FDA declines to approve Orexigen diet drug

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(AP) -- Orexigen Therapeutics Inc. shares plunged nearly 75 percent in pre-market trading Tuesday after U.S. health officials declined to approve the experimental weight loss pill Contrave.

The Food and Drug Administration said it wants the company to conduct an additional study to address potential heart safety issues. The FDA request suggests the agency may yet approve the drug, but makes that path more difficult.

Orexigen said it is disappointed with the FDA's decision and will work with the agency to determine its next step.

Analysts have viewed Contrave as the most promising of three new diet pills recently submitted to the agency. Contrave is a combination pill, mixing an antidepressant with an anti-addiction drug to curb appetite. Four out of 10 patients taking Contrave for a year lost at least 5 percent of their body weight. Those results narrowly met FDA's guidelines for effectiveness.

La Jolla, Calif.-based Orexigen does not currently have any products on the market, making Contrave a key to the company's growth and survival. In pre-market trading Tuesday, Orexigen shares tumbled $6.67, or 73 percent, to $2.42.

Analysts expect any obesity drug reaching the market to have the potential to become a billion-dollar seller.

With the U.S. obesity rate for adults nearing 35 percent, the FDA has acknowledged the need for new weight loss drugs. But the agency rejected two other drugs last year due to safety risks, a long-standing issue that has plagued weight loss treatments for decades. Those drugs were made by fellow California drug developers Vivus Inc. and Arena Pharmaceuticals Inc. Both companies have said they plan to resubmit their drugs for approval.

Contrave has been pegged as a more promising treatment because of its relative safety. Unlike the other two drugs reviewed last year, it received a positive vote from the FDA's panel of outside advisers, who voted 13-7 that the drug's modest weight loss benefits outweighed its risks.

But the FDA meeting assessing the drug was not free of criticism. FDA scientists and safety advocates complained that the company enrolled few elderly patients or patients with a history of heart disease in its trials, making it difficult to determine the drug's safety in patients who are likely to need it most.

Heart side effects have been an issue with diet drugs, most notably with Wyeth's diet drug combination fen-phen, which was pulled off the market in 1997. In October, Abbott Laboratories withdrew its drug Meridia after evidence it increased the risk of heart attack and stroke.

Currently there is just one prescription drug on the market for long-term weight loss: Roche's Xenical, which is not widely used. Several other generic drugs are approved for short-term weight loss, including phentermine.