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FDA panel backs Novo Nordisk injection for obesity

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Federal health experts say a diabetes drug from Novo Nordisk should be approved for a new use in treating obesity.

The panel of Food and Drug Administration advisers voted 14-1 that the injectable drug's benefits outweigh it risks for patients who are obese or dangerously overweight.

The FDA first approved the drug, liraglutide, under the brand name Victoza in 2010 as a daily injection for type 2 diabetes, in which the body does not properly use insulin. The drug is part of a new class of medicines called GLP-1 agonists, which spur the pancreas to create extra insulin after meals.

Danish drugmaker Novo Nordisk now wants the FDA to approve the drug as an obesity treatment based on company studies showing significant weight loss in most patients.

Sixty percent of patients taking the drug for over a year lost at least 5 percent of their body weight, and 31 percent of patients lost more than 10 percent, according to the company's research. Among patients taking a sham treatment only 24 percent lost 5 percent of their body weight and 9 percent lost more than 10 percent. The FDA said the difference between the two was statistically significant and meets the agency's criteria for effectiveness.

If approved, Novo Nordisk plans to market the drug under a new brand

name, Saxenda. It would be the first injectable drug approved for weight loss. The FDA panel recommended approving the drug for patients who have a body mass index of 30 or higher, which is the level at which people are considered to be obese. It would also be approved for people with a BMI of 27 or higher who also have a weight-related medical condition such as diabetes.

The FDA is not required to follow the advice of its experts, though it often does.

Dr. Maria Pena of Syosset Hospital in New York noted that some doctors already prescribe the drug "off-label" for weight loss, due to its effects on metabolism and the digestive process: "That increases the feeling of satiety and subsequently people tend to eat a little less and lose some weight," she said.

Earlier Thursday the FDA approved the long-delayed weight loss pill, Contrave, from Orexigen Therapeutics Inc. The FDA first rejected the drug in 2011, citing cardiovascular risks. Orexigen resubmitted its application to regulators in December after performing another analysis designed to rule out heart problems.

The pill 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.

Shares of Novo Nordisk AS rose 83 cents, or 1.8 percent, to close at $46.78.

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