NOVO NORDISK A S
Form 6-K
May 25, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

_____

FORM 6-K

_____

REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16

of the Securities Exchange Act of 1934

May 24, 2016

_____

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

(Address of principal executive offices)

_____

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-_____

IDegLira receives positive 16-0 vote in favour of approval from FDA Advisory Committee

Bagsværd, Denmark, 24 May 2016 - Novo Nordisk today announced that the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the US Food and Drug Administration (FDA) voted 16-0, recommending the approval of IDegLira for the treatment of adults with type 2 diabetes. IDegLira is a once-daily, single injection fixed combination of insulin degludec (Tresiba®) and liraglutide (Victoza®) for the treatment of adults with type 2 diabetes.

Based on the data contained in the New Drug Application (NDA) for IDegLira, the FDA asked the panel members to discuss whether Novo Nordisk has provided adequate evidence to establish the efficacy and safety profile of IDegLira for the treatment of adults with type 2 diabetes.

The recommendation for approval was based on data from clinical trials of IDegLira, including the DUAL phase 3 clinical trial programme, which involved more than 3,000 adults with type 2 diabetes. In addition to the DUAL

clinical trial programme, both insulin degludec and liraglutide have been studied extensively in separate clinical trial programmes and the products are commercially available across the globe.

"The unanimous recommendation from the Advisory Committee marks an important step towards making IDegLira available to adults with type 2 diabetes in the US. We look forward to working with the FDA as they complete their review of IDegLira," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

The NDA for IDegLira was submitted to the FDA in September 2015 under the FDA's Prescription Drug User Fee Act V (PDUFA V) regulation. In Europe, IDegLira was approved in September 2014 and is marketed under the brand name Xultophy®.

About advisory committee meetings

FDA advisory committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing new drug applications. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer new drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.

About IDegLira

IDegLira is a once-daily, single injection fixed combination product consisting of insulin degludec (Tresiba®), a once-daily new-generation basal insulin analogue, and liraglutide (Victoza®), a once-daily GLP-1 analogue.

For further information

Media:
Mike Rulis +45 3079 3573 mike@novonordisk.com
Ken Inchausti (US) +1 609 786 8316 kiau@novonordisk.com

Investors:
Peter Hugreffe Ankersen +45 3075 9085 phak@novonordisk.com
Melanie Raouzeos +45 3075 3479 mrz@novonordisk.com
Kasper Veje (US) +1 609 235 8567 kpvj@novonordisk.com

Company announcement No 42 / 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: May 24, 2016

Lars Rebien Sørensen,

Chief Executive Officer