Three-year data show early response to Saxenda® resulted in improvements in weight loss and cardiometabolic risk factors

Gothenburg, Sweden, 2 June 2016 – Today, data from a post hoc analysis of the three-year part of the phase 3a SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence) Obesity and Prediabetes trial were presented at the first European Obesity Summit (EOS 2016). Adults with prediabetes and obesity or who were overweight with comorbidities were randomised to receive Saxenda® (n=1,505) or placebo (n=749) for 160 weeks, both as an adjunct to a reduced-calorie diet and increased physical activity. People treated with Saxenda® who lost 5% or more of their body weight at 16 weeks (classified as ‘early responders’) demonstrated greater weight loss and improvements in cardiometabolic risk factors at week 160 compared with those who lost less than 5% of their body weight at 16 weeks (‘early non-responders’).1

At week 16, 68.0% of people treated with Saxenda® were early responders versus 22.3% of people treated with placebo. At week 160, Saxenda® early responders who completed the trial (n=580) achieved an average weight loss of 8.6% (9.1 kg), compared with 2.9% (3.1 kg) in early non-responders (n=210). In addition, Saxenda® early responders experienced improvements across a range of glycaemic measures including regression to normoglycaemia (69.8 vs 55.4%) and reduced development of type 2 diabetes (0.5 vs 3.2%) compared with early non-responders.1

“These findings demonstrate the predictive nature of an early response to treatment, which is important information that clinicians can use to identify those who are most likely to experience long-term benefits with Saxenda,” said Professor Sten Madsbad, Clinical Professor at the University of Copenhagen and SCALE™ clinical trial investigator. “It is also encouraging that we continue to see benefits in addition to weight loss experienced with Saxenda, including improvements in cardiometabolic risk factors and glycaemic status for people completing the trial.”

For those completing 160 weeks of treatment, Saxenda® early responders also experienced greater improvements in systolic blood pressure (-3.7 vs -3.3 mmHg), and improvements in health-related quality of life measures (IWQoL-Lite score 13.4 vs 9.5) compared with early non-responders.1

Saxenda® was generally well-tolerated, and observed side effects were in line with previous trials.2 Rates of adverse events were similar between early responders and early non-responders (97.1 vs 95.0%). The most common side effects reported by early
responders and early non-responders were related to the gastrointestinal system (75.3 vs 71.6%). Gallbladder disorders were more frequent in early responders compared with early non-responders (6.3 vs 2.2%).

**About obesity**

Obesity is a disease that requires long-term management. It is associated with many serious health consequences and decreased life-expectancy. Obesity-related comorbidities include type 2 diabetes, heart disease, obstructive sleep apnoea (OSA) and certain types of cancer. It is a complex and multi-factorial disease that is influenced by genetic, physiological, environmental and psychological factors.

The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems. In 2014, 13% of adults, or approximately 600 million adults, were living with obesity.

**About Saxenda®**

Saxenda® (liraglutide 3 mg) is a once-daily glucagon-like peptide-1 (GLP-1) analogue with 97% similarity to naturally occurring human GLP-1, a hormone that is released in response to food intake. Like human GLP-1, Saxenda® regulates appetite by increasing feelings of fullness and satiety, while lowering feelings of hunger and prospective food consumption, thereby leading to reduced food intake. As with other GLP-1 receptor agonists, Saxenda® stimulates insulin secretion and lowers glucagon secretion in a glucose-dependent manner. Saxenda® was evaluated in the SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence) phase 3a clinical trial programme.

In the EU, Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial BMI of ≥30 kg/m² (obese), or ≥27 kg/m² to <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

Guidance is given in the label that treatment with Saxenda® should be discontinued if 5% weight loss has not been achieved by 16 weeks.

**About the SCALE™ clinical development programme**

Novo Nordisk’s phase 3 development programme, called SCALE™, investigates liraglutide 3 mg for weight management. SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence) consists of four, placebo-controlled, multinational trials called: SCALE™ Obesity and Prediabetes, SCALE™ Diabetes, SCALE™ Sleep Apnoea and SCALE™ Maintenance. The trials include more than 5,000 people who are overweight (BMI ≥27 kg/m²) with comorbidities such as hypertension, dyslipidaemia, obstructive sleep apnoea (OSA) or type 2 diabetes or who have obesity (BMI ≥30 kg/m²), with or without comorbidities. The studies all involved a reduced-calorie diet and increased physical activity.

Key results from all trials in the SCALE™ clinical development programme have been published, with further data expected to be presented and published throughout 2016.
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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References

1. Madsbad S GF, Lau DCW, O’Neil P, Wilding JPH, Jacobsen PB, Skjøth TV, Fujioka K. Early weight loss responders to liraglutide 3.0 mg achieved greater weight loss and regression to normoglycaemia, and reduced development of T2D at 3 years, versus early non-responders in the SCALE Obesity and Prediabetes trial. EOS 2016.
