Denosumab Osteoporosis Trial Finds Patients Transitioned from Alendronate (Fosamax(R)) to Denosumab Achieved Significantly Greater Gains in Bone Mineral Density versus Those Continuing on Alendronate

September 15, 2008

Additional Data From Separate Head-to-Head Trial Showed More Than 75 Percent of Patients Prefer the Administration and Frequency of Twice-Yearly Subcutaneous Injection Compared to Weekly Oral Pill

MONTREAL--(BUSINESS WIRE)--Sept. 15, 2008--Amgen (NASDAQ:AMGN) today announced full data results from a non-pivotal Phase 3 head-to-head, double-blind trial comparing bone mineral density (BMD) gains in postmenopausal women with low bone mass who transitioned from weekly oral alendronate (Fosamax(R)) to denosumab versus those who continued alendronate therapy. In addition, patient preference data from another non-pivotal head-to-head trial comparing denosumab to weekly oral alendronate were announced today at the 2008 American Society of Bone and Mineral Research (ASBMR) Annual Meeting in Montreal.

"Data from these trials highlight the potential for a new treatment option for the millions of postmenopausal women worldwide with osteoporosis," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "In the bisphosphonate transition study, it is particularly exciting to see significant bone density gains in patients on denosumab who previously were treated with alendronate, as this type of result has not been reported in any previous study transitioning patients from one bisphosphonate to another. We believe these data coupled with data from a separate Phase 3 head-to-head trial that reported patient preference for twice-yearly subcutaneous injections versus a weekly oral therapy suggest denosumab offers the promise to be a welcome new option for patients."

Effect of Denosumab versus Alendronate on Bone Mineral Density (BMD) and Bone Turnover Markers (BTM) and Safety in Women Previously Treated with Alendronate (Abstract # 646)

Data presented from the bisphosphonate transition study, also known as the STAND (Study of Transitioning from AleNdronate to Denosumab) trial, demonstrated that subcutaneous injections of denosumab every six months achieved significantly greater increases in BMD versus those achieved with alendronate at all sites measured. For the primary endpoint, denosumab resulted in significant increases in BMD at the total hip compared with alendronate (1.9 percent vs. 1.05 percent, p less than 0.0001). Treatment with denosumab also resulted in significant increases in BMD compared with continued alendronate treatment at all secondary endpoints including the lumbar spine, femoral neck, hip trochanter and 1/3 radius. Top-line results of this trial were previously released in May 2008.

The incidence and types of adverse events observed in the study, including neoplasm and infection, were well-balanced between the denosumab and alendronate treatment groups. The most common adverse events across both treatment arms were back pain, arthralgia, and nasal pharyngitis.

Preference and Satisfaction with a 6-monthly Subcutaneous Injection Versus a Weekly Tablet for Treatment of Low Bone Mass (Abstract # 434)

As part of the DECIDE (Determining Efficacy: Comparison of Initiating Denosumab vs. AlEndronate) trial, patients were given a questionnaire after 12 months of treatment to gauge preference on mode of administration as well as satisfaction with frequency of dosing of twice-yearly subcutaneous injections versus weekly oral tablet. More than three-quarters of patients in both study arms preferred subcutaneous injection over oral pills (77 percent vs. 23 percent, p less than 0.0001). In addition, significantly more patients were more satisfied with twice-yearly dosing compared to weekly dosing (80 percent vs. 20 percent placebo injection vs. weekly oral alendronate, and 79 percent vs. 21 percent denosumab vs. weekly placebo tablet, p less than 0.0001 for both study groups). The BMD data from this study will be presented at ASBMR in the scientific oral session on Tuesday, Sept. 16.

About the 234 Bisphosphonate Transition Study (STAND)

The 234 bisphosphonate transition Phase 3 study was a randomized, double-blind, active controlled, parallel group study. Eligible patients had T-scores of less than -2.0 and greater than -4.0 at the lumbar spine or total hip, and had previously been treated with alendronate. A total of 504 women with low BMD participated in the study, with approximately 250 patients in each arm.

The study's primary endpoint was to evaluate the effect of denosumab treatment (twice-yearly 60 mg) on total hip BMD in women with low bone mass compared to patients continuing alendronate therapy (weekly 70 mg) at 12-months. The secondary endpoints included evaluation of the effects of transitioning to denosumab compared to continuing treatment with alendronate on percent change from baseline in BMD at the lumbar spine, hip trochanter, femoral neck, and 1/3 radius.

About the 141 Head-to-Head Study (DECIDE)

In this Phase 3 double-blind, double-dummy, active controlled study, 1,189 healthy postmenopausal women (T-score less than or equal to -2.0 total hip or spine), were randomized 1:1 to receive either denosumab injection (subcutaneous 60 mg, Q6M) plus placebo tablet (oral weekly), or placebo injection and oral alendronate (70 mg weekly). Patients were followed for one year to assess changes in BMD at the total hip compared to alendronate. Secondary endpoints were to evaluate the effect of denosumab on percent change from baseline in BMD at the lumbar spine, hip trochanter, femoral neck, and 1/3 radius compared to alendronate. Preference and satisfaction were assessed after 12-months of treatment, with patients being asked to complete a 34-item questionnaire to rate their preference and satisfaction with each mode and frequency of administration.

About Denosumab

Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, an essential regulator of osteoclasts (the cells that break down bone). Denosumab is being investigated for its potential to inhibit all stages of osteoclast activity through a targeted mechanism. Denosumab is being studied in a range of bone loss conditions including postmenopausal osteoporosis, rheumatoid

arthritis, and cancer treatment-induced bone loss (in breast cancer and prostate cancer patients), as well as for its potential to delay bone metastases and inhibit and treat bone destruction across many stages of cancer.

Osteoporosis: Impact and Prevalence

Often referred to as the "silent epidemic," osteoporosis is a global problem that is increasing in significance as the population of the world both increases and ages. More than 75 million people in Europe, Japan and the United States (U.S.) have osteoporosis, and most have an estimated lifetime risk for wrist, hip and vertebral fractures of around 15 percent, very similar to that of coronary heart disease. The World Health Organization (WHO) has recently identified osteoporosis as a priority health issue along with other major non-communicable diseases.

The economic burden of osteoporosis is comparable to that of other major chronic diseases; for example, in the U.S. the costs associated with osteoporosis-related fractures are equivalent to those of cardiovascular disease and asthma. It has been reported that osteoporosis results in more hospital bed-days than stroke, myocardial infarction or breast cancer.

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 and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics has 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 deep and broad 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 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 Sept. 15, 2008 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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SOURCE: Amgen