NOVO NORDISK A S
Form 6-K
May 03, 2019

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

April 26, 2019

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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-_____

Novo Nordisk files for EU regulatory approval of oral semaglutide for the treatment of type 2 diabetes

Bagsværd, Denmark, 26 April 2019 - Novo Nordisk today announced the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for oral semaglutide, a glucagon-like peptide-1 (GLP-1) analogue in a tablet taken once- daily, for the treatment of adults with type 2 diabetes.

The submission is based on the results from 10 PIONEER clinical trials, which included 9,543 adults with type 2 diabetes. In the PIONEER programme, people treated with oral semaglutide demonstrated greater HbA1c reductions and weight loss in all completed head-to-head trials versus sitagliptin, empagliflozin, liraglutide and dulaglutide, at the end of the trials. Across the PIONEER trials, oral semaglutide had a safe and well- tolerated profile consistent with the GLP-1 receptor agonist (RA) class, with the most common adverse event being nausea.

“Achieving glycaemic control remains a challenge for people with type 2 diabetes, and despite availability of several oral treatment options, a high proportion do not achieve target blood sugar levels,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We are excited about the regulatory filing of oral semaglutide in Europe, the first GLP-1 receptor agonist in a tablet, as we believe oral semaglutide has the potential to further improve the treatment of adults living with type 2 diabetes.”

Oral semaglutide has now been submitted for regulatory approval in the US, the EU and Canada.

Further information

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Novo Nordisk A/S

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CVR no:

24 25 67 90

Company announcement No 25 / 2019

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: April 26, 2019

Lars Fruergaard Jørgensen

Chief Executive Officer