Circulation Publishes Results From RUTHERFORD Study Which Showed AMG 145 Significantly Reduced LDL Cholesterol In Patients With Heterozygous Familial Hypercholesterolemia

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AMG 145 Combination Therapy With Statins Reduced LDL Cholesterol up to 56 Percent
Genetic Condition Creates Risk of Aggressive and Premature Cardiovascular Disease
Data Presented Simultaneously at American Heart Association Scientific Sessions 2012

THOUSAND OAKS, Calif., Nov. 5, 2012 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that treatment with AMG 145 in combination with statin therapy, with or without ezetimibe, resulted in a reduction in low density lipoprotein cholesterol (LDL-C), or "bad" cholesterol, by up to 56 percent in patients with heterozygous familial hypercholesterolemia (HeFH) in the Phase 2 RUTHERFORD study. AMG 145 is an investigational fully human monoclonal antibody directed against PCSK9, a protein that reduces the liver's ability to remove LDL-C from the blood. The study was published today in *Circulation* and simultaneously presented in a late-breaking clinical trial session at the American Heart Association Scientific Sessions 2012.

HeFH is one of the most common genetic disorders, affecting at least one out of every 500 people worldwide. HeFH causes severe elevations in total cholesterol and LDL-C, leading to the premature development of cardiovascular disease and early cardiovascular morbidity and mortality.

In the RUTHERFORD trial, treatment with AMG 145 every four weeks (Q4W) resulted in a significant LDL-C decrease versus placebo in HeFH patients on lipid-lowering therapy (statins with or without ezetimibe). At week 12, LDL-C reduction, measured by preparative ultracentrifugation, was 43 percent and 55 percent with AMG 145 350 mg and 420 mg, respectively, compared to a 1 percent increase with placebo ($p<0.001$ for both dose groups). At week 12, treatment with AMG 145 350 mg and 420 mg Q4W resulted in 70 percent and 89 percent of patients reaching LDL-C levels of <100 mg/dL and 44 percent and 65 percent achieving <70 mg/dL, respectively, compared to 2 percent and 0 percent of placebo subjects, respectively. Favorable reductions in total cholesterol, non-HDL-C, Lp(a) and ApoB were consistent with the reductions in LDL-C.

"Despite existing therapies and maintaining a healthy lifestyle, patients with heterozygous familial hypercholesterolemia are prematurely at risk for serious cardiovascular disease due to the difficulty in reducing their LDL-C levels," said Frederick Raal, M.D., Ph.D., Carbohydrate & Lipid Metabolism Research Unit, Division of Endocrinology & Metabolism, Department of Medicine, University of the Witwatersrand, Johannesburg. "Data from the RUTHERFORD study suggests that using AMG 145 as an add-on therapy to statins helped these high-risk patients achieve LDL-C goals and offers promise for the treatment of HeFH."

The most common adverse events (AEs) for AMG 145 in this trial were nasopharyngitis, injection-site reaction and headache.

This study is one of four Phase 2 studies of AMG 145 being presented at the American Heart Association Scientific Sessions 2012.

RUTHERFORD Study Design
RUTHERFORD (RedUction of LDL-C with PCSK9 InhibiTion in HEteRozygous Familial HyperchOlesteRolemia Disorder Study) was a randomized, double-blind, placebo-controlled study that evaluated AMG 145, dosed subcutaneously Q4W, in 168 patients with an LDL-C >100 mg/dL who were on a stable dose of statin, with or without ezetimibe. Patients were randomized to three treatment groups: AMG 145 at 350 mg, AMG 145 at 420 mg or placebo administered subcutaneously every four weeks. The primary endpoint was percentage change from baseline in LDL-C, measured by preparative ultracentrifugation, at week 12.

Webcast Information
Amgen will hold an analyst/investor event on Tuesday, Nov. 6, at 7:00 p.m. Pacific Standard Time to discuss data presented at the American Heart Association Scientific Sessions 2012. A webcast of the event can be found on Amgen's website at www.amgen.com, under Investors. The audio webcast will be archived and available for replay for at least 72 hours.

About AMG 145
AMG 145 is a fully human monoclonal antibody directed against proprotein convertase subtilisin/kexin type 9 (PCSK9). PCSK9 is a protein that reduces the liver's ability to remove LDL-C from the blood and thereby causes bad cholesterol to increase. AMG 145, developed by Amgen scientists, binds to PCSK9 circulating in the blood and prevents PCSK9 from binding to LDL receptors in the liver. Without PCSK9 bound to them, the LDL receptors can take up and remove LDL-C from the blood, recycle and remain available for binding additional LDL-C. The Amgen Phase 2 program for AMG 145 enrolled more than 2,000 patients across seven studies to evaluate the effects of AMG 145 across multiple patient populations who may benefit from additional cholesterol lowering treatment options. The Phase 2 program is evaluating the treatment of hyperlipidemia with AMG 145 in combination with statins, in patients with hyperlipidemia who cannot tolerate statins, as a stand-alone treatment in patients with hyperlipidemia, and in patients whose elevated cholesterol is caused by genetic disorders called heterozygous and homozygous familial hypercholesterolemia.

About Amgen
Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. 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 most recent 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 Nov. 5, 2012, 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.

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. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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