Amgen To Present New Data From Repatha® (evolocumab) Clinical Trials At ACC.18

February 26, 2018

Presentations Focus on Patients With Established Cardiovascular Disease and Include Data Exploring Consistency of LDL-C Reduction With Repatha

New Data Shows Patients at High Risk for Cardiovascular Events Continue to be Denied PCSK9 Inhibitors

THOUSAND OAKS, Calif., Feb. 26, 2018 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced new data from the Repatha® (evolocumab) clinical trial program to be featured at the American College of Cardiology's 67th Annual Scientific Session (ACC.18) in Orlando, Fla., March 10-12, 2018. Presentations to include additional analyses from the Repatha cardiovascular outcomes trial (FOURIER) and the Repatha coronary intravascular ultrasound imaging trial (GLAGOV).

"The depth and breadth of our clinical trial program continues to highlight different patient groups that may benefit from intensive LDL-C reduction with Repatha," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to sharing data showing the likelihood of coronary atherosclerosis regression with Repatha treatment, as well as results from the Repatha cardiovascular outcomes study evaluating efficacy in patients with residual inflammation."

A full listing of Amgen-related abstracts at ACC.18 include:

Oral Session:

- **Residual Inflammatory and Cholesterol Risk in the FOURIER Trial**
  Abstract 907-06, Highlighted Original Research: Acute and Stable Ischemic Heart Disease and the Year in Review, Monday, March 12, 8:25-8:35 a.m. ET

Moderated Poster Theaters:

- **Consistency of LDL-C Reduction With Evolocumab: An Analysis From FOURIER**
  Abstract 1140M-11, Taking a Broader View of Issues in Hyperlipidemia, Saturday, March 10, 11-11:10 a.m. ET
- **Statin Discontinuation, Perceived Lack of Need For a Statin and Cardiovascular Disease Risk: Data From the REasons for Geographic And Racial Differences in Stroke Study**
  Abstract 1140M-17, Taking a Broader View of Issues in Hyperlipidemia, Saturday, March 10, 11:45-11:55 a.m. ET
- **Prevalence of Familial Hypercholesterolemia and LDL Cholesterol Reduction Among Young Adults With Myocardial Infarction**
  Abstract 1180M-03, Familial Hypercholesterolemia: Recognizing the Prevalence and the Risks, Saturday, March 10, 3:45-3:55 p.m. ET
- **Levels of Non-High-Density Lipoprotein Cholesterol Do Not Negatively Impact the Ability of the PCSK9 Inhibitor, Evolocumab, to Promote Regression of Coronary Atherosclerosis**
  Abstract 1181M-03, Evolocumab: A Golden Knight For Atherosclerosis Regression? Saturday, March 10, 3:45-3:55 p.m. ET
- **Elevated CRP Levels Do Not Adversely Modulate the Ability of Evolocumab to Regress Coronary Atherosclerosis: Insights From GLAGOV**
  Abstract 1181M-05, Evolocumab: A Golden Knight For Atherosclerosis Regression? Saturday, March 10, 4-4:10 p.m. ET
- **Greater Likelihood of Regression of Coronary Atherosclerosis With the PCSK9 Inhibitor, Evolocumab, in Patients With Higher Lp(a) Levels**
  Abstract 1181M-07, Evolocumab: A Golden Knight For Atherosclerosis Regression? Saturday, March 10, 4:15-4:25 p.m. ET

Poster Sessions:

- **Sex-Related Difference in the Regression of Coronary Atherosclerosis With the PCSK9 Inhibitor, Evolocumab: Insights From GLAGOV**
  Abstract 1115-271, Plaque Morphology and Intravascular Imaging, Saturday, March 10, 10-10:45 a.m. ET
- **Cardiovascular Risk in Patients Denied Access to PCSK9i Therapy**
  Abstract 1129-408, The Latest on Dyslipidemia Care in the Age of Precision Medicine, Saturday, March 10, 10-10:45 a.m. ET
- **Predicting Cardiovascular Risk Using Common Utilization Management Criteria For Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors in Commercially Insured Patients With Atherosclerotic Cardiovascular Disease**
  Abstract 1129-409, The Latest on Dyslipidemia Care in the Age of Precision Medicine, Saturday, March 10, 10-10:45 a.m. ET
- **Statin Use in US Adults With Chronic Kidney Disease: A Comparison of Treatment Guidelines**
  Abstract 1129-413, The Latest on Dyslipidemia Care in the Age of Precision Medicine, Saturday, March 10, 10-10:45 a.m. ET

- **Getting to an imprOved Understanding of Low-Density Lipoprotein Cholesterol and Dyslipidemia Management (GOULD): A Registry of High Cardiovascular Risk Patients in the United States**
  Abstract 1129-415, The Latest on Dyslipidemia Care in the Age of Precision Medicine, Saturday, March 10, 10-10:45 a.m. ET
- **Lack of Urgency to Lower LDL-C and Subsequent CV Risk Among ASCVD Patients in the US**
  Abstract 1129-434, The Latest on Dyslipidemia Care in the Age of Precision Medicine, Saturday, March 10, 10-10:45 a.m. ET
- **Characteristics and Cardiovascular Disease Event Rates Among African Americans Who Meet the FOURIER Inclusion Criteria**
  Abstract 1129-425, The Latest on Dyslipidemia Care in the Age of Precision Medicine, Saturday, March 10, 10-10:45 a.m. ET
- **Recurrent Cardiovascular Event Rates in High-Risk Atherosclerotic Cardiovascular Disease Patients: Estimates From Swedish Population-Based Register Data**
  Abstract 1260-410, Risk Factor Assessment and Risk Prediction to Guide ASCVD Prevention, Sunday, March 11, 3:45-4:30 p.m. ET

Repatha Cardiovascular Outcomes (FOURIER) Study Design
FOURIER (Further Cardiovascular OUtcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk), a multinational Phase 3 randomized, double-blind, placebo-controlled trial, is designed to evaluate whether treatment with Repatha in combination with high- or moderate-intensity statin therapy compared to placebo plus statin therapy reduces cardiovascular events. The hard MACE composite endpoint is the time to cardiovascular death, myocardial infarction or stroke (key secondary endpoint). The extended MACE composite endpoint is the time to cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina or coronary revascularization (primary endpoint).

Eligible patients with high cholesterol (LDL-C ≥70 mg/dL or non-high-density lipoprotein cholesterol [non-HDL-C] ≥100 mg/dL) and established cardiovascular disease at more than 1,300 study locations around the world were randomized to receive Repatha subcutaneous 140 mg every two weeks or 420 mg monthly plus high- or moderate-intensity effective statin dose; or placebo subcutaneous every two weeks or monthly plus high- to moderate-intensity statin dose. Statin therapy was defined in the protocol as at least atorvastatin 20 mg or equivalent daily with a recommendation for at least atorvastatin 40 mg or equivalent daily where approved. The study was event driven and continued until at least 1,630 patients experienced a key secondary endpoint.

GLAGOV Study Design
GLAGOV (GLobal Assessment of Plaque ReGression with a PCSK9 AntibOdy as Measured by IntraVascular Ultrasound) is a Phase 3, multicenter, double-blind, randomized, placebo-controlled trial designed to evaluate the effect of Repatha on the change in burden of coronary artery disease (CAD) in 968 patients undergoing clinically indicated coronary angiogram and on optimized background statin therapy.

Patients were required to have been treated with a stable statin dose for at least four weeks and to have a LDL-C ≥80 mg/dL or between 60 and 80 mg/dL with one major cardiovascular risk factor (defined as non-coronary atherosclerotic vascular disease, myocardial infarction or hospitalization for unstable angina in the preceding two years or type 2 diabetes mellitus) or three minor cardiovascular risk factors (defined as current cigarette smoking, hypertension, low levels of HDL cholesterol, family history of premature coronary heart disease, high sensitivity C-reactive protein (hs-CRP) ≥2 mg/L or age ≥50 years in men and 55 years in women).

Patients were randomized 1:1 into two treatment groups to either receive monthly Repatha 420 mg or placebo subcutaneous injections. Optimized statin therapy was defined as at least atorvastatin 20 mg daily or equivalent, titrated to achieve LDL-C reduction per regional guidelines. Highly effective statin therapy (equivalent to atorvastatin 40 mg daily or higher) was recommended for all patients. Those patients with LDL-C >100 mg/dL not taking highly effective statin therapy, required investigators' attestation as to why such doses were not appropriate. The primary endpoint was change in percent atheroma volume (PAV) from baseline to week 78 compared to placebo, as determined by intravascular ultrasound (IVUS). IVUS is a high-resolution imaging tool that allows for the quantification of coronary atheroma in the coronary arteries.

Secondary endpoints included PAV regression (any reduction from baseline); change in total atheroma volume (TAV) from baseline to week 78; and regression (any reduction from baseline) in TAV.

About Repatha® (evolocumab)
Repatha® (evolocumab) 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.[1]

Repatha is approved in more than 50 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.

U.S. Repatha Indication

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 LDLC.

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.

Allergic reactions: Hypersensitivity reactions (e.g. 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 percent of Repatha-treated patients and occurring more frequently than placebo) in controlled trials involving patients with primary hyperlipidemia, including HeFH, were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2 percent of Repatha-treated patients and 1 percent of placebo-treated patients. The most common adverse reaction that led to Repatha treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3 percent versus 0 percent for Repatha and placebo, respectively).

Adverse reactions from a pool of the 52-week trial and seven 12-week trials: Local injection site reactions occurred in 3.2 percent and 3.0 percent of Repatha-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha-treated patients and placebo-treated patients were 0.1 percent and 0 percent, respectively.

Allergic reactions occurred in 5.1 percent and 4.7 percent of Repatha-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0 percent versus 0.5 percent for Repatha and placebo, respectively), eczema (0.4 percent versus 0.2 percent), erythema (0.4 percent versus 0.2 percent), and urticaria (0.4 percent versus 0.1 percent).

The safety profile of Repatha in the cardiovascular outcomes trial was generally consistent with the safety profile in the 12- and 52-week controlled trials involving patients with primary hyperlipidemia, including HeFH. Serious adverse events occurred in 24.8 percent and 24.7 percent of Repatha-treated and placebo-treated patients, respectively. Adverse events led to discontinuation of study treatment in 4.4 percent of patients assigned to Repatha and 4.2 percent assigned to placebo. Common adverse reactions (>5 percent of patients treated with Repatha and occurring more frequently than placebo) included diabetes mellitus (8.8 percent Repatha, 8.2 percent placebo), nasopharyngitis (7.8 percent Repatha, 7.4 percent placebo) and upper respiratory tract infection (5.1 percent Repatha, 4.8 percent placebo). Among the 16,676 patients without diabetes mellitus at baseline, the incidence of new-onset diabetes mellitus during the trial was 8.1 percent in patients assigned to Repatha compared with 7.7 percent in those assigned to placebo.

Homozygous Familial Hypercholesterolemia (HoFH): In 49 patients with homozygous familial hypercholesterolemia studied in a 12-week, double-blind, randomized, placebo-controlled trial, 33 patients received 420 mg of Repatha subcutaneously once monthly. The adverse reactions that occurred in at least 2 (6.1 percent) Repatha-treated patients and more frequently than in placebo-treated patients, included upper respiratory tract infection (9.1 percent versus 6.3 percent), influenza (9.1 percent versus 0 percent), gastroenteritis (6.1 percent versus 0 percent), and nasopharyngitis (6.1 percent versus 0 percent).

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.

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.[2] 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 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 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 one of the world's leading independent biotechnology companies, 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.

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. 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.

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References

1. Repatha® U.S. Prescribing Information. Amgen.
2. World Health Organization. Cardiovascular diseases (CVDs) fact sheet. http://www.who.int/mediacentre/factsheets/fs317/en/. Accessed October 30, 2017.

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