

NOVO NORDISK A S  
Form 6-K  
April 24, 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

**April 24, 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

6 April 2012

Victoza<sup>®</sup> label in the US updated to include data showing superior efficacy when compared to Januvia<sup>®</sup>

**Label update also includes FDA approval of combination therapy with basal insulin for the treatment of adults with type 2 diabetes**

Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved to update the product label for Victoza<sup>®</sup> (liraglutide [rDNA] injection) to include data showing superior blood sugar control and weight reduction when compared to Januvia<sup>®</sup> (sitagliptin).

The update also includes data demonstrating the safety and efficacy of adding basal insulin to Victoza<sup>®</sup> and metformin for the treatment of adults with type 2 diabetes.

The label update is based on data from two large, randomized, open-label studies in adults with type 2 diabetes. "The data from these studies further demonstrate the strong clinical profile and the value of Victoza<sup>®</sup> in the treatment of type 2 diabetes," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

**Victoza<sup>®</sup> vs. Januvia<sup>®</sup>**

The 26-week randomized open label clinical trial was conducted to evaluate the safety and efficacy of Victoza<sup>®</sup> 1.2 mg and 1.8 mg plus metformin compared to Januvia<sup>®</sup> plus metformin.

Patients treated with 1.2 mg and 1.8 mg of Victoza<sup>®</sup> experienced greater reductions in HbA<sub>1c</sub> than those treated with Januvia<sup>®</sup> 100 mg tablets (-1.2% and -1.5% versus -0.9%).

Victoza<sup>®</sup> furthermore provided greater weight loss versus patients treated with Januvia<sup>®</sup> (2.7 kg [5.94 lbs] and 3.3 kg [7.26 lbs] for 1.2 mg and 1.8 mg respectively, 0.8 kg [1.76 lbs] for Januvia<sup>®</sup>).

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### **Adding Levemir® to Victoza® in adults with type 2 diabetes**

The 26-week, randomised, open-label clinical trial was conducted to evaluate the safety and efficacy profile of adding once-daily Levemir® (insulin detemir) to treatment with Victoza® 1.8 mg plus metformin.

In the initial 12-week run-in period, patients were treated with Victoza® and metformin. After completing the 12 week run-in treatment, 50% of patients reached the ADA target for blood sugar control ( $HbA1_C < 7\%$ ).

During the following 26 weeks, patients achieving  $HbA1_C < 7\%$  in the run-in period remained on the same regimen in an observational group while the remaining patients were randomised to either add Levemir® to the existing Victoza® and metformin regimen or continue with Victoza® and metformin.

After 26 weeks, patients randomised to add on Levemir® to Victoza® and metformin had further  $HbA1_C$  reductions of 0.5%, while  $HbA1_C$  remained stable in the Victoza® and metformin group. At 26 weeks, 43% of patients in the Victoza®, metformin and Levemir® group reached the ADA target for blood sugar control ( $HbA1_C < 7\%$ ) vs. an additional 17% in the Victoza® and metformin group. Patients did not gain weight after Levemir® was added.

The proportion of patients reporting adverse events for the entire trial period was comparable between the two randomised treatment groups and the nonrandomised treatment group. There was no specific pattern or clustering of serious adverse events and the most commonly reported events were common infections and nausea.

### **About Victoza® (liraglutide [rDNA origin] injection)**

Victoza® (liraglutide) is the first and only human GLP-1 analogue (glucagon-like peptide-1) that is 97 percent similar to endogenous human GLP-1. Like natural GLP-1, Victoza® works by stimulating the beta cells to release insulin only when blood sugar levels are high.

Due to this glucose-dependent mechanism of action, Victoza® is associated with a low rate of hypoglycemia. The mechanism of blood sugar lowering also involves a delay in gastric emptying.

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*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 32,700 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).*

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: April 24, 2012

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer