NOVO NORDISK A S
Form 6-K
August 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

August 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 provides superior HbA_{1c} and weight reductions versus placebo in people with type 2 diabetes and renal impairment in the PIONEER 5 trial

Bagsværd, Denmark, 20 August 2018 - Novo Nordisk today announced the headline results from PIONEER 5, a phase 3a trial with oral semaglutide in adults with type 2 diabetes and moderate renal impairment. Oral semaglutide is an investigational GLP-1 analogue taken once daily as a tablet. The 26-week trial investigated the efficacy and safety of 14 mg oral semaglutide compared with placebo in 324 people with type 2 diabetes and moderate renal impairment inadequately controlled with metformin, sulfonylurea alone or in combination with metformin, or basal insulin alone or in combination with metformin.

Two distinct statistical approaches to evaluating the effects of oral semaglutide were applied in the PIONEER 5 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 compared to placebo at week 26. Furthermore, people treated with oral semaglutide achieved statistically significant and superior reductions in body weight compared to placebo at week 26.

When applying the secondary statistical approach, people treated with oral semaglutide experienced a statistically significantly greater reduction in HbA_{1c} of 1.1% compared to 0.1% with placebo. Reduction in body weight was statistically significantly greater with oral semaglutide at week 26, with a reduction of 3.7 kg compared to 1.1 kg with placebo. From a baseline HbA_{1c} of 8.0%, the proportion of people achieving the American Diabetes

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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.

Association (ADA) target of HbA_{1c} below 7.0% was statistically significantly greater with 14 mg oral semaglutide, with 64% achieving the target at week 26, compared to 21% with placebo.

In this 26-week trial, oral semaglutide was well-tolerated in people with moderate renal impairment, with a profile consistent with GLP-1-based therapies. The most common adverse event for oral semaglutide was mild to moderate nausea. In PIONEER 5, 19% of people treated with oral semaglutide experienced nausea, compared to 8% of people treated with placebo. The proportion of people who discontinued treatment due to adverse events was 15% for people treated with oral semaglutide compared to 6% with placebo.

“The results from PIONEER 5 showed that oral semaglutide is efficacious and has a solid safety profile in people with type 2 diabetes and moderate renal impairment, thereby further expanding the solid clinical profile of oral semaglutide,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “Renal impairment is a serious diabetes complication and people with this condition have limited oral anti-diabetic treatment options, and if approved oral semaglutide represents an efficacious new solution for these people.”

About PIONEER 5 and the PIONEER clinical trial programme

PIONEER 5 was a 26-week, randomised, double-blind, placebo-controlled, parallel-group, multicentre, multinational trial with two arms comparing the efficacy and safety of 14 mg oral semaglutide with placebo in people with type 2 diabetes and moderate renal impairment (estimated glomerular filtration rate [eGFR] 30–59 ml/min/1.73m^2) inadequately controlled with metformin, sulfonylurea alone or in combination with metformin, or basal insulin alone or in combination with metformin. PIONEER 5 randomised 324 people in a 1:1 manner to receive either a dose of 14 mg oral semaglutide or placebo once daily. The primary endpoint was change from baseline to week 26 in HbA_{1c}. Key secondary endpoints included change in body weight, change in fasting plasma glucose from baseline to week 26 and proportion of people achieving HbA_{1c} below 7.0% at 26 weeks.

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 66 / 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: August 20, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer