



## **News Release**

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January 23, 2020

### **AMGEN ASTELLAS BIOPHARMA TO BECOME A WHOLLY OWNED AMGEN AFFILIATE ON APRIL 1, 2020 THE NEW COMPANY NAME WILL BE AMGEN K.K. THE HEADQUARTERS WILL RELOCATE TO TOKYO MIDTOWN**

#### **Co-Promotion of Repatha<sup>®</sup>, EVENITY<sup>®</sup>, and BLINCYTO<sup>®</sup> to Continue with Astellas**

Amgen Inc. (Headquarters: Thousand Oaks, California, USA; Chairman and CEO: Robert A. Bradway; “Amgen”), Astellas Pharma Inc. (Headquarters: Tokyo; President and CEO: Kenji Yasukawa, PhD., “Astellas”), and Amgen Astellas BioPharma K.K. (Headquarters: Tokyo; President and Representative Director: Steve Sugino; “Amgen Astellas BioPharma”) announced that on April 1, 2020, Amgen will purchase the 49% of shares in Amgen Astellas BioPharma that are held by Astellas, based on the strategic alliance contract signed between Amgen and Astellas in 2013, making the company a wholly owned Amgen affiliate.

With this, Amgen Astellas BioPharma will change its name to Amgen K.K., and simultaneously relocate its Headquarters to Tokyo Midtown (9-7-1 Akasaka, Minato-ku, Tokyo). Steve Sugino will continue to serve as President and Representative Director of Amgen K.K.

Amgen Astellas BioPharma commenced business in October 2013, bringing together the strengths of Amgen, one of the world’s leading independent biotechnology companies, and Astellas, a company with deep knowledge of the medical needs in Japan and a wealth of experience in the development and marketing of pharmaceutical products, as well as a strong business foundation, to contribute to healthcare in Japan through the provision of innovative medicines created by Amgen.

Since then, Amgen Astellas BioPharma and Astellas have worked together to serve patients in Japan with cardiovascular disease, cancer, and bone disease, which are three areas of significant unmet medical needs, launching Repatha<sup>®</sup> for familial hypercholesterolemia (FH) or hypercholesterolemia for patients who have high cardiovascular event risk and do not adequately respond to HMG-CoA reductase inhibitors, BLINCYTO<sup>®</sup> for patients with relapsed or refractory B-cell acute lymphoblastic leukemia, and EVENITY<sup>®</sup> for osteoporosis patients at high risk of fracture. Amgen K.K. and Astellas will continue to co-promote these three products and Astellas will remain responsible for distribution and sales of the products beyond 2020.

Amgen K.K. will carry forward Amgen’s global mission to serve patients by delivering breakthrough-science-based medicines, while also striving to bring Amgen’s full global pipeline of innovative medicines to patients in Japan who face unmet medical needs.

## **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 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).

## **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 Astellas BioPharma**

Amgen Astellas BioPharma 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 BioPharma has grown into an organization with over 600 employees and comprehensive functions to be fully operational as a marketing authorization holder in Japan. Amgen Astellas BioPharma integrated the "Otezla<sup>®</sup>" business from Celgene Corporation in November 2019 by establishing a new Inflammation and Immunology Business Unit. On April 1, 2020, Amgen Astellas BioPharma will change its name to Amgen K.K. and become a wholly owned Amgen affiliate based on the strategic alliance contract signed between Amgen and Astellas in 2013.

## **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 any statements on the outcome, benefits and synergies of collaboration with any other company, including BeiGene, Ltd. or the Otezla<sup>®</sup> (apremilast) acquisition, including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion, as well as 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 our 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 we project. 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 us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop 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 we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our 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 our products and global economic conditions. In addition, sales of our 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, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. 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. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies or products and to integrate the operations of companies or in support of products we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The scientific information discussed in this news release related to our 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.

**Cautionary Notes (Astellas)**

In this press 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 press release is not intended to constitute an advertisement or medical advice.

**Cautionary Notes (Amgen Astellas BioPharma)**

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