

press release

More people with type 2 diabetes achieved blood sugar target with once-weekly insulin icodec compared with once-daily insulin degludec

Data presented today show more participants achieved greater treatment satisfaction when switching to once-weekly insulin icodec in ONWARDS 2 trial

Bagsværd, Denmark, Thursday 22 September 2022 – Novo Nordisk today presented new data from the phase 3a ONWARDS 2 trial, demonstrating that 37% of adults with type 2 diabetes treated with once-weekly insulin icodec achieved an HbA_{1c} <7.0%, without experiencing severe or clinically significant hypoglycaemia, compared with 27% of those treated with insulin degludec at 26 weeks¹. These results were presented at the 58th European Association for the Study of Diabetes (EASD) Annual Meeting 2022¹.

'Once-weekly insulin would be a remarkable step forward in insulin innovation,' said Dr Athena Philis-Tsimikas, Scripps Whittier Diabetes Institute, California, USA, and principal investigator of ONWARDS 2. 'It could offer people with type 2 diabetes reduced treatment complexity and burden by reducing the number of basal insulin injections from 365 to 52 per year, without compromising management of blood sugar.'

The trial achieved its primary endpoint of demonstrating non-inferiority in reducing HbA_{1c} at week 26 with insulin icodec compared with insulin degludec². From a mean baseline of 8.17% (icodec) and 8.10% (degludec), once-weekly insulin icodec achieved a superior reduction in estimated HbA_{1c} of 0.93% compared with 0.71% for insulin degludec².

People with diabetes in ONWARDS 2 reported significantly greater satisfaction in favour of once-weekly insulin icodec compared with insulin degludec at 26 weeks as assessed by the Diabetes Treatment Satisfaction Questionnaire (DTSQ)¹.

'We are very pleased to see the promising results from the ONWARDS programme so far,' said Martin Holst Lange, Executive Vice President Development, Novo Nordisk. 'The patient-reported outcomes data we see in ONWARDS 2 further strengthen our belief that insulin icodec has the potential to become the ideal insulin for people living with type 2 diabetes initiating insulin treatment.'

The mean weekly insulin dose was 268 U/week for insulin icodec vs 244 U/week for insulin degludec¹. The estimated mean change in body weight from baseline to week 26 was 1.40 kg for insulin icodec compared with -0.30 kg for insulin degludec¹.

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In the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile. There was less than 1 hypoglycaemic event per patient-year exposed for insulin icodec and insulin degludec (0.73 events and 0.27 events per patient-year exposed, respectively, with no statistically significant difference between arms). As previously reported, no severe hypoglycaemia events were observed for people treated with insulin icodec¹.

For more news and media materials from Novo Nordisk at EASD 2022, please visit: https://www.novonordisk.com/news-and-media/e-press-room.html?cid=nnref-1624925851

About insulin icodec

Insulin icodec is a novel once-weekly basal insulin analogue designed to cover the basal insulin requirements for a full week with a single subcutaneous injection. Currently, the basal insulin products with the longest duration are injected once daily¹. Insulin icodec is currently going through phase 3 clinical development.

About the ONWARDS clinical programme

The ONWARDS clinical development programme for once-weekly insulin icodec 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 diabetes². Top-line data for the ONWARDS 1, 2, 3, 4 and 6 trials have now read out, all meeting their primary endpoints²⁻⁴.

About ONWARDS 2

ONWARDS 2 trial is a phase 3a, 26-week efficacy and safety treat-to-target trial investigating once-weekly insulin icodec vs once-daily insulin degludec in 526 people with type 2 diabetes switching from daily insulin⁵. The primary endpoint was to assess the change in HbA_{1c} at week 26 with insulin icodec compared with insulin degludec².

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. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn and YouTube.

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References

- Philis-Tsimikas A, Asong M, Franek E, et al. Once-weekly Insulin Icodec Demonstrated Better Glycaemic Control vs Once-daily Insulin Degludec in Basal Insulin-Treated Type 2 Diabetes. European Association for the Study of Diabetes (EASD) – 58th Annual Meeting; 19–23 September 2022; Stockholm, Sweden.
- 2. Novo Nordisk. Company announcement. Once-weekly insulin icodec demonstrates superior reduction in HbA1c vs insulin degludec in people with type 2 diabetes in ONWARDS 2 phase 3a trial. Available at: https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=112839 Last accessed: September 2022.
- 3. Novo Nordisk. Company announcement. Novo Nordisk achieves primary objectives of ONWARDS 1 and 6 trials with once-weekly insulin icodec demonstrating superior reduction in HbA1c vs insulin glargine U100 in ONWARDS 1. Available at: https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-irmaterials/news-details.html?id=118349 Last accessed: September 2022.
- 4. Novo Nordisk. Company announcement. Novo Nordisk achieves primary objectives of ONWARDS 3 and 4 trials with once-weekly insulin icodec demonstrating superior reduction in HbA1c vs insulin degludec in ONWARDS 3. Available at: https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-irmaterials/news-details.html?id=127304 Last accessed: September 2022.
- 5. ClinicalTrials.gov. A Research Study to Compare Two Types of Insulin, a New Weekly Insulin, Insulin Icodec and an Available Daily Insulin, Insulin Degludec, in People With Type 2 Diabetes Who Use Daily Insulin (ONWARDS 2). Available at: https://clinicaltrials.gov/ct2/show/NCT04770532 Last accessed: September 2022.