Amgen Receives CHMP Positive Opinion for Prolia(TM) (Denosumab) in the European Union

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THOUSAND OAKS, Calif., Dec 18, 2009 /PRNewswire-FirstCall via COMTEX/ -- Amgen Inc. (Nasdaq: AMGN) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has announced a positive opinion for the marketing authorization of Prolia((TM)) (denosumab) 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. If approved by the European Commission, Amgen would receive marketing authorization for Prolia in all European Union (EU) Member States.

"Nearly two decades ago, Amgen researchers described a fundamental biochemical pathway that controls bone remodeling," said Roger M. Perlmutter, executive vice president of Research and Development at Amgen. "Armed with this information, our scientists identified a targeted therapy that acts via this normal control mechanism to reduce bone loss. Today's announcement by the CHMP offers the hope that this important new therapy will soon be available to European women with post menopausal osteoporosis, and to European men with prostate cancer who, as a result of hormone ablation therapy, have a significantly increased risk of fracture. With its ability to significantly reduce fractures at key skeletal sites throughout the body, a favorable benefit-risk profile, and convenient dosing every six months, Prolia addresses an important unmet medical need."

The CHMP positive opinion is based on data from six Phase 3 trials. Two Phase 3 pivotal studies with fracture endpoints in the osteoporosis and prostate cancer settings demonstrated that Prolia administered as a subcutaneous injection twice yearly (60mg) reduces the incidence of fractures. All six studies showed Prolia's ability to increase bone mineral density at all skeletal sites measured.

Results from the pivotal FREEDOM (*F*racture *RE*duction *E*valuation of *D*enosumab in *O*steoporosis every six *M*onths) study in 7,868 women with postmenopausal osteoporosis showed that women receiving a subcutaneous injection of Prolia twice-yearly experienced a 68 percent reduction in the risk of suffering a new vertebral (spine) fracture compared to those receiving placebo, as well as a 40 percent reduction in the risk of suffering a hip fracture and a 20 percent reduction in the risk of suffering a nonvertebral fracture.(i) Results from the pivotal *H*ormone *AbL*ation *T*herapy study in 1,468 men undergoing androgen deprivation therapy (ADT) for non-metastatic prostate cancer showed that patients treated with Prolia experienced a 62 percent reduction in the risk of suffering a new vertebral fracture with Prolia compared to placebo at 36 months, with significant reduction observed as early as month 12.(ii) In both pivotal studies, the incidence and types of adverse reactions observed with Prolia were similar to those seen in patients taking a placebo. The most common adverse reactions in both the Prolia and placebo groups were arthralgia, back pain, hypertension, nasopharyngitis, constipation and pain in an extremity. Serious adverse reactions of skin infections, predominantly cellulitis, were reported more commonly in the Prolia group (0.4 percent vs. <0.1 percent) in postmenopausal osteoporosis studies. In breast and prostate cancer studies, serious adverse reactions were similar in the Prolia and placebo groups (0.6 percent vs. 0.6 percent).

Prolia is also under regulatory review in the United States (U.S.), Switzerland, Australia and Canada for the treatment and prevention of postmenopausal osteoporosis and for the treatment of bone loss in patients undergoing hormone ablation therapy for breast or prostate cancer.

About Denosumab

Denosumab has a unique mechanism of action. It is the first and only therapy in late stage development that specifically targets RANK Ligand, an essential regulator of osteoclasts (the cells that break down bone). Administered every six months as a subcutaneous injection just under the skin, denosumab helps stop the process that causes bone loss, resulting in greater bone density, stronger bones and reduced risk for fractures at the spine, hip and other non-vertebral sites.

Given its potential to inhibit all stages of osteoclast development through a unique and targeted mechanism, denosumab is also being studied in a range of other bone loss conditions including rheumatoid arthritis, and for its potential to delay bone metastases and inhibit and treat bone destruction in patients with advanced 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. It is estimated that 30 percent of postmenopausal women in the EU have osteoporosis.(iii) The World Health Organization (WHO) has recently identified osteoporosis as a priority health issue along with other major non-communicable diseases.

Osteoporotic fractures impose a significant financial burden to individuals and health services.(iv) The total direct medical cost of osteoporosis in Europe has been estimated at more than euro 36 billion annually, and is expected to increase to euro 76.7 billion in 2050 as the population ages.(v)

Along with proper diet and weight-bearing exercise, medications can help slow bone loss and reduce the risk of fracture. Yet despite the availability of osteoporosis treatments for more than 10 years, the worldwide lifetime risk of fracture remains high at 30-50 percent for women and 15-30 percent for men(vi).It is estimated that fewer than 50 percent of patients adhere to their current therapy for more than one year(vii,viii,ix), which may leave many patients insufficiently protected against bone loss.

About Bone Loss Due to Hormone Ablation

Prostate cancer is the most common form of cancer in men in Europe and accounts for over 24 percent of cancer diagnoses.(x) It is common for prostate cancer patients to receive hormone ablation therapies that can lead to a decrease in bone mass and increased risk of fractures.

No EMA-approved therapies currently exist for the management of bone loss due to hormone ablation therapy in patients with prostate cancer.

About Denosumab Collaborations

In July 2009, Amgen and GlaxoSmithKline (GSK) 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 the drug for postmenopausal osteoporosis and oncology in the U.S. and Canada and for all oncology indications in Europe and in other specified markets.

In addition, GSK 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 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 Dec. 18, 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 payers, 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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