New data show long-term efficacy and safety of Tresiba®
in children and adolescents with type 1 diabetes

Vienna, Austria, 16 September - Today, at the 50th Annual Meeting of the European Association for the Study of Diabetes (EASD), Novo Nordisk announced new data from the BEGIN® YOUNG 1 trial. The study investigates once-daily Tresiba® (insulin degludec) versus insulin detemir, both in combination with bolus insulin aspart in a 52-week trial in children and adolescents with type 1 diabetes. This trial is the first to look into the long-term safety of Tresiba® in children and adolescents (from age 1 to less than 18 years). The results show that Tresiba® in combination with insulin aspart effectively improved long-term glycaemic control¹.

"When treating children and adolescents with type 1 diabetes, it is critical that the right balance between glycaemic control and side effect management is maintained to ensure the best possible long-term outcomes. These data show that Tresiba® has the potential to offer youngsters with diabetes a new treatment option, which may help them achieve better control of their diabetes," said Dr Nandu Thalange, paediatric endocrinologist at Norfolk and Norwich University Hospital, Norwich, United Kingdom.

The BEGIN® YOUNG 1 trial was a randomised controlled, 26 week open-label, treat-to-target trial (with a 26-week extension) investigating the efficacy and safety of Tresiba®, given once daily, and insulin detemir, given once or twice daily, both in combination with bolus insulin aspart in children and adolescents with type 1 diabetes.

Tresiba® met the primary endpoint of non-inferiority to insulin detemir for mean change in HbA1c (p<0.05) at 26 weeks. In the 26-week extension a lower insulin dose and a significantly greater reduction in fasting plasma glucose (FPG*) versus insulin detemir (p<0.05) was achieved¹. Both regimens had similar rates of overall and nocturnal hypoglycaemia, the rate of severe hypoglycaemia was numerically higher with insulin degludec plus insulin aspart¹. Of note, patients on Tresiba® had significantly lower rates of hyperglycaemia with ketosis (p<0.05)¹. Weight (measured as SD score**) increased with Tresiba® and remained unchanged with insulin detemir¹. Adverse event profiles were similar for insulin degludec and insulin detemir¹.

---

¹ FPG measures the concentration of glucose in the plasma after the patient has not eaten for at least eight hours.

** Standard deviation (SD) measures the amount of variation from the average. A low standard deviation indicates that the data points are close to the average; a high standard deviation indicates that the data points are spread out over a large range of values.
About Tresiba®
Tresiba® (insulin degludec) is a once-daily basal insulin that provides an ultra-long duration of action beyond 42 hours\(^2\)\(^3\). It is important for people with type 1 and type 2 diabetes to establish a routine for insulin treatment. On occasions when administration at the same time of day is not possible, Tresiba® allows for flexibility in day-to-day dosing time\(^3\)\(^5\).

Tresiba® has received regulatory approval in Argentina, Aruba, Bangladesh, Bosnia & Herzegovina, Brazil, Chile, Colombia, Costa Rica, El Salvador, the EU, Honduras, Hong Kong, Iceland, Israel, India, Japan, Kazakhstan, Lichtenstein, Lebanon, Macedonia, Mexico, Nepal, Norway, South Korea, Switzerland and Russia.

About Novo Nordisk
Headquartered in Denmark, Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Novo Nordisk employs approximately 40,700 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit novonordisk.com.

Further information:

**Media**
Katrine Sperling +45 4442 6718 krsp@novonordisk.com

**Investors:**
Kasper Roseeuw Poulsen +45 3079 4303 krop@novonordisk.com
Jannick Lindegaard Denholt +45 3079 8519 jlis@novonordisk.com
Daniel Bohsen +45 3079 6376 dabo@novonordisk.com
Frank Daniel Mersebach (US) +1 609 235 8567 fdni@novonordisk.com
References


