NOVO NORDISK A S
Form 6-K
December 18, 2015

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

December 17, 2015

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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 [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-_____

Novo Nordisk successfully completes fourth phase 3a trial with semaglutide in people with type 2 diabetes

Bagsværd, Denmark, 17 December 2015 - Novo Nordisk today announced the headline results from the fourth phase 3a trial for semaglutide, SUSTAIN2. Semaglutide is a new GLP-1 analogue administered subcutaneously once weekly. The double-blinded trial investigated the efficacy and safety of 0.5 mg and 1.0 mg semaglutide compared with 100 mg sitagliptin, a once-daily DPP-IV inhibitor, after 56 weeks of treatment in 1,231 people with type 2 diabetes, where both drugs were added on to metformin, thiazolidinedione (TZD) or a combination of metformin/TZD.

The trial successfully achieved its objective by demonstrating that from a mean baseline HbA_{1c} of 8.1%, people treated with 0.5 mg or 1.0 mg semaglutide achieved a statistically significant and superior improvement in HbA_{1c} of 1.3% and 1.6% respectively, compared to an improvement in HbA_{1c} of 0.5% with 100 mg sitagliptin.

69% of the people treated with 0.5 mg semaglutide and 78% of the people treated with 1.0 mg semaglutide achieved the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) treatment target of HbA_{1c} below 7% compared with 36% of the people treated with 100 mg sitagliptin.

Furthermore, from a mean baseline body weight of 89 kg, people treated with 0.5 mg and 1.0 mg semaglutide experienced a statistically significant and superior weight loss of 4.3 kg and 6.1 kg respectively, compared with a weight loss of 1.9 kg for people treated with 100 mg sitagliptin.

In the trial, semaglutide appeared to have a safe and well-tolerated profile. The most common adverse event was nausea which diminished over time. Nausea was reported by 18% of the people treated with 0.5 mg semaglutide and by 18% of the people treated with 1.0 mg semaglutide, compared with 7% of people treated with 100 mg sitagliptin. The discontinuation rate due to adverse events was 8% and 10% for people treated with 0.5 mg semaglutide and 1.0 mg semaglutide respectively, compared to 3% for people treated with 100 mg sitagliptin.

"We are excited about the results of SUSTAIN 2, showing superior efficacy in glycaemic control and weight loss with semaglutide administered once-weekly compared with 100 mg sitagliptin, which is consistent with the outcome seen across all SUSTAIN trials reported to date," says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "The results from the SUSTAIN programme thus far support that semaglutide has the potential to become the most efficacious GLP-1 product for people with type 2 diabetes."

Novo Nordisk expects to announce headline results of the two remaining SUSTAIN trials in the first half of 2016**.**

About Semaglutide

Semaglutide is a new glucagon-like peptide-1 (GLP-1) analogue that can help people with type 2 diabetes achieve substantial improvement of blood glucose with a low risk of hypoglycaemia. In addition, semaglutide induces weight loss by decreasing appetite and food intake. Semaglutide administered subcutaneously once weekly is in phase 3 development for the treatment of type 2 diabetes. Furthermore, semaglutide is being developed in an oral tablet version for treatment of type 2 diabetes as well as once-daily subcutaneous versions for treatment of type 2 diabetes and weight management.

About the SUSTAIN clinical programme

The SUSTAIN programme is a phase 3 clinical programme comprising six global trials of semaglutide administered subcutaneously once weekly encompassing more than 7,000 people with type 2 diabetes.

SUSTAIN 1 - a 30-week efficacy and safety trial of semaglutide versus placebo in 388 drug-naïve people with type 2 diabetes.

SUSTAIN 2 - a 56-week efficacy and safety trial of semaglutide versus sitagliptin once-daily as add-on to metformin and/or TZD in 1,231 people with type 2 diabetes.

SUSTAIN 3 - a 56-week efficacy and safety trial of semaglutide versus 2.0 mg exenatide once-weekly as add-on to 1-2 oral antidiabetic drugs in 813 people with type 2 diabetes.

SUSTAIN 4 - a 30-week efficacy and safety trial of semaglutide versus insulin glargine once-daily as add-on to metformin with or without sulfonylurea in 1,089 insulin-naïve people with type 2 diabetes.

SUSTAIN 5 - a 30-week efficacy and safety trial not yet reported of semaglutide versus placebo as add-on to basal insulin alone or basal insulin in combination with metformin in 397 people with type 2 diabetes.

SUSTAIN 6 - a 2-year trial not yet reported to evaluate cardiovascular and other long-term outcomes with semaglutide in 3,297 people with type 2 diabetes.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 40,300 people 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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Novo Nordisk A/S

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Company announcement No 79 / 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: December 17, 2015

NOVO NORDISK A/S

Lars Rebien Sørensen,

Chief Executive Officer