Semaglutide demonstrated superior improvements in glycaemic control vs sitagliptin (SUSTAIN 2) and exenatide ER (SUSTAIN 3) in two clinical trials in adults with type 2 diabetes

New Orleans, US, 12 June 2016 – Findings from two phase 3a clinical trials for semaglutide, an investigational glucagon-like peptide-1 (GLP-1) analogue, were presented today at the American Diabetes Association 76th Scientific Sessions.\textsuperscript{1,2} In the SUSTAIN 2 trial, 0.5 mg and 1.0 mg semaglutide administered once-weekly significantly improved glycaemic control compared to sitagliptin (100 mg), a dipeptidyl peptidase-4 (DPP-4) inhibitor, in adults with type 2 diabetes.\textsuperscript{1} In the SUSTAIN 3 trial, 1.0 mg semaglutide administered once-weekly significantly improved glycaemic control compared to 2.0 mg exenatide extended-release (ER), a GLP-1 receptor agonist, in adults with type 2 diabetes.\textsuperscript{2}

The SUSTAIN 2 trial showed that from a mean baseline HbA\textsubscript{1c} of 8.1%, adults with type 2 diabetes treated with 0.5 mg and 1.0 mg semaglutide achieved superior HbA\textsubscript{1c} reductions of 1.3% and 1.6%, respectively, vs 0.5% with 100 mg sitagliptin at 56 weeks (both p<0.0001), as add-on to metformin and/or thiazolidinediones.\textsuperscript{1}

In the 56-week SUSTAIN 3 trial, adults with type 2 diabetes and a mean baseline HbA\textsubscript{1c} of 8.3% achieved a superior HbA\textsubscript{1c} reduction of 1.5% when treated with 1.0 mg semaglutide vs 0.9% with 2.0 mg exenatide ER (p<0.0001), as add-on to one or two oral antidiabetics (metformin, sulfonylurea or thiazolidinediones).\textsuperscript{2}

“Many people with type 2 diabetes struggle to reach individualised treatment goals,” said Bo Ahrén, Professor of Clinical Metabolic Research at the Department of Clinical Sciences, Lund University, Sweden. “The superior glucose reductions achieved with once-weekly semaglutide vs sitagliptin in SUSTAIN 2 are encouraging as new treatment options are needed to address these treatment goal challenges.”

More adults with type 2 diabetes achieved the HbA\textsubscript{1c} target of <7% when treated with 0.5 mg and 1.0 mg semaglutide vs sitagliptin in SUSTAIN 2 (69% and 78% vs 36%)\textsuperscript{1} and with 1.0 mg semaglutide vs exenatide ER in SUSTAIN 3 (67% vs 40%).\textsuperscript{2}
In addition, from a mean baseline body weight of 89.5 kg, adults with type 2 diabetes achieved significantly greater reductions in mean body weight when treated with 0.5 mg and 1.0 mg semaglutide vs sitagliptin in SUSTAIN 2 (4.3 kg and 6.1 kg vs 1.9 kg; both p<0.0001).\(^1\) Similarly, from a mean baseline body weight of 95.8 kg, adults with type 2 diabetes achieved significantly greater reductions in mean body weight when treated with 1.0 mg semaglutide vs exenatide ER in SUSTAIN 3 (5.6 kg vs 1.9 kg; p<0.0001).\(^2\)

“The superior and sustained glycaemic control and weight loss demonstrated in SUSTAIN 2 and 3 add to the growing clinical evidence for our next-generation GLP-1 analogue, once-weekly semaglutide,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We are excited about these results and look forward to further data from the comprehensive SUSTAIN clinical trial programme being presented later this year.”

In SUSTAIN 2, the most common adverse events observed for adults treated with 0.5 mg and 1.0 mg semaglutide and sitagliptin were gastrointestinal (43.5% and 39.9% vs 23.6%). Comparable rates of serious adverse events were observed for all treatment groups (7.3% and 7.3% vs 7.1%). The proportions of adults discontinuing 0.5 mg, 1.0 mg or 100 mg sitagliptin due to adverse events were 8.1% and 9.5% vs 2.9%, respectively.\(^1\)

Similarly, in SUSTAIN 3, the most common adverse events observed for adults treated with 1.0 mg semaglutide and exenatide ER were also gastrointestinal (41.8% and 33.3%). Fewer adults reported injection site reactions with 1.0 mg semaglutide (1.2%) compared with exenatide ER (22.0%). The rates of serious adverse events observed for adults treated with 1.0 mg semaglutide compared with exenatide ER were 9.4% and 5.9%, respectively. The proportions of adults discontinuing due to adverse events were 9.4% and 7.2%.\(^2\)

**About semaglutide**

Semaglutide is an investigational 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.\(^3\) Semaglutide administered subcutaneously once-weekly is in phase 3 development for the treatment of adults with type 2 diabetes.

**About SUSTAIN 2**

SUSTAIN 2 is a randomised, double-blind, double-dummy, multicentre, multinational 56-week trial investigating the safety and efficacy of semaglutide, administered once-weekly, vs sitagliptin, a once-daily DPP-4 inhibitor, in 1,231 adults with type 2 diabetes, where both drugs were added on to metformin and/or thiazolidinediones. The primary endpoint was change in HbA\(_{1c}\) from baseline after 56 weeks of treatment. Secondary endpoints included change in body weight from baseline after 56 weeks of treatment. The trial was conducted in Argentina, Bulgaria, Czech Republic, Hong Kong, Hungary, India, Japan, Mexico, Norway, Portugal, Romania, Russia, South Africa, Spain, Sweden, Thailand, Turkey and Ukraine.
About SUSTAIN 3
SUSTAIN 3 is a randomised, open-label, multicentre, multinational 56-week trial investigating the safety and efficacy of semaglutide, administered once-weekly, vs 2.0 mg exenatide extended release (ER) once-weekly as add-on to one or two oral antidiabetic treatments in 813 adults with type 2 diabetes. The primary endpoint was change in HbA1c from baseline after 56 weeks of treatment. Secondary endpoints included change in body weight from baseline after 56 weeks of treatment. The trial was conducted in Argentina, Croatia, Finland, France, Germany, Greece, Italy, the Netherlands, Puerto Rico, Serbia, Switzerland, 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 41,600 people in 75 countries and markets its products in more than 180 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

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