FDA panel backs previously rejected obesity pill

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(AP) -- A panel of advisers to the Food and Drug Administration overwhelmingly backed approval for a highly anticipated anti-obesity pill called Qnexa, a drug which the FDA previously rejected due to safety concerns.

The FDA panel of outside physicians voted 20-2 Wednesday in favor of the weight loss drug from Vivus Inc., setting the stage for a potential comeback for a drug that has been plagued by safety questions since it was first submitted to the agency in 2010.

A majority of panelists ultimately backed the drug due to its impressive weight loss results, with most patients losing nearly 10 percent of their overall weight after a year on the drug. But the group stressed that the drugmaker must be required to conduct a large, follow-up study of the pill's effects on the heart. Studies of Qnexa show it raises heart rate and causes heart palpitations, a longtime concern with diet pills over the years. The group of experts said it is still unclear if those side effects lead to heart attack and more serious cardiovascular problems.

"The potential benefits of this medication seem to trump the side effects, but in truth, only time will tell," said Dr. Kenneth Burman of the Washington Hospital Center.

The FDA is not required to follow the advice of its panels, though it often does. A final decision on the drug is expected in April.

In a key question, the physicians said Vivus could conduct its study after FDA approval. Conducting the study ahead of market approval would cost the company millions of dollars and take at least three more years.

"There is an urgent need for better pharmacologic options for individual patients with obesity," said Dr. Elaine Morrato, of the University of Colorado. "I believe Qnexa demonstrated a meaningful efficacy benefit and that there are consequences to not treating obesity."

Vivus, based in Mountain View, Calif., is one of three small drugmakers racing to bring the first new prescription weight loss drug to market in more than a decade. In the past two years the Food and Drug Administration has rejected pills from all three: Arena Pharmaceuticals Inc., Orexigen Therapeutics Inc. and Vivus. All three companies are in the process of resubmitting their products.

The FDA rejected the diet pill Qnexa in October 2010, citing numerous side effects including raised heart rate, psychiatric problems and birth defects. Vivus has resubmitted the drug with additional follow-up information on safety, hoping for a more favorable ruling.

Vivus President Peter Tam said the overwhelming panel vote Wednesday underscores the need for effective weight loss drugs.

"I think they see the medical need," Tam said. "Right now there aren't any good treatments out there besides dieting and bariatric surgery, clearly there's a huge gap."

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. Analysts expect a new weight loss pill to garner at least 10 million users within a few years.

Qnexa is a combination of two older drugs: the amphetamine phentermine, which is approved for short-term weight loss, and topiramate, an antiseizure and antimigraine drug sold by Johnson & Johnson as Topamax. Phentermine helps suppress appetite, while topiramate is supposed to make patients feel more satiated.

Along with heart safety, panelists raised concerns about potential birth defects in women who become pregnant while taking Qnexa. One of the two ingredients in the combination pill, topiramate, is known to more than double the risk of birth defects.

There were 34 pregnancies among 3,386 women enrolled in Vivus' studies of Qnexa, despite precautions to make sure women used contraception. An FDA expert on birth defects estimated there would be five babies born with a cleft lip defect for every 1,000 women who became pregnant while taking Qnexa.

If approved, FDA scientists said they would require Vivus to train prescribers in the pregnancy risks of Qnexa and distribute warning pamphlets to patients. The drug would only be available from 10 mail-order pharmacies.