

## press release

### **Saxenda® demonstrated significant improvements in cardiometabolic risk factors over three years compared with placebo**

**Boston, US, 4 April 2016** – Today, new data from the three-year part of the phase 3a SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence) Obesity and Prediabetes trial were presented at the Endocrine Society's 98<sup>th</sup> Annual Meeting and Expo (ENDO 2016). The three-year part of the trial (n=2,254 adults with obesity or who were overweight with comorbidities and had prediabetes at baseline) data demonstrated that 160 weeks of treatment with Saxenda® (liraglutide 3 mg) (n=1,505) in combination with a reduced-calorie diet and increased physical activity resulted in significant improvements in cardiometabolic risk factors (such as blood pressure and cholesterol) compared with placebo (reduced-calorie diet and increased physical activity alone) (n=749).<sup>1</sup>

At week 160, individuals treated with Saxenda® had lost more weight (6.1%) than those treated with placebo (1.9%) (estimated treatment difference [ETD] -4.3% [95% CI -4.9; -3.7], p<0.0001).<sup>1</sup> In addition, treatment with Saxenda® achieved results beyond weight loss including improvements in some cardiometabolic risk factors such as blood pressure and cholesterol. At week 160, participants randomised to treatment with Saxenda® experienced a greater reduction in systolic blood pressure compared with placebo (ETD -2.8 mmHg [-3.8; -1.8], p<0.0001). Those treated with Saxenda® also experienced greater improvements in triglycerides (ETD -6% [-9; -3], p=0.0003) and total cholesterol levels (ETD -2% [-3; 0], p=0.03) compared with placebo. Additionally, people treated with Saxenda® showed a greater reduction in mean waist circumference compared with placebo (ETD -3.5 cm [-4.2; -2.8]).

"We know that weight loss of as little as 5 to 10% in people with obesity can have an impact on cardiometabolic risk factors," said Dr Ken Fujioka, Scripps Clinic, San Diego, California, US and a SCALE™ clinical trial investigator. "This is currently the longest weight-management trial with Saxenda®, and the observed improvements in blood pressure, lipids and waist circumference at three years are encouraging."

In addition, the three-year part of the SCALE™ Obesity and Prediabetes trial met its primary endpoint, demonstrating that continued treatment over three years with Saxenda®, in combination with a reduced-calorie diet and increased physical activity, delayed the onset of type 2 diabetes compared with placebo.<sup>1</sup>

Aligned with previous trials, during treatment with Saxenda®, mean pulse rate was increased (ETD +2 beats/min [+1.2; +2.7],  $p < 0.0001$ ). Saxenda® was generally well tolerated, and observed side effects were in line with previous trials.<sup>2</sup> Over 160 weeks, reports of serious adverse events were higher in those treated with Saxenda® compared with placebo (15.1% vs 12.9%). Rates of gallbladder-related adverse events and confirmed acute pancreatitis were low, but more frequent in those treated with Saxenda® (2.9 events per 100 patient-years of observation [PYO] and 0.29/100 PYO, respectively) vs placebo (1.2/100 PYO and 0.13/100 PYO, respectively). The frequency of adjudicated major adverse cardiovascular events was low, and comparable in those treated with Saxenda® and placebo (0.19 vs 0.20 events/100 PYO).<sup>1</sup>

### **About obesity**

Obesity is a disease<sup>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 genetic, physiological, environmental and psychological 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, a hormone that is released in response to food intake.<sup>10</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>2</sup> Saxenda® was evaluated in the SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence) phase 3 clinical trial programme.

Saxenda® is approved in the US as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity (BMI of  $\geq 30$  kg/m<sup>2</sup>) or who are overweight (BMI of  $\geq 27$  kg/m<sup>2</sup>) in the presence of at least one weight-related comorbid condition (e.g. hypertension, dyslipidaemia, type 2 diabetes).<sup>11</sup>

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>2</sup>

Guidance is given in the label that treatment with Saxenda® should be discontinued if a specific threshold of weight loss has not been achieved after a certain period of time.

### **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  $\geq 27$  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.

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 41,000 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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