Medical Xpress

FDA advisers recommend approving weight loss drug

May 10 2012, By LINDA A. JOHNSON , AP Business Writer

(AP) -- Advisers to government health regulators on Thursday recommended that that they approve sales of what would be the first new prescription weight-loss drug in the U.S. in more than a decade, despite concerns over cardiac risks.

A panel of expert advisers to the Food and Drug Administration voted 18-4 to recommend approval of lorcaserin, developed by Arena Pharmaceuticals Inc. They concluded that its benefits "outweigh the potential risks when used long term" in overweight and obese people. One panel member abstained from voting.

Lorcaserin is one of three experimental weight-loss drugs whose developers have been trying for a second time to win approval, after the FDA shot them all down in 2010 or early 2011 because of serious potential side effects.

The panel's vote Thursday comes two days after federal health regulators gave a surprisingly favorable assessment of lorcaserin, the same diet pill the agency turned down in 2010.

At the time, scientists raised concerns about health issues including tumors that developed in laboratory animals tested with the drug.

In the interim, the San Diego company again applied for approval, submitting additional data in hopes of swaying the agency to a favorable decision.

A review of all the research studies by FDA staff, posted online Tuesday, stated that new analysis Arena submitted suggests there's only a "negligible risk" of tumors in people taking the drug. However, questions remain about it possibly increasing risk of high blood pressure in diabetics or damaging heart valves, a life-threatening side effect that has been an issue with some earlier weight-loss pills.

The FDA is not bound to follow the advice of its advisory panels, but generally does so.

Earlier this year, rival Vivus Inc. won a surprising endorsement from an FDA panel for its diet drug, Qnexa. That move raised expectations for both Arena and Orexigen Therapeutics Inc., the third company racing to get the first new diet drug into drugstores.

But a month ago, Vivus said that the FDA had pushed back its target date for a final decision on Qnexa from April 17 until July 17. The agency said it needed more time to consider a new drug safety plan submitted by Vivus.

While patients and doctors are eager for new options to fight obesity, none of these drugs enable patients to magically shed pounds.

Research showed that study subjects taking lorcaserin had modest weight loss, on average losing just 3.1 percent of starting body weight over a year. More than 37 percent of patients lost 5 percent of their weight or more, which is enough to meet FDA standards for effectiveness. By comparison, average weight loss with Qnexa was 11 percent, with more than 83 percent of patients losing 5 percent of their weight or more.

In trading Thursday before the decision was announced, Arena shares rose 24 cents, or 7 percent, to $3.66. The stock was halted for trade in the after-hours. Shares of Orexigen added 12 percent, or 40 cents, to

$3.75 in late trading.

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