UCB News

RESULTS FROM PHASE 3 FRAME STUDY OF ROMOSOZUMAB SHOWED SIGNIFICANT REDUCTIONS IN BOTH NEW VERTEBRAL AND CLINICAL FRACTURES IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS

- **FRAME Data Simultaneously Published in *New England Journal of Medicine* and Presented at ASBMR Showed Treatment With Romosozumab Significantly Reduced New Vertebral and Clinical Fractures Through 12 Months**
- **Significant Bone Mineral Density Gains Shown at Six and 12 Months at the Lumbar Spine, Total Hip and Femoral Neck**
- **Bone Mineral Density Continued to Increase and Vertebral Fracture Risk Reduction Persisted With the Transition From Romosozumab to Denosumab Through 24 Months**

BRUSSELS, BELGIUM and THOUSAND OAKS, Calif. (Sept. 18, 2016) - UCB (Euronext Brussels: UCB) and Amgen (NASDAQ:AMGN) today announced findings from the FRAME study showing that the investigational agent romosozumab significantly reduced the incidence of new vertebral fractures in postmenopausal women with osteoporosis through 12 and 24 months, meeting the study's co-primary endpoints. The results from the Phase 3 study, the first to evaluate fracture risk reduction as early as one year as a primary endpoint, were published in the *New England Journal of Medicine* (NEJM), and presented in an oral session at the American Society for Bone Mineral Research (ASBMR) annual meeting in Atlanta, Georgia. Romosozumab works by binding and inhibiting the activity of the protein sclerostin, and as a result has a dual effect on bone, both increasing bone formation and decreasing bone breakdown.

"Treatment data show that only one in five women who have experienced an osteoporotic fracture are started on treatment for the disease[1], despite the fact that patients who experience an osteoporotic fracture are twice as likely to suffer a future fracture[2]," said study lead author Felicia Cosman, M.D., medical director of the Clinical Research Center at Helen Hayes Hospital and professor of medicine at Columbia University College of Physician and Surgeons in New York. "The FRAME results demonstrate that romosozumab, with its dual effect of increasing bone formation and decreasing bone resorption, has the potential to reduce the risk of new vertebral and clinical fractures within 12 months, in addition to showing improvements in bone mass, with sustained benefits upon transition to denosumab thereby addressing a critical treatment need for patients at increased risk of fracture."

FRAME (**FRA**cture study in postmenopausal wo**M**en with ost**E**oporosis), which enrolled 7,180 women, showed that those randomly assigned to receive a monthly subcutaneous 210 mg dose of romosozumab experienced a statistically significant 73 percent reduction in the relative risk of a new vertebral (spine) fracture through 12 months, the first co-primary endpoint, compared to those receiving placebo (fracture incidence 0.5 percent vs. 1.8 percent, respectively [p<0.001]). Of interest, the data showed that by six months, new vertebral fractures occurred in 14 romosozumab and 26 placebo patients, and between six to 12 months, fractures occurred in two additional romosozumab versus 33 additional placebo patients.

In those patients who received romosozumab in year one, fracture risk reduction persisted through month 24 after both groups transitioned to denosumab treatment in the second year of the study; there was a statistically significant 75 percent reduction in the risk of vertebral fracture at month 24 (the other co-primary endpoint) in

patients who received romosozumab followed by denosumab vs. placebo followed by denosumab (fracture incidence 0.6 percent vs. 2.5 percent, respectively [p<0.001]). In the second year of the study, new vertebral fractures occurred in five patients who transitioned from romosozumab to denosumab and 25 patients who transitioned from placebo to denosumab.

When looking at clinical fractures, which encompass all symptomatic fractures (both non-vertebral and painful vertebral fractures), patients receiving romosozumab experienced a statistically significant 36 percent reduction in the relative risk of a clinical fracture, a secondary endpoint, through 12 months compared to those receiving placebo (fracture incidence 1.6 percent vs. 2.5 percent, respectively [p=0.008]). A 33 percent reduction in relative risk of clinical fracture was observed through 24 months after patients transitioned from romosozumab to denosumab compared to patients transitioning from placebo to denosumab (nominal p=0.002, adjusted p=0.096).

Romosozumab resulted in a 25 percent reduction compared to placebo in the relative risk of non-vertebral fractures through month 12, another secondary endpoint, but the reduced risk was not statistically significant (fracture incidence 1.6 percent vs. 2.1 percent, respectively, [p=0.096]. For the non-vertebral fracture endpoint, the overall fracture incidence in the study was lower than expected (2.1 percent in the placebo group in year one versus an expected rate of 3.5 percent).

In a substudy of 126 subjects, romosozumab increased bone mineral density with gains of 9.7 percent and 4.7 percent from baseline by six months at the lumbar spine and total hip, respectively, and gains of 13.3 percent and 6.8 percent at 12 months (all comparisons versus placebo p<0.001). Bone mineral density continued to increase in the romosozumab group after transitioning to denosumab, reaching a 17.6 percent and 8.8 percent increase from baseline at the lumbar spine and total hip, respectively, at 24 months (p<0.001 compared to placebo-to-denosumab group for all comparisons).

"Osteoporotic fractures are common, resulting in far-reaching consequences for individuals and their families, as well as for society as a whole," said Dr. Pascale Richetta, head of bone and executive vice president, UCB. *"To reduce the growing global burden of this prevalent chronic disease more decisive steps need to be taken now for identifying, diagnosing and appropriately treating people with osteoporosis at an increased risk of fracture."*

"We are pleased to see nearly 15 years of sclerostin antibody research reinforced with these Phase 3 data. Romosozumab with its dual effect as a bone builder and anti-resorptive has the potential to play a distinct and important role in the treatment of women with postmenopausal osteoporosis at increased risk of fracture," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. *"These positive FRAME study results are the basis of our Biologics Licensing Agreement that we submitted to the FDA in July, and we look forward to working with regulatory authorities to help make this potential treatment option available to patients."*

The percentage of patients with adverse events and serious adverse events in the 12-month double-blind period and 24-month study period were balanced overall between the treatment groups. Injection site reactions, mostly mild in severity, were reported in 5.2 percent of patients in the romosozumab treatment group and 2.9 percent in the placebo group during the 12-month period. There were two positively adjudicated events of osteonecrosis of the jaw in the romosozumab treatment group, one after completing romosozumab dosing and the other after completing romosozumab treatment and receiving the initial dose of denosumab. There was one positively adjudicated event of atypical femoral fracture after three months of romosozumab treatment. Adjudicated serious cardiovascular events and cardiovascular deaths were balanced between treatment groups.

References

1. *Wilk A et al. Post-fracture pharmacotherapy for women with osteoporotic fracture: analysis of a managed care population in the USA. Osteoporosis Int. 2014;25(12):2777-2786.*

2. *International Osteoporosis Foundation. Stop at One. One Fracture Leads to Another. http://share.iofbonehealth.org/WOD/2012/patient_brochure/WOD12-patient_brochure.pdf. Accessed August 29, 2016.*

About Romosozumab

Romosozumab is an investigational bone-forming monoclonal agent and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the activity of 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 FRAME study

FRAME is a multi-center, international, randomized, double-blind, placebo-controlled, parallel-group study in postmenopausal women with osteoporosis, defined as low bone mineral density at the total hip or femoral neck. The study evaluated the effectiveness of romosozumab treatment, compared with placebo, in reducing the risk of new vertebral fractures through 12 months. The study also further evaluated if romosozumab treatment for 12 months followed by denosumab treatment for 12 months, compared with placebo followed by denosumab treatment, was effective in reducing the risk of new vertebral fractures through 24 months. In addition, clinical fracture (a composite endpoint which encompasses all symptomatic fractures, both non-vertebral and painful vertebral fractures) risk reduction, non-vertebral fracture (fractures outside of the spine, excluding sites that are not considered osteoporotic, fractures due to high trauma or pathologic fractures) risk reduction and other endpoints were assessed at 12 and 24 months.

7,180 patients were randomized 1:1 to receive either 210 mg romosozumab subcutaneous (SC) monthly (QM) or placebo SC QM for the 12-month double-blind study period. After the placebo-controlled study period, patients entered the open-label phase where all patients received 60 mg denosumab SC every six months (Q6M) for 12 months, while remaining blinded to initial treatment. An additional 12 month extension period of open-label 60 mg denosumab SC Q6M is currently ongoing.

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.

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 7,700 people in approximately 40 countries, the company generated revenue of € 3.9 billion in 2015. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

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 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.

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.

Forward-Looking Statements – Amgen

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 its 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 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 to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. 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 its products after they are on the market.

Amgen's results may be affected by its 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 its products and global economic conditions. In addition, sales of Amgen's 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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between it and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key manufacturing facilities and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. 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 its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all. Amgen is increasingly dependent on information technology systems, infrastructure and data security. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock.

The scientific information discussed in this news release related to Amgen's 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.] [Further,] 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.

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