News Release

HYPERCHOLESTEROLEMIA DRUG REPATHA® SC INJECTION RECEIVES SUPPLEMENTAL INDICATION APPROVAL AS MONOTHERAPY FOR TREATING HYPERCHOLESTEROLEMIA PATIENTS NOT SUITABLE FOR STATIN THERAPY

TOKYO (June 18, 2019) –, 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 has received approval in Japan for a supplemental indication for the hypercholesterolemia drug Repatha® SC Injection (evolocumab (Genetical Recombination), "Repatha®"). The supplemental indication is for treating hypercholesterolemia patients who are not suitable for HMG-CoA reductase inhibitor ("statin") therapy.

As defined in Precautions Related to Dosage and Administration section of the previous prescribing information, Repatha® was originally approved for use in combination with statins only. The approval for the supplemental indication will make it possible for Repatha® to be used alone in familial hypercholesterolemia or hypercholesterolemia patients for whom statin therapy is not suitable, due to a history of side effects or contraindication.

Shizuya Yamashita, M.D., Ph.D., Vice Chairman/Director of Rinku General Medical Center says, "The management of low-density lipoprotein (LDL) cholesterol (LDL-C) is key to the prevention of coronary artery disease such as angina pectoris and myocardial infarction. In regards to secondary prevention, patients with acute coronary syndrome, high-risk type 2 diabetes, or familial hypercholesterolemia, should target LDL-C <70 mg / dL according to Japan Atherosclerosis Society (JAS) Guidelines for Prevention of Atherosclerotic Cardiovascular Diseases 2017. There are a certain number of hypercholesterolemia patients for whom statin therapy is not suitable due to side effects such as muscle pain. This approval has great significance for such high-risk patients."

Jointly developed by Amgen Astellas and Astellas in Japan, Repatha® is a human IgG2 monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that reduces the ability of hepatic LDL receptors to remove LDL-C, or "bad" cholesterol, from the blood.[1,2] Repatha® was approved for the treatment of familial hypercholesterolemia or hypercholesterolemia, only in patients with a high risk of cardiovascular events and who do not adequately respond to statins, in Japan in January

[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.

2016 and was launched in April of that year. In July 2018, the results of the 27,564-patient (including 429 Japanese patients) Repatha® cardiovascular outcomes study (FOURIER) were added to the “clinical results” section of the Repatha® prescribing information due to the efficacy of Repatha® in the primary endpoint of cardiovascular event reduction in the treatment of hypercholesterolemia, supporting the indication for which Repatha® is approved.

Additionally, in drug price revisions in April 2018, the premium for verification of true clinical usefulness (5% premium) was applied to Repatha® on the basis of results of the FOURIER.

Amgen Astellas and Astellas are hopeful that this new approval for supplemental indications will lead to a new treatment alternatives for patients who are not suitable for statin therapy and will contribute further to meeting the needs of these patients in the treatment of hypercholesterolemia.

About Amgen Astellas BioPharma K.K.
Amgen Astellas BioPharma K.K. (http://www.aabp.co.jp/en/) 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 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 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
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.
For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

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 the world’s largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Cautionary Notes (Astellas)
In this news 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 news release is not intended to constitute an advertisement or medical advice.

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CONTACT

Amgen Astellas BioPharma K.K.
Corporate Affairs (TEL +81-3-5293-9861)
Astellas Pharma Inc.
Corporate Communications (TEL +81-3-3244-3201)