company announcement

COMBINE 3 phase 3a trial successfully completed with once-weekly IcoSema demonstrating non-inferior reduction in HbA_{1c} versus daily basal-bolus treatment (insulin glargine U100 and insulin aspart) in people with type 2 diabetes

Bagsværd, Denmark, 8 January 2024 – Novo Nordisk today announced topline results from the COMBINE 3 phase 3a trial of once-weekly IcoSema, a fixed-ratio combination of basal insulin icodec and semaglutide. COMBINE 3 was a 52-week, open-label treat-to-target trial comparing the efficacy and safety of once-weekly IcoSema vs once-daily insulin glargine U100 and insulin aspart (injected 2-4 times a day during mealtimes), dosed with or without oral glucose-lowering medications, in 679 people with type 2 diabetes inadequately controlled on daily basal insulin.

The trial achieved its primary endpoint of demonstrating non-inferiority in reducing HbA_{1c} at week 52 with once-weekly IcoSema compared with insulin glargine U100 and insulin aspart.

From an overall baseline HbA_{1c} of 8.30%, once-weekly IcoSema achieved an estimated reduction in HbA_{1c} of -1.47 percentage points compared with -1.40 percentage points for insulin glargine U100 and insulin aspart (estimated treatment difference: –0.06 percentage points). Further, from a baseline body weight of 85.8 kg, people treated with IcoSema achieved a superior reduction in estimated change of body weight a weight loss of -3.6 kg with IcoSema and a weight gain of 3.2 kg with insulin glargine U100 and insulin aspart (estimated treatment difference: -6.7 kg).

In the trial, IcoSema was superior to insulin glargine U100 and insulin aspart in estimated rates of severe or clinically significant (blood glucose below 3.0 mmol/L) hypoglycaemia, with 0.26 events per patient-year of exposure for once-weekly IcoSema and 2.18 events per patient-year of exposure for insulin glargine U100 and insulin aspart. In the trial, once-weekly IcoSema appeared to have a safe and well-tolerated profile. The most common adverse events for people treated with IcoSema were gastrointestinal consistent with GLP-1 receptor agonist class and the vast majority were mild to moderate.

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“We are very pleased to share the first phase 3a results for once-weekly IcoSema”, said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “The results demonstrate the potential of IcoSema to simplify insulin intensification by reducing the injection burden to a single injection per week compared to around 28 injections per week for people with type 2 diabetes inadequately controlled on basal insulin while providing glycaemic control as well as weight benefits and lower rates of hypoglycaemia.”

COMBINE 3 is the first trial to readout in the phase 3a COMBINE programme, and results from COMBINE 1 and COMBINE 2 will be shared later this year.

About once-weekly IcoSema

Once-weekly IcoSema is fixed-ratio combination of a once-weekly basal insulin icodec and once-weekly semaglutide (700U/2 mg per millilitre). IcoSema is titrated in the same way as insulin, with a maximum weekly dose of 350 dose steps (ie 350 U insulin icodec/1mg semaglutide).

About the COMBINE clinical development programme

Once-weekly IcoSema is being evaluated in the phase 3a COMBINE programme, which consists of three, multinational, multicentre, randomised, parallel-group, open-label, treat-to target trials.

COMBINE 1 is a 52-week trial comparing once-weekly IcoSema with insulin icodec. The objective of the trial is to assess the efficacy and safety of IcoSema in around 1.300 people with type 2 diabetes inadequately controlled on basal insulin treatment. The trial was initiated in the second quarter of 2022.

COMBINE 2 is a 52-week trial comparing once-weekly IcoSema with semaglutide 1.0 mg. The objective of the trial is to assess the efficacy and safety of IcoSema in around 700 people with type 2 diabetes inadequately controlled on GLP-1 treatment. The trial was initiated in the second quarter of 2022.

COMBINE 3 was a 52-week trial comparing once-weekly IcoSema with once-daily basal insulin glargine U100 and insulin aspart (injected 2-4 times a day during mealtimes) in 679 people with type 2 diabetes inadequately controlled on basal insulin treatment.

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 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 61,400 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, Facebook, Instagram, X, LinkedIn and YouTube.

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