NOVO NORDISK A S
Form 6-K
August 28, 2018

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 26, 2018

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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-_____

Ozempic® consistently reduced the risk of major cardiovascular events across type 2 diabetes populations at high CV risk regardless of prior CV events at baseline

Munich, Germany, 26 August 2018 – Ozempi® (semaglutide) consistently reduced the risk of the composite outcome of time to first occurrence of non-fatal heart attack, non-fatal stroke or cardiovascular death (collectively termed major adverse cardiovascular events, MACE) in people with type 2 diabetes at high cardiovascular risk regardless of previously having had a cardiovascular event at the start of the trial.[1] Findings from two post-hoc subgroup analyses of the SUSTAIN 6 trial and one post-hoc meta-analysis of MACE in the SUSTAIN 1-5 trials were presented today at the ESC Congress 2018, organised by the European Society of Cardiology, in Munich, Germany.[1]

"Cardiovascular disease remains the leading cause of disability and death in people with type 2 diabetes and there is an increasing focus on reducing cardiovascular risk in the clinic," said Professor Stephen Bain, School of Medicine, Swansea University, UK. "We have seen from clinical trials that diabetes treatments confer variable effects on cardiovascular outcomes and the results of these post-hoc analyses provide further evidence of the consistent cardiovascular risk reduction of Ozempic® in people with type 2 diabetes, with varying profiles of cardiovascular risk at baseline."

The SUSTAIN 6 post-hoc analyses found that reduction in the risk of MACE was consistent in people at high cardiovascular risk treated with Ozempic® regardless of their cardiovascular risk profile at the start of the trial, including whether or not they had a prior heart attack or stroke, and whether they had cardiovascular risk factors or established cardiovascular disease.[1] SUSTAIN 6 was a pre-approval cardiovascular outcomes trial in 3,297 people with type 2 diabetes and established cardiovascular disease or with at least one cardiovascular risk factor, compared to placebo, both in addition to standard of care.[2]

The post-hoc pooled meta-analysis of the SUSTAIN 1-5 efficacy trials, which included 4,807 people, trended towards a lower risk of MACE in people taking Ozempic®. The comparators

included in SUSTAIN 1-5 were placebo, sitagliptin, exenatide extended release and insulin glargine U100. The overall incidence of MACE was low across the SUSTAIN 1-5 trials and, due to the low number of events, this reduction did not achieve statistical significance.[1]

About Ozempic®

Ozempic® (semaglutide) is a once-weekly analogue of human glucagon-like peptide-1 (GLP-1) indicated for the treatment of adults with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes, as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes.[3] Ozempic® was approved by the U.S. Food and Drug Administration on 5 December, 2017, by Health Canada on 4 January, 2018, by the European Commission on 9 February, 2018 and on 23 March, 2018 by the Japanese Ministry of Health, Labour and Welfare.[4-7]

About the SUSTAIN clinical trial programme

The SUSTAIN global clinical development programme for Ozempic® comprises eight phase 3a trials, encompassing more than 8,000 adults with type 2 diabetes. The phase 3a programme involves a broad range of people with type 2 diabetes, including some with high cardiovascular risk profiles.

The primary analysis of the SUSTAIN 6 trial was published in *The New England Journal of Medicine*.[2] The primary outcome measure was a composite outcome of major adverse cardiovascular events (MACE), defined as non-fatal myocardial infarction, non-fatal stroke or cardiovascular death. Ozempic® treated patients had a significant 26% lower risk of MACE vs those receiving placebo over 2 years (hazard ratio 0.74; 95% confidence interval 0.58-0.95).[2] SUSTAIN 6 was designed to assess non-inferiority, i.e. demonstrate no increased risk of major cardiovascular events vs placebo, when added to standard of care. Testing for superiority was not part of the pre-specified analysis.

About Novo Nordisk

Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,100 people in 79 countries and markets its products in more than 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

Further information

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References

1. Bain S, Réa R, Warren ML*, et al.* Semaglutide consistently reduces cardiovascular risk in patients with type 2 diabetes regardless of baseline cardiovascular risk level: post hoc analyses of the SUSTAIN trial programme. Abstract number P-2859. Presented at the 2018 Congress of the European Society of Cardiology, Munich, Germany. 25-29 August.

2. Marso SP, Bain SC, Consoli A*, et al.* Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. *N Engl J Med*. 2016;375:1834-1844.

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6. Novo Nordisk. Ozempic® approved in Canada for the treatment of adults with type 2 diabetes. Available at: http://www.novonordisk.ca/content/dam/Canada/AFFILIATE/www-novonordisk-ca/News/Ozempic%20press%20release_Eng Last accessed: August 2018.

7. Novo Nordisk. Ozempic® approved in Japan for the treatment of type 2 diabetes. Available at: https://www.novonordisk.com/content/Denmark/HQ/www-novonordisk-com/en_gb/home/media/news-details.2178681.html. Last accessed: August 2018.

Novo Nordisk A/S

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August 2018

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 27, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer