EVENITY™ (romosozumab) Receives Approval In Japan For The Treatment Of Osteoporosis In Patients At High Risk Of Fracture

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EVENITY Approved to Reduce the Risk of Fractures and Increase Bone Mineral Density in Men and Postmenopausal Women With Osteoporosis at High Risk of Fracture

EVENITY in Japan is Being Co-Developed Through a Strategic Alliance With Amgen Astellas BioPharma

THOUSAND OAKS, Calif. and BRUSSELS, Belgium, Jan. 8, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and UCB (Euronext Brussels: UCB) today announced that the Japanese Ministry of Health, Labor and Welfare has granted a marketing authorization for EVENITY™ (romosozumab) for the treatment of osteoporosis in patients at high risk of fracture.[1] Amgen and UCB are co-developing EVENITY worldwide, with development in Japan being led by Amgen Astellas BioPharma K.K., a joint venture between Amgen and Astellas Pharma Inc., headquartered in Tokyo.

"The approval of EVENITY in Japan is a significant milestone that reinforces our commitment to bringing effective treatments to the millions of patients who suffer from osteoporosis," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "A patient with a prior osteoporotic fracture is twice as likely to suffer another fracture if left undiagnosed and without appropriate treatment.[2] With this approval, physicians in Japan now have a new medicine to help patients reduce their risk of fracture."

EVENITY is a bone forming agent that both increases bone formation and reduces bone resorption to increase bone mineral density (BMD) and reduce the risk of fracture. The approval is based on results from two pivotal Phase 3 studies: FRAME,[3] which included 7,180 postmenopausal women with osteoporosis, and BRIDGE,[4] which included 245 men with osteoporosis. The Japanese Pharmaceuticals and Medical Devices Agency undertook a thorough review of the safety profile of EVENITY, including the cardiovascular safety findings in the ARCH trial.

"In Japan, osteoporotic fracture is one of the leading causes for patients losing independence and needing nursing care. As the aged population of Japan increases, preventing such fractures should be given high priority," said Steve Sugino, Amgen vice president and president and representative director of AABP. "Japanese patients will be the first in the world to have a new therapeutic option for osteoporosis that reduces the risk of fracture by not only increasing bone formation but also decreasing bone resorption."[1]

"Patients with a prior fracture face the risk of having another fracture and particularly stand to benefit from the option of a new bone-forming agent," said Toshio Matsumoto, M.D., Ph.D., emeritus professor of Tokushima University and the advisor of the university's Fujii Memorial Institute of Medical Sciences. "Physicians have been waiting for a new therapeutic option. I have great hope that the approval of EVENITY will help reduce the fracture risk for patients in Japan."

Japan has one of the longest life expectancy rates in the world, and it is believed that by 2050, over 37 percent of the population will be aged 60 or older. [5] Age is one of the most common risk factors associated with developing osteoporosis, as bone mass is lost over time.[6,7] Today, the prevalence of osteoporosis in the country is around 12 million, and the hip fracture incidence rate in the population over 75 is increasing dramatically in both men and women.[8]

"With one of the longest life expectancy rates in the world, Japan is a country of longevity, but this means that the rate of osteoporosis will increase, leaving many people at high risk for fracture due to the condition," said Dr. Pascale Richetta, head of bone and executive vice president, UCB. "We are proud that EVENITY is now approved as a new treatment to help address this important public health issue and help people with their osteoporosis."

This is the first approval for EVENITY in the world, and the third approval of a new medicine through AABP.

The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are currently reviewing marketing applications for EVENITY and interactions with the agencies are ongoing.

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. 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 (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) 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 (PlaceBo-ContRolled Study EvaluatIng The Efficacy AnD Safety Of Romosozumab In TreatinG MEn 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 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.[2] 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.[9] Without proper care or access to effective intervention options, they remain at risk of painful and disabling fractures in the future.

About EVENITY™ (romosozumab)
EVENITY is an bone-forming monoclonal antibody approved in Japan.. It is designed to work by inhibiting the activity of sclerostin, which enables EVENITY to both 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 10,000 postmenopausal women with osteoporosis. Amgen and UCB are co-developing EVENITY.

Important Japan Product Information

Product Name:
EVENITY® subcutaneous injection 105mg syringe

Generic Name:
Romosozumab (Genetical Recombination) Injection

Indication:
Osteoporosis at high risk of fracture

Dosage and Administration:
The usual adult dosage is 210 mg as romosozumab (genetical recombination) by subcutaneous injection once a month for 12 months.

For more information, see the Japan Package Inserts.

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.

About Amgen Astellas BioPharma K.K.
Amgen Astellas BioPharma K.K. (AABP) is a Japanese company that began operations on Oct. 1, 2013, to provide breakthrough-science-based medicines to help address unmet medical needs of patients in Japan. The company is a joint venture between Amgen, one of the world's leading independent biotechnology companies, and Astellas Pharma Inc., a leading Tokyo-based R&D oriented global pharmaceutical company.

AABP has grown into an organization with over 400 employees and comprehensive functions to be fully operational as a marketing authorization holder in Japan. AABP's sales organization, with 19 regional sales offices located throughout Japan, will co-promote its products with Astellas. The joint venture will become a wholly-owned Amgen affiliate as soon as 2020.

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

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

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.

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