Amgen Reports Positive Data at ASCO from Three Studies of Denosumab in Cancer Patients

May 31, 2008

Phase 2 Study of Patients Previously Treated with IV Bisphosphonates Showed Denosumab Reduced Bone Resorption and Skeletal-Related Events

Comparison of Phase 2 Studies Showed Consistent Reduction of Bone Resorption with Denosumab in either Bisphosphonate-Naive or -Treated Patients

Sub-group Analysis of Phase 3 Study Showed Denosumab Increased Bone Mineral Density Throughout the Skeleton In Women With Non-Metastatic Breast Cancer Receiving Aromatase Inhibitor Treatment

ABSTRACT NUMBERS: 9574, 3596, and 546

CHICAGO--(BUSINESS WIRE)--May 31, 2008--Amgen (NASDAQ: AMGN) today announced results from three denosumab studies in cancer patients. A Phase 2 study of metastatic patients previously treated with IV bisphosphonates found that denosumab normalized a key marker of bone resorption at a significantly greater rate than that seen with continuation of IV bisphosphonates, and also patients receiving denosumab experienced fewer skeletal-related events (SREs). A separate retrospective analysis comparing the results of this study to another Phase 2 study of patients never treated with an IV bisphosphonate revealed that the effect of denosumab on bone turnover markers was similar regardless of previous exposure to bisphosphonates. In addition, a sub-analysis of a Phase 3 trial in an earlier-stage cancer population of non-metastatic breast cancer patients showed that denosumab increased bone mineral density (BMD) at all sites measured, including cortical bone. These results were presented at the 44th Annual Meeting of the American Society of Clinical Oncology (ASCO).

Phase 2 Data of Patients Previously Treated with IV Bisphosphonates

The study evaluated patients whose urinary N-telopeptide (uNTx) levels had not normalized despite treatment with IV bisphosphonates. The primary endpoint of patients with uNTx less than 50 at week 13 was achieved by 71 percent of patients in the denosumab arms compared with 29 percent in the IV bisphosphonate arm (p less than 0.001). In addition, denosumab induced suppression of uNTx levels faster than IV bisphosphonate (9 days versus 65 days, respectively).

At week 25, denosumab treatment was associated with fewer on-study SREs (8 percent) than were seen in those receiving IV bisphosphonate therapy (20 percent). Skeletal-related events include fractures, radiation or surgery to bone, and spinal cord compression.

The adverse event profile of denosumab was similar to that of advanced cancer patients receiving treatment, and balanced across treatment arms. The most common adverse events included bone pain, nausea, anemia, constipation, and asthenia. No neutralizing anti-denosumab antibodies were observed.

"Skeletal-related events can be a devastating complication of bone metastases," said Karim Fizazi, M.D., Ph.D., Head of the Department of Medical Oncology, Institut Gustave-Roussy, Villejuif, France. "Elevated markers of bone resorption are routinely accepted indicators of poor outcomes for our advanced cancer patients. So it was encouraging to see that in this study, denosumab was able to further suppress bone turnover in patients previously on bisphosphonates, and that denosumab patients also reported fewer skeletal-related events."

Comparison of Phase 2 Data on Bone Turnover Markers of IV Bisphosphonate-Treated Versus Bisphosphonate-Naive Patients

In a comparison of the effect of denosumab on bone turnover markers in two Phase 2 trials, one trial involving patients previously treated with IV bisphosphonates versus a second trial involving patients not previously treated, denosumab was found to suppress bone resorption to a similar extent, regardless of prior bisphosphonate exposure. This side-by-side comparison of changes in serum-C telopeptide (sCTx), a marker of bone breakdown, from baseline to week 25, showed that at the six months time point, denosumab suppressed bone resorption by 85 percent in bisphosphonate-naive patients compared with 80 percent in patients with prior exposure to IV bisphosphonates. In patients previously treated with IV bisphosphonates, denosumab suppressed bone resorption by 80 percent compared with 45 percent in patients who continued on IV bisphosphonates.

In this comparison, the incidence of serious adverse events was similar across treatment groups in both studies. Types of adverse events were consistent with a population of patients with advanced cancer, and patients treated with IV bisphosphonates. The most common adverse events across all treatment arms were arthralgia, bone pain, asthenia, and nausea.

Phase 3 Sub-Group Analysis of BMD in Women With Non-Metastatic Breast Cancer Undergoing Aromatase Inhibitor Treatment

Sub-group analysis results of a Phase 3 pivotal study also presented at ASCO showed denosumab increased BMD at all skeletal sites measured, including in highly cortical sites, in non-metastatic breast cancer patients receiving adjuvant aromatase inhibitor (AI) therapy. The new analysis showed consistent increased BMD at the lumbar spine, total hip, femoral neck, and distal 1/3 radius at 12 months, regardless of duration or type of AI therapy, prior tamoxifen use, age, body mass index, or baseline T-score. The sub-group analysis findings presented at ASCO remain consistent with the efficacy and safety findings presented at the 2007 San Antonio Breast Cancer Symposium (SABCS).

In this study, overall rates of adverse events were similar to those seen with placebo (91 percent denosumab versus 90 percent placebo). The most common adverse events, consistent with adverse events usually associated with AI therapy, were arthralgia, pain in extremity, back pain, and fatigue.

"Because denosumab specifically targets RANK Ligand, we believe it works in a different way from other bone loss and destruction treatments," said Roger Dansey, M.D., Global Development Leader for Denosumab Oncology at Amgen. "Results from the denosumab oncology program presented thus far are encouraging and we look forward to results from additional clinical trials in the bone loss and SRE settings."

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). With more than 19,000 patients participating in trials across indications worldwide, 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 induced bone disease. Over 11,000 patients are currently enrolled in denosumab oncology clinical trials testing the drug for bone loss associated with cancer treatment-induced bone loss in breast and prostate cancers, for the prevention of skeletal related events due to the spread of cancer to the bone in multiple myeloma and multiple solid tumors, and for its potential to delay bone metastases in prostate cancer. The denosumab oncology program has a specific commitment in prostate cancer, studying more than 4,300 patients to determine the treatment effect of denosumab to treat and prevent bone loss, treat and prevent SREs and delay bone metastases in men with prostate 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, 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 May 31, 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 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.

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SOURCE: Amgen