

Company Announcement

31 August 2012

Insulin degludec passed the review by the First Committee on Drugs of Pharmaceutical Affairs in Japan

Novo Nordisk today announced that insulin degludec has passed the review by the First Committee on Drugs of Japan's Pharmaceutical Affairs. The remaining step in the regulatory process will now be an official approval from the Ministry of Health, Labour and Welfare (MHLW).

The First Committee on Drugs of Pharmaceutical Affairs serves as an advisory body to the MHLW, related to pharmaceuticals including new drug applications. The passing of the review by the drug committee is a critical milestone in the Japanese review process prior to a marketing authorisation from the MHLW.

"We are very excited about the result of the review of insulin degludec," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "This is a significant milestone towards what may be the first approval of insulin degludec, an insulin with potential to fulfil unmet medical needs for millions of people with diabetes who require insulin."

Novo Nordisk expects to receive marketing authorisation from the MHLW within a few months and that insulin degludec will be launched shortly after completion of the subsequent price negotiations.

About insulin degludec

Insulin degludec is a once-daily, ultra-long-acting basal insulin analogue discovered and developed by Novo Nordisk. Insulin degludec has a distinct slow absorption which provides a flat and stable action profile. Insulin degludec has been studied in a large-scale clinical trial programme, BEGIN™, examining its impact on glucose control, hypoglycaemia and the possibility to flexibly adjust insulin degludec dosing time to suit patient needs.

Insulin degludec 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 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 33,300 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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