Merck gets US FDA nod for first-in-its-class oral cholesterol drug

The pill, branded as Lipfendra, is intended to treat patients with hypercholesterolemia, including those with hereditary forms of the disease, which causes elevated levels of LDL, the so-called "bad" cholesterol in the blood that often leads to plaque buildup in the arteries.

Bengaluru: The U.S. FDA approved Merck's cholesterol-lowering pill, it said on Thursday, the first in a class of drugs dominated by injections, which could potentially broaden the use of cholesterol medication among people at risk of heart disease.

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About one in four adults in the U.S. have high LDL cholesterol, according to the American Heart Association. With the U.S. Food and Drug Administration's approval, Lipfendra, also called enlicitide, would become the first oral treatment from the class of drugs that works by blocking a protein called PCSK9, high levels of which contribute to elevated cholesterol and cardiovascular disease.

Merck shares rose 4% in morning trading. Lipfendra will be sold at a list price of $10.50 a day -- around $315 per month. The company said the drug will be available in a matter of weeks.

Merck Executive Vice President Brian Foard said the company plans to target patients who are already on cholesterol-lowering treatments like statins to take the drug as an add-on treatment. "Seventy percent of those patients treated with those therapies are still not achieving guideline recommended goals. We believe this is the opportunity," Foard said. RBC Capital Markets analyst Trung Huynh said the drug carrieszero contraindications or hypersensitivity warnings for allergic reactions, unlike currently approved injectable competitors.

"Despite a decade of approved injectable options, an estimated 70% (and more) of eligible high-risk atherosclerotic cardiovascular disease patients remain undertreated; driven by injection aversion, prior authorization burden, and limited specialist access in primary care," Huynh said.

Huynh projects Lipfendra to reach peak sales of about $5 billion by 2034.

The FDA's decision was based on two late-stage trials that showed the once-daily pill lowered LDL cholesterol by nearly 60% in patients with hypercholesterolemia.

An ongoing clinical trial is studying the effect of Lipfendra on cardiovascular morbidity and mortality, said Merck.

Other cholesterol-lowering drugs include PCSK9-inhibitor injectables such as Amgen's Repatha, and Regeneron and Sanofi's Praluent.

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