Vivus weight loss drug faces FDA panel this week

13 July 2010

(AP) -- Vivus Inc.'s experimental drug Qnexa was effective in cutting weight, the Food and Drug Administration said Tuesday, while acknowledging lingering concerns over the drug's nervous system and psychiatric side effects.

Still, shares of Vivus jumped as the drug edged closer to approval, potentially the first new prescription drug therapy in more than a decade in the burgeoning obesity market.

The FDA raised some concerns in briefing documents posted online on Tuesday about a range of side effects. It said reviewers should take into account rates of depression, memory and concentration lapses, and heart-related issues, among others. The concerns were not a surprise to Wall Street, which has been following development of the drug over the last several years.

A panel of experts is scheduled to review the drug on Thursday, with the FDA making a regulatory decision in October.

"Given two-thirds of adults in the United States are either overweight or obese, weight loss products, such as Qnexa, may have widespread exposure, and the potential for associated safety issues must be considered," the agency said.

Qnexa is the first of several new weight loss drugs to come under FDA review this year and Wall Street has been following its progress through human studies to gauge its potential.

The drug met key goals in several studies, cutting between 13 percent and 15 percent of patients' body weight. But the FDA is concerned about five types of side effects, including heart risks, increased risk of suicide, metabolic issues, and the potential impact on pregnant women.

Vivus, in its own briefing documents, said research showing that 68 percent of adults in the U.S. are overweight indicate a clear medical need for Qnexa.

"Recent data suggest that if current increases in obesity rates continue over the next decade, the health consequences of obesity will negate the gains in health benefits achieved through the reduction in smoking rates," Vivus said.

In morning trading, shares of the Mountain View, Calif., company rose $1.75, or 16 percent, to $12.40, more than doubling from a low of $5.57 last July.

The obesity problem in America underscores the financial potential of any new weight loss drug. But the search for a new drug has faced decades worth of safety issues. A key example includes fen-phen, which was pulled off the market in 1997 because of links to heart-valve damage and lung problems.

Aside from Qnexa, the FDA is set to review Arena Pharmaceuticals Inc.'s lorcaserin in September, while Orexigen Therapeutics Inc.'s Contrave will be the subject of a December panel.