

company announcement

Novo Nordisk has decided to resubmit the New Drug Applications of Tresiba® and Ryzodeg® in the US

Bagsværd, Denmark, 26 March 2015 – Novo Nordisk today announced that the company has decided to submit the prespecified interim analysis of DEVOTE as part of a Class II Resubmission of the New Drug Applications (NDAs) of Tresiba® and Ryzodeg® to the US Food and Drug Administration (FDA). The resubmission is expected to take place within the next month.

The cardiovascular outcomes trial for Tresiba® (insulin degludec), DEVOTE, was initiated in October 2013 and the required number of major adverse cardiovascular events (MACE) for the prespecified interim analysis were accumulated by the end of January 2015.

The result of an interim analysis carries a higher level of uncertainty than the final study results as this preliminary estimate is built on a substantially lower number of observations. Accordingly, the relative risk estimate that has been derived from the interim analysis is thus only an indication of the final trial results.

In addition to the data from the interim analysis of DEVOTE, the Class II Resubmission will comprise a safety update including data from all clinical trials with insulin degludec as well as an overview of postmarketing data.

Following the submission of the Class II Resubmission, the FDA is expected to communicate either its acceptance of the filing or issue an 'Incomplete Response Letter'. This usually occurs within a month of resubmission.

To preserve the integrity of the ongoing DEVOTE trial, only a small team within Novo Nordisk has access to the data. Novo Nordisk management does not have access to the results of the interim analysis. The trial is expected to be completed in the second half of 2016.

Novo Nordisk is a global healthcare company with more than 90 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 41,500 employees 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](#)

For further information

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