News Release

EVENITY® SUBCUTANEOUS INJECTION 105mg SYRINGE RECEIVES THE-FIRST-IN-THE-WORLD APPROVAL IN JAPAN FOR THE TREATMENT OF OSTEOPOROSIS AT HIGH RISK OF FRACTURE

EVENITY® (romosozumab) Approved to Reduce the Risk of Fractures and Increase Bone Mineral Density in Postmenopausal Women and Men With Osteoporosis

TOKYO (January 9, 2019) - Amgen Astellas BioPharma K.K. (Headquarters, Tokyo; President and Representative Director: Steve Sugino, "Amgen Astellas"), Astellas Pharma Inc. (Headquarters, Tokyo; President and CEO: Kenji Yasukawa, Ph.D., "Astellas"), and UCB Japan (Headquarters, Tokyo; President: Kanako Kikuchi, "UCB Japan") announced that the Japanese Ministry of Health, Labor and Welfare has granted the world-first marketing authorization for humanized anti-sclerostin monoclonal antibody EVENITY® (generic name: romosozumab (Genetical Recombination) Injection) for the treatment of osteoporosis in patients at high risk of fracture which is jointly developed by Amgen Astellas and Astellas. [1]

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[2], which included 7,180 postmenopausal women with osteoporosis and BRIDGE[3], 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 Amgen Astellas. "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." [4]

"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]

"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.[9] With this approval, physicians in Japan now have a new medicine to help patients reduce their risk of fracture."

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

Amgen Astellas and Astellas will co-promote EVENITY. Based on an agreement between UCB and Amgen, UCB Japan is responsible for a disease state approach to raise awareness, understanding and treatment rates for patients with osteoporosis in Japan. UCB Japan's disease state efforts will not involve Evenity's product promotion.

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

This was publicly announced in the United States on January 8, 2019 PST.

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.

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.

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.

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, 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.[10] 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 worldwide.

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 Amgen Astellas BioPharma K.K.
Amgen Astellas BioPharma K.K. (http://www.aabp.co.jp/jp/) is a Japanese company that began operations on October 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. Amgen Astellas has grown into an organization with over 400 employees and comprehensive functions to be fully operational as a marketing authorization holder in Japan. The joint venture will become a wholly-owned Amgen affiliate as soon as 2020.

About Astellas
Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at https://www.astellas.com/en.

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 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 around 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).
Established in 1988, UCB Japan markets a number of products. The anti-epileptic drug E Keppra®, Vimpat® and the TNF-alpha inhibitor Cimzia® will be a platform for further growth. As a biopharma leader, UCB Japan is dedicated to making a continuing contribution to the treatment and health of patients with severe diseases such as neurology and immunology/inflammatory diseases.

Cautionary Notes (Astellas)
In this news release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this news release is not intended to constitute an advertisement or medical advice.

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