Semaglutide demonstrated superior HbA₁c reduction vs placebo as add-on to basal insulin alone or with metformin in adults with type 2 diabetes

Munich, Germany, 13 September 2016 – Novo Nordisk today announced that semaglutide, an investigational glucagon-like peptide-1 (GLP-1) analogue administered once-weekly, significantly improved glycaemic control compared to placebo, as add-on to basal insulin alone or in combination with metformin, in adults with a mean type 2 diabetes duration of 13 years. Results from SUSTAIN 5 were presented today at the 52nd Annual Meeting of the European Association for the Study of Diabetes (EASD) 2016.¹

The 30-week trial showed that, from a mean baseline HbA₁c of 8.4%, adults treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significant and superior HbA₁c reductions of 1.4% and 1.8%, respectively, vs 0.1% reduction with placebo. In addition, more adults treated with 0.5 mg and 1.0 mg semaglutide achieved HbA₁c targets compared with placebo: HbA₁c <7% (61% and 79% vs 11 %) and ≤6.5% (41% and 61% vs 5%).¹

Adults with type 2 diabetes treated with 0.5 mg and 1.0 mg semaglutide achieved superior weight loss vs placebo (3.7 kg and 6.4 kg vs 1.4 kg) from a mean baseline body weight of 91.7 kg.¹

“In the SUSTAIN 5 trial, we have seen that adding once-weekly semaglutide to basal insulin alone or in combination with metformin can help people with long-standing type 2 diabetes achieve glycaemic control and weight loss,” said Dr Helena Rodbard, SUSTAIN 5 investigator and Medical Director at Endocrine and Metabolic Consultants, Rockville, Maryland. “As a treating physician, I am encouraged by these findings as many people with long-standing type 2 diabetes experience suboptimal glucose control and weight gain.”

Adults treated with both doses of semaglutide demonstrated significantly greater reductions in fasting plasma glucose (FPG) vs placebo (1.6 mmol/L and 2.4 mmol/L vs 0.5 mmol/L), from a mean FPG baseline of 8.6 mmol/L. Furthermore, both semaglutide doses resulted in significant postprandial glucose reduction, measured as the postprandial increment of 7-point self-measured plasma glucose compared to placebo.¹
Adverse events were reported for 68.9% and 64.1% of adults treated with 0.5 mg and 1.0 mg semaglutide, respectively, and for 57.9% of adults treated with placebo. The rates of serious adverse events observed for adults treated with 0.5 mg and 1.0 mg semaglutide compared with placebo were 6.1% and 9.2% vs 6.8%. The proportion of adults treated with 0.5 mg and 1.0 mg semaglutide discontinuing due to adverse events were 4.5% and 6.1% vs 0.8% with placebo; the majority of discontinuations with semaglutide were due to gastrointestinal adverse events.1

About semaglutide
Semaglutide is a once-weekly investigational analogue of human glucagon-like peptide-1 (GLP-1) that stimulates insulin and suppresses glucagon secretion in a glucose-dependent manner, while decreasing appetite and food intake.2 With SUSTAIN 6, semaglutide administered subcutaneously once-weekly has completed six phase 3a clinical trials for the treatment of adults with type 2 diabetes.

About SUSTAIN 5
SUSTAIN 5 is a randomised, double-blind, placebo-controlled, parallel-group and multinational trial investigating the safety and efficacy of semaglutide, administered once-weekly, vs placebo both as add-on to basal insulin alone or basal insulin in combination with metformin in 397 adults with a mean type 2 diabetes duration of 13.3 years. The primary end point was change in HbA1c from baseline after 30 weeks of treatment. Secondary endpoints included change in body weight from baseline after 30 weeks of treatment. The trial was conducted in the US, Germany, Japan, Puerto Rico, Serbia and Slovakia.

About the SUSTAIN clinical programme
SUSTAIN (Semaglutide Unabated Sustainability in Treatment of Type 2 Diabetes) is a clinical programme for semaglutide, administered once-weekly, that comprises six phase 3a global clinical trials encompassing more than 7,000 adults with type 2 diabetes as well as two Japanese trials encompassing around 1,000 adults with type 2 diabetes.
About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,300 people in 75 countries and markets its products in more than 180 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

Further information

Media:
Katrine Sperling +45 4442 6718 krsp@novonordisk.com
Åsa Josefsson +45 3079 7708 aajf@novonordisk.com

Investors:
Peter Hugreff Ankersen +45 3075 9085 phak@novonordisk.com
Melanie Raouzeos +45 3075 3479 mrz@novonordisk.com
Hanna Ögren +45 3079 8519 haoe@novonordisk.com
Kasper Veje (US) +1 609 235 8567 kpvj@novonordisk.com

References
