



## Amgen Highlights Data to Be Presented at American Society for Bone and Mineral Research (ASBMR) Meeting

October 14, 2010

THOUSAND OAKS, Calif., Oct 14, 2010 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced that results from several Prolia(TM) (denosumab) studies, as well as analyses of the growing global burden of osteoporosis, will be presented at the 2010 American Society for Bone and Mineral Research (ASBMR) annual meeting in Toronto, Ontario from Oct. 15-19, 2010.

"The continued need to reduce fractures caused by postmenopausal osteoporosis is reinforced by data that will be presented at this year's ASBMR meeting. These data highlight the global economic burden associated with osteoporotic fractures, the challenges with adherence to oral therapies, and the link between adherence and fracture outcomes," said Catherine Stehman-Breen, M.D., vice president of Global Development at Amgen. "Additionally, safety and efficacy results from the Prolia FREEDOM extension study will be available along with two new analyses of FREEDOM that evaluated the effect of Prolia on bone strength."

ASBMR abstracts are available and can be viewed online at [www.asbmr.org](http://www.asbmr.org). Identified below are selected abstracts of interest on Amgen research.

### Prolia Clinical Data

- **Hip QCT Results From the FREEDOM Trial: Evidence for Positive BMD/BMC Changes in Integral, Trabecular, and Cortical Bone With Denosumab**

Lead Author: Prof. Harry K. Genant, University of California, San Francisco  
Abstract No. FR0410 Oral Plenary/Poster Presentation  
(Friday, Oct. 15, 5:10 p.m.-5:15 p.m. ET)

- **Four years of denosumab exposure in women with PMO: Results from the first year extension of the FREEDOM Trial**

Lead Author: Socrates Papapoulos, Leiden University Medical Center, The Netherlands  
Abstract No. 1025 Oral Presentation  
(Saturday, Oct. 16, 10:00 a.m.-10:15 a.m. ET)

- **Denosumab Improves Both Femoral and Vertebral Strength in Women With Osteoporosis: Results From the FREEDOM Trial**

Lead Author: Tony Keaveny, University of California, Berkeley  
Abstract No. 1099 Oral Presentation  
(Sunday, Oct. 17, 10:00 a.m.-10:15 a.m. ET)

### Global and International Health Economic Data

- **Incremental Cost of Osteoporosis-related Fractures in a Large U.S. Managed Care Population**

Lead Author: Hema Viswanathan  
Abstract No. MO0404  
(Monday, Oct. 18, 11:30 a.m.-1:30 p.m. ET)

- **Hospitalizations of Major Osteoporotic Fractures in Switzerland between 2000 and 2007**

Lead Author: Kurt Lippuner, Osteoporosis Policlinic, University of Bern, Switzerland Abstract No. SU0336  
(Sunday, Oct. 17, 11:00 a.m.-1:00 p.m. ET)

- **Economic burden of osteoporosis-related fracture hospitalizations in France**

Lead Author: Milka Maravic, Departement d'Information Medicale, Hopital Leopold Bellan, France  
Abstract No. SU0332 Poster Presentation  
(Sunday, Oct. 17, 11:00 a.m.-1:00 p.m. ET)

- **Medication Adherence and Fracture Risk Among Patients Using Osteoporosis Medications in a Large U.S. Health Plan**

Lead Author: Sally Wade

Abstract No. SU0398  
(Sunday, Oct. 17, 11:00 a.m.-1:00 p.m. ET)

## Compliance with Bisphosphonate Therapy and Change in Bone Mineral Density in Clinical Practice

Lead Author: Derek Weycker  
Abstract No. SU0397  
(Sunday, Oct. 17, 11:00 a.m.-1:00 p.m. ET)

### About Osteoporosis: Impact and Prevalence

In the United States (U.S.), one in two women over the age of 50 with postmenopausal osteoporosis will experience a fracture in her remaining lifetime.<sup>(1)</sup> These fractures can have severe clinical consequences.<sup>(2,3)</sup> In 2005, osteoporosis-related fractures were responsible for an estimated \$19 billion in costs and by 2025 experts predict that these costs will rise to approximately \$25 billion.<sup>(4,5)</sup>

Postmenopausal women with osteoporosis who have experienced a fracture are at increased risk for another fracture.<sup>(6,7,8)</sup>

### About Prolia

Prolia is approved for use in the U.S., the European Union, Canada, Australia and Switzerland. In the U.S., Prolia is approved 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, the first and only FDA-approved RANK Ligand inhibitor, is an every six month 60 mg subcutaneous injection administered by a health care professional.

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 demonstrated that Prolia, administered as a 60mg subcutaneous injection every six months, compared with placebo at three years resulted in:

- **A 68 percent reduction in vertebral fractures** (4.8 percent absolute risk reduction). The incidence of new spine fractures was 2.3 percent with Prolia vs. 7.2 percent with placebo;
- **A 40 percent reduction in hip fractures** (0.3 percent absolute risk reduction). The incidence of hip fractures was 0.7 percent with Prolia vs. 1.2 percent with placebo;
- **A 20 percent reduction in non-vertebral fractures** (1.5 percent absolute risk reduction). The incidence of non-spine fractures was 6.5 percent with Prolia vs. 8 percent with placebo;
- **Significant bone density increases at all key sites measured** (8.8 percent at the lumbar spine, 6.4 percent at the total hip, and 5.2 percent at the femoral neck).

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 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.

### 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 [www.amgen.com](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 Oct. 14, 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 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 health care 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 their 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.

### CONTACT: Amgen, Thousand Oaks

Kerry Beth Daly: (516) 982-9328 (U.S. media)

Arvind Sood: (805) 447-1060 (investors)

(1) Osteoporosis Fast Facts. Washington (DC): National Osteoporosis Foundation. Accessed on May 10, 2010 at <http://www.nof.org>.

(2) National Osteoporosis Foundation. <http://www.nof.org>. Accessed May 13, 2010.

(3) Cooper C. The crippling consequences of fractures and their impact on quality of life. *Am J Med.* 1997 Aug 18;103(2A):12S-17S; discussion 17S-19S.

(4) Burge R et al. Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. *J Bone Miner Res.* 2007 Mar;22(3):465-75.

(5) Osteoporosis Fast Facts. Washington (DC): National Osteoporosis Foundation. Accessed on April 29, 2010 at <http://www.nof.org>.

(6) Kanis JA et al. A Meta-Analysis of Previous Fracture and Subsequent Fracture Risk. *Bone.* 2004;35(2):375-82.

(7) Lindsay R et al. Risk of new vertebral fracture in the year following a fracture. *JAMA.* 2001 Jan 17;285(3):320-33.

(8) Klotzbuecher CM et al. Patients with prior fractures have an increased risk of future fractures: a summary of the literature and statistical synthesis. *J Bone Miner Res.* 2000 Apr;15(4):721-39.

(Logo: <http://photos.prnewswire.com/prnh/20081015/AMGENLOGO>)

(Logo: <http://www.newscom.com/cgi-bin/prnh/20081015/AMGENLOGO>)

