NOVO NORDISK A S
Form 6-K
August 25, 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

August 24, 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 completes second and final phase 3a trial with liraglutide as adjunct therapy to insulin for people with type 1 diabetes (NN9211)

Bagsværd, Denmark, 24 August 2015 – Novo Nordisk today announced headline results from the second and final phase 3a trial with liraglutide as adjunct therapy to insulin for people with type 1 diabetes. ADJUNCT ONE™ is a randomised, double-blind, placebo-controlled trial investigating efficacy and safety of daily doses of 0.6 mg, 1.2 mg and 1.8 mg liraglutide compared with placebo as adjunct to insulin treatment. 1,398 people with type 1 diabetes were treated for 52 weeks.

From a mean baseline HbA_{1c} of around 8.2%, people treated with 1.2 mg and 1.8 mg liraglutide as adjunct to insulin therapy achieved the primary objective of non-inferiority in HbA_{1c} and showed a greater improvement in HbA_{1c} of around 0.5% compared with 0.3% for people treated with placebo. The primary objective of HbA_{1c} non-inferiority was not confirmed for the 0.6 mg dose.

Furthermore, from a mean baseline weight of around 86 kg, people treated with 1.2 mg and 1.8 mg liraglutide as adjunct to insulin therapy achieved a statistically significantly greater weight loss between 3 kg and 4 kg whereas people treated with placebo experienced a weight gain of around 1 kg.

In the trial, the most common adverse events were related to the gastrointestinal system, primarily transient nausea and vomiting. The rate of severe hypoglycaemia appeared numerically, but not statistically significantly lower for all doses of liraglutide as adjunct to insulin therapy compared with placebo. A statistically significant higher rate of confirmed symptomatic hypoglycaemia was observed among people treated with liraglutide 1.2 mg and 1.8 mg compared with people treated with placebo. The proportion of people with serious adverse events was similar in all treatment groups.

Based on a risk/benefit assessment of the overall dataset from the two ADJUNCT trials, Novo Nordisk does currently not intend to submit an application to expand the label of Victoza® for use in type 1 diabetes. Novo Nordisk intends to conduct thorough analyses to evaluate the clinical data and define potential future clinical and regulatory initiatives.

“The results of the two ADJUNCT trials show that liraglutide as adjunct to insulin therapy met the primary end-point of improving blood glucose control for people with type 1 diabetes, however, unfortunately without the hypoglycaemic benefit experienced in type 2 diabetes ” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We are disappointed as we believed in the potential to provide people with type 1 diabetes with a new treatment option, and we will continue to invest in new treatment options for this group of people.”

About liraglutide

Liraglutide is a once-daily human analogue of the naturally occurring hormone Glucagon- Like Peptide-1 (GLP-1). The compound is approved for the treatment of type 2 diabetes, and is currently in phase 3 development for the treatment of type 1 diabetes as adjunct to insulin therapy. Liraglutide works by stimulating the release of insulin only when glucose levels become too high, supressing the glucagon production by the liver and by inhibiting appetite. In contrast to most other antidiabetic treatments, liraglutide also leads to weight loss instead of weight increase.

About the ADJUNCT clinical programme

The ADJUNCT programme is a phase 3 clinical programme comprising two global trials of liraglutide as adjunct to insulin therapy encompassing more than 2,000 people with type 1 diabetes.

ADJUNCT ONE™ (1,398 people randomised) – a 52-week, double-blind, placebo- controlled treat-to-target trial investigating liraglutide as adjunct to insulin therapy.

ADJUNCT TWO™ (835 people randomised) – a 26-week, double-blind, insulin-capped, placebo-controlled trial investigating the additional glucose control of liraglutide as adjunct to insulin therapy. The results were announced on 6 August 2015.

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 39,700 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

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Company announcement No 51 / 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.

NOVO NORDISK A/S

Date: August 24, 2015

Lars Rebien Sørensen,

Chief Executive Officer