NOVO NORDISK A S
Form 6-K
March 24, 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 24, 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-_____

Novo Nordisk receives positive opinion from the European regulatory authorities for Refixia® (nonacog beta pegol, N9-GP) for the treatment of haemophilia B

Bagsværd, Denmark, 24 March 2017 – Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP), under the European Medicines Agency (EMA), adopted a positive opinion for the use of Refixia® (nonacog beta pegol, N9-GP), recommending marketing authorisation for the treatment of adolescents and adults with haemophilia B.

The CHMP recommends Refixia®, the brand name for nonacog beta pegol, N9-GP, to be indicated for prophylaxis and on-demand treatment of bleeding as well as for surgical procedures in adolescent (≥12 years of age) and adult patients with haemophilia B (congenital factor IX deficiency). The recommendation is based on the results from the paradigm clinical trial programme, where 115 previously treated children and adults with haemophilia B were treated with Refixia®.

“We are excited about the positive opinion obtained for Refixia® and it represents a significant milestone in our efforts to expand the treatment options for patients with haemophilia,” said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk. “We believe Refixia® with its strong clinical profile provides haemophilia B patients better protection against bleeds, even into damaged joints, and an overall improved quality of life.”

About Refixia®

Refixia® (nonacog beta pegol, N9-GP) is an extended half-life factor IX molecule for replacement therapy in patients with haemophilia B. Glycopegylation, the prolongation technology used for the half-life extension, is a novel approach in haemophilia B. Pegylated products have been approved in haemophilia A and other therapeutic areas. The review of Refixia® was based on the paradigm programme, a phase 3 clinical programme enrolling children and adults with severe or moderately severe haemophilia B. In the programme, 115 previously treated patients had a total of more than 8,800 exposure days for up to 2.7 years of treatment with Refixia®.

About Novo Nordisk

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. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information

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Novo Nordisk A/S

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Company announcement No 22 / 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 24, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer