Prolia(R) (Denosumab) Granted Marketing Authorization in the European Union

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Given as an Injection Every Six Months, Prolia Reduced the Risk of Fractures in Treatment of Postmenopausal Osteoporosis in Women at Increased Risk of Fractures
First and Only Approved Treatment in Europe for Bone Loss Due to Hormone Ablation in Men with Prostate Cancer
First Prolia(R) Regulatory Approval

THOUSAND OAKS, Calif., May 28, 2010 /PRNewswire via COMTEX/ --Amgen Inc. (Nasdaq: AMGN) today announced that the European Commission (EC) has granted marketing authorization for Prolia(R) (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. Prolia has been approved in all 27 European Union member states plus Norway, Iceland and Liechtenstein. The European approval of Prolia marks the first approval of the product worldwide.

"The European approval of Prolia is a significant medical advance for patients with bone loss conditions," said Will Dere, senior vice president and international chief medical officer at Amgen. "In particular, we believe that Prolia will offer patients with postmenopausal osteoporosis at increased risk for fracture an important alternative to current treatments. Prolia reduces the risk of fracture through a convenient injection given every six months. Amgen is proud to make this new treatment available to physicians and their patients."

The marketing authorization for Prolia comprises data from six Phase 3 trials, including two pivotal Phase 3 studies with fracture endpoints in the osteoporosis and prostate cancer settings, which demonstrated that Prolia administered as a 60mg subcutaneous injection every six months reduces the incidence of fractures. All six studies showed Prolia's ability to increase bone mineral density (a measure of bone strength) at all skeletal sites measured.

"Osteoporosis is a serious, chronic disease that can significantly impact the lives of millions of affected women. Despite widely available treatments, new options are still needed to help protect against fractures," said Professor Socrates E. Papapoulos, professor of medicine, consultant physician and director of bone and mineral research at the department of endocrinology & metabolic diseases of the Leiden University Medical Center, The Netherlands. "By targeting RANK Ligand, Prolia offers an innovative new approach that helps reduce fracture risk."

"The approval of Prolia in the European Union is great news for patients as it is the first and only product approved in Europe for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures," said Professor Bertrand Tombal, chairman of the division of urology and associate professor of physiology at the Universite catholique de Louvain (UCL), Cliniques universitaires Saint-Luc, Brussels, Belgium. "Bone loss can be a serious problem for men undergoing hormone ablation therapy for prostate cancer and if left untreated it can lead to fractures."

Efficacy

Results from the pivotal three-year Phase 3 Fracture REduction Evaluation of Denosumab in Osteoporosis every six Months (FREEDOM) study in 7,808 women with postmenopausal osteoporosis showed that women receiving a subcutaneous injection of Prolia every six months experienced a 68 percent reduction in the relative risk of suffering a new vertebral (spine) fracture compared to those receiving placebo as well as a 40 percent reduction in the relative risk of suffering a hip fracture and a 20 percent reduction in the relative risk of suffering a nonvertebral fracture at 36 months.(i)

Results from the pivotal HALT (Hormone Ablation Bone Loss Trial) study which evaluated change from baseline in lumbar spine BMD 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 relative 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)

Safety and Administration

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 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.

The recommended dose of Prolia is 60mg administered as a single subcutaneous injection every six months.

About Prolia

Prolia (denosumab) has a unique mechanism of action. It is the first and only approved therapy that specifically targets RANK Ligand, an essential regulator of osteoclasts (the cells that break down bone).

Prolia is under regulatory review in the United States (U.S.), Switzerland, Australia and Canada.

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. The World Health Organization (WHO) has recently identified osteoporosis as a priority health issue along with other major

non-communicable diseases.

An estimated 30 percent of all post-menopausal women in Europe have osteoporosis, and more than 40 percent of them will suffer osteoporotic fractures in their lifetime.(iii) Osteoporotic fractures can 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.

About Cancer Treatment-Induced 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.(vi) Prostate cancer patients undergoing ADT experience accelerated bone loss and an increased fracture risk. 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.One in five men treated with hormone ADT for prostate cancer will experience a fracture within five years.(vii)

No other 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 Prolia's postmenopausal osteoporosis and oncology indications 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/.

About GlaxoSmithKline

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better, and live longer. For company information, visit GlaxoSmithKline at www.gsk.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 May 28, 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 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. 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.

Editors Note: The FDA has provisionally approved the trade name Prolia(TM) for 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 non-metastatic prostate or breast cancer, for which denosumab is administered twice-yearly subcutaneously at a 60mg dose. The Prolia(TM) trade name is only for these indications and may not apply for other indications of denosumab.

To view the Prolia (denosumab) Summary of Medicinal Product Characteristics, click here: www.amgen.com.

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i Cummings SR, et al. Twice Yearly Denosumab, a Monoclonal Antibody to RANK-ligand, for Prevention of Fractures in Postmenopausal Women with Osteoporosis. N Engl J Med, 2009 Aug. 20; published online at www.nejm.org on Aug. 11, 2009.'
ii Smith MR, et al. Denosumab for the Prevention of Bone Loss and Fractures in Men Receiving Androgen Deprivation Therapy in Non- Metastatic Prostate Cancer. N Engl J Med, 2009 Aug. 20; published online at www.nejm.org on Aug. 11, 2009.
iii Epidemiology." International Osteoporosis Foundation. Accessed at http://www.iofbonehealth.org/health-professionals/about-osteoporosis/epidemiology.html on 10 March 2009.
iv Cooper C. The crippling consequences of fractures and their impact on quality of life. Am J Med. 1997;103(2A):12S-17S.
v "Facts and statistics about osteoporosis and its impact." International Osteoporosis Foundation. Accessed at http:// www.iofbonehealth.org/facts-and-statistics.html on 10 March 2009.
vi Ferlay J, et al. Estimates of the cancer incidence and mortality in Europe in 2006. Annals of Oncology, 2007 Feb. 7.
vii Shahinian VB, Kuo YF, Freeman JL, Goodwin JS. Risk of fracture after androgen deprivation for prostate cancer. N Engl J Med. 2005;352(2):154-64.

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