast), our acquisitions of ChemoCentryx, Inc., Dark Blue Therapeutics, Ltd. or Horizon Therapeutics plc (including the prospective performance and outlook of Horizonâ??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.

default watermark

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

default watermark

EI SRL - P.IVA IT16017671005

markets on terms that are favorable to us, or at all.

CONTACT: Amgen, Thousand Oaksâ?¯ Madison Howard, 773-636-4910 (media)Elissa Snook, 609-251-1407 (media)Casey Capparelli, 805-447-1746 (investors)

REFERENCES

View original content to download multimedia:https://www.prnewswire.co.uk/news-releases/positive-chmp-opinion-supports-broader-use-of-amgens-repatha-before-a-first-heart-attack-or-stroke-302837810.html

Copyright 2026 PR Newswire. All Rights Reserved.

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE: Immediapress Ã¨ un servizio di diffusione di comunicati stampa in testo originale redatto direttamente dallâ??ente che lo emette. Lâ??Adnkronos e Immediapress non sono responsabili per i contenuti dei comunicati trasmessi

â??

immediapress/pr-newswire

default watermark

Categoria

1. Comunicati

Tag

1. ImmediaPress

Data di creazione
Luglio 29, 2026
Autore
redazione