NOVO NORDISK A S
Form 6-K
July 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

July 27, 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® has been approved in the EU as the only GLP-1 with a label to include prevention of cardiovascular events

Bagsværd, Denmark, 27 July 2017 – The European Commission has approved an update to the Victoza® (liraglutide) EU label that expands the indication to reflect both improving blood sugar and cardiovascular (CV) events as integral parts of type 2 diabetes treatment. Victoza® is the only GLP-1 that is proven to prevent CV events in people with type 2 diabetes and high CV risk.

The updated label includes results from the LEADER trial, which demonstrated that Victoza® statistically significantly reduced the risk of cardiovascular death, non-fatal myocardial infarction (heart attack) or 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.

“Cardiovascular disease is the number one cause of death for people with type 2 diabetes and requires treatment strategies that can tackle both blood glucose and cardiovascular risk to help improve outcomes,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “The European Commission’s approval of the expanded Victoza® label enables physicians to provide their patients with the only GLP-1 proven to prevent cardiovascular events in people with type 2 diabetes and high 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 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 type 2 diabetes. 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.

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 42,000 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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24 25 67 90

Company announcement No 57 / 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: July 27, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer