News Release

August 3, 2018

Application for Supplemental Indication Filed for Hypercholesterolemia Drug Repatha® SC Injection in Treating Statin-intolerant Patients

Amgen Astellas BioPharma K.K. (Headquarters, Tokyo; President and Representative Director: Steve Sugino, "Amgen Astellas") and Astellas Pharma Inc. (Headquarters, Tokyo; President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that Amgen Astellas filed an application for supplemental indication in Japan for Repatha® SC Injection 140 mg (evolocumab (Genetical Recombination), "Repatha®") in treating hypercholesterolemic patients with statin intolerance.

Patients with hypercholesterolemia are primarily treated with HMG-CoA reductase inhibitors (statins). However, certain patients in Japan have been shown to have statin intolerance, with an inability to continue with an effective dose of statins due to muscle-related side effects. If a patient is statin intolerant, their statin dosage is decreased or discontinued, and treatment with other non-statin drugs is considered.

"The population of hypercholesterolemic and statin-intolerant patients in Japan is currently unknown" says Koji Kajinami M.D., Ph.D., Professor of the Department of Cardiology, Kanazawa Medical University, "however, we face a clear challenge in treating such patients who cannot continue taking statins due to muscle-related side effects. Even with statins, LDL-cholesterol (LDL-C) levels can be difficult to control in many patients. When discontinuing statin therapy, we must use other drugs to achieve similar or better LDL-C levels. There is a need for new non-statin LDL-lowering alternatives."

The application for supplemental indication was filed on the basis of the outcomes of the Phase 3 randomized study Goal Achievement After Utilizing an Anti-PCSK9 Antibody in Statin Intolerant Subjects-4 (GAUSS-4) enrolling statin intolerant Japanese subjects. In GAUSS-4, results were statistically significant for the co-primary endpoints of percent change in LDL-C from baseline at the mean of weeks 10 and 12, and at week 12.

Jointly developed by Amgen Astellas and Astellas, Repatha® is a human IgG2 monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that reduces the liver's ability to remove LDL-C, or "bad" cholesterol, from the blood.[1, 2] Repatha was approved for the indication of familial hypercholesterolemia or hypercholesterolemia (only in patients with high risk of cardiovascular events and who do not adequately respond to HMG-CoA reductase inhibitors) in January 2016 and was launched in April of the same year in Japan. Additionally, in the drug price revision in April, the premium for true clinical utility (5% premium) was applied to Repatha® on the basis of the FOURIER study results.

Currently, Repatha® carries a precaution to administer as an adjunct to statin therapy. The present application for supplemental indication was filed to provide the alternative of Repatha® monotherapy in patients who are statin-intolerant.

Amgen Astellas and Astellas are hopeful that the application for supplemental indications will lead to the provision of new treatment alternatives for statin intolerant hypercholesterolemia patients and will contribute further to the treatment of hypercholesterolemia.

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. 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.

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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References (related documents)

1. Horton, J. D., Cohen, J. C., & Hobbs, H. H. (2007). Molecular biology of PCSK9: its role in LDL metabolism. Trends in biochemical sciences, 32(2), 71-77.
2. Brown, M. S., & Goldstein, J. L. (2006). Lowering LDL: Not only how low, but how long?. Science, 311(5768), 1721-1723.

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