Amgen Presents Nearly Two Dozen Abstracts From Romosozumab And Prolia® (Denosumab) At ASBMR

October 4, 2013

Prolia Open-Label Extension Trial Showed Continued Increases in Bone Mineral Density and Low Fracture Incidence for Up to Eight Years

THOUSAND OAKS, Calif., Oct. 4, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present data from several romosozumab and Prolia® (denosumab) studies at the American Society for Bone and Mineral Research (ASBMR) 2013 Annual Meeting in Baltimore from Oct. 4-7, 2013.

Romosozumab data include results from the Phase 2 study that demonstrate significant increases in volumetric bone mineral density. Romosozumab is being developed in collaboration with UCB. Prolia data include 19 abstracts, featuring several on long-term safety and efficacy data from the open-label extension study of the pivotal Phase 3 fracture trial for up to eight years.

"We are very encouraged by the long-term safety and efficacy data with Prolia treatment as well as by the clinical data we see from our pipeline bone-building molecule, romosozumab," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Amgen has led nearly a decade of clinical work in bone biology and, with fracture rates on the rise, we remain committed to advancing medicines that help treat bone disease."

SELECTED ABSTRACTS OF INTEREST INCLUDE:
Abstracts are available on the ASBMR website at www.asbmr.org and updated data will be presented at the meeting.

Prolia Abstracts of Interest:

- **Eight Years of Denosumab Treatment in Postmenopausal Women With Osteoporosis: Results From the First Five Years of the FREEDOM Extension**
  Abstract LB-MO26, Late Breaking Abstract Session, Monday, Oct. 7, 10:35 – 10:40 a.m. EDT (Discovery Hall-Hall C)
- **Denosumab Significantly Increases Bone Mineral Density Compared With Ibandronate and Risedronate in Postmenopausal Women Previously Treated With an Oral Bisphosphonate Who are at Higher Risk for Fracture**
  Abstract 1018, Oral Presentation, Saturday, Oct. 5, 8:15 – 8:30 a.m. EDT (Hall A)
- **Further Reduction in Nonvertebral Fracture Rate Is Observed Following Three Years of Denosumab Treatment: Results With Up to Seven Years in the FREEDOM Extension**
  Abstract 1017, Oral Presentation, Saturday, Oct. 5, 8:00 – 8:15 a.m. EDT (Hall A)

Romosozumab Abstract of Interest:

- **Effect of Romosozumab on Lumbar Spine and Hip Volumetric Bone Mineral Density (vBMD) as Assessed by Quantitative Computed Tomography (QCT)**
  Study 20060326, Oral Presentation, Saturday, Oct. 5, 9:15 – 9:30 a.m. EDT (Hall A)

About Osteoporosis
Postmenopausal osteoporosis (PMO) affects many women after menopause[1-2] and is a disease that weakens bones over time, making them thinner and more likely to break.[2]

In PMO, bone-removing cells get rid of bone at a rate that is too fast.[3] This puts postmenopausal women with osteoporosis at risk for breaking a bone.[3] Such a break, or fracture, may be a life-changing event. About half of all women over age 50 will have an osteoporosis-related fracture, and once that happens, the chances of another are much higher.[4] According to the National Osteoporosis Foundation, women who have suffered a hip fracture are at a four-times greater risk of a second one.[4]

The World Health Organization has officially declared osteoporosis a public health crisis, while the International Osteoporosis Foundation urges governments worldwide to make osteoporosis a healthcare priority.

Osteoporosis-related fractures are responsible for an estimated $19 billion in costs annually in the U.S., and are expected to rise to approximately $25 billion by 2025.[5] The direct medical cost of osteoporotic fractures in Europe is expected to rise from €31.7 billion in 2000 to €76.7 billion in 2050.[6]

About Romosozumab
Romosozumab is a bone-forming agent that inhibits sclerostin. It is currently being studied for its potential to reduce fracture risk in an extensive global Phase 3 program. This program includes two pivotal studies evaluating romosozumab against both placebo and active comparator in more than 10,000 women with postmenopausal osteoporosis. Romosozumab is being developed in collaboration with UCB.

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 also indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients with prostate cancer, Prolia reduced the incidence of vertebral fractures.

Prolia is indicated for treatment to increase bone mass in men 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. Prolia is contraindicated in women who are pregnant and may cause fetal harm. Prolia is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Patients receiving Prolia should not receive XGEVA® (denosumab), as both Prolia and XGEVA contain the same active ingredient, denosumab.

Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia®. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®. Hypocalcemia may worsen with the use of Prolia, especially in patients with severe renal impairment. All patients should be adequately supplemented with calcium and vitamin D. In the pivotal Phase 3 study of women with postmenopausal osteoporosis (n=7808), 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.

In clinical trials in women with postmenopausal osteoporosis, 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 and atypical femoral fractures have 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) in patients with postmenopausal osteoporosis were back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia and cystitis. The most common adverse reactions in men with osteoporosis were back pain, arthralgia and nasopharyngitis. Pancreatitis has also been reported with Prolia in patients with osteoporosis. The most common (per patient incidence >10 percent) adverse reactions reported with Prolia in patients with bone loss receiving androgen deprivation therapy for prostate cancer or adjuvant aromatase inhibitor therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

The extent to which Prolia is present in seminal fluid is unknown. For men treated with Prolia, there is a potential for fetal exposure if the sexual partner is pregnant. While the risk is likely to be low, patients should be advised of this potential risk.

Important EU Safety Information
The most common (≥1 percent) adverse reactions in clinical trials with Prolia in postmenopausal women with osteoporosis and breast or prostate cancer patients receiving hormone ablation were pain in extremity, urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, rash and eczema. Skin infections (predominantly cellulitis) leading to hospitalisation were 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 androgen deprivation therapy (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 rarely lead to hypocalcaemia. Prolia is contraindicated in patients with hypocalcaemia, and pre-existing hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy. Patients with severe renal impairment or receiving dialysis are at greater risk of developing hypocalcaemia. In the post-marketing setting, rare cases of severe symptomatic hypocalcaemia have been reported in patients at increased risk of hypocalcaemia. Osteonecrosis of the jaw (ONJ) has been reported rarely in clinical studies in patients receiving denosumab at a dose of 60 mg every 6 months for osteoporosis. In the osteoporosis clinical trial program, atypical femoral fractures were reported rarely in patients treated with Prolia. In the post-marketing setting, rare events of drug-related hypersensitivity, including anaphylactic reaction, have been reported in patients receiving Prolia. Hypersensitivity to the active substance or any of the excipients is a contraindication for Prolia.

Prolia is not recommended for use in pregnant women.

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 is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and 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 any subsequent 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. 4, 2013, 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 product liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. 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.

CONTACT: Amgen, Thousand Oaks
Ashleigh Koss, 805-313-6151 (media)
Arvind Sood, 805-447-1060 (investors)

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

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