NOVO NORDISK A S
Form 6-K
October 26, 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

October 25, 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-_____

Novo Nordisk submits application to regulatory authorities to include LEADER data in Victoza® label

Bagsværd, Denmark, 25 October 2016 – Novo Nordisk today announced the submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) and a Type II Variation application to the European Medicines Agency (EMA) for including data from the LEADER cardiovascular outcomes trial in the product information of Victoza® (liraglutide).

In the LEADER trial, Victoza® statistically significantly reduced the risk of cardiovascular death, non-fatal myocardial infarction (heart attack) and non-fatal stroke by 13% versus placebo, when added to standard of care. The overall risk reduction was derived from a statistically significant 22% reduction in cardiovascular death with Victoza® treatment versus placebo and non-significant reductions in non-fatal myocardial infarction and non- fatal stroke.

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

“Reducing the risk of cardiovascular death in people with type 2 diabetes remains a significant unmet need and it is encouraging that we now have the opportunity to help address this challenge,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “Victoza® is the first GLP-1 receptor agonist to show cardiovascular risk reduction in adults with type 2 diabetes at high cardiovascular risk and we look forward to working with the regulatory authorities as they review the data from the LEADER trial.”

About the LEADER trial

LEADER was a multicentre, international, randomised, double-blind, placebo-controlled trial investigating the long-term (3.5–5 years) effects of Victoza® (liraglutide up to 1.8 mg) compared to placebo, both in addition to standard of care, in people with type 2 diabetes at high risk of major cardiovascular events. Standard of care was comprised of lifestyle modifications, glucose-lowering treatments and cardiovascular medications.

LEADER was initiated in September 2010 and randomised 9,340 people with type 2 diabetes from 32 countries. 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 approved in the EU in 2009 and is commercially available in more than 85 countries, treating more than 1 million people with type 2 diabetes globally. In Europe, Victoza® is indicated for the treatment of adults with type 2 diabetes to achieve glycaemic control as monotherapy, when metformin is considered inappropriate, and 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. In the US, Victoza® was approved in 2010 as an adjunct to diet and exercise to improve blood glucose 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 42,300 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

Further information

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Company announcement No 72 / 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: October 25, 2016

Lars Rebien Sørensen,

Chief Executive Officer