



Amgen And UCB Receive Positive Vote From FDA Advisory Committee In Favor Of Approval For EVENITY™ (romosozumab)

January 16, 2019

Potential New Treatment Option for the Treatment of Postmenopausal Women With Osteoporosis at High Risk for Fracture

THOUSAND OAKS, Calif. and BRUSSELS, Jan. 16, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and UCB (Euronext Brussels: UCB) today announced strong support from the U.S. Food and Drug Administration (FDA) Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) for the approval of EVENITY™* (romosozumab) for the treatment of postmenopausal women with osteoporosis at high risk for fracture after reviewing safety and efficacy data from the pivotal Phase 3 studies. Eighteen of 19 members voted yes for approval. In their discussion, the Committee emphasized the need for post-marketing follow-up.

"We are pleased with the Committee's recommendation to approve EVENITY for the treatment of postmenopausal women with osteoporosis at high risk for fracture," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "A fracture due to osteoporosis can be devastating to the lives of patients. After an osteoporotic fracture, a woman is five times more likely to suffer another fracture within the first year, and her risk remains elevated over time if untreated.¹ Despite available therapies, these women who are at high risk for fracture could benefit from an additional treatment option that has the potential to both build new bone and slow existing bone loss. We are committed to working with the FDA to help make EVENITY available to appropriate patients."

The EVENITY development program includes 19 clinical studies that enrolled approximately 14,000 patients.² Notable Phase 3 studies include FRAME,³ a placebo-controlled study with 7,180 postmenopausal women with osteoporosis at risk for fracture; ARCH,⁴ an active comparator-controlled study with 4,093 postmenopausal women with osteoporosis and with prior history of fracture; and STRUCTURE,⁵ an active comparator-controlled study with 436 postmenopausal women with osteoporosis. The BRUDAC evaluated the FRAME and ARCH studies in its review of the clinical benefit:risk profile of EVENITY, including the cardiovascular safety finding seen in the ARCH study, for the potential to reduce the risk of fractures and increase bone mineral density (BMD) in postmenopausal women with osteoporosis.

"Evidence suggests that many women who sustain a fragility fracture are not appropriately treated for osteoporosis. This is why new treatment options, like EVENITY, are so important," said Dr. Pascale Richetta, head of bone and executive vice president, UCB. "The Committee's recommendation represents a step forward for patients and we look forward to working with our partner, Amgen, in the coming months to bring EVENITY to the patients that need it most."

While the FDA is not bound by the Advisory Committee's recommendations, it takes the advice into consideration when making its decision.

In the U.S., one in two women over the age of 50 will experience an osteoporotic fracture.⁶ Unfortunately, only 20 percent of women who have experienced a fracture receive any type of osteoporosis treatment during the first year post-fracture.⁷

EVENITY was granted marketing authorization – its first approval anywhere in the world – by the Japanese Ministry of Health, Labor and Welfare on Jan. 8, 2019, for the treatment of osteoporosis in patients at high risk of fracture.⁸ The European Medicines Agency (EMA) is currently reviewing the marketing application for EVENITY and interactions between our partner and the agency are ongoing.

About EVENITY™* (romosozumab)

EVENITY is an investigational bone-forming monoclonal antibody. It is designed to work by inhibiting the activity of sclerostin, which enables EVENITY to rapidly increase bone formation and reduce bone resorption simultaneously. The EVENITY development program includes 19 clinical studies that enrolled approximately 14,000 patients. 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 (Fracture study in postmenopausal women with osteoporosis) is a randomized, double-blind, placebo-controlled study that evaluated 7,180 postmenopausal women with osteoporosis at risk for fracture. The study evaluated the effectiveness of EVENITY treatment (210 mg administered monthly), 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 (Active-controlled fracture study in postmenopausal women with osteoporosis at high 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 administered monthly) followed by at least 12 months of alendronate treatment (70 mg), compared with alendronate treatment alone, to assess its effectiveness in reducing the incidence of clinical fracture (non-vertebral fracture and clinical vertebral fracture) and new vertebral fracture.

About the STRUCTURE Clinical Trial

STRUCTURE (Study evaluating effect of romosozumab compared with teriparatide in postmenopausal women with osteoporosis at high risk for fracture previously treated with bisphosphonate therapy) is a Phase 3, multi-center, international, randomized, open-label, teriparatide-controlled study that evaluated safety, tolerability and efficacy of romosozumab in women with postmenopausal osteoporosis. The trial included 436 postmenopausal women averaging 72 years of age who had postmenopausal osteoporosis and a history of bone fracture; patients were treated with bisphosphonate therapy for a minimum of three years prior to screening, with treatment with alendronate (70 mg weekly or equivalent) during the year immediately prior to screening.

About Fragility Fractures

Worldwide, one in three women and one in five men, over the age of 50, will suffer a fragility fracture due to osteoporosis and with an aging population these numbers will rise.⁹ Yet despite this, there is 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.⁷ Without proper care or access to effective intervention options, they remain at risk of painful and disabling fractures in the future.

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 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.

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 € 4.5 billion in 2017. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

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. 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, including in Puerto Rico, 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. 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 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.

*The trade name EVENITY™ is provisionally approved for use by the FDA and EMA.

CONTACT: Amgen, Thousand Oaks
Kelley Davenport, 202-585-9637 (media)
Kristen Davis, 805-447-3008 (media)
Arvind Sood, 805-447-1060 (investors)

CONTACT: UCB, Brussels
France Nivelles, Global Communications, UCB
T +32.2.559.9178, france.nivelles@ucb.com
Laurent Schots, Media Relations, UCB
T+32.2.559.92.64, laurent.schots@ucb.com
Antje Witte, Investor Relations, UCB
T +32.2.559.94.14, antje.witte@ucb.com
Isabelle Ghellynck, Investor Relations, UCB
T+32.2.559.9588, isabelle.ghellynck@ucb.com

References

1. Lindsay R, Silverman SL, Cooper C, et al. Risk of new vertebral fracture in the year following fracture. *JAMA*. 2001;285(3):320-323.
2. FDA Briefing Document. Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee. January 16, 2019. BLA 761062 Romosozumab Amgen, Inc. Available at: <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM629456.pdf>. Accessed January 14, 2019.
3. Efficacy and Safety of Romosozumab Treatment in Postmenopausal Women With Osteoporosis (FRAME). Available at: <https://clinicaltrials.gov/ct2/show/NCT01575834?term=NCT01575834&rank=1>. Accessed January 14, 2019.
4. Study to Determine the Efficacy and Safety of Romosozumab in the Treatment of Postmenopausal Women With Osteoporosis (ARCH). Available at: <https://clinicaltrials.gov/ct2/show/NCT01631214?term=NCT01631214&rank=1>. Accessed January 14, 2019.
5. An Open-label Study to Evaluate the Effect of Treatment With Romosozumab or Teriparatide in Postmenopausal Women (STRUCTURE). Available at: <https://clinicaltrials.gov/ct2/show/NCT01796301?term=STRUCTURE+ROMOSOZUMAB&rank=1>. Accessed January 14, 2019.
6. National Osteoporosis Foundation. Osteoporosis Fast Facts. <https://cdn.nof.org/wp-content/uploads/2015/12/Osteoporosis-Fast-Facts.pdf>. Accessed January 14, 2019.
7. International Osteoporosis Foundation. Facts and Statistics. <https://www.iofbonehealth.org/facts-statistics>. Accessed January 14, 2019.
8. Amgen Astellas BioPharma (2018) Evenity subcutaneous injection 105mg syringe: 2 syringes. [package insert] Tokyo, Japan.
9. International Osteoporosis Foundation. Patient Brochure. http://share.iofbonehealth.org/WOD/2012/patient_brochure/WOD12-patient_brochure.pdf. Accessed January 14, 2019.



 View original content to download multimedia:<http://www.prnewswire.com/news-releases/amgen-and-ucb-receive-positive-vote-from-fda-advisory-committee-in-favor-of-approval-for-evenity-romosozumab-300779812.html>

SOURCE Amgen