NOVO NORDISK A S
Form 6-K
November 30, 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 23, 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 a favourable cardiovascular safety profile and a significant reduction in cardiovascular death and all-cause mortality in people with type 2 diabetes in the PIONEER 6 trial

Bagsværd, Denmark, 23 November 2018 - Novo Nordisk today announced the headline results from the last global phase 3a trial, PIONEER 6, for oral semaglutide, an investigational GLP-1 analogue taken once daily as a tablet. This double-blinded trial investigated the cardiovascular safety of oral semaglutide 14 mg compared with placebo, both in addition to standard of care, in 3,183 adults with type 2 diabetes at high risk of cardiovascular events.

The trial achieved its primary endpoint by demonstrating non-inferiority of major adverse cardiovascular events (MACE) with oral semaglutide compared with placebo, both in addition to standard of care. The results are based on the accumulated occurrence of 137 major adverse cardiovascular events, with a median follow-up time of 16 months. The primary endpoint of the PIONEER 6 trial was defined as the MACE composite outcome of the first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke and showed a hazard ratio of 0.79 in favour of oral semaglutide compared with placebo. The 21% reduction in MACE in favour of oral semaglutide did not reach statistical significance.

The MACE results demonstrated by oral semaglutide were driven by a statistically significant reduction in cardiovascular death of 51% (HR 0.49, p=0.03), while non-fatal myocardial infarction (HR 1.18, non-significant) or non-fatal stroke (HR 0.74, non- significant) were broadly similarly distributed between the two treatment arms. In addition, a statistically significant reduction in all-cause mortality of 49% (HR 0.51, p=0.008) in favour of oral semaglutide was observed.

The improvements in secondary endpoints including HbA1c, body weight and blood pressure were similar to results reported throughout the PIONEER programme for oral semaglutide. Furthermore, the safety profile of oral semaglutide in PIONEER 6 was consistent with the established safety profile observed in previous PIONEER clinical trials.

“We are very encouraged that PIONEER 6 demonstrated cardiovascular safety as well as a significant reduction in both CV and all-cause mortality following oral semaglutide treatment in people with type 2 diabetes at high cardiovascular risk,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “Based on the strong clinical data reported throughout the PIONEER clinical trial programme, we have now established a solid efficacy and safety profile for oral semaglutide and we are looking forward to sharing the results with regulatory authorities during 2019.”

Novo Nordisk expects to file oral semaglutide for regulatory review in the US and EU in the first half of 2019.

As announced in August 2018, Novo Nordisk has since the approval of Ozempic® (once- weekly injectable semaglutide) engaged in a constructive dialogue with the US FDA (Food and Drug Administration) on minimising the need for additional separate large cardiovascular outcomes trials (CVOTs) to obtain a cardiovascular (CV) indication for semaglutide in different formulations Following the results of the PIONEER 6 trial, Novo Nordisk is now evaluating the potential to obtain a CV indication for Ozempic® based on the already obtained clinical data from the CVOT SUSTAIN 6 in combination with the CVOT PIONEER 6 with oral semaglutide. Novo Nordisk will continue these discussions with the FDA.

About PIONEER 6 and the PIONEER clinical trial programme

PIONEER 6 was an event-driven, pre-approval cardiovascular outcomes trial for oral semaglutide. It was a randomised, double-blinded, placebo-controlled trial evaluating the cardiovascular safety of oral semaglutide vs placebo when added to standard of care in 3,183 people with type 2 diabetes at high risk of cardiovascular events.

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 have all been completed 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.

Further information

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Novo Nordisk A/S

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24 25 67 90

Company announcement No 90 / 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 23, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer