NOVO NORDISK A S
Form 6-K
July 25, 2014
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

July 25, 2014

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 [X] 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 [X]

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

Novo Nordisk receives positive opinion on Xultophy® (IDegLira) from the European regulatory authorities

Bagsværd, Denmark, 25 July 2014 – Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) adopted a positive opinion, recommending marketing authorisation for Xultophy® for the treatment of type 2 diabetes mellitus in adults.

Xultophy® is the intended brand name for IDegLira, the first once-daily single injection combination of Tresiba® (insulin degludec) and Victoza® (liraglutide), developed for the treatment of type 2 diabetes. The CHMP positive opinion recommends that Xultophy® will be indicated for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with basal insulin do not provide adequate glycaemic control.

In both the DUAL™ I and II phase 3a trials in the clinical development programme, Xultophy® achieved an average HbA1c reduction of 1.9%. Among people treated with Xultophy®, 81% of those previously treated with oral anti-diabetics and 60% of those previously treated with basal insulin achieved the HbA1c treatment target of 7% as defined by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA). People treated with Xultophy® experienced a low rate of hypoglycaemia, which was comparable to that of Tresiba®, and achieved a reduction in body weight when compared to treatment with basal insulin.

“We are excited about the positive opinion for Xultophy® from the CHMP. We believe that Xultophy® represents a new treatment paradigm with the potential to transform how type 2 diabetes is treated. We look forward to making the product available to people with type 2 diabetes in Europe,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Novo Nordisk expects to receive final marketing authorisation from the European Commission within approximately three months. Subject to the Commission’s approval and completion of pricing and reimbursement discussions, Novo Nordisk expects to launch Xultophy® in the first European markets in the first half of 2015.

About Xultophy®
Xultophy® is a once daily, single injection combination product consisting of insulin degludec (Tresiba®), a once-daily basal insulin analogue with an ultra-long duration of action, and liraglutide (Victoza®), the once-daily human GLP-1 analogue. Xultophy® is administered independently of meals, and has shown consistent results in improving glycaemic control in both insulin-naïve people as well people with type 2 diabetes that are uncontrolled on basal insulin. For people uncontrolled on basal insulin therapy, Xultophy® has demonstrated a significant reduction in HbA1C of 1.9% with a mean weight loss of 2.7 kg and a low rate of hypoglycaemia comparable to that of Tresiba®. Xultophy® is being investigated in the clinical trial programme, DUAL™. Novo Nordisk submitted the regulatory filing for Xultophy® in the EU on 31 May 2013.

About phase 3a trials in the DUAL™ clinical programme
DUAL™ (DUal Action of Liraglutide and Insulin Degludec in Type 2 Diabetes) includes two phase 3a trials encompassing around 2,000 people with type 2 diabetes.

DUAL™ I (1,663 people) – a 26-week, randomised, parallel, three-arm, open-label, multicentre trial conducted at 271 sites across 19 countries. The trial compared the efficacy and safety of Xultophy® versus insulin degludec and liraglutide alone, in insulin- naïve adults with type 2 diabetes uncontrolled with metformin with or without pioglitazone. The top-line results were reported in 2012, and results from a 26-week extension of the main trial to generate longer-term safety and efficacy data were reported in 2013.

DUAL™ II (398 people) – a 26-week, randomised, parallel, two-arm, double-blinded, multicentre trial conducted at 75 sites across seven countries. The trial compared the efficacy and safety of Xultophy® and insulin degludec once daily, both added on to metformin in adults with type 2 diabetes uncontrolled on basal insulin (20–40 units) in combination with metformin with or without sulfonylurea/glinides. Sulfonylureas and glinides were discontinued at randomisation. In this trial, the allowed maximum dose of insulin degludec in the treatment arms was 50 units so as to be able to demonstrate the contribution of the liraglutide component of Xultophy® on glycaemic control. The top-line results were reported in 2012.

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.

Further information

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Company announcement
No 45 / 2014

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: July 25, 2014

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer