company announcement

FDA schedules Advisory Committee meeting for liraglutide 3 mg for the treatment of obesity

Bagsværd, Denmark, 20 May 2014 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has informed the company that an FDA Advisory Committee meeting is tentatively scheduled to be held on 11 September 2014 to discuss the New Drug Application (NDA) for liraglutide 3 mg for the treatment of obesity. The NDA was submitted to the FDA on 20 December 2013.

FDA Advisory Committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the Committee's recommendation, but it takes its advice into consideration when reviewing NDAs. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer new drugs to an Advisory Committee meeting, or alternatively justify why an Advisory Committee meeting was not requested.

About obesity
Obesity is a disease[1] 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 of 5–10 years. 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, or some 100 million people, live with obesity.

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 and food intake by decreasing hunger and increasing feelings of fullness and satiety after eating. The dual actions of liraglutide 3 mg on both appetite and blood glucose regulation (for people with prediabetes or type 2 diabetes) hold therapeutic potential for people with obesity, both those with and without diabetes.

Liraglutide 3 mg is an investigational product which is currently under regulatory review with the FDA and the European Medicines Agency (EMA).

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Victoza® (Liraglutide) is currently available at doses of 1.2 and 1.8 mg once-daily (0.9 mg in Japan), as an adjunct to diet and exercise to improve blood glucose control in people with type 2 diabetes. Victoza® is not approved for weight management.

About the SCALE™ clinical programme

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

SCALE™ Obesity and Prediabetes[2] (3,731 people randomised) – a 56-week and 160-week randomised, double-blind, placebo-controlled, multinational trial in adults without diabetes and adults who are overweight with comorbidities without diabetes, designed to demonstrate clinically meaningful weight loss after 56 weeks of treatment with liraglutide 3 mg in combination with diet and exercise. The 56-week top-line results were reported in May 2013. The 160-week treatment group is investigating the long-term efficacy of liraglutide 3 mg in combination with diet and exercise to delay the onset of type 2 diabetes is currently ongoing.

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

SCALE™ Diabetes[4] (846 people randomised) – a 56-week randomised, double-blind, placebo-controlled, multinational trial designed to demonstrate clinically meaningful weight loss with liraglutide 3 mg in adults with obesity, or adults or who are overweight, and with type 2 diabetes. Adults were randomised 2:1:1 to treatment with liraglutide 3 mg, liraglutide 1.8 mg or placebo. Top-line results of SCALE™ Diabetes were reported in March 2013.

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

About Novo Nordisk

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. Headquartered in Denmark, Novo Nordisk employs approximately 40,000 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

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References

[1] American Medical Association, (AMA). Declaration to classify obesity as a disease. Annual Meeting Report. 19 June 2013.
[2] ClinicalTrials.gov study registration: NCT01272219
[3] ClinicalTrials.gov study registration: NCT00781937
[4] ClinicalTrials.gov study registration: NCT01272232
[5] ClinicalTrials.gov study registration: NCT01557166