NOVO NORDISK A S
Form 6-K
February 04, 2013

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 19, 2012

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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-_____

The final phase 3a trial for IDegLira completed, and FIAsp approved for phase 3 development

Bagsværd, Denmark, 19 December 2012 - Novo Nordisk today announced the completion of the phase 3a programme for IDegLira, a fixed-ratio combination of insulin degludec (Tresiba®), a once-daily new-generation basal insulin analogue, with an ultra-long duration of action, and liraglutide (Victoza®), the once-daily human GLP-1 analogue, as well as the decision to initiate phase 3 development for FIAsp, a faster-acting formulation of insulin aspart (NovoRapid®).

Furthermore, within the biopharmaceutical therapy area it has been decided to discontinue further development of anti-NKG2D as a treatment for Crohn's disease.

Phase 3a completed for IDegLira (NN9068)

DUAL™ II, the second and final phase 3a trial with IDegLira for the treatment of patients with type 2 diabetes, has been completed.

In DUAL™ II, around 400 patients with type 2 diabetes, previously inadequately controlled on basal insulin in combination with 1–2 oral anti-diabetic agents, were randomised to 26 weeks of double-blinded treatment with either IDegLira or Tresiba®, in addition to metformin. In agreement with regulatory requirements, the maximum dose of Tresiba® in the trial was fixed in both treatment arms, to investigate the additional impact of the liraglutide component of the IDegLira product on glucose control.

After 26 weeks, patients randomised to Tresiba® arm, with a fixed maximum dose, obtained blood glucose control as expected from the findings in the phase 3a programme BEGIN™, while

patients randomised to IDegLira experienced a reduction in HbA_{1c} of 1.9% from baseline. The difference in HbA_{1c} reduction between the treatment groups was statistically significant, and the trial thus met its primary endpoint of achieving superiority compared to stand-alone therapy with Tresiba®.

Starting from a baseline HbA1c of 8.7%, approximately 60% of patients using IDegLira achieved the HbA1c treatment target of 7% recommended by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), and

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45% reached HbA_{1c} target of 6.5% as recommended by the American Academy of Clinical Endocrinology (AACE).

The rate of overall hypoglycaemia was low in both treatment arms and comparable to what has been observed in previous studies. Furthermore, patients treated with IDegLira experienced a weight loss of approximately 2.5 kg.

The previously reported safety and tolerability profiles of IDegLira and Tresiba® were confirmed and no apparent differences between the treatment groups were observed with respect to adverse events and standard safety parameters.

Together with the results from DUAL™ I, for which headline data were announced in August 2012, DUAL™ II reconfirms the competitive profiles of Tresiba® and Victoza®, and the trials show that patients can realise benefits from each of the components in the combination product. Pending marketing authorisations of Tresiba®, Novo Nordisk is planning regulatory filing for IDegLira in the EU and in US during 2013.

FIAsp approved for phase 3 development (NN1218)

The phase 1 proof–of-concept trials for FIAsp have now been completed. In these, the pharmacokinetic and pharmacodynamic properties of insulin aspart in a number of different formulations have been analysed in people with type 1 and type 2 diabetes, in order to identify the formulation with the most attractive profile with regard to speed of onset of appearance, as well as stability. The new formulation of insulin aspart selected for phase 3 development has a faster onset of appearance than NovoRapid® (NovoLog® in the US) and thereby mimics the endogenous insulin secretory response in a non-diabetic individual more closely. This potentially enables more flexible insulin administration in connection with meals, as well as improved post-prandial glucose control.

In the proof of concept trials, no apparent differences between NovoRapid® and the new formulations of insulin aspart were observed with respect to adverse events and standard safety parameters.

Novo Nordisk expects to initiate the phase 3 programme, onset®, expected to include around 3,000 people with type 1 or type 2 diabetes, towards the end of 2013.

Phase 2a trial with anti-NKG2D (NN8555) discontinued in patients with Crohn's Disease

Novo Nordisk has decided to discontinue further development of anti-NKG2D as a treatment for Crohn's disease following an interim futility analysis of an ongoing double-blinded, randomised, placebo-controlled phase 2a trial.

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The analysis performed on the basis of 74 randomised patients did not meet the pre-specified criteria for effect, and the study has therefore been discontinued.

No safety concerns were identified in the trial.

Novo Nordisk is a global healthcare company with 89 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 33,900 employees in 75 countries, and markets its products in more than 190 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

Further information

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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.

Date: December 19, 2012

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer