Merck continuing study of cholesterol drug in new class

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Merck & Co. said Friday that it will continue a huge patient study of an experimental cholesterol medicine, the last one standing in a once-promising class of drugs being developed to prevent heart attacks, after an independent monitoring committee recommended the study continue.

Merck, a pioneer in cholesterol treatment that sells the popular pills Zetia and Vytorin, has been testing a drug that uses a different mechanism to reduce artery-clogging cholesterol and ultimately prevent strokes, heart attacks, procedures to clear or replace blocked arteries, and deaths from heart disease. Tens of millions of people with too-high levels of bad cholesterol, called LDL, or too-low levels of good cholesterol, or HDL, take medicines to control their cholesterol regularly for years, even decades, making the category very lucrative.

The committee's recommendation follows its review of data collected so far in the study of anacetrapib, which is funded by Kenilworth, New Jersey-based Merck.

The 30,000-patient study, known by the acronym REVEAL, compares improvement in bad cholesterol levels in participants at high risk for heart disease who are given anacetrapib plus statins to levels in participants taking statins alone. The study, overseen by the UK's Oxford University, began in May 2011 and is expected to conclude in 2017.

Three other experimental drugs in the class, called CETP inhibitors, were tested by Merck rivals but scrapped, leading some analysts to predict Merck's drug would fail as well.

The other drugs were Pfizer Inc.'s torcetrapib, which flamed out in 2006 due to serious side effects; Roche Group's dalcetrapib, which failed in 2012 because of inadequate effectiveness, and Eli Lilly and Co.'s evacetrapib. Last month, Lilly stopped its late-stage study, usually the last before seeking regulatory approval, midway through the expensive trial because an interim analysis showed evacetrapib wasn't effective enough.

Zetia and Vytorin, plus older drugs in the class called statins such as Merck's Zocor and Pfizer Inc.'s Lipitor—both long available as cheap generics—help millions of people with cholesterol problems. But they don't lower bad cholesterol enough in many patients and statins carry side effects some can't tolerate, including muscle pain and weakness, plus risk of raised blood sugar levels and development of Type 2 diabetes.

Two more-powerful, injected drugs in a new class of cholesterol drugs, called PCSK9 inhibitors, were approved this summer: Amgen Inc.'s Repatha and Praluent, sold by Sanofi SA and Regeneron Pharmaceuticals Inc. Those genetically engineered drugs, the first big advance in managing cholesterol since statins arrived more than two decades ago, have list prices of more than $14,000 per year, though. Insurers are generally limiting access to patients not helped enough by the cheap older drugs or who are genetically predisposed to sky-high cholesterol.

More than 73 million U.S. adults, or nearly one-third, have high LDL cholesterol, doubling their risk of heart disease, the leading cause of death worldwide, according to the Centers for Disease Control and Prevention.

In afternoon trading, Merck shares were up 31 cents at $53.34.