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Amgen receives NMPA approval for Repatha in China

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Repatha is an innovative biologic medicine proven to effectively lower LDL-C

Biotech Company, Amgen has announced the National Medical Products Administration (NMPA) approval of a new indication for Repatha® (evolocumab) as the first PCSK9 inhibitor in China for adults with established atherosclerotic cardiovascular disease (ASCVD) to reduce the risk of myocardial infarction, stroke and coronary revascularization.

Low-density lipoprotein cholesterol (LDL-C) is one of the key modifiable risk factors for the development of cardiovascular disease. Decades of studies have demonstrated that reductions in cardiovascular risk are proportional to absolute reductions in LDL-C levels, making LDL-C the primary treatment target for the reduction of cardiovascular events. Yet, even among patients with cardiovascular disease currently taking a lipid-lowering therapy, many still do not meet recommended LDL-C goals and remain at risk for cardiovascular events.

Repatha is an innovative biologic medicine proven to effectively lower LDL-C. It inhibits circulating proprotein convertase subtilisin/kexin type 9 (PCSK9) from binding to LDL receptors (LDLR). By inhibiting the binding of PCSK9 to LDLR, Repatha increases the number of LDLRs available to clear LDL from the blood, thereby significantly lowering LDL-C levels, and further preventing the risk of myocardial infarction and stroke.

Murdo Gordon, executive vice president of Global Commercial Operations at Amgen said, "The new expanded label in China is an important milestone providing high-risk patients, who are unable to control their LDL-C with statin therapy alone, with a new treatment option to help prevent life-changing heart attacks and strokes. This is also an important step for Amgen as we continue to bring innovative medicines to China and build our presence."

The approval of the extended label recognizes the positive findings from the 27,564-patient Repatha cardiovascular outcomes study (FOURIER).

FOURIER is a multinational Phase 3 randomized, double-blind, placebo-controlled trial, is designed to evaluate whether treatment with Repatha in combination with high- or moderate-intensity statin therapy compared to placebo plus statin therapy reduces cardiovascular events.

Professor Changsheng Ma, Beijing Anzhen Hospital, Capital Medical University said, "Cardiovascular disease has become one of the greatest health challenges facing Chinese citizens today. High levels of LDL-C have been proven to increase the risk of developing ASCVD. If such levels of LDL-C fail to be managed, patients will become increasingly susceptible to strokes and heart attacks. However, existing therapies have limitations and many patients fail to effectively control their LDL-C levels to prevent recurrent cardiovascular events. The approval of this new indication offers hope for patients who continue

to struggle with achieving lower LDL-C levels, providing another treatment against cardiovascular events."

Repatha is approved in more than 60 countries, including the U.S., Japan, Canada and in all 28 countries that are members of the European Union. Applications in other countries are pending.