

FDA panel to weigh revoking key use of Abbott drug

17 May 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- A panel of advisers to the Food and Drug Administration will consider this week whether to revoke a key indication from Abbott's blockbuster cholesterol drug Trilipix.

Trilipix is a fibrate, a drug that lowers [blood fats](#) called triglycerides while boosting "good" cholesterol. The drug is approved for combination use with statins like Lipitor and Zocor, which lower "bad" cholesterol and are the most widely-used class of [cholesterol drugs](#).

But a 5,000-patient government study released in March showed that diabetic patients taking Trilipix plus a statin had just as many heart attacks as patients taking a statin alone. The study was designed to show that the combination reduced [heart attack](#), stroke and other deadly events in patients with Type 2 diabetes.

On Thursday, the FDA will ask an outside panel to consider several options for Trilipix, according to documents posted online Tuesday. Those options include revoking the drug's approval for use with statins, updating its label with information about the study, or simply leaving it on the market as is. The panel's recommendation is not binding.

The group will also discuss data from the study that showed a higher rate of heart attacks among women who took Trilipix in combination with a statin.

In its scientific review posted online, the FDA said drugs like Trilipix have shown "potential" to reduce heart attacks for over 40 years.

"However, data from large clinical outcomes trials have produced mixed results," the agency concludes.

Drugmaker Abbott Laboratories said it supports adding information to the label from the government study. But company executives say

two-thirds of the patients enrolled in the study would not be eligible for Trilipix based on physician prescribing guidelines.

"The patients who benefit from this drug are very easy to identify: they have high triglycerides and low HDL ([high-density lipoprotein](#)) cholesterol and that is reflected in the current labeling," said Dr. James Stolzenbach, an Abbott vice president who oversees cholesterol medications.

North Chicago-based Abbott Laboratories reported combined sales of \$1.6 billion last year for Trilipix and TriCor, an older drug that contains the same active ingredient. The drugs' primary use is as a combination with statins, though they are also approved as stand-alone drugs for certain patients with [bad cholesterol](#).

Wells Fargo analyst Larry Biegelsen said the most likely outcome of Thursday's meeting will be the addition of new study data to the Trilipix label. That step would have "modest" impact on the company's overall sales since Tricor is scheduled to lose patent protection next year, limiting future sales of the company's cholesterol franchise.

Company shares fell 74 cents to \$53.26 in midday trading.

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