press release

Novo Nordisk announces presentation of data from key semaglutide clinical trials in diabetes, obesity and chronic kidney disease at the 84th Scientific Sessions of the American Diabetes Association

- *FLOW kidney outcomes trial data evaluating efficacy and safety of once-weekly semaglutide 1.0 mg in people with type 2 diabetes*[1]
- *SELECT cardiovascular outcomes trial data evaluating efficacy and safety of once-weekly semaglutide 2.4 mg in people with obesity and established cardiovascular disease, without diabetes*[2]
- *STEP HFpEF trial programme data evaluating efficacy and safety of once-weekly semaglutide 2.4 mg in people with obesity-related heart failure with preserved ejection fraction (HFpEF), with and without diabetes*[3,4]

Bagsværd, Denmark, 18 June 2024 – Novo Nordisk today announced the presentation of 34 abstracts highlighting the breadth of its portfolio at the upcoming 84th Scientific Sessions of the American Diabetes Association (ADA). The conference will be held in-person and virtually from 21–24 June 2024 in Orlando, US.

Additional data from three landmark trials with semaglutide will also be presented in dedicated scientific sessions. The trials assess additional potential benefits of semaglutide, including evaluation of kidney and cardiovascular endpoints in people with type 2 diabetes and chronic kidney disease (FLOW, semaglutide 1.0 mg) and cardiovascular and glucose-related endpoints in people with obesity and CVD, with and without diabetes (SELECT and STEP HFpEF, semaglutide 2.4 mg).

“We recognise that cardiometabolic conditions like cardiovascular disease, chronic kidney disease, obesity and type 2 diabetes are often interlinked and might occur in the same patient. We need to develop medicines that address multiple facets of the diseases,” said Stephen Gough, senior vice president and global chief medical officer at Novo Nordisk. “The broad data being presented this year at ADA reflect this goal. In particular, data from FLOW and SELECT look at ways to treat common comorbidities of diabetes and obesity, such as kidney disease and cardiovascular disease.”

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All abstracts will be published on the website of the journal *Diabetes*®. Data from the scientific sessions will be made available after their presentation.

Summary of presentations

Scientific sessions

The following data will be presented in the dedicated scientific sessions as a part of the scientific agenda of the congress:

The first dedicated kidney outcome trial with a GLP1-RA once-weekly semaglutide – FLOW trial results (scientific session; 24 June, 13:30–15:00 EST)
SELECT trial – New looks at glycemia, inflammation, and heart failure (scientific session; 22 June, 08:00–09:00 EST)
The STEP-HFpEF and STEP-HFpEF-DM trials – Targeting obesity to treat heart failure (scientific session; 23 June, 16:30–18:00 EST)

Poster and oral presentations

The following abstracts were submitted by Novo Nordisk and are accepted for presentation at the congress:

Diabetes
Ozempic® (once-weekly semaglutide 1.0 mg)
• Comparative effectiveness of semaglutide in T2D – year 2 results of a randomized pragmatic clinical trial (230-OR)
• Long-term effectiveness associated with maintenance doses of once-weekly semaglutide in US adults with poorly controlled T2D (766-P)
• Semaglutide in patients with peripheral arterial disease and type 2 diabetes: comorbidities and concomitant medications from the STRIDE trial (784-P)
• Real-world impact of once-weekly injectable semaglutide on weight, BMI and HbA_{1c} outcomes in type 2 diabetes: an observational study (PAUSE) (857-P)
• Real-World Impact of Once-Weekly Injectable Semaglutide (sema OW) vs. Sodium–Glucose Cotransporter 2 Inhibitors (SGLT2i) on HbA1c, Weight, and Health Care Resource Utilization (HCRU) Outcomes in Type 2 Diabetes (T2D)—An Observational Study (PAUSE) (1884-LB)
Rybelsus® (once-daily oral semaglutide)
• Evaluating the efficacy of oral semaglutide in Chinese patients with T2D by baseline characteristics: post hoc analysis of PIONEER 11 and 12 (752-P)

• Real-world impact of fasting on adherence to dosing instructions and efficacy of oral semaglutide during Ramadan in people with type 2 diabetes: O-SEMA-Fast sub-analysis (808-P)
CagriSema
• CagriSema improves insulin sensitivity in diet-induced obese rats (763-P)
Once-weekly insulin icodec
• Healthcare resource utilization and costs with timely vs delayed basal insulin initiation (816-P)
• Demographic, clinical, and treatment characteristics of patients with timely vs. delayed basal insulin initiation (817-P)
• No evidence of increased physical activity-related hypoglycemia with once-weekly insulin icodec versus once-daily basal insulin in T1D: ONWARDS 6 (824-P)
• Efficacy and safety of once-weekly insulin icodec versus once-daily basal insulin in individuals with T2D by kidney function: ONWARDS 1–5 (826-P)
• No evidence of increased physical activity-related hypoglycemia with once-weekly insulin icodec versus once-daily basal insulin in T2D: ONWARDS 1-5 (830-P)
• Adherence to app-based dose guidance for once-weekly insulin icodec in insulin-naive T2D: post hoc analysis of ONWARDS 5 (836-P)
• Impact of age on the efficacy and safety of once-weekly insulin icodec versus once-daily insulin in T2D (ONWARDS 1–5) (838-P)
• Efficacy and safety of once-weekly insulin icodec versus once-daily basal insulin in type 2 diabetes according to baseline glucagon-like peptide-1 receptor agonist use: ONWARDS 1–5 (840-P)
• Efficacy and safety of once-weekly insulin icodec vs once-daily basal insulin in T2D by ethnicity and race: ONWARDS 1–5 (841-P)
• Cost-effectiveness of insulin icodec for the treatment of type 2 diabetes in Canada (1046-P)
• Efficacy and safety outcomes with once-weekly insulin icodec versus once-daily insulin degludec in T1D according to glycemic variability: ONWARDS 6 post hoc analysis (1882-LB)
Daily insulins
• Influence of the functionally selective insulin analog NNC-965 on cardiac structure and function versus insulin glargine (IGla) (822-P)
• Improved glycemic control in people with type 2 diabetes (T2D) initiating or switching

to insulin degludec/insulin aspart (IDegAsp) in a real-world setting in China (publication only)
General diabetes
• Persistence and adherence of once weekly GLP-1 receptor agonists in patients with type 2 diabetes and atherosclerotic cardiovascular disease in a real-world setting (740-P)
• Impact of newer GLP-1 RAs on HbA1c in US adults with type 2 diabetes: a population-level time-series analysis (774-P)
• Understanding attitudes about basal insulin: insights from a global survey of people with type 2 diabetes (833-P)
• The value of the guideline-recommended management of type 2 diabetes: A novel population-level system dynamics approach (1040-P)
• Prevalence of atherosclerotic cardiovascular diseases in adults with type 2 diabetes in Jordan: the PACT-MEA Study (1789-LB)
• In vivo chain-splitting of human insulin (2032-LB)
Digital Health
• Improvement in time in range after smart insulin pen initiation in Austria (842-P)
• Multinational analysis of factors associated with missed bolus insulin injections using smart pen data (843-P)
Obesity
Wegovy® (once-weekly semaglutide 2.4 mg)
• CONCRETE – characterization of patients receiving telemedicine and branded antiobesity medication for medical weight management: a retrospective analysis (1684-P)
• Clinical outcomes in patients with obesity or overweight treated with semaglutide 2.4 mg: a real-world retrospective cohort study in the United States (SCOPE 2) (1691-P)
• Modeling the Impact of Semaglutide 2.4 mg in U.S. Patients with Atherosclerotic Cardiovascular Disease and BMI ≥27 kg/m2 (1981-LB)
General obesity
• Patient-centered weight management clinical decision support: a proof-of-concept study (1101-P)
• Prevalence, characteristics, and clinical burden among patients with overweight or obesity and established ASCVD in a US real world setting (1692-P)

About Ozempic®
Once-weekly subcutaneous semaglutide is approved in 0.5 mg, 1.0 mg and 2.0 mg doses under the brand name Ozempic® and indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes and established cardiovascular disease.

About Rybelsus®
Oral semaglutide is administered once daily and is approved for use in three therapeutic doses, 3 mg, 7 mg and 14 mg under the brand name Rybelsus®. It is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise.

About Wegovy®
Once-weekly subcutaneous semaglutide 2.4 mg is approved under the brand name Wegovy® and is indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight, as well as to reduce excess body weight and maintain weight reduction long term in adults and paediatric patients aged 12 years and older with obesity and in adults with overweight in the presence of at least one weight-related comorbid condition.

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 66,000 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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2. ClinicalTrials.gov. Semaglutide Effects on Heart Disease and Stroke in Patients With Overweight or Obesity (SELECT). Available athttps://clinicaltrials.gov/study/NCT03574597. Last accessed: June 2024.
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