XGEVA(TM) (Denosumab) Significantly Improved Bone Metastasis-Free Survival in Men With Prostate Cancer

December 13, 2010

Pivotal Phase 3 '147 Study Meets Primary Endpoint
First Bone-Targeted Therapy to Delay the Onset of Bone Metastases in Patients with Prostate Cancer

THOUSAND OAKS, Calif., Dec. 13, 3010, 2010 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced top-line results from a Phase 3 trial evaluating XGEVA(TM) (denosumab) versus placebo in 1,432 men with castrate-resistant prostate cancer. The trial, known as the '147 study, demonstrated that XGEVA significantly improved median bone metastasis-free survival by 4.2 months (HR=0.85, 95 percent CI 0.73-0.98, p=0.03) compared to placebo (primary endpoint), and significantly improved time to first occurrence of bone metastases (secondary endpoint). Overall survival was similar between the XGEVA and placebo groups (secondary endpoint).

Overall rates of adverse events and serious adverse events were generally similar between XGEVA and placebo, with hypocalcemia and osteonecrosis of the jaw (ONJ) observed at increased frequencies in the XGEVA arm. The yearly rate of ONJ in the XGEVA-treated group was similar to what has been observed in prior XGEVA trials.

"Our data demonstrate that XGEVA, which antagonizes the RANK Ligand axis, limits the ability of tumors to colonize bone, an important finding for men at risk for bone metastases and their healthcare providers," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "We look forward to presenting these landmark data at an upcoming medical conference."

The RANK Ligand pathway, first discovered by Amgen scientists in the mid-1990s, is believed to play a central role in cancer-induced bone destruction, regardless of cancer type. Data suggest that in bone metastasis, the invasion of cancer is facilitated by bone destruction. Hence, increased bone resorption due to increased RANK Ligand expression appears to augment bone metastasis.

XGEVA is a fully human monoclonal antibody that binds to RANK Ligand, a protein essential for the formation, function and survival of osteoclasts (the cells that break down bone). XGEVA prevents RANK Ligand fromactivating its receptor, RANK, on the surface of osteoclasts, thereby decreasing bone destruction and halting release of growth factors, making the environment less conducive to tumor growth.

About Study '147

Study '147 was a randomized, placebo-controlled, multi-center Phase 3 study comparing the treatment effect of XGEVA with placebo on prolonging bone metastasis-free survival in men with hormone-refractory (castrate-resistant) prostate cancer with rapidly-rising PSA levels who had no bone metastases at baseline. The primary endpoint of the trial was time to first occurrence of bone metastasis or death from any cause, with secondary endpoints including time to first occurrence of bone metastasis (excluding death) and overall survival.

XGEVA Skeletal-Related Events Regulatory Status

XGEVA was approved by the U.S. Food and Drug Administration (FDA) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors on Nov. 18, 2010. XGEVA is not indicated to prevent SREs in patients with multiple myeloma.

Administered as a single 120 mg subcutaneous injection every four weeks, XGEVA provides a new option for urologists and oncologists to prevent serious bone complications in men with prostate cancer.

Amgen has also submitted marketing applications for XGEVA in the European Union, Australia, Canada and Switzerland. In Japan, Amgen is working with its licensing partner, Daiichi-Sankyo Company, Limited and a marketing application was submitted.

XGEVA Important Safety Information

XGEVA can cause severe hypocalcemia. Correct pre-existing hypocalcemia prior to XGEVA treatment. Monitor calcium levels and administer calcium, magnesium, and vitamin D as necessary. Advise patients to contact a healthcare professional for symptoms of hypocalcemia.

Osteonecrosis of the jaw (ONJ) can occur in patients receiving XGEVA. Patients who are suspected of having or who develop ONJ while on XGEVA should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

The most common adverse reactions in patients receiving XGEVA were fatigue/asthenia, hypophosphatemia, and nausea. The most common serious adverse reaction in patients receiving XGEVA was dyspnea. The most common adverse reactions resulting in discontinuation of XGEVA were osteonecrosis and hypocalcemia. Please visit www.amgen.com for full prescribing information.

Denosumab is also marketed as Prolia(TM) in other indications.

Bone Metastases: 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)

The total economic burden of patients with bone metastases in the U.S. alone estimated to be $12.6 billion annually.

Denosumab and Amgen's Research in Bone Biology

The denosumab 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. In addition to study 147, XGEVA is also being investigated for its potential to delay bone metastases in 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 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, visithttp://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. 13, 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 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.

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.

(i) Coleman RE. Skeletal complications of malignancy. Cancer. 1997; 80(suppl): 1588-1594.

CONTACT: Amgen, Thousand Oaks
Christine Regan: +1 (805) 447-5476 (media)
Arvind Sood: +1 (805) 447-1060 (investors)

(Logo: http://photos.prnewswire.com/prnh/20081015/AMGENLOGO)

SOURCE Amgen