Prolia(R) (denosumab) Open-Label Extension Trial Showed Continued Increase in Bone Mineral Density Over Five Years of Treatment With Similar Safety Profile Observed in Pivotal Trial

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Amgen (Nasdaq: AMGN) today announced new long-term data showing that during the fourth and fifth years of Prolia(R) (denosumab) treatment, postmenopausal women with osteoporosis receiving Prolia continued with further, statistically significant, year-over-year increases in lumbar spine and total hip bone mineral density (BMD), a key measurement of bone strength. The overall adverse event profile was similar for the fourth and fifth years of consecutive Prolia treatment.

The data, which were presented at the annual European Congress Osteoporosis and Osteoarthritis (ECCEO11-IOF) in Valencia, Spain, showed that treatment with Prolia, the first and only approved RANK Ligand inhibitor for the treatment of postmenopausal osteoporosis, resulted in robust BMD gains after five continuous years of treatment (13.7 percent for lumbar spine BMD and 7.0 percent for total hip BMD).

The FREEDOM Study and the 5-Year Prolia Data

The pivotal FREEDOM (Fracture REduction Evaluation of Denosumab in Osteoporosis every 6 Months) study established the efficacy and safety of Prolia based on three years of data from approximately 7,800 postmenopausal women. The open-label extension of FREEDOM is evaluating the long-term (up to 10 years) efficacy and safety of Prolia in 4,550 postmenopausal women. Seventy percent of eligible women from the FREEDOM study continued enrollment in the extension study; 2,343 women continued to receive Prolia treatment, and 2,207 transitioned from placebo to Prolia.

Continued treatment with Prolia resulted in consistent year-over-year gains in BMD at the lumbar spine and total hip. In years 4 and 5 respectively, women taking Prolia experienced further 1.9 percent and 1.7 percent increases in lumbar spine BMD and further 0.7 percent and 0.6 percent increases in total hip BMD (all $P<0.0001$ compared with extension baseline).

The incidences of new osteoporotic fractures also remained low for women taking Prolia for five years.

The women who transitioned from placebo to Prolia in the extension study showed significant BMD increases during the first two years of Prolia treatment: 7.9 percent increase in lumbar spine BMD and 4.1 percent increase in total hip BMD (all $P<0.0001$ compared with extension baseline).

Rates of adverse events (AEs) were 83.4 percent for women who continued on Prolia and 82.8 percent for women transitioned from placebo to Prolia. Rates of serious AEs were 18.9 percent and 19.4 percent for the two groups respectively. Two subjects in the group that transitioned from placebo to Prolia had AEs adjudicated to osteonecrosis of the jaw (ONJ) that healed without further complications. One of these subjects continued Prolia, and one subject discontinued. No atypical femoral fractures were reported in either group.

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 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. 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 available in 12 European countries, the U.S., Canada and Australia. Applications in the rest of the world are pending.

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

Important EU Safety Information

The most common adverse reactions with Prolia were urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, rash, 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). 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.

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.

In the 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 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.

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, Brazil, 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.

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 March 23, 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 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.

Editor's Note: Prolia(R) (denosumab) currently is not commercialized in Spain.

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