

NOVO NORDISK A S  
Form 6-K  
October 22, 2012

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**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

**October 22, 2012**

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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  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-\_\_\_\_\_



## Company Announcement

19 October 2012

Tresiba® (insulin degludec) and Ryzodeg® (insulin degludec/insulin aspart) receive positive opinions from the European regulatory authorities

Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) adopted positive opinions, recommending marketing authorisations, for Tresiba® and Ryzodeg® for the treatment of diabetes mellitus in adults.

Tresiba®, the intended brand name for insulin degludec, is a new generation of once-daily basal insulin. In 'treat-to-target' studies supporting the new drug application, where Tresiba® was compared to insulin glargine, Tresiba® demonstrated a significantly lower risk of overall and nocturnal hypoglycaemia, while successfully achieving equivalent reductions in HbA<sub>1c</sub>. Further, with a duration of action beyond 42 hours, Tresiba® is the first basal insulin to offer patients the possibility of adjusting the time of injection, when needed.

Ryzodeg®, the intended brand name for insulin degludec/insulin aspart, contains the new-generation once-daily basal insulin degludec in a soluble formulation with insulin aspart. Ryzodeg® can be administered once or twice daily with the main meal(s). In 'treat-to-target' studies supporting the new drug application, where Ryzodeg® was compared to NovoMix®, Ryzodeg® demonstrated a significantly lower risk of overall and nocturnal hypoglycaemia while successfully achieving equivalent reductions in HbA<sub>1c</sub>.

In Europe, Tresiba® and Ryzodeg® will be available in FlexTouch®, Novo Nordisk's latest prefilled insulin pen, which has an easy auto-injector mechanism. Tresiba® will be offered in two concentrations enabling maximum doses of 80 and 160 units per injection, respectively.

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<b>Novo Nordisk A/S</b>	Novo Allé	Telephone:	Internet:	CVR no:
Investor Relations	2880 Bagsværd	+45 4444 8888	novonordisk.com	24256790
	Denmark	Telefax:		
		+45 4444 6626		



“We are very happy about the positive opinions from the CHMP. This gives us confidence, that we soon can make Tresiba® and Ryzodeg® available to many people with diabetes in Europe,” said Mads Krosgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Novo Nordisk expects to receive final marketing authorisation from the European Commission within approximately two months. Subject to the Commission’s approval and completion of pricing and reimbursement discussions, Novo Nordisk expects to launch Tresiba® in a number of European markets in the beginning of 2013. Ryzodeg® is currently expected to be launched approximately one year after Tresiba®, in the respective markets.

### **About Tresiba® and Ryzodeg®**

**Tresiba®** is the intended brand name for insulin degludec, which is a once-daily new-generation basal insulin analogue, with an ultra-long-acting duration of action, discovered and developed by Novo Nordisk. Tresiba® has a distinct slow absorption which provides a flat and stable action profile. Tresiba® has been studied in a large-scale clinical trial programme, BEGIN™, examining its impact on glucose control, hypoglycaemia and the possibility to flexibly adjust Tresiba® dosing time to suit patient needs.

**Ryzodeg®** is the intended brand name for insulin degludec/insulin aspart, which contains the new-generation basal insulin degludec in a formulation with a bolus boost of insulin aspart. Ryzodeg® is the first and only soluble insulin combination of ultra-long-acting insulin degludec and the most prescribed rapid-acting insulin, NovoRapid® (NovoLog® in the US), providing both fasting and post-prandial glucose control.

Tresiba® and Ryzodeg® were submitted to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in September 2011 for regulatory review. In addition, applications have been submitted for regulatory approval in Japan, Canada, Switzerland and a range of other countries. Tresiba® was approved in Japan in September this year.

*Novo Nordisk is a global healthcare company with 89 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 33,300 employees in 75 countries, and markets its products in more than 190 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](http://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: October 22, 2012

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer

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