Amgen To Highlight Cardiovascular Portfolio At American Heart Association Scientific Sessions 2015

November 2, 2015

Repatha™ (Evolocumab) Data Analysis Examines Effect of Dosing on LDL-C Reduction and Duration of Response
Corlanor® (Ivabradine) Session Features Post-Hoc Safety Analysis of Continued Treatment in Patients Hospitalized With Worsening Heart Failure

THOUSAND OAKS, Calif., Nov. 2, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present 14 abstracts at the American Heart Association (AHA) Scientific Sessions 2015, from Nov. 7–11 in Orlando, Fla. New data analyses evaluating Repatha ™(evolocumab), an injectable proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor approved for certain patients with high low-density lipoprotein cholesterol (LDL-C), or "bad" cholesterol,[1] and Corlanor® (ivabradine), an oral medicine for certain people who have chronic (long-lasting) heart failure caused by the lower-left part of their heart not contracting well,[2] will be presented at the meeting.

"We look forward to sharing data at AHA that continue to add to our clinical understanding of the products in our cardiovascular portfolio," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Repatha and Corlanor, which were both approved in the U.S. earlier this year, are testaments to our ongoing commitment to improving care for patients with cardiovascular disease."

Repatha, approved by the U.S. Food and Drug Administration (FDA) on Aug. 27, is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C; and as an adjunct to diet and other LDL-lowering therapies for the treatment of 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.

Corlanor, approved by the FDA on April 15, 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 percent, who are in sinus rhythm with resting heart rate ≥70 beats per minute and either are on maximally tolerated doses of beta blockers or have a contraindication to beta blocker use.

In addition to Repatha and Corlanor clinical trial analyses, data from Amgen's Center for Observational Research will be presented, including a poster and oral presentation on findings from the REGARDS (REasons for Geographic And Racial Differences in Stroke) study, and an oral presentation on the benefits of initiating beta blocker treatment in heart failure patients within seven days following hospital discharge. A global health economics study on the association between achievement of LDL-C reduction targets and cardiovascular disease risk among patients with familial hypercholesterolemia will also be presented.

Data to be presented at AHA Scientific Sessions 2015 include:

Repatha

Clinical Presentation

- **Comparisons of Peak LDL-C Reduction and Duration of Effect with Lower or Higher Dosing Regimens of the PCSK9 Inhibitor Evolocumab**
  Abstract M 2060, Abstract Poster Session, Monday, Nov. 9, 9-10:15 a.m. ET (A2, Population Science)

Center for Observational Research Presentations

- **Medicare Beneficiaries with Indicators of Statin Intolerance Have Increased Coronary Heart Disease Risk**
  Abstract M 2056, Abstract Poster Session, Monday, Nov. 9, 9-10:15 a.m. ET (A2, Population Science)

- **Differences Between Observed and Predicted Cardiovascular Event Rates Using the Framingham and REACH Equations: The Case of High-intensity Statin Users in the United Kingdom**
  Abstract M 2131, Abstract Poster Session, Monday, Nov. 9, 2-3:15 p.m. ET (A2, Population Science)

- **Achievement Of LDL-cholesterol Reduction Targets is Associated with Reduced Cardiovascular Disease Risk Among Patients with Familial Hypercholesterolemia in a Large Electronic Medical Record Database**
  Abstract M 2145, Abstract Poster Session, Monday, Nov. 9, 2-3:15 p.m. ET (A2, Population Science)

- **Rates of Cardiovascular Events in Patients Receiving High-intensity Statin Therapy in the United Kingdom**
  Abstract M 2147, Abstract Poster Session, Monday, Nov. 9, 2-3:15 p.m. ET (A2, Population Science)

- **Pcsk9 Loss-of-function Variants, Low-density Lipoprotein Cholesterol, and Risk of Coronary Heart Disease and Stroke: Data From the REGARDS Study and CHARGE Consortium**
  Abstract 392, Abstract Oral Session, Tuesday, Nov. 10, 9:30-9:45 a.m. ET (W202)

Global Health Economics Presentations

- **Long-term Increased Inpatient and Outpatient Visits Associated with Cardiovascular Events: A Large Real World Study**
  Abstract S 2117, Abstract Poster Session, Sunday, Nov. 8, 2-3:15 p.m. ET (A2, Population Science)

- **Treatment Trends Among High Cardiovascular Disease Risk Patients Treated with Lipid-lowering Therapies: A United States Real-world Study**
  Abstract M 2097, Abstract Poster Session, Monday, Nov. 9, 2-3:15 p.m. ET (A2, Population Science)

Corlanor

Clinical Presentation

- **Safety of Continuing Ivabradine Treatment During Hospitalization for Worsening of Heart Failure in the SHIFT Study**
  Abstract 547, Abstract Oral Session, Tuesday, Nov. 10, 5:45-6 p.m. ET (W300)

Center for Observational Research Presentations

- **Prescriptions for and Use of β-Blocker Following Heart Failure Hospitalization: The REasons for Geographic and Racial Differences in Stroke (REGARDS) Study**
  Abstract S 4206, Abstract Poster Session, Sunday, Nov. 8, 9-10:15 a.m. ET (A2, Clinical Science)

- **Filling a β-blocker in the Week After Discharge for a Heart Failure Hospitalization is Associated with a Lower Risk of Rehospitalization Among Medicare Beneficiaries**
  Abstract 292, Abstract Oral Session, Monday, Nov. 9, 11:45 a.m-12 p.m. ET (Sunburst - W340A)

Global Health Economics Presentations

- **Budget Impact of Adding Corlanor® (Ivabradine) to Existing Standard of Care in the United States: A Commercial Payer Perspective**
  Abstract M 4271, Abstract Poster Session, Monday, Nov. 9, 2-3:15 p.m. ET (A2, Clinical Science)

- **Years of Life Lost Due to Heart Failure in the United States (US)**
  Abstract T 4342, Abstract Poster Session, Tuesday, Nov. 10, 2-3:15 p.m. ET (A2, Clinical Science)

- **Cost-effectiveness of Ivabradine as a Treatment for Systolic Chronic Heart Failure in the United States**
  Abstract T 4350, Abstract Poster Session, Tuesday, Nov. 10, 2-3:15 p.m. ET (A2, Clinical Science)

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]

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 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 that 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 Les Laboratoires Servier. Through a collaboration with Servier, Amgen has rights to commercialize Corlanor in the U.S.

Important U.S. Product Information
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 $\leq$ 35%, who are in sinus rhythm with resting heart rate $\geq$ 70 beats per minute (bpm) and either are on maximally tolerated doses of beta blockers or have a contraindication to beta blocker use.

Important 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®. 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%).

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 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.[3] 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 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 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.

Amgen Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen or us) and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. 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 (SEC) reports filed by Amgen Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Nov. 2, 2015, and expressly disclaims any duty to update information contained in this news release.

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 and our partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. 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 business may be impacted by government investigations, litigation and product liability claims. 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. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products (including products of our wholly-owned subsidiaries) are affected by the 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 as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while we and our partners routinely obtain patents for products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, 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 integrate the operations of companies we have acquired may not be successful. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our ongoing restructuring plan. 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 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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References

1. Repatha ™U.S. Prescribing Information. Amgen.
2. Corlanor® U.S. Prescribing Information. Amgen.
3. World Health Organization. Cardiovascular diseases (CVDs) fact sheet. http://www.who.int/mediacentre/factsheets/fs317/en/. Accessed October 2015.

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