Amgen Highlights Landmark Repatha® (Evolocumab) Cardiovascular Outcomes Study Amongst Data To Be Presented At ACC.17

March 6, 2017

Additional Presentations Include an Assessment of Repatha's Effect on Cognitive Function and Challenges Associated With Access to PCSK9 Inhibitor Therapy

Late-Breaking Repatha Presentations Will be Webcast Live

THOUSAND OAKS, Calif., March 6, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that detailed results of the Repatha® (evolocumab) cardiovascular outcomes trial will be presented, as well as new data from across the cardiovascular portfolio, at the American College of Cardiology 66th Annual Scientific Session (ACC.17) in Washington, D.C., March 17-19, 2017.

Detailed results from the Repatha cardiovascular outcomes trial (FOURIER) will be featured as a late-breaking oral presentation on Friday, March 17 at 9 a.m. ET. A second late-breaking oral presentation, the Repatha cognitive function trial (EBBINGHAUS), will be presented on Saturday, March 18 at 9 a.m. ET. Live audio and video of the presentations will be webcast over the internet simultaneously with the presentations. Amgen announced in February that FOURIER met its primary composite endpoint and key secondary composite endpoint and EBBINGHAUS met its primary endpoint.

"As cardiovascular disease remains the leading health burden in the world, we sought to answer whether adding Repatha would provide further risk reduction for patients who are already well-treated with statins," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The data from this large cardiovascular outcomes trial will provide a new understanding of the role that Repatha plays in the lives of the millions of people living with uncontrolled high cholesterol."

Additionally, data from two separate analyses will explore prescription rejection rates and access barriers for PCSK9 inhibitors, including a comparison of the patient characteristics amongst those approved and denied access.

Harper continued, "As we prepare to share our outcomes data with the cardiovascular community, patients continue to face unacceptable barriers to getting the additional LDL lowering that Repatha can provide, despite their physician's treatment recommendations."

Webcast Information for Late-Breaking Clinical Trial Presentations

Live audio and video of the two late-breaking clinical trial presentations will be webcast over the internet simultaneously with the presentations and will be available to members of the news media, investors and the general public. The webcasts, as with other selected presentations regarding developments in Amgen's business given at certain investor and medical conferences, can be accessed from 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.

Amgen-sponsored abstracts to be presented at ACC.17 include:

Repatha

Clinical

- **Primary Results of the Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk (FOURIER) Trial**
  Abstract 400-14, Opening Session and the Joint American College of Cardiology and Journal of American College of Cardiology Late-Breaking Clinical Trials Featuring the Simon Dack Lecture, Friday, March 17, 9 – 9:12 a.m. ET
- **Primary Results of EBBINGHAUS, a Cognitive Study of Patients Enrolled in the FOURIER Trial**
  Abstract 404-16, Joint American College of Cardiology/Journal of the American Medical Association Late-Breaking Clinical Trials, Saturday, March 18, 9 – 9:10 a.m. ET
- **Impact of Evolocumab Therapy in Patients With Discordance Between LDL-C and LDL-P**
  Abstract 1106-065, Advances in Cholesterol Measurement and Management, Friday, March 17, 10 – 10:45 a.m. ET

Observational Research

- **Prevalence and Correlates of Statin Side Effects and Willingness to Be Re-Challenged on a Statin: Data From the Reasons for Geographic and Racial Differences in Stroke (REGARDS) Study**
  Abstract 1106-044, Advances in Cholesterol Measurement and Management, Friday, March 17, 10 – 10:45 a.m. ET
- **Psychosocial Factors and Statin Intolerance: Data From the Reasons for Geographic And Racial Differences in Stroke (REGARDS) Study**
  Abstract 1106-045, Advances in Cholesterol Measurement and Management, Friday, March 17, 10 – 10:45 a.m. ET
- **Use of Recommended and Contraindicated Statins in HIV Patients**
  Abstract 1148-069, Current Issues in Cardiovascular Epidemiology, Disparities, and Safety, Friday, March 17, 3:45 – 4:30 p.m. ET
- **A Retrospective Descriptive Analysis of PCI Patients by Indication for Treatment, Comorbidities, and Lipid Therapy Using Real-World, Linked NCDR Registry and Pharmacy Claims Data**

Abstract 1148-070, Current Issues in Cardiovascular Epidemiology, Disparities, and Safety, Friday, March 17, 3:45 – 4:30 p.m. ET

- **Characteristics of Patients Approved and Denied Access to PCSK9i Therapy by Payers**
  Abstract 1258-435, Innovations in Advocacy and Patient Centered Care, Saturday, March 18, 3:45 – 4:30 p.m. ET
- **Trends in the Use of High-Intensity Statin Therapy After Myocardial Infarction, 2011-2014**
  Abstract 1253-335, Acute Coronary Syndromes, Diagnosis, Management and Outcomes, Saturday, March 18, 2017, 3:45 – 4:30 p.m. ET
- **PCSK9 Variants and Neurocognitive Impairment: Data From the Reasons for Geographic and Racial Differences in Stroke (REGARDS) Study**
  Abstract 911-04, Highlighted Original Research: Prevention and the Year in Review, Sunday, March 19, 8:12 – 8:22 a.m. ET
- **Early Challenges for PSCK9 Inhibitor Prescriptions and Patients: Rejections and Rates Unfilled**
  Abstract 415-08, Featured Clinical Research III, Sunday, March 19, 2 – 2:10 p.m. ET

Health Economics

- **Cardiologist Perspectives in Treatment of Dyslipidemia Patients With Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors and Other Lipid Lowering Therapies**
  Abstract 1203-312, Advances in Lipid Management, Saturday, March 18, 9:45 – 10:30 a.m. ET
- **Persistence and Adherence With Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors in Clinical Practice**
  Abstract 1203-313, Advances in Lipid Management, Saturday, March 18, 9:45 – 10:30 a.m. ET
- **Clinical Characteristics of Early Adopters of Proprotein Convertase Subtilisin/Kexin Type 9 inhibitors (PCSK9i)**
  Abstract 1277-065, Diabetes and Other Issues in Cardiovascular Prevention, Sunday, March 19, 9:45 – 10:30 a.m. ET
- **Observed Versus Predicted Cardiovascular Event Rates in Primary Prevention Diabetic Patients Receiving High-Intensity Statins in the United Kingdom**
  Abstract 1277-048, Diabetes and Other Issues in Cardiovascular Prevention, Sunday, March 19, 9:45 – 10:30 a.m. ET
- **Comparison of the Use of Cardiovascular Risk Equations by Health Technology Assessment Bodies and Clinical Guidelines**
  Abstract 1277-070, Diabetes and Other Issues in Cardiovascular Prevention, Sunday, March 19, 9:45 – 10:30 a.m. ET

Corlanor® (ivabradine)

Observational Research

- **Serial Assessment of Heart Rate and Beta Blocker Use in Chronic Heart Failure Patients With Reduced Ejection Fraction in a Large Integrated Healthcare Network**
  Abstract 1123-273, Making Progress in Understanding Heart Failure, Friday, March 17, 10 – 10:45 a.m. ET
- **Genetics of Heart Rate Observational Study (GenHRate)**
  Abstract 1226M-03, Put Your Codon! Genetic Insights Into Heart Failure, Saturday, March 18, 12:30 – 12:40 p.m. ET

Omecamtiv Mecarbil

Clinical

- **The Cardiac Myosin Activator, Omecamtiv Mecarbil, Improves Left Ventricular Myocardial Deformation in Chronic Heart Failure (COSMIC-HF)**
  Abstract 1248-244, Heart Failure and Cardiomyopathies: What Next When All Else Is Failing?, Saturday, March 18, 3:45 – 4:30 p.m. ET

Amgen Webcast Investor Meeting
Amgen will host a webcast investor meeting at ACC.17 on Friday, March 17, 2017, at noon ET. 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 cardiovascular program and data presented at ACC.17.

Live audio of the conference call will be broadcast over the internet simultaneously 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 at certain investor and medical conferences, can be accessed 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.

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 statin therapy compared to placebo plus statin therapy reduces cardiovascular events. The primary endpoint is the time to cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization. The key secondary endpoint is the time to cardiovascular death, myocardial infarction or stroke.

Eligible patients with high cholesterol (LDL-C ≥70 mg/dL or non-high-density lipoprotein cholesterol [non-HDL-C] ≥100 mg/dL) and clinically evident atherosclerotic 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 effective statin dose; or placebo subcutaneous every two weeks or monthly plus effective statin dose. Optimized statin therapy was defined 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.

Repatha Cognitive Function (EBBINGHAUS) Study Design
EBBINGHAUS (Evaluating PCSK9 Binding antiBody Influence oN coGnitive HeAlth in high cardiovascUlar risk Subjects) is a double-blind, placebo-controlled randomized non-inferiority trial involving approximately 1,900 patients enrolled in the FOURIER outcomes study. The primary endpoint in the study is the Spatial Working Memory strategy index of executive function. Secondary endpoints are working memory, as assessed by the CANTAB Spatial Working Memory (SWM) test between-errors score; memory function, as assessed by the CANTAB Paired Associates Learning (PAL) test; and psychomotor speed, as assessed by the CANTAB Reaction Time (RTI) test.

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 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.

U.S. Repatha Indication:
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 Corlanor® (ivabradine)

Corlanor® (ivabradine) blocks the hyperpolarization-activated cyclic nucleotide-gated (HCN) channel responsible for the cardiac pacemaker, which regulates heart rate. Corlanor reduces the spontaneous pacemaker activity of the cardiac sinus node by selectively inhibiting the I_f current ("funny" current) to slow the heart rate with no effect on ventricular repolarization and no effects on myocardial contractility.[2] Corlanor was developed by Servier. Through a collaboration with Servier, Amgen has rights to commercialize Corlanor in the U.S.

U.S. Corlanor Indication:

Corlanor® is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute (bpm) and either are on maximally tolerated doses of beta blockers or have a contraindication to beta blocker use.

Important U.S. Safety Information

Contraindications: Corlanor® is contraindicated in patients with acute decompensated heart failure, blood pressure < 90/50 mmHg, sick sinus syndrome, sinoatrial block, 3rd degree atrioventricular (AV) block (unless a functioning demand pacemaker is present), a resting heart rate < 60 bpm prior to treatment, severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker) and concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors.

- **Fetal Toxicity:** Corlanor® may cause fetal toxicity when administered to a pregnant woman.
- **Atrial Fibrillation:** Corlanor® increases the risk of atrial fibrillation. The rate of atrial fibrillation in patients treated with Corlanor® compared to placebo was 5% vs. 3.9% per patient-year, respectively.
- **Bradycardia and Conduction Disturbances:** Bradycardia, sinus arrest and heart block have occurred with Corlanor®. Bradycardia may increase the risk of QT prolongation which may lead to severe ventricular arrhythmias, including torsades de pointes, especially in patients with risk factors such as use of QTc prolonging drugs. Concurrent use of verapamil or diltiazem also increases Corlanor® exposure and should be avoided. Avoid use of Corlanor® in patients with 2nd degree atrioventricular block unless a functioning demand pacemaker is present.
- **Adverse Reactions:** The most common adverse drug reactions reported at least 1% more frequently with Corlanor® than placebo and that occurred in more than 1% of patients treated with Corlanor® were bradycardia (10% vs. 2.2%), hypertension or increased blood pressure (8.9% vs. 7.8%), atrial fibrillation (8.3% vs. 6.6%), and luminous phenomena (phosphenes) or visual brightness (2.8% vs. 0.5%). In postmarketing experience, torsades de pointes has been observed.

Please contact Amgen Medinfo at 800-77-AMGEN (800-772-6436) regarding Corlanor availability or find out more information, including full Prescribing Information and Medication Guide at www.amgen.com and www.Corlanor.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.[3-5]

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. Amgen has also entered an alliance with Servier for exclusive commercialization rights in Europe as well as the Commonwealth of Independent States, including Russia. Servier contributes funding for development and provides strategic support to the program.

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.[6] 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. 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. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. 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. 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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