Treatment with Saxenda® for three years reduced the risk of developing type 2 diabetes compared with placebo

Bagsværd, Denmark, 22 May 2015 – Today, Novo Nordisk announced the headline results from the SCALE™ Obesity and Prediabetes three-year extension trial in adults with obesity or who were overweight with comorbidities, and had prediabetes at baseline. The trial met its primary endpoint, demonstrating that ongoing treatment with Saxenda® (liraglutide 3 mg) in combination with a reduced-calorie diet and increased physical activity delayed the onset of type 2 diabetes, compared with placebo (diet and exercise alone).

Over the course of this 160-week, randomised, blinded phase 3a trial, the time to onset of type 2 diabetes was 2.6 times longer with Saxenda® compared with placebo treatment. In addition, the risk of developing type 2 diabetes was reduced by approximately 80% and statistically significant (p<0.0001) for those being treated with Saxenda®.

“People with obesity are at an increased risk of developing type 2 diabetes, which is a serious disease,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer. “We are encouraged by these three-year data demonstrating that Saxenda® can help to delay the onset of type 2 diabetes, in addition to providing sustained long-term weight loss.”

At 160 weeks, Saxenda® provided an average body weight loss of 6.1% from baseline, compared with 1.8% for placebo treatment (p<0.0001), both in combination with a reduced calorie diet and increased physical activity. 49.6% of people treated with Saxenda® achieved a clinically meaningful weight loss of at least 5% of their baseline body weight, compared with 23.4% on placebo treatment; 24.3% lost more than 10% of their body weight when treated with Saxenda® compared to 9.4% with placebo.

In the trial, Saxenda® was generally well tolerated and no new safety issues were identified. The 160-week completion rate was 52.6% and 45.0% for Saxenda® and placebo respectively. Withdrawals due to adverse events were 12.7% with Saxenda® and 5.7% with placebo, and the most frequently reported adverse events were gastrointestinal in nature.
About obesity
Obesity is a disease\textsuperscript{1} that requires long-term management. It is associated with many serious health consequences and decreased life-expectancy.\textsuperscript{2, 3} Obesity-related comorbidities include type 2 diabetes, heart disease, obstructive sleep apnoea (OSA) and certain types of cancer.\textsuperscript{3-5} It is a complex and multi-factorial disease that is influenced by genetic, physiological, environmental and psychological factors.\textsuperscript{6}

The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems. In the EU, obesity affects approximately 10–30% of adults.\textsuperscript{7}

About Saxenda\textsuperscript{®}
Saxenda\textsuperscript{®} (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.\textsuperscript{8} Like human GLP-1, Saxenda\textsuperscript{®} 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\textsuperscript{®} stimulates insulin secretion and lowers glucagon secretion in a glucose-dependent manner.\textsuperscript{9} These effects can lead to a reduction of fasting and post-prandial blood glucose. Saxenda\textsuperscript{®} was evaluated in the SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence in Nondiabetic and Diabetic people) phase 3 clinical trial programme.

Saxenda\textsuperscript{®} was granted European marketing authorisation on 23 March 2015 by the European Commission (EC). In the EU, Saxenda\textsuperscript{®} 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 $\geq 30$ kg/m$^2$ (obese), or $\geq 27$ kg/m$^2$ to $<30$ kg/m$^2$ (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.\textsuperscript{9}

Saxenda\textsuperscript{®} was approved by the FDA on 23 December 2014 and Health Canada on 26 February 2015. Please refer to local label for further information.

Guidance is given in all labels that treatment with Saxenda\textsuperscript{®} should be discontinued if a specific level of weight loss is not achieved within a certain period of time.

About SCALE™ Obesity and Prediabetes
The SCALE™ Obesity and Prediabetes trial is a randomised, double-blind, placebo-controlled, multinational trial in non-diabetic adults with obesity and non-diabetic adults who are overweight with comorbidities. There were 3,731 participants randomised to treatment with Saxenda\textsuperscript{®} (liraglutide 3 mg) or placebo in combination with reduced-calorie diet and increased physical activity. In addition, participants were further stratified to 56 weeks or 160 weeks of treatment based on prediabetes status at baseline screening.\textsuperscript{9}
The objectives of this trial were to demonstrate clinically meaningful weight loss at 56 weeks, as well as to investigate the long-term potential efficacy of Saxenda® to delay the onset of type 2 diabetes in participants with prediabetes at baseline screening.9

It is the largest of the phase 3a trials in the SCALE™ clinical development programme, which encompassed more than 5,000 adults with obesity or adults who are overweight with comorbidities. The headline results from the first 56 weeks of the trial were announced in May 2013.

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 39,000 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