

## **News Release**

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# **POSITIVE TOP-LINE RESULTS FROM PHASE 3 STUDY EVALUATING ROMOSUZUMAB IN MEN WITH OSTEOPOROSIS**

## **BRIDGE Study Met Primary and All Secondary Endpoints**

### **Results Add to Growing Body of Positive Late-Stage Data Evaluating Efficacy and Safety of Romosozumab in Patients with Osteoporosis**

TOKYO (March 22, 2016) – Amgen Astellas BioPharma K.K. (Headquarters, Tokyo; General Manager and Representative Director: Eiichi Takahashi, “Amgen Astellas”) and Astellas Pharma Inc. (Headquarters, Tokyo; President and CEO: Yoshihiko Hatanaka, “Astellas”) today announced positive top-line results for romosozumab from the pivotal Phase 3 placebo-controlled study evaluating the efficacy and safety of romosozumab in treating men with osteoporosis (BRIDGE). These data showed the BRIDGE study met the primary endpoint, demonstrating a statistically significant increase in bone mineral density (BMD) at the lumbar spine (as assessed by dual energy x-ray absorptiometry) in men with osteoporosis treated with romosozumab compared with placebo at 12 months.

All secondary endpoints comparing romosozumab with placebo were also met. Patients receiving romosozumab experienced a statistically significant increase in BMD at the femoral neck and total hip at 12 months and a statistically significant increase in BMD at the lumbar spine, femoral neck, and total hip at six months, compared with those receiving placebo.

In the BRIDGE study, a total of 245 men were randomized 2:1 to receive either 210 mg romosozumab subcutaneous (SC) every month (QM) or matched placebo SC QM for the duration of the 12-month treatment period.

The overall patient incidence of adverse events and serious adverse events (SAEs) was generally balanced between arms. The most frequently reported adverse events (greater than five percent in the romosozumab arm) were nasopharyngitis, back pain, hypertension, headache and constipation. Injection site reactions were reported in 5.5 percent of patients in the romosozumab treatment group and 3.7 percent in the placebo group during the 12-month period. Most injection site reactions were reported as mild in

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severity. The patient incidence of positively adjudicated cardiovascular (CV) SAEs was 4.9 percent (8/163) in the romosozumab group and 2.5 percent (2/81) in the placebo group. The patient incidence of positively adjudicated cardiovascular death was 0.6 percent (1/163) in the romosozumab group and 1.2 percent (1/81) in the placebo group. Amgen Astellas BioPharma and Astellas recently reported the results of the FRAME study in 7,180 postmenopausal women with osteoporosis in which the overall patient incidences of adjudicated CV SAEs were balanced.

Further analysis of the Phase 3 BRIDGE study data is ongoing and will be submitted to a future medical conference and for publication.

### **About Romosozumab**

Romosozumab 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 protein sclerostin, and has a dual effect on bone, both increasing bone formation and decreasing bone breakdown. Romosozumab is being studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program. This program includes two large fracture trials comparing romosozumab to either placebo or active comparator in more than 10,000 postmenopausal women with osteoporosis. Amgen Astellas BioPharma and Astellas are co-developing romosozumab in Japan.

### **About the BRIDGE study**

BRIDGE is a multi-center, international, randomized, double-blind, placebo-controlled study in men with osteoporosis, defined as low bone mineral density (BMD) at the spine, total hip or femoral neck. The study evaluated the effectiveness of romosozumab treatment for 12 months, compared with placebo, in increasing BMD at the lumbar spine, as well as the effect on BMD at the femoral neck and total hip at 12 months and on BMD at the lumbar spine, femoral neck, and total hip at six months.

### **About Amgen Astellas BioPharma K.K.**

Amgen Astellas BioPharma K.K. 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. The joint venture will become a wholly-owned Amgen affiliate as soon as 2020. Amgen Astellas leverages the capabilities of both companies – Amgen's science and pipeline candidates coupled with Astellas' deep knowledge of Japanese patient and physician needs, long-term commercial and regulatory experience, and strong presence as a leading company in Japan – to contribute to the creation of a healthy society.

### **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. We focus on Urology, Oncology, Immunology, Nephrology

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and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at [www.astellas.com/en](http://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 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.

For more information, visit [www.amgen.com](http://www.amgen.com) and follow us on [www.twitter.com/amgen](https://www.twitter.com/amgen).

### **Forward-Looking Statements – Amgen**

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of March 20, 2016, and expressly disclaims any duty to update information contained in this news release.

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

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models. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. In addition, 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 expect similar variability in the future. 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 relationships. Also, Amgen or others could identify safety, side effects or manufacturing problems with Amgen's 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 Amgen and the U.S. government, Amgen could become subject to significant sanctions. Amgen performs a substantial amount of its 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 Amgen products and its product candidate development.

In addition, sales of Amgen products are affected by the 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. Government and others' regulations and reimbursement policies as well as political and public scrutiny may affect the development, usage and pricing of Amgen's products. 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. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. Amgen expects to face increasing competition from biosimilars. In addition, while Amgen routinely obtains patents for products and technology, the protection of its products offered by patents and patent applications may be challenged, invalidated or circumvented by competitors and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for its products or product candidates or to prevail in intellectual property litigation. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be volatile and may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, 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 Amgen's business and results of operations. Amgen's

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efforts to acquire other companies or products and to integrate the operations of companies it has acquired may not be successful. Amgen may not be able to access the capital and credit markets on terms that are favorable to Amgen, or at all. Amgen's business performance could affect or limit the ability of its Board of Directors to declare a dividend or its ability to pay a dividend or repurchase common stock.

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.

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