Interim Phase 2 Results of Open-Label Clinical Trial of Denosumab in Giant Cell Tumor of Bone Demonstrated 87 Percent Response Rate

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Giant Cell Tumor is a Rare Bone Tumor Afflicting Younger Adults For Which Few Treatment Options Exist ABSTRACT NUMBER: 10500

CHICAGO, May 31, 2008 (BUSINESS WIRE) -- Amgen (NASDAQ:AMGN) today announced interim results of an open-label Phase 2 study demonstrating a positive response rate to administration of denosumab in subjects with recurrent or unresectable giant cell tumor of bone. The study was presented at the 2008 American Society of Clinical Oncology (ASCO) annual meeting.

Interim results from the twelve-month, open-label Phase 2 study show that 120 mg of denosumab, administered subcutaneously once monthly with a loading dose at days 8 and 15 of month one, met the primary and all secondary endpoints. The primary endpoint was tumor response (elimination of greater than or equal to 90 percent of giant cells or no radiographic progression of the target lesion). Out of 35 patients enrolled in the study, 25 were eligible for this interim analysis, with 24 receiving denosumab and 15 being eligible for efficacy analysis based on availability of pre- and post-radiology and histology assessments. Thirteen of 15 patients (87 percent) had tumor response to denosumab treatment. Of those, 9 of 9 had a histologic response which showed almost complete or complete elimination of giant cells. In addition, 4 of 6 patients had a radiographic response demonstrating no further progression. The two patients who did not meet radiographic response criteria were considered stable by investigators. Three subjects reported evidence of new bone formation and repair visible by radiology.

"Denosumab has shown profound effect in this small group of subjects" said David Thomas, FRACP, Ph.D., Department of Haematology and Medical Oncology, Peter MacCallum Cancer Centre, East Melbourne, Victoria, Australia. "For researchers in this field and our patients this represents an important advance in the understanding of potential treatment approaches for this rare disease."

Other observations included: reduction in activity on PET scan, stabilization of tumors within the bone, reduction in soft tissue expansion outside the bone, and evidence of new bone formation and repair. Some subjects had improvement in function evidenced by reduction in pain, improved mobility, and in some cases, return to work.

In this study, denosumab appeared generally well-tolerated. The most frequent adverse events reported were headache (3 (13 percent)) and nasopharyngitis (3 (13 percent)). No treatment-related serious adverse events related to denosumab or deaths were reported, and no neutralizing anti-denosumab antibodies were observed.

Giant cell tumor of bone is rich in RANK Ligand positive cells, which results in giant osteoclasts that destroy the bone locally.

"Giant cell tumor patients have limited treatment options, so we are very encouraged by these results," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "These data also support the scientific view that RANK Ligand may play a key role in bone loss and destruction, including in advanced cancer, where denosumab is being studied in breast, prostate, and other solid tumors."

About Giant Cell Tumor

Giant cell tumor of bone is a locally aggressive, benign tumor afflicting younger adults between the ages 20 to 40. Approximately 800 new giant cell tumor of bone cases are identified in the United States each year, which account for about one fifth of all benign primary bone tumors.

Most tumors occur in the long bones of the body, often around joints, but can spread to the lung. Patients can experience severe bone pain, swelling, loss of mobility if the tumor is close to a joint, and pathologic fracture. Giant cell tumors are slow growing, but have a 20 percent recurrence rate within three years of onset. When tumors recur, they become more likely to spread to other parts of the body. Currently, treatment options are very limited. The primary option is surgery, which may include joint replacement and amputation.

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.

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.

SOURCE: Amgen

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