NOVO NORDISK A S
Form 6-K
April 03, 2017

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

March 31, 2017

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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-_____

FDA posts briefing materials prior to Advisory Committee meeting for nonacog beta pegol, a long-acting factor IX for the treatment of haemophilia B

Bagsværd, Denmark, 31 March 2017 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has published the briefing documents ahead of the Advisory Committee meeting to discuss the Biologics License Application for nonacog beta pegol, a long-acting factor IX for the treatment of haemophilia B. The meeting takes place on 4 April 2017.

The briefing documents from Novo Nordisk and the FDA, which will form the basis for the Advisory Committee's discussion, provide an overview of the non-clinical and clinical data for nonacog beta pegol for the treatment of haemophilia B.

The briefing materials can be accessed on the FDA webpage:
https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm543914.htm

About advisory committee meetings

FDA advisory committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing new drug applications. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer new drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.

About nonacog beta pegol

Nonacog beta pegol is a factor IX molecule with an extended half-life intended for replacement therapy in patients with haemophilia B. GlycoPEGylation is a well- established technique commonly used to prolong the circulating half-life of drugs.

The BLA for nonacog beta pegol was submitted to the FDA in May 2016 under the US FDA's Prescription Drug User Fee Act V (PDUFA V) regulation. In Europe, nonacog beta pegol received a positive CHMP opinion on 24 March 2017.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 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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CVR no:
24 25 67 90

Company announcement No 25 / 2017

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: March 31, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer