NOVO NORDISK A S
Form 6-K
November 23, 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

November 22, 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 both HbA1c and body weight compared to Victoza® in Japanese people with type 2 diabetes

Bagsværd, Denmark, 22 November 2018 - Novo Nordisk today announced the headline results from PIONEER 9, a 52-week trial with oral semaglutide vs Victoza® (0.9 mg liraglutide) and vs placebo, all as monotherapy, in Japanese adults with type 2 diabetes. Oral semaglutide is an investigational GLP-1 taken once daily as a tablet. PIONEER 9 was a phase 3a safety and efficacy trial investigating 3, 7 and 14 mg oral semaglutide compared with Victoza® and with placebo in 243 Japanese adults with type 2 diabetes.

The trial successfully achieved its primary objective[1] by demonstrating that, from a mean baseline HbA_{1c} of 8.2%, people treated with 3, 7 and 14 mg oral semaglutide experienced statistically significant reductions in HbA_{1c} of 1.1%, 1.5% and 1.7%, respectively, compared to a reduction of 0.1% with placebo after 26 weeks. Furthermore, 14 mg oral semaglutide achieved a statistically significantly greater reduction in HbA_{1c} compared to a reduction of 1.4% with Victoza®.

After 52 weeks, people treated with 3, 7 and 14 mg oral semaglutide experienced statistically significantly greater reductions in HbA_{1c} of 0.9%, 1.3% and 1.5%, respectively, compared to an increase of 0.5% for people treated with placebo. Furthermore, people treated with Victoza® experienced a reduction in HbA_{1c} of 1.1%, which was not statistically significant in favour of oral semaglutide.

The Japan Diabetes Society (JDS) treatment target of HbA_{1c} <7.0% was achieved by 50%, 67% and 80% of people treated with 3, 7 and 14 mg oral semaglutide, respectively, compared to 49% of people treated with Victoza® and 12% of people treated with placebo at week 52.

From a mean baseline body weight of 71.1 kg, people treated with 14 mg oral semaglutide experienced a statistically significantly greater weight reduction of 2.8 kg after 52 weeks compared to 1.0 kg with placebo and a weight increase of 0.4 kg with Victoza®. People treated with 3 and 7 mg oral semaglutide experienced a body weight reduction of 0.0 kg and 0.6 kg, respectively.

[1] Analysed by Mixed Models for Repeated Measurements (MMRM), which was the similar statistical methodology as applied in the SUSTAIN programme for subcutaneous semaglutide.

In this 52-week trial, oral semaglutide was well-tolerated and with a safety profile consistent with GLP-1-based therapy. The most common adverse events for oral semaglutide were constipation and mild to moderate nausea, which diminished over time. The proportion of people who discontinued treatment due to adverse events was 2-4% for people treated with oral semaglutide.

"Achieving target blood glucose levels remains a challenge for many people living with type 2 diabetes," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "In PIONEER 9, an impressive 80% of Japanese people with type 2 diabetes treated with the highest dose of oral semaglutide achieved the Japan Diabetes Society target for good glycaemic control, with a safety profile consistent with injectable GLP-1 therapies."

About PIONEER 9 and the PIONEER clinical trial programme

PIONEER 9 was a 52-week, randomised, double-blinded placebo-controlled and open-label active-controlled phase 3 safety and efficacy trial. It had 5 treatment arms comparing the dose-response, safety, and efficacy of 3, 7 and 14 mg oral semaglutide with placebo and with Victoza® 0.9 mg in Japanese people with type 2 diabetes, treated with diet and exercise alone or in addition to an oral anti-diabetic drug as monotherapy. PIONEER 9 randomised 243 people in a 1:1:1:1:1 manner to receive once-daily treatment with either a dose of oral semaglutide 3, 7 or 14 mg, Victoza® or placebo. The primary endpoint was the change in baseline HbA_{1c} to week 26. Key secondary endpoints included change in HbA_{1c} at week 52, change in plasma glucose, body weight and number of participants achieving a target of HbA_{1c} <7% at weeks 26 and 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 43,200 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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Company announcement No 89 / 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: November 22, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer