

company announcement

Once-weekly insulin icodec demonstrates superior reduction in HbA_{1c} in combination with a dosing guide app versus once-daily basal insulin in people with type 2 diabetes in ONWARDS 5 phase 3a trial

Bagsværd, Denmark, 3 October 2022 – Novo Nordisk today announced headline results from the ONWARDS 5 phase 3a trial with once-weekly insulin icodec in people with type 2 diabetes.

The ONWARDS 5 trial was a 52-week, open-label efficacy and safety treat-to-target trial investigating once-weekly insulin versus once-daily basal insulin (insulin degludec or insulin glargine U100/U300) in 1,085 insulin-naïve people with type 2 diabetes in a clinical practice setting including fewer trial visits compared to the other ONWARDS phase 3a trials. Once-weekly insulin icodec was used in combination with a dosing guide app to guide titration.

The trial achieved its primary endpoint of demonstrating non-inferiority in reducing HbA_{1c} at week 52 with insulin icodec compared with once-daily basal insulin analogues. From an overall baseline HbA_{1c} of 8.9%, once-weekly insulin icodec achieved a superior reduction in estimated HbA_{1c} of -1.68%-points compared with -1.31%-points for the once-daily basal insulins (estimated treatment difference: -0.38%-points).

In the trial, there was no statistically significant difference in estimated rates of severe or clinically significant hypoglycaemia (blood glucose below 3 mmol/L) with 0.19 events per patient-year exposed to once-weekly insulin icodec and 0.14 events per patient-year exposed to the once-daily basal insulins. In the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile.

“We are very pleased to share the positive results from the ONWARDS 5 trial. These results include real-world elements and a dosing guide app, which help us better understand how insulin icodec can make a difference for patients in a clinical practice setting,” said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “Today’s results confirm the results from the previous reported ONWARDS trials and highlight that insulin icodec has the

potential to be an ideal insulin for people with type 2 diabetes. We now look forward to sharing the results with regulatory authorities.”

Novo Nordisk expects to file for regulatory approval of once-weekly insulin icodec in the US, the EU and China in the first half of 2023.

About the ONWARDS clinical development programme

The ONWARDS 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. Following the completion of the main phase of the trial, a 26-week extension phase is ongoing. The results of the main phase were reported on 3 June 2022.

ONWARDS 2 was 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 a once-daily insulin. Results were reported on 28 April 2022.

ONWARDS 3 was a 26-week trial comparing once-weekly insulin icodec with once-daily insulin degludec. The objective of the trial was to assess the efficacy and safety of insulin icodec in 588 insulin-naïve people with type 2 diabetes. Results were reported on 29 July 2022.

ONWARDS 4 was a 26-week trial comparing once-weekly insulin icodec with once-daily insulin glargine, both in combination with mealtime insulin. The objective of the trial was to assess the efficacy and safety of insulin icodec in 582 people with type 2 diabetes treated with basal and bolus insulin. Results were reported on 29 July 2022.

ONWARDS 5 was a 52-week trial comparing once-weekly insulin icodec with once-daily basal insulin (insulin degludec and insulin glargine U100 and U300) The objective of the trial was to assess the effectiveness and safety of insulin icodec, with an app providing dosing recommendation, in 1,085 insulin-naïve people with type 2 diabetes in a clinical practice setting including no upper limit at HbA_{1c} at time of inclusion, no limitations on use of oral antidiabetic treatments and fewer planned site visits compared to the other ONWARDS phase 3a trials (every third month in accordance with recommended clinical practice)

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. Following the

completion of the main phase of the trial, a 26-week extension phase is ongoing. The results of the main phase were reported on 3 June 2022.

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 50,800 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, [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#).

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