FDA panel backs Amgen cholesterol drug for some patients (Update)

10 June 2015, byMatthew Perrone

This Nov. 9, 2014 file photo shows signage at the entrance to Amgen Inc. offices in Thousand Oaks, Calif. Federal health advisers on Wednesday, June 10, 2015 said that a highly-anticipated cholesterol-lowering drug from Amgen should be approved for patients with dangerously high levels of the artery-clogging substance. (AP Photo/Mark J. Terrill, File)

Federal health advisers said Wednesday that a highly-anticipated cholesterol-lowering drug from Amgen Inc. should be approved for patients with dangerously high levels of the artery-clogging substance.

But as with their review of a similar drug a day earlier, the Food and Drug Administration experts stressed that long-term results are needed to judge the drug's real benefit.

The FDA advisory panel voted that Amgen's injectable drug Repatha appears safe and effective for some patients at high-risk from cholesterol, particularly those with inherited conditions that cause cholesterol buildup. The FDA is not required to follow the group's advice, though it often does.

The endorsement came despite pending study results on whether Repatha ultimately lowers rates of heart attack and death. Results from an Amgen study on that question aren't expected until 2017.

Repatha is part of a new class of biotech drugs that lower cholesterol more than older statin medications, which have been the standard treatment for more than 20 years.

Amgen is racing rivals Sanofi and Regeneron Pharmaceuticals, who received a positive vote on Tuesday for their own drug, Praluent.

An approval decision on Amgen's drug is due by Aug. 27, about a month after Sanofi and Regeneron's July 24 target date.

Both drugs lower low-density lipoprotein, or LDL, cholesterol more powerfully and in a different way than statins. They block a substance called PCSK9, which interferes with the liver's ability to remove cholesterol from the blood. Adding the new drugs to older statins has been shown to reduce LDL, or "bad," cholesterol, by 40 percent to 60 percent. Statins alone generally lower levels of the wax-like substance by about 30 to 50 percent.

GlobalData, a medical analytics company group, expects the PCSK9 class to generate sales of nearly $18 billion by 2023, based on sales projections for major pharmaceutical markets.

But the prospect of approving a pricey new class of drugs for one of the most common medical conditions in America is already drawing concerns from health insurers, employers and other payers who would absorb the costs. None of the companies developing the products have discussed their plans for pricing. But some industry analysts estimate new PCSK9 drugs could cost $10,000 or more per year, compared with just a few hundred dollars per year for currently-used statin drugs.

More than 73 million U.S. adults, or nearly one-third, have high LDL cholesterol, according to the

Centers for Disease Control and Prevention. Those patients have twice the risk of heart disease, the leading cause of death in the U.S. Panelists made clear this week that the new drugs should only be used for patients who cannot manage their condition with statins.

How doctors prescribe the drugs will be heavily influenced by the prescribing label written by the FDA. The agency will consider its advisers' recommendations as it crafts that language.

Amgen said in a statement the panel results show "there is a critical need for additional treatment options for patients who are unable to control their high cholesterol despite currently available therapies." Repatha is designed to be self-injected by the patient every two or four weeks, depending on the dose.

Shares of Thousand Oaks, California-based Amgen rose 1 percent to $157.20 in afterhours trading Wednesday. Shares of Regeneron Pharmaceuticals Inc., which is based in Tarrytown, New York, fell $13.77, or 2.6 percent, to close at $512.32 in regular trading. Paris-based Sanofi rose $1.17, or 2.4 percent, to $40.60 in regular trading.