

press release

Investigational, once-weekly insulin icodec showed comparable efficacy and safety to once-daily insulin glargine U100 in phase 2 trial

Bagsværd, Denmark, 15 June 2020 – Today, Novo Nordisk announced results from a phase 2 clinical trial of investigational insulin icodec, a once-weekly basal insulin analogue. In the trial, adults with type 2 diabetes randomised to once-weekly insulin icodec achieved similar blood sugar control and a similar safety profile compared with adults with type 2 diabetes randomised to once-daily insulin glargine U100. Results were presented during the 80th Scientific Sessions of the American Diabetes Association.¹

This 26-week, randomised, double-blind, double-dummy, treat-to-target phase 2 clinical trial involved 247 insulin-naïve adults with type 2 diabetes inadequately controlled with metformin with or without a DPP-4i. The primary endpoint showed that the change from baseline to week 26 in blood sugar control (HbA_{1c}) was similar in participants receiving once-weekly insulin icodec compared to once-daily insulin glargine U100 (-1.33% vs -1.15% points, respectively, $p=0.08$).¹ Secondary endpoints included change in fasting plasma glucose (FPG) from baseline to week 26, which was similar for insulin icodec and insulin glargine U100 (-58mg/dL and -54mg/dL respectively), and the change from baseline to week 26 of the mean of the nine-point self-monitoring of blood glucose (SMBG) profile, which was greater for icodec (-7.9 mg/dL; $p=0.01$).¹

“Many people with type 2 diabetes are reluctant to start on insulin therapy due to the need for daily injections,” said Dr Julio Rosenstock, lead trial investigator and clinical professor of medicine, University of Texas Southwestern Medical Center, US. “I’m truly excited about the potential of such innovative treatments which could reduce the number of basal insulin injections for my patients with diabetes.”

Hypoglycaemia, also known as a hypo or low blood sugar, was similar for both treatment groups (observed rates of level 2 [<54 mg/dL] and 3 [severe] hypoglycaemia were 52.5 and 45.6 events per 100 patient years of exposure for insulin icodec and insulin glargine U100 respectively).¹ No new safety issues were identified in relation to once-weekly insulin

icodec in this trial. The proportion of patients that had an adverse event was similar between the insulin icodec and glargine U100 arms.¹

“Novo Nordisk has been at the forefront of insulin innovation for almost 100 years, and we continuously conduct disruptive research that can lead to fundamentally more convenient and improved treatments with the potential to change the lives of people with diabetes,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “This phase 2 trial showed that once-weekly insulin icodec was comparable to insulin glargine U100 in terms of efficacy and safety, it could provide people with type 2 diabetes with a new option that, among other things, would reduce the number of basal insulin injections to one a week.”

Novo Nordisk expects to initiate the phase 3 clinical development programme for once-weekly insulin icodec later in 2020.

For more news and media materials from Novo Nordisk at ADA 2020, please visit www.epresspack.net/novonordiskADA2020

About the phase 2 trial

This 26-week, randomised, double-blind, double-dummy, treat-to-target phase 2 clinical trial of once-weekly insulin icodec compared with once-daily insulin glargine U100* involved 247 insulin-naïve adults with type 2 diabetes inadequately controlled with metformin ± a DPP-4i. The primary endpoint was change in HbA_{1c} from baseline to Week 26. Secondary endpoints included change in fasting plasma glucose from baseline to Week 26 and hypoglycaemic episodes. This phase 2 trial was conducted in the US, Canada, Czech Republic, Greece, Poland, Slovakia and Slovenia.

About insulin icodec

Insulin icodec is an investigational, long-acting basal insulin analogue with a half-life of 196 hours.² Once injected, insulin icodec binds strongly but reversibly to albumin. This results in a continuous, slow and steady reduction of blood sugar over the week. The injection volume of once-weekly insulin icodec is equivalent to daily insulin glargine U100 due to the concentrated formulation.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 43,100 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#).

Further information

Media:

Mette Kruse Danielsen +45 4442 3883 mkd@novonordisk.com

Investors:

Daniel Muusmann Bohsen +45 3075 2175 dabo@novonordisk.com

Valdemar Borum Svarrer +45 3079 0301 jvls@novonordisk.com

Ann Søndermølle Rendbæk +45 3075 2253 arnd@novonordisk.com

Mark Joseph Root +45 3079 4211 mjhr@novonordisk.com

*NCT03751657: A Research Study to Compare Insulin 287 Once a Week to Insulin Glargine (100 Units/mL) Once a Day in People With Type 2 Diabetes.

References

1. Rosenstock J, Kjærsgaard MIS, Møller DV, *et al.* Once-Weekly Basal Insulin Icodec Offers Comparable Efficacy and Safety vs Once-Daily Insulin Glargine U100 in Insulin Naïve Patients with T2D Inadequately Controlled on OADs. Abstract 238-OR. Presented at the 80th Scientific Sessions of the Virtual American Diabetes Association Annual Meeting, Insulin Therapies, 18:15 CDT on 14 June 2020.
2. Hövelmann U, Brøndsted L, Kristensen NR. *et al.* Insulin Icodec: An Insulin Analog Suited for Once-Weekly Dosing in Type 2 Diabetes. Abstract 237-OR. Presented at the 80th Scientific Sessions of the American Diabetes Association, Insulin Therapies, 18:00 CDT on 14 June 2020.