

# **Amgen And Astellas Announce Japan Alliance**

May 29, 2013

### Innovative Joint Venture to Address Unmet Medical Needs of Patients in Japan

THOUSAND OAKS, Calif. and TOKYO, May 29, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN), the world's largest independent biotechnology company, and Astellas Pharma Inc. (Tokyo Stock Exchange: 4503, "Astellas"), a leading Tokyo-based global pharmaceutical company, today announced the companies have entered into a strategic alliance to provide new medicines to help address serious unmet medical needs of Japanese patients.

The alliance leverages the complementary capabilities of both companies through an innovative business model that combines Amgen's pipeline candidates 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.

The first element of the alliance is a long-term collaboration between the two companies that will focus on the co-development and co-commercialization in Japan of five Amgen pipeline medicines. The five medicines, which include four biologics and one small molecule, are focused on the treatment of cardiovascular and bone diseases and cancer. The pipeline medicines range from early to late stages of development in Japan, with the first potential commercial launch expected as early as 2016.

The second element of the alliance is the establishment of a Tokyo-based joint venture company through which the companies will work together to enable Amgen to rapidly build on-the-ground capabilities in Japan. The joint venture will operate under the name Amgen Astellas BioPharma KK and will be led by Eiichi Takahashi, who will serve as general manager. Additional management roles will be appointed by Amgen and Astellas. The joint venture will be staffed by seconded employees from Astellas, transferred employees from Amgen and newly hired employees. It is expected that the joint venture will start operations on Oct. 1, 2013, and will become a wholly owned Amgen affiliate as soon as 2020 with the long-term collaboration continuing.

"Through this alliance, Amgen will work closely with Astellas to leverage its extensive knowledge of the local market," said Robert A. Bradway, chairman and chief executive officer at Amgen. "With Astellas' strong capabilities and excellent reputation, this alliance will help accelerate development and commercialization of Amgen medicines for patients in Japan. This alliance reflects our long-term commitment to the Japan market and is an important step in our global expansion efforts."

"We look forward to entering this alliance with Amgen and believe it will strengthen our pipeline to address unmet medical needs, as well as enable us to obtain growth drivers," said Yoshihiko Hatanaka, president and CEO of Astellas. "We will work closely with Amgen to build the joint venture, which will provide innovative medicines to patients in Japan."

Goldman, Sachs & Co. is acting as financial advisor to Amgen in connection with this transaction. Morrison & Foerster LLP served as external legal counsel to Astellas.

### Five Amgen Pipeline Medicines Included in the Amgen Astellas Alliance

Molecule	Lead Indication	Mode of Action	Development Stage	
			Global	Japan
AMG 145	Hyperlipidemia	Anti-PCSK-9 mAb	Phase 3	Phase 2
Romosozumab (AMG 785) <sup>1</sup>	Osteoporosis	Anti-Sclerostin mAb	Phase 3	Phase 2/3
Rilotumumab (AMG 102)	Gastric Cancer	Anti-HGF mAb	Phase 3	Phase 1
AMG 337	Gastric Cancer	MET inhibitor	Phase 1	
Blinatumomab (AMG 103)	Acute Lymphoblastic Leukemia (ALL) and Non-Hodgkin's Lymphoma (NHL)	Anti-CD19 BiTE <sup>®</sup>	Phase 2	

## **About Amgen**

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping people around the world in the fight against serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. For more information, visit <a href="https://www.amgen.com">www.twitter.com/amgen.</a>.

#### **About Astellas**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in urology, immunology (including transplantation) and infectious diseases, oncology, neuroscience and DM complications and kidney diseases. For more information on Astellas Pharma Inc., please visit the company website at <a href="https://www.astellas.com/en">www.astellas.com/en</a>.

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

This news release contains forward-looking statements that are based on Amgen's current expectations and beliefs 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, 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 (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Form 10-K and any subsequent Forms 10-Q and 8-K for additional information on the uncertainties and risk factors related to Amgen's business. Unless otherwise noted, Amgen is providing this information as of May 29, 2013, 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 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. 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 Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development.

In addition, sales of Amgen's 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 as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. In addition, Amgen competes with other companies with respect to some 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. In addition, 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 and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for its products or product candidates. 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 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.

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<sup>1</sup> Developed in collaboration with UCB

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