New data demonstrated Saxenda® provides benefits beyond weight loss

Bagsværd, Denmark, Friday 8 May 2015 – Today, new data from a post-hoc analysis of the phase 3a SCALE™ clinical trial programme were presented at the European Congress on Obesity (ECO), demonstrating the weight-loss-dependent and independent effects of Saxenda® (liraglutide 3 mg).

“For the first time, we have looked at the SCALE™ clinical trial programme to explore to what degree the benefits of liraglutide 3 mg could be assigned to the drug itself, or to the effect of the weight loss a person may achieve while taking liraglutide 3 mg, the post-hoc analysis confirmed that weight loss has a positive impact on a number of cardiometabolic risk factors, including high blood pressure and cholesterol. However, importantly we also saw the direct effect of liraglutide 3 mg on glycaemic control and other endpoints, independent of weight loss.” Said Professor Luc Van Gaal, head of the Department of Endocrinology, Diabetology and Metabolism, Antwerp University Hospital, and SCALE™ trial investigator.

A mediation model was applied to determine weight-loss-dependent effects, with a score of 100% indicating full dependence. Endpoints primarily driven by weight loss (88-100%) included waist circumference, diastolic blood pressure, triglycerides, high density lipoprotein (HDL) cholesterol levels, apnoea-hypopnoea index (sleep apnoea severity), impact of weight on quality of life (IWQoL) total score and physical function score.¹

Endpoints which improved due to liraglutide 3 mg treatment, but were independent of weight loss (18-32%) included glycaemic endpoints (HbA₁c and fasting plasma glucose), as well as a reduction in use of oral anti-diabetic treatments. However, reduction in bodyweight still contributed to these treatment effects.¹

Across the SCALE™ clinical development programme, liraglutide 3 mg was generally well tolerated. The most common side effects observed were related to the gastrointestinal system.²
**About obesity**

Obesity is a disease that requires long-term management. It is associated with many serious health consequences and with 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 the EU, obesity affects approximately 10-30% of adults.

**About liraglutide 3 mg**

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, liraglutide 3 mg 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, liraglutide 3 mg stimulates insulin secretion and lowers glucagon secretion in a glucose-dependent manner. These effects can lead to a reduction of fasting and post-prandial blood glucose.

Liraglutide 3 mg was evaluated in the SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence in Nondiabetic and Diabetic people) phase 3 clinical trial program.

Liraglutide 3 mg was granted European marketing authorisation on 23 March 2015 by the European Commission (EC). In the EU, liraglutide 3 mg 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.

Liraglutide 3 mg 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 liraglutide 3 mg 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 in Non-diabetic and Diabetic people) 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).
kg/m\(^2\)), 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 in 2015.

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 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

Further information
Media:
Katrine Sperling +45 4442 6718 krsp@novonordisk.com
Sharon Corbitt (US) +1 609 578 9974 shct@novonordisk.com

Investors:
Kasper Roseeuw Poulsen +45 3079 4303 krop@novonordisk.com
Melanie Raouzeos +45 3075 3479 mrz@novonordisk.com
Daniel Bohsen +45 3079 6376 dabo@novonordisk.com
Frank Daniel Mersebach (US) +1 609 235 8567 fdni@novonordisk.com

References