Prolia® (Denosumab) Phase 2 Extension Study Showed Continued Increase in Bone Mineral Density Over Eight Years of Treatment

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Amgen (NASDAQ: AMGN) today announced new long-term data showing that Prolia® (denosumab) treatment for up to eight years in postmenopausal women with low bone mass or osteoporosis was associated with a continued increase in bone mineral density (BMD), an important determinant of bone strength, and a persistent reduction in markers of bone turnover. The data were presented at the annual meeting of the American Society for Bone and Mineral Research (ASBMR) in San Diego.

Results of the Phase 2 study extension showed that for postmenopausal women with low bone mass or osteoporosis who received up to eight years of continued treatment with Prolia, BMD at the lumbar spine and total hip increased on average by 16.8 percent and 6.9 percent as compared to baseline, respectively. The overall adverse event profile is consistent with events previously reported.

"We don't yet have a cure for osteoporosis, and many postmenopausal women with this condition who are at high risk for fractures require long-term therapy for this serious disease," said lead author Michael McClung, M.D., founding director, Oregon Osteoporosis Center. "This study provides additional data that Prolia continues to increase bone mineral density progressively over a treatment period of eight years. This study supports the long-term clinical experience of Prolia for women with this chronic condition."

This Phase 2 study extension sought to determine the effects of up to eight years of continued treatment with Prolia on BMD and bone turnover markers in postmenopausal women with low bone mass or osteoporosis.

In the original Phase 2 dose-ranging trial for Prolia, 412 postmenopausal women with a BMD T-score (amount of matter per cubic centimeter of bones) between -1.8 and -4.0 (lumbar spine) and/or -1.8 and -3.5 (total hip or femoral neck) were enrolled. Of the 262 women who completed the parent study, 200 enrolled in the extension study, all of whom received Prolia (60 mg every 6 months). Results focused on patients who received Prolia treatment for up to eight years, where BMD showed gains at the lumbar spine and total hip of 16.8 percent and 6.9 percent, respectively, compared with their parent study baseline.

Osteoporosis: Impact and Prevalence

Referred to as a "silent epidemic" by the International Osteoporosis Foundation (IOF), osteoporosis is a global problem that is increasing in significance as the population of the world both increases and ages. The World Health Organization has officially declared osteoporosis a public health crisis, and the IOF is urging governments worldwide to make osteoporosis a healthcare priority.

Osteoporosis-associated fractures are a significant cause of mortality and morbidity. In 2000, the number of osteoporotic fractures in Europe was estimated at 3.79 million, of which 890,000 were hip fractures.(1) Since 2001, the incidence of hip fractures in European countries has risen significantly.(2) In the United States (U.S.), the number of fractures due to osteoporosis is expected to rise to more than three million by 2025.(3)

The direct medical cost of osteoporotic fractures in Europe is expected to rise from euro 31.7 billion in 2000 to euro 76.7 billion in 2050.(4) In 2005, osteoporosis-related fractures were responsible for an estimated $19 billion in cost in the U.S., and this cost is expected to rise to approximately $25 billion by 2025.(5)

About Prolia

Prolia is the first approved therapy that specifically targets RANK Ligand, an essential regulator of osteoclasts (the cells that break down bone).

Prolia is approved in the U.S. for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Prolia is approved in the European Union (EU) for the treatment of osteoporosis in postmenopausal women at increased risk of fractures, and for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

Prolia is approved in the U.S., Canada, Australia and in all 27 EU member states as well as in Norway, Iceland and Liechtenstein. Applications in the rest of the world are pending.

Prolia is administered as a single subcutaneous injection of 60 mg once every six months. For further information on Prolia, including prescribing information and medication guide, please visit: www.prolia.com.

Important U.S. Safety Information

Prolia is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia. Hypocalcemia may worsen, especially in patients with severe renal impairment. All patients should be adequately supplemented with calcium and vitamin D. Patients receiving Prolia should not receive XGEVA® (denosumab), as both Prolia and XGEVA contain the same active ingredient, denosumab.

In the Phase 3 pivotal study, serious infections leading to hospitalizations were reported more frequently in the Prolia-treated patient group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia. Patients should be advised to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis. Endocarditis was reported more frequently in the Prolia-treated patient group. Epidermal and dermal adverse events such as dermatitis, rashes and eczema have been reported. Discontinuation of Prolia should be considered if severe symptoms develop.

Prolia resulted in significant suppression of bone remodeling. The significance of these findings is unknown. The long-term consequences of the degree of suppression of bone remodeling observed with Prolia may contribute to adverse outcomes such as osteonecrosis of the jaw (ONJ), atypical fractures and delayed fracture healing. ONJ has been reported in patients with Prolia. Patients should be monitored for these adverse outcomes. The most common adverse reactions (> 5 percent and more common than placebo) were back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia and cystitis. Pancreatitis has also been reported with Prolia.

Important EU Safety Information

The most common adverse reactions with Prolia were urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, rash and pain in extremity. The most serious adverse reactions were those of skin infections, predominantly cellulitis, reported more commonly in the Prolia group compared with placebo (0.4 percent vs. 0.1 percent) in postmenopausal osteoporosis studies. In breast and prostate cancer studies, serious adverse reactions of skin infection were similar in the Prolia and placebo groups (0.6 percent vs. 0.6 percent). In the Phase 3 placebo-controlled clinical trial in patients with prostate cancer receiving ADT, an imbalance in cataract adverse events was observed with Prolia compared with placebo (4.7 percent vs. 1.2 percent placebo). No imbalance in cataract adverse events was observed in postmenopausal women with osteoporosis or in women undergoing aromatase inhibitor therapy for nonmetastatic breast cancer.

Prolia may lead to hypocalcaemia. Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy. ONJ has been reported rarely in clinical studies in patients receiving denosumab at a dose of 60 mg every 6 months for osteoporosis.

Denosumab Commercialization Collaborations

In July 2009, Amgen and GlaxoSmithKline announced a collaboration agreement to jointly commercialize Prolia for postmenopausal osteoporosis in Europe, Australia, New Zealand and Mexico once the product is approved in these countries. Amgen will commercialize Prolia's postmenopausal osteoporosis and potential oncology indications in the U.S. and Canada and for all oncology indications in Europe and in other specified markets.

In addition, GlaxoSmithKline will register and commercialize denosumab for all indications in countries where Amgen does not currently have a commercial presence, including China, India and South Korea but excluding Japan. The structure of the collaboration allows Amgen the option of an expanded role in commercialization in both Europe and certain emerging markets in the future.

Amgen and Daiichi Sankyo Company, Limited have a collaboration and license agreement for the development and commercialization of denosumab in Japan.

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, 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, bone disease 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 vital medicines, visit www.amgen.com. Follow us on www.twitter.com/amgen.

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 Sept. 17, 2011 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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(2) "Osteoporosis in the European Union in 2008: Ten years of progress and ongoing challenges." Accessed at http://www.iofbonehealth.org/publications/eu-policy-report-of-2008.html on February 4, 2011

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(4) "Facts and statistics about osteoporosis and its impact." International Osteoporosis Foundation. Accessed at http://www.iofbonehealth.org/facts-and-statistics.html on February 4, 2011

(5) "Fast Facts" National Osteoporosis Foundation. Accessed at http://www.nof.org/node/40 on February 4, 2011

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