Company Announcement

28 September 2012

Tresiba® (insulin degludec) approved in Japan

Novo Nordisk today announced that the Japanese Ministry of Health, Labour and Welfare has approved Tresiba® (insulin degludec) for the treatment of diabetes.

Tresiba® is a new generation of once-daily basal insulin, which has been discovered and developed by Novo Nordisk. In Japanese studies, the duration of action for Tresiba® has been tested up to 26 hours, whereas global studies have shown a duration of action lasting beyond 42 hours.

The global clinical programme supporting the new drug application for Tresiba® involved close to 10,000 people with type 1 or type 2 diabetes. In the 'treat-to-target' studies, where Tresiba® was compared to insulin glargine, Tresiba® successfully achieved equivalent reductions in HbA_{1c} and was associated with significantly lower risk of nocturnal hypoglycaemia.

In Japan, Tresiba® 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 this first approval of Tresiba®, which will soon be available to patients in Japan", said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "Tresiba® can help patients achieve good glycaemic control with a lower risk of hypoglycaemia, especially during night time".

Novo Nordisk expects to launch Tresiba® in Japan as soon as price negotiations have been completed.

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About Tresiba®

Tresiba® is the intended global brand name for insulin degludec, the first once-daily basal insulin with an ultra-long duration of action, 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.

Tresiba® was submitted for regulatory approval to the Japanese Ministry of Health, Labour and Welfare (MHLW) in December 2011 and to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in September 2011. In addition, applications have been submitted for regulatory approval in 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 33,300 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.

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