Amgen to Highlight 19 Abstracts on Osteoporosis Disease State and Treatment at American Society for Bone and Mineral Research Annual Meeting

September 7, 2016

Results From Phase 3 FRAME Study of Romosozumab Evaluate Fracture Risk Reduction in Women With Postmenopausal Osteoporosis

Real-World and Clinical Data Focus on Long-Term Efficacy and Safety of Prolia® (Denosumab), Provide Insights on Therapy Compliance in Patients With Postmenopausal Osteoporosis

THOUSAND OAKS, Calif., Sept. 7, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present data from multiple studies for its investigational agent romosozumab and for Prolia® (denosumab) at the Annual Meeting of the American Society for Bone and Mineral Research (ASBMR) in Atlanta on Sept. 16-19, 2016. At the congress, Amgen will highlight a diverse set of data across its osteoporosis clinical programs, as well as real-world data that provide important insights on living with osteoporosis and underscore the Company's commitment to pioneering novel treatment options that can help reduce fracture risk.

"As a leader in bone biology, Amgen is committed to translating innovative science into treatments that make a difference in the lives of people," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The breadth and depth of clinical and real-world data we're presenting at ASBMR demonstrates our commitment to finding potential options for patients with osteoporosis. We look forward to sharing detailed data from our Phase 3 FRAME study of romosozumab, along with new clinical data and real-world research on Prolia."

The romosozumab FRAME abstract, "Fracture Risk Reduction With Romosozumab: Results of the Phase 3 FRAME Study (**FRA**cture study in postmenopausal wo**M**en with ost**E**oporosis)," has been awarded the 2016 ASBMR Most Outstanding Clinical Abstract Award, which is given to the lead investigator of the highest ranking abstract submitted to a clinical category for presentation at the ASBMR Annual Meeting. Lead author Dr. Felicia Cosman, medical director of the Clinical Research Center at Helen Hayes Hospital, professor of Medicine at Columbia University College of Physicians and Surgeons in New York, will be presented with the award on Sunday, Sept. 18.

Prolia presentations will include additional analyses from the three-year FREEDOM trial and its seven-year extension, further characterizing the long-term (up to 10 years) efficacy and safety of Prolia in postmenopausal women with osteoporosis, as well as real-world data showing long-term (two-year) persistence rates for Prolia and other osteoporosis therapies among postmenopausal women.

Osteoporosis disease-state study presentations will provide key insights on unmet needs among patients at high risk for fracture.

Romosozumab is being co-developed by Amgen and UCB.

SELECTED ABSTRACTS OF INTEREST

Romosozumab Oral Presentation

- **Fracture Risk Reduction With Romosozumab: Results of the Phase 3 FRAME Study (FRActure study in postmenopausal woMen with ostEoporosis)**
  Abstract 1096, Oral Presentation, Sunday, Sept. 18, 9:45 a.m.-10 a.m. ET (Sidney Marcus Auditorium – Building A)

Romosozumab Pre-clinical Oral Presentation

- **Effects of Romosozumab on Remodeling and Bone Strength at the Distal Radius in Ovariectomized Cynomolgus Monkeys**
  Abstract 1024, Oral Presentation, Friday, Sept. 16, 3:45 p.m.-4 p.m. ET (Room A411/412)

Romosozumab Abstract of Interest

- **Romosozumab Blocks the Binding of Sclerostin to the Two Key Wnt Signaling Co-receptors, LRP5 and LRP6, but not to LRP4**
  Abstract MO0300, Poster Presentation, Monday, Sept. 19, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)

Prolia Late-Breaking Abstract of Interest

- **Effects of Up to 10 Years of Denosumab Treatment on Bone Matrix Mineralization: Results From the FREEDOM Extension**
  Abstract LB-1163, Late-Breaking Oral Presentation, Monday, Sept. 19, 11:48 a.m.-noon ET (Room A404/405)

Prolia Oral Presentations

- **Effect of 10 Years of Denosumab Treatment on Bone Histology and Histomorphometry in the FREEDOM Extension Study**
  Abstract 1005, Oral Presentation, Friday, Sept. 16, 1:45 p.m.-2 p.m. ET (Sidney Marcus Auditorium – Building A)

- **Discontinuation of Denosumab and Associated Fracture Incidence: Analysis From FREEDOM and its Extension**
  Abstract 1100, Oral Presentation, Sunday, Sept. 18, 10:45 a.m.-11 a.m. ET (Sidney Marcus Auditorium – Building A)

Prolia Abstracts of Interest

- **The Risk of Subsequent Osteoporotic Fractures Is Decreased in Patients Experiencing Fracture While on Denosumab: Results From the FREEDOM and FREEDOM Extension Studies**
  Abstract FR0288 and SA0288, Plenary Poster, Friday, Sept. 16, 5:30 p.m.-7 p.m. ET and Saturday, Sept. 17, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Denosumab Treatment for 10 Years in Postmenopausal Women With Osteoporosis Was Associated With Substantially Lower Fracture Incidence Relative to Their Baseline FRAX-Predicted Probability**
  Abstract FR0289 and SA0289, Plenary Poster, Friday, Sept. 16, 5:30 p.m.-7 p.m. ET and Saturday, Sept. 17, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Fracture Risk After Discontinuation of Denosumab**
  Abstract FR0294 and SA0294, Plenary Poster, Friday, Sept. 16, 5:30 p.m.-7 p.m. ET and Saturday, Sept. 17, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Bone Microarchitecture After Discontinuation of Denosumab in Postmenopausal Women With Low Bone Mass**
  Abstract SU0285, Poster Presentation, Sunday, Sept. 18, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Denosumab (DMAb) and Total Lean Body Mass: Exploratory Analyses from the FREEDOM Study**
  Abstract SU0286, Poster Presentation, Sunday, Sept. 18, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Persistence with Osteoporosis Therapies in Postmenopausal Women in a Large US National Health Plan**
  Abstract SU0296, Poster Presentation, Sunday, Sept. 18, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Long-Term Persistence with Osteoporosis Therapies Among Postmenopausal Women in a Commercially-Insured Population in the United States**
  Abstract SU0293, Poster Presentation, Sunday, Sept. 18, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)

Osteoporosis Disease State Abstracts of Interest

- **Estimating the Long-Term Functional Burden of Osteoporosis-Related Fractures**
  Abstract MO0243, Poster Presentation, Monday, Sept. 19, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **High Risk of Second Fracture Within 1, 2, 5 Years After Prior Fracture Among Women 65 years or Older**
  Abstract FR0233 and SA0233, Plenary Poster, Friday, Sept. 16, 5:30 p.m.-7 p.m. ET and Saturday, Sept. 17, 12:30 p.m.-2:30 p.m. ET (Room ASBMR Discovery Hall – Expo Hall A1)
- **Prediction of Two-Year Risk of Fracture Among Older US Women**
  Abstract FR0237 and SA0237, Plenary Poster, Friday, Sept. 16, 5:30 p.m.-7 p.m. ET and Saturday, Sept. 17, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Predictors of Imminent Fracture Risk in Medicare-Enrolled Men and Women**
  Abstract SU0227, Poster Presentation, Sunday, Sept. 18, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Predictors of Imminent Risk of Non-Vertebral Fracture in Older Women: The Framingham Osteoporosis Study**
  Abstract MO0232, Poster Presentation, Monday, Sept. 19, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)
- **Characteristics of Patients at High One-Year Fracture Risk**
  Abstract MO0223, Poster Presentation, Monday, Sept. 19, 12:30 p.m.-2:30 p.m. ET (ASBMR Discovery Hall – Expo Hall A1)

Amgen Webcast Investor Call

Amgen will host a webcast call for the investment community on Monday, Sept. 19, 2016, at 11:30 a.m. ET. Sean E. Harper, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team and clinical investigators, will participate in the call to discuss Amgen's clinical data presented at ASBMR, including the romosozumab Phase 3 study (FRAME).

Live audio of the investor call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

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.[1,2] This bone loss leads to weakened bones over time, increasing the potential for a break.[3]

It is estimated that one in three women over the age of 50 will experience an osteoporotic fracture.[4,5] Patients who experience an osteoporosis-related fracture are twice as likely to experience a future fracture.[6]

The World Health Organization has officially declared osteoporosis a public health crisis,[7,8] and the International Osteoporosis Foundation urges governments worldwide to make osteoporosis a healthcare priority.[9]

About Prolia® (denosumab)
Prolia® is indicated 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. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip 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 indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures.

Prolia is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Important Safety Information (U.S.)

Contraindications

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. Reactions have included anaphylaxis, facial swelling and urticaria.

Same Active Ingredient
Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®.

Hypersensitivity
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
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.

Osteonecrosis of the Jaw (ONJ)
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®. The risk of ONJ may increase with duration of exposure to 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 Femoral Fractures
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.

Serious Infections
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.

Dermatologic Adverse Reactions
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.

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

Suppression of Bone Turnover
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 these consequences, including ONJ, atypical fractures, and delayed fracture healing.

Adverse Reactions
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® group. 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.

The most common (per patient incidence ≥ 10%) adverse reactions reported with Prolia® in patients with bone loss receiving ADT for prostate cancer or adjuvant AI therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials. Additionally, in Prolia®-treated men with nonmetastatic prostate cancer receiving ADT, a greater incidence of cataracts was observed.

Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Prolia® Postmarketing Active Safety Surveillance Program
The surveillance program is available to collect information from prescribers on specific adverse events. Please see www.proliasafety.com or call 1-800-772-6436 for more information.

For more information, please see the Prolia Important Safety Information, Prescribing Information, and Medication Guide.

About Romosozumab
Romosozumab is an investigational bone-forming agent and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the protein sclerostin, and has a dual effect on bone, both 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 postmenopausal women with osteoporosis. Amgen and UCB are co-developing romosozumab.

About the Amgen and UCB Collaboration
Since 2004, Amgen and UCB have been working together under a collaboration and license agreement to research, develop and market antibody products targeting the sclerostin protein. As part of this agreement, the two companies continue to collaborate on the development of romosozumab for the treatment of osteoporosis. This gene-to-drug project demonstrates how Amgen and UCB are joining forces to turn genetic discoveries into new medicine, turning conceptual science into a reality. If approved, Amgen will lead romosozumab commercialization in the United states, Canada, Mexico and Japan, and UCB will lead commercialization in all EU member countries, as well as Switzerland, Norway, Australia and New Zealand.

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 the current expectations and beliefs of Amgen. 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 reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. 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 results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and 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. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. 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. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. 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. Further, 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, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. 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 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 or European Commission, 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 U.S. Food and Drug Administration or the European Medicines Agency 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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