NOVO NORDISK A S
Form 6-K
October 23, 2012

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

October 22, 2012

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé
DK- 2880, Bagsvaerd
Denmark
(Address of principal executive offices)

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-_____

Company Announcement

19 October 2012

Japan s Pharmaceuticals and Medical Devices Agency publishes assessment report of Tresiba®

Novo Nordisk today announced that Japan s Pharmaceuticals and Medical Devices Agency (PMDA) has published their assessment report of Tresiba® (insulin degludec). The report forms the basis of the approval of the product announced on 28 September 2012.

The assessment report is the first extensive review of the data in the New Drug Application (NDA) for Tresiba®. The review of efficacy is primarily based on the studies including Japanese patients, while the safety review is based on both these studies and data from the global clinical programme.

The 157 page assessment report is available in Japanese on PMDA s webpage:
http://www.info.pmda.go.jp/shinyaku/P201200136/620023000_22400AMX013 93000_A100_1.pdf

In the assessment report, the overall conclusion of PMDA is that the efficacy of Tresiba® for the treatment of insulin-requiring patients with diabetes mellitus has been demonstrated and that the benefit-risk profile is favourable.

Following the routine for newly approved pharmaceutical products in Japan, PMDA has requested that Novo Nordisk conducts a post-marketing observational study to further demonstrate the efficacy and safety profile of Tresiba®. The study will monitor efficacy parameters such as HbA1c and fasting plasma glucose (FPG), together with relevant safety variables including hypoglycaemia, injection site reactions, allergic reactions, cardiovascular events, neoplasms and antibody development. It is also planned to collect information on the safety and efficacy in Japanese patients with type 2 diabetes when they change the time of injecting Tresiba®. The study will also collect safety information from patients with renal impairment, patients with hepatic impairment and elderly patients.

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Efficacy data:

Overall, PMDA concluded that efficacy for Tresiba® was demonstrated. Specifically, the agency concluded that non-inferiority on the primary end-point for Tresiba®, HbA1c, versus comparators was achieved in both type 1 and type 2 diabetes. Furthermore, the PMDA concluded that given the pharmacological characteristics of Tresiba®, patients who miss a dose can take it as soon as practically possible.

Safety data:

Overall, PMDA concluded that the safety profile of Tresiba® was acceptable, and there was no marked difference in the adverse event profile versus comparators. Specific events of interest, related to diabetes and insulin, described in the assessment report and based on the global pooled data, include:

Hypoglycaemia: A meta-analysis of seven therapeutic confirmatory trials comparing once-daily Tresiba® with once-daily insulin glargine showed a statistically significant 9% reduction in the rate of confirmed hypoglycaemia (rate ratio 0.91, 95% confidence interval: [0.83;0.99]) and a statistically significant 26% reduction in nocturnal hypoglycaemia (rate ratio 0.74, 95% confidence interval: [0.65;0.85]) across patients with type 1 and type 2 diabetes.

Injection site reactions: The event rate of injection site reaction was 7.6 vs 8.4 events per 100 patient year exposure (PYE) in the combined Tresiba®/ Ryzodeg® (intended brand name for insulin degludec/insulin aspart) group and in the comparator group, respectively. The PMDA concluded there was no marked difference versus the comparator group.

Allergic reactions: The percentage of subjects with immunogenicity-related events was 0.7% and 0.4% in the combined Tresiba®/Ryzodeg® group and in the comparator group, respectively. The PMDA concluded there was no marked difference versus the comparator group.

Cardiovascular events: The pre-specified Major Adverse Cardiovascular Event (MACE) meta-analysis showed an MACE incidence rate of 1.48 and 1.44 events per 100 PYE in the combined Tresiba®/Ryzodeg® group and in the comparator group, respectively. The estimated hazard ratio for Tresiba®/Ryzodeg® versus comparators was 1.10 and not statistically significantly different (95% confidence interval: [0.68; 1.77]). The PMDA concluded there was no marked difference versus the comparator group.

Neoplasms: The percentage of patients with malignant neoplasms was 0.5% in both the combined Tresiba®/Ryzodeg® group and in the comparator group. The corresponding event rates of malignant neoplasms were comparable at 0.9 and 0.8 events per 100 PYE, respectively. The PMDA concluded there was no marked difference versus the comparator group.

Antibody development: The immunogenic potential of Tresiba® was low, and development of insulin antibodies had no impact on the safety of Tresiba®. The PMDA concluded that antibodies did not markedly increase after administration of Tresiba®.

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About Tresiba® and Ryzodeg®

Tresiba® is the intended global brand name for insulin degludec, the first once-daily basal insulin with an ultra-long duration of action, 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 global 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 for regulatory approval to the Japanese Ministry of Health, Labour and Welfare (MHLW) in December 2011 and March 2012, respectively. On 28 September 2012, Tresiba® was approved by the MHLW. Tresiba® and Ryzodeg® have also been submitted for regulatory approval to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in September 2011. In addition, applications have been submitted for regulatory approval in a range of other countries.

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.

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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