Development of new diabetes drug halted by maker

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Avandia. Photo: GlaxoSmithKline

Failure of aleglitazar might affect FDA deliberations on whether to ease restrictions on similar drug Avandia.

(HealthDay)—The development of what might have become a significant diabetes drug has been halted by its maker amid concerns that the medication raises the risk for fractures, kidney problems and heart failure in those taking it.

Roche reported Wednesday that it would shut down a late-stage clinical trial of the drug aleglitazar after a monitoring committee found signs of troubling side effects and a lack of effectiveness in patients with type 2 diabetes who had heart problems. The Swiss pharmaceutical giant also closed all other studies of the drug.

"We are disappointed by this outcome as we hoped that aleglitazar would provide significant benefit for patients with type 2 diabetes who are at risk of cardiovascular disease," Dr. Hal Barron, chief medical officer at

Roche, said in a company statement.

The drug was being tested to see if it could prevent heart attacks and strokes, in addition to lowering blood sugar levels.

The failure of aleglitazar might color any decision the U.S. Food and Drug Administration may soon make about the troubled diabetes drug Avandia, which is similar to aleglitazar, *The New York Times* reported.

In 2010, Avandia's use was severely restricted in the United States because evidence suggested it raised the chances of heart attacks and stroke.

An FDA advisory committee recommended in June, however, that the restrictions on Avandia be eased. Thirteen members of the 26-person panel voted to ease the controls, while seven voted to lift them altogether. No decision on that recommendation has been made yet by the agency, although it often follows the advice of its expert panels.

Meanwhile, critics of Avandia argue that the entire class of drugs is dangerous and Avandia's use should remain tightly controlled, the *Times* reported.

Roche noted in its statement, however, that aleglitazar did not increase the risk of heart attacks or strokes, which may bolster the argument that Avandia also does not raise cardiovascular risks, the newspaper added.

In the aleglitazar study, more than 7,000 people with diabetes who had also suffered a recent heart attack or the onset or worsening of cardiac pain were involved. The study was supposed to last five years, until the beginning of 2015.

More information: For more on thiazolidinediones, the class of drugs

to which Avandia belongs, visit the U.S. National Institute of Diabetes and Digestive and Kidney Diseases.