NOVO NORDISK A S
Form 6-K
November 22, 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

November 21, 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 receives US FDA approval for Xultophy® 100/3.6

Bagsværd, Denmark, 21 November 2016 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Xultophy® 100/3.6. Xultophy® 100/3.6 is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to

1.8 mg daily).

Xultophy® 100/3.6, the approved brand name for IDegLira in the US, is a once-daily, single injection fixed combination of long-acting insulin degludec (Tresiba®) and the GLP- 1 analogue liraglutide (Victoza®). In the DUAL phase 3 clinical trial programme, Xultophy® 100/3.6 consistently showed an improvement of glycaemic control in adults with type 2 diabetes uncontrolled on liraglutide or basal insulin therapy. For adults inadequately controlled on insulin glargine U100, treatment with Xultophy® 100/3.6 demonstrated a reduction in HbA1c of 1.7% after 26 weeks. Xultophy® 100/3.6 can be taken at the same time each day with or without food and will be available

in a prefilled pen.

“We are pleased with the approval of Xultophy® 100/3.6 and look forward to launching it in the US in the first half of 2017”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We believe Xultophy® 100/3.6 offers significant benefits and is an important and convenient treatment option especially for people not achieving sufficient glycaemic control with basal insulin”.

The approval follows the recommendation of the FDA’s Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC), which voted 16–0 in favour of an approval of Xultophy® 100/3.6 for the treatment of adults with type 2 diabetes, at its meeting on 24 May 2016.

About Xultophy® 100/3.6

Xultophy® 100/3.6 is a once-daily, single injection fixed combination of long-acting insulin degludec (Tresiba®) and the GLP-1 analogue liraglutide (Victoza®). The Xultophy® 100/3.6 pen delivers doses from 10 to 50 units with each injection. Each unit of Xultophy® 100/3.6 contains 1 unit of insulin degludec and 0.036 mg of liraglutide.

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 42,600 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

Media:

Katrine Sperling	+45 3079 6718	krsp@novonordisk.com
Ken Inchausti (US)	+1 609 786 8316	kiau@novonordisk.com

Investors:

Peter Hugreffe Ankersen	+45 3075 9085	phak@novonordisk.com
Melanie Raouzeos	+45 3075 3479	mrz@novonordisk.com
Hanna Ögren	+45 3079 8519	haoe@novonordisk.com
Anders Mikkelsen	+45 3079 4461	armk@novonordisk.com
Kasper Veje (US)	+1 609 235 8567	kpvj@novonordisk.com

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: November 21, 2016

Lars Rebien Sørensen,

Chief Executive Officer