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Amgen seeks approval for anti-cholesterol drug in Japan

23 March 2015 | News | By BioSpectrum Bureau

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US-based Amgen has announced that an application seeking marketing approval of Repatha (evolocumab) for the treatment of high cholesterol has been submitted for review to the Ministry of Health, Labour and Welfare in Japan.

Repatha is being developed in Japan by Amgen Astellas BioPharma K.K., a joint venture between Amgen and Astellas Pharma Inc., a pharmaceutical company headquartered in Tokyo, Japan.

Repatha is an investigational fully human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that reduces the liver's ability to remove low-density lipoprotein cholesterol (LDL-C), or 'bad' cholesterol, from the blood.

In Japan, LDL-C levels are not adequately controlled for many patients taking statins, nearly half of whom have not reached their LDL-C goal.

The Japanese New Drug Application for marketing approval for Repatha contains data from approximately 7,200 patients with high cholesterol in 11 Phase 3 trials, including Japanese patients from studies conducted in Japan.

Overall, the Phase 3 studies evaluated the safety and efficacy of Repatha in patients with elevated cholesterol on statins with or without other lipid-lowering therapies; patients who cannot tolerate statins; patients with heterozygous familial hypercholesterolemia (HeFH); and patients with homozygous familial hypercholesterolemia (HoFH), a rare and serious genetic disorder.