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# Regeneron, Sanofi's Praluent set to reduce heart problems

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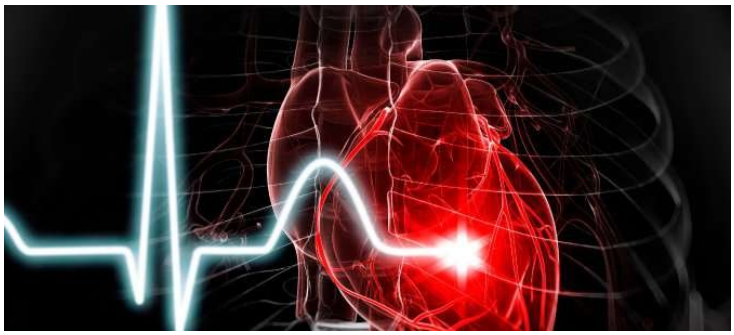
**Praluent is the first PCSK9 inhibitor that has shown a meaningful reduction in death from any cause**



Regeneron Pharmaceuticals, Inc. and Sanofi have announced that the U.S. Food and Drug Administration (FDA) has approved Praluent® (alirocumab) to reduce the risk of heart attack, stroke and unstable angina requiring hospitalization in adults with established cardiovascular (CV) disease.

"Heart disease accounts for one quarter of all American deaths each year and many others are at risk for heart attack and stroke due to uncontrolled LDL-C levels," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer, Regeneron. "The Phase 3 ODYSSEY OUTCOMES trial showed that people who received Praluent significantly reduced their risk for serious cardiovascular events. There was also a clinically-meaningful reduction in death from any cause with Praluent treatment. With this approval, and the recent introduction of a lower U.S. Praluent list price, we hope that more patients in need will be able to access Praluent."

High levels of "bad" cholesterol, also known as low-density lipoprotein cholesterol (LDL-C), increase patients' risk for serious CV events such as heart attack or stroke. Adults who experience a heart attack or stroke have an approximately one in three chance to have another CV event.

The FDA approval is based on data from ODYSSEY OUTCOMES. The FDA also approved Praluent as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce LDL-C.

Praluent was the first PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor approved by the FDA and is the only PCSK9 inhibitor available in two doses with two levels of efficacy as a single 1 mL injection (75 mg and 150 mg) once every two weeks. It can also be administered as 300 mg once every four weeks (monthly), enabling physicians to tailor treatment based on an individual patient's LDL-C-lowering needs.