Press Release

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Investigational insulin degludec shows 43% lower rates of night-time hypoglycaemia than insulin glargine in a 2-year study investigating 1,030 people with type 2 diabetes who had not previously used insulin

Berlin, Germany – New data presented today at the Annual Meeting of the European Association for the Study of Diabetes (EASD) show that patients with type 2 diabetes starting insulin therapy had a 43% lower rate of night-time hypoglycaemia* when using insulin degludec compared with those using insulin glargine (0.27 [insulin degludec] versus 0.46 [insulin glargine] episodes per patient per year, p<0.001) with equivalent improvements in glucose control**[1].

In this 2-year (1 year initial and 1 year extension) phase 3a study, comparing the efficacy and safety of once-daily insulin degludec versus once-daily insulin glargine (both in combination with OADs), the rates of overall hypoglycaemia were similar between the two groups (1.72 [insulin degludec] versus 2.05 [insulin glargine] episodes per patient per year, p=NS). Furthermore, while the rates of severe hypoglycaemia were infrequent, they were significantly lower with insulin degludec compared with insulin glargine (0.01 [insulin degludec] versus 0.02 [insulin glargine] episodes per patient per year, p=0.02). This randomised, open-label, treat-to-target study included 1,030 patients with type 2 diabetes not previously treated with insulin, of which 659 completed 2 years of treatment[1].

"Hypoglycaemia, and particularly night-time hypoglycaemia, is a major concern for people living with diabetes and the principal limiting factor to effective glucose control, thereby increasing their risk of long-term complications", said Dr Helena Rodbard, lead author and medical director, Endocrine and Metabolic Consultants, Rockville, Maryland. "The reduction in rates of nocturnal hypoglycaemia with insulin degludec will hopefully allay some of this concern and encourage patients and physicians to aim for more ambitious glucose targets".

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Lower rates of night-time hypoglycaemia with insulin degludec versus insulin glargine confirmed in a meta-analysis of phase 3a trials, also presented at EASD

In a separate, prospectively planned meta-analysis also presented at EASD, patient level data from 4,330 patients in seven randomized, open-label, treat-to-target phase 3a trials of 26 or 52 weeks showed that insulin degludec significantly reduced the rate of night-time hypoglycaemia in adults with type 1 and type 2 diabetes, while obtaining equivalent improvements in glucose control, when compared with insulin glargine[2].

Patients with type 2 diabetes who had not previously been treated with insulin showed the greatest reductions in night-time hypoglycaemia when using insulin degludec compared with insulin glargine:

- 36% ($p<0.05$) reduction in night-time hypoglycaemia with insulin degludec compared with insulin glargine (0.3, 0.2 and 0.8 episodes per patient per year with IDeg versus 0.4, 0.3 and 1.2 episodes per patient per year with IGlar for the trials 3579, 3672 and 3586 respectively) [2].
- 17% ($p<0.05$) reduction in overall hypoglycaemia with insulin degludec compared with insulin glargine (1.5, 1.2 and 3.0 episodes per patient per year with IDeg versus 1.8, 1.4 and 3.7 episodes per patient per year with IGlar for the trials 3579, 3672 and 3586 respectively) [2].
- 86% ($p<0.05$) reduction in the rates of severe hypoglycaemia with insulin degludec compared with insulin glargine (0.003, 0 and 0 episodes per patient per year with IDeg versus 0.02, 0 and 0.01 episodes per patient per year with IGlar for the trials 3579, 3672 and 3586 respectively)[2].

*Classified as low blood sugar occurring between 00:01 – 05:59 inclusive.
**Regulatory authorities require that studies of glucose-lowering agents be designed as treat-to-target trials. The use of treat-to-target trials, to treat the test and comparator groups to similar glucose goals, allows for comparison in frequency and severity of hypoglycaemia to inform risk-benefit assessments[3].

About insulin degludec
Insulin degludec is a basal insulin analogue discovered and developed by Novo Nordisk. Insulin degludec has an ultra-long duration of action that extends beyond 42 hours with a flat and stable profile[4,5]. Once-daily 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 the insulin degludec dosing time to suit patient needs. Insulin degludec has been submitted for once-daily use to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in September 2011 for regulatory review. In addition, insulin degludec has been submitted for regulatory approval in a range of other countries. On 28 September 2012 insulin degludec was approved in Japan. Novo Nordisk expects to launch insulin degludec in Japan as soon as price negotiations have been successfully completed. At present, insulin degludec does not have marketing authorisation in other countries.

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Headquartered in Denmark, 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. For more information, visit novonordisk.com.

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References

[1] Rodbard HW *et al*. Reduced nocturnal hypoglycaemia with insulin degludec as compared to insulin glargine: results of a 2-year randomised trial in type 2 diabetes. Poster presented at the European Association of the Study of Diabetes (EASD) 48th Annual meeting, October 2012.

[2] Gough SCL *et al*. Prospectively planned meta-analysis comparing hypoglycaemia rates of insulin degludec with those of insulin glargine in all patients and an elderly (≥65 year) subgroup. Poster presented at the European Association of the Study of Diabetes (EASD) 48th Annual meeting, October 2012.

[3] U.S. Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research (CDER), February 2008: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071624.pdf, *(Draft guidance, publication in progress).* Accessed 22 August 2012

[4] Heise T *et al*. Insulin degludec: two-fold longer half-life and a more consistent pharmacokinetic profile compared to insulin glargine. IDF 2011 21th World Congress Abstract Book. IDF: Dubai, 2011; p 471 (Poster P-1444).

[5] Nosek L *et al*. Ultra-long-acting insulin degludec has a flat and stable glucose-lowering effect. IDF 2011 21th World Congress Abstract Book. IDF: Dubai, 2011; p 474 (Poster P-1452).

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