

# company announcement

## Once-weekly insulin icodec demonstrates superior reduction in HbA<sub>1c</sub> vs insulin degludec in people with type 2 diabetes in ONWARDS 2 phase 3a trial

**Bagsværd, Denmark, 28 April 2022** – Novo Nordisk today announced headline results from the ONWARDS 2 trial, a phase 3a, 26-week efficacy and safety treat-to-target trial investigating once-weekly insulin icodec vs insulin degludec in 526 people with type 2 diabetes switching from daily insulin.

The trial achieved its primary endpoint of demonstrating non-inferiority in reducing HbA<sub>1c</sub> at week 26 with insulin icodec compared to insulin degludec.

From an overall baseline HbA<sub>1c</sub> of 8.13%, once-weekly insulin icodec achieved a superior reduction in estimated HbA<sub>1c</sub> of 0.93% compared to 0.71% for insulin degludec (estimated treatment difference: -0.22%).

In the trial, there was no statistical difference in estimated hypoglycaemia rates, and no severe hypoglycaemia events were observed for people treated with insulin icodec. The rates of severe or clinically significant hypoglycaemia (blood glucose below 3 mmol/L) were 0.73 events per patient year exposed to once-weekly insulin icodec and 0.27 events per patient-year exposed to insulin degludec. In the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile.

“We are very pleased with the results seen in ONWARDS 2, and once-weekly insulin icodec is the first insulin to demonstrate the ability to reduce the number of yearly basal insulin injections from 365 to 52 in a phase 3 trial”, says Martin Holst Lange, executive vice president for Development at Novo Nordisk. “Novo Nordisk has for 100 years been committed to develop insulin treatment to improve glycaemic outcome and reduce the disease burden for people living with diabetes and we are excited to share additional results of the ONWARDS programme later this year.”

## About the ONWARDS clinical programme

The ONWARDS clinical development programme for once-weekly insulin icodec currently comprises six phase 3a global clinical trials, including a trial with real-world elements, involving more than 4,000 adults with type 1 or type 2 diabetes.

ONWARDS 1 is a 78-week trial comparing the efficacy and safety of once-weekly insulin icodec with once-daily insulin glargine U100 both in combination with non-insulin anti-diabetic treatment in 984 insulin-naïve people with type 2 diabetes.

ONWARDS 3 is a 26-week trial comparing once-weekly insulin icodec with once-daily insulin degludec. The objective of the trial is to assess the efficacy and safety of insulin icodec in 588 insulin-naïve people with type 2 diabetes.

ONWARDS 4 is a 26-week trial comparing once-weekly insulin icodec with once-daily insulin degludec, both in combination with mealtime insulin. The objective of the trial is to assess the efficacy and safety of insulin icodec in 582 people with type 2 diabetes treated with basal and bolus insulin.

ONWARDS 5 is a 52-week trial comparing once-weekly insulin icodec with once-daily basal insulin. The objective of the trial is to assess the effectiveness and safety of insulin icodec, with an app providing dosing recommendation, in 1085 insulin-naïve people with type 2 diabetes in a clinical practice setting.

ONWARDS 6 is a 52-week trial comparing once-weekly insulin icodec with once-daily insulin degludec, both in combination with mealtime insulin. The objective of the trial is to assess the efficacy and safety of insulin icodec in 583 people with type 1 diabetes.

## 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 47,800 people in 80 countries and markets its products in around 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit [novonordisk.com](https://www.novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#)*

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