

NOVO NORDISK A S
Form 6-K
January 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

January 7, 2016

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

Edgar Filing: NOVO NORDISK A S - Form 6-K

(Address of principal executive offices)

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 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

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 of long-acting factor IX in the EU for the treatment of haemophilia B

Bagsværd, Denmark, 7 January 2016 - Novo Nordisk today announced the submission to the European Medicines Agency of the Marketing Authorisation 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.

Novo Nordisk expects to file the Biologics License Application (BLA) for nonacog beta pegol to the US Food and Drug Administration during first half of 2016.

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 blood 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 an improvement in quality of life during the trial.

“With the regulatory filing of our long-acting factor IX, patients with haemophilia B 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 very low ABRs, 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 an extended half-life factor IX molecule intended for replacement therapy in patients with haemophilia B. Glycopegylation, the prolongation technology

Page 2 of 3

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 8,800 exposure days for up to 2.7 years of treatment with nonacog beta pegol.

The paradigm 1 PK trial (16 people 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 people treated) – 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 people treated) – 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 people treated) – 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 people 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.

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 40,300 people in 75 countries and markets its products in more than 180 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

Page 3 of 3

Further information

Media:

Katrine Sperling +45 3079 6718 krsp@novonordisk.com
Ken Inchausti (US) +1 609 514 8316 kiau@novonordisk.com

Investors:

Peter Hugrefte Ankersen +45 3075 9085 phak@novonordisk.com
Daniel Bohsen +45 3079 6376 dabo@novonordisk.com
Melanie Raouzeos +45 3075 3479 mrz@novonordisk.com
Kasper Veje +45 3079 8519 kpvj@novonordisk.com
Frank Daniel Mersebach (US) +1 609 235 8567 fdni@novonordisk.com

		Internet:
Novo Nordisk A/S	Novo Allé	Telephone: www.novonordisk.com
Investor Relations	2880 Bagsværd	+45 4444 8888 CVR no:
	Denmark	24 25 67 90
		Company announcement No 2 / 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: January 7, 2016

Lars Rebien Sørensen.

Chief Executive Officer