

company announcement

Awikli® (once-weekly basal insulin icodec) recommended for approval for the treatment of diabetes by the European regulatory authorities

Bagsværd, Denmark, 21 March 2024 – Novo Nordisk today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending marketing authorisation for Awikli® (the brand name for once-weekly basal insulin icodec) for treatment of diabetes in adults.

The positive CHMP opinion is based on results from the ONWARDS phase 3a clinical trial programme. Once-weekly basal insulin icodec achieved superior blood sugar reduction¹ (measured by a change in HbA_{1c}) and superior Time in Range² (time spent within recommended blood sugar range), compared with daily basal insulin in people with type 2 diabetes. In people with type 2 diabetes who have not previously been treated with insulin, overall observed rates of clinically significant or severe hypoglycaemia³ were below one event per patient-year of exposure with both once-weekly basal insulin icodec and comparators. In people with type 1 diabetes, once-weekly basal insulin icodec demonstrated non-inferiority in reducing HbA_{1c} with a statistically significant higher estimated rate of severe or clinically significant hypoglycaemia compared with insulin degludec⁴. Across the programme, once-weekly basal insulin icodec appeared to have a safe and well-tolerated profile.

“We believe that by reducing the number of basal insulin injections from seven to one per week, Awikli® has the potential to have a significant impact and improve treatment for people living with diabetes,” said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “We are committed to driving innovation in diabetes treatment, and Awikli® has the potential to become the insulin of choice for people with type 2 diabetes initiating insulin treatment.”

Novo Nordisk expects to receive final marketing authorisation from the European Commission within approximately two months.

About Awiqli® (once-weekly basal insulin icodec) and the ONWARDS programme

Awiqli® is a once-weekly basal insulin analogue designed to cover the basal insulin requirements for a full week with a single subcutaneous injection.

The ONWARDS clinical development programme comprised six phase 3a global clinical trials, which investigated the efficacy and safety of once-weekly basal insulin icodec, involving more than 4,000 adults with type 1 or type 2 diabetes, including a trial with real-world elements.

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 63,400 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](#), [Instagram](#), [X](#), [LinkedIn](#) and [YouTube](#).

Contacts for further information

Media:

Ambre James-Brown

+45 3079 9289

abmo@novonordisk.com

Liz Skrbkova (US)

+1 609 917 0632

lzsk@novonordisk.com

Investors:

Daniel Muusmann Bohsen

+45 3075 2175

dabo@novonordisk.com

Jacob Martin Wiborg Rode

+45 3075 5956

jrde@novonordisk.com

David Heiberg Landsted

+45 3077 6915

dhel@novonordisk.com

Mark Joseph Root (US)

+1 848 213 3219

mjhr@novonordisk.com

Sina Meyer

+45 3079 6656

azey@novonordisk.com

Frederik Taylor Pitter

+45 3075 8259

fptra@novonordisk.com

1. vs insulin glargine U100 and insulin degludec in ONWARDS 1,2 and 3
2. vs insulin glargine U100 in ONWARDS 1
3. Clinically significant hypoglycaemia defined as blood glucose below 3 mmol/L; severe hypoglycaemia defined as hypoglycaemia associated with severe cognitive impairment requiring external assistance for recovery
4. vs insulin degludec in ONWARDS 6