NOVO NORDISK A S
Form 6-K
September 29, 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

September 29, 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 endorses Tresiba® label update in the EU – new label reflects significant reduction in the risk of severe hypoglycaemia

Bagsværd, Denmark, 29 September 2017 – Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP), under the European Medicines Agency (EMA), has endorsed an update of the EU label with immediate effect for Tresiba® (insulin degludec) to include results from the DEVOTE trial on severe hypoglycaemia. DEVOTE is a randomised, multinational and double-blinded trial conducted to confirm the cardiovascular safety of Tresiba® compared to insulin glargine U100 when added to standard of care, in people with type 2 diabetes.

In the trial, the primary endpoint was achieved by demonstrating non-inferiority of major adverse cardiovascular events (MACE) with Tresiba® compared to insulin glargine U100. Severe hypoglycaemia was evaluated as a secondary endpoint and 27% fewer patients in the Tresiba® treated group experienced an episode of severe hypoglycaemia, resulting in a 40% overall rate reduction of total episodes of adjudicated severe hypoglycaemia. Furthermore, patients in the Tresiba® treated group experienced a 53% relative reduction in the rate of nocturnal

severe hypoglycaemia. These differences were all statistically significant.

“Our ambition is to help people with type 2 diabetes reach their treatment goals and at the same time reduce their risk of severe hypoglycaemia,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “With the CHMP’s endorsement of the updated label for Tresiba® we have passed a major milestone in insulin therapy.”

About the DEVOTE trial

DEVOTE is the first cardiovascular outcomes trial (CVOT) comparing two basal insulins. DEVOTE is a multinational, double-blinded clinical trial which investigated the cardiovascular safety of Tresiba® compared with insulin glargine U100 over 104 weeks. In the trial, 7,637 people with type 2 diabetes at high risk of, or existing, cardiovascular disease were randomised to treatment with either Tresiba® or insulin glargine U100 in vial in addition to standard of care.

In the trial, the primary endpoint was achieved by demonstrating non-inferiority of MACE with Tresiba® compared to insulin glargine U100. The primary endpoint was defined as the MACE composite outcome of the first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke and showed a hazard ratio of 0.91 in favour of Tresiba® relative to insulin glargine U100, with no statistically significant difference between the two treatments.

About Tresiba®

Tresiba® (insulin degludec) is a once-daily basal insulin that provides duration of action of at least 42 hours. 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, but ensuring there are at least eight hours between doses. Tresiba® was approved by the European Commission in January 2013 and has since been approved in more than 80 countries globally.

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 41,400 people in 77 countries and markets its products in more than 165 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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Novo Nordisk A/S

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Company announcement No 73 / 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: September 29, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer