New Analyses Of Phase 2 Study Presented At ASBMR Show Romosozumab Treatment Resulted In Continued Increases In Bone Mineral Density

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Romosozumab Currently in Phase 3 Clinical Development, Pivotal Data Expected in 2016

THOUSAND OAKS, Calif. and BRUSSELS, Sept. 15, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and UCB (Euronext Brussels:UCB) today announced results from several exploratory analyses of the Phase 2 study evaluating romosozumab in postmenopausal women with low bone mineral density (BMD). 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. These data were presented at the American Society for Bone and Mineral Research (ASBMR) 2014 Annual Meeting in Houston, Sept. 12-15, 2014.

"Fractures or broken bones due to osteoporosis are very common and often have a life altering impact on an older woman and her family," said Michael McClung, M.D., director of the Oregon Osteoporosis Center. "It is encouraging to see that treatment with romosozumab for a second year provided additional increases in bone mineral density beyond what was seen during the first 12 months of treatment."

Results from one analysis showed that treatment with romosozumab led to significant increases in lumbar spine and total hip BMD during the first 12 months, with continued increases through year two. After year two, patients transitioned to either treatment with Prolia® (denosumab) for 12 months, which led to further BMD increases, or to placebo, in which case BMD decreased towards initial baseline. An additional analysis of the Phase 2 study found that women treated with romosozumab had greater improvements in cortical parameters of the vertebrae, including thickness and mass, compared with those taking open-label Forteo® (teriparatide) or placebo at 12 months.

"We are very excited about the potential of romosozumab to significantly build bone for people at high risk for fracture, in particular those who have already fractured, given the impact this can have on a patient," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to continued investigation of romosozumab in our extensive global Phase 3 program, which includes two large fracture trials comparing the treatment to either placebo or active comparators in more than 10,000 patients with osteoporosis."

Postmenopausal osteoporosis (PMO) affects many women after menopause as their ability to form new bone cannot counter the rate at which bone is being removed. This bone loss leads to weakened bones over time, increasing the potential for a broken bone or fracture.[1,2] Such a break, or fracture, may be a life-changing event.[2,3] About half of all women over age 50 will have an osteoporosis-related fracture in their remaining lifetime, and once that happens, the chances of another are much higher.[4,5]

"Despite continuing progress in the management and treatment of patients with osteoporosis, there remains a considerable need for new therapeutic approaches for individual patients," said Professor Dr. Iris Loew-Friedrich, chief medical officer and executive vice president, UCB. "Investigational studies to date suggest that the bone building capacity of romosozumab may show promise as a new treatment option to manage this serious disease. We look forward to reporting the results of the romosozumab Phase 3 program in 2016."

In the Phase 2 study, after 12 months of treatment with romosozumab adverse events were similar across groups, except for mild, generally non-recurring injection site reactions observed more frequently with romosozumab compared with placebo, but with no observed dose-related relationship. These reactions did not lead to study drug discontinuation or study withdrawal. The most frequent adverse events included nasopharyngitis and arthralgia. The romosozumab adverse event profile in year two was comparable to year one of the study. The overall proportions of subjects reporting adverse events and serious adverse events in the 24 month period were balanced across treatment groups. In year three of the study, the overall subject incidence of adverse events and serious adverse events were balanced across treatment groups. No new safety findings were observed.

Selected Abstracts of Interest

"Effects of 2 Years of Treatment with Romosozumab Followed by One Year of Denosumab or Placebo in Postmenopausal Women with Low BMD"

Results:

- In this exploratory analysis, romosozumab led to increases in lumbar spine and total hip BMD during year one with continued increases through year two. The largest gains in BMD were observed with the 210 mg monthly dose, achieving an increase of 15.7 percent (lumbar spine BMD) and 6.0 percent (total hip BMD). Women receiving romosozumab 210 mg monthly who then transitioned to treatment with Prolia after 12 months continued to accrue BMD at a rate similar to what was seen during the second year of treatment with romosozumab; in those who transitioned to placebo, BMD returned towards pre-treatment levels.

Methods:

- The study enrolled 419 postmenopausal women aged 55 to 85 years with a lumbar spine, total hip or femoral neck T score ≤-2.0 and ≥-3.5. Women received one of five regimens of romosozumab (70 mg monthly, 140 mg monthly, 210 mg monthly, 140 mg once every three months, 210 mg once every three months), or placebo for two years. At the end of two years, eligible subjects entered a one year double blind extension phase and were re-randomized 1:1 within their original treatment group to placebo or denosumab 60 mg once every six months. Only women who entered the extension were

included in this analysis (n=260).

"Romosozumab and Teriparatide Effects on Vertebral Cortical Mass, Thickness and Density in Postmenopausal Women with Low BMD"

Results:

- In this exploratory analysis, results showed that treatment with romosozumab resulted in a mean (95 percent CI) cortical thickness (CTh) increase of 11.2 percent (9.0 to 13.4), a cortical bone mineral density (CBMD) increase of 1.6 percent (0.2 to 2.9), a cortical mass (CMass) increase of 12.7 percent (10.8 to 14.7) and a trabecular BMD (TBMD) increase of 22.2 percent (19.2 to 25.3). The improvements in CTh (p<0.001) and CMass (p<0.001) with romosozumab were significantly greater than those observed with open-label teriparatide.
- Treatment with teriparatide resulted in a CTh increase of 5.6 percent (3.9 to 7.4), a CMass increase of 4.6 percent (3.4 to 5.8), a TBMD increase of 17.4 percent (12.2 to 22.6), and a slight but not significant CBMD reduction of 0.5 percent (–1.8 to 0.7).
- In the placebo group, the statistically significant change was a reduction of 4.3 percent (–6.7 to –1.9) in TBMD.

Methods:

- Baseline and 12 month L1 vertebral computed tomography (CT) scans from postmenopausal women treated with romosozumab (210 mg monthly, n=17), teriparatide (20 µg daily, n=19) and placebo (n=20) were evaluated.
- Cortical measurements were performed, blinded to treatment, using the Stradwin software tool, which is able to measure and map CBMD, TBMD directly adjacent to the cortex, CTh and CMass (CMass=0.1 × CTh × CBMD).
- Transferring these maps to a canonical vertebral surface allows evaluation and topographical illustration of longitudinal changes to determine differences between treatments.

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 hospitalization 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 hypocalcemia, and pre-existing hypocalcemia 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 hypocalcemia. In the post-marketing setting, rare cases of severe symptomatic hypocalcemia have been predominantly reported in patients at increased risk of hypocalcemia, with most cases occurring in the first weeks of initiating therapy. Osteonecrosis of the jaw has been reported rarely in clinical studies in patients receiving denosumab at a dose of 60 mg every six 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.

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) 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 Amgen's business. Unless otherwise noted, Amgen is providing this information as of Sept. 15, 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 Amgen projects. 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 Amgen and its partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development.

In addition, sales of Amgen's products (including products of Amgen's 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 Amgen's products. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have

lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. In addition, while Amgen and its partners routinely obtain patents for their products and technology, the protection of Amgen's products offered by patents and patent applications may be challenged, invalidated or circumvented by its competitors and there can be no guarantee of Amgen's or its partners' ability to obtain or maintain patent protection for Amgen's products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations. Amgen's efforts to integrate the operations of companies it has acquired may not be successful. Cost savings initiatives may result in Amgen incurring impairment or other related charges on Amgen's assets. Amgen may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from its recently announced restructuring plans. Amgen's business performance could affect or limit the ability of Amgen's Board of Directors to declare a dividend or Amgen's ability to pay a dividend or repurchase common stock.

The scientific information discussed in this news release relating to new indications for Amgen's products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration 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.

About UCB
UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8500 people in approximately 40 countries, the company generated revenue of € 3.4 billion in 2013. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

UCB Forward Looking Statements
This press release contains forward-looking statements based on current plans, estimates and beliefs of management. 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 information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners.

Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.

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