UCB News

EVENITY™ (*romosozumab*) ARCH Study Results Published in the *New England Journal of Medicine*

- **EVENITY Followed by Alendronate Reduced the Incidence of New Vertebral, Clinical, Non-Vertebral and Hip Fractures Compared to Alendronate Alone**

- **Additional Details on Observed Cardiovascular Safety Signal Provided**

BRUSSELS, Belgium and THOUSAND OAKS, Calif. (11th Sept, 2017) – UCB (Euronext Brussels: UCB) and Amgen (NASDAQ:AMGN) today announced detailed results from the Phase 3 ARCH study showing that 12 months of EVENITY™* (*romosozumab*) followed by alendronate was superior in reducing new vertebral, clinical, non-vertebral and hip fracture risk in postmenopausal women with osteoporosis at high risk for fracture, compared to alendronate alone. Overall adverse events and serious adverse events were generally similar between the treatment groups with the exception of the previously reported imbalance in positively adjudicated cardiovascular serious adverse events. The results were simultaneously published in the *New England Journal of Medicine* (NEJM) and presented today as a late-breaking abstract at an oral scientific session at the Annual Meeting of the American Society for Bone Mineral Research (ASBMR) in Denver.[1]

The study found that through 24 months, postmenopausal women with osteoporosis in the *romosozumab* treatment group experienced a statistically significant 48.0 percent relative reduction in the risk of a new vertebral (spine) fracture compared with those receiving alendronate alone (6.2 percent versus 11.9 percent, respectively [p<0.001]). At primary analysis, women in the *romosozumab* treatment group also experienced a statistically significant 27.0 percent relative reduction in the risk of clinical fracture, which includes non-vertebral fracture and clinical vertebral fracture (9.7 percent versus 13.0 percent, respectively [(p<0.001]).

“The ARCH study shows that romosozumab can provide superior fracture risk reduction over alendronate, a commonly used, first-line osteoporosis treatment,” said study lead author Kenneth F. Saag, M.D., M.Sc., professor of medicine at the University of Alabama at Birmingham School of Medicine. “By sharing the detailed results of efficacy and safety, we aim to help clinicians understand the potential future benefit:risk profile of romosozumab and its potential as a treatment option for postmenopausal women living with osteoporosis.”

At primary analysis, postmenopausal women in the *romosozumab* treatment group experienced a statistically significant 19.0 percent relative reduction in the risk of non-vertebral fractures (8.7 percent versus 10.6 percent, respectively [p=0.04]). A 38.0 percent relative reduction in the risk of hip fractures was also observed (2.0 percent versus 3.2 percent, respectively [nominal p=0.015]), when compared to those receiving alendronate alone.

Postmenopausal women who received *romosozumab* achieved greater gains in bone mineral density (BMD) from baseline at all measured sites and at all time points of the study versus those receiving alendronate alone. At month 12, the percentage change from baseline was greater with *romosozumab* versus alendronate at the lumbar spine (13.7 percent versus 5.0 percent, respectively [p<0.001]) and total hip (6.2 percent versus 2.8 percent, respectively [p<0.001]). In a subset of patients assessed every six months, significant gains were observed beginning at month six (p<0.001) for all sites.

Overall, adverse events and serious adverse events were generally similar between the treatment groups. An imbalance in adjudicated cardiovascular serious adverse events was observed during the 12-month period in 50 patients (2.5 percent) treated with *romosozumab* versus 38 patients (1.9 percent) treated with alendronate, with cardiac ischemic events and cerebrovascular events accounting for the imbalance.

*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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The percentage of patients with adverse events and serious adverse events throughout the study as well as in the initial 12-month *romosozumab* treatment period were balanced between the groups, including incidences of osteoarthritis, hypersensitivity, cancer and hypocalcemia. Injection site reactions, mostly mild in severity, 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.

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.

References

1. Saag K, Petersen J, Brandi ML, et al. Romosozumab or alendronate for fracture prevention in women with osteoporosis. N Engl J Med 2017; DOI: 10.1056/NEJMoa1708322

About the ARCH Study

*ARCH (**A**ctive-cont**R**olled Fra**C**ture Study in Postmenopausal Women with Osteoporosis at **H**igh Risk of Fracture) is a Phase 3 multicenter, international, randomized, double-blind, alendronate-controlled study of romosozumab in 4,093 postmenopausal women with osteoporosis at high risk for fracture based on previous fracture history.*

Patients were randomized 1:1 to receive either 210 mg romosozumab 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. The incidence of new vertebral fracture was assessed at 24 months. The incidence of clinical fracture was assessed at the primary analysis, when 330 fractures occurred or the last patient was on the study for 24 months, whichever was later. In addition, other key fracture endpoints including non-vertebral fracture and hip fracture were assessed at primary analysis.

About Romosozumab

Romosozumab is an investigational bone-forming monoclonal antibody and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the activity of sclerostin, which enables romosozumab to rapidly increase bone formation and reduce bone resorption simultaneously. 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 UCB and Amgen 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 romosozumab 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.

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

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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.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction. UCB is providing this information as of the date of this presentation 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.

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 current reports on 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, including its devices, 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'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 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

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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.

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