NOVO NORDISK A S
Form 6-K
December 05, 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

December 5, 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 files for regulatory approval of once- weekly semaglutide in the US and EU for the treatment of type 2 diabetes

Bagsværd, Denmark, 5 December 2016 – Novo Nordisk today announced the submission of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) and a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for semaglutide, a new glucagon-like peptide-1 (GLP-1) analogue administered once-weekly, for the treatment of adults with type 2 diabetes.

The submission is based on the results from the SUSTAIN clinical trial programme, which included more than 8,000 adults with type 2 diabetes. In the SUSTAIN programme, once-weekly semaglutide was studied in combination with oral-antidiabetic agents and basal insulin. Semaglutide demonstrated statistically significant and sustained blood glucose control compared to sitagliptin, exenatide extended-release, once-daily insulin glargine U100 and placebo. Furthermore, the cardiovascular outcomes trial, SUSTAIN 6, demonstrated a statistically significant cardiovascular

risk reduction compared to placebo, as add-on to standard of care in patients with high cardiovascular risk. In addition, semaglutide demonstrated statistically significantly greater reductions in mean body weight versus comparators.

Across the SUSTAIN clinical trial programme, once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea.

“Achieving blood glucose control, weight loss and reducing the risk of cardiovascular events remains a significant challenge for adults with type 2 diabetes,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We are excited with this regulatory filing, as results from the SUSTAIN programme show that once-weekly semaglutide has the potential to further improve the treatment of adults with type 2 diabetes.”

About semaglutide

Semaglutide is a new once-weekly analogue of human GLP-1 that stimulates insulin and suppresses glucagon secretion in a glucose-dependent manner, while decreasing appetite and food intake. Novo Nordisk intends to make once-weekly semaglutide available in a prefilled delivery device based on the same technology platform as FlexTouch®.

About the SUSTAIN phase 3a clinical trial programme

SUSTAIN is a global clinical trial programme for once-weekly semaglutide that comprises seven phase 3a clinical trials and a cardiovascular outcomes trial, involving more than 8,000 adults with type 2 diabetes.

In July 2015, the SUSTAIN 1 trial showed that, from a mean baseline HbA_{1c} of 8.1%, 388 adults treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significantly greater HbA_{1c} reductions of 1.5% and 1.6%, respectively, vs <0.1% with placebo. The trial also demonstrated that adults treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significantly greater reductions from baseline in mean body weight of 3.7 kg and 4.5 kg, respectively, vs 1.0 kg with placebo.

In December 2015, the SUSTAIN 2 trial showed that from a mean baseline HbA_{1c} of 8.1%, 1,231 adults with type 2 diabetes treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significantly greater HbA_{1c} reductions of 1.3% and 1.6%, respectively, vs 0.5% with 100 mg sitagliptin at 56 weeks (both p<0.0001), as add-on to metformin and/or thiazolidinediones. In addition, from a mean baseline body weight of 89.5 kg, adults with type 2 diabetes achieved statistically significantly greater reductions in mean body weight when treated with 0.5 mg and 1.0 mg semaglutide vs sitagliptin (4.3 kg and 6.1 kg vs 1.9 kg; both p<0.0001).

In September 2015, the SUSTAIN 3 trial with 813 adults with type 2 diabetes and a mean baseline HbA_{1c} of 8.3% achieved a statistically significantly greater HbA_{1c} reduction of 1.5% when treated with 1.0 mg semaglutide vs 0.9% with 2.0 mg exenatide extended-release (ER) (p<0.0001), as add-on to one or two oral antidiabetics (metformin, sulfonylurea or thiazolidinediones). Furthermore, from a mean baseline body weight of 95.8 kg, adults with type 2 diabetes achieved statistically significantly greater reductions in mean body weight when treated with 1.0 mg semaglutide vs exenatide ER in SUSTAIN 3 (5.6 kg vs 1.9 kg; p<0.0001).

In November 2015, the SUSTAIN 4 trial showed that from a mean baseline HbA_{1c} of 8.2%, 1,089 adults with type 2 diabetes receiving metformin with or without sulfonylurea, achieved statistically significantly greater improvements in HbA_{1c} reductions of 1.2% and 1.6% when treated with 0.5 mg and 1.0 mg semaglutide, respectively, vs a 0.8% reduction with insulin glargine U100 (p<0.0001 for both). End of trial mean dose of insulin glargine U100 was 29 IU/day. Additionally, from a mean baseline body weight of 93.4 kg, adults treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significantly greater reductions in mean body weight of 3.5 kg and 5.2 kg compared to an increase of 1.2 kg with insulin glargine U100 (p<0.0001 for both).

In February 2016, the SUSTAIN 5 trial showed that, from a mean baseline HbA_{1c} of 8.4%, 397 adults treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significantly greater HbA_{1c} reductions of 1.4% and 1.8%, respectively, vs 0.1% reduction with placebo, when added on to basal insulin with or without metformin. In addition, adults with type 2 diabetes treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significantly greater weight loss vs placebo (3.7 kg and 6.4 kg vs 1.4 kg) from a mean baseline body weight of 91.7 kg.

In April 2016, in the SUSTAIN 6 trial, once-weekly semaglutide statistically significantly reduced the risk of major adverse cardiovascular events (MACE), defined as the composite endpoint of time to first occurrence of either cardiovascular (CV) death, non- fatal myocardial infarction or non-fatal stroke, by 26% vs placebo, when added to standard of care in 3,297 adults with type 2 diabetes at high CV risk.

In March 2016, the SUSTAIN Japan Monotherapy trial showed that, from a mean baseline HbA_{1c} of 8.1%, 308 adults with type 2 diabetes treated once-weekly with 0.5 mg and 1.0 mg semaglutide achieved statistically significantly greater HbA_{1c} reductions of 1.9% and 2.2%, respectively, vs 0.7% with 100 mg sitagliptin at 30 weeks, both as monotherapy. Additionally, from a mean baseline body weight of 69.3 kg, adults treated with 0.5 mg and 1.0 mg semaglutide achieved statistically significantly greater weight loss of 2.2 kg and 3.9 kg, respectively, compared with no change in body weight with sitagliptin.

In May 2016, the SUSTAIN Japan OAD combination trial showed that, from a mean baseline HbA_{1c} of 8.1%, 595 adults with type 2 diabetes treated once-weekly with 0.5 mg and 1.0 mg semaglutide, as monotherapy or in combination with one OAD treatment, achieved statistically significantly greater HbA_{1c} reductions of 1.7% and 2.0%, respectively, vs 0.7% with OAD therapy at 56 weeks. In addition, from a mean baseline weight of 71.5 kg, adults treated with 0.5 mg and 1.0mg semaglutide achieved statistically significant weight loss of 1.4 kg and 3.2 kg, respectively, compared with a weight gain of 0.4 kg with OAD therapy.

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 42,600 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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CVR no:

24 25 67 90

Company announcement No 86 / 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: December 5, 2016

Lars Rebien Sørensen,

Chief Executive Officer