UCB News

UCB and Amgen Resubmit Biologics Licence Application (BLA) for EVENITY™ (Romosozumab) to the U.S. FDA

- **BLA Includes Data From Pivotal Phase 3 Studies of More Than 11,000 Patients**

Brussels, Belgium and Thousand Oaks, Calif (July 13, 2018, 07:00 CET) – UCB (Euronext Brussels: UCB) and Amgen (NASDAQ:AMGN) today announced the resubmission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for EVENITY™* (romosozumab), an investigational monoclonal antibody for the treatment of osteoporosis in postmenopausal women at high risk for fracture. Romosozumab increases bone formation and reduces bone resorption simultaneously to increase bone mineral density (BMD), and reduce the risk of fracture.

“The burden of osteoporosis can have tremendous impact on a patient’s life,” said Dr Pascale Richetta, head of bone and executive vice president at UCB. “We are one step closer in our ability to bring this first of its kind treatment to thousands of women affected by fragility fractures each year.”

The BLA for romosozumab now adds results from two more recent pivotal Phase 3 trials: the ARCH study, an alendronate-active comparator trial including 4,093 postmenopausal women with osteoporosis who experienced a fracture and the BRIDGE study, including 245 men with osteoporosis. The FDA will evaluate the clinical benefit-risk profile of romosozumab, including the cardiovascular safety signal seen in the ARCH study, for the potential to reduce the risk of fractures and increase BMD in postmenopausal women with osteoporosis. The original FDA submission included data from a comprehensive Phase 1 and Phase 2 program and the Phase 3 placebo-controlled FRAME study, including 7,180 postmenopausal women with osteoporosis.

“A fracture due to osteoporosis can be a life-altering event, and romosozumab has the potential to reduce fracture risk in patients at high risk due to a prior fracture,” said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. “We look forward to continuing our work with the FDA to demonstrate the benefit-risk profile for romosozumab. Our hope is to bring to patients an innovative treatment option that addresses a serious unmet medical need.”

In the U.S., one in two women, over the age of 50, will suffer a fragility (or osteoporotic) fracture due to osteoporosis, and with an aging population these numbers will likely rise.[1] Yet despite this, we are currently seeing a large gap in the management and treatment of osteoporosis, especially in the post-fracture setting, with an estimated four out of five patients remaining undiagnosed and untreated after a fracture.[2] Without proper care or access to effective intervention options, they remain at risk of painful and disabling fractures in the future.

The European Medicines Agency (EMA) and the Pharmaceuticals and Medical Device Agency (PMDA) in Japan are currently reviewing marketing applications for romosozumab and interactions with the agencies are ongoing.

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

About EVENITY™* (romosozumab)

EVENITY 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 EVENITY to rapidly increase bone formation and reduce bone resorption simultaneously. EVENITY has been studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program. This program included two large fracture trials comparing EVENITY to either placebo or active comparator in more than 11,000 postmenopausal women with osteoporosis. Amgen and UCB are co-developing EVENITY.

About the Pivotal EVENITY Clinical Trials

*FRAME (**FRA**cture study in postmenopausal wo**M**en with ost**E**oporosis) is a randomized, double-blind, placebo-controlled study that evaluated 7,180 postmenopausal women with osteoporosis. The study evaluated the effectiveness of EVENITY treatment (210 mg), compared with placebo, in reducing the risk of new vertebral fractures through 12 months. The study also evaluated the effectiveness of treating with EVENITY for 12 months followed by denosumab for 12 months, compared with placebo followed by denosumab, in reducing the risk of new vertebral fractures through 24 months.*

*ARCH (**A**ctive-cont**R**olled fra**C**ture study in postmenopausal women with osteoporosis at **H**igh risk of fracture) is a randomized, double-blind, alendronate-controlled study of EVENITY in 4,093 postmenopausal women with osteoporosis at high risk for fracture based on previous fracture history. The study evaluated 12 months of EVENITY treatment (210 mg) followed by at least 12 months of alendronate treatment (70 mg), compared with alendronate treatment alone, to determine effectiveness in reducing the incidence of clinical fracture (non-vertebral fracture and clinical vertebral fracture) and new vertebral fracture.*

*BRIDGE (place**B**o-cont**R**olled study evaluat**I**ng the efficacy an**D** safety of romosozumab in treatin**G** m**E**n with osteoporosis) is a randomized, double-blind, placebo-controlled study of 245 men aged 55-90 years with osteoporosis and a history of fragility fracture (excluding hip fracture) or vertebral fracture. The study evaluated the effectiveness of EVENITY treatment for 12 months, compared with placebo, in increasing BMD at the lumbar spine and the effect on BMD at the femoral neck and total hip.*

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 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 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.

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 in immunology and neurology. With more than 7,500 people in approximately 40 countries, the company generated revenue of € 4.5 billion in 2017. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

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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 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 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. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data.

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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. Amgen may or may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

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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References

1. National Osteoporosis Foundation. What is Osteoporosis and What Causes It? https://nof.org/patients/what-is-osteoporosis. Accessed June 28, 2018.

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2. Nguyen TV, Center JR, Eisman JA (2004) Osteoporosis: underrated, underdiagnosed and undertreated. Med J Aust 180:S18.

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