Amgen Presents Pooled Analysis Showing AMG 145 Significantly Reduced LDL Cholesterol In Over 1,200 Patients

September 1, 2013

Pooled Data from Four Phase 2 Studies Demonstrated Consistent Reductions in LDL Cholesterol of Up to 59 Percent
Results of Analyses Presented at ESC Congress 2013

THOUSAND OAKS, Calif., Aug. 31, 2013 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced treatment with AMG 145 resulted in significant reductions in low-density lipoprotein cholesterol (LDL-C), or "bad" cholesterol, of up to 59 percent in an efficacy analysis of pooled data from four 12-week Phase 2 studies evaluating AMG 145 in patient populations with high cholesterol. AMG 145 is an investigational human monoclonal antibody that inhibits PCSK9, a protein that reduces the liver's ability to remove LDL-C from the blood. Amgen presented the data at the ESC Congress 2013, organized by the European Society of Cardiology, in Amsterdam.

Elevated LDL-C is recognized as a major risk factor for cardiovascular (CV) disease.[1,2] Despite the availability of various treatments to lower LDL-C, it is estimated that in two-thirds of treated, high-risk patients, LDL-C is not well-controlled.[3,4]

"Millions of people around the world are unable to control their LDL cholesterol with currently available treatment options," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The data that we have accumulated in our Phase 2 clinical program is evidence that AMG 145 has the potential to help patients reach their cholesterol goals. We are conducting a large and comprehensive Phase 3 clinical program evaluating AMG 145 in multiple patient populations and utilizing two dosing schedules, with the hopes of advancing care and improving the lives of patients with uncontrolled high LDL cholesterol."

Results from the efficacy analysis showed mean reductions in LDL-C from baseline to week 12, as measured by preparative ultracentrifugation, ranged from 40 to 59 percent across AMG 145 doses in comparison to 0.1 to 0.5 percent for placebo (p=0.001). AMG 145 treatment was also associated with improvements in other lipid parameters, including high-density lipoprotein cholesterol (HDL-C), triglycerides, apolipoprotein B, lipoprotein(a) and apolipoprotein A1, within each targeted dose frequency of AMG 145.

In the safety analysis, adverse events (AEs) were observed more frequently with AMG 145 than placebo (57 percent vs. 49 percent) with the most frequent AEs being nasopharyngitis (8.3 percent vs. 7.5 percent) and upper respiratory tract infection (4.1 percent vs. 3.3 percent). Serious AEs were 2.0 percent with AMG 145 and 1.2 percent with placebo. The rates of injection-site reactions were similar between patients treated with AMG 145 and those treated with placebo (4.1 percent vs. 3.3 percent) while muscle-related AEs and anti-drug binding antibodies were 6.0 percent vs. 3.9 percent and 0.1 percent vs. 0.3 percent, respectively.

About the Pooled Analyses
The pre-specified, pooled analyses of data were from four Phase 2, placebo-controlled, randomized trials of AMG 145 in various patient populations with hyperlipidemia. In each trial, treatment duration was 12 weeks and the primary endpoint was percentage change in LDL-C from baseline, as measured by ultracentrifugation. Patients enrolled in the trials received various doses of AMG 145 subcutaneously every two weeks or monthly. Three of the four trials permitted stable background statin therapy. The trials included:

– MENDEL (Monoclonal Antibody Against PCSK9 to Reduce Elevated LDL-C in Patients Currently Not Receiving Drug Therapy for Easing Lipid Levels) evaluated the efficacy, safety and tolerability of AMG 145 administered subcutaneously every two weeks and every four weeks in hyperlipidemic patients (LDL-C ³ 100 mg/dL and < 190 mg/dL) who were not receiving statin therapy.

– LAPLACE-TIMI 57 (LDL-C Assessment with PCSK9 MonoclonaL Antibody Inhibition Combined With Statin ThErapy – Thrombolysis In Myocardial Infarction-57) evaluated the efficacy, safety and tolerability of AMG 145 administered subcutaneously every two weeks and every four weeks in hyperlipidemic patients at risk for CV disease (LDL-C ≥ 85 mg/dL) when added to a stable dose of statin, with or without ezetimibe.

– RUTHERFORD (RedUction of LDL-C With PCSK9 InhibiTion in HEteRozygous Familial HypercholesteRolemia Disorder Study) evaluated AMG 145 administered subcutaneously every month, in heterozygous familial hypercholesterolemic patients with an LDL-C >100 mg/dL who were on a stable dose of statin, with or without ezetimibe.

– GAUSS (Goal Achievement After Utilizing an anti-PCSK9 Antibody in Statin Intolerant Subjects) evaluated the efficacy, safety and tolerability of AMG 145 dosed subcutaneously every month, in hyperlipidemic patients who could not tolerate effective statin doses due to muscle-related side effects.

About AMG 145
AMG 145 is a human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9). 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.[5] AMG 145, 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.[6]

About the AMG 145 Clinical Trial Program
PROFICIO, which stands for the Program to Reduce LDL-C and Cardiovascular Outcomes Following Inhibition of PCSK9 In Different POpulations, is the large and comprehensive clinical trial program evaluating AMG 145.

The Phase 3 clinical trial program for AMG 145 builds upon the successful Phase 2 studies and includes 12 trials, with a combined planned enrollment of more than 27,000 patients. The Phase 3 studies will evaluate AMG 145 administered every two weeks and monthly in multiple patient populations, including in combination with statins in patients with hyperlipidemia (LAPLACE-2), in patients with hyperlipidemia who cannot tolerate statins (GAUSS-2), as a stand-alone treatment in patients with hyperlipidemia (MENDEL-2), and in patients whose elevated cholesterol is caused by genetic

disorders called heterozygous (RUTHERFORD-2) and homozygous (TESLA and TAUSSIG) familial hypercholesterolemia.

Five studies of AMG 145 will provide long-term safety and efficacy data, including the FOURIER (Further Cardiovascular OUtcomes Research with PCSK9 Inhibition in
Subjects with Elevated Risk) study, which will assess whether treatment with AMG 145 compared to placebo reduces recurrent cardiovascular events in approximately 22,500 patients with cardiovascular disease.

Additional information about clinical trials of AMG 145 can be found at www.clinicaltrials.gov.

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 Aug. 31, 2013, 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.

CONTACT: Amgen, Thousand Oaks
Ashleigh Koss, 805-559-0746 (media)
Arvind Sood, 805-447-1060 (investors)

1. American Heart Association (2012). Why cholesterol matters. http://www.heart.org/HEARTORG/Conditions/Cholesterol/WhyCholesterolMatters/Why-Cholesterol-Matters_UCM_001212_Article.jsp. Accessed August 2013
2. World Health Organization. Global status report on noncommunicable diseases 2010. Geneva, 2011.
3. Roger V et al. Heart disease and stroke statistics – 2011 update: A report from the American Heart Association. *Circulation*.2011;123:e18-e209.
4. Durrington P. Dyslipidaemia.*The Lancet*.2003;362:717–311.

5. Abifadel M et al. Mutations in PCSK9 cause autosomal dominant hypercholesterolemia. *Nat Genet* 2003;34:154-156.
6. Amgen data on file, Investigator Brochure.

(Logo: http://photos.prnewswire.com/prnh/20081015/AMGENLOGO)

SOURCE Amgen