

# Company Announcement

19 October 2012

## Tresiba® (insulin degludec) and Ryzodeg® (insulin degludec/insulin aspart) receive positive opinions from the European regulatory authorities

Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) adopted positive opinions, recommending marketing authorisations, for Tresiba® and Ryzodeg® for the treatment of diabetes mellitus in adults.

Tresiba®, the intended brand name for insulin degludec, is a new generation of once-daily basal insulin. In 'treat-to-target' studies supporting the new drug application, where Tresiba® was compared to insulin glargine, Tresiba® demonstrated a significantly lower risk of overall and nocturnal hypoglycaemia, while successfully achieving equivalent reductions in HbA<sub>1c</sub>. Further, with a duration of action beyond 42 hours, Tresiba® is the first basal insulin to offer patients the possibility of adjusting the time of injection, when needed.

Ryzodeg®, the intended brand name for insulin degludec/insulin aspart, contains the new-generation once-daily basal insulin degludec in a soluble formulation with insulin aspart. Ryzodeg® can be administered once or twice daily with the main meal(s). In 'treat-to-target' studies supporting the new drug application, where Ryzodeg® was compared to NovoMix®, Ryzodeg® demonstrated a significantly lower risk of overall and nocturnal hypoglycaemia while successfully achieving equivalent reductions in HbA<sub>1c</sub>.

In Europe, Tresiba® and Ryzodeg® will be available in FlexTouch®, Novo Nordisk's latest prefilled insulin pen, which has an easy auto-injector mechanism. Tresiba® will be offered in two concentrations enabling maximum doses of 80 and 160 units per injection, respectively.

"We are very happy about the positive opinions from the CHMP. This gives us confidence, that we soon can make Tresiba<sup>®</sup> and Ryzodeg<sup>®</sup> available to many people with diabetes in Europe," said Mads Krosgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Novo Nordisk expects to receive final marketing authorisation from the European Commission within approximately two months. Subject to the Commission's approval and completion of pricing and reimbursement discussions, Novo Nordisk expects to launch Tresiba<sup>®</sup> in a number of European markets in the beginning of 2013. Ryzodeg<sup>®</sup> is currently expected to be launched approximately one year after Tresiba<sup>®</sup>, in the respective markets.

### **About Tresiba<sup>®</sup> and Ryzodeg<sup>®</sup>**

**Tresiba<sup>®</sup>** is the intended brand name for insulin degludec, which is a once-daily new-generation basal insulin analogue, with an ultra-long-acting duration of action, discovered and developed by Novo Nordisk. Tresiba<sup>®</sup> has a distinct slow absorption which provides a flat and stable action profile. Tresiba<sup>®</sup> has been studied in a large-scale clinical trial programme, BEGIN<sup>™</sup>, examining its impact on glucose control, hypoglycaemia and the possibility to flexibly adjust Tresiba<sup>®</sup> dosing time to suit patient needs.

**Ryzodeg<sup>®</sup>** is the intended brand name for insulin degludec/insulin aspart, which contains the new-generation basal insulin degludec in a formulation with a bolus boost of insulin aspart. Ryzodeg<sup>®</sup> is the first and only soluble insulin combination of ultra-long-acting insulin degludec and the most prescribed rapid-acting insulin, NovoRapid<sup>®</sup> (NovoLog<sup>®</sup> in the US), providing both fasting and post-prandial glucose control.

Tresiba<sup>®</sup> and Ryzodeg<sup>®</sup> were submitted to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in September 2011 for regulatory review. In addition, applications have been submitted for regulatory approval in Japan, Canada, Switzerland and a range of other countries. Tresiba<sup>®</sup> was approved in Japan in September this year.

*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 33,300 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](http://novonordisk.com).*

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