



Amgen To Give 23 Presentations On Osteoporosis Disease And Treatment At American Society For Bone And Mineral Research Annual Meeting

October 6, 2015

Open-Label Extension Study Highlights Safety Data for up to 10 Years of Treatment With Prolia® (denosumab) for Women With Postmenopausal Osteoporosis at High Risk for Fracture Data From Both Prolia and Investigational Romosozumab Reinforce Amgen's Understanding of Osteoporosis and Leadership in Bone Biology

THOUSAND OAKS, Calif., Oct. 6, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that it will present data from multiple studies for Prolia® (denosumab) and investigational molecule romosozumab at the annual meeting of the American Society for Bone and Mineral Research (ASBMR) in Seattle on Oct. 9-12, 2015. The data highlight Amgen's ongoing commitment to providing wide-ranging information emerging from its bone biology portfolio.

"Amgen's leadership in bone biology is clearly articulated in the findings shared at this year's ASBMR meeting," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Osteoporosis is a silent disease with no symptoms until a fracture occurs, a potentially life-changing event for postmenopausal women and their families. We are excited to share a broad set of results that reinforce the clinical profile of our bone biology portfolio with our heritage product Prolia and our investigational compound, romosozumab."

Presentations will include results from a head-to-head, double-blind, randomized study evaluating the safety and efficacy of Prolia compared with zoledronic acid in postmenopausal women with osteoporosis previously treated with oral bisphosphonates; and new results from a previously reported exploratory sub-study of the Phase 2 trial¹ comparing the effects of romosozumab versus open-label teriparatide on bone strength in postmenopausal women with low bone mass. Osteoporosis disease-state study presentations will provide key insights around unmet needs among patients at high risk for fracture, and the potentially serious consequences of inadequate osteoporosis treatment.

Romosozumab is being co-developed by Amgen and UCB.

SELECTED ABSTRACTS OF INTEREST

Late-Breaking Abstracts of Interest

- **Ten Years of Denosumab Treatment in Postmenopausal Women With Osteoporosis: Results From the FREEDOM Extension Trial**

Abstract LB-1157, Oral Presentation, Monday, Oct. 12, 12:18 p.m.–12:30 p.m. PT (Room 6C)

Prolia Oral Presentations

- **Effects of Denosumab on Bone Matrix Mineralization: Results From the Phase 3 FREEDOM Trial**
Abstract 1054, Oral Presentation, Saturday, Oct. 10, 3:15 p.m.-3:30 p.m. PT (Hall 4A)
- **Relationship Between Total Hip BMD T-score and Incidence of Nonvertebral Fracture With up to 8 Years of Denosumab Treatment**
Abstract 1146, Oral Presentation, Monday, Oct. 12, 11:15 a.m.-11:30 a.m. PT (Room 6E)

Prolia Abstracts of Interest

- **Denosumab Compared With Zoledronic Acid in Postmenopausal Women With Osteoporosis Previously Treated With Oral Bisphosphonates: Efficacy and Safety Results From a Randomized Double-blind Study**
Abstract SU0340, Poster Presentation, Sunday, Oct. 11, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Can We Use Bone Turnover Markers as Targets for Antiresorptive Treatment in Postmenopausal Osteoporosis? An Analysis From the DECIDE and STAND Clinical Trials**
Abstract SU0337, Poster Presentation, Sunday, Oct. 11, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Safety Observations With Three Years of Denosumab Exposure: Comparison Between Subjects Who Received Denosumab During FREEDOM and Subjects Who Crossed Over to Denosumab During the FREEDOM Extension**
Abstract SU0346, Poster Presentation, Sunday, Oct. 11, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Incidence Rate of Osteonecrosis of the Jaw among Women With Postmenopausal Osteoporosis Treated with Prolia or Bisphosphonates**
Abstract MO0345, Poster Presentation, Monday, Oct. 12, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Effect of Denosumab on BMD Outcomes in Persistent Patients in a Prospective Observational Study**
Abstract SA0341, Poster Presentation, Saturday, Oct. 10, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Factors Affecting Persistence With Denosumab (Prolia®) in Postmenopausal Women With Osteoporosis: Results From a Prospective Observational Study**
Abstract MO0344, Poster Presentation, Monday, Oct. 12, 12:30 p.m.-2:30 p.m. PT (Hall 4B)

Romosozumab Oral Presentations

- **Romosozumab Improves Strength at the Lumbar Spine and Hip in Postmenopausal Women With Low Bone Mass Compared With Teriparatide**
Abstract 1143, Oral Presentation, Monday, Oct. 12, 10:30 a.m.-10:45 a.m. PT (Room 6E)
- **Romosozumab (Sclerostin Antibody) Improves Bone Mass and Bone Strength in Ovariectomized Cynomolgus Monkeys After 12 Months of Treatment**
Abstract 1019, Oral Presentation, Friday, Oct. 9, 2 p.m.-2:15 p.m. PT (Room 6E)

Romosozumab Abstracts of Interest

- **Effects of Romosozumab in Japanese Women With Postmenopausal Osteoporosis: Phase 2 Trial Results**
Abstracts FR0331 and SA0331, Poster Presentation, Friday, Oct. 9, 5:30 p.m.-7 p.m. PT and Saturday, Oct. 10, 12:30 p.m.-2:30 p.m. PT (Hall 4B)

Osteoporosis Disease State Abstracts of Interest

- **The Loss of Quality of Life From Non-Traumatic Fractures**
Abstract SU0282, Poster Presentation, Sunday, Oct. 11, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Potential Years of Life Lost (PYLL) From Non-Traumatic Fractures in Canada**
Abstract MO0284, Poster Presentation, Monday, Oct. 12, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Predicting Imminent Risk for Fracture in Patients With Osteoporosis Using Commercially Insured Claims Data**
Abstract 1066, Oral Presentation, Saturday, Oct. 10, 5:15 p.m.-5:30 p.m. PT (Room 6B)
- **Analysis of the Osteoblast Lineage Reveals Inhibition of Mitogenesis and Cell Cycle Progression Associated With Attenuation of Bone Formation in Response to Sclerostin Antibody in Ovariectomized Rats**
Abstract MO0193, Poster Presentation, Monday, Oct. 12, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Stereological Analysis Reveals Differential Effects of Sclerostin Antibody and Parathyroid Hormone on the Osteoblast Lineage in Young Female Rats**
Abstract MO0154, Poster Presentation, Monday, Oct. 12, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Change in Physical Function Following Hip Fracture Among Elderly Osteoporotic Women**
Abstract MO0307, Poster Presentation, Monday, Oct. 12, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Predictors of Imminent Fracture Risk in Women Aged ≥ 65 Years With Osteoporosis**
Abstract SA0282, Poster Presentation, Saturday, Oct. 10, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Imminent Fracture Risk in Elderly Osteoporotic Women: Underlying Relationships Between Risk Factors and Outcome**
Abstract MO0292, Poster Presentation, Monday, Oct. 12, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Utilization of Osteoporosis Medication After a Fragility Fracture Among Elderly Medicare Beneficiaries**
Abstract MO0350, Poster Presentation, Monday, Oct. 12, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Hospitalizations for Osteoporosis-Related Fractures: Economic Cost and Clinical Outcomes**
Abstract SA0302, Poster Presentation, Saturday, Oct. 10, 12:30 p.m.-2:30 p.m. PT (Hall 4B)
- **Awareness and Reasons for Lack of Post-Fracture Osteoporosis Therapy: A Survey of Post-Menopausal Women**
Abstract MO0350, Poster Presentation, Saturday, Oct. 10, 12:30 p.m.-2:30 p.m. PT (Hall 4B)

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.^{2,3} This bone loss leads to weakened bones over time, increasing the potential for a break.^{4,5}

About half of all women over age 50 will have an osteoporosis-related fracture in their remaining lifetime.⁶ Additionally, patients with a previous hip fracture have a threefold greater risk of a subsequent fracture within two years.^{7,8}

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 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 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 non-metastatic prostate cancer.

Prolia is administered as a single subcutaneous injection of 60 mg once every six months. Please see the Important Safety Information below.

Important Safety Information (U.S.)

Prolia is contraindicated in patients with hypocalcemia. Preexisting 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. Reactions have included anaphylaxis, facial swelling and urticaria.

Prolia[®] contains the same active ingredient (denosumab) found in XGEVA[®]. Patients receiving Prolia[®] should not receive XGEVA[®].

Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia[®]. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria. 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. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia[®] injection. Adequately supplement all patients with calcium and vitamin D.

ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving Prolia[®]. An oral exam should be performed by the prescriber prior to initiation of Prolia[®]. A dental examination with appropriate preventive dentistry is recommended prior to treatment in patients with risk factors for ONJ such as invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g. chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders. Good oral hygiene practices should be maintained during treatment with Prolia[®].

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia[®] should be considered based on individual benefit-risk assessment.

Atypical low-energy, or low trauma fractures of the shaft have been reported in patients receiving Prolia[®]. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with anti-resorptive agents.

During Prolia[®] treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of Prolia[®] therapy should be considered, pending a risk/benefit assessment, on an individual basis.

In a clinical trial (N = 7808) in women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported more frequently in the Prolia[®] group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia[®].

Endocarditis was also reported more frequently in Prolia[®]-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia[®], prescribers should assess the need for continued Prolia[®] therapy.

In the same clinical trial in women with postmenopausal osteoporosis, epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate with Prolia[®] compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia[®] if severe symptoms develop.

Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia[®]. Consider discontinuing use if severe symptoms develop.

In clinical trials in women with postmenopausal osteoporosis, Prolia[®] resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.

The most common adverse reactions (>5% and more common than placebo) in women with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis.

The most common adverse reactions (> 5% and more common than placebo) in men with osteoporosis are back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with Prolia[®].

In women with postmenopausal osteoporosis, the overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia[®] groups. In men with osteoporosis, new malignancies were reported in no patients in the placebo group and 4 (3.3%) patients in the Prolia[®] group. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

The Prolia Postmarketing Active Safety Surveillance Program is available to collect information from prescribers on specific adverse events. Please see <https://www.proliasafety.com/> or call 18007726436 for more information.

For more information, please see the Prolia [Prescribing Information](#), and [Medication Guide](#).

About Romosozumab

Romosozumab is an investigational bone-forming monoclonal antibody and is not approved by any regulatory authority for the treatment of

osteoporosis. It 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 evaluating the safety and efficacy of romosozumab includes two large fracture trials comparing romosozumab to either placebo or active comparator in more than 10,000 postmenopausal patients with osteoporosis. First results from the Phase 3 study FRAME are expected in the first half of 2016. Romosozumab is being co-developed by Amgen and UCB.

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 one of the world's leading independent biotechnology companies, 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. 6, 2015, 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 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. Our efforts to integrate the operations of companies we have acquired may not be successful. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our ongoing restructuring plan. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our 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 (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. 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 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.

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