NOVO NORDISK A S
Form 6-K
November 30, 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

November 29, 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 a safe cardiovascular profile and reduces the risk of severe hypoglycaemia compared to insulin glargine U100 in the DEVOTE trial

Bagsværd, 29 November 2016 – Today, Novo Nordisk announced the headline results from the DEVOTE trial, a long-term, randomised, double-blinded and event-driven trial conducted to confirm the cardiovascular safety of Tresiba® (insulin degludec) compared to insulin glargine U100 when added to standard of care. In the trial, more than 7,500 people with type 2 diabetes at high risk of major adverse cardiovascular events were treated for a period of approximately two years.

The trial achieved its primary endpoint by demonstrating non-inferiority of major adverse cardiovascular events (MACE) with Tresiba® compared to insulin glargine U100. The trial thereby confirmed the results of the DEVOTE interim analysis submitted to the US Food and Drug Administration (FDA) in March 2015, on the basis of which Tresiba® and Ryzodeg® 70/30 were approved in the US in September 2015.

The primary endpoint of the DEVOTE study was defined as the MACE composite outcome of the first occurrence of cardiovascular death, non-fatal myocardial infarction or non- fatal stroke and showed a hazard ratio of 0.91 in favour of Tresiba® relative to insulin glargine U100, with no statistically significant difference between the two treatments.

From a mean HbA1c baseline of 8.4%, the trial showed a similar reduction with Tresiba® compared to insulin glargine U100 with an end-of-trial treatment difference of 0.01 percentage-points between the two treatment arms, thus fulfilling the requirements for objectively comparing hypoglycaemia rates between the two treatments.

In the trial, Tresiba® demonstrated superiority on the secondary confirmatory endpoint of severe hypoglycaemia: 27% fewer patients in the Tresiba® treated group experienced an episode of severe hypoglycaemia, resulting in a 40% overall reduction of total episodes of adjudicated severe hypoglycaemia. Furthermore, patients in the Tresiba® treated group experienced a 54% relative reduction in the rate of nocturnal severe hypoglycaemia. These differences were all statistically significant.

Tresiba® appeared to have a safe and well-tolerated profile consistent with previous clinical studies conducted with Tresiba®.

			Internet:
	Novo Allé	Telephone:	
Novo Nordisk A/S			www.novonordisk.com
	2880 Bagsværd	+45 4444 8888	
Investor Relations			CVR no:
	Denmark		
			24 25 67 90

Company announcement No 84 / 2016

“We are very pleased that the DEVOTE study demonstrates the cardiovascular safety of Tresiba® and also confirms the hypoglycaemia benefit of this new generation insulin. Severe hypoglycaemia remains the most serious treatment risk related to insulin therapy. The DEVOTE results further strengthen the potential of Tresiba® to become the new standard of care within basal insulin therapy,” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Novo Nordisk expects to present the detailed results of the DEVOTE trial at a scientific meeting and submit the findings for review with regulatory authorities during the first half of 2017.

Conference call

On 30 November 2016 at 8.00 am CET, corresponding to 2.00 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 DEVOTE

DEVOTE is a long-term, multi-centre, multi-national, randomised, double-blinded, parallel group and event-driven trial conducted to confirm the cardiovascular safety of Tresiba® (insulin degludec) compared to insulin glargine U100. In the trial, 7,637 people with type 2 diabetes at high risk of cardiovascular disease were randomised to treatment with either Tresiba® or insulin glargine U100 in vial in addition to standard of care. The DEVOTE trial has been conducted in response to a Complete Response Letter received from the FDA in February 2013 requesting additional cardiovascular data from a dedicated cardiovascular outcomes trial before the review of the New Drug Applications for Tresiba® and Ryzodeg® 70/30 could be concluded. Tresiba® and Ryzodeg® 70/30 were approved in the US in September 2015 on the basis of an interim analysis of DEVOTE.

About Tresiba®

Tresiba® (insulin degludec) is a once-daily basal insulin that provides duration of action of at least 42 hours. Tresiba® is taken once daily, at any time of day. Patients who miss or are delayed in taking their dose of Tresiba® can take their dose as soon as they remember, but ensuring there are at least eight hours between doses. Tresiba® received its first regulatory approval in September 2012 and has since been approved in more than 80 countries globally. It was approved by the US FDA in September 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 42,600 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.

Novo Nordisk A/S

Investor Relations

Novo Allé

2880 Bagsværd

Denmark

Telephone:

+45 4444 8888

Internet:

www.novonordisk.com

CVR no:

24 25 67 90

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Further information

Media:

Katrine Sperling	+45 4442 6718	krsp@novonordisk.com
Ken Inchausti (US)	+1 609 786 8316	kiau@novonordisk.com

Investors:

Peter Hugreffe Ankersen	+45 3075 9085	phak@novonordisk.com
Melanie Raouzeos	+45 3075 3479	mrz@novonordisk.com
Hanna Ögren	+45 3079 8519	haoe@novonordisk.com
Anders Mikkelsen	+45 3079 4461	armk@novonordisk.com
Kasper Veje (US)	+1 609 235 8567	kpvj@novonordisk.com

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: November 29, 2016

Lars Rebien Sørensen,

Chief Executive Officer