



Amgen's PCSK9 Inhibitor Reduced LDL Cholesterol up to 81 Percent in Phase 1b Study

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Robust AMG 145 Phase 2 Program Expected to Deliver Results in 2012

THOUSAND OAKS, Calif., March 25, 2012 /PRNewswire/ -- Amgen (NASDAQ:AMGN) announced today positive results from a Phase 1b clinical study of AMG 145, an investigational PCSK9 inhibitor, in patients with high cholesterol who were taking statins. The study demonstrated that multiple doses of AMG 145 significantly reduced serum low density lipoprotein cholesterol (LDL-C), also known as "bad" cholesterol, by up to 81 percent versus placebo (maximum reduction) in subjects on low to moderate doses of statins ($p < 0.001$). The cholesterol lowering effects of AMG 145 were similar among patients on high doses of statins (80 mg atorvastatin and 40 mg rosuvastatin) and patients on low to moderate doses of statins. No deaths or serious adverse events (AEs) were reported in the study. Full results of the study were presented for the first time today in an oral session at the American College of Cardiology Scientific Session in Chicago. (Abstract # 923-4)

High LDL cholesterol (LDL-C) is a major public health issue in most countries as it contributes to the risk of developing cardiovascular disease, the leading cause of death among men and women. Most patients who are treated for high cholesterol take drugs known as statins. While statins are effective, many patients still have difficulty reaching their cholesterol goals and others cannot tolerate statin therapy. AMG 145 is a fully human monoclonal antibody that inhibits PCSK9, a protein that reduces the liver's ability to remove LDL-C from the blood.

"Early studies have shown that AMG 145 lowers levels of PCSK9 in the body and brings LDL-cholesterol levels down as a result," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Based on these results, Amgen initiated a robust Phase 2 program that will provide a deeper understanding of the benefit-risk profile of inhibiting PCSK9 in a wide variety of patients whose high cholesterol cannot be controlled with existing therapies. We look forward to seeing the results of these studies later this year."

The Phase 1b study of 51 patients on stable doses of statins was designed to assess the safety and tolerability of AMG 145 and its effect on LDL-C levels versus placebo. Patients on low to moderate doses of statins who received AMG 145 every two weeks had mean LDL-C reductions of up to 75 percent versus placebo at week six (three subcutaneous doses). The patients on low to moderate doses of statins who received AMG 145 every four weeks demonstrated up to a 66 percent reduction in LDL-C at week eight (two subcutaneous doses). The magnitude and duration of effect were dose-dependent. Plasma PCSK9 was undetectable at higher doses. Patients on high doses of statins who received AMG 145 every two weeks had a mean reduction in LDL-C of up to 63 percent versus placebo at week six (three subcutaneous doses).

AE profiles were similar for AMG 145 and placebo with the most common AEs observed encompassing nasopharyngitis (3 [7 percent] AMG 145 versus 1 [7 percent] placebo), injection site hematoma (2 [5 percent] AMG 145 versus 2 [14 percent] placebo), and viral upper respiratory tract infection (2 [5 percent] AMG 145 versus 1 [7 percent] placebo).

About AMG 145

AMG 145 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 LDL-C from the blood causing 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. Amgen is currently conducting a Phase 2 program for AMG 145 that will enroll approximately 1,900 patients across six 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 AMG 145 in combination with statins in patients with or at risk for cardiovascular disease, in patients who cannot tolerate statins, as a stand-alone treatment in patients with low cardiovascular risk, and in patients whose cholesterol is caused by a genetic disorder called heterozygous 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 March 25, 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. Further, the scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (FDA) for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses. Only the FDA can determine whether the products are safe and effective for these uses. 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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