News Release

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Application for Marketing Approval Submitted for Bispecific CD19-directed CD3 T Cell Engager (BiTE®) Antibody Construct Blinatumomab for Relapsed or Refractory B-cell Precursor Acute Lymphoblastic Leukemia in Japan

TOKYO (January 9, 2018) - Amgen Astellas BioPharma K.K. (Headquarters Tokyo; President and Representative Director Steve Sugino "Amgen Astellas BioPharma") and Astellas Pharma Inc. (Headquarters Tokyo; President and CEO Yoshihiko Hatanaka "Astellas") today announced that an application was submitted in Japan for the marketing authorization for bispecific CD19-directed CD3 T cell engager (BiTE®) antibody construct blinatumomab (Genetically Recombination) (generic name, development code: AMG 103, "blinatumomab") to treat relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). In Japan, blinatumomab is jointly developed by Amgen Astellas BioPharma and Astellas.

ALL affects approximately 5,000 patients in Japan[1], out of which an estimated 670 per year have relapsed or refractory ALL[2,3,4]. There are several limitations to current treatment options, including their limited efficacy in adult and pediatric patients with relapsed or refractory ALL and dependency on a limited number of drugs with similar mechanisms of action. Improved outcomes for relapsed or refractory ALL patients calls for the development of drugs such as blinatumomab which demonstrate efficacy as a monotherapy and have mechanisms of action dissimilar to cytotoxic agents.

The submission of application for marketing approval in Japan was based on the results from multiple global clinical studies including the Phase 3 randomized study (TOWER study), and the Japanese Phase 1b/2 study. In the TOWER study, blinatumomab was shown to extend overall survival compared to standard-of-care (SOC) chemotherapy in adult patients with relapsed or refractory ALL. Blinatumomab is considered to have the potential to address the serious unmet medical needs of ALL patients.

Blinatumomab received Orphan Drug designation from the Ministry of Health, Labour and Welfare effective September 29, 2017.

About Blinatumomab

Blinatumomab (genetically recombinant antibody) is a bispecific CD19-directed CD3 T cell engager (BiTE®) antibody construct that binds specifically to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T cells. Blinatumomab was granted breakthrough therapy and priority review designations by the U.S. Food and Drug Administration, and is now approved in the U.S. for the treatment of relapsed or refractory B-cell precursor ALL in adult and pediatric patients. In November 2015, the EU granted conditional marketing authorization for blinatumomab for the treatment of adults with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor ALL. Amgen

Inc. is seeking to gain approval for blinatumomab in countries around the world.

TOWER Study
The TOWER study was a Phase 3 randomized study investigating the efficacy of blinatumomab versus SOC chemotherapy in 405 adult patients with Ph- relapsed or refractory B-cell precursor ALL. The study enrolled a difficult-to-treat patient population, which included patients from several stages of relapse. In the blinatumomab arm, this included 35% of patients that had relapsed post–allogenic hematopoietic stem cell transplant (alloHSCT), and excluded those with late first relapse (≥ 12 months after initial remission). Patients were randomized in a 2:1 ratio to receive blinatumomab (n = 271) or one treatment with investigator's choice out of 4 types of SOC chemotherapy regimens (n = 134). The determination of efficacy was based on overall survival. Per the recommendation of the data monitoring committee, the study was ended early for evidence of superior OS in the blinatumomab arm vs SOC chemotherapy from the pre-specified interim analysis.
These results are published in the New England Journal of Medicine.[5]

About BiTE® Technology
Bispecific T cell engager (BiTE®) antibody constructs are being investigated for fighting cancer by helping the body's immune system to detect and target malignant cells. The modified antibodies are designed to engage two different targets simultaneously, thereby juxtaposing T cells (a type of white blood cell capable of killing other cells perceived as threats) to cancer cells. BiTE® antibody constructs help place the T cells within reach of the targeted cell, with the intent of allowing T cells to inject toxins and trigger the cancer cell to die (apoptosis). BiTE® antibody constructs are currently being investigated for their potential to treat a wide variety of cancers. For more information, visit www.biteantibodies.com.

About Amgen's Commitment to Oncology
Amgen Oncology is committed to helping patients take on some of the toughest cancers, such as those that have been resistant to drugs, those that progress rapidly through the body and those where limited treatment options exist. Amgen's supportive care treatments help patients combat certain side effects of strong chemotherapy, and our targeted medicines and immunotherapies focus on more than a dozen different malignancies, ranging from blood cancers to solid tumors. With decades of experience providing therapies for cancer patients, Amgen continues to grow its portfolio of innovative and biosimilar oncology medicines.

About Amgen Astellas BioPharma
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.

AABP 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 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 and follow us on 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. We focus on Urology, Oncology, Immunology, Nephrology 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 https://www.astellas.com/en.

Forward-Looking Statements (Amgen)
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 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. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. 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.

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.

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For information on this matter contact:
Corporate Affairs, Amgen Astellas BioPharma K.K. (TEL 03-5293-9694)
Corporate Communications, Astellas Pharma Inc. (TEL 03-3244-3201)

Reference

1. Ministry of Health, Labour and Welfare. 2014 patient survey.
2. National Cancer Center's Cancer Information Service, Acute Lymphocytic Leukemia/Lymphoblastic Lymphoma, Basic Knowledge. http://ganjoho.jp/public/cancer/ALL/index.html Accessed September 2017.
3. Takeuchi J, Kyo T, Naito K, et al. Induction therapy by frequent administration of doxorubicin with four other drugs, followed by intensive consolidation and maintenance therapy for adult acute lymphoblastic leukemia: the JALSG-ALL93 study. Leukemia. 2002;16:1259–1266.
4. Koh K, Ogawa C, Okamoto Y, et al. Phase 1 study of clofarabine in pediatric patients with relapsed/refractory acute lymphoblastic leukemia in Japan. Int J Hematol. 2016;104: 245-255.
5. Kantarjian H, Stein A, Gökbuget N, Fielding AK, Schuh AC, Ribera JM, Wei A, Dombret H, Foà R, Bassan R, Arslan Ö. Blinatumomab versus chemotherapy for advanced acute lymphoblastic leukemia. New England Journal of Medicine. 2017 Mar 2;376(9):836-47.