Early response to Saxenda® resulted in weight maintenance and additional weight loss over 56 weeks

Porto, Portugal, 17 May 2017 – Today, results from a post-hoc analysis of data from the SCALE Maintenance trial were presented at the 24th European Congress on Obesity (ECO) 2017. In the trial, adults who lost at least 5% of their initial weight during a low-calorie run-in period were randomised to receive Saxenda® (liraglutide 3 mg) or placebo. After 16 weeks of treatment with Saxenda®, participants who lost an additional 5% or more of their body weight (defined as ‘early responders’) were more likely to maintain weight loss and achieve greater additional weight loss over 56 weeks, compared with people losing less than 5% body weight after 16 weeks of Saxenda® treatment (‘early non-responders’).1

“In the obesity specialist setting, low-calorie diets combined with increased physical activity are commonly used to induce an initial weight loss in people with obesity. However, when the initial weight loss reaches a plateau and patients enter the ‘weight maintenance phase’ with less stringent calorific restriction, we often see that many experience weight regain,” said Dr Sean Wharton, medical director at the Wharton Medical Clinic, Ontario and SCALE clinical trial investigator. “As a consequence, pharmacotherapy can be used to help people with obesity in maintaining the weight loss that has already been achieved by a low-calorie diet and increased physical activity. These data are very encouraging to clinicians in this specialist setting, because they show that early responders to Saxenda® are able to both maintain and achieve additional weight loss”.

Of those who completed 56 weeks of treatment with Saxenda®, 68% were early responders to Saxenda® at week 16 and 32% were early non-responders. In addition to weight loss achieved during the run-in period, early responders experienced 9.9% weight loss, compared with 0.0% in early non-responders at 56 weeks.1

Following 56 weeks of treatment, 91.7% of early responders and 47.1% of early non-responders, had maintained or lost additional weight following the run-in period. No early responders regained their run-in weight loss over 56 weeks of treatment with Saxenda®, compared with 3.9% of early non-responders.1
There were similar incidences of total adverse events in early responders (92.7%) and early non-responders (91.0%). Gastrointestinal adverse events were more frequent in early responders compared with early non-responders (78.9% vs 62.7%). Saxenda® was generally well-tolerated, with observed side effects in line with previous trials.

**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 physiological, psychological, environmental, socio-economic and genetic 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 after 12 weeks on the liraglutide 3.0 mg/day dose, if patients have not lost at least 5% of their initial body weight.

**About the SCALE Maintenance clinical trial**

In the SCALE Maintenance clinical trial, adults with obesity (BMI ≥30 kg/m²) or who were overweight (BMI ≥27 kg/m² to <30 kg/m²) with comorbidities (dyslipidaemia and/or hypertension), who lost at least 5% of their initial weight during a low-calorie diet (1200–1400 kcal/day) run-in period, were randomised to receive Saxenda® (n=212) or placebo (n=210) for 56 weeks, both as an adjunct to a reduced-calorie diet and increased physical activity.
Novo Nordisk’s phase 3 development programme, called SCALE, investigated liraglutide 3 mg for weight management. The SCALE clinical development programme consisted of four, placebo-controlled, multinational trials called: SCALE Obesity and Prediabetes, SCALE Diabetes, SCALE Sleep Apnoea and SCALE Maintenance.12-16

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 42,000 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information
Media:
Katrine Sperling  +45 4442 6718  krsp@novonordisk.com
Åsa Josefsson  +45 3079 7708  aajf@novonordisk.com

Investors:
Peter Hugreff Ankersen  +45 3075 9085  phak@novonordisk.com
Anders Mikkelsen  +45 3079 4461  armk@novonordisk.com
Hanna Ögren  +45 3079 8519  haoe@novonordisk.com
Kasper Veje (US)  +1 609 235 8567  kpvj@novonordisk.com

References
1. Wharton S, Jacobsen P, Arrone L. Early responders to liraglutide 3.0 mg as adjunct to diet and exercise from the SCALE Maintenance trial. Oral presentation number RS3:3. ECO. 2017


