

FDA confirms benefits of Crestor in more patients

December 11 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- Federal scientists say AstraZeneca's cholesterol pill Crestor lowers the risk of heart attack, death and stroke in patients without a history of heart disease, though some safety concerns remain.

In documents posted online Friday, the [Food and Drug Administration](#) cites the findings of AstraZeneca's study released last November. The study showed that [patients](#) with lower [cholesterol](#) and few heart risks could still benefit from taking Crestor, setting the stage for a dramatic expansion in use of the drug that already exceeds \$1 billion in annual sales.

The British drugmaker wants the FDA to broaden Crestor's labeling based on those results.

But the FDA's review also cites several safety concerns, including a higher rate of diabetes in patients taking Crestor.

About 2.8 percent of patients taking Crestor in the 17,000-patient Jupiter study developed diabetes, compared with 2.3 percent of patients taking a dummy pill. The difference was statistically significant, according to the FDA.

But one FDA reviewer suggests that diabetes is a side effect of all drugs in that class, which include Crestor, Pfizer's Lipitor and other cholesterol-lowering pills.

"It is this clinical reviewer's opinion that the treatment benefit observed in the Jupiter trial outweighs the risk, but further clinical trials are needed to further define this benefit-risk ratio," writes the unnamed reviewer.

The FDA on Tuesday will ask a panel of outside experts to weigh in on whether Crestor use should be expanded. The agency is not required to follow the group's advice, though it often does.

The panel also will discuss 13 deaths due to gastrointestinal disorders seen in Crestor patients, compared with just one in the placebo group. The agency review suggests the higher rate was a "chance finding."

The FDA also will raise questions about 18 Crestor patients who reported a "confusional state," compared with four in the [placebo](#) group.

AstraZeneca's Jupiter study focused on patients with lower cholesterol and elevated C-reactive protein, a key indicator of inflammation that can lead to clogged arteries. Under current guidelines, those patients are not recommended for treatment with statins, the best-selling class of cholesterol-lowering drugs.

Patients taking Crestor experienced a 44 percent reduction in major heart problems, including heart attack, stroke and death. It's unclear whether the positive results seen in Jupiter were due to lower cholesterol or C-reactive protein, since Crestor reduces both.

In its own briefing documents, [AstraZeneca](#) points out that half of all [heart](#) problems occur in patients with normal cholesterol levels, who stand to benefit from expanded use of Crestor.

Broader FDA labeling for the drug would expand the potential U.S. market by at least 6 million patients, according to the FDA. Sales of the

drug already rose 30 percent in the last quarter to \$1.15 billion compared with the prior year period.

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Citation: FDA confirms benefits of Crestor in more patients (2009, December 11) retrieved 4 May 2024 from <https://medicalxpress.com/news/2009-12-fda-benefits-crestor-patients.html>

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