

## press release

### **Wegovy™ demonstrated significant and sustained weight loss in two-year study in adults with obesity**

- The STEP 5 trial demonstrated an average weight loss of 15.2% with Wegovy™ at 104-weeks when used with a reduced calorie meal plan and increased physical activity vs. 2.6% with placebo
- The trial also showed that 77.1% of study participants who received Wegovy™ lost at least 5% of their body weight, compared to 34.4% of those who received placebo

**Bagsværd, Denmark, 5 November 2021** – Results from the STEP 5 phase 3b trial, presented today at the ObesityWeek® 2021 interactive congress, showed that adults treated with Wegovy™ (semaglutide 2.4 mg injection) achieved significant and sustained weight loss over the two-year study period. The STEP 5 trial investigated Wegovy™ vs. placebo, both used with a reduced calorie meal plan and increased physical activity for the treatment of obesity (BMI ≥30 kg/m<sup>2</sup>) or overweight (BMI ≥27 kg/ m<sup>2</sup>) in 304 adults with at least one weight-related comorbidity for 104 weeks (two years).<sup>1</sup>

In the STEP 5 trial, results showed that Wegovy™ used with a reduced calorie meal plan and increased physical activity significantly reduced body weight from baseline to week 104 compared to placebo (-15.2% vs. -2.6%, estimated treatment difference: -12.6% -points [95% CI: -15.3, -9.8]; p<0.0001)\*. The study also demonstrated that adults with overweight or obesity were more likely to lose at least 5% of their body weight with Wegovy™ vs. placebo (77.1% vs. 34.4%; p<0.0001).

“People with obesity try on average seven times to lose weight before seeking medical care. Once weight is lost, however, it all too often comes back, which is why it is critically important to find options to help people living with obesity lose weight and keep it off,” said W. Timothy Garvey, MD, Professor of Medicine, Department of Nutrition Sciences at the University of Alabama in Birmingham. “Results from the STEP 5 clinical trial demonstrated that adults with obesity were able to lose weight whilst taking Wegovy™ and maintain the weight loss at two years, which can help us better treat and manage obesity as a chronic disease.”

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\* Based on treatment policy estimand results

Based on 68-week trials, the most frequently reported adverse events with Wegovy™ were nausea, diarrhoea, vomiting, constipation and abdominal pain.<sup>2,3</sup> In the STEP 5 trial, the safety profile of Wegovy™ was in line with previous STEP phase 3a trials; 5.9% of patients treated with Wegovy™ and 4.6% of patients treated with placebo permanently discontinued treatment as a result of adverse reactions.<sup>1</sup>

“With current obesity treatments we tend to see a waning of the weight-lowering effects of the treatment over time. We set out to investigate if that would hold true also for semaglutide 2.4 mg. It is very encouraging for us to see that even after two years of treatment with semaglutide 2.4 mg, we still see a significant and sustained weight loss of 15%. We are very pleased with the promise these findings offer to people living with obesity. For many people, maintaining an achieved weight loss over time is an equally big challenge as achieving the weight loss in the first place,” said Martin Holst Lange, executive vice president, Development at Novo Nordisk.

### **About STEP 5 and the STEP clinical trial programme**

STEP 5 was a phase 3b randomised, double-blind, placebo-controlled trial that investigated the effect of semaglutide 2.4 mg as an adjunct to lifestyle intervention (–500 kcal/day diet together with 150 minutes/week of physical activity) on sustained weight loss (for 2 years) in 304 adults with obesity, without type 2 diabetes. Participants were randomly assigned (in a 1:1 ratio) to once-weekly subcutaneous semaglutide 2.4 mg or placebo for ~~68~~ 104 weeks.

<b>68 corrected to 104</b> 16 Nov 2021
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The primary endpoint of the trial was a change in body weight (%) and a proportion of participants who achieved greater than or equal to 5% weight loss at week 104. Key secondary objectives included the proportion of participants achieving a body weight reduction  $\geq 10\%$  or  $\geq 15\%$  from baseline at 104 weeks and change from baseline to week 104 in waist circumference and systolic blood pressure.<sup>1</sup>

STEP (**S**emaglutide **T**reatment **E**ffect in **P**eople with obesity) is a phase 3 clinical development programme with once-weekly subcutaneous semaglutide 2.4 mg in obesity. The global clinical phase 3a programme consists of four trials and has enrolled approximately 4,500 adults with overweight or obesity.<sup>2</sup> In the STEP trials, the primary estimand (treatment policy estimand) assessed effects regardless of treatment adherence or initiation of other anti-obesity therapies. The secondary estimand (trial product estimand) assessed effects if all people adhered to treatment and did not initiate other anti-obesity therapies.

### **About Wegovy™ (semaglutide 2.4 mg) for weight management**

Wegovy™ (semaglutide 2.4 mg) is currently approved for weight management as an adjunct to diet and exercise in the US and UK only and is under review by the European Medicines Agency (EMA) and several other health authorities.

Semaglutide is an analogue of the human glucagon-like peptide-1 (GLP-1) hormone, with 94% similarity to the native human GLP-1 molecule.<sup>4,5</sup> It induces weight loss by reducing hunger,

increasing feeling of fullness and thereby helping people eat less and reduce their food cravings.<sup>4</sup>

### About obesity

Obesity is a chronic disease that requires long-term management.<sup>6,7</sup> It is associated with many serious health complications and decreased life expectancy.<sup>8,9</sup> Obesity-related complications are numerous and include type 2 diabetes,<sup>7</sup> heart disease,<sup>7</sup> obstructive sleep apnoea,<sup>10</sup> non-alcoholic fatty liver disease<sup>11</sup> and certain types of cancer.<sup>12</sup> The current COVID-19 pandemic has highlighted that obesity also increases the risk for severe illness and hospitalisation due to COVID-19.<sup>13,14</sup>

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.<sup>15</sup>

### 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 47,000 people in 80 countries and markets its products in around 170 countries. For more information, visit [novonordisk.com](http://novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#).*

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### References

1. Garvey WT, et al. Two-year Effect of Semaglutide 2.4 mg vs Placebo in Adults with Overweight or Obesity (STEP 5). Presented at the 39th Annual Meeting of The Obesity Society (TOS) held at ObesityWeek®, November 1–5, 2021.

2. Kushner RF, Calanna S, Davies M, *et al.* Semaglutide 2.4 mg for the Treatment of Obesity: Key Elements of the STEP Trials 1 to 5. *Obesity*. 2020; 28:1050-1061.
3. FDA. Wegovy®(semaglutide 2.4 mg) prescribing information. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/215256s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215256s000lbl.pdf). Last Accessed: November 2021.
4. Blundell J, Finlayson G, Axelsen M, *et al.* Effects of once-weekly semaglutide on appetite, energy intake, control of eating, food preference and body weight in subjects with obesity. *Diabetes Obes Metab*. 2017; 19:1242-1251.
5. Lau J, Bloch P, Schaffer L, *et al.* Discovery of the Once-Weekly Glucagon-Like Peptide-1 (GLP-1) Analogue Semaglutide. *J Med Chem*. 2015; 58:7370-7380.
6. American Medical Association. A.M.A Adopts New Policies on Second Day of Voting at Annual Meeting. Obesity as a Disease. Available at: <http://news.cision.com/american-medical-association/r/ama-adopts-new-policies-on-second-day-of-voting-at-annual-meeting.c9430649>. Last accessed: November 2021.
7. WHO. Obesity: Preventing and managing the global epidemic. Available at: <http://www.who.int/iris/handle/10665/42330> Last accessed: November 2021.
8. Peeters A, Barendregt JJ, Willekens F, *et al.* Obesity in adulthood and its consequences for life expectancy: a life-table analysis. *Ann Intern Med*. 2003; 138:24-32.
9. Guh DP, Zhang W, Bansback N, *et al.* The incidence of co-morbidities related to obesity and overweight: a systematic review and meta-analysis. *BMC Public Health*. 2009; 9:88.
10. Gami AS, Caples SM and Somers VK. Obesity and obstructive sleep apnea. *Endocrinology and Metabolism Clinics of North America*. 2003; 32:869-894.
11. Vernon G, Baranova A and Younossi ZM. Systematic review: the epidemiology and natural history of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis in adults. *Aliment Pharmacol Ther*. 2011; 34:274-285.
12. Whitlock G, Lewington S, Sherliker P, *et al.* Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. *Lancet*. 2009; 373:1083-1096.
13. Finer N, Garnett SP and Bruun JM. COVID-19 and obesity. *Clin Obes*. 2020; 10:e12365.
14. Ryan DH, Ravussin E and Heymsfield S. COVID 19 and the Patient with Obesity - The Editors Speak Out. *Obesity (Silver Spring)*. 2020; 28:847.
15. World Health Organization. Obesity and Overweight Factsheet no. 311. Available at: <http://www.who.int/mediacentre/factsheets/fs311/en/>. Last accessed: November 2021.