

# company announcement

## Novo Nordisk to initiate phase 3a development in obesity with oral semaglutide

**Bagsværd, Denmark, 21 April 2021** – Novo Nordisk today announced the decision to enter phase 3a development in obesity with oral semaglutide 50 mg. The decision follows the completion of the STEP phase 3a clinical programme with once-weekly subcutaneous (sc) semaglutide 2.4 mg.

Novo Nordisk intends to initiate a pivotal phase 3a programme with approximately 1,000 people with obesity or overweight with comorbidities. The global 68-week trial is planned for initiation in the second half of 2021 and will investigate the efficacy and safety of oral semaglutide compared to placebo.

“There is a significant unmet medical need within obesity treatment today. With oral semaglutide we aim to introduce a convenient and effective treatment option for people with obesity and healthcare providers enabling broader use of anti-obesity medication,” said Martin Holst Lange, executive vice president, Development at Novo Nordisk. “As a complement to our injectable anti-obesity medications, oral semaglutide has the potential to help more people living with obesity achieve weight loss goals and improve their health.”

### About obesity

Obesity is a chronic disease that requires long-term management. It is associated with many serious health complications and decreased life expectancy. Obesity-related complications are numerous and include type 2 diabetes, cardiovascular disease, obstructive sleep apnoea, non-alcoholic fatty liver disease and certain types of cancer. The current COVID-19 pandemic has shown that obesity also increases the risk of severe illness and hospitalisation due to COVID-19.

The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems. Approximately 650 million adults are estimated to live with obesity worldwide.

## About semaglutide 2.4 mg for weight management and STEP

Once-weekly sc semaglutide 2.4 mg is currently under regulatory review in the US and the EU as a treatment for adults with obesity. Semaglutide is an analogue of the human glucagon-like peptide-1 (GLP-1) hormone. It induces weight loss by reducing hunger, increasing feeling of fullness and thereby helping people eat less and reduce their calorie intake.

The submissions for regulatory review are based on the results from the STEP (Semaglutide Treatment Effect in People with obesity) phase 3 clinical development programme. The global clinical phase 3a programme consisted of four trials and enrolled approximately 4,500 adults with overweight or obesity.

## About oral semaglutide

Oral semaglutide (7 mg and 14 mg) is approved as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes in the US, EU and Japan under the trade name, Rybelsus®. The approval of Rybelsus® is based on the results from 10 clinical trials which included 9,543 adults with type 2 diabetes. Rybelsus® demonstrated a safe and well-tolerated profile across the clinical trials, with the most common adverse event being mild to moderate nausea which diminished over time.

## About Novo Nordisk

*Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 45,000 people in 80 countries and markets its products in around 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit [novonordisk.com](http://novonordisk.com), [Facebook](https://www.facebook.com/novonordisk), [Twitter](https://twitter.com/novonordisk), [LinkedIn](https://www.linkedin.com/company/novonordisk), [YouTube](https://www.youtube.com/novonordisk).*

## Further information

### Media:

Mette Kruse Danielsen	+45 3079 3883	<a href="mailto:mkd@novonordisk.com">mkd@novonordisk.com</a>
Michael Bachner (US)	+1 609 664 7308	<a href="mailto:mzyb@novonordisk.com">mzyb@novonordisk.com</a>

### Investors:

Daniel Muusmann Bohsen	+45 3075 2175	<a href="mailto:dabo@novonordisk.com">dabo@novonordisk.com</a>
Valdemar Borum Svarrer	+45 3079 0301	<a href="mailto:jvls@novonordisk.com">jvls@novonordisk.com</a>
Ann Søndermølle Rendbæk	+45 3075 2253	<a href="mailto:arnd@novonordisk.com">arnd@novonordisk.com</a>
Mark Joseph Root	+45 3079 4211	<a href="mailto:mjhr@novonordisk.com">mjhr@novonordisk.com</a>
Kristoffer Due Berg (US)	+1 609 235 2989	<a href="mailto:krdb@novonordisk.com">krdb@novonordisk.com</a>