NOVO NORDISK A S
Form 6-K
June 21, 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

June 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 shows statistically significantly greater reductions in HbA_{1c} and weight compared to Victoza® and sitagliptin in the PIONEER 4 and 7 trials

Bagsværd, Denmark, 20 June 2018 - Novo Nordisk today announced the successful completion and headline results of the phase 3a trials PIONEER 4 comparing oral semaglutide as a treatment for adults with type 2 diabetes to Victoza® (1.8 mg liraglutide) and placebo, and PIONEER 7 comparing oral semaglutide as a treatment for adults with type 2 diabetes to sitagliptin 100 mg. Oral semaglutide is a new GLP-1 analogue taken once daily as a tablet.

Two distinct statistical approaches to evaluate the effects of oral semaglutide were applied in the PIONEER 4 and 7 trials; a primary statistical approach[1] required by recent regulatory guidance, 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.

PIONEER 4

PIONEER 4 was a 52-week double-blinded, double-dummy trial investigating the efficacy and safety of 14 mg oral semaglutide compared with Victoza® 1.8 mg and placebo in 711 people with type 2 diabetes inadequately controlled on metformin, with or without an SGLT-2 inhibitor.

PIONEER 4 achieved its primary objective according to the primary statistical approach by demonstrating a non-inferior reduction in HbA_{1c} and statistically significant and superior weight loss at 26 weeks with oral semaglutide compared to Victoza®.

Furthermore, oral semaglutide provided statistically significant and superior reductions in HbA_{1c} and weight compared to placebo.

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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) and a logistics regression model).

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

When applying the secondary statistical approach for week 26 and week 52, respectively, people treated with oral semaglutide experienced a reduction in HbA_{1c} of 1.3% and 1.2% compared to 1.1% and 0.9% with Victoza® whereas placebo declined by 0.1% and increased by 0.2%. Reductions in HbA_{1c} were statistically significantly greater with oral semaglutide compared to both Victoza® and placebo. Reduction in body weight from baseline was statistically significantly greater with oral semaglutide at 4.7 and 5.0 kg at 26 and 52 weeks, respectively, compared to 3.2 and 3.1 kg with Victoza®, and 0.7 and 1.2 kg with placebo. The American Diabetes Association (ADA) treatment target of HbA_{1c} below 7.0% was achieved by 69% of people treated with oral semaglutide, 63% of people treated with Victoza® and 18% of people treated with placebo after 52 weeks; the difference between oral semaglutide and placebo was statistical significant.

In the trial, oral semaglutide was well-tolerated and with a profile consistent with GLP-1- based therapy. The most common adverse event for oral semaglutide was mild to moderate nausea which diminished over time. In PIONEER 4, 20% of people treated with oral semaglutide experienced nausea, compared to 18% of people treated with Victoza® and 4% of people treated with placebo. The proportion of people who discontinued treatment due to adverse events was 11% for people treated with oral semaglutide compared to 9% for people treated with Victoza® and 4% for people receiving placebo.

PIONEER 7

PIONEER 7 was a 52-week open-label trial investigating the efficacy and safety of oral semaglutide with dose adjustment based on clinical evaluation of glycaemic control and drug tolerability compared with the DPP-IV inhibitor 100 mg sitagliptin in 504 people with type 2 diabetes, inadequately controlled on 1-2 oral antidiabetics.

The trial achieved its primary objective according to the primary statistical principle by demonstrating that oral semaglutide was statistically significant and superior to sitagliptin 100 mg in the proportion of people achieving the American Diabetes Association (ADA) treatment target of HbA_{1c} below 7% at week 52. Oral semaglutide also demonstrated statistically significant and superior reductions in body weight versus sitagliptin.

When applying the secondary statistical approach, people treated with oral semaglutide experienced a statistically significant reduction in HbA_{1c} of 1.4% compared to 0.7% with sitagliptin at week 52. From a baseline HbA_{1c} of 8.3%, 63% of people treated with oral semaglutide achieved the target HbA_{1c} below 7% after 52 weeks of treatment compared to 28% of people treated with sitagliptin, and the difference was statistically significant. The reduction in body weight of 2.9 kg with oral semaglutide was statistically significantly greater at week 52 compared to 0.8 kg with sitagliptin. After 52 weeks of treatment, approximately 9% of the people receiving oral semaglutide treatment were receiving 3 mg oral semaglutide, while approximately 31% and 60% were receiving 7 mg and 14 mg oral

semaglutide, respectively.

In the trial, oral semaglutide was well-tolerated and with a profile consistent with GLP-1- based therapy. The most common adverse event for oral semaglutide was mild to

moderate nausea, which diminished over time. In PIONEER 7, 21% of people treated with oral semaglutide experienced nausea, compared to 2% of people treated with sitagliptin. The proportion of people who discontinued treatment due to adverse events was 9% for people treated with oral semaglutide compared to 3% for people treated with sitagliptin.

“With the significant one-year results in a real-world dose setting, oral semaglutide was superior to sitagliptin by documenting a greater proportion of people achieving the ADA target,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “At the same time, we have shown that oral semaglutide is even more efficacious in lowering glucose and body weight than the most widely used injectable GLP-1 treatment, Victoza®”.

About PIONEER 4, PIONEER 7 and the PIONEER clinical trial programme

PIONEER 4 was a 52-week, randomised, double-blinded, double-dummy, active- and placebo-controlled, parallel-group, multicentre, multinational trial with three arms comparing the efficacy and safety of 14 mg oral semaglutide compared to Victoza® and vs placebo in people with type 2 diabetes, inadequately controlled on metformin with or without a sodium-glucose co-transporter-2 (SGLT-2) inhibitor. PIONEER 4 randomised 711 people in a 2:2:1 manner to receive either 14 mg oral semaglutide, Victoza® 1.8 mg, or placebo once daily. The primary endpoint was change from baseline to week 26 in HbA_{1c}. Key secondary endpoints included change in HbA_{1c} and body weight from baseline to week 52.

PIONEER 7 was a 52-week, randomised, open-label, active-controlled, parallel-group, multicentre, multinational trial with two arms comparing the efficacy and safety of oral semaglutide using a flexible dose adjustment (3, 7 or 14 mg) based on clinical evaluation (glycaemic target and tolerability) of their response to treatment compared with sitagliptin in people with type 2 diabetes mellitus, inadequately controlled on 1-2 oral antidiabetics. PIONEER 7 enrolled 504 people randomised 1:1 to receive either oral semaglutide or 100 mg sitagliptin once daily. The primary endpoint was HbA_{1c} below 7% as per the ADA treatment target at week 52. Key secondary endpoints included change in HbA_{1c} and body weight from baseline to week 52.

Novo Nordisk plans to report the PIONEER 3 trial comparing 3, 7 and 14 mg oral semaglutide with 100 mg sitagliptin before the end of second quarter of 2018.

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 42,700 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.

Further information

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Company announcement No 51 / 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: June 20, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer