

NOVO NORDISK A S
Form 6-K
March 26, 2015
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

March 25, 2015

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 ☒ 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-_____

Novo Nordisk completes phase 3a trials comparing faster-acting insulin aspart with NovoRapid® in people with type 1 and type 2 diabetes

Bagsværd, Denmark, 25 March 2015 – Novo Nordisk today announced headline results from the final phase 3a trials for faster-acting insulin aspart, onset® 1 and onset®2. The trials investigated the efficacy and safety of faster-acting insulin aspart compared with NovoRapid® (insulin aspart) in a basal-bolus regimen in people with type 1 and type 2 diabetes, respectively.

Both trials achieved their primary objectives by demonstrating that treatment with faster-acting insulin aspart is non-inferior to NovoRapid® with regard to lowering of HbA1c. For people with type 1 diabetes, the HbA1c lowering achieved with faster-acting insulin aspart was statistically significantly larger than that achieved with NovoRapid® when the insulins were given at mealtime. In addition, treatment with faster-acting insulin aspart was associated with less increase of postprandial glucose than NovoRapid® during meal tests in both trials.

In both trials, the previously reported safety and tolerability profiles of faster-acting insulin aspart and NovoRapid® were confirmed, and there were no apparent differences between the two treatment groups with respect to adverse events and other safety parameters.

“We are encouraged by the results of these trials, which show that faster-acting insulin aspart has the potential to help people with diabetes improve their blood glucose control around meals,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “Onset® 1 shows that faster-acting insulin aspart has the potential to offer either an additional reduction of HbA1c or added flexibility compared with NovoRapid®.”

Novo Nordisk expects to file faster-acting insulin aspart for regulatory review in the US and EU around the turn of the year.

Onset® 1

In onset® 1, a total of 1,290 people with type 1 diabetes had their basal insulin therapy optimised during an eight-week run-in period. After the run-in period, 1,143 people with

type 1 diabetes, who had successfully optimised their basal insulin therapy following conversion to Levemir®, were randomised in a double-blinded fashion to addition of either faster-acting insulin aspart or NovoRapid® at mealtimes for 52 weeks, or to open- label treatment with faster-acting insulin aspart post-meal for a period of 26 weeks.

After 26 weeks, the mean baseline HbA1c of 7.6% was reduced by 0.32%, 0.17% and 0.13% for people treated with mealtime faster-acting insulin aspart, mealtime NovoRapid® and post-meal faster-acting insulin aspart, respectively. This confirmed the trial's primary objective of non-inferiority in HbA1c improvement for mealtime faster- acting insulin aspart compared to NovoRapid®. The HbA1c improvement with mealtime faster-acting insulin aspart was statistically significantly greater than with NovoRapid® and the improvement with post-meal faster-acting insulin aspart was non-inferior compared with NovoRapid® at mealtime.

In the trial, people treated with faster-acting insulin aspart achieved statistically significantly larger improvements in both 1- and 2-hour postprandial glucose (PPG) increments during a meal test compared with people treated with NovoRapid®. The largest difference in PPG increment was achieved at 1 hour and was more than 1 mmol/l.

The overall rate of severe or blood glucose confirmed hypoglycaemia was similar for faster-acting insulin aspart and NovoRapid®. A higher rate of hypoglycaemia was observed for mealtime faster-acting insulin aspart within the first hour after start of a meal.

Onset® 2

In onset® 2, a total of 881 people with type 2 diabetes inadequately controlled on a combination of basal insulin and oral antidiabetic drugs had their basal therapy optimised during an eight-week run-in period. The 689 people who had reached the prespecified HbA1c target of 7.0–9.5% in the run-in period were randomised to addition of either faster-acting insulin aspart or NovoRapid® as mealtime insulin for a period of 26 weeks.

After 26 weeks, the mean HbA1c had improved from around 7.9% to around 6.6% for both people treated with faster-acting insulin aspart and people treated with NovoRapid®. This confirmed the primary objective of non-inferiority in HbA1c.

In the trial, people treated with faster-acting insulin aspart achieved a statistically significantly larger improvement of around 0.6 mmol/l in 1-hour PPG increment during a meal test compared with people treated with NovoRapid®. The improvement in 2-hour PPG increment was numerically larger for people treated with faster-acting insulin aspart compared with NovoRapid® but the difference was not statistically significant.

The overall rate of severe or blood glucose confirmed hypoglycaemia was similar for faster-acting insulin aspart and NovoRapid®. A higher rate of hypoglycaemia was observed for faster-acting insulin aspart within the first two hours after start of a meal.

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About faster-acting insulin aspart

Faster-acting insulin aspart is a mealtime insulin for control of postprandial glucose excursions in type 1 and type 2 diabetes as well as in pump treatment. Faster-acting insulin aspart is insulin aspart (NovoRapid®) in a new formulation in which two new excipients have been added to ensure early and fast absorption.

About the onset® clinical programme

The onset® programme is a phase 3 clinical programme with faster-acting insulin aspart that consists of four trials encompassing more than 2,000 people with type 1 and type 2 diabetes mellitus.

The onset® 1 trial (1,143 people randomised) – a 26+26-week randomised, double-blind, basal-bolus, treat-to-target trial investigating faster-acting insulin aspart compared to NovoRapid®, both in combination with Levemir® in adults with type 1 diabetes.

The onset® 2 trial (689 people randomised) – a 26-week randomised, double-blind, basal-bolus, treat-to-target trial investigating faster-acting insulin aspart compared to NovoRapid®, both in combination with insulin glargine in adults with type 2 diabetes.

The onset® 3 trial (236 people randomised) – an 18-week randomised, open-label, basal-bolus vs basal trial confirming superiority (in terms of HbA1c) of mealtime faster-acting insulin aspart in a full basal-bolus regimen versus basal insulin therapy, both in combination with metformin. The results were reported in January 2015.

The onset® 4 trial (37 people randomised) – a six-week randomised, double-blind, parallel-group trial confirming pump compatibility and safety of faster-acting insulin aspart and NovoRapid® in type 1 diabetes. The results were reported in August 2014.

Novo Nordisk is a global healthcare company with more than 90 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 41,500 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

For further information

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Company announcement No 22 / 2015

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: March 25, 2015

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer