Sanofi, Regeneron gaining edge in cholesterol race

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NEW YORK. Regeneron Pharmaceuticals and Sanofi (SAN) may get a head start on their biggest competitor by bringing a new class of cholesterol drugs to the US market.

The US food and drug administration has until July 24 to make a decision on the companies’ application to market their jointly developed drug alirocumab. Regeneron and Sanofi said in a statement.

Alirocumab (AMG 145) is developing a competing drug, evolocumab, that’s scheduled to get an FDA ruling by August 27. The drugs belong to a class called PCSK9 inhibitors that can drastically cut levels of bad, or LDL, cholesterol associated with cardiovascular disease. Alirocumab has reduced LDL cholesterol by 40 to 60 per cent in various studies.

Analysts, surveyed by Bloomberg, project the cholesterol drug will generate sales of more than $5 billion a year.

In its bid to leapfrog Amgen, Sanofi (SNY) and Regeneron deployed a special-waiver drug that gives them an expedited, six-month review time for the drug.

The companies bought the voucher in July for $67.6 million from BioMarin Pharmaceutical and said they planned to use it for their cholesterol-lowering drug. Being first to market means drugmakers can get prescription written for patients who may be reluctant to switch later to a new drug.

Although an earlier approval deadline is advantageous, it’s no guarantee of

New project

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writing approval more quickly, if at all. If they win the approval race, Regeneron, based in Tarrytown, New York, and Sanofi, based in France, will have the opportunity to set the first price for the new drug class, which will be closely watched by health-insurance plans looking to constrain costs on a wave of expensive new medications.

Typical FDA reviews take about 16 months. The priority vouchers are part of a 2007 law designed to reward drugmakers that develop treatments for neglected diseases, so they can sell the patents as a reward.

Initially the drugs may be used mostly by a limited population with particularly severe high cholesterol, such as patients who have a genetic disorder called familial hypercholesterolemia.