

press release

Fiasp® is effective at controlling blood sugar levels in children and adolescents living with type 1 diabetes, when compared to conventional insulin aspart

Hyderabad, India, 12 October 2018 – For children and adolescents (1 to <18 years old) living with type 1 diabetes, Fiasp® (an ultra-fast acting formulation of insulin aspart) could be an option to better manage their blood sugar levels, when used as part of a multiple daily injection routine (also known as a basal-bolus regimen)¹.

New data presented today at the 44th Annual Conference of the International Society for Pediatric and Adolescent Diabetes (ISPAD) showed that the study population receiving Fiasp® achieved superior reductions in overall blood sugar levels (HbA_{1c}), compared to the group on conventional insulin aspart, when both treatments were dosed at mealtime (estimated treatment difference (ETD) -0.17%). In addition, significantly lower overall post-meal blood sugar levels (1-hour after the meal) were achieved with Fiasp® compared to conventional insulin aspart¹.

"Fiasp® has already helped to reduce challenges around mealtime blood sugar control for adults with diabetes, and it is exciting to see that similar benefits are achieved with children and adolescents in this trial," said Dr Bruce Bode, Diabetes Specialist with Atlanta Diabetes Associates in Atlanta, Georgia, and lead research of the study. "These findings show that Fiasp® may offer a suitable option to improve blood sugar control and better meet the needs of this specific population."

Another group of study participants, that injected Fiasp® 20 minutes after the start of the meal, achieved similar overall blood sugar levels to those taking conventional insulin aspart dosed at mealtime (non-significant ETD of 0.13% in favour of conventional insulin aspart). These results confirm the non-inferior profile of action of Fiasp® when dosed 20 minutes after the start of the meal, compared with conventional insulin aspart dosed at mealtime¹.

"It can be hard for the parents and caregivers of children with type 1 diabetes to know exactly how much or how fast their children will eat, making the dosing of mealtime insulin challenging in relation to both timing and quantity," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "These results show that Fiasp® may be able to ease some of the burden of diabetes management at mealtimes for children and adolescents, as well as those who care for

them. We hope to make this ultra-fast treatment option available to benefit this population as soon possible.”

There were no significant differences in the overall rate of severe or blood-sugar confirmed hypoglycaemic episodes, or overall rates of other adverse events such as nausea or injection site reactions, confirming the safety profile of Fiasp® in comparison to conventional insulin aspart¹.

About the study¹

The onset 7 trial (777 people randomised) was a 26-week, phase 3a, partially double-blind, basal-bolus, treat-to-target trial, evaluating the efficacy and safety of Fiasp® compared with conventional insulin aspart in children and adolescents with type 1 diabetes.

The study investigated Fiasp® dosed at mealtime (0-2 minutes before starting the meal) and 20 minutes after the start of the meal, in comparison to conventional insulin aspart dosed at mealtime (0-2 minutes before starting the meal). All treatment arms involved a multiple daily injection routine (basal-bolus) using Tresiba® (insulin degludec) as the basal insulin.

About Fiasp®

Fiasp® (fast-acting insulin aspart) is the only approved, new-generation, ultra-fast acting²⁻⁴ mealtime insulin injection. Fiasp® is insulin aspart in an innovative formulation, in which two excipients have been added: Vitamin B3 (niacinamide) to increase the speed of absorption and a naturally occurring amino acid (L-Arginine) for stability⁵. The result is a mealtime insulin that more closely mimics the natural physiological insulin response of a person without diabetes after a meal, compared with conventional insulin aspart⁵.

Fiasp® (fast-acting insulin aspart) is approved in the US, Canada, Switzerland, Australia and the EU (including Norway & Iceland), along with a number of other markets. It is also currently under regulatory review in several other countries around the world. Fiasp® is currently indicated for the treatment of adults with type 1 and type 2 diabetes only.

About Novo Nordisk

Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,100 people in 79 countries and markets its products in more than 170 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#).

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