NOVO NORDISK A S
Form 6-K
September 20, 2018

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 20, 2018

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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-_____

Oral semaglutide demonstrates greater reductions in HbA_{1c} and body weight and comparable number of adverse events vs dulaglutide in Japanese people with type 2 diabetes

Bagsværd, Denmark, 20 September 2018 - Novo Nordisk today announced the headline results from PIONEER 10, a phase 3a trial with oral semaglutide vs once-weekly subcutaneous dulaglutide, both in combination with one oral antidiabetic drug in Japanese adults with type 2 diabetes. Oral semaglutide is an investigational GLP-1 analogue taken once daily as a tablet. The trial investigated the safety, tolerability and efficacy of 3, 7 and 14 mg oral semaglutide compared with 0.75 mg once-weekly dulaglutide in 458 Japanese people with type 2 diabetes. Prior to enrolment, participants were inadequately controlled on one oral antidiabetic drug.

The trial achieved its primary objective by demonstrating a comparable number of adverse events with oral semaglutide compared to 0.75 mg dulaglutide. The proportion of people treated with 3, 7 and 14 mg oral semaglutide who experienced gastro-intestinal adverse events were 31%, 39% and 54%, respectively, compared to 40% with dulaglutide; the most frequently reported events being constipation and nausea. The proportion of people who discontinued treatment due to adverse events was between 3% and 6% of people treated with oral semaglutide, compared to 3% of people treated with dulaglutide.

Two distinct statistical approaches to evaluating the efficacy of oral semaglutide vs dulaglutide were applied in the PIONEER 10 trial; a primary statistical approach[1] evaluating the effect regardless of discontinuation of treatment and use of rescue medication, and a secondary statistical approach[2] describing the effect while on treatment and without use of rescue medication.

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[1] Treatment policy estimand approach: treatment effect regardless of discontinuation of treatment or initiation of rescue medication (analysed by pattern mixture model using multiple imputations to handle missing data with an analysis of covariance (ANCOVA)).

[2] Hypothetical estimand approach: treatment effect while on treatment without use of rescue medication (analysed by Mixed Models for Repeated Measurements (MMRM)). Similar statistical methodology as applied in the SUSTAIN programme for subcutaneous semaglutide.

When applying the primary statistical approach, statistically significantly greater reductions in HbA_{1c} and body weight were seen with oral semaglutide 14 mg than 0.75 mg dulaglutide at week 52.

When applying the secondary statistical approach, from a baseline of 8.3%, people treated with 14 mg oral semaglutide experienced a statistically significantly greater reduction in HbA_{1c} of 1.8% compared to 1.3% with 0.75 mg dulaglutide after 52 weeks. The reductions in HbA_{1c} were 0.7% and 1.4% for people treated with 3 and 7 mg oral semaglutide, respectively. Reductions in body weight from baseline were also statistically significantly greater with 14 mg oral semaglutide at week 52, with a reduction of 1.9 kg compared to a weight gain of 1.1 kg with dulaglutide. People treated with 3 and 7 mg oral semaglutide experienced a weight gain of 0.1 kg and weight reduction of 1.0 kg, respectively.

In addition, applying the secondary statistical approach, The Japanese Diabetes Society (JDS) treatment target of HbA_{1c} below 6.5% was achieved by 21%, 43% and 58% of people on treatment with 3, 7 and 14 mg oral semaglutide, respectively, compared to 41% of the people treated with 0.75 mg dulaglutide.

“Many people with type 2 diabetes in Japan remain uncontrolled on oral antidiabetic treatments,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “When adding oral semaglutide to the treatment of this group of people, this study has demonstrated that oral semaglutide is both well tolerated and more efficacious compared to subcutaneous dulaglutide.”

About PIONEER 10 and the PIONEER clinical trial programme

PIONEER 10 was a 57-week, randomised, open-label, active-controlled, parallel-group, multi-centre, single country trial with four treatment arms comparing the safety, tolerability and efficacy of 3, 7 and 14 mg oral semaglutide with 0.75 mg dulaglutide (the approved dose by the Pharmaceutical and Medical Devices Agency (PMDA) in Japan) in Japanese people with type 2 diabetes inadequately controlled with one oral antidiabetic drug (sulfonylurea, glinide, thiazolidinedione, alpha-glucosidase inhibitor or sodium glucose cotransporter-2 inhibitor). PIONEER 10 randomised 458 people in a 2:2:2:1 manner to receive either a dose of oral semaglutide 3, 7 or 14 mg once daily or 0.75 mg dulaglutide once weekly. The primary endpoint was the number of adverse events during exposure to the drug, assessed up to 57 weeks. Key secondary endpoints included the change from baseline to week 26 and 52 in HbA_{1c} and change from baseline to week 26 and 52 in body weight.

The PIONEER phase 3a clinical development programme for oral semaglutide is a global development programme with enrolment of 8,845 people with type 2 diabetes across 10 clinical trials, which are all expected to complete in

2018.

Novo Nordisk is a global healthcare company with 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 43,100 people in 79 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, YouTube.

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Novo Nordisk A/S

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CVR no:

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Company announcement No 74 / 2018

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 20, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer