

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 in 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.

Amgen (AMGN) 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 that each drug will generate sales of more than \$2 billion a year.

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

The companies bought the voucher in July for \$67.5 million from BioMarin Pharmaceutical and said they planned to use it for their cholesterol-lowering drug. Being first to market means drugmakers can get prescriptions 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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gaining approval more quickly, if at all. If they win the approval race, Regeneron, based in Tarrytown, New York, and Sanofi, based in Paris, 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 control costs on a wave of expensive new medicines.

Typical FDA reviews take about 10 months. The priority review vouchers are part of a 2007 law designed to reward drugmakers that develop treatments for neglected diseases, so they can sell the passes 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.

New drug