Amgen Presents New XGEVA(TM) (Denosumab) Breast Cancer Skeletal-Related Event Prevention Data at SABCS

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XGEVA Long Term Extension Data Demonstrate XGEVA Delayed Skeletal-Related Events by Five Months Compared to Zometa(R)

Additional Data Shows Advanced Breast Cancer Patients Treated with XGEVA Experienced Less Disruption of Daily Functioning from Pain and Improvements in Health-Related Quality of Life

THOUSAND OAKS, Calif., Dec. 10, 2010 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced results from new analyses comparing XGEVA(TM) (denosumab), the first new treatment for advanced cancer patients with bone metastases in nearly a decade to prevent skeletal-related events, to Zometa(R) (zoledronic acid). These results underscore the efficacy profile of XGEVA in preventing skeletal-related events (SREs) in patients with bone metastases from advanced breast cancer, as well as explore XGEVA's impact on pain and quality of life outcomes, compared to Zometa. These new results were presented at the 33rd Annual San Antonio Breast Cancer Symposium.

XGEVA was approved on Nov. 18, 2010 by the U.S. Food and Drug Administration (FDA) after a priority review, a designation reserved for drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. XGEVA is indicated for the prevention of SREs in patients with bone metastases from solid tumors. XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma.

New Extended Treatment Phase Data from Pivotal Phase 3 Study "136" Demonstrates Continued Superiority of XGEVA Compared to Zometa (Abstract Number: P6-14-01)

San Antonio Sponsored Press Briefing, Dec. 10, 2010 at 12:30 p.m. CT

An additional four months of double-blinded treatment data from the pivotal Phase 3 "136" study was presented in a press briefing at SABCS today. The data showed that XGEVA was superior to Zometa in delaying the time to first on-study SRE by 18 percent and time to first-and-subsequent on-study event by 22 percent. Further, the median time to first on-study SRE was five months longer for the patients at risk in the XGEVA group (32.4 months) versus the Zometa group (27.4 months) in patients with advanced breast cancer and bone metastases HR 0.82 (95 percent CI 0.71, 0.95), p= 0.0096 (superiority). Additionally, continued XGEVA treatment significantly reduced the proportion of patients who experienced pathologic fractures or radiation to bone compared with Zometa.

Overall survival and disease progression were similar for both treatment groups and a similar percentage of patients reported adverse events and serious adverse events. Osteonecrosis of the jaw was reported in 2.5 percent of XGEVA patients and 1.8 percent of Zometa patients, while hypocalcemia was reported in 6.1 percent of XGEVA treated patients and 3.7 Zometa treated patients.

"These results reinforce the superior efficacy profile of XGEVA versus Zometa and provide us additional reassurance of this important new product's safety profile," said Allison Stopeck M.D. associate professor of Medicine, Arizona Cancer Center, University of Arizona Health Sciences Center, Tucson, Ariz. "I feel confident that XGEVA can provide patients with advanced breast cancer that have developed a bone metastases an excellent option to prevent debilitating and costly bone complications."

Patients Receiving XGEVA Experienced Less Pain, and Report Pain Interfered Less with Daily Functioning, Compared to Patients Receiving Zometa (Abstract Number: P1-13-01)

Bone pain is one of the first signs that metastatic disease has spread to the bone, and affects approximately 70 percent of patients with metastatic disease(i), and nearly 80 percent of patients with advanced breast cancer.(ii) A new analysis of study "136" data showed that those patients treated with XGEVA experienced less pain-related interference with their daily functioning than those receiving Zometa.

The analysis, presented yesterday, was based on a patient completed Brief Pain Inventory (BPI). Results demonstrated that patients on XGEVA tended to experience a reduction in pain interference with their daily functioning compared to those on Zometa (n=1124; median: 70 days XGEVA vs. 86 days Zometa; p=0.09) and time to pain worsening tended to be longer with XGEVA compared to Zometa (n=1676; median: 394 days XGEVA vs. 310 days Zometa; p=0.13).

In patients with no or mild pain at the beginning of the study, XGEVA also demonstrated a trend for shorter time to improvement for pain interference with daily functioning (n=388; 93 days XGEVA vs. 120 days Zometa; p=0.06) and levels of pain took a longer time to worsen, interfering with daily functioning (n=755; 369 days XGEVA vs. 232 days Zometa; p=0.12).

Breast Cancer Patients' Health-Related Quality of Life Improved When Receiving XGEVA Compared to those Receiving Zometa (Abstract Number: P1-13-05)

A third analysis presented yesterday found that a greater proportion of breast cancer patients treated with XGEVA had a meaningful improvement in health-related quality of life compared to those treated with Zometa, regardless of their pain level at baseline.

Specifically, among patients who reported no or mild pain at the beginning of the study, more patients receiving XGEVA had a meaningful (greater than 5 point increase) in their functional assessment score (as measured by FACT-G) compared to patients receiving Zometa. Over the 18 month period, an average of 4.1 percent more (range: -0.6 percent to 9.3 percent) XGEVA-treated patients experienced meaningful improvement in health-related quality of life than Zometa patients. Additionally, fewer patients on XGEVA experienced a meaningful decrease in health-related quality of life over the same timeframe (average of 2.4 percent fewer [range:-4.4 percent to 6.3 percent fewer]).

Similar patterns were found in patients with moderate to severe pain at the beginning of the study. An average of three percent more (range:-1.7 percent to 7.9 percent) XGEVA-treated patients experienced a meaningful increase in their health-related quality of life compared with Zometa patients over 18 months. Also, a lower proportion of XGEVA patients (3.5 percent fewer [range: -1.1 percent to 11.5 percent fewer]) than Zometa treated patients had a meaningful decrease in health-related quality of life over the 18 months.

Interim Results Demonstrate Skeletal-Related Events in Breast Cancer Patients are Associated with Considerable Health Resource Utilization (Abstract Number: P1-13-06)

SREs have an adverse financial impact on healthcare systems, consuming significant resources. The first interim results from the breast cancer section (n=67) of an ongoing study assessing the health resource utilization per type of SRE (119 discreet SREs) found that pathologic fracture required the longest hospital stay (19 days, n=18), with spinal cord compression requiring the second most days (13.3 days, n=5). Additionally, radiation to bone required the most procedures (14.7, n=87), such as imaging, followed by spinal cord compression (10.4, n=5).

This section of an ongoing observational, multinational study assessed SRE-related utilization of health resources by SRE type (surgery or radiation to bone, pathologic fracture, or spinal cord compression) in breast patients with bone metastases. Data was collected on inpatient hospitalizations, length of stay, outpatient visits, emergency room (ER) visits, nursing home/long-term care facility stays, home health visits, procedures, and medications.

Acute Phase Reactions Following Treatment with Zometa or XGEVA (Abstract Number: P6-14-09)

An analysis of the Phase 3 "136" data compared the potential for acute phase reactions following treatment with either Zometa or XGEVA. Results of this analysis will be presented Sunday, Dec. 12 at 7:00 a.m. CT.

About the XGEVA Phase 3 Breast Cancer SRE Prevention Study "136"

Study "136" is an international, Phase 3, randomized, double-blind study comparing XGEVA with Zometa in the treatment of bone metastases in patients with advanced breast cancer to prevent SREs. Patients enrolled in the study were randomized in a one-to-one ratio to receive either 120 mg of XGEVA subcutaneously every four weeks (Q4W) or Zometa administered intravenously at a dose of 4 mg in a 15 minute infusion every four weeks adjusted for renal function as per the Zometa label instructions.

The primary endpoint of the study was to evaluate if XGEVA was non-inferior to Zometa with respect to the first, on-study SRE in patients with advanced breast cancer and bone metastases. Secondary endpoints were to evaluate if denosumab was superior to Zometa with respect to the first, on-study SRE, as well as the first-and-subsequent on-study SREs, and to assess the safety and tolerability of denosumab compared with Zometa.

Results from the primary analysis of the "136" study showed that XGEVA was superior to Zometa in delaying time to first on-study skeletal-related event in patients with breast cancer and bone metastases and that XGEVA was superior to Zometa in delaying the time to first-and-subsequent on-study SREs.

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.

D-CARE: XGEVA Adjuvant Breast Cancer Study Enrolling Patients Now

As part of Amgen's continued commitment to improving outcomes for people living with breast cancer, XGEVA is also being investigated as adjuvant treatment for women with early-stage breast cancer who are at high-risk of disease recurrence. A large Phase 3 study known as D-CARE is comparing the treatment effect of denosumab with that of placebo on prolonging bone metastasis-free survival (BMFS), and on prolonging disease-free survival (DFS). The trial will enroll 4,500 patients. For more information, please visit www.clinicaltrials.gov (identifier number01077154).

XGEVA FIRST STEP(TM) COUPON PROGRAM

Amgen is committed to supporting patient access to important medicines through innovative programs including our newly established commercial co-pay program for XGEVA, the Safety Net Foundation, which provides free Amgen products to uninsured patients who qualify, and financial support to independent third party co-pay foundations. The XGEVA FIRST STEP(TM) Coupon Program is a landmark program among oncology commercial co-pay programs, as it is the first program under the medical benefit with no income eligibility requirement. The program offers a coupon to eligible patients that can be used to help meet their deductible, co-insurance, and/or co-payment requirements under the medical benefit for XGEVA. For more information, please visit http://www.amgenfirststep.com/.

XGEVA Regulatory Status

XGEVA was approved by the FDA for the prevention of 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 submitted marketing applications for XGEVA in the prevention of SREs 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 in August.

Bone Metastases and SREs: Economic Burden, Prevalence and Impact

The total economic burden of patients with bone metastases in the U.S. alone is estimated to be $12.6 billion annually.(iii) 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. (iv)(v)(vi) In addition, once patients experience an SRE, the risk of a subsequent SRE is increased. The costs of SREs vary by type and severity, ranging from relatively low costs for minor fractures to high cost events like spinal cord compression associated with hospitalization. Studies have shown that the costs of treating SREs are a significant cost burden.

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.(vii)

Approximately 50-70 percent of cancer patients with bone metastases will experience debilitating SREs. (viii)(ix)(x) Events considered to be SREs include fractures, spinal cord compression, and severe bone pain that may require surgery or radiation.(xi) Such events can profoundly disrupt a patient's life and can cause disability and pain. (xii)(xiii)(xiv)

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 this newly approved indication, XGEVA is also being investigated for its potential to delay bone metastases in prostate and 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. 10, 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.

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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