Amgen Showcases Cardiovascular Pipeline At ACC.15 With New Cholesterol-Lowering And Chronic Heart Failure Data

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Data Evaluating the Effect of Repatha™(Evolocumab) on LDL-C and Cardiovascular Events to be Featured in Late-Breaking Session

Corlanor® (Ivabradine) Chronic Heart Failure Data to be Presented in an Oral Abstract Session

THOUSAND OAKS, Calif., March 2, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present 15 abstracts, including data evaluating Repatha™ (evolocumab), an investigational cholesterol-lowering medication, and Corlanor® (ivabradine), an investigational drug for chronic heart failure, at the upcoming American College of Cardiology's 64th Annual Scientific Session (ACC.15), being held March 14-16 in San Diego.

Repatha is a fully human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that reduces the liver's ability to remove low-density lipoprotein cholesterol (LDL-C), or "bad" cholesterol, from the blood.[1] Corlanor is an oral drug that acts on the body's cardiac pacemaker to slow the heart rate without negative effects on myocardial contractility or ventricular repolarization.[2]

"As we head into a milestone-filled year for our cardiovascular pipeline, we are eager to share safety analyses and data exploring the effect of Repatha on LDL cholesterol and cardiovascular events and new analyses on the efficacy of Corlanor in patients with chronic heart failure at ACC's Scientific Session this year," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are working with regulatory agencies to bring both of these cardiovascular therapies to patients, which we believe will provide new options for those with high cholesterol or chronic heart failure who continue to struggle with their conditions and are in need of additional therapies."

Among the abstracts is a Late-Breaking Clinical Trial presentation of LDL-C lowering and major adverse cardiovascular event data after one year of treatment from the OSLER-1 and -2 (Open Label Study of Long TERm Evaluation Against LDL-C) studies in the Repatha program, and an oral presentation of long-term data from the OSLER-1 trial evaluating the safety and efficacy of Repatha after two years of treatment. Repatha data presentations also include a pooled safety analysis in over 6,000 patients from Phase 2 and 3 short- and long-term clinical trials.

The Phase 3 results from the YUKAWA-2 (StudY of LDL-Cholesterol Reduction Using a Monoclonal PCSK9 Antibody in Japanese Patients With Advanced Cardiovascular Risk) study evaluating Repatha in combination with statin therapy in Japanese patients with high cardiovascular risk and high cholesterol will also be presented.

Additionally, two analyses from the Phase 3 SHIFT (Systolic Heart failure treatment with the If Inhibitor Ivabradine Trial) study evaluating Corlanor will be presented. These data include an oral presentation on the efficacy profile of Corlanor in patients with chronic heart failure and angina, and a poster on whether the addition of Corlanor to optimized background therapy affects beta blocker usage.

Data to be presented at ACC.15 include:

Repatha

Late-Breaking and Oral Presentations

- **Effect of the PCSK9 Inhibitor Evolocumab on Cardiovascular Outcomes (OSLER-1 and -2)**
  Abstract 402-08, Late-Breaking Clinical Trials, Oral Presentation, Sunday, March 15, 8-8:10 a.m. PT (Hall H, Main Tent)
- **Two Year Analysis of the Safety and Tolerability of Evolocumab: The OSLER-1 Study**
  Abstract 914-10, Oral Presentation, Monday, March 16, 11:45-11:57 a.m. PT (Room 6B)

Poster Presentations

- **LDL Cholesterol Reduction in Elderly Patients with the PCSK9 Monoclonal Antibody Evolocumab (AMG 145): A Pooled Analysis of 1779 Patients in Phase 2, 3 and Open Label Extension Studies**
  Abstract 1107-101, Poster Presentation, Saturday, March 14, 10-10:45 a.m. PT (Poster Hall B1)
- **Effects of Evolocumab (AMG 145) Treatment on Vitamin E Levels: Results from the 52-Week Phase 3 Double-Blind, Randomized, Placebo-Controlled DESCARTES Study**
  Abstract 1107-102, Poster Presentation, Saturday, March 14, 10-10:45 a.m. PT (Poster Hall B1)
- **Clinical Equivalence of Evolocumab 140 mg Every Two Weeks and 420 mg Monthly Dosing Regimens: A Pooled Analysis of 3146 Patients in Phase 3 Studies**
  Abstract 1107-103, Poster Presentation, Saturday, March 14, 10-10:45 a.m. PT (Poster Hall B1)
- **Effects of Evolocumab (AMG 145) in Hypercholesterolemic, Statin-Treated, Japanese Patients at High Cardiovascular Risk: Results from the Phase III YUKAWA 2 Study**
  Abstract 1107-104, Poster Presentation, Saturday, March 14, 10-10:45 a.m. PT (Poster Hall B1)
- **A Comprehensive Safety Analysis of 6026 Patients from Phase 2 and 3 Short and Long Term Clinical Trials with Evolocumab (AMG 145)**
  Abstract 1164M-07, Moderated Poster Presentation, Saturday, March 14, 4:15-4:25 p.m. PT (Prevention Moderated Poster

Theater, Poster Hall B1)

Corlanor

Oral Presentation

- **Efficacy Profile of Ivabradine in Patients with Heart Failure Plus Angina Pectoris**
  Abstract 902-06, Oral Presentation, Sunday, March 15, 8:30-8:42 a.m. PT (Room 6C)

Poster Presentation

- **Beta Blocker Dosage and Use Over Time in the Systolic Heart Failure Treatment with the *If* Inhibitor Ivabradine Trial (SHIFT) Study**
  Abstract 1146-202, Poster Presentation, Saturday, March 14, 3:45-4:30 p.m. PT (Poster Hall B1)

Observational Research

- **Effect of LDL-C on Risk of Recurrent Myocardial Infarction, Unstable Angina, and Ischemic Stroke in a High Risk, Secondary Prevention Patient Population**
  Abstract 1104-080, Poster Presentation, Saturday, March 14, 10-10:45 a.m. PT (Poster Hall B1)
- **Unmet Patient Need in Statin Intolerance: The Epidemiology, Clinical Characteristics, and Management**
  Abstract 1178-113, Poster Presentation, Sunday, March 15, 9:45-10:30 a.m. PT (Poster Hall B1)
- **Trends in Combination Lipid Lowering Therapy in the Medicare Population with Coronary Heart Disease**
  Abstract 1211-118, Poster Presentation, Sunday, March 15, 3:45-4:30 p.m. PT (Poster Hall B1)

Health Economics

- **Use of β-Blockers in Medicare Beneficiaries with Systolic Heart Failure and Hypotension, Asthma, Chronic Obstructive Pulmonary Disease or Peripheral Vascular Disease**
  Abstract 1146-200, Poster Presentation, Saturday, March 14, 3:45-4:30 p.m. PT (Poster Hall B1)
- **Current Heart Failure Management Patterns in Medicare Advantage Patients: A Contemporary United States Claims Database Analysis**
  Abstract 1251-192, Poster Presentation, Monday, March 16, 9:45-10:30 a.m. PT (Poster Hall B1)
- **Heart Failure Management Patterns in a Large United States Commercial Claims Database**
  Abstract 1251-193, Poster Presentation, Monday, March 16, 9:45-10:30 a.m. PT (Poster Hall B1)

Amgen will host a webcast investor call on Monday, March 16, at 1 p.m. PT. Sean E. Harper, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team, will participate in the call to discuss Amgen's cardiovascular program, including Repatha and Corlanor data presented at ACC.15.

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.

The FDA has provisionally approved the trade names Repatha and Corlanor.

About Repatha™ (evolocumab)

Repatha™ (evolocumab) is a fully human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9).[1] PCSK9 is a protein that targets LDL receptors for degradation and thereby reduces the liver's ability to remove LDL-C, or "bad" cholesterol, from the blood.[3] Repatha, being developed by Amgen scientists, is designed to bind to PCSK9 and inhibit PCSK9 from binding to LDL receptors on the liver surface. In the absence of PCSK9, there are more LDL receptors on the surface of the liver to remove LDL-C from the blood.[1]

About PROFICIO: Repatha™ (evolocumab) Clinical Trial Program

PROFICIO, which stands for the Program to Reduce LDL-C and Cardiovascular Outcomes Following Inhibition of PCSK9 In Different POpulations, is a large and comprehensive clinical trial program evaluating Repatha™ (evolocumab) in 22 clinical trials, with a combined planned enrollment of approximately 35,000 patients.

The Phase 3 program includes 16 trials to evaluate Repatha administered every two weeks and monthly in multiple patient populations, including in combination with statins in patients with hyperlipidemia (LAPLACE-2 and YUKAWA-2); in patients with hyperlipidemia who cannot tolerate statins (GAUSS-2 and GAUSS-3); as a stand-alone treatment in patients with hyperlipidemia (MENDEL-2); in patients whose elevated cholesterol is caused by genetic disorders called heterozygous (RUTHERFORD-2 and TAUSSIG) and homozygous (TESLA and TAUSSIG) familial hypercholesterolemia; the effects of Repatha on lipoprotein metabolism (FLOREY); and the administration of Repatha in statin-treated hyperlipidemic patients (THOMAS-1 and THOMAS-2).

Five ongoing studies in the Repatha Phase 3 program will provide long-term safety and efficacy data. These include FOURIER (Further

Cardiovascular OUtcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk), which will assess whether treatment with Repatha in combination with statin therapy compared to placebo and statin therapy reduces recurrent cardiovascular events in approximately 27,500 patients with cardiovascular disease; EBBINGHAUS (Evaluating PCSK9 Binding AntiBody Influence oN CoGnitive HeAlth in High CardiovascUlar Risk Subjects), which will evaluate the effect of Repatha on cognitive function in a subset of patients enrolled in FOURIER; OSLER-2 (Open Label Study of Long TERm Evaluation Against LDL-C Trial-2) in patients with high cholesterol who completed any of the Phase 3 studies; GLAGOV (GLobal Assessment of Plaque ReGression with a PCSK9 AntibOdy as Measured by IntraVascular Ultrasound), which will determine the effect of Repatha on coronary atherosclerosis in approximately 950 patients undergoing cardiac catheterization; and TAUSSIG (Trial Assessing Long Term USe of PCSK9 Inhibition in Subjects with Genetic LDL Disorders), which will assess the long-term safety and efficacy of Repatha on LDL-C in patients with severe familial hypercholesterolemia including patients with homozygous familial hypercholesterolemia. The DESCARTES (Durable Effect of PCSK9 Antibody CompARed wiTh PlacEbo Study) study, a long-term safety and efficacy trial in patients with hyperlipidemia at risk for cardiovascular disease, has been completed.

About Corlanor® (ivabradine)

Corlanor® (ivabradine) is an investigational oral drug that inhibits the I_f current ("funny" current) in the sinoatrial node, the body's cardiac pacemaker.[2] Corlanor works to slow the heart rate without negative effects on myocardial contractility or ventricular repolarization.[2] Developed by Les Laboratoires Servier, Corlanor was approved by the European Medicines Agency (EMA) as PROCORALAN® in 2005 for the symptomatic treatment of stable angina and in 2012 for chronic heart failure in patients with elevated heart rates. As of April 2014, Corlanor was approved for use in 102 countries for the treatment of angina and in 89 countries for the treatment of chronic heart failure. Through a collaboration with Servier, Amgen has rights to commercialize Corlanor in the U.S.

About Amgen's Commitment to Cardiovascular Disease

Amgen is dedicated to addressing important scientific questions in order to advance care and improve the lives of patients with cardiovascular disease. Through its own research and development efforts and innovative partnerships, Amgen has built a robust cardiology pipeline consisting of several 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.

Forward-Looking Statements

This news release contains forward-looking statements that are based on management's current expectations and beliefs 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, including Amgen'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'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 March 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 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 products liability claims. 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 are affected by the reimbursement policies imposed by third-party payors, 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 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 and there can be no guarantee of our 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 recently announced restructuring plan. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our common stock.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

CONTACT: Amgen, Thousand Oaks
Kristen Davis, 805-447-3008 (media)
Arvind Sood, 805-447-1060 (investors)

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3. Abifadel M, Varret M, Rabes JP, et al. Mutations in PCSK9 Cause Autosomal Dominant Hypercholesterolemia. *Nat Genet*. 2003;34:154-156.

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