Amgen Presents Denosumab and Sclerostin Antibody Data at American Society for Bone and Mineral Research Annual Meeting; Data Suggest the Potential for Targeting the Key Proteins, RANK Ligand and Sclerostin, for Bone Loss Conditions

September 19, 2006

PHILADELPHIA--(BUSINESS WIRE)--Sept. 19, 2006--Amgen (NASDAQ:AMGN), the world's largest biotechnology company, announced today the presentation of data at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting highlighting its expertise in bone biology research and commitment to developing therapies that address the burden of bone disease. The studies evaluated denosumab and a sclerostin antibody, two of the company's investigational therapies. These antibodies target key proteins responsible for the regulation of bone destruction and formation.

"Amgen scientists are committed to fulfilling the promise of biotechnology by developing novel therapeutics aimed at improving bone health," said Willard Dere, M.D., senior vice president of Global Development and chief medical officer, Amgen. "Our research has the potential to transform the scientific understanding of bone biology and the treatment of conditions associated with bone loss."

Denosumab is an investigational fully human monoclonal antibody that targets RANK Ligand, a primary mediator of the formation, function and survival of osteoclasts (cells which resorb or break down bone). Denosumab is the first therapy in late stage development that targets RANK Ligand.

Results from a post-hoc exploratory analysis of an ongoing, multicenter, Phase 2 study, showed that subjects treated with denosumab subcutaneously, 60 mg twice yearly for up to 24 months, experience an improvement not only in bone mineral density (BMD) but also in parameters of hip structural analysis (HSA), a technique that estimates geometric properties of bone strength.

In the study, patients were evaluated with dual energy X-ray absorptiometry (DXA), the recognized measure for BMD. The DXA scans were then analyzed with HSA software, providing an estimated measurement of bone geometry. Specifically, denosumab therapy resulted in a 6.69 percent increase in the measure of cortical thickness at the femoral shaft; there was a 0.31 percent decrease, from baseline, in the placebo group (p less than 0.001). In the open label alendronate cohort, there was a 1.82 percent increase in cortical thickness at the femoral shaft (p less than 0.041). These results are consistent with previous reports highlighting the effects of denosumab at highly cortical sites; cortical bone, the dense outer shell of the skeleton, comprises approximately three-quarters of the total skeletal mass. The full data from this study will be presented at the ASBMR meeting on September 19.

"Increasing thickness at highly cortical sites is an effective way to improve bone strength and mechanical integrity of the skeleton," said Thomas Beck, ScD, associate professor, The Johns Hopkins University. "These observations support the potential of targeting RANK Ligand to improve bone structural strength."

This analysis extended the previously-reported two-year results that demonstrated twice-yearly subcutaneous injections of denosumab (60 mg) increased BMD at the lumbar spine (7.4 percent), total hip (5.1 percent), femoral neck (4.6 percent), distal 1/3 radius (1.8 percent) and total body (2.6 percent) compared to placebo at 24 months. Per protocol, the study concluded at 12 months; the post-12 month analyses are exploratory.

Amgen is also reporting on preclinical data for denosumab at the meeting. In this study, designed to evaluate the effects of denosumab administration in aged primates after estrogen depletion (OVX), researchers found that long-term denosumab administration (16 months) is associated with increases in the mass and density of cancellous and cortical bone.

Sixteen monthly injections of denosumab at 50 mg/kg resulted in significant increases from baseline in lumbar BMD (+12 percent); the OVX arm resulted in a -4.9 percent change and sham resulted in a +0.8 percent change in lumbar BMD (p less than 0.001 for both groups). Total hip BMD was also increased with denosumab treatment (+7.4 percent); the OVX arm experienced a -7.4 percent change and the sham group experienced a -0.6 percent change in total hip BMD (p less than 0.01 for both groups). Cortical bone mass (volumetric bone mineral content (BMC) measured by pQCT/ peripheral quantitative computed tomography) increased at the radial diaphysis with denosumab treatment (+1.3 percent); the OVX arm had a -5.6 percent change (p less than 0.001) and sham a -2.3 percent change (p less than 0.05).

In the osteoporosis setting, denosumab is being investigated as a twice-yearly subcutaneous injection and appears well-tolerated in clinical trials to date. Occurrence of adverse events in a multicenter, Phase 2 dose-ranging trial was similar among the denosumab-, placebo-, and alendronate-treated groups with the exception of dyspepsia, which was more common among those receiving alendronate. The most common adverse events among all groups were upper respiratory infection, joint pain, sore throat, back pain, and headache. To date, no neutralizing antibodies have been observed and there have been no gastrointestinal or renal effects.

Data for an Investigational Antibody Targeting Sclerostin

A sclerostin-neutralizing monoclonal antibody is being developed by Amgen and UCB, a Belgian-based biopharmaceutical company. Sclerostin, a naturally occurring protein in the body, plays a critical role in controlling bone mass by inhibiting the activity of bone-forming cells called osteoblasts. The investigational sclerostin antibody targets this key inhibitor of bone-forming cells.

In data featured at the annual ASBMR meeting, scientists presented preclinical results from a small study in which three sclerostin-neutralizing monoclonal antibodies were tested in primates. The goal of the study was to evaluate the effects of sclerostin inhibition on bone and bone biology in young female cynomolgus monkeys. Sclerostin-neutralizing antibodies were administered at 3, 10 and 30 mg/kg once-monthly over a two-month period. Specific results in this particular study for the sclerostin antibody under development included increased total BMC at the distal radius (20 percent increase in BMC for the sclerostin antibody-treated, 10 mg/kg dose group at the two-month time point versus a one percent increase in BMC for the vehicle control group). In relation to the vehicle control group, there was a 5.5-fold increase in the rate of bone formation in lumbar vertebrae for the sclerostin antibody-treated 30 mg/kg dose group in the first month. By the end of the two-month study, the strength of lumbar vertebrae increased for the sclerostin antibody-treated, 30 mg/kg dose group (a 53 percent increase in peak load for the sclerostin antibody-treated group versus a vehicle-

treated control group). Peak load is one of several accepted measurements for assessing bone strength.

Safety and efficacy data will become available once the clinical development program is initiated.

Understanding the Needs, Lifestyles of Osteoporosis Patients

As part of Amgen's commitment to developing potential treatments for osteoporosis, the company has initiated a large, comprehensive multicenter study of 6,000 postmenopausal women in the U.S. and Europe, entitled "Prospective Observational Scientific Study Investigating Bone Loss Experience (POSSIBLE)." At the ASBMR meeting, baseline data were presented from this study which was designed to collect and analyze: the pattern of use of current osteoporosis therapies; patient-attributed side-effect rates for these therapies; patient-reported compliance rates; the associations among current treatment and health-related quality of life, treatment satisfaction, and resource utilization.

About Denosumab

Denosumab is an investigational fully human monoclonal antibody being studied for its potential to prevent and treat osteoporosis in postmenopausal women. Denosumab is also being studied for its potential in a broad range of bone loss conditions including bone metastases, treatment-induced bone loss, multiple myeloma, and bone erosions in rheumatoid arthritis.

Denosumab: Clinical Studies in Bone Loss

Underscoring Amgen's commitment to science, its researchers have created a robust clinical program for denosumab as they explore the bone biology of various diseases associated with the RANK Ligand pathway. In addition to three Phase 3 and two Phase 2 trials in postmenopausal osteoporosis, Amgen is conducting a Phase 2 study in the treatment of bone erosions in rheumatoid arthritis. In the oncology setting, researchers are evaluating denosumab in four Phase 3 and two Phase 2 studies in advanced cancer patients with, or at risk for, bone metastases. In a Phase 2 study, they are evaluating denosumab as a possible treatment for patients with multiple myeloma.

For more information about ongoing denosumab clinical trials, please visit www.amgentrials.com or www.clinicaltrials.gov.

About Osteoporosis

Often referred to as the "silent epidemic", osteoporosis is a global problem which is increasing in significance as the population of the world both grows and ages. The World Health Organization (WHO) has recently identified osteoporosis as a priority health issue along with other major non-communicable diseases.

Osteoporosis is a disease in which the density and quality of bone are reduced, leading to weakness of the skeleton and increased risk of fracture, particularly of the spine, wrist, hip, pelvis and upper arm. Osteoporosis and associated fractures are an important cause of mortality and morbidity.

More than 75 million people in Europe, Japan and the USA alone suffer from osteoporosis, with an estimated lifetime risk for wrist, hip and vertebral fractures of around 15 percent, very similar to that of coronary heart disease.

Across the globe, the costs to healthcare systems from osteoporosis-related hospitalization are significant. The annual direct costs of treating osteoporosis fractures of people in the workplace in the EU, Canada, and U.S. is approximately $48 billion per year. In the U.S., costs are estimated at more than $30 billion; in Europe, more than $17 billion; and in Canada, more than $1.9 billion.

About Amgen

Amgen discovers, develops 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 and 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, and other serious illnesses. With a broad and deep pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

Forward-Looking Statement

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended December 31, 2005, and in Amgen's periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future.

Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify side effects or manufacturing problems with Amgen's products after they are on the market. In addition, sales of Amgen's products are affected by the availability of reimbursement and the reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. In addition, Amgen competes with other companies with respect to some of Amgen's marketed products as well as for the discovery and development of new products. Amgen believes that some of the newer products, product candidates or new indications for existing products, may face competition when

and as they are approved and marketed. Amgen 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 Amgen routinely obtains patents for Amgen's products and technology, the protection offered by Amgen's patents and patent applications may be challenged, invalidated or circumvented by Amgen's competitors and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for Amgen's products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of Amgen's existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of Amgen's products or product candidates.

Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's 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 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.

EDITOR'S NOTE: An electronic version of this news release may be accessed via our Web site at www.amgen.com. Journalists and media representatives may sign up to receive all news releases electronically at time of announcement by filling out a short form in the Media section of the Web site.

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SOURCE: Amgen