

## press release

### **Saxenda® provides consistent weight loss and improvements in blood glucose control across BMI categories after three years of treatment**

**Munich, Germany, 14 September 2016** – Results 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 show that people treated with Saxenda® (liraglutide 3 mg) experienced consistent weight loss and improved blood glucose control across baseline body mass index (BMI) categories over three years as compared to placebo treatment. These data were presented today at the 52<sup>nd</sup> Annual Meeting of the European Association for the Study of Diabetes (EASD) 2016.

In the trial, 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.<sup>1</sup>

“Treating obesity and related comorbidities can be complex and challenging,” said Professor Sten Madsbad, clinical professor at the University of Copenhagen and a SCALE clinical trial investigator. “It is encouraging to now have three-year data demonstrating that, regardless of starting BMI, people in the trial experienced consistent weight loss and improvements in several measures of glycaemic control.”

As part of this analysis, measures of blood glucose control and the overall safety profile across baseline BMI categories in people treated with Saxenda® vs placebo were assessed. These baseline BMI categories were classified as; overweight: BMI 27–29.9 kg/m<sup>2</sup>, obesity class 1: BMI 30–34.9 kg/m<sup>2</sup>, obesity class 2: BMI 35–39.9 kg/m<sup>2</sup> and obesity class 3 and over: BMI ≥40 kg/m<sup>2</sup>. People treated with Saxenda® experienced consistent weight loss across all BMI categories: 5.7%, BMI 27–29.9 kg/m<sup>2</sup>; 6.5%, BMI 30–34.9 kg/m<sup>2</sup>; 6.2%, BMI 35–39.9 kg/m<sup>2</sup>; 5.9%, BMI ≥40 kg/m<sup>2</sup> compared to 1.8%, 1.7%, 1.8% and 2.1% in the same categories with placebo treatment. The percentage of individuals who reverted to normal blood glucose levels at 160 weeks on Saxenda® was also similar at: 67%, 67%, 70% and 63%, respectively, in each of the four BMI categories and significantly greater compared to 36%, 34%, 40% and 33%, respectively, with placebo (p<0.05).<sup>1</sup>

In addition, consistent improvements were observed with Saxenda® treatment across BMI categories for several measures of blood glucose control, including HbA<sub>1c</sub>, fasting plasma glucose (FPG), fasting insulin, beta-cell function and insulin resistance.<sup>1</sup> There were similar incidences of total and serious adverse events as well as gastrointestinal and hypoglycaemic events, across BMI categories.<sup>1</sup> Saxenda® was generally well-tolerated, with observed side effects in line with previous trials.

### **About obesity**

Obesity is a disease<sup>2,3</sup> that requires long-term management. It is associated with many serious health consequences and decreased life-expectancy.<sup>4,5</sup> Obesity-related comorbidities include type 2 diabetes, heart disease, obstructive sleep apnoea (OSA) and certain types of cancer.<sup>4,6,7</sup> It is a complex and multi-factorial disease that is influenced by physiological, psychological, environmental, socio-economic and genetic factors.<sup>8</sup>

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.<sup>9</sup>

### **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,<sup>10</sup> a hormone that is released in response to food intake.<sup>11</sup> 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.<sup>10</sup> 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  $\geq 30$  kg/m<sup>2</sup> (obese), or  $\geq 27$  kg/m<sup>2</sup> to  $< 30$  kg/m<sup>2</sup> (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.<sup>10</sup>

Guidance is given in the label that treatment with Saxenda® should be discontinued if 5% weight loss has not been achieved by 16 weeks.<sup>10</sup>

### **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.<sup>12-15</sup> The trials include more than 5,000 people who are overweight (BMI  $\geq 27$  kg/m<sup>2</sup>) with comorbidities such as hypertension, dyslipidaemia, obstructive sleep apnoea (OSA) or type 2 diabetes or who have obesity (BMI  $\geq 30$  kg/m<sup>2</sup>), with or without comorbidities. The studies all involved a reduced-calorie diet and increased physical activity.<sup>10</sup>

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 42,300 people in 75 countries and markets its products in more than 180 countries. For more information, visit [novonordisk.com](http://novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#)*

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