Amgen Investigational Therapy for Bone Loss, AMG 162, Increased Bone Mineral Density with Twice Yearly Injection

October 3, 2004

Phase 2 One Year Trial Results in Postmenopausal Women Released at
American Society for Bone and Mineral Research Annual Meeting

SEATTLE--(BUSINESS WIRE)--Oct. 3, 2004-- Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that at all doses studied, twice yearly injections of AMG 162, the company's investigational therapy for bone loss, significantly increased bone mineral density (BMD) at the total hip compared with placebo at 12 months. AMG 162, at all doses, also increased total hip BMD, similar to or greater than that resulting from FOSAMAX(R) (alendronate)(a) treatment in the same time frame.

The one year results of the ongoing multi-center, Phase 2 dose ranging trial in healthy postmenopausal women with low BMD were presented at the American Society for Bone and Mineral Research (ASBMR) 26th Annual Meeting in Seattle. The double blind trial was designed to evaluate the safety and efficacy of AMG 162 compared with placebo with an open label cohort comparison to FOSAMAX(R).

"This study suggests that AMG 162 significantly improves bone mineral density in postmenopausal patients experiencing bone loss," said Michael McClung, M.D., FACE, principal investigator of the AMG 162 study and founding director of the Oregon Osteoporosis Center in Portland. "The medical community should be very encouraged by these data that suggest AMG 162, when administered twice a year, may offer a promising alternative for the treatment of osteoporosis."

"With the development of AMG 162, Amgen scientists have validated an entirely new pathway and novel mechanism of action for addressing conditions associated with bone loss," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development, Amgen. "These Phase 2 results with our investigational agent are very compelling and give us great confidence as we actively enroll and initiate our pivotal trial."

The effects of AMG 162 (at 60 mg twice yearly) at the total hip BMD were significantly (p less than 0.001) greater than FOSAMAX(R) (at 70 mg once weekly) at 12 months. AMG 162 across all doses and dosing intervals increased the BMD of the lower spine by 4 to 7 percent, similar to the 5 percent increase in the FOSAMAX(R) group, after 12 months of treatment. AMG 162 also had a positive effect on BMD at the hip, distal 1/3 radius and total body.

In this trial, AMG 162 was well-tolerated. The most common adverse event in any of the treatment groups was dyspepsia (4 percent, 5 percent and 20 percent in the placebo, AMG 162 and the open label FOSAMAX(R) groups, respectively).

The company recently announced the initiation of a pivotal Phase 3 study of AMG 162 in postmenopausal women with osteoporosis. Ongoing investigations of AMG 162 are also evaluating treatment-induced bone loss, rheumatoid arthritis (RA) and bone metastases.

About AMG 162

AMG 162 is an investigational, fully human monoclonal antibody with a unique mechanism of action that exclusively targets and binds with high affinity to, and inhibits the activity of human RANK (receptor activator of nuclear factor kappa B) Ligand, the primary mediator of bone resorption. Amgen scientists have confirmed the essential role of RANK Ligand pathway in the formation, activation and survival of osteoclasts, the cells that are associated with bone resorption.

RANK Ligand is responsible for osteoclast-mediated bone loss in a range of conditions including osteoporosis, treatment-induced bone loss (bone loss due to glucocorticoid treatment and immunosuppression), rheumatoid arthritis, bone metastases and multiple myeloma. The body naturally produces a protein called osteoprotegerin (OPG) to modulate the effects of excess RANK Ligand. OPG acts as a decoy receptor, preventing RANK Ligand from binding to its receptor, RANK, on the surface of osteoclasts and osteoclast precursors. By binding to RANK Ligand, OPG prevents the formation and activation of osteoclasts and helps keep the bone loss process in check. Amgen developed AMG 162 to mimic the effects of OPG, enhancing the body's own process to specifically inhibit the effects of RANK Ligand.

Observations from pre-clinical studies confirm that inhibition of RANK Ligand activity demonstrates significantly greater effects on blocking bone resorption compared to other therapies. The preclinical studies also showed that inhibition of RANK Ligand resulted in improvements in bone mass, bone density and bone strength, indicating that bone quantity and quality were improved. These studies, conducted by Amgen, also documented that inhibition of Rank Ligand activity does not interfere with the function of osteoblasts, the cells involved in bone formation.

AMG 162 Study Design

Investigators randomized 411 postmenopausal women, average age 63, with low lumbar spine BMD to receive AMG 162, placebo or FOSAMAX(R). The primary endpoint of the study was to determine the safety and efficacy of AMG 162 on lumbar spine BMD compared with placebo. A secondary endpoint evaluated the cohort of patients randomized to receive open label FOSAMAX(R). The doses of AMG 162 evaluated included 6, 14 or 30 mg every three months or 14, 60, 100 or 210 mg every six months. The researchers administered all doses of AMG 162 via subcutaneous injection. Patients receiving FOSAMAX(R) followed the approved indication and oral dosing instructions of 70 mg once weekly.

At entry, the women averaged -2.2 +/- 0.8 on their T scores, an X-ray-based rating of BMD in which scores between -1.0 and -2.5 indicate osteopenia (thinning bone) and below -2.5 indicate osteoporosis, according to the World Health Organization (WHO).

About Osteoporosis

Osteoporosis is a disease characterized by low bone mass and structural deterioration that causes bones, most commonly of the hip, wrist and spine, to become brittle and susceptible to fracture. Approximately 200 million women worldwide suffer from osteoporosis, according to the International Osteoporosis Foundation. An osteoporosis-related hip fracture may limit mobility and lead to a loss of independence. A vertebral fracture can result in loss of height and stooped posture, as well.

About Amgen

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

Forward-Looking Statements

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, 2003, 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 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 side effects or manufacturing problems with our products after they are on the market. In addition, sales of our 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 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 it 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.

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.

(a) FOSAMAX(R) is a registered trademark of Merck & Co., Inc.

CONTACT: Amgen, Thousand Oaks
Andrea Rothschild, 805-447-4587 (media)
Laura Biswas, 805-447-1060 (investors)

SOURCE: Amgen Inc.