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-_____

Tresiba® demonstrates significantly lower rate of hypoglycaemia than insulin glargine U100 in blinded phase 3b trial in people with type 1 diabetes

Bagsværd, Denmark, 23 February 2016 - Novo Nordisk today announced the headline results from SWITCH 1, the second of two 2x32-weeks randomised, double-blind, cross-over, treat-to-target trials, comparing the safety and efficacy of Tresiba® (insulin degludec) and Lantus® (insulin glargine U100). The overall purpose of the trial was to compare the hypoglycaemia occurrence in people with type 1 diabetes treated with Tresiba® or insulin glargine.

In the trial, 501 people with type 1 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100 in combination with insulin aspart. The timing of the daily injections of both Tresiba® and insulin glargine was randomised equally to take place either in the morning or evening. The primary end-point of the trial was the number of treatment emergent severe or blood glucose confirmed symptomatic hypoglycaemia episodes during the maintenance period (ie after 16 weeks of treatment) in each treatment period.

From a mean baseline of 7.6%, the trial showed non-inferiority in HbA_{1c} reduction for Tresiba® compared to insulin glargine, thus fulfilling the requirements for objectively comparing hypoglycaemia rates between the two treatments. Likewise, the end-of-trial insulin doses were similar at the end of treatment in the two treatment periods.

The trial met the primary end-point by demonstrating non-inferiority in the rate of severe or blood glucose confirmed symptomatic hypoglycemia of Tresiba® compared to insulin glargine. The observed rate was 2,201 events per 100 patient years exposed to Tresiba® and 2,463 events per 100 patient years exposed to insulin glargine during the maintenance period, corresponding to a statistically significant reduction of 11%.

Similarly, non-inferiority was demonstrated for the rate of severe or blood glucose confirmed symptomatic nocturnal hypoglycaemia in the maintenance period. The observed rate of severe or blood glucose confirmed symptomatic nocturnal hypoglycaemia was 277 events per 100 patient years exposed to Tresiba® and 429 events per 100 patient years exposed to insulin glargine, corresponding to a statistically significant 36% reduction with Tresiba® compared to insulin glargine.

Finally, superiority was demonstrated for the confirmatory secondary endpoint of proportions of subjects experiencing severe hypoglycaemia during the maintenance period. The proportion of patients experiencing severe hypoglycaemia was 10% for Tresiba® and 17% for insulin glargine, corresponding to a statistically significant reduction with Tresiba® compared to insulin glargine. The rates of severe hypoglycaemia were 69 and 92 events per 100 patient years exposed, respectively, corresponding to a statistically significant 35% reduction.

All of the above analyses showed similar results for the total treatment period.

In the trial, Tresiba® appeared to have a safe and well-tolerated profile. Adverse events were comparable between the two treatment arms. The most common adverse events were nasopharyngitis, upper respiratory tract infections and hypoglycaemia.

"We are very excited about these trial results, which document that Tresiba® also in people with type 1 diabetes significantly reduces the risk of hypoglycaemia compared to insulin glargine" says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "We expect to initiate filing of the data from the SWITCH trials with regulatory authorities in Q3 2016 with the aim of updating the label for Tresiba®".

Conference call

On 24 February 2016 at 8.30 am CET, corresponding to 2.30 am EST, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com.

About SWITCH 1 and 2

The two 2x32-weeks randomised, double-blind, cross-over, treat-to-target trials were initiated in January 2014 with the purpose of comparing the safety and efficacy of Tresiba® and Lantus® (insulin glargine U100). The overall purpose of the trials is to document the hypoglycaemia profile in type 1 diabetes and type 2 diabetes respectively, compared to insulin glargine U100. In SWITCH 1, 501 people with type 1 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100 in combination with insulin aspart. In SWITCH 2, 721 people with type 2 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100 in combination with oral antidiabetics. The results from SWITCH 2 were reported on 29 January 2016.

Lantus® is a registered trademark of Sanofi.

Further information

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Company announcement No 17 / 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