

US regulators give limited approval to cholesterol drug

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US regulators on Friday approved a new cholesterol drug called Praluent, made by Sanofi and Regeneron, for people with certain genetic risk factors for heart disease.

The injectable drug is the first of its kind to gain approval on the US market, and offers an alternative to popular pill-based statins.

However, the US Food and Drug Administration approved it only for adults with an inherited condition that predisposes them to high cholesterol and raises the risk of heart attack and stroke.

"Praluent is approved for use in addition to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or patients with clinical atherosclerotic cardiovascular disease such as heart attacks or strokes, who require additional lowering of LDL cholesterol," the FDA said in a statement.

HeFH is an inherited condition that causes high levels of the bad kind of cholesterol, known as low-density lipoprotein (LDL) <u>cholesterol</u>.

Known also as alirocumab, the treatment is part of a new class of drugs known as proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors.

These drugs block the PCSK9 gene in the liver, which results in plummeting levels of LDL.



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