

## **News Release**

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# **AMGEN ASTELLAS BIOPHARMA AND ASTELLAS INTRODUCE REPATHA<sup>®</sup> (EVOLOCUMAB) FOR THE TREATMENT OF HIGH CHOLESTEROL**

## **FIRST PCSK9 INHIBITOR IN JAPAN, PROVIDING A NEW TREATMENT OPTION FOR CERTAIN PATIENTS WHO HAVE HIGH RISK IN CARDIOVASCULAR EVENTS AND DO NOT ADEQUATELY RESPOND TO STATINS**

TOKYO (April 21, 2016) – Amgen Astellas BioPharma K.K. (Headquarters, Tokyo; General Manager and Representative Director: Eiichi Takahashi, “Amgen Astellas”) and Astellas Pharma Inc. (Headquarters, Tokyo; President and CEO: Yoshihiko Hatanaka, “Astellas”) announced that proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor Repatha<sup>®</sup> SC Injection (generic name: Evolocumab (Genetically Recombination) Injection) 140 mg Syringe has become available in the Japanese market today.

Repatha<sup>®</sup> is indicated for the treatment of patients with familial hypercholesterolemia (FH) or hypercholesterolemia who have high risk of cardiovascular events and do not adequately respond to HMG-CoA reductase inhibitors (statins).

Repatha<sup>®</sup> is a human monoclonal antibody that inhibits PCSK9.<sup>1</sup> Repatha<sup>®</sup> binds to PCSK9 and inhibits circulating PCSK9 from binding to the low-density lipoprotein (LDL) receptor (LDLR), preventing PCSK9-mediated LDLR degradation and permitting LDLR to recycle back to the liver cell surface. By inhibiting the binding of PCSK9 to LDLR, Repatha<sup>®</sup> increases the number of LDLRs available to clear LDL from the blood, thereby lowering LDL-C levels.<sup>2</sup>

Yukiya Suzuki, the Head of Sales and Marketing of Amgen Astellas said, “Amgen Astellas is a Tokyo-based joint venture between Amgen, a biotechnology company with a history of more than 35 years of providing innovative medicines worldwide, and Astellas Pharma Inc., a company with a deep understanding and expertise in serving the medical needs of Japanese patients and physicians. Amgen Astellas began operations in 2013, and today we are pleased to begin providing Repatha<sup>®</sup>, the first product of Amgen Astellas and Japan’s first PCSK9 inhibitor. We are committed to serving the medical needs of the country and are excited about the potential of Repatha<sup>®</sup> to help improve the treatment of patients with high cholesterol who have high risk in cardiovascular events and do not adequately respond to statins.”

Yukihiko Sato, Senior Vice President, Sales & Marketing Japan of Astellas said, “We expect Repatha<sup>®</sup> as a new therapeutic option will contribute further to the patients with cardiovascular disease.”

Amgen Astellas and Astellas will co-promote Repatha<sup>®</sup>.

Product outline of “Repatha® SC Injection 140mg Syringe” is as follows.

Brand name:	Repatha® SC Injection 140mg Syringe
Generic name:	Evolocumab (Genetically Recombination)
Indication:	Familial Hypercholesterolemia, Hypercholesterolemia Only when patients who have high risk in cardiovascular events and do not adequately respond to HMG-CoA Reductase Inhibitors
Precautions Related to Indications:	(1) Prior to evolocumab therapy, patients should have a confirmed diagnosis of familial hypercholesterolemia or hypercholesterolemia by going through assessment. (2) When applying evolocumab to patients with non-familial hypercholesterolemia, it should be carefully considered for patients who have high risk of cardiovascular events based on risk factors e.g. comorbid conditions including coronary artery disease, non-cardiogenic stroke, peripheral arterial disease, diabetes and chronic renal disease or medical history.
Dosage regimen:	Heterozygous Familial Hypercholesterolemia and Hypercholesterolemia : In general, for adults, evolocumab (genetically recombination) of 140mg is administrated every 2 weeks or evolocumab of 420mg is administrated every 4 weeks subcutaneously Homozygous Familial Hypercholesterolemia : In general, for adults, evolocumab (genetically recombination) of 420mg is administrated every 4 weeks subcutaneously. Evolocumab of 420mg every 2 weeks can be administered when the efficacy is not adequate. If evolocumab is administered as adjunctive therapy for patients with LDL apheresis, as starting dose, evolocumab of 420mg every 2 weeks can be administered subcutaneously
Precautions Related to Dosage and Administration:	Evolocumab should be administered as an adjunct to HMG-CoA reductase inhibitor therapy [Efficacy and safety of evolocumab monotherapy in Japanese patients not confirmed.]
Price	Repatha® SC Injection 140mg Syringe : 22,948yen
Drug Price Listing Date	April 20, 2016
Launch Date	April 21, 2016

\* For more information, please see the latest Japan Prescribing Information.

\* The official guidance of point to consideration regarding Repatha® under the coverage of National Health Insurance is issued by Medical Affairs Division of Ministry of Health, Labour and Welfare.



#### About Amgen Astellas BioPharma K.K.

Amgen Astellas BioPharma K.K. 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. The joint venture will become a wholly-owned Amgen affiliate as soon as 2020. Amgen Astellas leverages the capabilities of both companies – Amgen's science and pipeline candidates coupled 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 – to contribute to the creation of a healthy society.

Amgen Astellas has grown into an organization equipped with comprehensive functions to be fully operational as a marketing authorization holder. The total number of employees today exceeds 300, including its sales organization in 19 regional sales offices located across Japan, under the leadership of three regional sales directors to adequately serve the medical needs of the country.

#### 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.

#### 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 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 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).

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#### References

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2. Data on File: Study 20120122 Phase III in Japanese study report.