Amgen Highlights Repatha® (Evolocumab) GLAGOV Imaging Study Amongst Data To Be Presented At AHA Scientific Sessions 2016

October 31, 2016

Additional New Data and Analyses Reinforce Amgen's Commitment to Patients With Heart Disease

THOUSAND OAKS, Calif., Oct. 31, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present detailed results from the Phase 3 coronary intravascular imaging trial, the GLAGOV (GLobal Assessment of Plaque ReGression with a PCSK9 AntibOdy as Measured by IntraVascular Ultrasound) study, at the upcoming American Heart Association (AHA) Scientific Sessions 2016, being held Nov. 12-16 in New Orleans.

The GLAGOV study evaluated whether Repatha® (evolocumab), a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor for the treatment of certain patients with high low-density lipoprotein cholesterol (LDL-C), would modify atherosclerotic plaque build-up in the coronary arteries of patients already treated with optimized statin therapy. Amgen announced in September that the study met its primary and secondary endpoints. The detailed results from this study will be featured as a late-breaking oral presentation on Tuesday, Nov. 15 at 10:58 a.m. CT.

"Amgen is committed to unlocking the full potential of biotechnology in the global fight against cardiovascular disease," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The robust clinical, observational and health economics data to be presented at AHA 2016 continue to grow our body of knowledge and demonstrate our dedication to improving care for patients with cardiovascular disease."

A second late-breaking oral presentation will review results of a genome-wide association study (GWAS) exploring whether genetic factors influence statin-associated muscle symptoms. In addition, a new analysis of left atrial size and function from the COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure) study evaluating omecamtiv mecarbil, a novel and investigational cardiac myosin activator for treatment of chronic heart failure, will be presented.

Data from Amgen's Center for Observational Research and Global Health Economics providing real-world data on the potential use and impact of some of the medicines in Amgen's cardiovascular portfolio will also be shown.

Amgen-sponsored abstracts at AHA Scientific Sessions 2016 include:

Repatha

Clinical

- **GLAGOV – Effect of Evolocumab on Progression of Coronary Atherosclerosis in Statin-Treated Patients: A Placebo-Controlled Intravascular Ultrasound Trial**
  Session LBCT.03, Late-Breaking Clinical Trials, Tuesday, Nov. 15, 10:58 – 11:08 a.m. CT (Main Event 1)
- **GAUSS-3 – A Genome-Wide Association Study (GWAS) Identifies Novel Loci Associated With Clinically Defined Statin-Associated Muscle Symptoms in a Double-Blind Cross-Over Re-Challenge Trial**
  Session CSSR.02, Clinical Science: Special Report, Tuesday, Nov. 15, 3:45 – 4 p.m. CT (Main Event 2)
- **Effect of Evolocumab on Lipoprotein Profiles in Patients With and Without Diabetes**
  Abstract M 2056, Abstract Poster Session, Monday, Nov. 14, 10:45 a.m. – noon CT (Science and Technology Hall, Population Science)

Observational Research

- **Lipid Lowering Therapy Prescriptions Immediately Before and After the Diagnosis of Diabetes or Atherosclerotic Cardiovascular Disease**
  Abstract S 2048, Abstract Poster Session, Sunday, Nov. 13, 2 – 3:15 p.m. CT (Science and Technology Hall, Population Science)
- **Low Density Lipoprotein Cholesterol Response After Statin Initiation Among HIV-Positive Persons With High Risk for Cardiovascular Disease Events**
  Abstract T 2020, Abstract Poster Session, Tuesday, Nov. 15, 10:45 a.m. – noon CT (Science and Technology Hall, Population Science)
- **Age, Sex, and Race Differences in Statin Discontinuation and Side Effect Patterns. The REasons for Geographic And Racial Differences in Stroke (REGARDS) Study**
  Abstract T 2019, Abstract Poster Session, Tuesday, Nov. 15, 10:45 a.m. – noon CT (Science and Technology Hall, Population Science)
- **Reasons for Statin Discontinuation With and Without a Physician's Advice: Data From the Reasons for Geographic and Racial Differences in Stroke (REGARDS) Study**
  Abstract T 2011, Abstract Poster Session, Tuesday, Nov. 15, 10:45 a.m. – noon CT (Science and Technology Hall, Population Science)
- **Willingness to Reinitiate Statins by Cardiovascular Disease Risk: Data From the Reasons for Geographic and Racial Differences in Stroke (REGARDS) Study**

Abstract T 2015, Abstract Poster Session, Tuesday, Nov. 15, 10:45 a.m. – noon CT (Science and Technology Hall, Population Science)

- **Statin Use and Titration Patterns in the First Year Following a Cardiovascular Event in Commercially-Insured Populations**
  Abstract T 2010, Abstract Poster Session, Tuesday, Nov. 15, 10:45 a.m. – noon CT (Science and Technology Hall, Population Science)
- **Statin Use and Titration Patterns in the First Year Following a T2DM Diagnosis in Commercially-Insured Populations**
  Abstract T 2017, Abstract Poster Session, Tuesday, Nov. 15, 10:45 a.m. – noon CT (Science and Technology Hall, Population Science)

Health Economics

- **Effect of 2013 ACC/AHA Blood Cholesterol Guidelines on Statin Treatment Patterns and Low Density Lipoprotein Cholesterol (LDL-C) Levels in Patients With Atherosclerotic Cardiovascular Disease (ASCVD)**
  Abstract M 2107, Abstract Poster Session, Monday, Nov. 14, 10:45 a.m. – noon CT (Science and Technology Hall, Population Science)

Omecamtiv Mecarbil

Clinical

- **Cardiac Myosin Activator Omecamtiv Mecarbil Improves Left Atrial Structure and Function in Chronic Heart Failure (COSMIC-HF)**
  Abstract M 4180, Abstract Poster Session, Monday, Nov. 14, 2 – 3:15 p.m. CT (Science and Technology Hall, Clinical Science Section)

Observational Research

- **Shorter Left Ventricular Ejection Time is Associated With Adverse Outcomes in Heart Failure Patients With Reduced Ejection Fraction**
  Abstract S 4046, Abstract Poster Session, Sunday, Nov. 13, 2 – 3:15 p.m. CT (Science and Technology Hall, Clinical Science)

Amgen Webcast Investor Meeting
Amgen will host a webcast investor meeting at AHA on Tuesday, Nov. 15, 2016, at 7 p.m. CT. Sean E. Harper, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team and clinical investigators, will participate at the investor meeting to discuss Amgen's data presented at AHA, including the Repatha coronary imaging study (GLAGOV) Phase 3 results.

Live audio of the investor meeting will be simultaneously broadcast over the internet and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

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 cardiac catheterization 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 (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) ≥2mg/dL 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. 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.

COSMIC-HF Trial Design
COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure) was a double-blind, randomized, placebo-controlled, multicenter, Phase 2 trial designed to evaluate an oral formulation of omecamtiv mecarbil in chronic heart failure patients with reduced ejection fraction. The trial consisted of two parts, a dose escalation phase and a larger and longer expansion phase. The dose escalation phase, which completed in 2013, assessed the pharmacokinetics and tolerability of three oral modified-release formulations of omecamtiv mecarbil and was used to select one formulation for further evaluation in the expansion phase. In the dose escalation phase, 96 patients were randomized 1:1:1:1 to placebo or one of three oral modified-release formulations of omecamtiv mecarbil in two cohorts (25 mg twice daily or 50 mg twice daily). Each patient cohort was

followed for 35 days.

The expansion phase evaluated 448 chronic heart failure patients with reduced ejection fraction who were dosed with the selected oral formulation of omecamtiv mecarbil for 20 weeks and followed for a total of 24 weeks. Patients were randomized 1:1:1 to receive either placebo or treatment with omecamtiv mecarbil 25 mg twice daily or 25 mg with dose escalation to 50 mg twice daily, depending on plasma concentrations of omecamtiv mecarbil after two weeks of treatment. The pharmacokinetic-based dose titration strategy was designed to maintain patient exposure to omecamtiv mecarbil in a targeted plasma concentration range; approximately 60 percent of patients in the dose titration group were escalated to a dose of 50 mg twice daily.

The primary endpoints for the expansion phase were to assess the maximum and pre-dose plasma concentration of omecamtiv mecarbil. The secondary endpoints were to assess changes from baseline in systolic ejection time, stroke volume, left ventricular end-systolic diameter, left ventricular end-diastolic diameter, heart rate and N-terminal pro-brain natriuretic peptide (a biomarker associated with the severity of heart failure) at week 20, as well as the safety and tolerability of omecamtiv mecarbil including incidence of adverse events from baseline to week 24.

COSMIC-HF was not designed to assess the impact of omecamtiv mecarbil on cardiovascular outcomes in heart failure patients.

COSMIC-HF was conducted by Amgen in collaboration with Cytokinetics.

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]

The FOURIER outcomes trial is designed to evaluate whether treatment with Repatha or placebo on top of optimized statin therapy, reduces the risk of cardiovascular events in patients with clinically evident atherosclerotic disease. The trial completed patient enrollment in June 2015. The primary endpoint for the FOURIER trial is major cardiovascular events defined as the composite of cardiovascular death, myocardial infarction (MI), stroke, hospitalization for unstable angina or coronary revascularization. The key secondary end point is the composite of cardiovascular death, MI or stroke. The trial is planned to continue until at least 1,630 patients experience the secondary endpoint, thereby providing 90 percent power to detect a relative reduction of 15 percent in this endpoint. Top-line results from the approximately 27,500-patient event-driven FOURIER study are anticipated in the first quarter of 2017.

Repatha is approved in more than 40 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 U.S. Product Information

Repatha® is indicated as an adjunct to diet and:

- Maximally tolerated statin therapy for treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C)
- 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 effect of Repatha® on cardiovascular morbidity and mortality has not been determined.

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

The safety and effectiveness of Repatha® have not been established 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% of Repatha® -treated patients and more common than placebo) 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% of Repatha® -treated patients and 1% 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% versus 0% 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% and 3.0% 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% and 0%, respectively.

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%).

Neurocognitive events were reported in less than or equal to 0.2% in Repatha®-treated and placebo-treated patients.

In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1,988 patients treated with Repatha® had at least one LDL-C value <25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and Repatha® dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by Repatha® are unknown.

Musculoskeletal adverse reactions were reported in 14.3% of Repatha® -treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for Repatha® and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).

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%) Repatha®-treated patients and more frequently than in placebo-treated patients, included upper respiratory tract infection (9.1% versus 6.3%), influenza (9.1% versus 0%), gastroenteritis (6.1% versus 0%), and nasopharyngitis (6.1% versus 0%).

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 Omecamtiv Mecarbil
Omecamtiv mecarbil is a novel cardiac myosin activator. Cardiac myosin is the cytoskeletal motor protein in the cardiac muscle cell that is directly responsible for converting chemical energy into the mechanical force resulting in cardiac contraction. Cardiac myosin activators are thought to accelerate the rate-limiting step of the myosin enzymatic cycle and shift the enzymatic cycle in favor of the force-producing state. Preclinical research has shown that cardiac myosin activators increase contractility in the absence of changes in intracellular calcium in cardiac myocytes.[2-4]

Omecamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, worldwide license to omecamtiv mecarbil and related compounds, subject to Cytokinetics' specified development and commercialization rights. Servier has exercised an exclusive option granted by Amgen for the commercialization of omecamtiv mecarbil in Europe, as well as the Commonwealth of Independent States, including Russia.

About Amgen Cardiovascular
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.[5] 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 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 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. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. 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 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. 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. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. 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.

The scientific information discussed in this news release relating to new indications is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration or European Commission 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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