press release

Semaglutide demonstrated superior improvements in glycaemic control vs placebo in adults with type 2 diabetes

Boston, US, 2 April 2016 – Findings from the first phase 3a clinical trial for semaglutide, an investigational glucagon-like peptide-1 (GLP-1) analogue, demonstrated that treatment with semaglutide administered once-weekly, significantly improved glycaemic control compared to placebo in adults with type 2 diabetes previously managed with diet and exercise alone. Results from the SUSTAIN 1 trial were presented today at the Endocrine Society’s 98th Annual Meeting and Expo (ENDO 2016) in Boston, MA, US.¹

The 30-week SUSTAIN 1 trial, evaluating the efficacy and safety of semaglutide monotherapy vs placebo in 388 adults with type 2 diabetes,¹ showed that, from a mean baseline HbA₁c of 8.1%, adults treated with 0.5 mg and 1.0 mg semaglutide achieved significantly greater HbA₁c reductions of 1.5% and 1.6%, respectively, vs <0.1% with placebo.

In addition, more adults treated with 0.5 mg and 1.0 mg semaglutide achieved HbA₁c targets compared with placebo: HbA₁c <7% (74% and 72% vs 25%) and ≤6.5% (59% and 60% vs 13%). The trial also demonstrated that adults treated with 0.5 mg and 1.0 mg semaglutide achieved significantly greater reductions from baseline in mean body weight of 3.7 kg/8.16 lb and 4.5 kg/9.92 lb, respectively, vs 1.0 kg/2.20 lb with placebo.¹

"Achieving glycaemic control remains a significant challenge for people with type 2 diabetes and their treating physicians," said Christopher Sorli, SUSTAIN 1 investigator and Chair of the Department of Diabetes, Endocrinology and Metabolism, Billings Clinic, US. "It is encouraging that almost three out of four adults treated with semaglutide in the SUSTAIN 1 trial achieved the HbA₁c target of less than seven percent."

Furthermore, adults treated with both doses of semaglutide demonstrated significantly greater reductions from baseline in fasting plasma glucose compared with placebo (2.5 mmol/L or 45.2 mg/dL and 2.3 mmol/L or 42.1 mg/dL, respectively, vs 0.6 mmol/L or 9.9 mg/dL).¹
The most common adverse events observed for adults treated with 0.5 mg and 1.0 mg semaglutide and placebo were gastrointestinal, which were mainly mild or moderate (nausea: 20.3% and 23.8% vs 7.8%; vomiting: 3.9% and 6.9% vs 1.6%; diarrhoea: 12.5% and 10.8% vs 2.3%). The rate of nausea diminished over time. Comparable rates of severe adverse events were observed for adults treated with 0.5 mg and 1.0 mg semaglutide compared with placebo (5.5% and 5.4% vs 3.9%). The proportion of adults discontinuing due to adverse events was low across treatment groups (6.3% and 5.4% vs 2.3%).

**About semaglutide**
Semaglutide is an analogue of native human glucagon-like peptide-1 (GLP-1) that stimulates insulin and suppresses glucagon secretion in a glucose-dependent manner, as well as decreases appetite and food intake. Semaglutide administered subcutaneously once-weekly is in phase 3 development for the treatment of type 2 diabetes.

**About SUSTAIN 1**
SUSTAIN 1 is a randomised, double-blind, placebo-controlled, multicentre, multinational 30-week trial investigating the safety and efficacy of semaglutide, administered once-weekly, versus placebo in 388 people with type 2 diabetes who had not received any blood glucose lowering therapies 90 days prior to trial participation. The trial was conducted in Canada, Italy, Japan, Mexico, Russia, South Africa, UK and the US.

**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 people with type 2 diabetes as well as two Japanese trials encompassing around 1,000 people 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 41,000 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
Daniel Bohsen      +45 3079 6376    dabo@novonordisk.com
Melanie Raouzeos +45 3075 3479    mrz@novonordisk.com
Kasper Veje        +45 3079 8519    kpvj@novonordisk.com

References