Medical Xpress

FDA backs Vytorin for kidney disease patients

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(AP) -- The Food and Drug Administration says Merck's cholesterol drug Vytorin helps reduce heart attack, stroke and related problems in patients with kidney disease, a potential new use for the blockbuster drug.

The agency's online review also found no new safety concerns with Vytorin, which came under scrutiny for potential cancer risks in 2008.

Merck has asked the FDA to approve the drug for a new use in reducing heart-related problems chronic kidney disease patients. The combination pill is already cleared to reduce bad cholesterol.

FDA says that Vytorin lowered kidney disease patients' heart-related problems by 16 percent compared with placebo. However results varied depending on whether patients were receiving dialysis, standard treatment for patients with late-stage kidney disease who can no longer remove waste from their blood. Patients on dialysis only saw a six percent drop in heart problems, compared with a 22 percent reduction for healthier patients not on dialysis.

On Wednesday, the FDA will ask non-government advisers to comment on the disparity and to vote on the overall safety and efficacy of the drug for kidney disease patients.

Vytorin, a $2 billion-a-year drug for Merck, combines two brand-name cholesterol pills Zocor and Zetia.

In July 2008, preliminary results from a four-year study indicated a possible increased risk of cancer in patients getting Vytorin. But FDA's latest review found no evidence of a link between Vytorin and cancer.

"We believe these data should help lay to rest investor concerns about Vytorin and Zetia's safety," Leerink Swann analyst Seamus Fernandez wrote in a research note Monday.

Shares of Merck & Co. Inc. fell 23 cents to $34.88 in morning trading Monday.

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