



Diabetes Drug Increases Bladder Cancer Risk



Takeda Pharmaceutical's Actos diabetes drug can increase the risk of bladder cancer if used for more than a year, U.S. drug regulators said on Wednesday.

The Food and Drug Administration said it is adding this information to the label for the drug after reviewing the preliminary five-year results of an ongoing 10-year study.

The announcement comes after France and Germany suspended sales of Actos last week due to similar worries about a possible risk to bladder cancer.

Japan's Takeda has garnered close to \$5 billion in worldwide sales from Actos, its best-selling drug. However, Actos faces looming generic competition, potentially muting any financial impact from regulatory actions.

The FDA said that studies showed that patients who had the longest exposure to Actos, and those taking the highest cumulative dose of the drug, had an increased risk of bladder cancer -- although Actos did not lead to an increased risk of bladder cancer in the study overall.

About 2.3 million patients filled a prescription for a product containing pioglitazone, the clinical name for Actos, from January to October of 2010, the FDA said.

The FDA said it will continue to evaluate data from the ongoing ten-year epidemiological study, and will also review the results from a French study, which prompted the suspension of Actos in France.

(Source: Reuters)

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