NOVO NORDISK A S
Form 6-K
March 20, 2019

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 20, 2019

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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 files oral semaglutide for US regulatory approval of glycaemic control, as well as for CV risk reduction for oral semaglutide and Ozempic®

Bagsværd, Denmark, 20 March 2019 - Novo Nordisk today announced the submission of two New Drug Applications (NDAs) to the US Food and Drug Administration (FDA) for oral semaglutide, a once-daily glucagon-like peptide-1 (GLP-1) analogue in a tablet, as well as a supplemental NDA (sNDA) for once-weekly Ozempic® (semaglutide).

An NDA was submitted for oral semaglutide seeking approval for an indication for the treatment of adults with type 2 diabetes. A priority review voucher (PRV) has been applied to the NDA, leading to an anticipated review time of six months from the submission date, according to standard FDA review timelines.

The submission for oral semaglutide for the treatment of glycaemic control in adults with type 2 diabetes is based on the results from 10 PIONEER clinical trials, which included 9,543 adults with type 2 diabetes. In the PIONEER programme, people treated with oral semaglutide achieved greater blood glucose reductions compared to sitagliptin, empagliflozin, liraglutide and placebo. In addition, oral semaglutide demonstrated greater reductions in mean body weight vs most comparators. Across the PIONEER trials, oral semaglutide had a safe and well-tolerated profile, with the most common adverse event being nausea.

A second NDA was submitted for oral semaglutide seeking approval for a cardiovascular (CV) risk reduction indication in adults with type 2 diabetes. The NDA for an oral semaglutide cardiovascular risk reduction indication has an anticipated 10-month review time from the submission date, according to standard FDA review timelines.

Finally, an sNDA was submitted for Ozempic® for a cardiovascular risk reduction indication in adults with type 2 diabetes. The sNDA for an Ozempic® cardiovascular risk reduction indication has an anticipated 10-month review time from the submission date, according to standard FDA review timelines.

The applications for the oral semaglutide and Ozempic® cardiovascular risk reduction indications are based on the results of two cardiovascular outcomes trials (CVOTs)

evaluating the effects of adding semaglutide or placebo to standard of care on the risk of cardiovascular events; PIONEER 6 with oral semaglutide and SUSTAIN 6 with Ozempic®.

“Achieving glycaemic control and managing cardiovascular risk remains a challenge for many adults living with type 2 diabetes,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We are excited about the regulatory filings of the first GLP-1 receptor agonist in a tablet, as we believe oral semaglutide has the potential to further improve the treatment of adults living with type 2 diabetes.”

About the PIONEER clinical trial programme

PIONEER is the global clinical trial programme for oral semaglutide that comprises 10 phase 3a clinical trials, including a cardiovascular outcomes trial, and involving 9,543 adults with type 2 diabetes across all 10 trials.

About PIONEER 6 and SUSTAIN 6

PIONEER 6 was an event-driven, pre-approval CVOT for oral semaglutide. It was a randomised, double-blinded, placebo-controlled trial evaluating the cardiovascular safety of oral semaglutide vs placebo when added to standard of care in 3,183 adults with type 2 diabetes at high risk of cardiovascular events. The trial achieved its primary objective by ruling out an excess cardiovascular risk of 80% vs placebo, both in addition to standard of care.

SUSTAIN 6 was an event and time-driven, pre-approval CVOT for Ozempic®. It was a randomised, double-blinded, placebo-controlled trial evaluating the cardiovascular safety of Ozempic® vs placebo when added to standard of care in 3,297 adults with type 2 diabetes at high risk of cardiovascular events. In SUSTAIN 6, Ozempic® significantly reduced the risk of the primary composite endpoint of major adverse cardiovascular events by 26% vs placebo, both in addition to standard of care.

Novo Nordisk is a global healthcare company with more than 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,200 people in 80 countries and markets its products in more than 170 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 and YouTube.

Further information

Media:
Mette Kruse Danielsen +45 4442 3883 mkd@novonordisk.com
Ken Inchausti (US) +1 609 240 9429 kiau@novonordisk.com

Investors:
Peter Hugreffe Ankersen +45 3075 9085 phak@novonordisk.com
Valdemar Borum Svarrer +45 3079 0301 jvls@novonordisk.com
Ann Søndermølle Rendbæk +45 3075 2253 arnd@novonordisk.com
Kristoffer Due Berg (US) +1 609 235 2989 krdb@novonordisk.com

Novo Nordisk A/S

Investor Relations

Novo Allé

2880 Bagsværd

Denmark

Telephone:

+45 4444 8888

Internet:
www.novonordisk.com
CVR no:

24 25 67 90

Company announcement No 18 / 2019

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 20, 2019

Lars Fruergaard Jørgensen

Chief Executive Officer