FDA to review first of 3 new weight loss drugs

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(AP) -- Dieters, doctors and investors get their first extensive look at the first of a trio of new weight loss drugs this week. The hope is that the new drugs can succeed where many others have failed: delivering significant weight loss without risky side effects.

With U.S. obesity rates nearing 35 percent of the adult population, expectations are high for the first new prescription drug therapies to emerge in more than a decade. Even a modestly effective drug has blockbuster potential.

None of the three medicines represents a breakthrough in research. Drugmakers have made little headway in understanding and treating the causes of overeating. Two of the drugs submitted for approval simply combine existing drugs - an anticonvulsant and an amphetamine - but have worrying side effects. The third, a new medication, is safer but less effective.

The quest for a blockbuster weight loss drug has been plagued for decades by safety issues. The most notable was Wyeth's diet pill drug combination fen-phen, which was pulled off the market in 1997 due to links to heart valve damage and lung problems.

The FDA is expected to post its review of Vivus Inc.'s pill Qnexa on Monday and will hold a public meeting Thursday to review the data. Orexigen Therapeutics Inc.'s Contrave is set for review in October, and Arena Pharmaceuticals Inc.'s lorcaserin is set for December.

"There's no obvious clear winner," said Leerink Swann analyst Steve Yoo. "If you look at different aspects, each drug shines."

To be considered effective, obesity drugs should reduce total body weight by at least 5 percent after one year, according to FDA guidance to companies.

Qnexa showed the best weight loss results in clinical trials, with patients losing between 13 percent and 15 percent of their body weight. But the drug also had the highest rate of patient dropouts due to side effects, which include memory and concentration problems.

Qnexa is a combination of two older drugs: the amphetamine phentermine and topiramate, an anticonvulsant drug sold by Johnson & Johnson as Topamax. According to the company, phentermine helps suppress appetite, while topiramate makes patients feel more satiated.

Contrave is also a combination pill, mixing an antidepressant with an anticonvulsant drug. The drug has shown weight loss between 5 percent and 10 percent with side effects such as nausea.

University of Liverpool Professor Jason Halford said drug companies are taking a multi-pronged approach to obesity therapies because science has shown there are multiple brain signals that drive food intake.

"We're using combinations of old drugs with a very broad spectrum of pharmacotherapy, it's very much the shotgun approach," said Halford, a health psychologist who has consulted for drug companies on obesity treatments.

The one truly novel drug under FDA review showed the weakest results in clinical trials. Arena Pharmaceuticals' lorcaserin is a first-of-a-kind drug that acts on serotonin, a brain chemical associated with feelings of

well-being and satiation. But patients in company trials lost just 5 percent of their body weight.

While Arena's drug trails its competitors in weight loss, it appears to have the least side effects, an important factor in FDA approval.

Investors clearly favor Vivus in the three-way race. Shares of Vivus have nearly doubled over the past year to close Friday at $11.52.

Arena Pharmaceuticals shares have fallen nearly 4 percent over the past year on lackluster results for its drug. Orexigen shares have fallen 21 percent over the past year, to close Friday at $4.17, marking a bouncy descent from a June 2007 peak of $17.70 a share.

Decision Resources, a drug industry analysis firm, believes all three drugs could eventually win approval and find a place in the global obesity market. The firm expects the global market to soar from $500 million to $3.4 billion a year by 2018.

Still, the history of diet drugs is littered with stumbling blocks.

The diet drug fenfluramine, which was half of the fen-phen combination, was withdrawn in 1997 after it was linked with heart damage. The drug's combination with phentermine was popular but never approved by FDA.

Two years ago Sanofi-Aventis SA discontinued studies of its highly anticipated pill Acomplia due to psychiatric side effects, including depression and suicidal thoughts.

Side effects have kept the small number of weight-loss drugs currently on the market from being blockbuster sellers. Abbott Laboratories' appetite suppressant Meridia was pulled from the market in Europe last

November due to data showing increased heart attack risks. And in May, the FDA warned consumers that the over-the-counter weight loss pill alli, which has been sold for years at a higher dose as the prescription drug Xenical, could cause severe liver damage. The drug works by limiting the amount of fat the body can absorb.

Derek Lowe, a pharmaceutical researcher and blogger, says the new combination drugs under review hold promise because they work on multiple brain chemicals that drive overeating.

"No single agent is going to shut down this behavior," said Lowe, whose blog "In the Pipeline" focuses on drug development. "But if you can come in and hit two or more of these different pathways at the same time, maybe then you'll get somewhere."