NOVO NORDISK A S
Form 6-K
June 28, 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 28, 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 superior reductions in HbA_{1c} and weight compared to sitagliptin in the long-term safety and efficacy trial, PIONEER 3

Bagsværd, Denmark, 28 June 2018 - Novo Nordisk today announced the headline results from PIONEER 3, 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 78-week trial investigated the efficacy and long-term safety of 3, 7 and 14 mg oral semaglutide compared with 100 mg sitagliptin in 1,864 people with type 2 diabetes inadequately controlled with metformin, with or without sulfonylurea. The confirmatory endpoints were assessed after 26 weeks of treatment.

Two distinct statistical approaches to evaluating the effects of oral semaglutide were applied in the PIONEER 3 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.

The trial achieved its primary objective according to the primary statistical approach by demonstrating statistically significant and superior reductions in HbA_{1c} with oral semaglutide 7 and 14 mg compared to sitagliptin at week 26. Furthermore, people treated with oral semaglutide 7 and 14 mg achieved statistically significant and superior reductions in body weight compared to sitagliptin at week 26.

When applying the secondary statistical approach for week 26 and week 78, respectively, people treated with 7 and 14 mg oral semaglutide experienced statistically significantly greater reductions in HbA_{1c} of 1.1% and 0.7% with 7 mg oral semaglutide, 1.4% and 1.1% with 14 mg oral semaglutide compared to 0.8% and 0.4% with sitagliptin. Reductions in HbA_{1c} with 3 mg oral semaglutide at 26 and 78 weeks were 0.5% and

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.

0.3%, respectively, and the reduction was statistically significantly less than sitagliptin at 26 week, but was not statistically different at week 78. Reductions in body weight from baseline were statistically significantly greater with 3, 7 and 14 mg oral semaglutide at week 26 and 78, respectively, with reductions of 1.2 and 1.9 kg for 3 mg oral semaglutide, 2.2 and 2.7 kg for 7 mg oral semaglutide and 3.3 and 3.5 kg for 14 mg oral semaglutide compared to 0.7 and 1.1 kg with sitagliptin.

In this 78-week 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 3, 7-15% of people treated with oral semaglutide experienced nausea, compared to 7% of people treated with sitagliptin. The proportion of people who discontinued treatment due to adverse events was 6-12% for people treated with oral semaglutide compared to 5% with sitagliptin.

“With the results from the PIONEER 3 trial, we have shown that the two highest doses of oral semaglutide achieved superior improvements in glycaemic control and body weight compared to sitagliptin with a favourable safety profile consistent with GLP-1-based therapy” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “Furthermore, PIONEER 3 is an important trial, as it demonstrates long-term safety and efficacy of oral semaglutide”

About PIONEER 3 and the PIONEER clinical trial programme

PIONEER 3 was a 78-week, randomised, double-blind, double-dummy, active-controlled, parallel-group, multicentre, multinational trial with four arms comparing the efficacy and safety of 3, 7 and 14 mg oral semaglutide with 100 mg sitagliptin in people with type 2 diabetes inadequately controlled with metformin, with or without sulfonylurea. PIONEER 3 randomised 1,864 people in a 1:1:1:1 manner to receive either a dose of oral semaglutide 3, 7 and 14 mg or 100 mg sitagliptin 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 78.

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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Novo Nordisk A/S

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Company announcement No 53 / 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 28, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer