



New Amgen Data To Be Presented At ESC Congress 2019 Highlight Additional Evidence For Repatha® (Evolocumab) Effectiveness In Cardiovascular Disease Across Multiple Patient Groups

August 28, 2019

Amgen to Host Health Screening and Education Program at ESC Congress Public Event in Paris to Help Identify Patients at Risk for Cardiovascular Events

THOUSAND OAKS, Calif., Aug. 28, 2019 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced the presentation of 14 cardiovascular scientific research abstracts, including studies evaluating the safety and efficacy of Repatha® (evolocumab) by race and ethnicity and further examining its clinical benefit in patients with familial hypercholesterolemia (FH).^{1,2} The data will be presented at ESC Congress 2019, organized by the European Society of Cardiology, in Paris, Aug. 31–Sept. 4.

Further independent data, generated in Europe, will be presented for Repatha from the EVOlocumab for early reduction of LDL-cholesterol levels in Patients with Acute Coronary Syndromes (EVOPACS) study.³

"Cardiovascular disease is one of the greatest health challenges we face today, impacting more than 49 million people in the EU alone.⁴ While it is critical to reduce low-density lipoprotein cholesterol (LDL-C) levels in patients who have had multiple cardiovascular events or a recent heart attack, we continue to see elevated LDL-C in high-risk patients, despite treatment with statins and other traditional lipid-lowering therapies," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Amgen is committed to building a body of evidence to support the clinical profile of Repatha and demonstrate its high value in patients at elevated risk of suffering another event."

Lowering LDL-C, or "bad" cholesterol, is a key modifiable risk factor in reducing the risk of cardiovascular events such as heart attack and stroke.⁵ Alongside ESC Congress 2019, Amgen is hosting #ProtectUrLife, an innovative, European-city-based heart screening and education program at the ESC Congress public event in Paris. Members of the public will be offered a free non-invasive screening that measures cholesterol levels, one of the most important risk factors associated with an increased risk of heart attack.

"Our #ProtectUrLife screening and education program aims to improve the prevention, evaluation and care of serious medical conditions, including cardiovascular disease, that continue to be underdiagnosed and undermanaged. Moving on from the traditional 'break and fix' approach, the program uses a 'predict and prevent' model, providing education on risk reduction and empowering the public to act on knowledge to help prevent life-altering events such as heart attacks and stroke," said Isma Benattia, M.D., vice president of Medical for the European Region at Amgen.

The two-day #ProtectUrLife event will be held at the Public Event Village in front of the Hôtel de Ville in Paris from 11 a.m. to 7 p.m. CEST during the weekend of Aug. 31–Sept. 1, 2019. The Public Event Village is organized by the ESC, the City of Paris and the French Society of Cardiology, and around 10,000 visitors are expected to attend each day.

A list of Amgen-sponsored abstracts at ESC Congress 2019 can be found [online](#) and below:

Repatha® (evolocumab) data

- **Effectiveness of evolocumab for patients with familial hypercholesterolemia (FH) in European clinical practice**
Lipids, Saturday, Aug. 31, 12:35-1:25 p.m. CET
- **Clinical profile of patients initiating evolocumab in Spanish Cardiology Units: A RETrospective, Qbservational Study of Real-World Clinical Practice (RETOSS-Cardio)**
Hypertension risk factors and lifestyle, Sunday, Sept. 1, 10:05-10:55 a.m. CET
- **Cost-effectiveness of evolocumab in patients with high atherosclerotic cardiovascular risk in Sweden**
How good/bad are we in treating lipids, Sunday, Sept. 1, 10:05-10:55 a.m. CET
- **Effect of evolocumab on lipoprotein(a) levels: results across 15 studies**
Lipids, Tuesday, Sept. 3, 10:05-10:55 a.m. CET
- **Effects of evolocumab on LDL-C by race and ethnicity: an analysis of double-blind and open-label extension studies**
Lipids, Tuesday, Sept. 3, 3:50-4:40 p.m. CET

Cardiovascular disease treatment studies

- **Lower use of statins among patients with peripheral artery disease compared with those with coronary heart disease**
Lipids, Saturday, Aug. 31, 12:35-1:25 p.m. CET
- **Association of adherence and treatment intensity of lipid-lowering therapy with cardiovascular outcomes and all-cause mortality in very high-risk patients in Germany**
Lipids, Saturday, Aug. 31, 12:35-1:25 p.m. CET
- **Screening and treatment of familial hypercholesterolemia (FH) in a French sample of ambulatory care: a retrospective longitudinal study**
Lipids, Saturday, Aug. 31, 12:35-1:25 p.m. CET
- **Patient characteristics and treatment patterns in patients on lipid-lowering therapies following an acute coronary**

syndrome in France

Lipids, Saturday, Aug. 31, 12:35-1:25 p.m. CET

- **Oxidized phospholipids on apolipoprotein B-100 among black U.S. adults with and without PCSK9 loss-of-function variants**

Lipids, Tuesday, Sept. 3, 10:05-10:55 a.m. CET

Cardiovascular disease state

- **Electronic health records (EHRs) data validation in atherosclerotic/cardiovascular clinical phenotypes**
Digital health, Saturday, Aug. 31, 12:35-1:25 p.m. CET
- **Contrasting the risk for atherosclerotic cardiovascular disease events among individuals with lower extremity peripheral artery disease, coronary heart disease and cerebrovascular disease**
Clinical epidemiology and prevention, Monday, Sept. 2, 10:05-10:55 a.m. CET
- **Recurrent coronary heart disease in the year following myocardial infarction among U.S. men and women between 2008 and 2015**
Coronary Artery Disease – Epidemiology, Prognosis, Outcome, Tuesday, Sept. 3, 11 a.m. CET
- **Death, debility, and destitution following recurrent myocardial infarction in older adults**
Risk Factors and Prevention, Tuesday, Sept. 3, 3:50-4:40 p.m. CET

Investigator sponsored studies

- **EVolocumab for early reduction of LDL-cholesterol levels in Patients with Acute Coronary Syndromes (EVOPACS) – A randomized, double-blind, placebo-controlled multicenter study (ISS)**
Acute Coronary Syndromes, Late-Breaking Science, Saturday, Aug. 31, 09:17 a.m. CET

About Amgen in the Cardiovascular Therapeutic Area

Building on more than three decades of experience in developing biotechnology medicines for patients with serious illnesses, Amgen is dedicated to addressing important scientific questions to advance care and improve the lives of patients with cardiovascular disease, the leading cause of morbidity and mortality worldwide.⁷ Amgen's research into cardiovascular disease, and potential treatment options, is part of a growing competency at Amgen that utilizes human genetics to identify and validate certain drug targets. Through its own research and development efforts, as well as partnerships, Amgen is building a robust cardiovascular portfolio consisting of several approved and investigational molecules in an effort to address a number of today's important unmet patient needs, such as high cholesterol and heart failure.

About #ProtectUrLife

The #ProtectUrLife campaign aims to improve heart and bone health through prevention, evaluation and care of cardiovascular disease and osteoporosis. Using the 'predict and prevent' model, #ProtectUrLife events offer free screening and individualized risk assessments for members of the public to help predict who is at risk for heart attacks, stroke and bone fractures. Education for improving heart and bone health is offered, empowering the public to act on knowledge to help prevent life-altering events. The #ProtectUrLife initiative is also designed to empower cities and policy-makers to develop sustainable healthcare systems that benefit their residents.

Launched in 2018, the campaign is led by Amgen and has been developed in partnership with EIT Health, the International Osteoporosis Foundation, the World Heart Federation, the Technical University of Munich, the University of Barcelona and BePatient. The campaign unites a European consortium composed of experts, start-ups, professional societies, patient associations, healthcare professionals, hospitals and cities.

For more information about the campaign visit www.protecturlife.eu and follow us on www.twitter.com/protecturlife and www.facebook.com/ProtectUrLife19/

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

About Repatha[®] (evolocumab)⁶

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 approved in more than 60 countries, including the U.S., Japan, Canada and in all 28 countries that are members of the European Union. Applications in other countries are pending.

Important EU Product Information

In Europe, Repatha is approved for use in:

Hypercholesterolaemia and mixed dyslipidaemia

Repatha is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, 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 hypercholesterolaemia

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

Established atherosclerotic cardiovascular disease

Repatha is indicated in adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial 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 hypercholesterolaemia and mixed dyslipidaemia 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 hypercholesterolaemia 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.

Established atherosclerotic cardiovascular disease in adults

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

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:** There is limited experience with Repatha in patients with severe renal impairment (defined as eGFR < 30 mL/min/1.73 m²). 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 ($\geq 1/100$ 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.

Important U.S. Product Information

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

- to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
- as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) to reduce low-density lipoprotein cholesterol (LDL-C).

- as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

The safety and effectiveness of Repatha have not been established in pediatric patients with HoFH who are younger than 13 years old or in pediatric patients with primary hyperlipidemia or HeFH.

Important U.S. Safety Information

Contraindication: Repatha is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha.

Allergic reactions: Hypersensitivity reactions (e.g. angioedema, rash, urticaria) have been reported in patients treated with Repatha, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha, treat according to the standard of care, and monitor until signs and symptoms resolve.

Adverse reactions: The most common adverse reactions (>5% of patients treated with Repatha and occurring 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.

Allergic reactions occurred in 5.1% and 4.7% of Repatha-treated and placebo-treated patients, respectively. The most common allergic 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%).

The most common adverse reactions in the Cardiovascular Outcomes Trial (>5% of patients treated with Repatha and occurring 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 assigned to Repatha compared with 7.7% in those assigned to placebo.

Homozygous Familial Hypercholesterolemia (HoFH): 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.

Immunogenicity: Repatha is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with Repatha.

Please contact Amgen Medinfo at 800-77-AMGEN (800-772-6436) or 844-REPATHA (844-737-2842) regarding Repatha[®] availability or find more information, including full [Prescribing Information](#), at www.amgen.com and www.Repatha.com.

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 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 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. 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. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. 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. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. A breakdown, cyberattack or information security breach 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 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.

The scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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References

- ¹ Effects of evolocumab on LDL-C by race and ethnicity: an analysis of double-blind and open-label extension studies. Presented at ESC 2019, Lipids, Tuesday 3 September, 15:50-16:40 CET.
- ² Effectiveness of evolocumab for patients with familial hypercholesterolaemia (FH) in European clinical practice. Presented at ESC 2019, Lipids, Saturday 31 August, 12:35-13:25 CET.
- ³ EVOlocumab for early reduction of LDL-cholesterol levels in Patients with Acute Coronary Syndromes (EVOPACS) – A randomized, double-blind, placebo-controlled multicenter study (ISS) Acute Coronary Syndromes, Late-Breaking Science, Saturday, Aug. 31, 09:17 CET.
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