press release

New phase 3a data demonstrate that 9 out of 10 adults with obesity lost weight with liraglutide 3 mg and clinical trial completers lost an average of 9.2%

Boston, US, 4 November 2014 – Today, new data from the phase 3a SCALE™ Obesity and Prediabetes trial were presented at ObesityWeek 2014, the 2nd Annual Congress of The American Society for Metabolic and Bariatric Surgery and The Obesity Society. 92% (9 out of 10) of trial participants lost weight with liraglutide 3 mg treatment, in combination with diet and exercise, compared with 65% on placebo treatment.1 People who completed the trial (56 weeks) demonstrated significantly greater weight loss of 9.2% compared with a 3.5% reduction in the placebo group (estimated difference [ED] 5.7%, p<0.0001).1

In addition, weight loss with liraglutide 3 mg was similar across a range of baseline body mass index (BMI) subgroups in people with obesity, from overweight to Class III obesity,* at 56 weeks (p=0.054, %; p=0.54, kg) and independent of prediabetes status at screening (−8.0% with vs −7.9% without, p=0.59).1 A larger proportion of people treated with liraglutide 3 mg completed the trial compared with those on placebo (72% vs. 64%).1 All treatment groups followed a reduced-calorie diet and an increased physical activity programme.

Weight loss associated with liraglutide 3 mg was accompanied by improvements in health-related quality of life (HRQoL) as measured by three different questionnaires.2 Greater improvements were seen with liraglutide 3 mg vs placebo.2 The Impact of Weight on Quality of Life-Lite (IWQoL),3 total score improved mostly due to better physical function. Both the Short-Form (36) Health Survey (SF-36)4 summary of physical scores and mental health scores improved.2

“Obesity is more than a disease of excess weight,” said Dr Ken Fujioka, Department of Nutrition and Metabolic Research, Scripps Clinic, La Jolla, California and a SCALE™ clinical trial investigator. “We know that people with obesity may experience increased physical and mental health problems, as well as a reduced quality of life. It is encouraging to see data suggesting that the weight loss benefits of liraglutide 3 mg are associated with improved health-related quality of life for people with obesity.”
In addition, the total Treatment Related Impact Measure-Weight (TRIM-W) score was better at 56 weeks with liraglutide 3 mg compared with placebo treatment.2

**About obesity**

Obesity is a disease that requires chronic management. It is associated with serious comorbidities including type 2 diabetes, heart disease, obstructive sleep apnoea (OSA), certain types of cancer and a decreased life expectancy. The risk of morbidity and mortality increases with the severity of obesity. 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 US, approximately 35% of adults, equivalent to around 80 million adults, live with obesity.7, 8

**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.9 Like human GLP-1, liraglutide 3 mg regulates appetite and food intake by decreasing hunger and increasing feelings of fullness and satiety after eating.10, 11 The dual actions of liraglutide 3 mg on both appetite and blood glucose regulation (for adults with prediabetes or type 2 diabetes) hold therapeutic potential for adults with obesity, both those with and without type 2 diabetes.

Liraglutide 3 mg is an investigational product and is not approved by the FDA or the European Medicines Agency (EMA).

**About SCALE™ Obesity and Prediabetes**

The SCALE™ Obesity and Prediabetes trial12 is a randomised, double-blind, placebo-controlled, multinational trial in non-diabetic people with obesity and non-diabetic people who are overweight with comorbidities. There were 3,731 participants randomised to treatment with liraglutide 3 mg or placebo in combination with diet and exercise. In addition, participants were further stratified to 56 weeks or 160 weeks of treatment based on prediabetes status at screening.

The objectives of this trial were to demonstrate clinically meaningful weight loss at 56 weeks, as well as to investigate the long-term efficacy of liraglutide 3 mg to delay the onset of type 2 diabetes in participants with prediabetes at screening.

It is the largest of the phase 3a trials in the SCALE™ clinical development programme, which encompassed more than 5,000 people with obesity or people who are overweight with comorbidities.

**About Novo Nordisk**

Headquartered in Denmark, Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Novo Nordisk employs approximately
40,700 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit novonordisk.com.

**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
Jannick Lindegaard Denholt +45 3079 8519 jlis@novonordisk.com
Daniel Bohsen +45 3079 6376 dabo@novonordisk.com
Frank Daniel Mersebach (US) +1 609 235 8567 fdni@novonordisk.com

This information was presented at ObesityWeek 2014, the inaugural scientific event by The Obesity Society and the American Society for Metabolic and Bariatric Surgery.

*BMI subgroups: ≥27–29.9 kg/m², 30–34.9 kg/m², 35–39.9 kg/m², ≥40 kg/m².

**References**


12. SCALE™ Obesity and Prediabetes ClinicalTrials.gov study registration: NCT01272219.