FDA approves highly anticipated weight-loss pill

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(AP) — The Food and Drug Administration on Tuesday approved a new weight loss drug from Vivus Inc. that many doctors consider the most effective therapy in a new generation of anti-obesity pills designed to help patients safely shed pounds.

The agency cleared the pill Qsymia for adults who are obese or overweight and have at least one weight-related condition such as high blood pressure, diabetes or high cholesterol.

Patients taking Qsymia for a year lost 6.7 percent of their body weight in one study and 8.9 percent in another study, the FDA said. That was more than two other weight loss pill recently reviewed by the FDA.

Despite its impressive performance in clinical trials, Qsymia is not exactly a scientific breakthrough, and its development underscores the slow pace of research for obesity treatments.

The drug is actually a combination of two older drugs that have long been known to help with weight loss: phentermine and topirimate.

Phentermine is a stimulant that suppresses the appetite, and has long been used for short-term weight loss. Topiramate is an anticonvulsant, sold by Johnson & Johnson as Topamax, that makes people feel more satiated after eating.

Researchers say the innovation of Qsymia lies in targeting multiple brain

signals that drive people to overeat.

"We now know there are multiple pathways that determine how much energy we take in every day," said Dr. Tim Garvey of the University of Alabama at Birmingham. "If you intervene on one pathway it's hard to make much of a difference, you really need to attack multiple mechanisms to get a pronounced effect."

Garvey helped conduct several pivotal trials of the drug.

Qsymia is the second weight loss drug approved by the FDA in less than a month, following Arena Pharmaceutical's pill Belviq in late June. Previously the agency had not approved a new drug for long-term weight loss since 1999.

With U.S. obesity rates nearing 35 percent of the adult population, many doctors have called on the FDA to approve new weight loss treatments. But a long line of prescription diet pills have been associated with dangerous side effects, particularly heart problems.

In 1997, the popular diet drug combination fen-phen was linked to heart valve damage. The cocktail of phentermine and fenfluramine was a popular weight loss combination prescribed by doctors, though it was never approved by the FDA. Fenfluramine was eventually withdrawn from the market.

Other safety failures for diet pills have continued to pile up in recent years. In 2010, Abbott Laboratories withdrew its drug Meridia after a study showed it increased heart attack and stroke.

The FDA's successive approval of Qsymia and Belviq suggests a new willingness to make weight loss medications available, even in the face of lingering safety issues.

The FDA initially rejected Vivus' drug in 2010 over concerns that it can cause birth defects if taken by pregnant women. The agency laid out a risk-management plan Tuesday specifically designed to minimize the chance of the women becoming pregnant while using the drug. It recommends that women of childbearing age test negative for pregnancy before starting the drug and take a monthly pregnancy test while taking it.

The agency also said patients with recent or unstable heart disease or stroke aren't good candidates for the drug because its effect on heart rates in those patients is not known. Vivus has to do studies of the heart effects of Qsymia, the FDA said.

Analysts estimate the new pill could garner more than $1 billion in sales by 2016, though Mountain View, California-based Vivus Inc. plans a slow rollout.

The pill will launch in the last quarter of the year with a relatively small sales force of 150 representatives. Company executives say their initial marketing efforts will focus on obesity specialists, not general doctors.

"We're going to have to grow our sales organization in order to support the primary care market," said Vivus president Peter Tam, in an interview with the Associated Press.

Vivus had originally planned to market the drug under the brand name Qnexa. However, FDA regulators ordered the company to change the name to avoid potential confusion with similar sounding drugs.

Rival Arena Pharmaceuticals Inc. of San Diego plans to start selling Belviq in early 2013. A third California drugmaker, Orexigen Therapeutics Inc., is still running clinical trials of its product, Contrave, and is working toward an FDA approval date in 2014.