Published Results Show Denosumab Superior to Zometa(R) in Delaying or Preventing Bone Complications in Patients With Bone Metastases From Advanced Breast Cancer

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Bone is One of the Most Common Sites for Distant Metastases Affecting up to 75 percent of Patients with Advanced Breast Cance

THOUSAND OAKS, Calif., Nov. 8, 2010 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced the publication of results from a pivotal Phase 3 study of 2,046 patients which compared denosumab with Zometa(R) (zoledronic acid) in delaying or preventing skeletal-related events (SREs) in breast cancer patients with bone metastases. An SRE consists of any of the following: a pathologic fracture, the need for radiation or surgery to ameliorate bone pathology secondary to tumor growth, or spinal cord compression. The study, published today in the *Journal of Clinical Oncology*, found that denosumab was superior to Zometa in delaying or preventing SREs in breast cancer patients with bone metastases.

"Patients with bone metastases from cancer are at increased risk of experiencing debilitating pathologic fractures and other skeletal-related events. The results of this study show that denosumab is better than the current standard of care (Zometa) in delaying or preventing these skeletal complications for our patients with advanced breast cancer," said Alison Stopeck, M.D., associate professor of Medicine, Arizona Cancer Center, University of Arizona Health Sciences Center. "In addition to improving skeletal outcomes, denosumab has no requirement for renal monitoring and is administered as a simple subcutaneous injection."

Study Results

In the study, denosumab was superior to Zometa in delaying time to first on-study SRE (hazard ratio [HR] 0.82; 95 percent CI: 0.71-0.95; P=0.01 superiority) and time to first and subsequent (multiple) SREs (rate ratio0.77; 95 percentCI:0.66-0.89; P=0.001). Reduction in bone turnover markers was greater with denosumab.

The incidence of adverse events (AEs) (96 percent denosumab, 97 percent Zometa) and serious AEs (44 percent denosumab, 46 percent Zometa) was consistent with what has previously been reported for these two agents. AEs potentially associated with renal toxicity occurred in 4.9 percent of patients treated with denosumab compared to 8.5 percent in patients treated with Zometa.

Osteonecrosis of the jaw (ONJ) was seen infrequently in both treatment groups (20 patients receiving denosumab (2.0 percent) as compared with 14 patients (1.4 percent) receiving Zometa). There was no statistically significant difference in the rate of ONJ between the two treatment arms. Hypocalcemia occurred more frequently with denosumab. No AEs of hypocalcemia were reported as fatal, and grade 3 or 4 AEs of hypocalcemia were similar between groups (1.6 percent denosumab, 1.2 percent zoledronic acid). Overall survival (hazard ratio 0.95, 95 percent CI: 0.81, 1.11; p=0.50) and time to cancer progression (hazard ratio 0.99, 95 percent CI: 0.89, 1.11; p=0.90) was balanced between treatment arms.

Study Design

This study was an international, randomized, double-blind, double-dummy, active-controlled study, in which breast cancer patients were randomized to receive either subcutaneous denosumab 120mg and intravenous placebo (N=1,026), or Zometa administered intravenously as at least a 15 minute infusion at a dose of 4 mg (or equivalent creatinine clearance-adjusted dose in patients with baseline creatinine clearance $\leq$ 60mL/min) every four weeks as per the labeled instructions. All patients were strongly recommended to take daily calcium and vitamin D supplements. The primary endpoint was time to first on-study SRE.

Bone Metastases and Skeletal Related Events (SREs): Prevalence and Impact

Bone metastases occur in more than 1.5 million patients with cancer worldwide and are most commonly associated with cancers of the prostate, lung, and breast, with incidence rates as high as 75 percent of patients with metastatic disease.(i)

Approximately 50-70 percent of cancer patients with bone metastases will experience debilitating SREs.(ii) (iii) (iv) Events considered to be SREs include fractures, spinal cord compression, and severe bone pain that may require surgery or radiation. (v) Such events can profoundly disrupt a patient's life and can cause disability, pain or even death. (vi) (vii) (viii)

Patients who experience an SRE as a result of bone metastases incur significantly higher medical costs compared with those who do not experience such events. (ix) (x) (xi) Studies have shown that the costs of treating a SRE are significant. (x) (xii) In fact, the total economic burden of patients with bone metastases in the U.S. alone is estimated to be $12.6 billion annually.(xiii)

About Denosumab and Amgen's Research in Bone Biology

Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, the essential regulator of osteoclasts (the cells that break down bone). The denosumab development program is the largest ever initiated by Amgen. This broad and deep development program demonstrates Amgen's commitment to researching and delivering pioneering medicines to patients with unmet medical needs. Amgen is studying denosumab in numerous tumor types across the spectrum of cancer-related bone diseases. Over 11,000 patients have been enrolled in the denosumab oncology clinical trials, testing the drug for the reduction of SREs in patients with breast and prostate cancer, as well as other solid tumors and multiple myeloma, for the amelioration of treatment-induced bone loss in patients with non-metastatic breast or prostate cancers, and for its potential to delay bone metastases in prostate and breast cancers.

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 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 Nov. 8, 2010 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 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 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 theinvestigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for theseuses. Only the FDA can determine whether the products are safe and effective for these uses. Healthcareprofessionals shouldrefer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

Editor's Note: Denosumab administered as a 60 mg single subcutaneous injection every six months has been approved under the trade name Prolia(TM) in the United States for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. Prolia has also been approved in the EU to treat osteoporosis in postmenopausal women at increased risk of fracture and for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. The Prolia trade name may not apply for future indications of denosumab. For full Prolia prescribing information, please visit www.prolia.com.

Denosumab is currently under global regulatory review for the reduction of SREs in patients with advanced cancer. The advanced cancer program is evaluating 120 mg denosumab administered as a monthly subcutaneous injection.

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