NOVO NORDISK A S
Form 6-K
October 26, 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

October 26, 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 statistically significant reductions in HbA_{1c} and body weight in people with long duration of type 2 diabetes treated with insulin

Bagsværd, Denmark, 26 October 2018 - Novo Nordisk today announced the headline results from PIONEER 8, a phase 3a trial with oral semaglutide for the treatment of adults with type 2 diabetes. Oral semaglutide is an investigational GLP-1 analogue taken once daily as a tablet. The 52-week trial investigated the efficacy and safety of 3, 7 and 14 mg oral semaglutide compared with placebo in 731 people with type 2 diabetes treated with insulin and an average duration of diabetes of 15 years. During the first 26- week treatment period, the total daily insulin dose was not allowed to be increased above baseline followed by a 26-week period where the insulin treatment was adjusted without restrictions.

Two distinct statistical approaches to evaluating the effects of oral semaglutide were applied in the PIONEER 8 trial; 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.

When applying the primary statistical approach, the trial achieved its primary objective by demonstrating statistically significant and superior reductions in HbA_{1c} and body weight with all three doses of oral semaglutide compared to placebo, all in addition to insulin, at week 26.

When applying the secondary statistical approach, from a mean baseline of 8.2%, people treated with 3, 7 and 14 mg oral semaglutide achieved reductions in HbA_{1c} of 0.6%, 1.0% and 1.4% respectively, compared to no reduction (0.0%) in people treated with placebo, all in addition to insulin, at week 26, and 0.5%, 0.8% and 1.2% respectively, compared with 0.0% at week 52. The American Diabetes Association (ADA) treatment

[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.

target of HbA_{1c} below 7.0% was achieved by 36%, 47% and 64% of people treated with 3, 7 and 14 mg oral semaglutide respectively, compared to 10% of people treated with placebo at week 52. In addition, from a mean baseline body weight of 85.9 kg, people treated with 3, 7 and 14 mg oral semaglutide experienced a weight loss of 1.0 kg, 2.9 kg and 4.3 kg, respectively, compared to a weight increase of 0.6 kg in people treated with placebo at week 52, all in addition to insulin. The mean total insulin dose at baseline was 60, 62 and 54 units/day for people treated with 3, 7 and 14 mg oral semaglutide respectively, compared to 56 IU/day for people treated with placebo, and the total insulin dose at week 52 was increased by 2 units/day, reduced by 6 units/day and reduced by 7 units/day for people treated with 3, 7 and 14 mg oral semaglutide respectively, compared to an increase of 10 units/day for people treated with placebo.

In the 52-week trial, people treated with 3, 7 and 14 mg oral semaglutide experienced few and comparable levels of severe or blood glucose-confirmed hypoglycaemic episodes compared to placebo. 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 8, 11-23% of people treated with oral semaglutide experienced nausea, compared to 7% of people treated with placebo. The proportion of people who discontinued treatment due to adverse events was 7-14% for people treated with oral semaglutide compared to 3% with placebo.

“For people with type 2 diabetes and requiring insulin treatment, it can be challenging to reach optimal blood sugar control levels due to weight gain and risk of hypoglycaemia,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “In PIONEER 8, oral semaglutide was able to improve blood sugar control for people with a long duration of diabetes and already treated with insulin, with the benefit of clinically meaningful weight reduction, and without increasing the risk of hypoglycaemia.”

About PIONEER 8 and the PIONEER clinical trial programme

PIONEER 8 was a 52-week, randomised, double-blinded, placebo-controlled, parallel- group, multicentre, multinational trial with four arms comparing the efficacy and safety of 3, 7 and 14 mg oral semaglutide with placebo in people with type 2 diabetes treated with basal insulin alone or basal/bolus insulin in any combination or premix insulin including combinations of soluble insulins. The insulin treatment could be combined with metformin. The 52-week randomised treatment period was split into two; an initial 26- week period during which the insulin dose was capped at pre-randomisation levels, followed by a 26-week period where insulin treatment was adjusted without any restrictions. PIONEER 8 randomised 731 people with an average of duration of diabetes of 15 years in a 1:1:1:1 manner to receive either a dose of oral semaglutide 3, 7 and 14 mg or placebo in addition to insulin. The primary endpoint and confirmatory secondary endpoints were change from baseline to week 26 in HbA_{1c} and body weight. Key secondary endpoints included change in HbA_{1c} and bodyweight from baseline to week 52.

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.

Further information

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Novo Nordisk A/S

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Company announcement No 81 / 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: October 26, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer