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FDA approves Amgen's Repatha (evolocumab)

07 December 2017 | News

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Amgen has announced that following priority review of its supplemental Biologics License Application, the U.S. Food and Drug Administration (FDA) approved Repatha (evolocumab) as the first PCSK9 inhibitor to prevent heart attacks, strokes and coronary revascularizations in adults with established cardiovascular disease.

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The FDA also approved Repatha to be used as an adjunct to diet, alone or in combination with other lipid-lowering therapies, such as statins, for the treatment of adults with primary hyperlipidemia to reduce low density lipoprotein cholesterol (LDL-C).

Sean E. Harper, M.D., executive vice president of Research and Development at Amgen said, “We are pleased that the FDA made the inclusion of our outcomes data a priority so that patients can benefit from Repatha's ability to reduce life-changing events of heart attacks and strokes. Despite treatment with current best therapy, many patients are still at high risk for cardiovascular events. Physicians now have a new FDA-approved treatment option to prevent cardiovascular events by dramatically lowering LDL cholesterol with Repatha, especially for patients already on maximally-tolerated statin therapy who need further LDL cholesterol lowering."

Anthony C. Hooper, executive vice president of Global Commercial Operations at Amgen said, “In the U.S., every 40 seconds someone has a heart attack or stroke, and nearly one in three of these patients will have another event, leading to a societal cost that exceeds $600 billion annually. With this approval, it's now more important than ever that appropriate patients obtain access to Repatha in order to avoid preventable heart attacks and strokes. We will continue to work with payers to help ensure the patients who need Repatha the most are able to get this innovative medicine.”