US clears first new weight-loss pill in 13 years

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(AP) — The Food and Drug Administration has approved Arena Pharmaceutical's anti-obesity pill Belviq, the first new prescription drug for long-term weight loss to enter the U.S. market in over a decade.

Despite only achieving modest weight loss in clinical studies, the drug appeared safe enough to win the FDA's endorsement, amid calls from doctors for new weight-loss treatments.

The agency cleared the pill Wednesday for adults who are obese or are overweight with at least one medical complication, such as diabetes or high cholesterol.

The FDA denied approval for Arena's drug in 2010 after scientists raised concerns about tumors that developed in animals studied with the drug. The company resubmitted the drug with additional data earlier this year, and the FDA said there was little risk of tumors in humans.

"The approval of this drug, used responsibly in combination with a healthy diet and lifestyle, provides a treatment option for Americans who are obese or are overweight and have at least one weight-related comorbid condition," said FDA's drug center director, Dr. Janet Woodcock, in a statement.

Arena and its partner Eisai Inc. expect to launch the drug in early 2013.

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 weight loss offerings have been associated with safety problems, most notably the fen-phen combination, which was linked to heart valve damage in 1997. The cocktail of phentermine and fenfluramine was a popular weight loss combination prescribed by doctors, though it was never approved by FDA.

In a rare move, the FDA explicitly stated in a press release that Belviq "does not appear to activate" a chemical pathway that was linked to the heart problems seen with fen-phen.

The FDA said the drug acts on a different chemical pathway in the brain, which is believed to reduce appetite by boosting feelings of satiety and fullness.

Obesity Society President Patrick O'Neil said he's encouraged by the drug's approval because it underscores the idea that lifestyle changes alone are not enough to treat obesity.

"This is good news because it tells us that the FDA is indeed treating obesity seriously. On the other hand, it's not the answer to the problem — or even a big part of the answer," said O'Neil, who teaches at Medical University of South Carolina and was the lead researcher on several studies of Belviq.

Even if the effects of Belviq are subtle, experts say it could be an important first step in a new line of treatments that attack the underlying causes of obesity.

"The way these things tend to work is you have some people who do extremely well and other people don't lose any weight at all. But if we had 10 medicines that were all different and worked like this, we would

have a real field," said Dr. Louis Aronne, director of the weight loss program at Weill-Cornell Medical College.

Belviq 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.

Vivus Inc.'s Qnexa is thought to be the most promising of the drugs, achieving the most weight loss. But the FDA has delayed a decision on that pill until July.

Shares of San Diego-based Arena Pharmaceuticals Inc. jumped $2.54, or 28.7 percent, to close at $11.39. SharesVivus rose $1.94, or 7.4 percent, to $28.33.

Arena's studies showed that patients taking Belviq, known generically as lorcaserin, had modest weight loss. On average patients lost just 3 to 3.7 percent of their starting body weight over a year. About 47 percent of patients without diabetes lost at least 5 percent of their weight or more, which was enough to meet FDA standards for effectiveness. By comparison, average weight loss with Qnexa is 11 percent, with more than 83 percent of patients losing 5 percent of their weight or more.

The FDA said patients should stop taking Belviq after three months if they fail to lose 5 percent of their body weight. Patients are unlikely to see any significant weight loss by staying with the drug.

Side effects with the drug include depression, migraine and memory lapses.

In May a panel of expert advisers to the FDA voted 18-4 to recommend approval of Arena's drug, concluding that its benefits "outweigh the

potential risks when used long term" in overweight and obese people.

Experts say the challenge of weight loss drug development lies in safely turning off one of the body's fundamental directives: to eat enough food to maintain its current weight.

While several drugs are available for short-term weight loss, until Wednesday there was only one FDA-approved prescription drug for long-term weight loss: Xenical from Roche, which is seldom prescribed because of unpleasant digestive side effects and modest weight loss. Belviq is the first new prescription drug approved to treat obesity since Xenical's approval 13 years ago.

Other safety failures for diet pills have continued to pile up in recent years.

Four years ago Sanofi-Aventis SA discontinued studies of its highly anticipated pill Acomplia due to psychiatric side effects, including depression and suicidal thoughts. In 2010, Abbott Laboratories withdrew its drug Meridia after a study showed it increased heart attack and stroke.