NOVO NORDISK A S
Form 6-K
March 04, 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

March 4, 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-_____

Victoza® significantly reduces the risk of major adverse cardiovascular events in the LEADER trial

Bagsværd, Denmark, 4 March 2016 - Novo Nordisk today announced the top-line results from the LEADER trial, which investigated the cardiovascular safety of Victoza® (liraglutide) over a period of up to 5 years in more than 9,000 adults with type 2 diabetes at high risk of major adverse cardiovascular events. The trial compared the addition of either Victoza® or placebo to standard of care and met the primary endpoint of showing non-inferiority as well as demonstrating superiority, with a statistically significant reduction in cardiovascular risk. The primary endpoint of the study was defined as the composite outcome of the first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke. The superior reduction of major adverse cardiovascular events demonstrated by Victoza® was derived from all three components of the endpoint.

The safety profile of Victoza® in LEADER was generally consistent with previous liraglutide clinical studies.

“People with type 2 diabetes generally have a higher risk of experiencing major adverse cardiovascular events. That’s why we are very excited about the results from LEADER, which showed that Victoza®, in addition to helping people with type 2 diabetes control their blood sugar levels, also reduces their risk of major adverse cardiovascular events ”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “LEADER is the largest and longest Novo Nordisk clinical trial to report to date, and we look forward to sharing the detailed results with the medical community and submitting the findings to the regulatory authorities.”

The detailed results are planned to be presented at the 76th Scientific Sessions of the American Diabetes Association in June 2016.

Conference call

On 4 March 2016 at 2.00 pm CET, corresponding to 8.00 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 LEADER

LEADER was a multicentre, international, randomised, double-blind, placebo-controlled trial investigating the long-term effects of Victoza® (1.2 and 1.8 mg) compared to placebo, both in addition to standard of care, in people with type 2 diabetes at high risk of cardiovascular events. The trial was initiated in September 2010 and randomised 9,340 people with type 2 diabetes from 32 countries that were followed for 3.5–5 years. The primary endpoint was the first occurrence of a composite cardiovascular outcome comprising cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.

About Victoza®

Victoza® (liraglutide) is a human glucagon-like peptide-1 (GLP-1) analogue with an amino acid sequence 97% similar to endogenous human GLP-1.

Victoza® was launched in the EU in 2009 and is commercially available in more than 80 countries with more than 3 million patient years of use in people with type 2 diabetes globally. In Europe, Victoza® is indicated for treatment of adults with type 2 diabetes to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. Victoza® was approved by the U.S. Food and Drug Administration in 2010, as an adjunct to diet and exercise to improve glycaemic control in adults 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

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Company announcement No 20 / 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.

Date: March 4, 2016

NOVO NORDISK A/S

Lars Rebien Sørensen,

Chief Executive Officer