# Amgen to Participate in Reproductive Health Drugs Advisory Committee Meeting in August

June 22, 2009

Advisory Committee to Review Denosumab Data

THOUSAND OAKS, Calif., June 22 /PRNewswire-FirstCall/ -- Amgen Inc. (Nasdaq: AMGN) today announced that the U.S. Food and Drug Administration (FDA) has asked the company to participate in a meeting of the Reproductive Health Drugs Advisory Committee (RHDAC) on Aug. 13, 2009. The RHDAC will review data supporting the Biologics License Application (BLA) for denosumab, a RANK Ligand inhibitor for which Amgen is seeking approval for prevention and treatment of postmenopausal osteoporosis and prevention and treatment of bone loss in patients undergoing hormone ablation for either prostate or breast cancer.

"In the U.S., one woman in two over the age of 50 will experience an osteoporotic fracture in her remaining lifetime. Although osteoporosis treatments are available, there remains a need for other options that deliver robust efficacy and support adherence to therapy," said Sean Harper, M.D., chief medical officer and head of Global Development at Amgen. "Likewise, there is currently no approved treatment for the men and women receiving hormone ablation therapy for prostate or breast cancer who are at increased risk for bone loss and consequently fracture. We look forward to discussing the data from our denosumab trials in these settings with the members of the Committee."

Amgen's BLA submission contains data from six Phase 3 trials involving more than 11,000 patients and approximately 13,000 patient years of exposure to denosumab. Two Phase 3 pivotal studies with fracture endpoints, in the osteoporosis and prostate cancer settings, demonstrated denosumab's ability to reduce the incidence of fractures, and all six studies showed denosumab's ability to increase bone mineral density at all skeletal sites measured. In the two pivotal studies with fracture endpoints, the incidence and types of adverse events with denosumab were similar to placebo. The most common adverse events in both the denosumab and placebo groups were arthralgia, back pain, hypertension, nasopharyngitis, constipation and pain in extremity.

The FDA has provisionally approved the trade name Prolia(TM) for denosumab in the proposed indications of treatment and prevention of osteoporosis in postmenopausal women, and treatment and prevention of bone loss in patients undergoing hormone ablation for prostate or breast cancer.

About Denosumab

Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, an essential regulator of osteoclasts (the cells that break down bone). Denosumab is being investigated for its potential to inhibit all stages of osteoclast activity through a targeted mechanism. Denosumab is being studied in a range of bone loss conditions including postmenopausal osteoporosis and bone loss in patients undergoing hormone ablation for prostate and breast cancer, as well as for its potential to delay bone metastases and inhibit and treat bone destruction across many stages of cancer.

About Osteoporosis

Often referred to as the "silent epidemic," osteoporosis is a global problem that is increasing in significance as the population of the world both increases and ages. In the U.S. today, nearly eight million women suffer from osteoporosis.(i) The World Health Organization (WHO) has recently identified osteoporosis as a priority health issue along with other major non-communicable diseases.

The economic burden of osteoporosis is comparable to that of other major chronic diseases; for example, in the U.S., the costs associated with osteoporosis-related fractures are equivalent to those of cardiovascular disease and asthma.(ii, iii, iv) It has been reported that osteoporosis results in more hospital bed-days than stroke, myocardial infarction or breast cancer.(v)

Hormone Ablation-Induced Bone Loss

In the U.S., prostate cancer is the most common cancer in men and breast cancer is the most common cancer in women. It is common for prostate cancer and breast cancer patients to receive hormone ablation therapies that can lead to a decrease in bone mass and increased risk of fractures. Currently there are no approved therapies for bone loss in patients undergoing hormone ablation for either prostate or 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, 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 June 22, 2009 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 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 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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(i) http://www.nof.org/osteoporosis/diseasefacts.htm, accessed, 3/18/2009: Main bullet #5

(ii) Burge R, et al. J Bone Miner Res. 2007; 22:465-475

(iii) "Osteoporosis Fast Facts." Washington (DC): National Osteoporosis Foundation. Accessed on February 24, 2009 at http://www.nof.org/osteoporosis/stats.html.

(iv) "Economic Cost of Cardiovascular Diseases." Dallas (TX): American Heart Association. Accessed on February 24, 2009 at http://www.americanheart.org/statistics/10econom.html

(v) Lippuner K, et al. "Incidence and direct medical costs of hospitalisations due to osteoporotic fractures in switzerland." Osteoporosis International. 1997;7:414-25.

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