NOVO NORDISK A S
Form 6-K
August 28, 2017

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

August 25, 2017

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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® approved in the US as the only type 2 diabetes treatment indicated to reduce the risk of major adverse cardiovascular events

Bagsværd, Denmark, 25 August 2017 - The U.S. Food and Drug Administration (FDA) has approved a new indication for Victoza® (liraglutide) to reduce the risk of major adverse cardiovascular (CV) events in adults with type 2 diabetes and established CV disease.

The FDA's decision is based on the results from the landmark LEADER trial, which demonstrated that Victoza® statistically significantly reduced the risk of cardiovascular death, non-fatal heart attack or non-fatal stroke by 13% vs placebo, when added to standard of care, with an absolute risk reduction of 1.9%. The overall risk reduction was derived from a statistically significant 22% reduction in cardiovascular death with Victoza® treatment vs placebo, with an absolute risk reduction of 1.3%, and non- significant reductions in non-fatal heart attack and non-fatal stroke.

"This approval marks an important milestone for millions of Americans living with type 2 diabetes, as cardiovascular disease is the number one cause of death in this patient population," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "Victoza® now offers people with type 2 diabetes and established cardiovascular disease an effective treatment option to both lower their blood glucose and reduce their cardiovascular risk."

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 95 countries, treating more than 1 million people with type 2 diabetes globally. 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 and now approved to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes and established cardiovascular disease. In Europe, Victoza® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes

together with diet and exercise, as monotherapy when metformin is considered inappropriate due to intolerance or contraindications and in addition to other medicinal products for the treatment of diabetes.

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) 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. The landmark LEADER trial 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 heart attack or non-fatal stroke.

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 41,400 people in 77 countries and markets its products in more than 165 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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Novo Nordisk A/S

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Company announcement No 67 / 2017

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: August 25, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer