US FDA accepts Novo Nordisk's application for oral Wegovy for weight loss

Novo Nordisk's oral GLP-1 drug Rybelsus, which also has the same active ingredient semaglutide, is already approved for blood sugar control in adults with diabetes.

Bengaluru: The U.S. Food and Drug Administration has accepted Novo Nordisk's marketing application for an oral version of its weight-loss drug Wegovy and will decide in the fourth quarter, the Danish drugmaker said on Friday.

The company's experimental once-daily version will become the first oral GLP-1 for chronic weight management, if approved.

U.S.-listed shares of Novo added to session gains and were last up 5.72% at $69.36 following the news.

Novo Nordisk's oral GLP-1 drug Rybelsus, which also has the same active ingredient semaglutide, is already approved for blood sugar control in adults with diabetes.

Novo, Eli Lilly and several drug developers are racing to introduce oral weight-loss pills as an easy-to-use treatment in a market dominated by injections, encouraged by estimates that obesity treatment sales could hit $150 billion in the coming years.

Last month, Lilly said its experimental pill, orforglipron, helped patients with type 2 diabetes lose 16 pounds, or nearly 8% of their body weight, over 40 weeks.

The company will report data from another trial for the pill for weight management later in the year. It plans to file for approval with global regulators for weight loss by the end of this year and for diabetes next year.

Lilly's injectable tirzepatide is sold under the brand names Mounjaro for diabetes and Zepbound for weight loss.

Novo's application is based on results from a late-stage trial, which studied 25 milligram dose of oral semaglutide compared to placebo in 307 adults with obesity with one or more comorbidities.

The company is also studying weight-loss pill amycretin, which targets the same gut hormone that Wegovy mimics, known as GLP-1, but also a pancreas hormone called amylin that affects hunger. It is also testing a subcutaneous version of the drug.

Novo has come under pressure as investors worried about the growing competition with Lilly as well as disappointing data from its next-generation weight-loss candidate CagriSema, which the company hopes will be a powerful successor to Wegovy.

News Source:

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/us-fda-accepts-novo-nordisks-application-for-oral-wegovy-for-weight-loss/120839125?utm_source=whatsapp_web&utm_medium=social&utm_campaign=socialsharebuttons