

FDA approves weight-loss drug Contrave (Update)

September 11 2014, by Matthew Perrone

U.S. regulators have greenlighted a new weight-loss drug called Contrave, the third in a string of approvals for prescription medications aimed at the nation's 78 million obese adults.

The pill, Contrave, is a combination of two drugs that are already approved, naltrexone and bupropion. Naltrexone is used to treat alcohol and narcotic dependence. Bupropion is an antidepressant also used to help people quit smoking.

Contrave joins two similar drugs from Arena Pharmaceuticals and Vivus Inc. which FDA approved in 2012 after a 13-year drought of new prescription weight-loss medicines. Analysts initially predicted those drugs would garner up to \$1 billion in annual sales, considering that more than one-third of all U.S. adults are obese. But sales of Vivus' Qsymia and Arena's Belviq have been far below expectations due to limited insurance coverage and high out-of-pocket costs for patients.

Dr. Ronald Tamler of Mount Sinai Hospital's diabetes center says he prescribes weight loss drugs only when patients have failed to lose weight through lifestyle changes. Even then, he says insurers are reluctant to cover the medications.

"With any of these weight-loss medications, the minute you stop taking it, you start regaining the weight," Tamler said. "That means the patient is facing a life of being on medication, which is not attractive for patients or third-party payers."

Contrave was developed by Orexigen Therapeutics Inc., based in La Jolla, California. The Food and Drug Administration said Thursday that it is approved for use by people who have a body mass index of 30 or higher, which is the level at which people are considered to be obese. It is also approved for use by people with a BMI of 27 or higher who also have a weight-related medical condition such as diabetes.

The agency approved the drug for use in combination with a reduced-calorie diet and exercise.

Experts say patients need to have realistic expectations about how much weight they can lose by taking a pill. Patients on Contrave for a year lost 4.2 percent more weight than patients taking a dummy pill.

That compares with weight loss between 3 percent and 3.7 percent for Belviq and 6.7 percent to 8.9 percent for Qsymia, both also measured against placebo.

Drug-induced weight loss is much smaller than that seen with surgical procedures, such as gastric bypass, which can produce a 25 percent to 30 percent drop in weight, on average.

Doctors who treat obesity say they use drugs like Contrave as a chance to educate patients on choosing a healthier, low-calorie diet.

Contrave will have a boxed warning about the risk of suicidal thoughts associated with antidepressants like Bupropion.

Experts caution that potentially dangerous drug interactions are a risk with the new generation of weight-loss drugs.

"Physicians prescribing these brain medications have to review patients other medications because they're frequently on antidepressants and

there's an interaction," said Tamler.

Additional Contrave risks include the possibility of seizures, as well as increased blood pressure and heart rates.

The heart effects created a long road to approval for Contrave. The FDA refused to approve the drug in 2011, citing cardiovascular risks.

Orexigen resubmitted its application to regulators in December, saying that the drug fared well in an early analysis of a study designed to rule out excessive cardiovascular risk.

Contrave will have an uphill battle in the U.S. market after the disappointing performance of rival treatments from Vivus Inc. and Arena Pharmaceuticals Inc. In the most recent quarter Vivus reported sales of \$11 million for Qsymia, while Arena Pharmaceuticals reported \$9.9 million in Belviq sales.

Contrave will be distributed in the U.S. by Japanese drugmaker Takeda Pharmaceuticals, which will pay Orexigen royalties on sales. Orexigen and Takeda plan to start selling the drug this fall.

Shares of Orexigen Therapeutics Inc. fell 51 cents, or 8.6 percent to \$5.39 in trading.

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