

# company announcement

## **Novo Nordisk files for regulatory approval of liraglutide 3 mg for the treatment of obesity**

**Bagsværd, Denmark, 20 December 2013** – Novo Nordisk today announced two separate regulatory submissions for a 3 mg dose of liraglutide, a once-daily human GLP-1 analogue, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity, or who are overweight with comorbidities. The company filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA).

The submissions for liraglutide 3 mg include data from the Phase 3 SCALE™ clinical trial programme, which involved more than 5,000 people with obesity (BMI  $\geq 30$  kg/m<sup>2</sup>), or who are overweight (BMI  $\geq 27$  kg/m<sup>2</sup>) with comorbidities. In addition to the data from the SCALE™ programme, data from earlier development phases and data related to the use of liraglutide in type 2 diabetes were also included in the submissions.

Data from the SCALE™ clinical trial programme have consistently demonstrated that liraglutide 3 mg, in combination with diet and exercise, induces and maintains weight loss, while also significantly improving obesity-related comorbidities such as hypertension, dyslipidaemia and sleep apnoea. Furthermore, in people with obesity and type 2 diabetes or prediabetes, trials have demonstrated that liraglutide 3 mg significantly improves glycaemic control, in addition to lowering weight.

“We believe that liraglutide 3 mg has the potential to make a significant difference in the management of obesity by providing both a sustainable weight loss and an improvement in several obesity-related comorbidities”, said Mads Krosgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

### **About obesity**

Obesity is a disease<sup>1</sup> that requires chronic management. It is often linked to serious comorbidities – including type 2 diabetes, heart disease, obstructive sleep apnoea and certain types of cancer – accompanied by a decreased life expectancy of 5–10 years. The risk of morbidity and mortality increases with the severity of obesity. It is a complex and

multifactorial disease, influenced by genetic, physiological, environmental and psychological factors.

The global increase in the prevalence of obesity is a public health issue with huge cost implications to healthcare systems. In the US, approximately 35% of adults, or some 100 million people are obese. A sustained weight loss of 5–10% has been shown to be associated with significant health benefits.

### **About liraglutide 3 mg**

Liraglutide 3 mg is a once-daily GLP-1 analogue with 97% homology to naturally occurring human GLP-1. Like human GLP-1, liraglutide 3 mg regulates appetite by increasing feelings of fullness and reducing feelings of hunger, allowing people to feel satisfied with eating less. GLP-1 also plays an important role in maintaining normal blood glucose levels. This dual action of GLP-1 holds therapeutic potential for the treatment of people with obesity. Liraglutide 3 mg is not an approved treatment.

Liraglutide is currently approved and marketed at lower doses (1.2 and 1.8 mg once-daily, as well as 0.9 mg in Japan) for type 2 diabetes, under the brand name Victoza<sup>®</sup>. Victoza<sup>®</sup> is not approved for weight management and should not be prescribed for this treatment.

### **About the SCALE<sup>™</sup> clinical programme**

SCALE<sup>™</sup> (Satiety and Clinical Adiposity – Liraglutide Evidence in Non-diabetic and Diabetic people) consists of four trials encompassing more than 5,000 people who are overweight (BMI  $\geq 27$  kg/m<sup>2</sup>) and with comorbidities such as hypertension, dyslipidaemia, or type 2 diabetes, or who have obesity (BMI  $\geq 30$  kg/m<sup>2</sup>) with or without comorbidities. In addition to demonstrating safety and efficacy for weight management with liraglutide 3 mg, each of the four trials had a specific focus:

SCALE<sup>™</sup> Obesity and Prediabetes<sup>2</sup> (3,731 people randomised) – a 56-week and 160-week randomised, placebo-controlled trial in people with obesity, or overweight people with comorbidities, designed to demonstrate clinically meaningful and safe weight loss after 56 weeks of treatment with liraglutide 3 mg. The 56-week results were reported in May 2013. The 160-week extension study is ongoing and investigates the long-term effect of liraglutide 3 mg, in combination with diet and exercise, on the progression to type 2 diabetes.

SCALE<sup>™</sup> Maintenance<sup>3</sup> (422 people randomised) – a 56-week randomised, placebo-controlled trial designed to show maintenance of weight loss in people with obesity or overweight people with comorbidities, who have successfully achieved a 5% or greater weight loss during a three-month run-in period that included a lifestyle intervention programme of low-calorie diet and exercise alone. The results of SCALE<sup>™</sup> Maintenance were reported in 2010.

SCALE<sup>™</sup> Diabetes<sup>4</sup> (846 people randomised) – a 56-week randomised, placebo-controlled trial designed to demonstrate clinically meaningful and safe weight loss with liraglutide

3 mg in people with obesity, or overweight people with type 2 diabetes. The results of SCALE™ Diabetes were reported in March 2013.

SCALE™ Sleep Apnoea<sup>5</sup> (359 people randomised) – a 32-week randomised, double-blind, placebo-controlled trial in people with obesity with moderate or severe obstructive sleep apnoea (OSA) to investigate the effect of liraglutide 3 mg, in combination with diet and exercise, in reducing the severity of OSA. The results of SCALE™ Sleep Apnoea were reported in August 2013.

*Headquartered in Denmark, Novo Nordisk is a global healthcare company with 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. Headquartered in Denmark, Novo Nordisk employs approximately 37,000 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit [novonordisk.com](http://novonordisk.com).*

## Further information

### Media:

Mike Rulis	+45 4442 3573	<a href="mailto:mike@novonordisk.com">mike@novonordisk.com</a>
Ken Inchausti (US)	+1 609 514 8316	<a href="mailto:kiau@novonordisk.com">kiau@novonordisk.com</a>

### Investors:

Kasper Roseeuw Poulsen	+45 3079 4303	<a href="mailto:krop@novonordisk.com">krop@novonordisk.com</a>
Frank Daniel Mersebach	+45 3079 0604	<a href="mailto:fdni@novonordisk.com">fdni@novonordisk.com</a>
Lars Borup Jacobsen	+45 3075 3479	<a href="mailto:lbpj@novonordisk.com">lbpj@novonordisk.com</a>
Daniel Bohsen	+45 3079 6376	<a href="mailto:dabo@novonordisk.com">dabo@novonordisk.com</a>
Jannick Lindegaard (US)	+1 609 235 8567	<a href="mailto:jlis@novonordisk.com">jlis@novonordisk.com</a>

## References

<sup>1</sup> American Medical Association, (AMA). Declaration to classify obesity as a disease. Annual Meeting Report. 19 June 2013.

<sup>2</sup> ClinicalTrials.gov study registration: NCT01272219

<sup>3</sup> ClinicalTrials.gov study registration: NCT00781937

<sup>4</sup> ClinicalTrials.gov study registration: NCT01272232

<sup>5</sup> ClinicalTrials.gov study registration: NCT01557166