

NOVO NORDISK A S  
Form 6-K  
October 26, 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 26, 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

25 October 2012

FDA discloses focus of Advisory Committee meeting on insulin degludec and insulin degludec/insulin aspart

Novo Nordisk today announced that the US Food and Drug Administration (FDA) has published information pertaining to the focus of the Advisory Committee meeting scheduled for 8 November 2012 to discuss the New Drug Applications for insulin degludec and insulin degludec/insulin aspart.

The information can be found in a document on the agency's website:

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Endocrinology/UCM270411.pdf>

In this document, the following is stated about the focus of the meeting:

"This meeting will focus on the cardiovascular safety of two products, insulin degludec/insulin aspart [rDNA origin] and insulin degludec [rDNA origin], as meta-analyses of several clinical trials suggest an excess risk for cardiovascular events with this insulin over its comparators. The meeting will also discuss any perceived benefits of this product to enable decisions to be made on both a benefit and a risk analysis. With respect to benefit, several analyses suggest that this insulin product may be associated with a lower risk of hypoglycaemia than the comparator insulin. Insulin is a requirement in type 1 diabetes and is necessary for continued adequate glycemic control in many type 2 diabetics. However, the risk of hypoglycaemia may be a hurdle for effective titration of these therapies. As such, the possibility that degludec and degludec/aspart have a lower risk for hypoglycaemia will be an important consideration in the overall benefit-risk assessment of this product."

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## **About advisory committee meetings**

FDA advisory committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing new drug applications. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer new drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.

## **About insulin degludec and insulin degludec/insulin aspart**

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

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

Insulin degludec and insulin degludec/insulin aspart 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. Insulin degludec was approved in Japan in September 2012, and in October 2012 insulin degludec and insulin degludec/insulin aspart received positive CHMP opinions in Europe.

*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 26, 2012

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer

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