News Release

EVENITY® SUBCUTANEOUS INJECTION 105 mg SYRINGE LAUNCHED IN JAPAN FOR THE TREATMENT OF OSTEOPOROSIS WITH HIGH RISK OF FRACTURE

TOKYO (March 4, 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") today announced the world-first launch of the humanized anti-sclerostin monoclonal antibody EVENITY® (generic name: romosozumab (Genetical Recombination) Injection) in Japan for the treatment of osteoporosis in patients with a high risk of fracture.[1]

Satoshi Soen M.D., Ph.D, professor at the Department of Orthopedic Surgery and Rheumatology, Kindai University Nara Hospital said, "EVENITY® not only increases bone formation, but also reduces bone resorption. Further, it inhibits cortical bone porosity. It demonstrates a significant increasing effect for bone mineral density at an early stage after administration, and a reduction in the incidence of vertebral fracture, non-vertebral fracture, and hip fracture has been confirmed. It is supported by the evidence from multiple clinical trials that EVENITY® can be a first-line treatment for patients with osteoporosis at high risk of fracture such as those with a prior vertebral fracture or those with a significant decrease in bone mineral density".

Yukiya Suzuki, the Head of Sales of Amgen Astellas said, "Japan is becoming a super-aged society, and fractures caused by osteoporosis, which are expected to further increase, significantly affect not only healthy life expectancy but also life prognosis as they can result in care and assistance becoming necessary. Through its dual effect, EVENITY® significantly increases bone mineral density for a short period and also reduces the risk of fractures. We are very delighted to provide EVENITY® as a new therapeutic option to physicians and healthcare professionals in Japan."

Nobuaki Tanaka, Senior Vice President, Sales & Marketing Japan of Astellas said, "Through the world-first launch of EVENITY®, we would like to address the unmet medical needs of Japanese patients with osteoporosis at high risk of fracture."

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 will not be involved in product promotion for EVENITY®.

EVENITY® is jointly developed by Amgen Astellas and Astellas in Japan. 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.

Important Japan Product Information

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.

NHI drug price
EVENITY® SUBCUTANEOUS INJECTION 105 mg: JPY24,720 per syringe

NHI price listing date
February 26, 2019

Launch date
March 4, 2019

Product image

* For more information, please see the latest Japan Prescribing Information.
* The official guidance of point to consideration regarding EVENITY® under the coverage of National Health Insurance is issued by Medical Affairs Division of Ministry of Health, Labour and Welfare.

About Amgen Astellas BioPharma K.K.
Amgen Astellas BioPharma K.K. (http://www.aabp.co.jp/en/) 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 of the immune system or of the central nervous system. With around 7 500 people in approximately 40 countries, the company generated revenue of € 4.6 billion (approximately 600 billion yen) in 2018. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.
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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<u>References</u>
1. Pharmaceuticals and Medical Devices Agency Prescription Drug Database.