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Europe approves Amgen's first-in-class cholesterol drug

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Amgen on Tuesday received European approval for its first-of-a-kind cholesterol drug that lowers levels of the artery-clogging substance more than older drugs that have been prescribed for decades.

The highly-anticipated decision introduces a new option for patients at risk for heart disease. But questions remain about the drug's price—estimated by one analyst at about $3,750 per year outside the U.S.—and its ability to reduce heart attack and death in the long term.

The European Commission cleared Repatha for patients with dangerously high cholesterol levels, including those with inherited conditions that drive up levels of the wax-like substance. The injectable drug may also be used by patients who cannot control their cholesterol with older statin drugs, or cannot tolerate them due to side effects, the group said.

Repatha is the first in a new class of medications that lower bad cholesterol more than statins, which have been the standard treatment for over 20 years.

The U.S. Food and Drug Administration is scheduled to make a decision on a similar drug from Sanofi and Regeneron Pharmaceuticals this Friday. The FDA's target date for reviewing Amgen's drug is Aug. 27.

Both drugs lower low-density lipoprotein, or LDL, cholesterol more powerfully and in a different ways than currently available drugs. 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 reduces LDL cholesterol by about 40 percent to 60 percent. Statins alone generally lower levels of bad cholesterol by about 25 to 35 percent.

But the prospect of introducing pricey, injectable drugs for one of the most common medical conditions in the world is drawing concerns from health insurers, providers and payers. Some analysts estimate the drugs could cost $10,000 or more per year in the U.S.

A spokeswoman for Thousand Oaks, California-based Amgen Inc. declined to offer specifics on pricing Tuesday.

"Our prices are managed with consideration to competition, the local pricing and reimbursement environment and patient-cost sharing obligation, which vary considerably by country," said Kristen Davis, in a statement.

Deutsche Bank analyst Robyn Karnauskas said it will take time to establish Repatha's pricing in Europe, but she estimates the drug's price outside the U.S. will average about $3,750 per year. She expects European sales of $26 million this year, according to a research note.

Repatha and other PCSK9 drugs are expected to grow into blockbuster products, though prescribing may be limited at first by strict reimbursement.

Doctors are awaiting studies of whether Repatha and similar drugs actually result in fewer heart attacks and deaths in patients with high cholesterol. Preliminary analyses published earlier this year suggest patients taking the new drugs had half the risk of dying or suffering a heart problem compared to those receiving older drugs. But definitive

results aren't expected until 2017 or later.

Global Data expects the entire class of PCSK9 drugs—including drugs from Sanofi and Pfizer—to generate sales of $17.8 billion by 2023.

Evercore ISI analyst Mark Schoenbaum noted the European Commission granted Repatha "a broad label," encompassing many patients with various forms of high cholesterol. However, he said in a research note that "today's decision has very little read across to the U.S."

Amgen shares slipped 38 cents to $163.96 in afternoon trading Tuesday. Its shares are up more than 37 percent over the past year.