UCB News

UCB AND AMGEN ANNOUNCE TOP-LINE PHASE 3 DATA FROM ACTIVE-COMPARATOR STUDY OF EVENITY™ (ROMOSOZUMAB) IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS

- **ARCH Study Met Primary and Key Secondary Endpoints by Reducing the Incidence of New Vertebral, Clinical and Non-Vertebral Fractures**
- **Imbalance in Cardiovascular Events Observed as New Safety Signal**

BRUSSELS and THOUSAND OAKS, Calif. (00:01, May 22, 2017): Regulated Information – Inside Information – UCB (Euronext Brussels: UCB) and Amgen (NASDAQ:AMGN) today announced that the romosozumab ARCH study met both primary endpoints and the key secondary endpoint. At the primary analysis, treatment with romosozumab for 12 months followed by alendronate significantly reduced the incidence of new vertebral fractures through 24 months, clinical fractures (primary endpoints) and non-vertebral fractures (key secondary endpoint) in postmenopausal women with osteoporosis at high risk for fracture, compared to alendronate alone. An imbalance in positively adjudicated cardiovascular serious adverse events was observed as a new safety signal (2.5 percent romosozumab versus 1.9 percent alendronate at 12 months).

“We are impressed with the statistically significant superior fracture risk reduction of romosozumab over alendronate, a current standard of care in osteoporosis. When we think that patients who have had a fracture are highly likely to suffer another one, the importance of post-fracture care cannot be emphasized enough,” said Professor Iris Loew-Friedrich, UCB’s chief medical officer. “We are working on understanding the observed cardiovascular safety signal and will continue to discuss these results with global regulators and experts in the field.”

Romosozumab is an investigational bone-forming agent that rapidly increases bone formation and reduces bone resorption simultaneously, increases bone mineral density and reduces the risk of fracture. In this study, women received subcutaneous injection of romosozumab monthly for 12 months followed by oral alendronate weekly for at least 12 months. At 24 months, women in the romosozumab treatment group experienced a statistically significant 50 percent reduction in the relative risk of a new vertebral (spine) fracture compared to those receiving alendronate alone. Women in the romosozumab treatment group also experienced a statistically significant 27 percent reduction in the relative risk of clinical fracture (non-vertebral fracture and clinical vertebral fracture) at the primary analysis. Additionally, non-vertebral fractures were statistically significantly reduced by 19 percent in the romosozumab treatment group, including a nominally significant reduction in hip fractures.

“The efficacy results from this study comparing romosozumab to an active control are robust. At the same time, the newly observed cardiovascular safety signal will have to be assessed as part of the overall benefit:risk profile for romosozumab,” said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. “Together with UCB, we will engage with global regulators and medical experts in the field to conduct a thorough evaluation of these data.”

Overall adverse events and serious adverse events were generally similar between the treatment groups throughout the study and also in the initial 12-month romosozumab treatment period. In the initial 12-month romosozumab treatment period, the three most commonly reported adverse events in both arms were

*The trade name EVENITY™ is provisionally approved for use by the U.S. Food and Drug Administration and the European Medicines Agency
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nasopharyngitis, back pain and arthralgia. Injection site reactions were reported in 4.4 percent of patients in the romosozumab treatment group and 2.6 percent in the alendronate group during the initial 12-month period. Most injection site reactions were reported as mild in severity. During the open-label alendronate period, there were two positively adjudicated events of osteonecrosis of the jaw, one in a patient treated with romosozumab followed by alendronate and one treated with alendronate alone. There were six patients with positively adjudicated events of atypical femoral fracture during the open-label alendronate period (two patients treated with romosozumab followed by alendronate and four treated with alendronate alone). The patient incidence of positively adjudicated cardiovascular serious adverse events at 12 months was 2.5 percent in the romosozumab group compared to 1.9 percent in the alendronate group. No imbalance in cardiovascular serious adverse events was seen in the 7,180-patient placebo-controlled FRAME study.

Regulatory submissions for romosozumab based on the FRAME study results are currently under review with the U.S. Food and Drug Administration (FDA), Health Canada and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. Amgen has agreed with the FDA that the ARCH data should be considered in the regulatory review prior to the initial marketing authorization, and as a result the Company does not expect approval of romosozumab in the US to occur in 2017. Engagement with PMDA and Health Canada will occur as part of the ongoing review process. The preparation for the European regulatory submission will continue as planned. Further analysis of the Phase 3 ARCH study data is ongoing and will be submitted to a future medical conference and for publication.

These data do not impact the financial outlook for 2017 provided by UCB.

About Evenity (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 activity of sclerostin and has a dual effect on bone, increasing bone formation and decreasing bone resorption. 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 ARCH study

ARCH (Active-contRolled FraCture Study in Postmenopausal Women with Osteoporosis at High Risk of Fracture) is a Phase 3 multicenter, international, randomized, double-blind, alendronate-controlled study of EVENITY in postmenopausal women with osteoporosis at high risk for fracture based on previous fracture history. The study evaluated 12 months of EVENITY treatment followed by at least 12 months of alendronate treatment, compared with alendronate treatment alone. The purpose of this study was to determine if EVENITY treatment is effective in reducing the incidence of clinical fracture (non-vertebral fracture and clinical vertebral fracture) and new vertebral fracture. The incidence of clinical fracture was event-driven and the primary analysis occurred when 330 fractures occurred or the last patient was on the study for 24 months, whichever was later.

Patients (4,093) were randomized 1:1 to receive either 210 mg EVENITY subcutaneously every month or 70 mg alendronate orally every week for the duration of the 12-month double-blind alendronate-controlled study period. After the double-blind active-comparator study period, patients received alendronate while remaining blinded to their initial treatment assignment.

About the FRAME study

FRAME (FRActure study in postmenopausal woMen with ostEoporosis) is a multicenter, 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 protein sclerostin. As part of this agreement, the two companies continue to collaborate on the development of EVENITY for the treatment of osteoporosis. This gene-to-drug project demonstrates how Amgen and UCB are joining forces to translate a genetic discovery into a 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 7 500 people in approximately 40 countries, the company generated revenue of € 4.2 billion in 2016. 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.

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 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. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amge'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.

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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* The trade name EVENITY™ is provisionally approved for use by the U.S. Food and Drug Administration and the European Medicines Agency

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