

# company announcement

## **Novo Nordisk achieves primary objectives of ONWARDS 3 and 4 trials with once-weekly insulin icodec demonstrating superior reduction in HbA<sub>1c</sub> vs insulin degludec in ONWARDS 3**

**Bagsværd, Denmark, 29 July 2022** – Novo Nordisk today announced headline results from the ONWARDS 3 and ONWARDS 4 phase 3a trials with once-weekly insulin icodec in adults with type 2 diabetes.

### **ONWARDS 3 (insulin-naïve people with type 2 diabetes)**

ONWARDS 3 is a phase 3a, double-blind 26-week efficacy and safety treat-to-target trial investigating once-weekly insulin icodec vs insulin degludec. Both are in combination with non-insulin anti-diabetic treatment in 588 people with type 2 diabetes who have not previously been treated with insulin.

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

From an overall baseline HbA<sub>1c</sub> of 8.5%, once-weekly insulin icodec achieved a superior reduction in estimated HbA<sub>1c</sub> of -1.57% compared with -1.36% for insulin degludec (estimated treatment difference: -0.21%).

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 0.31 events per patient-year exposed to once-weekly insulin icodec and 0.15 events per patient-year exposed to insulin degludec. In the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile.

### **ONWARDS 4 (basal-bolus treatment in people with type 2 diabetes)**

ONWARDS 4 is a phase 3a, 26-week efficacy and safety treat-to-target trial investigating once-weekly insulin icodec vs insulin glargine U100, both in combination with mealtime insulin (insulin aspart administered two to four times daily), in 582 people with type 2 diabetes.

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

From an overall baseline HbA<sub>1c</sub> of 8.3% once-weekly insulin icodec achieved a reduction in estimated HbA<sub>1c</sub> of -1.16% compared with -1.18% for insulin glargine (estimated treatment difference: 0.02%).

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 5.64 events per patient-year exposed to once-weekly insulin icodec and 5.62 events per patient-year exposed to insulin glargine. In the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile.

“We are very pleased to see that the results from ONWARDS 3 and 4 reinforce the potential of once-weekly insulin icodec to simplify basal insulin therapy for people with type 2 diabetes as an ideal starter insulin and as an attractive option in combination with mealtime insulin”, said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “We are now looking forward to sharing the results from ONWARDS 5 - the last remaining trial in the ONWARDS programme in the second half of this year”.

### **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 is to assess the efficacy and safety of insulin icodec in 588 insulin-naïve people with type 2 diabetes.

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 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 1,085 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. 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 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 American Depository Receipts are listed on the New York Stock Exchange. For more information, visit [novonordisk.com](http://novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#).*

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