

company announcement

Novo Nordisk achieves primary objectives of ONWARDS 1 and 6 trials with once-weekly insulin icodec demonstrating superior reduction in HbA_{1c} vs insulin glargine U100 in ONWARDS 1

Bagsværd, Denmark, 3 June 2022 – Novo Nordisk today announced headline results from the main phases of ONWARDS 1 (52 weeks) and ONWARDS 6 (26 weeks) phase 3a trials with once-weekly insulin icodec.

ONWARDS 1 (insulin naïve people with type 2 diabetes)

ONWARDS 1 is a phase 3a, 78-week efficacy and safety treat-to-target trial investigating once-weekly insulin icodec vs insulin glargine U100 (insulin glargine), both in combination with non-insulin anti-diabetic treatment, in 984 insulin-naïve people with type 2 diabetes.

The trial achieved its primary endpoint of demonstrating non-inferiority in reducing HbA_{1c} at week 52 with insulin icodec compared to insulin glargine.

From an overall baseline HbA_{1c} of 8.5% once-weekly insulin icodec achieved a superior reduction in estimated HbA_{1c} of -1.55% compared to -1.35% for insulin glargine (estimated treatment difference: -0.19%). Superior time in range (TIR) was also achieved for once-weekly insulin icodec compared to insulin glargine.

In the trial, there was no statistically significant difference in estimated rates of severe or clinically significant hypoglycaemia (blood glucose below 3mmol/L) with 0.30 events per patient year exposed to once-weekly insulin icodec and 0.16 events per patient-year exposed to insulin glargine. In the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile.

ONWARDS 6 (basal-bolus treatment in people with type 1 diabetes)

ONWARDS 6 is a phase 3a, 52-week efficacy and safety treat-to-target trial investigating once-weekly insulin icodec vs insulin degludec, both in combination with three daily mealtime insulin injections, in 582 people with type 1 diabetes.

The trial achieved its primary endpoint of demonstrating non-inferiority in reducing HbA_{1c} at week 26 with insulin icodec compared to insulin degludec.

From an overall baseline HbA_{1c} of 7.6%, once-weekly insulin icodec achieved a reduction in estimated HbA_{1c} of -0.47% compared to -0.51% for insulin degludec (estimated treatment difference: 0.05%).

In the trial, there was a statistically significant higher estimated rate of severe or clinically significant hypoglycaemia (blood glucose below 3 mmol/L) with 19.93 events per patient year exposed to once-weekly insulin icodec and 10.37 events per patient-year exposed to insulin degludec. In the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile.

“The results of the main phase of ONWARDS 1 confirm the strong results seen in ONWARDS 2 and strengthen the profile of once-weekly insulin icodec which has the potential to become the ideal insulin for people with type 2 diabetes initiating insulin treatment”, says Martin Holst Lange, executive vice president for Development at Novo Nordisk. “The results of the main phase of ONWARDS 6 reflect the complexity of introducing a once-weekly insulin in basal bolus treatment for people with type 1 diabetes. Novo Nordisk remains confident that once-weekly insulin icodec holds the potential to become a safe and efficacious treatment in type 1 diabetes.”

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. Following the completion of the main phase of the trial, a 26-week extension phase is ongoing.

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. The results were reported on 28 April 2022.

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. Following the completion of the main phase of the trial, a 26-week extension phase is ongoing.

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 49,300 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](#)

Further information

Media:

Ambre Brown Morley	+45 3079 9289	abmo@novonordisk.com
Natalia Salomao Abrahao	+1 848 304 1027	niaa@novonordisk.com

Investors:

Daniel Muusmann Bohsen	+45 3075 2175	dabo@novonordisk.com
Ann Søndermølle Rendbæk	+45 3075 2253	arnd@novonordisk.com
David Heiberg Landsted	+45 3077 6915	dhel@novonordisk.com
Jacob Martin Wiborg Rode	+45 3075 5956	jrde@novonordisk.com
Mark Joseph Root (US)	+1 848 213 3219	mjhr@novonordisk.com

Novo Nordisk A/S
Investor Relations

Novo Allé
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888

Internet:
www.novonordisk.com
CVR no:
24 25 67 90

Company announcement No 49 / 2022