NOVO NORDISK A S Form 6-K December 23, 2010

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549
FORM 6-K
REPORT OF FOREIGN PRIVATE ISSUER
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934
December 23, 2010
<del></del>
NOVO NORDISK A/S
(Exact name of Registrant as specified in its charter)
Novo Allé DK- 2880, Bagsvaerd
DR- 2000, Baysvaeru Denmark
(Address of principal executive offices)
<del></del>
Indicate by check mark whether the registrant files or will file annual reports under cover of Form $20\text{-F}$ or Form $40\text{-F}$
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

## Company Announcement

### 22 December 2010

Degludec significantly reduces risk of hypoglycaemia during the night compared to insulin glargine in two long-term studies

Novo Nordisk today announced clinical results from two 52-week phase 3a treat-to-target studies comparing Degludec, an ultra long-acting basal insulin, to insulin glargine in basal-bolus treatment of type 1 and type 2 diabetes. Basal-bolus treatment is comprised of treatment with long-acting (basal) insulin and a rapid-acting (bolus) insulin, and in both studies insulin aspart was used as the bolus insulin. These studies, as well as three additional studies reported today, are part of the largest clinical development programme ever conducted for an insulin.

Degludec versus insulin glargine in type 2 diabetes in basal-bolus treatment (NN1250-3582)

In this 52-week phase 3a treat-to-target study, 1,006 people with type 2 diabetes were randomised 3:1 to either Degludec or insulin glargine, both given once daily. Insulin aspart was used as bolus insulin in both treatment arms, in addition to treatment with metformin and/or pioglitazone.

Degludec effectively improved long-term glycaemic control, achieving the primary objective of showing HbA<sub>1c</sub> non-inferiority to insulin glargine, with HbA<sub>1c</sub> decreasing by around 1.2 percentage points to 7.1% in both treatment arms.

Degludec also showed a lower risk of hypoglycaemia compared to insulin glargine; the rate of confirmed hypoglycaemic events (need for third party assistance or plasma glucose level below 3.1 mmol/l) was overall lower in the group treated with Degludec, and Degludec reduced the risk of nocturnal hypoglycaemia by 25% compared to insulin glargine. The difference in both the nocturnal and overall hypoglycaemia rate was statistically significant.

Degludec demonstrated a good safety and tolerability profile and there were no apparent differences between the treatment groups with respect to adverse events and standard safety parameters.

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Degludec versus insulin glargine in type 1 diabetes in basal-bolus treatment (NN1250-3583)

In this 52-week phase 3a treat-to-target study, 629 people with type 1 diabetes were randomised 3:1 to either Degludec or insulin glargine, both given once daily. Insulin aspart was used as bolus insulin in both treatment arms.

Degludec effectively improved long-term glycaemic control, achieving the primary objective of showing  $HbA_{1c}$  non-inferiority to insulin glargine, with  $HbA_{1c}$  decreasing by around 0.4 percentage points to 7.3% in both treatment arms.

The rate of confirmed nocturnal hypoglycaemia was 24% lower in the group treated with Degludec compared to the group treated with insulin glargine. This decreased risk of hypoglycaemia was statistically significant.

Degludec demonstrated a good safety and tolerability profile and there were no apparent differences between the treatment groups with respect to adverse events, antibody development and standard safety parameters.

"Nocturnal hypoglycaemia – episodes of too low blood sugar during the night – is a major worry for many people with diabetes," says Mads Krogsgaard Thomsen, executive vice president and Chief Science Officer of Novo Nordisk. "It is therefore encouraging that Degludec, in the studies announced today, significantly reduces the risk of nocturnal hypoglycaemia in comparison with insulin glargine in both type 1 and type 2 diabetes."

Update on additional trial results for Degludec and DegludecPlus

In a trial in insulin naïve people with type 2 diabetes (NN1250-3580), comparing Degludec to sitagliptin as add-on therapy to pre-existing oral therapy, Degludec demonstrated statistically significant greater  $HbA_{1c}$  lowering than sitagliptin. This was the primary endpoint of the study. As anticipated, the rate of overall hypoglycaemia in the study was low, with more events in the Degludec arm and with no statistically significant difference in the rate of nocturnal hypoglycaemia.

In two trials, NN5401-3590 and NN5401-3593, comparing once-daily administration of DegludecPlus, a fixed ratio combination of the ultra long-acting basal insulin degludec and insulin aspart, to insulin glargine in people with type 2 diabetes, DegludecPlus met the primary endpoint by demonstrating non-inferiority for  $HbA_{1c}$  lowering. In both studies, the overall rates of hypoglycaemia in the DegludecPlus arms were statistically significantly higher, whereas the rate of nocturnal hypoglycaemia was lower for DegludecPlus, with the difference being statistically significant in NN5401-3590.

Also in these three studies, Degludec and DegludecPlus demonstrated good safety and tolerability profiles and there were no apparent differences between the treatment groups with respect to adverse events and standard safety parameters.

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Novo Nordisk expects to communicate headline results from the remainder of the phase 3a trial programme for Degludec and DegludecPlus in connection with the release of 2010 full year results on 2 February 2011.

#### Conference call details

At 10.00 CET 23 December 2010, a conference call will be held. Investors will be able to listen in via a link on novonordisk.com, which can be found under 'Investors – Download centre'. Presentation material for the conference call will be made available approximately one hour before on the same page.

Novo Nordisk is a global healthcare company with 87 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 30,100 employees in 76 countries, and markets its products in 179 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:

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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: December 23, 2010 NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer

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