

NOVO NORDISK A S
Form 6-K
March 24, 2015
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

March 23, 2015

NOVO NORDISK A/S
(Exact name of Registrant as specified in its charter)

Novo Allé
DK- 2880, Bagsvaerd
Denmark
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F

Form 20-F Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b):82-_____

Saxenda® approved in Europe for the treatment of obesity

Bagsværd, Denmark, 23 March 2015 — Novo Nordisk today announced that the European Commission has granted marketing authorisation for Saxenda® (liraglutide 3 mg) for the treatment of obesity. The authorisation covers all 28 European Union (EU) member states.

Saxenda® is the brand name of liraglutide 3 mg, the first once-daily human glucagon-like peptide-1 (GLP-1) analogue for the treatment of obesity approved in Europe. Saxenda® is indicated in the EU as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (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.

“The approval of Saxenda® in the EU is an important development for people with obesity who also suffer from weight-related comorbidities,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We believe Saxenda® has the potential to help some of these people achieve and maintain clinically significant weight loss and improve their weight-related comorbidities.”

Novo Nordisk expects to launch Saxenda® in several European markets starting in 2015.

About obesity

Obesity is a disease that requires long-term management. It is associated with 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 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 and lowers body weight through decreased food intake. As with other GLP-1 receptor agonists, liraglutide stimulates insulin secretion and reduces glucagon secretion in a glucose-dependent manner. These effects can lead to a reduction of blood glucose.

Saxenda® was evaluated in the SCALE™ (Satiety and Clinical Adiposity-Liraglutide Evidence in Nondiabetic and Diabetic people) phase 3 clinical trial programme, which involved more than 5,000 people with obesity (BMI ≥30 kg/m²) or who were overweight (BMI ≥27 kg/m²) with at least one weight-related comorbidity.

Saxenda® was approved in the US in December 2014 and in Canada in February 2015, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity (BMI ≥30 kg/m²) or who are overweight (BMI ≥27 kg/m²) with at least one weight-related comorbidity.

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 41,500 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

For further information

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Company announcement No 21 / 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf of the undersigned, thereunto duly authorized.

Date: March 23, 2015

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer