NOVO NORDISK A S
Form 6-K
April 29, 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 receives positive opinion from the European regulatory authorities for Esperoct® (turoctocog alfa pegol, N8-GP) for the treatment of haemophilia A

Bagsværd, Denmark, 26 April 2019 – 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 Esperoct® (turoctocog alfa pegol, N8-GP) recommending marketing authorisation for the treatment of adolescents and adults with haemophilia A.

The CHMP recommends Esperoct®, the brand name for turoctocog alfa pegol, N8-GP, to be indicated for prophylaxis and on-demand treatment of bleeding as well as for surgical procedures in adolescents (≥12 years of age) and adults with haemophilia A (congenital factor VIII deficiency). The recommendation is based on the results from the largest pre- registration clinical programme conducted in haemophilia A, with inclusion of 270 previously treated people (PTPs) with severe haemophilia A and more than 5 years of clinical exposure.

“We are happy to receive the positive opinion for Esperoct® in the EU, and we consider it an important expansion of the treatment options Novo Nordisk can offer people with haemophilia A,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We are confident that Esperoct® can provide a less burdensome and simple dosing regimen for prophylaxis and treatment of bleeding episodes, resulting in improved quality of life for people with haemophilia A.”

About Esperoct®

Esperoct® (turoctocog alfa pegol, N8-GP) is an extended half-life factor VIII molecule for replacement therapy in people with haemophilia A, which provides a 1.6-fold half-life prolongation in adults/adolescents compared to standard half-life factor VIII products.

Esperoct® was shown to provide effective routine prophylaxis in people with severe haemophilia A through a simple, fixed dosing regimen of one injection every 4 days in adults and adolescents. Esperoct® provided effective prophylaxis and maintained a low median ABR of 1.18 when dosed at 50 IU/kg every 4 days in adults and adolescents.

Furthermore, Esperoct® was found to be efficacious in treatment and control of bleeding episodes and perioperative management. Across the clinical trials and age groups, Esperoct® was well tolerated and no safety concerns were identified. The overall safety profile of Esperoct® is similar to what has been reported for other long-action FVIII products.

Novo Nordisk is a global healthcare company with more than 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 80 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 and YouTube.

Further information

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Company announcement No 26 / 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