Ryzodeg® (insulin degludec/insulin aspart) approved in Japan

Bagsværd, Denmark, 25 December 2012 – Novo Nordisk today announced that the Japanese Ministry of Health, Labour and Welfare has approved Ryzodeg® (insulin degludec/insulin aspart) for the treatment of diabetes.

Ryzodeg® is a soluble formulation of Tresiba® (insulin degludec), a once-daily new-generation basal insulin analogue with an ultra-long duration of action, and NovoRapid® (insulin aspart which in the US is marketed under the brand name NovoLog®). Ryzodeg® can be administered once or twice daily with the main meal(s). In global ‘treat-to-target’ studies supporting the new drug application, where Ryzodeg® was compared to NovoMix®, Ryzodeg® demonstrated a significantly lower risk of nocturnal hypoglycaemia while successfully achieving equivalent reductions in HbA1c.

In Japan, Ryzodeg® will be available in FlexTouch®, Novo Nordisk’s latest prefilled insulin pen, which has an easy auto-injector mechanism, and in Penfill® for Novo Nordisk’s durable insulin pens.

“We are excited about the approval of Ryzodeg®”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “The unique properties of Ryzodeg® provide the potential to improve treatment for people with diabetes in Japan”.

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

Ryzodeg®, the global brand name for insulin degludec/insulin aspart contains Tresiba®, a once-daily new-generation basal insulin analogue in a formulation with a bolus boost of NovoRapid®. Ryzodeg® is the first and only soluble insulin combination of Tresiba® and
the most prescribed rapid-acting insulin, NovoRapid® (NovoLog® in the US), providing both fasting and post-prandial glucose control.

Tresiba® and Ryzodeg® were submitted for regulatory approval to the Japanese Ministry of Health, Labour and Welfare in December 2011 and March 2012, respectively. Tresiba® was approved in Japan in September 2012. In October 2012, Tresiba® and Ryzodeg® received positive CHMP opinions in the EU. In November, the products received a positive vote for approval from an FDA Advisory Committee. In addition, applications have been submitted for regulatory approval in Canada, Switzerland and a range of other countries.

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.

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