NOVO NORDISK A S
Form 6-K
September 23, 2016

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

September 23, 2016

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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-_____

Novo Nordisk submits application in the US for including data from the two SWITCH trials in Tresiba® label

Bagsværd, Denmark, 23 September 2016 – Novo Nordisk today announced the submission of a supplemental application to the US Food and Drug Administration (FDA) for including data from the two SWITCH phase 3b trials in the label for Tresiba®.

In SWITCH 1, people with type 1 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100, respectively, both in combination with insulin aspart. During the study's maintenance period, people treated with Tresiba® on average had 11% fewer episodes of overall symptomatic blood glucose confirmed hypoglycaemia, 36% fewer episodes of nocturnal blood glucose confirmed symptomatic hypoglycaemia and 35% fewer episodes of severe hypoglycaemia. All of the above results were statistically significant and similar results were seen in the full treatment period.

In SWITCH 2, people with type 2 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100, respectively, both in combination with oral antidiabetic drugs. During the study's maintenance period, people treated with Tresiba® on average had 30% fewer episodes of overall blood glucose confirmed symptomatic hypoglycaemia and 42% fewer episodes of nocturnal blood glucose confirmed symptomatic hypoglycaemia, both favouring Tresiba® over insulin glargine U100. Both observations were statistically significant and similar results were observed for the full treatment period. For severe hypoglycaemia there was a 46%, but not statistically significant reduction of the episodes in the maintenance period, and a statistically significant 51% reduction of the episodes in the full treatment period for Tresiba® compared to insulin glargine U100.

In both studies, the mean baseline for HbA1c was 7.6%, and both studies showed that Tresiba® was non-inferior in terms of HbA1c reduction compared to insulin glargine U100. This means that the requirements for objectively comparing hypoglycaemia episodes between the two treatments were fulfilled. In both studies, Tresiba® generally appeared to have a safe and well-tolerated profile.

"Hypoglycaemia continues to be a real challenge for many people with type 1 and type 2 diabetes. We believe that inclusion of the SWITCH trial results in the prescribing information for Tresiba® will provide healthcare professionals with important information

to make an informed choice when prescribing basal insulin" said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

About Tresiba®

Tresiba® (insulin degludec) is a once-daily basal insulin that provides a duration of action beyond 42 hours. It is important for people with type 1 and type 2 diabetes to establish a routine for insulin treatment. Tresiba® is taken once daily, at any time of day. Patients who miss or are delayed in taking their dose of Tresiba® can take their dose as soon as they remember, making sure there are at least eight hours between doses. Tresiba® received its first regulatory approval in September 2012 and has since been approved in more than 70 countries globally. It was approved by the FDA in the United States on 25 September 2015.

About SWITCH 1 and 2

The two phase 3b, 2x32-weeks randomised, double-blind, cross-over, treat-to-target trials were initiated in January 2014 to compare the safety profile and efficacy of Tresiba® and insulin glargine U100. In the trials, people were treated for a 16-week titration period followed by a 16-week maintenance period and subsequently switched to the comparator drug. The overall objective was to document the hypoglycaemia profile in type 1 diabetes and type 2 diabetes, respectively. In SWITCH 1, 501 people with type 1 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100 in combination with insulin aspart. In SWITCH 2, 721 people with type 2 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100 in combination with oral antidiabetic drugs.

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 42,300 people 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

Further information

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Company announcement No 64 / 2016

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: September 23, 2016

Lars Rebien Sørensen,

Chief Executive Officer