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press release

Faster-acting insulin aspart showed a statistically significant reduction in HbA$_{1c}$ in type 1 diabetes and a comparable HbA$_{1c}$ reduction in type 2 diabetes versus NovoRapid® (insulin aspart)

Faster-acting insulin aspart improved postprandial glucose (PPG) control in type 1 and type 2 diabetes

MISSISSAUGA, ON, June 13, 2016 – New phase 3a findings showed that faster-acting insulin aspart demonstrated a statistically significant reduction in HbA$_{1c}$ in type 1 diabetes, compared with NovoRapid® (insulin aspart),[1] a comparable HbA$_{1c}$ reduction in type 2 diabetes versus NovoRapid®[2] and improved post-meal or postprandial glucose (PPG) control in type 1 and type 2 diabetes.[1,2] Results from the onset® 1 and onset® 2 treat-to-target trials comparing faster-acting insulin aspart with NovoRapid® were presented at the 76th annual Scientific Sessions of the American Diabetes Association (ADA) in New Orleans, USA.

In onset® 1, after 26 weeks of randomized therapy, faster-acting insulin aspart showed statistically significantly greater HbA$_{1c}$ reduction versus NovoRapid® in adults with type 1 diabetes when dosed at mealtime ([95% confidence interval (CI)] -0.15 [-0.23; -0.07]). Faster-acting insulin aspart also showed comparable HbA$_{1c}$ reduction when dosed 20 minutes after starting a meal, compared with NovoRapid® dosed at mealtime ([95% CI] 0.04 [-0.04; 0.12]).[1]

Trial results for onset® 1 also showed superior reduction in two-hour PPG increment* ([95% CI] -0.67 [-1.29; -0.04] mmol/L) versus NovoRapid®. The change in one-hour PPG increment*, a secondary supportive endpoint, was also reduced ([95% CI] -1.18 [-1.65; -0.71] mmol/L).[1]

In onset® 2, faster-acting insulin aspart demonstrated non-inferiority in HbA$_{1c}$ reduction compared with NovoRapid® ([95% CI] -0.02 [-0.15; 0.10]) in adults with type 2 diabetes. Trial results could not confirm a statistically significant reduction in two-hour PPG increment† ([95% CI] -0.36 [-0.81; 0.08] mmol/L). However, a statistically significant reduction in one-hour PPG increment* was shown with faster-acting insulin

* Postprandial glucose (PPG) increment is the increase in blood glucose levels after eating
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aspart ([95% CI] -0.59 [-1.09; -0.09] mmol/L)[2] which was a secondary supportive endpoint.

"For people living with type 1 and type 2 diabetes, it is often challenging to control blood glucose levels around mealtimes, resulting in post-meal hyperglycemia," said Dr. Rémi Rabasa-Lhoret, endocrinologist at the Institut de Recherches Cliniques de Montréal and onset® investigator. "The data from the onset® 1 and 2 trials are encouraging as they show some improvement in HbA_{1c} and even greater improvement in postprandial glucose control with faster-acting insulin aspart."

As with other insulin, the most commonly reported adverse event with faster-acting insulin aspart in onset® 1 and 2 was hypoglycemia. There were no significant differences in the overall rate of severe or confirmed hypoglycemia in people with type 1 and type 2 diabetes compared with NovoRapid®.[1,2]

Other common adverse events (≥5%) included nasopharyngitis, upper respiratory tract infection, urinary tract infection, headache, nausea, diarrhea, wrong drug administration and back pain.[3,4]

Also presented during the scientific meeting were additional trial results assessing the pharmacokinetic (PK) and pharmacodynamic (PD) properties of faster-acting insulin aspart versus NovoRapid®:

- Results from a pooled analysis evaluating early exposure and glucose-lowering effect of faster-acting insulin aspart versus NovoRapid® in people with type 1 diabetes (Abstract 929-P).[5]
- Results from a clinical study evaluating the early glucose-lowering effect with faster-acting insulin aspart (Abstract 969-P).[6]

About the onset® 1 and onset® 2 trials

The onset® program is a phase 3 clinical program with faster-acting insulin aspart that consists of four trials encompassing more than 2,100 people with type 1 and type 2 diabetes.

The onset® 1 trial (1,143 people randomized): a 26+26-week randomized, partially double-blind, basal-bolus, treat-to-target trial investigating faster-acting insulin aspart dosed at mealtime or 20 minutes after starting a meal compared with NovoRapid® dosed at mealtime, both in combination with a basal insulin in adults with type 1 diabetes. Only the data from the first 26 weeks were reported at the 76th annual Scientific Sessions of the ADA. The primary endpoint was change from baseline HbA_{1c} versus NovoRapid®, and a secondary endpoint was change from baseline in two-hour PPG increment* versus NovoRapid®.

The onset® 2 trial (689 people randomized): a 26-week randomized, double-blind,

* Postprandial glucose (PPG) increment is the increase in blood glucose levels after eating

basal-bolus, treat-to-target trial investigating faster-acting insulin aspart compared with NovoRapid®, both dosed at mealtime and in combination with a basal insulin and metformin in adults with type 2 diabetes. The primary endpoint was change from baseline HbA_{1c} versus NovoRapid®, and a secondary endpoint was change from baseline in two-hour PPG increment* versus NovoRapid®.

About faster-acting insulin aspart
Faster-acting insulin aspart is an investigational mealtime (bolus) insulin that is not approved for use in Canada. It was developed by Novo Nordisk for improved blood glucose control in adults with type 1 and type 2 diabetes. Faster-acting insulin aspart is insulin aspart (NovoRapid®) in a new formulation in which two excipients have been added, a vitamin and an amino acid, to increase the initial absorption rate and foster an earlier blood glucose lowering effect.

About NovoRapid® (insulin aspart)
NovoRapid® is a man-made insulin used to control high blood sugar in adults and children with diabetes mellitus.

About Novo Nordisk Canada
Novo Nordisk Canada is an affiliate of Novo Nordisk A/S, a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: hemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 40,300 employees in 75 countries, and markets its products in more than 180 countries.

Novo Nordisk's company history has deep Canadian roots, with company founders Marie and August Krogh traveling to Toronto in 1922 to meet with Banting, Best, Collip and MacLeod to discuss the insulin preparation. Novo Nordisk would become the first company in Europe to produce insulin in 1923.

Further information

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