NOVO NORDISK A S
Form 6-K
February 20, 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

February 19, 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 US FDA approval of ESPEROCT®

(turoctocog alfa pegol, N8-GP)

Bagsværd, Denmark, 19 February 2019 - Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved the Biologics License Application for ESPEROCT® for the treatment of adults and children with haemophilia A.

ESPEROCT® is the brand name for turoctocog alfa pegol, N8-GP. ESPEROCT® is indicated for use in adults and children with haemophilia A (congenital factor VIII deficiency) for routine prophylaxis to reduce the frequency of bleeding episodes, on-demand treatment and control of bleeding episodes and perioperative management of bleeding.

The approval of ESPEROCT® is based on the results from the largest pre-registration clinical programme conducted in haemophilia A, which included 270 previously treated people (PTPs) with severe haemophilia A and more than 5 years of clinical exposure. 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 or every 3-4 days (twice-weekly) in children. 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.

"We are excited about the approval of ESPEROCT® in the US, 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® will provide people with haemophilia A a less burdensome and simple, fixed dosing regimen for prophylaxis and treatment of bleeding episodes, resulting in improved quality of life."

Due to third-party IP agreements, Novo Nordisk will not be able to launch ESPEROCT® before 2020 in the USA.

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 and a 1.9-fold half-life prolongation in children, compared to standard half-life factor VIII products.

About the pathfinder clinical programme

ESPEROCT® has been evaluated in 270 people (202 adults/adolescents and 68 children) in five prospective, multi-centre clinical trials in previously treated people (PTPs) with severe haemophilia A (<1% endogenous FVIII activity) and no history of inhibitors. Total exposure to ESPEROCT® was 80,425 exposure days corresponding to 889 patient years of treatment. ESPEROCT® was well tolerated across all age groups and indications, and no safety concerns were identified after more than 5 years of clinical exposure.

Further information

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Company announcement No 11 / 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: February 19, 2019

Lars Fruergaard Jørgensen

Chief Executive Officer