NOVO NORDISK A S
Form 6-K
March 24, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 6-K

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REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16

of the Securities Exchange Act of 1934

March 24, 2017

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NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

(Address of principal executive offices)

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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-_____

CHMP provides positive opinion for EU label update for Novo Nordisk's Tresiba® based on data from SWITCH trials

Bagsværd, Denmark, 24 March 2017 – Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP), under the European Medicines Agency (EMA), has issued a positive opinion, recommending an update of the label for Tresiba® (insulin degludec) to include data from the SWITCH 1 and 2 clinical trials. In the trials, Tresiba®, the new-generation once-daily basal insulin, demonstrated clinically relevant reductions in hypoglycaemia compared with insulin glargine U100 in people with type 1 and type 2 diabetes.

For the SWITCH 1 trial, the CHMP recommends the updated label to include results reflecting the significant reductions in hypoglycaemia. In the trial, adults with type 1 diabetes treated with Tresiba® vs. insulin glargine U100, both in addition to meal-time insulin aspart, experienced statistically significant reductions in hypoglycaemia, including 11% reduction of overall symptomatic hypoglycaemia (severe or blood glucose confirmed), 36% reduction

in nocturnal symptomatic hypoglycaemia and 35% reduction in severe hypoglycaemia during the trial maintenance period.

For the SWITCH 2 trial, the CHMP recommends the updated label to include results reflecting the significant reductions in hypoglycaemia. In the trial, adults with type 2 diabetes treated with Tresiba® vs. insulin glargine U100 experienced statistically significant reductions in hypoglycaemia, including 30% reduction in overall symptomatic hypoglycaemia (severe or blood glucose confirmed) and 42% decrease in nocturnal symptomatic hypoglycaemia, during the trial maintenance period.

“Following the submission of the application to the EMA in November 2016, we are very pleased to have received a positive opinion from the CHMP for the label update already at this point in time,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer at Novo Nordisk. “An inclusion of the SWITCH trial results in the label will further support the clinical profile of Tresiba®”.

The CHMP positive opinion is now referred for final action to the European Commission, which grants approval in the EU. Novo Nordisk expects to receive the updated marketing authorisation in the second quarter of 2017.

About Tresiba®

Tresiba® (insulin degludec) is a once-daily basal insulin that provides duration of action beyond 42 hours with a flat and stable glucose-lowering effect. It provides low within-day variability and day-to-day variability and a lower risk of overall, nocturnal and severe hypoglycaemia vs. insulin glargine U100. On occasions when administration at the same time of day is not possible, Tresiba® allows for flexibility in day-to-day dosing time with a minimum of eight hours between injections. Tresiba® received its first regulatory approval in September 2012 and has since been approved in more than 80 countries globally. It was approved by the FDA in the United States on 26 September 2015. It is now commercially available in more than 50 countries.

About SWITCH 1 and 2

The two phase 3b, 2x32-week randomised, double-blind, crossover, treat-to-target trials were initiated to investigate the hypoglycaemia profile of Tresiba® compared to insulin glargine U100 in people with type 1 and type 2 diabetes, respectively. The primary endpoint was the number of severe or blood glucose confirmed symptomatic hypoglycaemic episodes observed in participants. The two secondary endpoints included: the number of severe or blood glucose confirmed nocturnal episodes experienced in participants; and the proportion of people with one or more severe hypoglycaemic episodes. In SWITCH 1, 501 people with type 1 diabetes were randomised to crossover treatment with Tresiba® and insulin glargine U100 in combination with insulin aspart. In SWITCH 2, 721 people with type 2 diabetes were randomised to crossover treatment with Tresiba® and insulin glargine U100 in combination with oral antidiabetic drugs.

About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information

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Company announcement No 21 / 2017

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.

NOVO NORDISK A/S

Date: March 24, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer