press release

Investigational 2.0 mg dose of Ozempic® (semaglutide) demonstrates superior reductions in blood sugar vs Ozempic® 1.0 mg in adults with type 2 diabetes in a phase 3 trial

Bagsværd, Denmark, 26 June 2021 – Novo Nordisk today presented data showing that an investigational 2.0 mg dose of Ozempic® (semaglutide) provided statistically significant and superior reductions in blood sugar (HbA_{1C}) compared with Ozempic® 1.0 mg[1]. These data were the outcome of the SUSTAIN FORTE trial, a phase 3b, 40-week, efficacy and safety trial comparing once-weekly semaglutide 2.0 mg vs Ozempic® 1.0 mg as add-on to metformin with or without sulfonylureas in 961 adults with type 2 diabetes in need of additional blood sugar reduction. The results were presented at the 81st Annual Scientific Sessions of the American Diabetes Association (ADA)[1, 2] and primary results are in press for publication in *The Lancet Diabetes & Endocrinology.*

The trial met its primary endpoint, where people treated with once-weekly semaglutide 2.0 mg with an elevated mean baseline HbA_{1C} of 8.9% demonstrated a statistically significant and superior 2.2% reduction in HbA_{1C} compared with a reduction of 1.9% seen with Ozempic® 1.0 mg after 40 weeks, when taken as intended*[1].

Further post-hoc subgroup analyses, presented at the congress, showed that semaglutide 2.0 mg demonstrated greater reductions in blood sugar at 40 weeks compared with Ozempic® 1.0 mg, across baseline HbA_{1C} subgroups (Table 1)[2].

”Some people living with type 2 diabetes require additional support to reach their blood glucose targets,” said Dr Juan Pablo Frias, medical director of the National Research Institute, Los Angeles, and principal investigator of SUSTAIN FORTE. “The reductions in blood glucose seen with semaglutide 2.0 mg demonstrate that a higher dose of Ozempic® may offer individuals the opportunity to further improve their diabetes control, with comparable tolerability to Ozempic® 1.0 mg."

*Based on the trial product estimand: treatment effect if all people adhered to treatment and did not initiate other type 2 diabetes therapies. When applying the treatment policy estimand, which is the treatment effect regardless of treatment adherence or initiation of other type 2 diabetes therapies, people treated with semaglutide 2.0 mg experienced a reduction in HbA_{1C} of 2.1% compared to 1.9% for people treated with the 1.0 mg dose at Week 40.

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From a mean baseline body weight of 99.3 kg, semaglutide 2.0 mg demonstrated a statistically significant weight reduction of 6.9 kg compared with 6.0 kg with Ozempic 1.0 kg®*. Further post-hoc analyses presented across baseline BMI subgroups showed greater non-significant reductions in body weight with semaglutide 2.0 mg compared with the 1.0 mg dose (Table 1).

The incidence of adverse events (AEs) was similar for both doses in the primary analysis and included gastrointestinal events (nausea, diarrhoea and vomiting) across baseline HbA_{1C} and BMI subgroups[1,2]. This is consistent with AEs seen across the GLP-1 RA class.

"Ozempic® has helped millions of people with type 2 diabetes worldwide lower their blood sugar, reduce their risk of major cardiovascular events in adults with established cardiovascular disease and has demonstrated weight reduction for some patients," said Martin Lange, executive vice president of Novo Nordisk. "For almost a century, our mission has been to drive change in diabetes treatment and innovation to improve the lives of people living with diabetes. These data show us that with a higher 2.0 mg dose of semaglutide, we can help even more adults living with type 2 diabetes, who are not at glycaemic control, lower their HbA_{1c}."

	Post-hoc subgroup analysis of primary endpoint: Change in HbA_{1C}[2]				**Post-hoc subgroup analysis of secondary endpoint: Change in body weight[2]**			
Baseline	HbA_{1C} <9.0%	HbA_{1C} ≥9.0%	BMI <35	BMI ≥35	HbA_{1C} <9.0%	HbA_{1C} ≥9.0%	BMI <35	BMI ≥35
Semaglutide 2.0 mg	-1.9%	-2.6%	-2.2%	-2.1%	-7.4 kg	-6.3 kg	-6.6 kg	-7.4 kg
Ozempic® 1.0 mg	-1.7%	-2.3%	-1.9%	-2.0%	-6.2 kg	-5.8 kg	-5.2 kg	-7.1 kg

*Table 1. Post-hoc subgroup analysis showing change in mean HbA_{1C} and body weight stratified from baseline to Week 40**.*

On the basis of the primary results, Novo Nordisk previously announced submission of a label extension application to the European Medicines Agency (EMA) in December 2020, and to the US Food and Drug Administration (FDA) in May 2021, to evaluate an additional higher dose of 2.0 mg Ozempic® for adults with type 2 diabetes.

For more news and media materials from Novo Nordisk at ADA 2021, please visit: https://novonordiskada2021.mediahub.cplus.live/

About Ozempic®

*Based on the trial product estimand: treatment effect if all people adhered to treatment and did not initiate other type 2 diabetes therapies. Based on the treatment policy estimand, people treated with semaglutide 2.0 mg experienced a statistically non-significant weight reduction of 6.4 kg compared with 5.6 kg with Ozempic® 1.0 mg. Treatment policy estimand: treatment effect regardless of treatment adherence or initiation of other type 2 diabetes therapies.

**Treatment-by-treatment subgroup interactions were non-significant. Data are estimated mean values and represent all randomised participants who had not discontinued treatment or initiated additional antidiabetic medications.

Ozempic® (semaglutide) injection 0.5 mg or 1.0 mg is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist indicated along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes mellitus[3, 4] and to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes mellitus with known heart disease[4].

About the SUSTAIN clinical programme

The SUSTAIN clinical development programme for once-weekly subcutaneous semaglutide injection currently comprises 11 phase 3 global clinical trials, including a cardiovascular outcomes trial, involving more than 11,000 adults with type 2 diabetes in total.

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 45,800 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

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