Semaglutide demonstrated superior glycaemic control vs insulin glargine U100 in adults with type 2 diabetes

Orlando, US, 27 May 2016 – Findings from a 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 insulin glargine U100 in adults with type 2 diabetes. Results from the SUSTAIN 4 trial were presented today at the American Association of Clinical Endocrinologists 25th Annual Scientific and Clinical Congress (AACE) in Orlando, US.¹

The 30-week SUSTAIN 4 trial showed that, from a mean baseline HbA₁c of 8.2%, adults with type 2 diabetes receiving metformin with or without sulfonylurea, achieved statistically significant and superior improvements in HbA₁c reductions of 1.2% and 1.6% when treated with 0.5 mg and 1.0 mg semaglutide, respectively, vs a 0.8% reduction with insulin glargine U100 (p<0.0001 for both).¹ End of trial mean dose of insulin glargine U100 was 29 IU/day.

“Type 2 diabetes is a complex disease and many patients on insulin are still uncontrolled,” said Vanita Aroda, SUSTAIN 4 investigator and Physician Investigator at the MedStar Health Research Institute, Hyattsville, MD, US. “The results of SUSTAIN 4 are encouraging, as once-weekly semaglutide demonstrated superior glycaemic control compared to insulin glargine U100 in people that generally had a relatively long duration of type 2 diabetes.”

More adults treated with 0.5 mg and 1.0 mg semaglutide achieved HbA₁c targets compared with insulin glargine U100: HbA₁c <7% (57.5% and 73.3% vs 38.1%) and ≤6.5% (37.3% and 54.2% vs 17.5%).¹ Additionally, from a mean baseline body weight of 93.4 kg, adults treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significant and superior reductions in mean body weight of 3.5 kg/7.72 lb and 5.2 kg/11.46 lb compared to an increase of 1.2 kg/2.65 lb with insulin glargine U100 (p<0.0001 for both).¹

The most common adverse events observed for adults treated with 0.5 mg and 1.0 mg semaglutide were gastrointestinal (nausea: 21.3% and 22.2% vs insulin glargine U100, 3.6%; diarrhoea: 16.3% and 19.2% vs insulin glargine U100, 4.4%; vomiting: 6.6% and 10.3% vs insulin glargine U100, 3.1%). Rates of serious adverse events were
comparable across treatment groups (6.1% and 4.7% vs 5.0%). Fewer adults reported severe or blood glucose-confirmed hypoglycaemia with either semaglutide dose compared to insulin glargine U100 (4.4% and 5.6% vs 10.6%). The proportion of adults treated with 0.5 mg and 1.0 mg semaglutide discontinuing treatment due to adverse events was 5.5% and 7.5% vs 1.1% for insulin glargine U100.1

**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.2 Semaglutide administered subcutaneously once-weekly is in phase 3 development for the treatment of adults with type 2 diabetes.

**About SUSTAIN 4**
SUSTAIN 4 was a randomised, open-label, multicentre, multinational 30-week trial investigating the safety and efficacy of semaglutide, administered once-weekly, vs once-daily insulin glargine (U100/mL), both added on to metformin with or without sulfonylurea in 1,089 adults with an overall type 2 diabetes duration of 8.6 years and who had not previously received any insulin-based therapies. Secondary endpoints included change in body weight from baseline after 30 weeks of treatment. The trial was conducted in Argentina, Croatia, France, Germany, India, Macedonia, Mexico, the Netherlands, Puerto Rico, Romania, Slovakia, Slovenia, 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**
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References
