Diabetes Pill Actos May Pose Cancer Risk

FDA Reviewing Suggesting Possible Link

WASHINGTON — The Food and Drug Administration is reviewing data suggesting a possible link between the widely used diabetes medication Actos and bladder cancer.

The agency said Friday that five-year results from an ongoing study show that patients who have taken Actos for the longest period of time had a higher risk of bladder cancer. Bladder cancer was also more prevalent in patients who had taken the largest cumulative dose of the drug.

Actos manufacturer Takeda Pharmaceuticals is conducting the study, which is scheduled to run 10 years.

“The agency has not concluded that Actos increases the risk of bladder cancer,” the agency said in a statement. Patients should continue taking Actos unless told otherwise by their doctor, according to the agency statement.

Actos agreed to study the risk of bladder cancer with its drug in 2003. But a company executive said Friday the results are too preliminary to make any conclusions about the drug.

“This interim analysis raises a question, but it doesn’t answer anything,” said Dr. Robert Spanheimer, vice president of medical affairs at Takeda. “We are committed to finishing the study because I think that’s when you’re going to get the greater understanding.”

Prescriptions for Actos have risen since 2007, when its chief competitor, Avandia, was first associated with cardiovascular problems. The FDA is considering whether to withdraw Avandia, which is marketed by British drugmaker GlaxoSmithKline. Actos and Avandia work similarly to control blood sugar and are the only drugs in their class currently on the market. A third drug called Rezulin was withdrawn in the U.S. in 1997 due to liver toxicity.

Critics of Avandia have called on the FDA to recall the drug, arguing that Actos offers the same benefits without risks of heart attack and stroke.

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