

Merck: FDA won't OK its combo cholesterol drug now

March 5 2012, By LINDA A. JOHNSON , AP Business Writer

(AP) -- Federal regulators have rejected Merck & Co.'s new combination cholesterol drug, which includes a generic version of the mega-blockbuster Lipitor - at least for now.

It's unclear how long the ruling, announced Monday, might delay approval of the drug, as the Food and Drug Administration is requiring additional study data on the compound. It combines generic Lipitor, the top-selling drug of all time, with Merck's cholesterol medicine Zetia.

Approval could boost Merck's sagging cholesterol franchise by essentially replacing its existing combo pill, Vytorin, with one likely to be seen as more powerful. Vytorin sales have been dwindling for a few years due to concerns about how well it works, and now Merck has to contend with patients possibly defecting to the generic versions of Pfizer Inc.'s Lipitor that came on the market at the end of November.

Merck said Monday that company officials will talk with the FDA to determine the next steps, adding that some new data expected later this year may address the FDA's concerns.

Wall Street seemed unfazed by the news, perhaps because the FDA increasingly asks for additional data before approving many new drugs. In morning trading, Merck shares were up 38 cents at \$38.31.

The experimental drug, still known only as MK-0653C, contains medicines that fight high cholesterol in two different ways to reduce risk

of heart attack and stroke.

Lipitor, known chemically as atorvastatin, is part of the widely used class of drugs called statins that reduce the amount of cholesterol naturally produced in the liver.

Zetia, on the other hand, reduces the amount of cholesterol absorbed from the food the patient eats.

Vytorin includes Zetia and an older statin, Merck's Zocor, also called simvastatin.

Sales of Vytorin and Zetia both were hurt when Merck, under pressure from a congressional probe, in early 2008 finally released unfavorable results from a study it had hoped would bolster Vytorin sales. Instead, it showed that Vytorin was no better at reducing plaque buildup in neck arteries than just Zocor, which had been available as a cheap generic since 2006. Zetia, also known as ezetimibe, is protected by patent in the U.S. until 2017.

Lipitor, which had peak sales of around \$13 billion, is a more powerful statin than Zocor. That could mean that if the new combination [drug](#) is approved, it would be tried by at least some patients who have not been able to get their [cholesterol](#) numbers to their goal with Vytorin or other treatments.

Meanwhile, last year Lipitor maker Pfizer sued, alleging Merck's application for the FDA to approve the Zetia-atorvastatin combination infringed on a Pfizer patent covering atorvastatin.

A Merck spokeswoman said Monday that the lawsuit "has the potential for holding up FDA approval of the [Merck](#) product until" the first quarter of 2014.

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