FDA panel recommends approval for Contrave

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A Food and Drug Administration panel on Tuesday recommended that the agency approve Orexigen Therapeutics Inc.'s weight loss drug Contrave, making it the first in group of competitors to get a positive nod from experts.

The panel of experts voted 13 to 7 for Contrave's approval, and 11 to 8, with an abstention, that additional studies be conducted on heart risks. Experts had voiced safety concerns on the drug, but determined the benefits outweigh the risks.

The move marks an about-face on weight loss drugs after the agency in October rejected Arena Pharmaceuticals Inc.'s lorcaserin and Vivus Inc.'s Qnexa because of safety concerns.

The FDA is not required to follow the advice of its expert panels, but often does. The agency is scheduled to make a decision on Contrave by Jan. 31.

Scientists at the FDA are concerned over Contrave's effects on the heart, an issue that has weighed heavy on potential weight loss drugs. Complaints focused on the company's lack of elderly patients with a history of heart disease in clinical trials. That lack of data made it difficult to determine the drug's safety in patients at risk for heart attack and stroke.

Contrave is a combination pill, mixing the antidepressant bupropion with

the anti-addiction drug naltrexone. FDA reported higher rates of side effects already linked to the drugs, including high blood pressure, dizziness and insomnia.

Also, the company didn't quite meet all the criteria the agency had set for obesity drugs.

Studies showed that patients taking the drug, on average, lost 4.2 percent more weight than patients taking a placebo. Those results did not meet an FDA guideline that there should be at least a 5 percent difference in weight loss between the groups. The drug did meet a second measure of effectiveness involving the number of patients who lost at least 5 percent or more of their weight.

U.S. obesity rates are near 35 percent among adults and physicians and health officials have said new weight-loss therapies are desperately needed. But the search for that treatment has been fraught with safety issues. Earlier this year Abbott Laboratories' Meridia weight loss pill was pulled from the market because of concerns over the risk of heart attack and stroke.

Qnexa was rejected in part because it was linked to potential heart problems and birth defects, despite showing significant effectiveness. Lorcaserin faced concerns over cancerous tumors found in laboratory rats.

Safety concerns were palpable during the panel vote. The role and image of the FDA has come under fire over the last several years for approving products that wound up being recalled because of safety issues.

In a statement ahead of the panel vote, Dr. Sidney Wolfe, director of Public Citizen's health research group, said the FDA should eventually reject Contrave because of safety concerns.

"The diet pill Contrave is the latest in a long line of dangerous and, ultimately, failed weight loss drugs," he said in a statement, citing drugs that have been pulled from the market, including fen-phen.

He said his main concern with Contrave is the potential for heart-related side effects. Part of the drug's formula, bupropion, is already known to increase blood pressure.

The drug, if approved by the FDA, would be a boon to La Jolla, Calif.-based Orexigen, which does not currently have a marketed product.

The safety concerns, particularly over heart-related side effects, were not a surprise to the company, said Orexigen President and CEO Michael A. Narachi, in an interview with The Associated Press following the vote.

"The meeting today was incredibly valuable across the board on the input," he said. "We look forward to incorporating the input we got today to move the program forward."

Orexigen's stock had been halted throughout the day ahead of the panel meeting and vote. It later rocketed 155 percent to $4.87 in after-market trading.

Meanwhile, shares of Arena surged 17 cents, or 12 percent, to $1.58 in after-hours trading after gaining 3 cents to close the regular session at $1.41. Shares of Vivus jumped 85 cents, or 11 percent, to $8.65 in after-hours trading after rising 75 cents, or 10.6 percent, to close the regular trading session at $7.80.