Amgen Announces 23 Abstracts To Be Presented At The American Society for Bone and Mineral Research 2014 Annual Meeting

September 10, 2014

Data Include Eight Year Analyses of Bone Mineral Density Results for Prolia® (Denosumab) and Further Evidence for Significant Bone-Building With Romosozumab

THOUSAND OAKS, Calif., Sept. 10, 2014 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that it will present data from multiple Prolia® (denosumab) and romosozumab study analyses at the American Society for Bone and Mineral Research (ASBMR) 2014 Annual Meeting being held in Houston, Sept. 12-15, 2014. The data that will be presented reinforce Amgen's continued commitment to discovering and developing novel treatments for patients suffering from bone-related diseases.

Prolia data consist of 18 abstracts, including several exploratory analyses evaluating eight years of Prolia therapy from the open-label extension study of the pivotal Phase 3 fracture trial. Analyses report the percentage of women who achieved non-osteoporotic bone mineral density (BMD) T-scores and the long-term effects of Prolia on reducing cortical bone loss. A separate analysis reports compliance and persistence among women at high risk of fracture identified in a commercially-insured database. Data for romosozumab include two exploratory analyses from the Phase 2 trial and open-label extension study in postmenopausal women with low BMD. The first analysis evaluated the effect of treatment with romosozumab over two years, as well as data on a third year where patients received either Prolia or placebo; another examined the effect of romosozumab treatment on vertebral cortical mass, thickness and density. Romosozumab is being co-developed by Amgen and UCB (Euronext: UCB).

"Given that more than 200 million women worldwide have osteoporosis,[1] and many of these have experienced a fracture, additional therapies are needed to help manage the continuum of the disease," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Limited data exists on the risks and benefits of the long-term treatment of osteoporosis, and we're excited to help address this gap with the large body of Prolia data we will present at this year's meeting."

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

Prolia Abstracts of Interest

- **Percentage of Women Achieving Non-Osteoporotic BMD T-scores at the Spine and Hip Over 8 Years of Denosumab Treatment**, Abstract FR0391, Friday, Sept. 12, 4:15 – 4:20 p.m. CDT (Grand Ballroom BC)
- **Denosumab Restores Cortical Bone Loss at the Distal Radius Associated With Aging and Reduces Wrist Fracture Risk: Analyses From the FREEDOM Extension Cross-over Group**, Abstract 1047, Saturday, Sept. 13, 3:15 – 3:30 p.m. CDT (Grand Ballroom BC)
- **Persistence with Osteoporosis Therapies among Osteoporotic Women at High Risk for Fracture Within a Commercially-Insured Population in the United States**, Abstract 1138, Monday, Sept. 15, 8:45 – 9 a.m. CDT (Discovery Hall-Hall E)

Romosozumab Abstracts of Interest

- **Romosozumab and Teriparatide Effects on Vertebral Cortical Mass, Thickness, and Density in Postmenopausal Women With Low Bone Mineral Density (BMD),** Abstract 1049, Saturday, Sept. 13, 3:30 – 3:45 p.m. CDT (Grand Ballroom BC)
- **Effects of 2 Years of Treatment With Romosozumab Followed by 1 Year of Denosumab or Placebo in Postmenopausal Women With Low Bone Mineral Density**, Abstract 1152, Monday, Sept. 15, 11:15 – 11:30 a.m. CDT (Grand Ballroom BC)

About Osteoporosis
Osteoporosis affects many women after menopause as their ability to form new bone cannot counter balance the rate at which bone is being removed. This bone loss leads to weakened bones over time, increasing the potential for a break.[2]

About half of all women over age 50 will have an osteoporosis-related fracture in their remaining lifetime.[3] Only 24 percent of women who suffer an osteoporotic fracture received treatment during the following year.[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.

About Romosozumab
Romosozumab is an investigational bone-forming agent that is designed to work by inhibiting the protein sclerostin, thereby increasing bone formation and decreasing bone breakdown. Romosozumab is being studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program. This program includes two large fracture trials comparing romosozumab to either placebo or active comparator in more than 10,000 patients with osteoporosis. Romosozumab is being co-developed by Amgen and UCB.

About Prolia® (denosumab)
Prolia is the first approved therapy that specifically targets RANK Ligand, an essential regulator of bone-removing cells (osteoclasts).

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 approved 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 EU plus Switzerland, Norway, Iceland and Liechtenstein for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. Prolia is also approved in the EU for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

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.

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.

Osteonecrosis of the jaw (ONJ) and atypical femoral fractures have been reported in patients with Prolia. In the pivotal Phase 3 study of women with postmenopausal osteoporosis (n=7,808), 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. Epidermal and dermal adverse events such as dermatitis, rashes and eczema have been reported. Discontinuation of Prolia should be considered if severe symptoms develop.

Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported. 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 ONJ, atypical fractures and delayed fracture healing. 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 patients with osteoporosis and breast or prostate cancer patients receiving hormone ablation were urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, abdominal discomfort, rash, eczema, pain in extremity and musculoskeletal pain. Skin infections (predominantly cellulitis) leading to hospitalisation were reported more frequently 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 a 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). 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 predominantly reported in patients at increased risk of hypocalcaemia, with most cases occurring in the first weeks of initiating therapy. 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 Collaboration
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 the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen, we or us) 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 Inc., including Amgen Inc.'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 Inc.'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 Sept. 10, 2014, 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 and our partners 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 (including products of our wholly-owned subsidiaries) 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 and our partners routinely obtain patents for our and their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' 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. Our efforts to integrate the operations of companies we have acquired may not be successful. Cost savings initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plans. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase common stock.

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, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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