



Amgen Preclinical Study Demonstrated Anti-Tumor Activity in Mammary Tumor Model

April 19, 2010

Study Shows Effect of RANKL Inhibition on Extraskelatal Tumor Development

THOUSAND OAKS, Calif., April 19, 2010 /PRNewswire via COMTEX/ --Amgen (Nasdaq: AMGN) today announced results of a preclinical study demonstrating a positive response to administration of RANK-Fc against mammary tumor formation in mouse models. OPG-Fc and RANK-Fc bind to and block the action of RANKL. These molecules have a comparable mechanism of action to denosumab. The study was presented today in a late-breaking abstract at the American Association for Cancer Research (AACR) 101st Annual Meeting 2010 in Washington, D.C.

As denosumab does not recognize rodent RANKL and the pharmacodynamic mechanism of denosumab is aligned with that of OPG-Fc or RANK-Fc, investigations conducted with these molecules in rodents are deemed appropriate to gain further understanding of the mechanism of action of RANKL in cancer.

Using a hormone (MPA) and carcinogen (DMBA)-induced mammary tumor model in wild-type (WT) mice, the study showed that treatment with RANK-Fc at the initiation of DMBA treatment delayed the time to mammary tumor formation vs. control-treated mice ($P < 0.0001$). RANK-Fc treatment also decreased the incidence of palpable mammary tumors at 32 weeks post last DMBA (22 percent in RANK-Fc treated mice vs. 94 percent in control-treated mice).

The study also tested three different doses of zoledronic acid (0.025, 0.2 and 0.5 mg/kg weekly at DMBA initiation) in WT mice for anti-tumor activity. Zoledronic acid had no effect at any dose on time to tumor formation compared to the control. Additionally, zoledronic acid had no effect at any dose on mammary tumor incidence at 32 weeks post last DMBA (92, 100 and 95 percent mammary tumor incidence for 0.5 mg/kg, 0.2 mg/kg and 0.025 mg/kg treated groups respectively).

"In this preclinical study, RANKL inhibition reduced mammary tumor formation in hormone-dependent mouse models," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "These studies suggest that RANKL inhibition might also prove effective in the treatment of human malignancy. We are encouraged by these results, which could ultimately prove important for patients with breast cancer."

In previous preclinical studies, RANKL inhibition has been shown to reduce skeletal tumor progression and improve survival of tumor-bearing animals. The current study demonstrates the additional ability of RANKL inhibition to reduce the development of tumors outside the skeleton in hormone-dependent mammary tumor models.

RANKL and its target receptor RANK are key factors in bone remodeling and bone destruction associated with bone metastasis. Denosumab, a fully human monoclonal antibody that specifically inhibits RANKL, inhibits osteoclastogenesis and osteoclast-mediated bone destruction.

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 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 have been enrolled in the denosumab oncology clinical trials testing the drug for the amelioration of treatment-induced bone loss in patients with breast or prostate cancers, for the prevention of skeletal related events due to the spread of cancer to the bone in patients with multiple myeloma or those suffering from a variety of solid tumors or those suffering from multiple myeloma, 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 <http://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 April 19, 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 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.

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

(Logo: <http://www.newscom.com/cgi-bin/prnh/20081015/AMGENLOGO>)

SOURCE Amgen