NOVO NORDISK A S
Form 6-K
February 23, 2016

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

February 23, 2016

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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 fifth phase 3a trial with semaglutide in people with type 2 diabetes

Bagsværd, Denmark, 23 February 2016 - Novo Nordisk today announced the headline results from the fifth phase 3a trial for semaglutide, SUSTAIN 5. Semaglutide is a new GLP-1 analogue, which is administered subcutaneously once weekly in the SUSTAIN trials. The double-blinded trial investigated the efficacy and safety of 0.5 mg and 1.0 mg semaglutide compared with placebo as add-on to basal insulin alone or basal insulin in combination with metformin, after 30 weeks of treatment in 397 people with type 2 diabetes.

The trial successfully achieved its objective by demonstrating that people treated with 0.5 mg or 1.0 mg semaglutide achieved a statistically significant and superior improvement in HbA1c of 1.4% and 1.8% respectively, from a mean baseline HbA1c of 8.4%, compared with an improvement in HbA1c of 0.1% with placebo. Additionally, the end of trial insulin dose for people treated with 0.5 mg and 1.0 mg semaglutide was reduced by 10% and 15% respectively, compared with 3% for the placebo group.

61% of the people treated with 0.5 mg semaglutide and 79% of the people treated with 1.0 mg semaglutide achieved the treatment target of HbA1c below 7% set by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), compared with 11% of the people treated with placebo.

From a mean baseline body weight of 92 kg, people treated with 0.5 mg and 1.0 mg semaglutide experienced a statistically significant and superior weight loss of 3.7 kg and 6.4 kg respectively, compared with a weight loss of 1.4 kg for people treated with placebo.

In the trial, semaglutide appeared to have a safe and well-tolerated profile. The most common adverse event was nausea. Nausea was reported by 11% of the people treated with 0.5 mg semaglutide and by 17% of the people treated with 1.0 mg semaglutide, compared with 5% of people treated with placebo. Severe or blood glucose-confirmed symptomatic hypoglycaemia was experienced by 8% and 11% of people treated with 0.5 mg or 1.0 mg once-weekly semaglutide respectively, compared with 5% in the placebo group. The discontinuation rate due to adverse events was 5% and 6% for people

treated with 0.5 mg semaglutide and 1.0 mg semaglutide respectively, compared to 1% for people treated with placebo.

“We are excited about the results of SUSTAIN 5, showing superior efficacy in glycaemic control and weight loss with semaglutide administered once-weekly in patients inadequately controlled on basal insulin” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “The results from the first five SUSTAIN trials support the potential for broad usage of semaglutide in people with type 2 diabetes, as results have been consistent when treating people with both early onset as well as late stage type 2 diabetes.”

Novo Nordisk expects to announce headline results of the final SUSTAIN trial, SUSTAIN 6 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. The results were reported in July 2015.

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. The results were reported in December 2015.

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. The results were reported in September 2015.

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. The results were reported in November 2015.

SUSTAIN 5 – a 30-week efficacy and safety trial 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 41,000 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

Further information

Media:

Katrine Sperling	+45 3079 6718	krsp@novonordisk.com
Ken Inchausti (US)	+1 609 786 8316	kiau@novonordisk.com

Investors:

Peter Hugreffe Ankersen	+45 3075 9085	phak@novonordisk.com
Daniel Bohsen	+45 3079 6376	dabo@novonordisk.com
Melanie Raouzeos	+45 3075 3479	mrz@novonordisk.com
Kasper Veje	+45 3079 8519	kpvj@novonordisk.com

Novo Nordisk A/S Novo Allé Telephone: Internet:

Investor Relations 2880 Bagsværd +45 4444 8888 www.novonordisk.com

Denmark CVR no:

24 25 67 90

Company announcement No 18 / 2016

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.

NOVO NORDISK A/S

Date: February 23, 2016

Lars Rebien Sørensen,

Chief Executive Officer