NOVO NORDISK A S
Form 6-K
January 29, 2016

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

January 29, 2016

_____

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 [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 in blinded phase 3b trial in people with type 2 diabetes

Bagsværd, Denmark, 29 January 2016 - Novo Nordisk today announced the headline results from SWITCH 2, the first of two 2x32-weeks randomised, double-blind, cross- over, treat-to-target trials, comparing the safety and efficacy of Tresiba® (insulin degludec) and insulin glargine. The overall purpose of the trial was to compare the hypoglycaemia occurrence in people with type 2 diabetes treated with Tresiba® or insulin glargine.

In the trial, 721 people with type 2 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine in combination with metformin. 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 HbA1c reduction of 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 observed rate of severe or blood glucose confirmed symptomatic hypoglycemia was 186 events per 100 patient years exposed to Tresiba® and 265 events per 100 patient years exposed to insulin glargine during the maintenance period. This reduction was statistically significant, and the trial thus met its primary endpoint by demonstrating a reduction of 30% when people were treated with Tresiba® compared to insulin glargine.

The observed rate of severe or blood glucose symptomatic nocturnal confirmed hypoglycaemia in the maintenance period was 55 events per 100 patient years exposed to Tresiba® and 94 events per 100 patient years exposed to insulin glargine, corresponding to a 42% reduction with Tresiba® compared to insulin glargine and showing statistical significance on this confirmatory secondary end-point.

The confirmatory secondary endpoint of proportions of subjects experiencing severe hypoglycaemia during the maintenance period did not reach statistical significance. However, the supportive end-point, rate of severe hypoglycaemia, showed a 46% reduction with Tresiba® in the maintenance period and a statistical significant reduction of 51% with Tresiba® in the full 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 and upper respiratory tract infections.

“We are excited about these trial results, which in a blinded setting confirm the significant reduction in the risk of hypoglycaemia for Tresiba® compared to insulin glargine” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We look forward to reporting the outcome of the SWITCH 1 trial in people with type 1 diabetes and to evaluating the results from both trials”.

Novo Nordisk expects to announce headline results of SWITCH 1 later in the first quarter of 2016.

About SWITCH 1 and 2

The two 2x32-weeks randomised, double-blind, cross-over, treat-to-target trials were initiated in January 2014 with purpose of comparing the safety and efficacy of Tresiba® and insulin glargine. 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. In SWITCH 1, 501 people with type 1 diabetes were randomised to crossover treatment with Tresiba® and insulin glargine in combination with insulin aspart. In SWITCH 2, 721 people with type 2 diabetes were randomised to crossover treatment with Tresiba® and insulin glargine in combination with oral antidiabetics.

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

Media:		
Mike Rulis	+45 3079 3573	mike@novonordisk.com
Ken Inchausti (US)	+1 609 514 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 6 / 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: January 29, 2016

Lars Rebien Sørensen,

Chief Executive Officer