NOVO NORDISK A S
Form 6-K
December 09, 2015

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

December 9, 2015

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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 of faster-acting insulin aspart in the US for the treatment of type 1 and 2 diabetes

Bagsværd, Denmark, 9 December 2015 - Novo Nordisk today announced the submission of the New Drug Application (NDA) for faster-acting insulin aspart to the US Food and Drug Administration (FDA). Faster-acting insulin aspart is a mealtime insulin for improved control of postprandial glucose excursions and has been developed for the treatment of people with type 1 and type 2 diabetes.

The filing of faster-acting insulin aspart is based on the results from the 'onset' clinical trial programme which involved around 2,100 people with type 1 and 2 diabetes. In the onset programme, people treated with faster-acting insulin aspart achieved improvements in postprandial control versus NovoLog® (marketed as NovoRapid® outside the US) and an HbA_{1c} reduction on par with NovoLog®. For people with type 1 diabetes, faster-acting insulin aspart results from the double-blinded onset 1 trial showed statistically significantly greater HbA_{1c} reduction when dosed at mealtime or similar HbA_{1c} reduction when dosed 20 minutes after a meal compared to NovoLog®. Across the onset trials, faster-acting insulin aspart had a safe and well tolerated profile, with the most common adverse event being hypoglycaemia, similar to the levels observed with NovoLog®.

"We are happy to be able to file faster-acting insulin aspart for regulatory approval in the US and have the opportunity to address unmet medical needs for people requiring improved blood glucose control around meals," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "Onset 1 shows that faster-acting insulin aspart has the potential to offer improved postprandial glucose and either an additional reduction of HbA_{1c} or added flexibility compared with NovoLog®."

Novo Nordisk intends to make faster-acting insulin aspart available in the prefilled delivery device FlexTouch®.

About faster-acting insulin aspart
Faster-acting insulin aspart is a mealtime insulin for the control of postprandial glucose excursions in type 1 and type 2 diabetes as well as in pump treatment. Faster-acting insulin aspart is insulin aspart (NovoLog®) in a new formulation in which two new excipients have been added to ensure early and fast absorption.

About the onset clinical programme
The onset programme is a phase 3 clinical programme with faster-acting insulin aspart consisting of four trials encompassing more than 2,100 people with type 1 and type 2 diabetes.

The onset 1 trial (1,143 people randomised) - a 26+26-week randomised, double-blinded, basal-bolus, treat-to-target trial investigating faster-acting insulin aspart compared to NovoLog®, both in combination with Levemir® in adults with type 1 diabetes. The results were reported in March and October 2015.

The onset 2 trial (689 people randomised) - a 26-week randomised, double-blinded, basal-bolus, treat-to-target trial investigating faster-acting insulin aspart compared to NovoLog®, both in combination with insulin glargine in adults with type 2 diabetes. The results were reported in March 2015.

The onset 3 trial (236 people randomised) - an 18-week randomised, open-label, basal bolus vs basal trial confirming superiority (in terms of HbA_{1c}) of mealtime faster-acting insulin aspart in a full basal-bolus regimen versus basal insulin therapy, both in combination with metformin. The results were reported in January 2015.

The onset 4 trial (37 people randomised) - a six-week randomised, double-blinded, parallel-group trial confirming pump compatibility and safety of faster-acting insulin aspart and NovoLog® in type 1 diabetes. The results were reported in August 2014.

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

Further information

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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: December 9, 2015

Lars Rebien Sørensen,

Chief Executive Officer