NOVO NORDISK A S
Form 6-K
June 03, 2013

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 31, 2013

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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 IDegLira in the EU for the treatment of type 2 diabetes

Bagsværd, Denmark, 31 May 2013 – Novo Nordisk today announced the submission to the European Medicines Agency of the marketing authorisation application for the approval of IDegLira, the combination product of insulin degludec (Tresiba®), the once-daily new-generation basal insulin analogue, with an ultra-long duration of action, and liraglutide (Victoza®), the once-daily human GLP-1 analogue. IDegLira has been developed for the treatment of people with type 2 diabetes.

The filing of IDegLira is based on results from the DUAL™ clinical trial programmes which involved around 2,000 people with type 2 diabetes, together with the extensive clinical data generated in the development programmes of the individual components insulin degludec and liraglutide.

In the DUAL™ programme people treated once-daily with IDegLira achieved an average HbA_{1c} reduction of 1.9% in both trials. Among people treated with IDegLira, 81% of those previously treated with oral anti-diabetics and 60% of those previously treated with basal insulin achieved the ADA and the European Association for the Study of Diabetes (EASD) HbA_{1c} treatment target of 7%. People treated with IDegLira experienced a low rate of hypoglycaemia, which was comparable to that of Tresiba®, and achieved a reduction in body weight.

“IDegLira has the potential to become a breakthrough in type 2 diabetes treatment and we look forward to making the first combination product of insulin and GLP-1 available to people with type 2 diabetes in the EU”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Novo Nordisk intends to make IDegLira available in a prefilled delivery device based on the same technology platform as FlexTouch®.

Novo Nordisk A/S
Investor Relations

Novo Allé
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888
Internet:
www.novonordisk.com

CVR No:
24 25 67 90

Company announcement No 41 / 2013

About IDegLira

IDegLira is a once-daily combination product consisting of insulin degludec (Tresiba®), the once-daily new-generation basal insulin analogue, with an ultra-long duration of action, and liraglutide (Victoza®), the once-daily human GLP-1 analogue with 97% homology to human GLP-1, in a single administration. IDegLira has been investigated as treatment for type 2 diabetes in the clinical development programme DUAL™.

About the DUAL™ clinical programme

DUAL™ (DUal Action of Liraglutide and Insulin Degludec in Type 2 Diabetes), consists of two phase 3a trials encompassing around 2,000 people with type 2 diabetes.

DUAL™ I (around 1,600 people randomised) – a 26-week randomised, open-label trial comparing the efficacy and safety of IDegLira, Tresiba® and Victoza® in people with type 2 diabetes inadequately controlled with metformin with or without pioglitazone. The results of DUAL™ I were reported in August 2012, and results of a 26-week extension were reported in May 2013.

DUAL™ II (around 400 people randomised) – a 26-week randomised, double-blinded trial comparing IDegLira and Tresiba® in people with type 2 diabetes inadequately controlled on basal insulin in combination with 1–2 oral anti-diabetic agents. In this trial, the maximum dose of Tresiba® was fixed in both treatment arms to investigate the additional impact of the liraglutide component of IDegLira on glucose control. The results of DUAL™ II were reported in December 2012.

Novo Nordisk is a global healthcare company with 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 35,000 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

Further information

Media:

Mike Rulis	+45 3079 3573	mike@novonordisk.com
Ken Inchausti (US)	+1 609 240 2919	kiau@novonordisk.com

Investors:

Kasper Roseeuw Poulsen	+45 4442 4303	krop@novonordisk.com
Frank Daniel Mersebach	+45 4442 0604	fdni@novonordisk.com
Lars Borup Jacobsen	+45 3075 3479	lbpj@novonordisk.com
Jannick Lindegaard (US)	+1 609 786 4575	jlis@novonordisk.com

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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.

Date: May 31, 2013

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer