NOVO NORDISK A S
Form 6-K
May 16, 2016

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

May 16, 2016

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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 regulatory approval in the US of long-acting factor IX for the treatment of haemophilia B

Bagsværd, Denmark, 16 May 2016 - Novo Nordisk today announced the submission to the US Food and Drug Administration (FDA) of the Biologics License Application for the approval of long-acting factor IX, nonacog beta pegol. Nonacog beta pegol is a glycopegylated recombinant factor IX with a significantly improved pharmacokinetic (PK) profile, developed for patients with haemophilia B.

The filing of nonacog beta pegol is based on the results from the paradigm clinical trial programme which involved 115 patients with severe or moderately severe haemophilia B. Nonacog beta pegol was found to be efficacious in routine prophylaxis, treatment of bleeding episodes and surgery for adults, adolescents and children. Furthermore, nonacog beta pegol appeared to be well-tolerated and no safety concerns were identified.

Compared to standard factor IX products, nonacog beta pegol has a five times longer half-life. Patients in the paradigm study achieved a higher level of factor IX in the circulation despite less frequent dosing of nonacog beta pegol. In the phase 3 trials, once-weekly administration of 40 IU/kg nonacog beta pegol maintained factor IX activity levels above 15%, reduced the median annualised bleeding rate (ABR) to 1.0 and showed a potential to prevent bleeds in target joints. Furthermore, these patients reported a significant improvement in quality of life during the trial.

"With the regulatory filings in 2016 of our long-acting factor IX, people with haemophilia B in both the EU and the US are one step closer to having a new treatment option" said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "With its high factor activity level, less frequent dosing and reduced bleeding rate, nonacog beta pegol has the potential to improve the quality of life for both patients and their families."

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, the prolongation technology used for the half-life extension, is a novel approach in haemophilia B, already proven safe and efficacious in haemophilia A and other therapeutic areas.

About the paradigm clinical programme

The paradigm clinical trial programme for nonacog beta pegol enrolled children and adults with severe or moderately severe haemophilia B. A total of 115 previously treated patients with a total of more than 10,625 exposure days for up to 3.3 years of treatment with nonacog beta pegol.

The paradigm 1 PK trial (16 patients treated) - a single-dose escalation trial evaluating safety and PK of nonacog beta pegol compared with marketed recombinant and plasma-derived factor IX products. Nonacog beta pegol showed up to twofold increase in recovery, higher activity levels and a fivefold prolongation of half-life compared to existing treatment.

The paradigm 2 pivotal trial (74 patients treated, including a subset of patients from the paradigm 1 trial) - a 52-week single-blinded randomised trial evaluating safety, efficacy and PK for adults and adolescents in routine prophylaxis and treatment of bleeds. When provided prophylactic at 40 IU/kg weekly, nonacog beta pegol appeared to have a safe and well-tolerated profile and showed a median annualised spontaneous bleeding rate of 0.0. Furthermore, 97% of breakthrough bleeds were treated successfully and 90% of target joints no longer classified as such.

The paradigm 3 surgery trial (13 patients treated, including a subset of people from the paradigm 2 trial) - a dedicated trial confirming safety and efficacy during and after major surgical procedures. In all patients, a single preoperative dose provided effective haemostatic coverage, and no patient required additional doses on the day of surgery. Additionally, three doses proved sufficient in maintaining haemostasis during the first two weeks following the procedure.

The paradigm 4 extension trial (71 patients previously treated in the paradigm 2 or paradigm 3 trials) - a safety extension trial with longer-term exposure demonstrated a well-tolerated profile with no inhibitors or other safety signals identified.

The paradigm 5 paediatric trial (25 patients treated) - a 52-week single-arm trial evaluating once-

weekly prophylaxis and treatment of bleeding episodes in previously treated children 1-12 years of age. Nonacog beta pegol appeared to have a safe profile, and all patients maintained mean factor activity levels above 15% one week after dosing of 40 IU/kg and a median ABR of 0.0 and 2.0 for children aged 0-6 and 7-12 years old respectively.

For further information

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Company announcement No 39 / 2016

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: May 16, 2016

Lars Rebien Sørensen,

Chief Executive Officer