FDA rejects highly-anticipated diet drug Qnexa

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(AP) -- Federal health regulators have decided not to approve an experimental diet pill called Qnexa, which had been touted by many experts as the most promising weight-loss drug in more than a decade.

The drug's maker, Vivus Inc., said in a statement Thursday that the Food and Drug Administration declined to approve the drug in its present form. The agency asked for more study results and additional information on its possible health risks, including major cardiovascular events and risks for women of childbearing potential.

The FDA did not ask for any new clinical studies, but more may be required if the agency's concerns aren't addressed, Vivus said.

The company plans to respond to the FDA in about six weeks.

"We remain confident in the efficacy and safety profile of Qnexa demonstrated in the clinical development program and look forward to continue working with the FDA towards the approval for the treatment of obesity," Vivus CEO Leland Wilson said in a statement.

Its shares added 5 cents to $6.18 in aftermarket trading Thursday. The stock added 5 cents to $6.13 during the regular session.

Vivus, based in Mountain View, Calif., is one of three small drugmakers racing to win approval for their weight-loss drugs. Many analysts picked Qnexa as the most promising contender because of the high level of

weight loss reported in company studies: On average, patients lost more than 10 percent total body mass. That compared to weight loss of under 5 percent with drugs currently on the market, like Roche's Xenical.

But Qnexa's outlook took a significant hit in July, when a panel of experts assembled by the FDA voted 10-6 to not recommend the drug's approval. Panelists said the drug was associated with a number of dangerous side effects, including suicidal thoughts, heart palpitations, memory lapses and birth defects.

With rates of obesity and diabetes rising globally, doctors say new weight-loss drugs are needed, though the drug class has a history of safety problems.

Vivus is the second weight-loss drug rejected by the FDA in the past week. On Saturday, Arena Pharmaceuticals announced that the agency declined to approve its drug lorcaserin, citing tumors seen in rats during early stage testing. The San Diego-based company said it still hopes to win approval for the drug and would submit more detailed information, at the agency's request.

FDA's rejection of drugs from Vivus and Arena will focus new attention on the third competitor in the weight-loss drug race: Orexigen Therapeutics. The company's drug Contrave has shown weight loss between 5 and 10 percent with modest side effects, though FDA's decisions this week suggest a strict standard for safety.

One of the key researchers in the development of Qnexa warned that the FDA's negative decision on the drug could have a cooling effect on industry efforts.

"If there isn't any kind of path forward for this drug I think it is going to shut down all obesity drug development for a decade," said Dr. Tim

Garvey of the University of Alabama. Garvey conducted two clinical trials of Qnexa and has consulted for Vivus.

"Why would a company put all that investment into developing a drug if the FDA signals they aren't willing to approve it," he said.

With U.S. obesity rates nearing 35 percent among adults, doctors and public health officials say new weight-loss therapies are desperately needed. And even a modestly effective drug could have blockbuster potential.

But the search for a drug that helps patients safely shed pounds has been largely unsuccessful. Two weeks ago Abbott Laboratories withdrew its pill Meridia from U.S. and Canadian markets after regulators said it increased the risk of heart attack and stroke.