Pivotal Phase 3 Data Show Denosumab Increased Bone Density Throughout Skeleton in Non-Metastatic Breast Cancer Patients on Adjuvant Aromatase Inhibitor Therapy

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A Study Evaluating Twice Yearly Dosing with Denosumab Met All Primary and Secondary Endpoints

SAN ANTONIO--(BUSINESS WIRE)--Dec. 14, 2007--Amgen (NASDAQ:AMGN) today announced results of the first Phase 3 pivotal study to complete in the denosumab oncology development program. The study evaluated denosumab's effect on bone density across the skeleton in women with non-metastatic breast cancer who were receiving adjuvant Aromatase Inhibitor (AI) Therapy. These results were presented during the Late Breaking Session at this year's 30th Annual San Antonio Breast Cancer Symposium (SABCS) in San Antonio, Texas.

Results from the Phase 3 HALT Breast Cancer 135 study show that denosumab, a fully human monoclonal antibody under investigation as a twice yearly subcutaneous injection, increased bone density worsened by AI therapy, including in highly cortical areas of the skeleton. In addition to increasing bone mineral density (BMD) of the trabecular bone (spongy bone matrix), denosumab showed increases in cortical bone, the dense outer shell of the skeleton which is responsible for the supportive and protective function of the skeleton.

"The risk of bone loss for women with breast cancer is a genuine concern and needs to be proactively managed when treating with aromatase inhibitors," said Georgiana Kehr Ellis, M.D., Associate Professor, Department of Medicine, Division of Oncology, University of Washington School of Medicine, Seattle, WA. "In this study, denosumab data looks promising, and as a clinician, I look forward to having a potential alternative to existing therapies."

Skeletal integrity is normally maintained through complex biological processes that carefully regulate the bone remodeling process. However, disruption of these processes with AI therapy in postmenopausal breast cancer patients, already in a state of accelerated bone loss, can lead to worsening imbalances in bone resorption and formation. Bone loss can occur with over stimulation of osteoclasts; the cells responsible for bone resorption. Too much resorption causes progressive bone loss and weakens cortical and trabecular bone throughout the skeleton. RANK Ligand inhibition is being investigated for the clinical potential to both prevent bone resorption and halt active bone destruction.

The Phase 3 data show that lumbar spine BMD increased significantly at all time points with the denosumab group (n=127) as early as one month. At month 12 (primary endpoint) a 5.5 percent (p less than 0.0001) difference from placebo (n=125) was observed. Additionally, a consistent effect of denosumab was demonstrated on the Total Hip BMD (3.7 percent difference from placebo) and Femoral Neck BMD (2.5 percent difference from placebo) at 12 months (secondary endpoints).

In addition, exploratory endpoints evaluated the effect of denosumab at the distal radius and on total body. A 3.8 percent change in BMD at the distal radius was observed at month 12 with denosumab compared to placebo and at 24 months that difference increased to 6.1 percent. A 3 percent increase in BMD on Total Body was shown at month 12 with denosumab compared to placebo and at 24 months BMD in the denosumab arm increased to 4.2 percent compared to placebo.

In the study, denosumab was generally well tolerated, with overall rates of adverse events similar to placebo. The most common adverse events (AEs) were consistent with those usually associated with AI therapy, and included, arthralgia, pain in extremity, fatigue, back pain, constipation, cough, and insomnia.

"The results of this pivotal study provide a promising glimpse of the potential of denosumab to help manage bone disease in multiple tumor types and stages of disease in the cancer setting," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "This data on denosumab evaluating its effect on BMD throughout the skeleton, including cortical sites, should be encouraging to clinicians who witness the devastating effects of cancer and cancer treatment on their patients' bones."

About Denosumab

Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, the essential mediator of osteoclasts (the cells that break down bone). Denosumab inhibits all stages of osteoclast activity through a targeted mechanism that does not incorporate into bone matrix. In the oncology setting, denosumab is being investigated in treatment-induced bone loss (in breast cancer and prostate cancer patients) and for its potential to delay bone metastases as well as inhibit and treat bone destruction across many stages of cancer.

About RANK Ligand Inhibition

RANK Ligand is found in all parts of trabecular and cortical bone and RANK Ligand inhibition represents a highly targeted and specific approach to treating osteoclast-mediated bone destruction.

About Amgen in Bone Biology

Amgen is a leader in bone biology and is committed to developing medicines to help the millions of patients with osteoporosis, rheumatoid arthritis and other bone conditions. We have initiated a robust clinical trial program with more than 18,000 patients worldwide to evaluate the benefit/risk profile of denosumab across a number of therapeutic areas. Denosumab is also being studied in a range of bone-loss conditions outside of the oncology setting including postmenopausal osteoporosis and in the treatment of bone erosions in rheumatoid arthritis.

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 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 Dec. 14, 2007 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 health care cost containment as well as United States (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 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.

CONTACT: Amgen, Thousand Oaks
Lisa Rooney: (805) 559-0739 (media)
Arvind Sood: (805) 447-1060 (investors)

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