

company announcement

Novo Nordisk successfully completes AM833 phase 2 trial and phase 1 combination trial with AM833 and semaglutide in obesity

Bagsværd, Denmark, 18 June 2020 – Novo Nordisk today announced the headline results from two clinical trials with a novel once-weekly subcutaneous amylin analogue (AM833), a phase 2 monotherapy trial and a phase 1 combination trial of AM833 and once-weekly subcutaneous semaglutide 2.4 mg.

AM833 phase 2 monotherapy trial

The 26-week blinded phase 2 monotherapy trial with AM833 investigated safety, tolerability and efficacy for weight management in 706 people with obesity or overweight with at least one weight-related comorbidity. The patients were randomised to treatment with five different weekly doses of AM833 (0.3 mg, 0.6 mg, 1.2 mg, 2.4 mg, 4.5 mg), liraglutide 3.0 mg or placebo. Approximately 100 people were included in each treatment arm. All treatments were administered in combination with lifestyle intervention therapy. The mean baseline body weight in the trial was 107.4 kg.

The trial reached its primary endpoint by demonstrating a weight loss of 10.8% at week 26 with AM833 at the 4.5 mg dose, compared to a weight loss of 3.0 % with placebo¹. The treatment difference was statistically significant. AM833 appeared to have a safe and well-tolerated profile.

AM833 and semaglutide phase 1 combination trial

The 20-week multiple ascending dose phase 1 trial investigated safety, tolerability, pharmacokinetics and weight loss potential of AM833 administered in combination with semaglutide 2.4 mg in 80 people with obesity or overweight.

After 20 weeks of treatment, participants receiving the highest dose lost an average of 17.1% body weight from a mean baseline body weight of 95.1 kg (secondary endpoint)¹.

¹ Based on trial product estimand: treatment effect if all people adhered to treatment and did not initiate other anti-obesity therapies

The trial investigated the number of treatment-emergent adverse events (primary endpoint) and AM833 was well-tolerated, with the most common adverse events being gastrointestinal disorders including nausea and vomiting, the majority being non-serious and mild or moderate in severity. The level of gastrointestinal disorders observed for the combination of AM833 and semaglutide in the trial was comparable to what is generally seen for glucagon-like peptides-1 (GLP-1) in monotherapy.

"We are encouraged by these impressive results and we look forward to further assessing the efficacy and safety of AM833," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "The phase 1 and 2 data with AM833 for weight management, especially the combination with semaglutide, further strengthen Novo Nordisk's obesity pipeline and hold potential to close the gap between pharmacotherapy and bariatric surgery" said Mads Krogsgaard Thomsen.

About obesity and AM833 for weight management

Obesity is a chronic disease that requires long-term management. It is associated with many serious health consequences and decreased life expectancy. Obesity-related complications are numerous and include type 2 diabetes, heart disease, obstructive sleep apnoea, chronic kidney disease, non-alcoholic fatty liver disease and cancer.

AM833 is being investigated by Novo Nordisk for weight management in people with obesity and overweight with at least one weight-related comorbidity. AM833 is an acylated long-acting analogue of the human amylin hormone that induces weight loss by reducing energy intake.

About sc semaglutide 2.4 mg for weight management

Once-weekly sc semaglutide 2.4 mg is being investigated by Novo Nordisk as a treatment for adults with obesity. Semaglutide is an analogue of the human GLP-1 hormone. It induces weight loss by reducing hunger, increasing feelings of fullness and thereby helping people eat less and reduce their calorie intake.

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 43,100 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, Facebook, Twitter, LinkedIn, YouTube.

Further information

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