Amgen to Highlight New Data at Upcoming ESC Congress 2013

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THOUSAND OAKS, Calif., Aug. 27, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present new data on omecamtiv mecarbil, a small molecule cardiac myosin activator that is being studied for the treatment of heart failure in collaboration with Cytokinetics. Amgen will also present data on AMG 145, an investigational 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] Amgen will present the data at the upcoming ESC Congress 2013, organized by the European Society of Cardiology, in Amsterdam.

Data from the Phase 2b ATOMIC-AHF study (Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure), which evaluates the safety, tolerability and efficacy of an intravenous formulation of omecamtiv mecarbil in patients with acute heart failure, will be featured during a Hot Line Late Breaking Trials Session on Sept. 3 at 11:00 a.m. CEST.

Additionally, Amgen will highlight findings from the AMG 145 clinical program, including efficacy and safety data from a pooled analysis of four Phase 2 studies, which include MENDEL, LAPLACE-TIMI 57, GAUSS and RUTHERFORD.

"The data presented at this year's ESC Congress 2013 will highlight what we are doing through our R&D efforts to develop novel treatments that we hope will meet today's urgent cardiovascular needs," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Amgen is establishing its presence in cardiovascular medicine and is committed to addressing difficult scientific questions, with the goal of advancing cardiac care and improving the lives of patients worldwide."

Data presented on omecamtiv mecarbil will include:

- **ATOMIC-AHF: Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure: Results from ATOMIC-AHF**
  Abstract 4503, Hot Line Late Breaking Oral Presentation, Tuesday, Sept. 3, 11:18 – 11:30 a.m. CEST (Amsterdam - Central Village)

Data presented on AMG 145 will include:

- **Efficacy of AMG 145, a Fully Human Monoclonal Antibody to PCSK9: Data from 1252 Patients in Four Phase 2 Studies**
  Abstract 831, Oral Presentation, Sunday, Sept. 1, 8:30 – 8:45 a.m. CEST (Algiers - Village 4)
- **Safety of AMG 145, a Fully Human Monoclonal Antibody to PCSK9: Data from Four Phase 2 Studies in 1314 Patients**
  Abstract 683, Poster Presentation, Saturday, Aug. 31, 2:00 – 6:00 p.m. CEST (Posters - Village 9)
- **Statin Therapy is a Major Determinant of PCSK9 Plasma Concentration: Data from Four Clinical Trials with AMG 145**
  Abstract P681, Poster Presentation, Saturday, Aug. 31, 2:00 – 6:00 p.m. CEST (Posters - Village 9)
- **Intolerance to Statins and Response to PCSK9 Inhibition with AMG 145**
  Abstract P682, Poster Presentation, Saturday, Aug. 31, 2:00 – 6:00 p.m. CEST (Posters - Village 9)
- **Safety, Tolerability, and Efficacy of Long-Term Administration of AMG 145: Preliminary Results from the OSLER Study**
  Abstract P4182, Poster Presentation, Monday, Sept. 2, 2:00 – 6:00 p.m. CEST (Posters – Village 9)

About Omecamtiv Mecarbil

Omecamtiv mecarbil is a small molecule activator of cardiac myosin, the motor protein that causes cardiac contraction.[2,3] The compound is being evaluated in both intravenous and oral formulations as a potential treatment for heart failure. Omecamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics.

About the Omecamtiv Mecarbil Clinical Trial Program

The Phase 2b clinical trial known as ATOMIC-AHF (Acute Treatment of Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure) is an international, multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability and efficacy of an intravenous formulation of omecamtiv mecarbil in approximately 600 patients with left ventricular systolic dysfunction who were hospitalized with acute heart failure.[4]

Oral formulations of omecamtiv mecarbil are currently being evaluated in a Phase 2 trial known as COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure). COSMIC-HF is a multicenter, randomized, double-blind, placebo-controlled, dose escalation study designed to evaluate the safety and efficacy of oral omecamtiv mecarbil in approximately 420 patients with chronic heart failure and left ventricular systolic dysfunction.[5]

Additional information about clinical trials of omecamtiv mecarbil can be found at www.clinicaltrials.gov.

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. AMG 145, being developed by Amgen scientists, is designed to bind to PCSK9 and inhibit PCSK9 binding to LDL receptors on the liver's 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 a large and comprehensive clinical trial program evaluating AMG 145.[7,8]

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.[3] 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.[7]

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.[9-13]

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. 27, 2013, and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and act ual 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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(Logo: http://photos.prnewswire.com/prnh/20081015/AMGENLOGO)

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