FDA Says Xarelto Reduced Deadly Heart Attacks

WASHINGTON (AP) — The Food and Drug Administration said Monday that a blood thinner from Johnson & Johnson appears to reduce life-threatening blood clots in high-risk patients, although it also increases the risk of internal bleeding.

The FDA posted its review of J&J's Xarelto for the new use ahead of a public meeting Wednesday where medical experts will vote on its safety and effectiveness. Along with bleeding risk, FDA regulators will also ask the experts about inconsistent findings and missing data from J&J's main study of Xarelto.

J&J already markets the pill for two patient groups: those with irregular heartbeat and those undergoing hip or knee replacement surgery.

The New Brunswick, N.J.-based company is now asking the FDA to approve it as a preventive measure against life-threatening blood clots in patients with acute coronary artery disease. That's a condition in which a narrowed blood vessel reduces flow to the heart muscle, increasing the risk of heart attack and other catastrophic problems.

The FDA's drug reviewer recommended approving the drug for the new use, in documents posted online Monday. The reviewer said J&J's 15,500-patient study showed Xarelto significantly reduced the risk of heart attack, stroke and death.

"Overall, the benefit-risk ratio for Xarelto appears to be favorable, predominantly because there is a reduction in cardiovascular death, despite an increased risk of major and fatal bleeding," states FDA reviewer Karen Hicks.

Patients taking Xarelto were three times more likely to have major internal bleeding, compared with patients taking placebo. Hicks writes that bleeding "may represent the biggest problem for both patients and health care providers."

While FDA backed the overall benefits of Xarelto, reviewers complained about inconsistencies and omissions in J&J's applications.

More than 15 percent of patients enrolled in the study dropped out before completion. As a result, the company did not follow up on the status of over 1,000 patients.

On Wednesday, the FDA will ask its panel of advisers whether this missing data may have skewed the accuracy of the company's study. The panel will take a final vote on whether to recommend approval of Xarelto for acute coronary syndrome. The

FDA is not required to follow the group's advice, though it often does. A final decision is expected by June 29.

Wells Fargo analyst Larry Biegelsen said he expects "a very heated debate" over Xarelto's safety at the panel meeting, but concluding with a positive panel vote.

Biegelsen expects Xarelto to generate about $1.6 billion in sales by 2016, with the new indication accounting for about 22 percent.

Xarelto is part of a new group of blood thinners intended to supplant the longtime standard treatment, warfarin, which is cheap but requires frequent blood tests to get dosing right and can interact with numerous foods and other medicines.