Phase 3 Pivotal Data On Amgen's Novel Investigational Cholesterol-Lowering Medicine To Be Featured At The American College of Cardiology's 63rd Annual Scientific Session

March 24, 2014

Five Phase 3 Studies With Evolocumab (AMG 145) to be Featured in Late-Breaking and Clinical Research Presentations - Data Form the Basis of Global Filing Plan

THOUSAND OAKS, Calif., March 24, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present pivotal Phase 3 data from five clinical studies evaluating evolocumab (AMG 145), an investigational fully human monoclonal antibody that inhibits PCSK9, a protein that reduces the liver's ability to remove low-density lipoprotein cholesterol (LDL-C), or "bad" cholesterol, from the blood.[1] The results from the five Phase 3 studies with evolocumab will be presented in three Featured Clinical Research and two Late-Breaking Clinical Trial sessions at the upcoming American College of Cardiology's 63rd Annual Scientific Session (ACC.14), being held March 29 – 31 in Washington, D.C.

"We are eager to share the detailed findings from our Phase 3 cholesterol-lowering studies of evolocumab at ACC," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The robust data from these studies in more than 4,000 patients form the basis of our global filing plan and we look forward to potentially providing a new treatment option to improve the lives of patients with high cholesterol, who have increased LDL-C levels despite existing therapies."

Among the abstracts are five oral presentations from the large and comprehensive evolocumab clinical trial program, PROFICIO (Program to Reduce LDL-C and Cardiovascular Outcomes Following Inhibition of PCSK9 In Different POpulations). Data from three Phase 3 studies will be presented in a Featured Clinical Research session on Saturday, March 29, at 2 p.m. EDT and results from two Phase 3 studies will be featured in a Late-Breaking Clinical Trials session on Sunday, March 30, at 8 a.m. EDT.

Data presented on evolocumab will include:

Featured Clinical Research

- **Efficacy and Safety of Evolocumab (AMG 145) Monotherapy Compared With Ezetimibe and Placebo in Hypercholesterolemic Subjects: A Phase 3 Randomized Clinical Trial**
  Abstract 400-03, Featured Clinical Research, Oral Presentation, Saturday, March 29, 2 – 2:18 p.m. EDT (Room 147 B)
- **Long-term Tolerability and Efficacy of Evolocumab (AMG 145) in Hyperlipidemic Subjects: A 52-week Phase 3 Double-blind, Randomized, Placebo-controlled Study**
  Abstract 400-04, Featured Clinical Research, Oral Presentation, Saturday, March 29, 2:18 – 2:36 p.m. EDT (Room 147 B)
- **The Addition of Evolocumab (AMG 145) Allows the Majority of Heterozygous Familial Hypercholesterolemic Patients to Achieve Low-density Lipoprotein Cholesterol Goals - Results from the Phase 3 Randomized, Double-blind, Placebo-controlled Study**
  Abstract 400-05, Featured Clinical Research, Oral Presentation, Saturday, March 29, 2:36 – 2:54 p.m. EDT (Room 147 B)

Late-Breaking Clinical Trials

- **The Low-density Lipoprotein Cholesterol Assessment With PCSK9 Monoclonal Antibody Inhibition Combined With Statin Therapy - 2 Trial: A Phase 3, Double-blind, Randomized, Placebo and Ezetimibe Controlled, Multicenter Study to Evaluate Safety, Tolerability and Efficacy of Evolocumab (AMG 145) in Combination With Statin Therapy in Subjects With Primary Hypercholesterolemia and Mixed Dyslipidemia**
  Abstract 402-10, Late-Breaking Clinical Trials, Oral Presentation, Sunday, March 30, 8:15 – 8:25 a.m. EDT (Hall D, Main Tent)
- **A Phase 3 Double-blind, Randomized Study to Assess the Safety and Efficacy of Evolocumab (AMG 145) in Hypercholesterolemic Subjects Unable to Tolerate an Effective Dose of Statin**
  Abstract 402-16, Late-Breaking Clinical Trials, Oral Presentation, Sunday, March 30, 9 – 9:10 a.m. EDT (Hall D, Main Tent)

Additional Poster Presentation

- **Effects of Evolocumab on Lipoprotein Particles and Subclasses in Hypercholesterolemic and Heterozygous Familial Hypercholesterolemia Subjects on Statin Therapy**
  Abstract 1183-134, Poster Presentation, Sunday, March 30, 9:45 – 10:30 a.m. EDT (Hall C)

Amgen will also host a webcast investor meeting at ACC.14 on Sunday, March 30, at 7 p.m. EDT. 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, including the primary analyses of five Phase 3 evolocumab studies being presented at ACC.14.

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.

About Evolocumab

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.[2] Evolocumab, 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: The 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 evolocumab in 20 clinical trials, with a combined planned enrollment of nearly 30,000 patients.

The Phase 3 program includes 14 trials to evaluate evolocumab 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; as well as the administration of evolocumab (THOMAS-1 and THOMAS-2).

Five studies in the evolocumab 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 evolocumab in combination with statin therapy compared to placebo and statin therapy reduces recurrent cardiovascular events in approximately 22,500 patients with cardiovascular disease; DESCARTES (Durable Effect of PCSK9 Antibody CompARed wiTh PlacEbo Study) in patients with hyperlipidemia at risk for cardiovascular disease; 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 evolocumab 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 evolocumab on LDL-C in patients with severe familial hypercholesterolemia.

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 the world's largest independent biotechnology company, 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 24, 2014, 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 Amgen Inc. and its subsidiaries (which are collectively referred to as we, or us) 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 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.

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.

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References

1. Amgen Data on File, Investigator Brochure.
2. Abifadel M, et al. Mutations in PCSK9 cause autosomal dominant hypercholesterolemia. *Nat Genet.* 2003;34:154-156.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/mnr/7061853-amgen-at-american-college-of-cardiology-acc-14

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