



# Novo Nordisk – a focused healthcare company

**Novo Nordisk investor event in connection with ADA  
New Orleans, 05 June 2022**

# Forward-looking statements

Novo Nordisk's reports filed with or furnished to the US Securities and Exchange Commission (SEC), including the statutory Annual Report 2021 and Form 20-F, which both were filed with the SEC in February 2022 in continuation of the publication of this Annual Report 2021, this presentation, and written information released, or oral statements made, to the public in the future by or on behalf of Novo Nordisk, may contain forward-looking statements. Words such as 'believe', 'expect', 'may', 'will', 'plan', 'strategy', 'prospect', 'foresee', 'estimate', 'project', 'anticipate', 'can', 'intend', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance identify forward-looking statements. Examples of such forward-looking statements include, but are not limited to:

- Statements of targets, plans, objectives or goals for future operations, including those related to Novo Nordisk's products, product research, product development, product introductions and product approvals as well as cooperation in relation thereto,
- Statements containing projections of or targets for revenues, costs, income (or loss), earnings per share, capital expenditures, dividends, capital structure, net financials and other financial measures,
- Statements regarding future economic performance, future actions and outcome of contingencies such as legal proceedings, and
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For an overview of some, but not all, of the risks that could adversely affect Novo Nordisk's results or the accuracy of forward-looking statements in this Annual Report 2021, reference is made to the overview of risk factors in 'Risk management' of this Annual Report 2021.

Unless required by law, Novo Nordisk is under no duty and undertakes no obligation to update or revise any forward-looking statement after the distribution of this Annual Report 2021, whether as a result of new information, future events, or otherwise.

## Important drug information

Victoza® and Ozempic® are approved for the management of type 2 diabetes only  
Saxenda® and Wegovy® are approved for the treatment of obesity only

# Today's speakers



**Karsten Munk Knudsen**  
Executive Vice President and  
Chief Financial Officer



**Martin Holst Lange**  
Executive Vice President and  
Head of Development



**Mads Frederik Rasmussen**  
Senior Vice President and  
Head of Clinical Drug Development

# Agenda

## Introduction

Karsten Munk Knudsen

## Obesity care

*Post hoc analysis of STEP 1 and 4,  
STEP TEENS results and SELECT-LIFE*

Martin Holst Lange

## GLP-1 Diabetes

*Semaglutide in chronic kidney disease and  
peripheral artery disease*

Mads Frederik Rasmussen

## Insulin

*Insulin icodec hypoglycaemia frequency, results from  
ONWARDS 1, ONWARDS 2, and ONWARDS 6*

Martin Holst Lange

## Q&A

All

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Mads Frederik Rasmussen

Martin Holst Lange

All



# Strategic Aspirations 2025 | Highlights first three months 2022



**Purpose and sustainability (ESG)**

**Progress towards zero environmental impact:**


- Carbon emissions increased by 46% vs first quarter of 2021 and decreased 25% vs first quarter of 2019

**Adding value to society:**

- Positive scientific opinion from EMA on human insulin with more flexible storage option without refrigeration
- Two months' supply of diabetes and haemophilia medication donated to the Ukrainian Ministry of Health

**Being recognised as a sustainable employer:**

- Share of females in senior leadership positions has increased to 37% from 35% in the first quarter of 2021




**Commercial execution**

**Diabetes value market share increased by 1.2 percentage point to 30.5%<sup>1</sup>**

**Obesity care sales increased by 107% at CER to DKK 3.4 billion**

**Rare disease sales increased by 3% at CER to DKK 5.4 billion**



**Innovation and therapeutic focus**

**Further raise innovation-bar for Diabetes treatment:**

- Approval of Ozempic® 2.0 mg in the US
- Successful completion of first phase 3 trial with once-weekly insulin icodec
- Phase 1 trial with Ideal Pump insulin successfully completed
- Phase 1 initiated with a once-daily oral GLP-1/GIP agonist

**Strengthen and progress Rare disease pipeline**

- Concizumab phase 3 trial successfully completed in people with haemophilia A and B with inhibitors



**Financials**

**Sales growth of 18% and Operating profit growth of 18%:**

- Sales in International Operations grew by 13%
- Sales in the US grew by 23% with 67% of sales coming from products launched since 2015

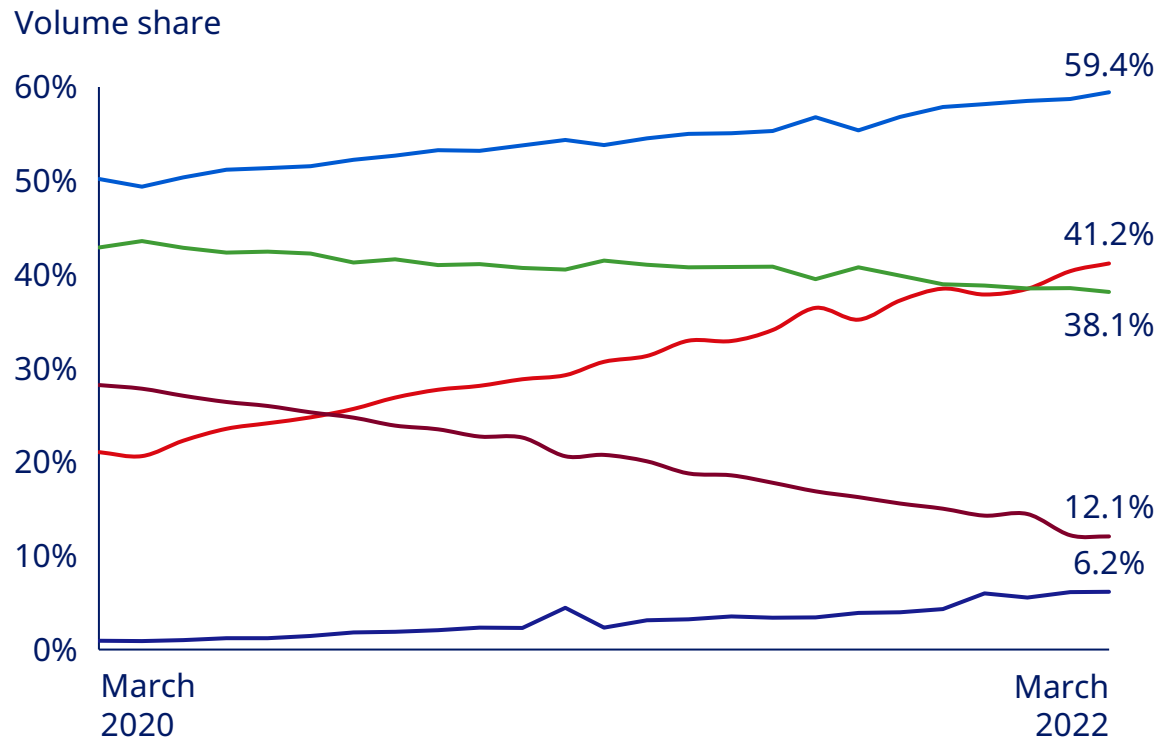
**Gross margin positively impacted** by continued productivity gains in Product Supply

**Free cash flow** of DKK 21.6 billion and DKK 20 billion returned to shareholders during first quarter

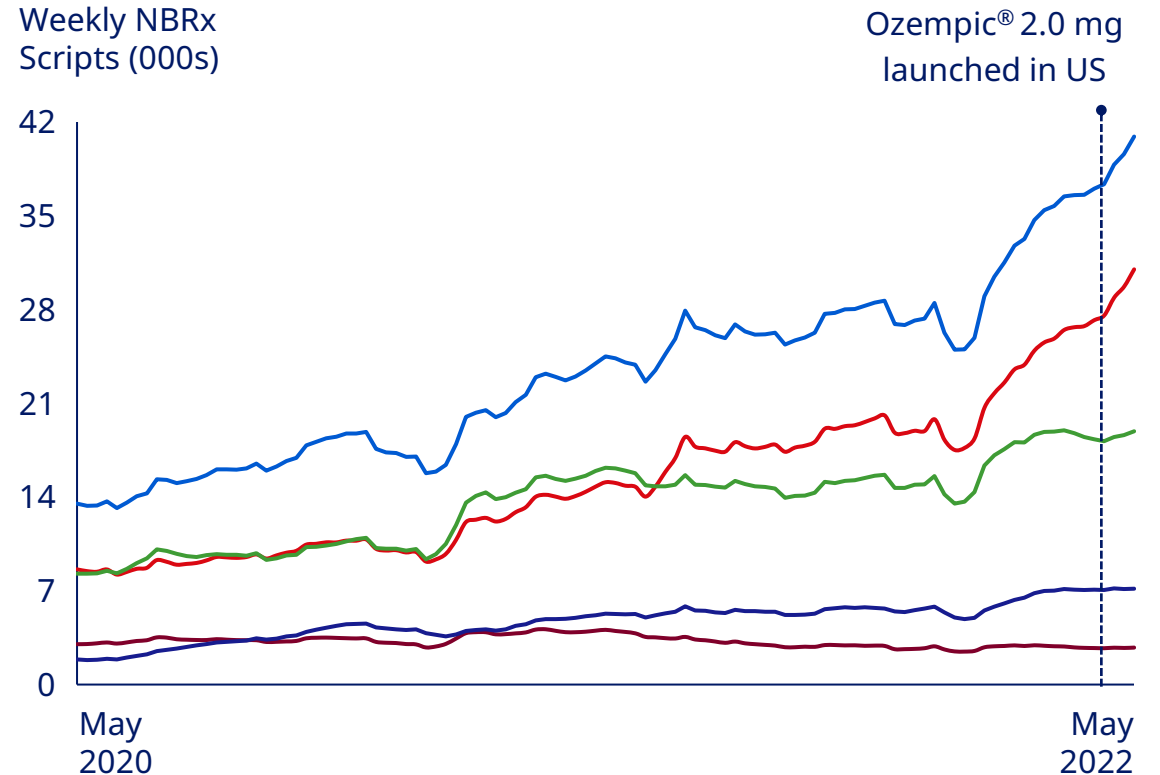
<sup>1</sup> MAT (Moving annual total) value market share. IO: International Operations  
The strategic aspirations are not a projection of Novo Nordisk's financial outlook or expected growth.

# Ozempic® is now the global GLP-1 volume market leader and the 2.0 mg dose has just been launched in the US

Global GLP-1 volume market share



US GLP-1 weekly NBRx prescriptions



— NN GLP-1 — Ozempic® — Victoza® — Rybelsus® — dulaglutide


NBRx: New-to-brand prescriptions; Scripts: prescriptions; RHS: Right-hand-side, LHS: Left-hand-side  
 Source: LHS: IQVIA Midas applied IQVIA spot rate, monthly data. RHS: IQVIA Xponent, Weekly (ending 13 May 2022) Each data points represents a rolling four-week average

# Strategic Aspirations 2025 | Today with emphasis on Innovation and therapeutic focus




**Purpose and sustainability (ESG)**

- Progress towards zero environmental impact
- Being respected for adding value to society
- Being recognised as a sustainable employer



**Commercial execution**

- Strengthen Diabetes leadership - aim at global value market share of more than 1/3
- More than 25 billion DKK in Obesity sales by 2025
- Secure a sustained growth outlook for Rare disease



**Innovation and therapeutic focus**

- **Further raise the innovation-bar for diabetes treatment**
- **Develop a leading portfolio of superior treatment solutions for obesity**
- **Strengthen and progress the Rare disease pipeline**
- **Establish presence in Other serious chronic diseases focusing on CVD, NASH and CKD**



**Financials**

- Deliver solid sales and operating profit growth
  - Deliver 6-10% sales growth in IO
  - Transform 70% of sales in the US<sup>1</sup>
- Drive operational efficiencies across the value chain to enable investments in future growth assets
- Deliver free cash flow to enable attractive capital allocation to shareholders

<sup>1</sup> From 2015 to 2022, 70% of sales to come from products launched from 2015. IO: International Operations; CVD: Cardiovascular disease; NASH: Non-alcoholic steatohepatitis; CKD: Chronic kidney disease.  
Note: The strategic aspirations are not a projection of Novo Nordisk's financial outlook or expected growth.



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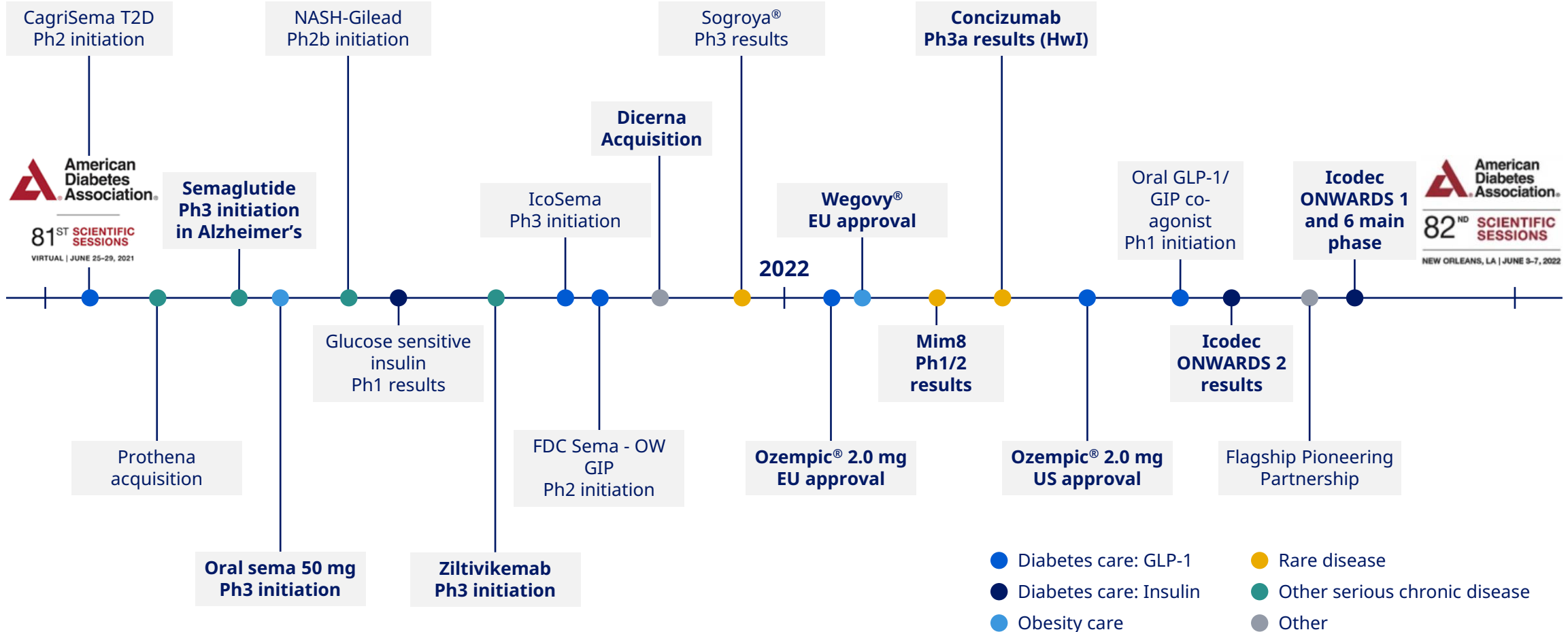
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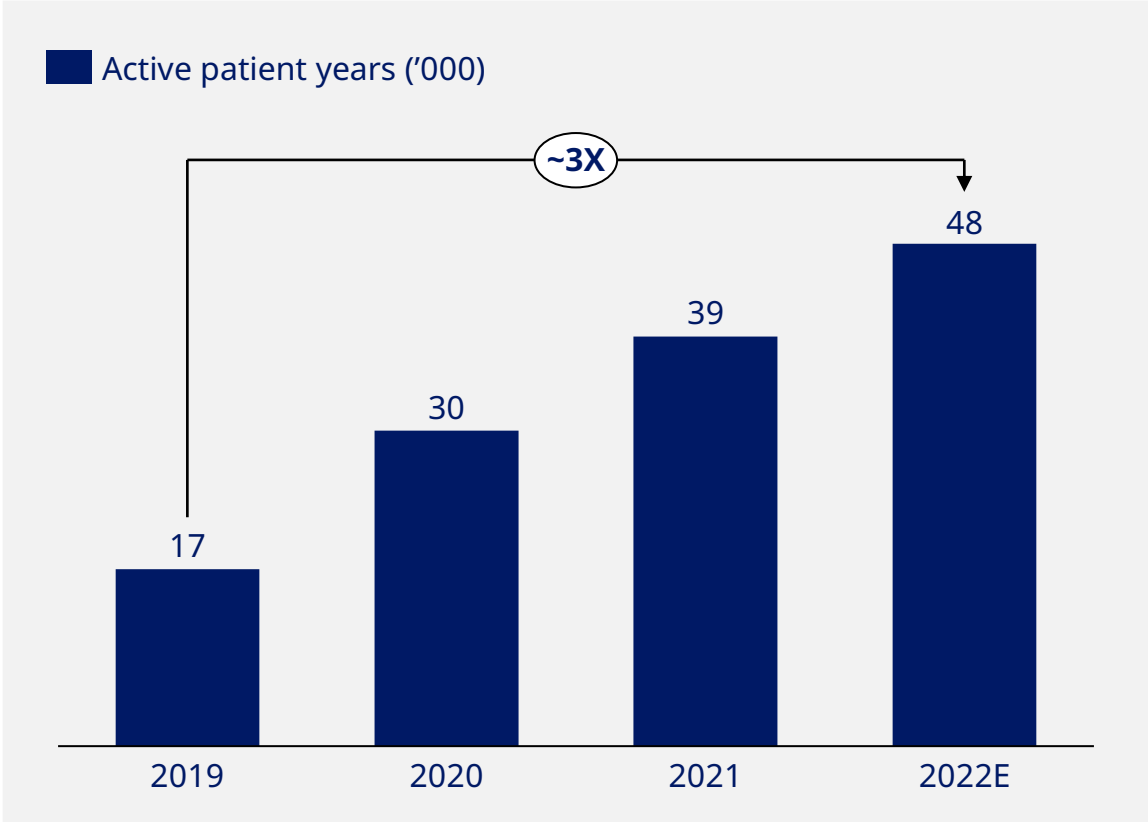
# Since the ADA 2021, progress has been made across the Novo Nordisk pipeline



T2D: Type 2 diabetes; Sema: Semaglutide; Ph: Phase; OW: Once-weekly; HwI: Haemophilia with inhibitors  
 Note: Timeline non-exhaustive

# Research and development activity is at an all time high

Patient years in trials increasing over last four years

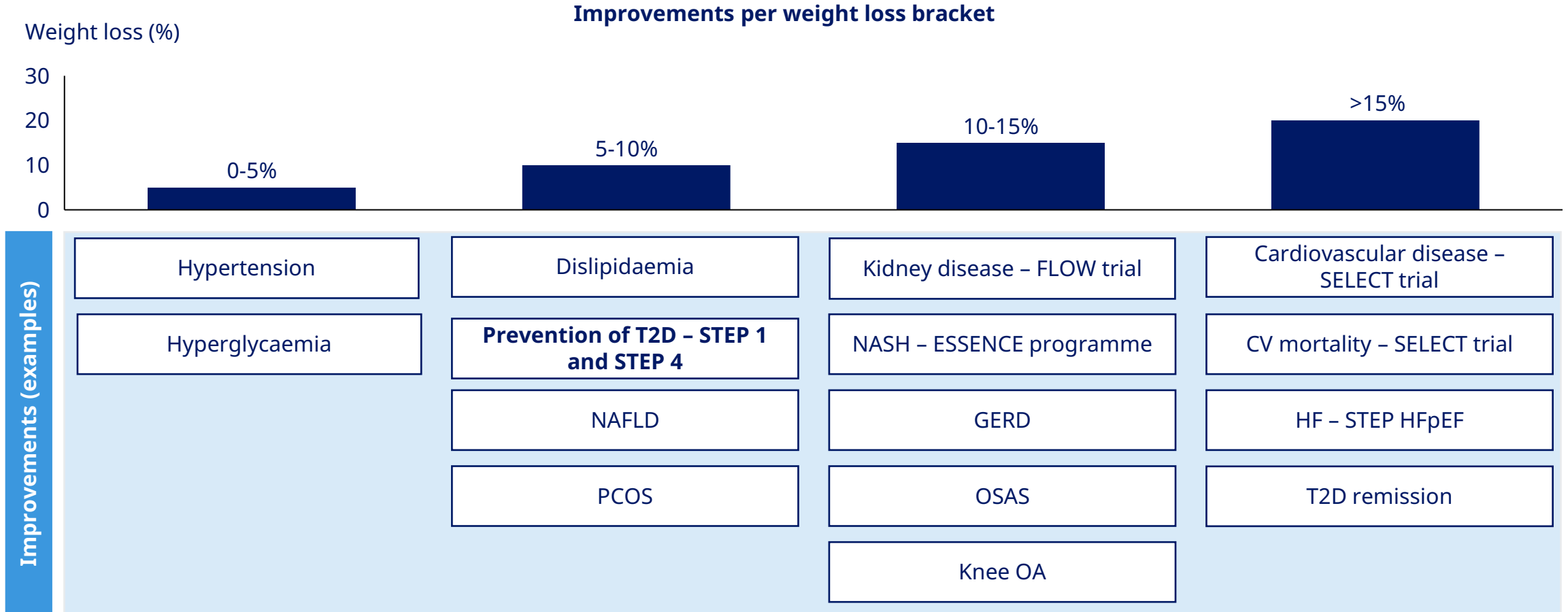


Active phase 3 trials across all therapy areas



CKD: Chronic kidney disease; CVD: Cardiovascular disease; RBD: Rare blood disorders; RED: Rare endocrine disorders

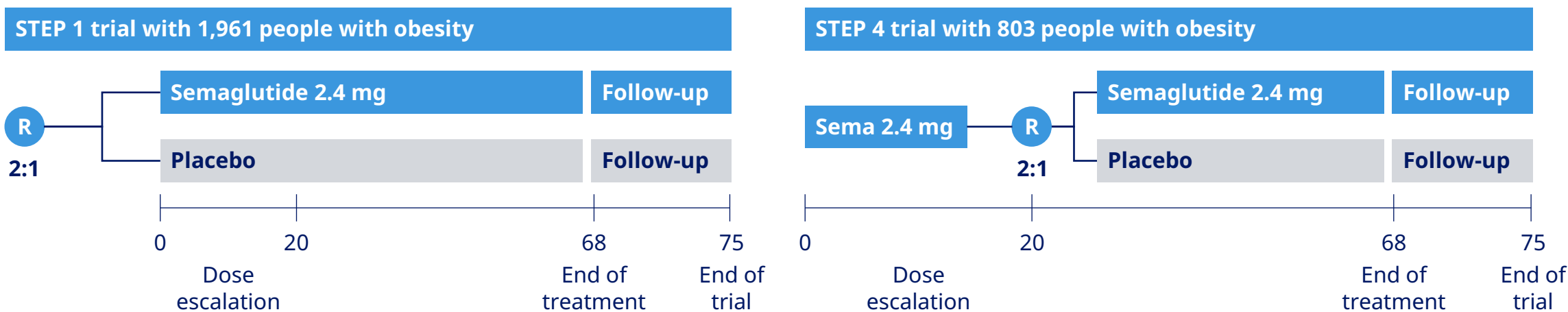
# Weight loss is associated with improvements of multiple comorbidities



T2D: Type 2 diabetes; NAFLD: Non-alcoholic fatty liver disease; PCOS: Polycystic ovary syndrome; NASH: Non-alcoholic steatohepatitis; GERD: Gastroesophageal reflux disease; OSAS: Obstructive sleep apnoea syndrome; OA: Osteoarthritis  
 HF: Heart failure  
 Sources: Garvey WT et al. Endocr Pract 2016;22 (Suppl. 3):1-203; Look AHEAD Research Group. Lancet Diabetes Endocrinol 2016;4:913-21; Lean ME et al. Lancet 2018;391:541-5; Benraoune F and Litwin SE. Curr Opin Cardiol 2011;26:555-61; Sundström J et al. Circulation 2017;135:1577-85., Morales E and Praga M. Curr Hypertens Rep 2012;14:170-176

# The 10-year risk of type 2 diabetes was assessed post hoc in STEP 1 and STEP 4

## STEP 1 and STEP 4 trial design



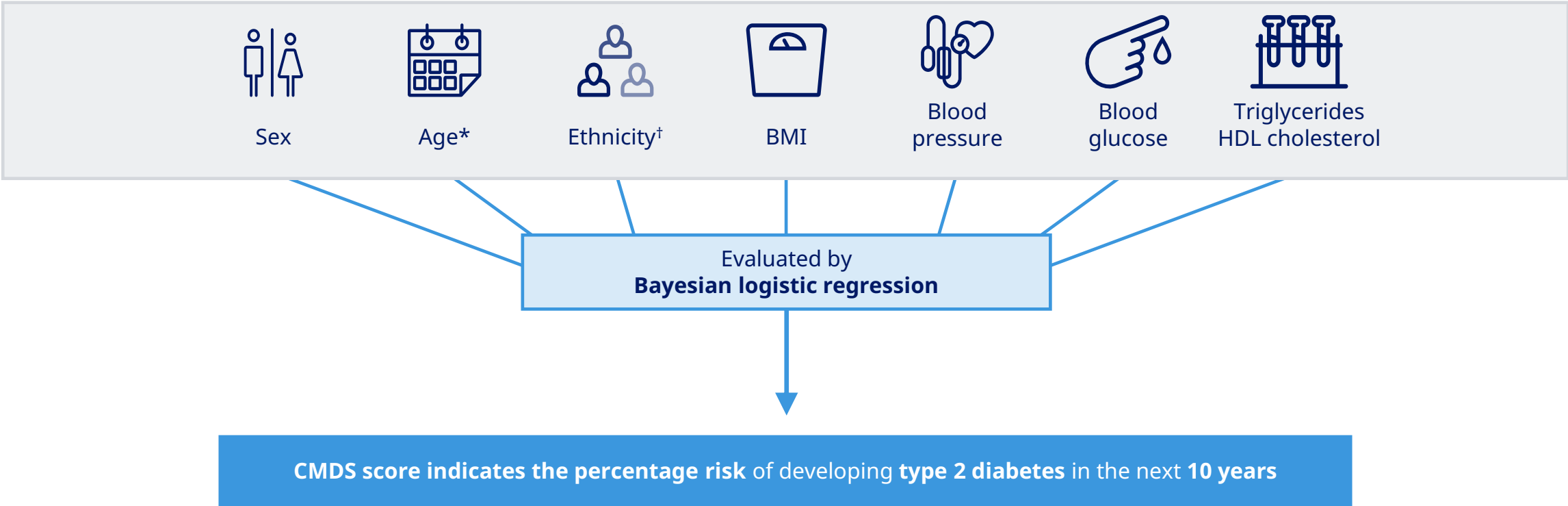
The effect of once-weekly s.c. semaglutide (sema) 2.4 mg on the risk of developing T2D in people with obesity is unknown.

Weight management with sema vs placebo plus diet and exercise was assessed<sup>1</sup> in participants with overweight/obesity in STEP 1 and STEP 4.

<sup>1</sup>The 10-year T2D risk was calculated post hoc using Cardiometabolic Disease Scoring (CMDS).  
 T2D: Type 2 diabetes; s.c.: Subcutaneous; sema: semaglutide  
 Source: Garvey, et. al. Poster 2-LB presented at the 82<sup>nd</sup> Scientific Sessions of the American Diabetes Association 2022, June 3-7, 2022 (New Orleans, LA, USA) meeting)

# Cardiometabolic Disease Scoring (CMDS) is a validated tool to assess 10-year type 2 diabetes risk

CMDS was applied post hoc to the STEP 1 and 4 trials of once-weekly s.c. semaglutide 2.4 mg

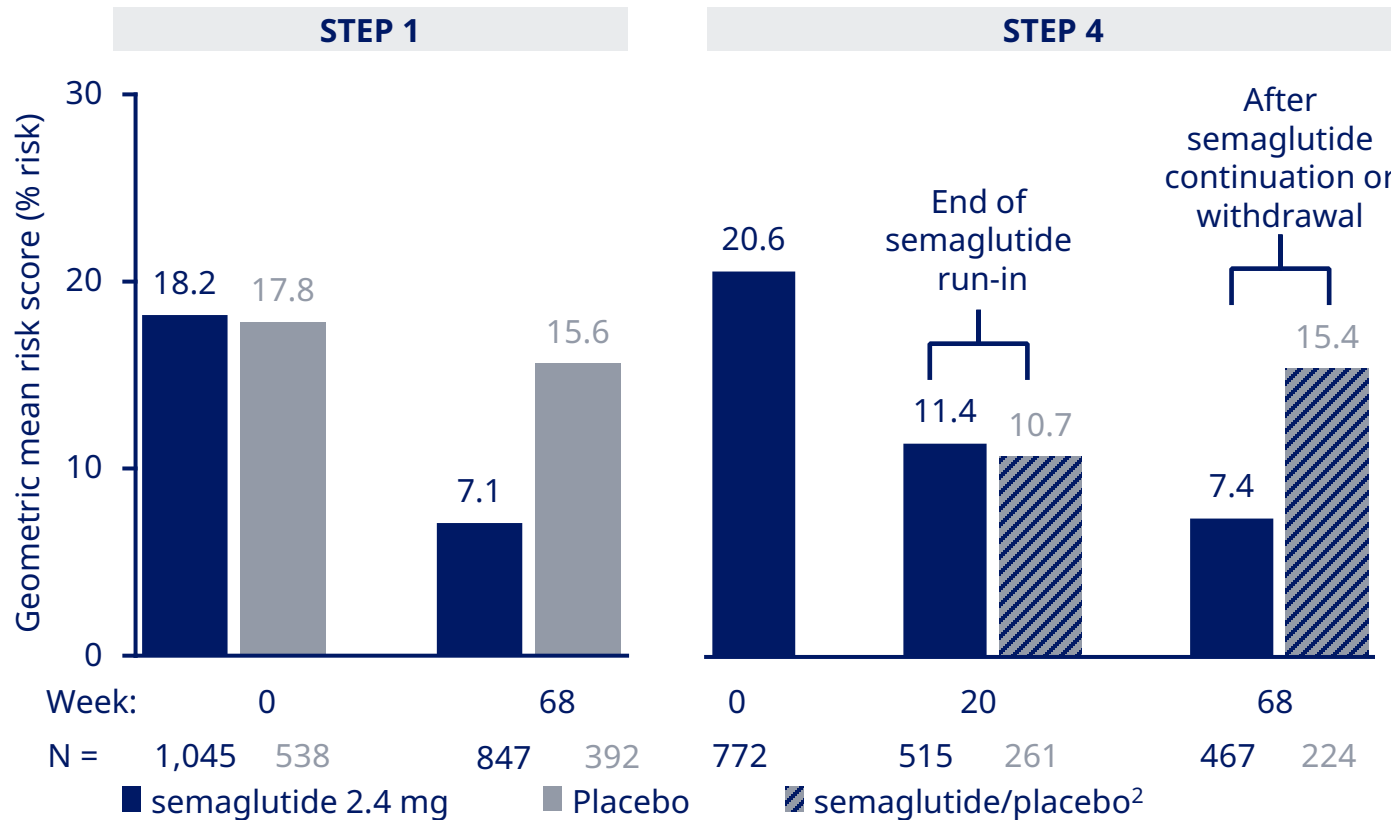


\*CMDS was developed and validated in individuals aged ≥45 years. †CMDS was developed and validated in Black and White individuals. ADA, American Diabetes Association; ARIC, Atherosclerotic Risk in Communities; ATP, Adult Treatment Panel; BMI, body mass index; CMDS, Cardiometabolic Disease Scoring; HDL, high-density lipoprotein; REGARDS, Reasons for Geographic And Racial Differences in StrokeSource Wilkinson L, Yi N, Mehta T, Judd S, Garvey WT. Development and validation of a model for predicting incident type 2 diabetes using quantitative clinical data and a Bayesian logistic model: A nationwide cohort and modeling study. PLoS Med. 2020 Aug 7;17(8):e1003232. doi



# CMDS analysis indicates that sema 2.4 mg reduces the 10-year risk of developing T2D in people with overweight/obesity by ~60%

Absolute 10-year T2D risk scores in the overall STEP 1 and STEP 4



## Semaglutide 2.4 mg could help prevent T2D in people with obesity

- Semaglutide 2.4 mg treatment reduces the 10-year risk of T2D by ~60% regardless of initial glycaemic status
- Sustained treatment required to maintain this benefit
- Treatment effect similar in participants with normoglycaemia and prediabetes

<sup>1</sup>The 10-year T2D risk was calculated post hoc using Cardiometabolic Disease Scoring (CMDS). <sup>2</sup> 20 weeks of semaglutide followed by 48 weeks of placebo  
 T2D: Type 2 diabetes; s.c.: Subcutaneous; sema: semaglutide  
 Source: Garvey, et al. Poster 2-LB presented at the 82<sup>nd</sup> Scientific Sessions of the American Diabetes Association 2022, June 3-7, 2022 (New Orleans, LA, USA)

# Semaglutide 2.4 mg was investigated in an adolescent population in the STEP TEENS phase 3 trial

## Childhood obesity affects the life of many

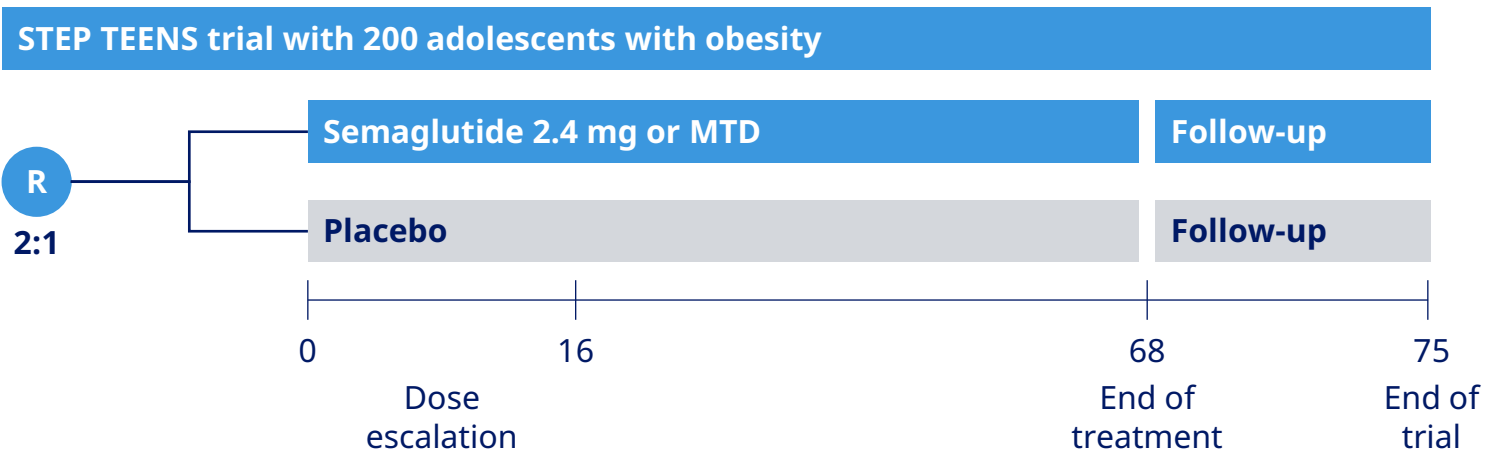


### Characteristics:

- Increasing rapidly
- Associated with multiple obesity-related complications
- Independent risk factor for obesity in adulthood
- Predisposing to both reduced life expectancy and quality of life

Besides Saxenda®, very few pharmacotherapies approved for use in adolescents with obesity

## STEP TEENS comparing the effects and safety and tolerability of sema 2.4 mg vs placebo



### Endpoints

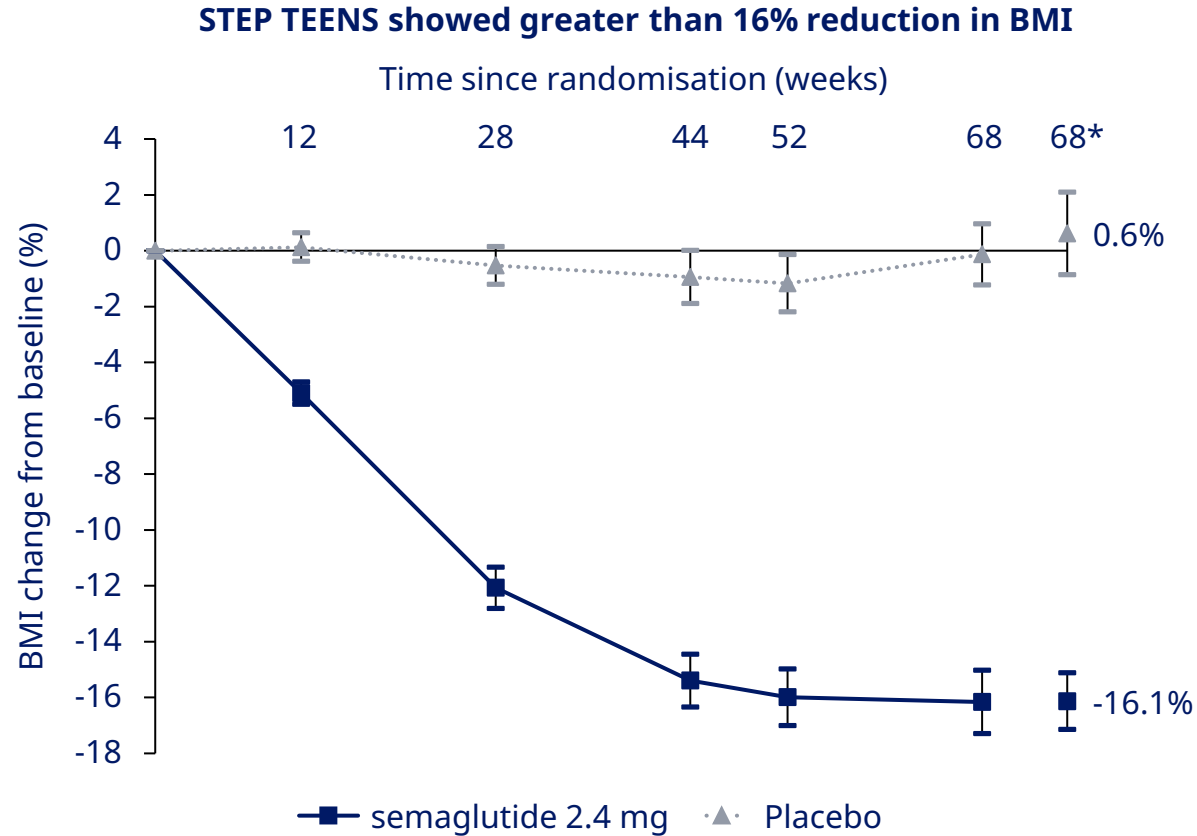
- Primary: Change in BMI (%)
- Confirmatory secondary: ≥5% body weight reduction
- Supporting secondary endpoints include : IWQOL-Kids, lipids, etc.

### Key inclusion criteria


- 12 to <18 years
- Tanner stage 2-5
- BMI ≥95th percentile\* or BMI ≥85th percentile\* with ≥1 weight-related comorbidity<sup>1</sup>


\*On sex-specific BMI-for-age Growth Charts (cdc.gov). <sup>1</sup> Hypertension, dyslipidaemia, obstructive sleep apnoea or Type 2 diabetes  
 MTD: Maximum tolerated dose; s.c.: Subcutaneous; Sema: Semaglutide; BMI: Body Mass Index; IWQOL: Impact of Weight on Quality of Life  
 Source: Atlas of Childhood Obesity, October 2019 (estimating +250m children living with obesity in 2025)

# BMI reduction of 16% in adolescents treated with semaglutide 2.4 mg in the STEP TEENS trial




**Data from STEP TEENS**

-  Average age 15.4 years
- 62% female
- Average BMI of 37.0 kg/m<sup>2</sup>

 **Semaglutide 2.4 mg was superior to placebo on %-change in BMI and 5% body weight responders**

- BMI: 16.7% ETD, 5% body weight responders: 72.5%
- Improvements seen in all other weight-related parameters as well as also CV risk factors and glucose metabolism

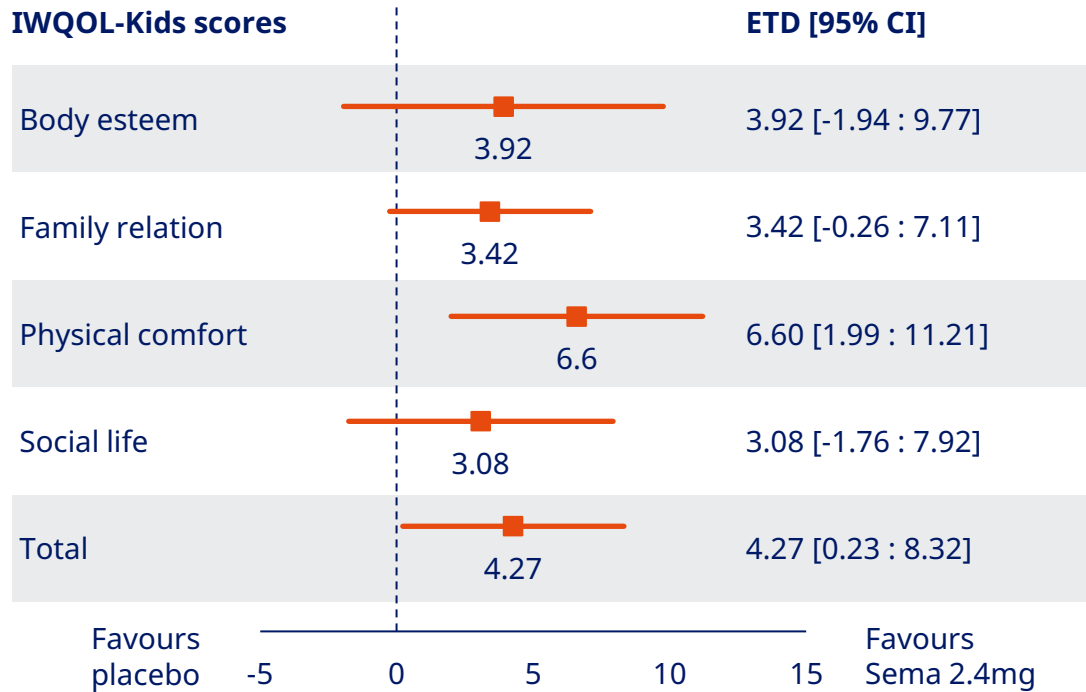
 **Semaglutide 2.4 mg appeared well-tolerated**

- Safety and tolerability were consistent phase 3 data in adults and the GLP-1 RA class in general

\* Lines are based on observed mean data where the value denoted after 68 weeks is the estimated mean value  
Note: Treatment policy estimand  
IWQOL-Kids: Impact of Weight on Quality of Life-Kids; ETD: Estimated treatment difference; CV: Cardiovascular

# First anti-obesity medication showing weight-related quality of life benefit in a study of an adolescent population

**Sema 2.4 mg showed a statistically significant treatment difference versus placebo in the IWQOL-Kids**



## Exploratory endpoint: Impact of Weight on Quality of Life-Kids



Semaglutide 2.4 mg improved weight-related quality of life as measured by IWQOL-kids



Results suggest a benefit of semaglutide 2.4mg vs placebo across all domains giving a statistically significant benefit on total score

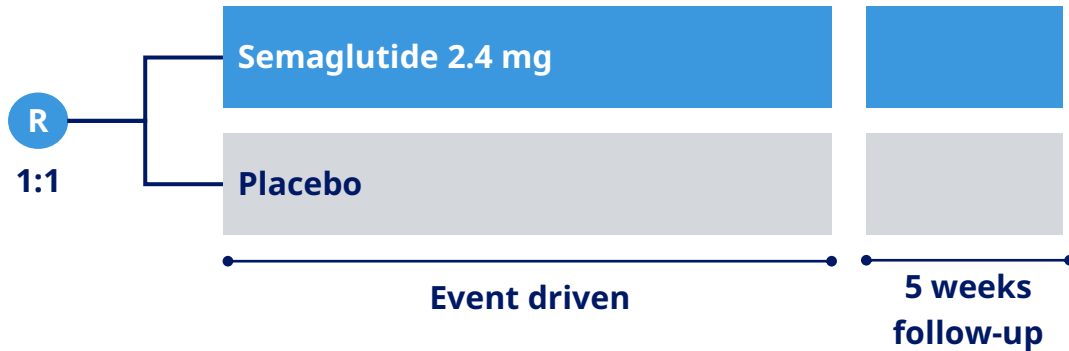


Strongest benefit of semaglutide 2.4mg vs placebo was seen in the physical comfort score (statistically significant)

ETD derived based on multiple imputation; sema: Semaglutide; AOM: Anti-obesity medication  
 IWQOL-Kids: Impact of Weight on Quality of Life-Kids, ETD: estimated treatment difference, CI: confidence interval, Sema: Semaglutide.

# The interim analysis for the SELECT trial is expected to be conducted in the third quarter of 2022

## SELECT trial with 17,500 people with obesity



### Objective

Demonstrate that semaglutide 2.4 mg lowers the incidence of MACE vs placebo

### Primary endpoint

Time from randomisation to first occurrence of MACE<sup>1</sup>

### Secondary endpoints

CV death, all-cause death, 5-point MACE composite, composite HF, composite nephropathy, glucose metabolism, other metabolic parameters

### Stopping at interim

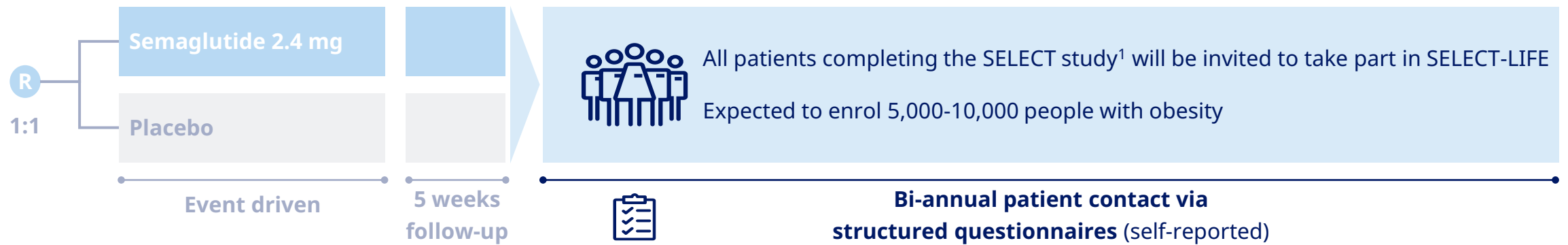
A decision to stop the trial based on the interim analysis follows assessment of the totality of the data

<sup>1</sup> MACE includes non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death. MACE: Major adverse cardiovascular events; HF: Heart failure; CV: Cardiovascular

# SELECT-LIFE is a 10-year observational follow-up study with twice-yearly collection of self-reported patient data

SELECT trial with 17,500 people with obesity

SELECT-LIFE extension 10-year extension



## Purpose of SELECT-LIFE

Improve understanding of obesity and its complications, positively impact future treatment guidelines and contribute to improved clinical care in people living with obesity and CVD



Regular data publications are expected

## Examples of endpoint focus areas

Survival

Cardiovascular events

Type 2 diabetes

Obesity-related complications

<sup>1</sup> Within countries participating in SELECT-LIFE  
CVD: Cardiovascular Disease



# Obesity: Key take-aways

A post hoc analysis of STEP 1 and 4 indicates a ~60% reduction in the 10-year risk of developing type 2 diabetes

STEP TEENS in adolescents reads out with around 16% reduction in BMI

SELECT interim analysis expected to be conducted in the third quarter of 2022

SELECT-LIFE, a 10-year observation follow-up study, to improve understanding of obesity and its complications long-term



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# Investigating semaglutide effects beyond glucose lowering in people with type 2 diabetes



## FOCUS

### Diabetic retinopathy outcomes trial

Semaglutide 1.0 mg, injectable + standard of care

- ~1,500 patients with T2D for 10 or more years
- Primary endpoint: Presence of  $\geq 3$  steps ETDRS patient level progression
- Estimated completion in 2027



## SOUL

### Cardiovascular outcomes trial

Semaglutide 14 mg, oral

- ~9,600 patients with T2D, established CVD or CKD
- Primary endpoint: Time to first major adverse cardiovascular event<sup>1</sup>
- Estimated completion in 2024



## FLOW

### Chronic kidney disease outcomes trial

Semaglutide 1.0 mg, injectable

- ~3,500 patients with T2D, moderate to severe CKD
- Primary endpoint: Time to first occurrence of a composite outcome event<sup>2</sup>
- Estimated completion in 2024

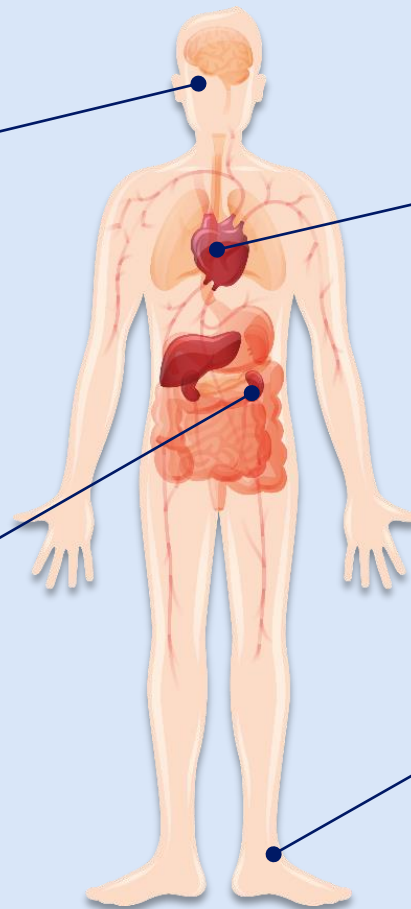


## STRIDE

### Peripheral arterial disease

Semaglutide 1.0 mg, injectable

- ~800 patients with type 2 diabetes and PAD
- Primary endpoint: Change in maximum walking distance
- Estimated completion in 2024



<sup>1</sup>Major adverse cardiovascular event defined as CV death, non-fatal stroke or non-fatal myocardial infarction; <sup>2</sup>Defined as persistent eGFR decline of  $\geq 50\%$  from trial start, reaching end stage renal disease, death from kidney disease or death from cardiovascular disease  
T2D: Type 2 diabetes; CVD: Cardiovascular disease; PAD: Peripheral arteries disease; ETDRS: Early treatment diabetic retinopathy study; CKD: Chronic kidney disease

# Investigating semaglutide effects beyond glucose lowering in people with type 2 diabetes

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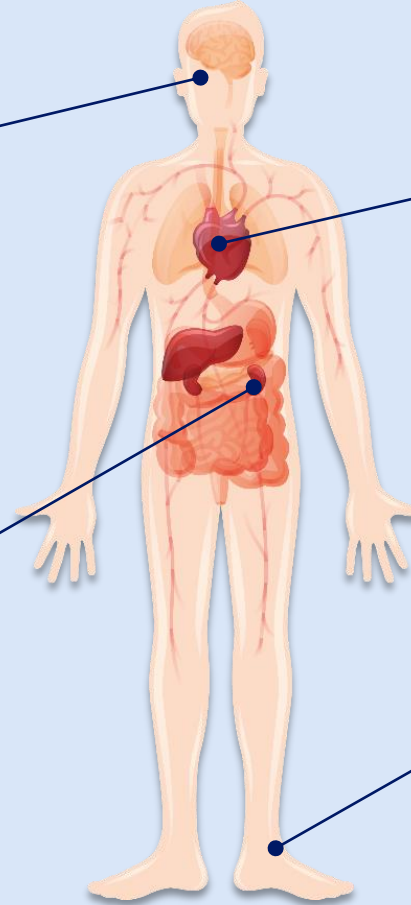
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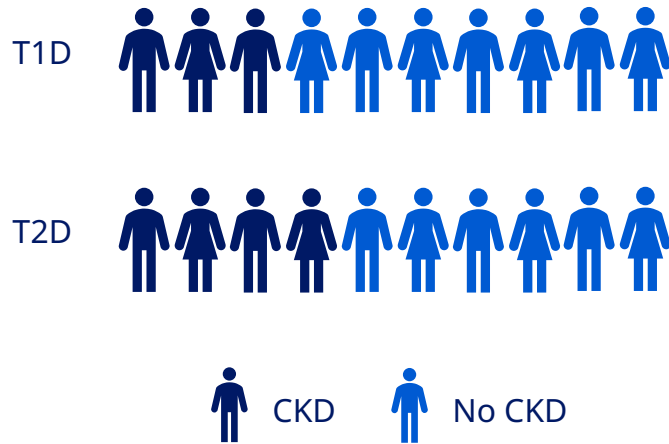
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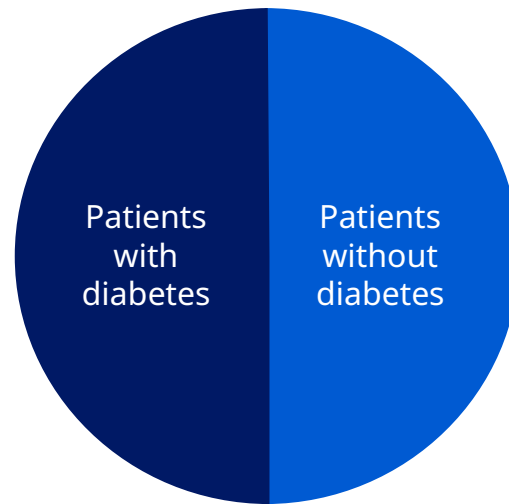
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T2D: Type 2 diabetes; CVD: Cardiovascular disease; PAD: Peripheral arteries disease; ETDRS: Early treatment diabetic retinopathy study; CKD: Chronic kidney disease

# Chronic kidney disease is common in patients with diabetes and remains a large unmet need

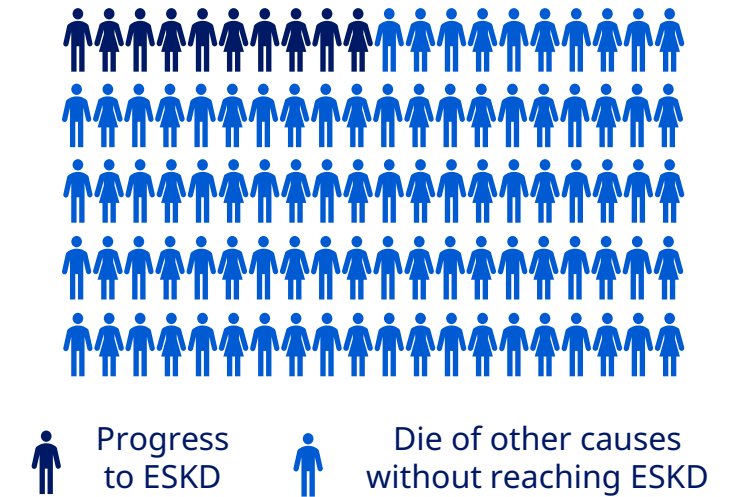
Chronic kidney disease (CKD) is common in patients with diabetes



Diabetes is directly correlated with ~ 50% of all ESKD cases

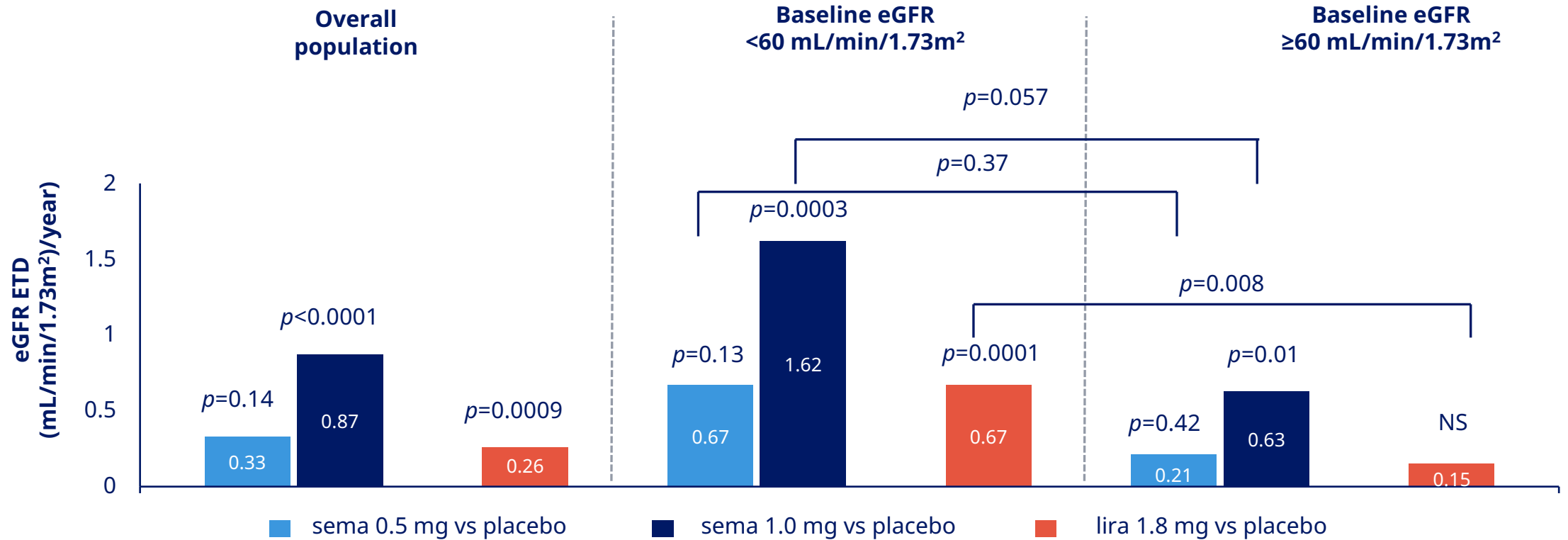


10 in 100<sup>1</sup> patients with diabetic kidney disease progress to ESKD



<sup>1</sup>4-17% at 20 years  
CKD: Chronic Kidney Disease; ESKD: End Stage Kidney Disease; T1D: Type 1 diabetes; T2D: type 2 diabetes  
Sources: Alicic RZ et al. Clin J Am Soc Nephrol 2017; Zelnick LR et al. Clin J Am Soc Nephrol 2017; Ghaderian SB et al. J Renal Inj Prev 2015; Pálsson R & Patel UD. Adv Chronic Kidney Dis 2014; Afkarian M et al. J Am Soc Nephrol 2013

# Attenuated loss of kidney function observed across SUSTAIN 6 and LEADER



CI: confidence interval; eGFR: estimated glomerular filtration rate; HR, hazard ratio; ETD: Estimated treatment difference; eGFR: estimated glomerular filtration rate; Sema: Semaglutide; Lira: Liraglutide; NS: Non-significant  
 Source: Presented at the 56th European Renal Association - European Dialysis and Transplant Association (ERA-EDTA) Congress, 13-16 June 2019; Budapest, Hungary, Poster F482

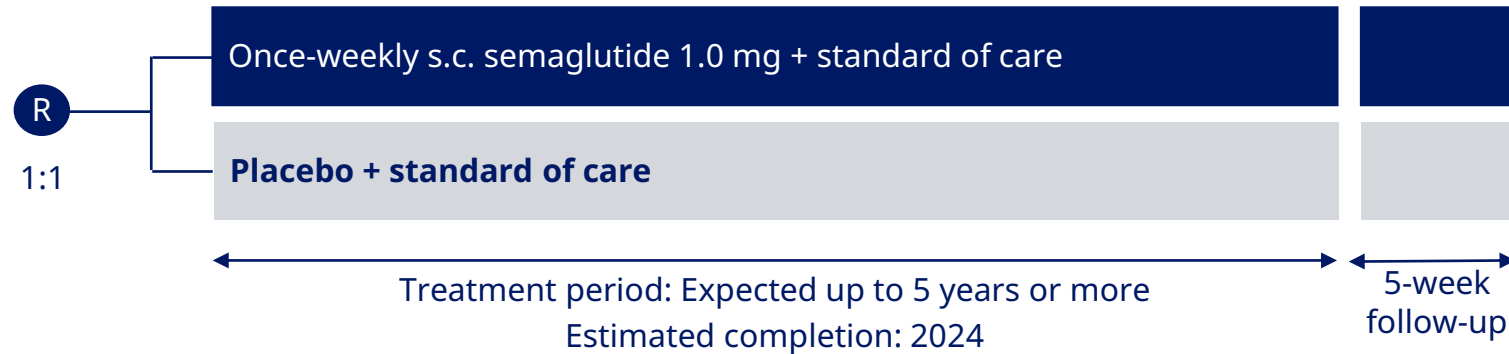


# Semaglutide 1.0 mg is investigated in people with diabetes and chronic kidney disease in the ongoing phase 3b trial FLOW

## Phase 3b trial for semaglutide 1.0 mg in ~3,500 people with type 2 diabetes and chronic kidney disease

### Inclusion

- T2D, HbA<sub>1c</sub> ≤10%
- eGFR ≤75 to ≥50<sup>1</sup> and UACR >300 to <5,000 mg/g OR eGFR <50 to ≥25<sup>1</sup> and UACR >100 to <5,000 mg/g
- RAAS blocker



### Trial objective

- Demonstrate that semaglutide delays the progression of renal impairment and lowers risk of renal - and CV mortality

### Primary end-points

- Time to first occurrence of a composite endpoint:
- Onset of persistent ≥50% reduction in eGFR
  - Onset of persistent eGFR <15 mL/min/1.73 m<sup>2</sup>
  - Initiation of chronic renal replacement therapy (dialysis or kidney transplantation)
  - Renal death
  - CV death

### Secondary end-points

- Change in eGFR (total eGFR slope)
- 3-point MACE
- All-cause death

<sup>1</sup> mL/min/1.73 m<sup>2</sup>  
 T2D: Type 2 diabetes; UACR: Urine albumin-creatinine ratio; RAAS: Renin-angiotensin-aldosterone system; CV: Cardiovascular; MACE: Major adverse cardiovascular events; eGFR: estimated glomerular filtration rate; Sc: Subcutaneous

# FLOW is investigating kidney outcomes and the role of GLP-1 in a trial population with multiple risk factors and comorbidities

## Trial baseline characteristics

	Trial population, N=3,535
Age, years mean (SD)	66.6 (9.0)
HbA <sub>1c</sub> , % mean (SD)	7.8 (1.3)
Diabetes duration, years mean (SD)	17.4 (9.3)
eGFR, mL/min/1.73m <sup>2</sup> mean (SD)	47.0 (15.1)
UACR, mg/g, median (min.-max.)	567 (1-11,852)
<b>Diabetic comorbidities</b>	
Diabetic neuropathy <sup>1</sup> (%)	1,519 (43.0)
Diabetic retinopathy in at least one eye <sup>2</sup> (%)	1,578 (44.6)
Diabetic macular edema in at least one eye <sup>2</sup> (%)	241 (6.8)
Very high CKD progression risk, n (%)	2,414 (68.2%)

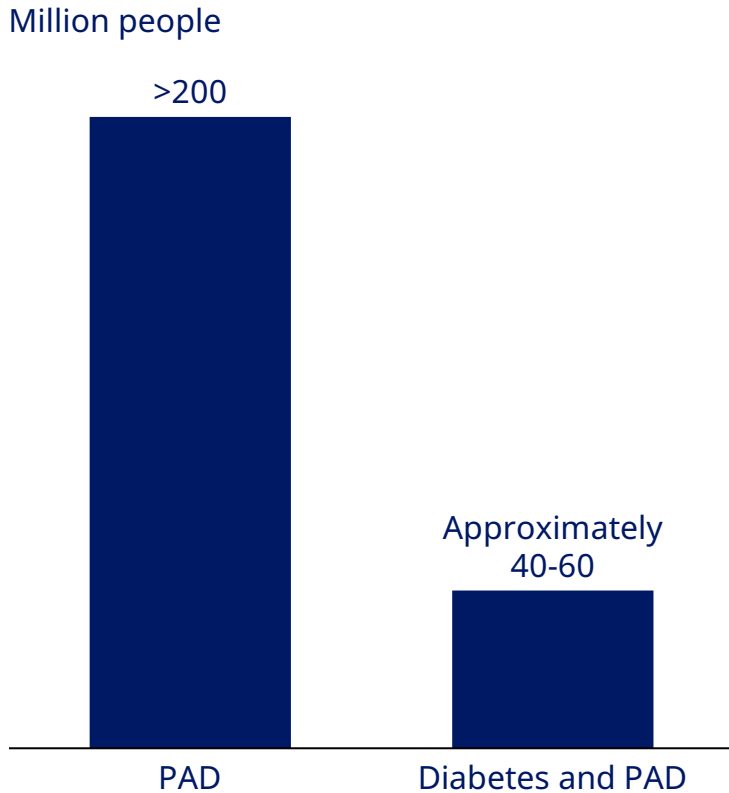
## Key take-aways

- First and only kidney outcomes trial specifically designed and powered to assess whether treatment with a GLP-1 can reduce risk of kidney failure and loss of kidney function
- Patients with high risk of CKD progression with long diabetes duration, high medication use and prevalent comorbidities
- No observed association of HbA<sub>1c</sub> or diabetes duration with KDIGO risk category
- FLOW, alongside SOUL, SELECT and REMODEL trials, will assess the effect of semaglutide in the interconnected disease areas of CKD, T2D, obesity and CVD

<sup>1</sup>Based on medical history; <sup>2</sup>Based on eye examination at baseline  
 UACR: Urine albumin-creatinine ratio; CKD: Chronic kidney disease; SD: Standard deviation; eGFR: estimated glomerular filtration rate; T2D: Type 2 diabetes; CVD: Cardiovascular disease; KDIGO: Kidney Disease: Improving Global Outcomes  
 Source: ADA 2022 poster 747-P: Baseline characteristics of subjects in the once-weekly semaglutide FLOW kidney outcomes trial (diabetes status)


# Limited treatment options for the millions of people with type 2 diabetes and peripheral artery disease (PAD)


20-30% of people with PAD have diabetes





People with type 2 diabetes are at higher risk of suffering from PAD

**Factors increasing risk of PAD in people with type 2 diabetes**

  
 Duration of diabetes


  
 Age


  
 Presence of peripheral neuropathy

  
 Poor glycaemic control

---

**Low diagnosis rates and limited treatment options**

 Difficult to diagnose due to peripheral neuropathy

 Treatment is

- diet, exercise, secondary prevention medicine
- endovascular treatment and surgical thromboendarterectomy
- open surgical revascularisation or amputation

**Unmet need:** Limited treatment options for people with type 2 diabetes and PAD

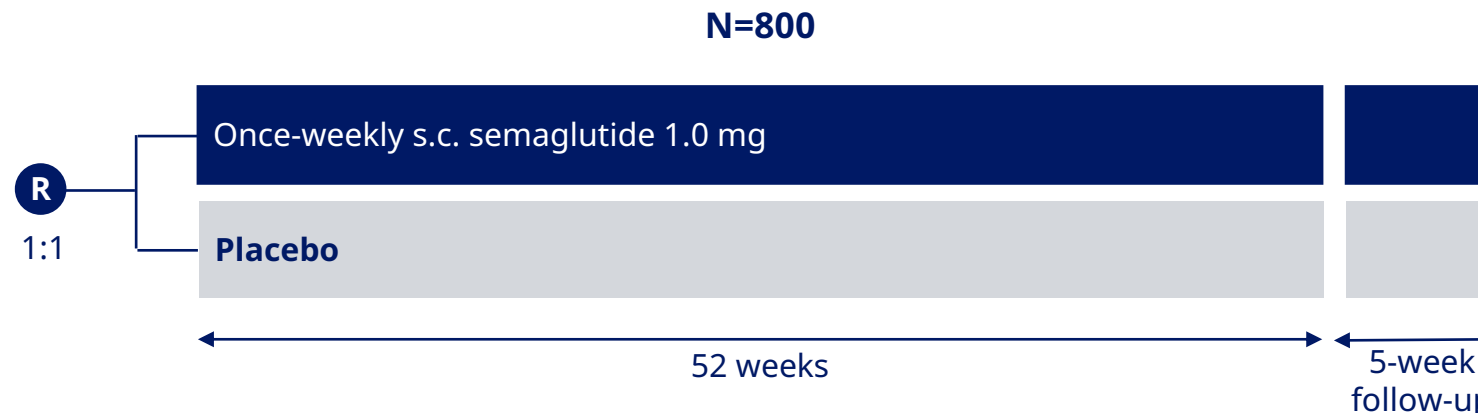
PAD: Peripheral artery disease; MACE: Major adverse cardiovascular events. Sources: Fowkes FG et al. Lancet 2013;382:1329-40 (LHS). RHS: Thiruvoipati T et al. World J Diabetes 2015;6:961-69 (RHS); Aboyans V et al. Eur Heart J 2018;39:763-816; Gerhard-Herman MD et al. Circulation 2017;135:e686-e725; Komai H. Ann Vasc Dis 2019;12:151-6; Salhiyyah K et al. Cochrane Database Syst Rev. 2015;9(9):CD005262; Hennion DR and Siano KA. Am Fam Physician. 2013 Sep 1;88(5):306-310.

# The ongoing STRIDE phase 3a trial investigates semaglutide for the treatment of peripheral artery disease in people with T2D

Phase 3a trial (STRIDE) for semaglutide 1.0 mg in type 2 diabetes for treatment of PAD expected to read out in 2024

## Inclusion criteria

- Adults with T2D and PAD
- Intermittent claudication stage Fontaine IIa ≥ 3 months
- Max walking distance ≤ 600m



## Primary end-point

Change in maximum walking distance on a constant load treadmill test

## Secondary end-points

- Change in pain-free walking distance on a constant load treadmill test
- Change in Vascular Quality of Life Questionnaire-6 (VascuQoL-6) score

## Next steps

Estimated completion is during 2024

# GLP-1: Key take-aways

Chronic kidney disease and peripheral artery disease have large overlaps with diabetes, with a large population affected and a high unmet need

Evidence from previous GLP-1 trials forms the basis for the decision for Novo Nordisk to address new disease areas

Novo Nordisk continues to investigate opportunities to expand the label of semaglutide through eg FLOW, SOUL, FOCUS and STRIDE



# Agenda

## Introduction

Karsten Munk Knudsen

## Obesity care

*Post hoc analysis of STEP 1 and 4, STEP TEENS results and SELECT-LIFE*

Martin Holst Lange

## GLP-1 Diabetes

*Semaglutide in chronic kidney disease and peripheral artery disease*

Mads Frederik Rasmussen

## Insulin

*Insulin icodec hypoglycaemia frequency, results from ONWARDS 1, ONWARDS 2, and ONWARDS 6*

Martin Holst Lange

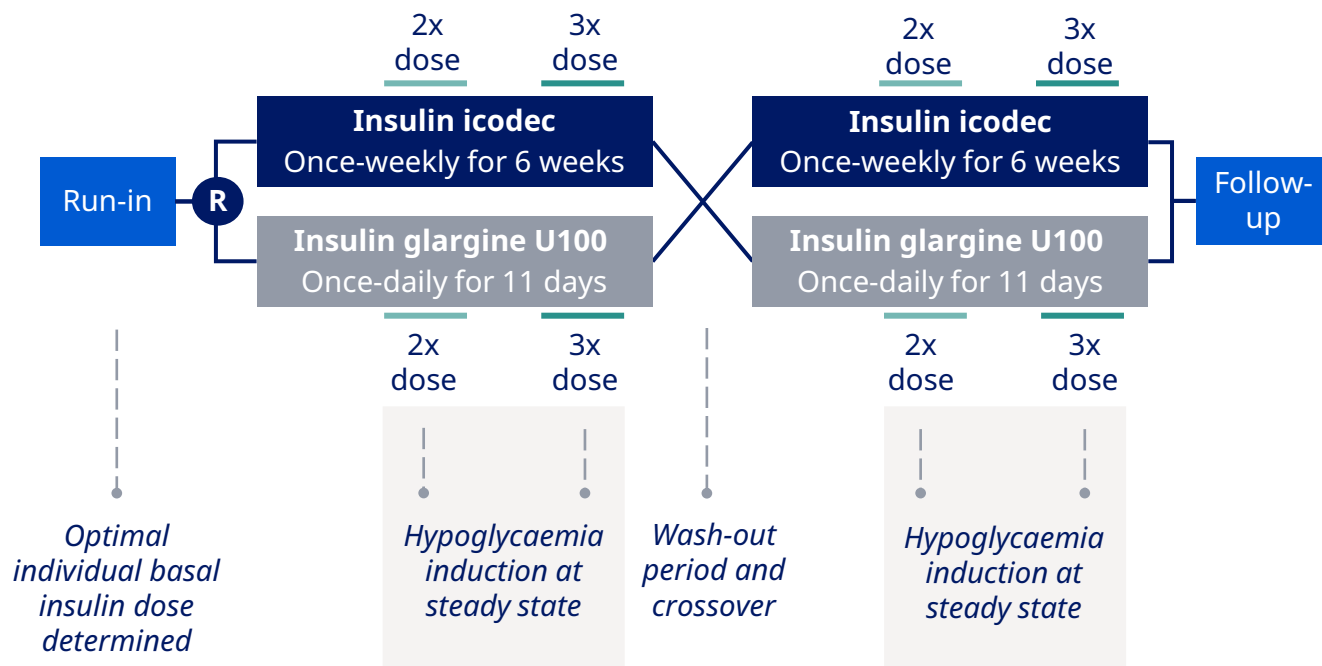
## Q&A

All



# Hypoglycaemia frequency and physiological response to double or triple doses of insulin icodec vs insulin glargine U100

## Design of the two-period crossover trial



## Objective

To compare between once-weekly insulin icodec and once-daily insulin glargine U100 in people with type 2 diabetes

Specifically:

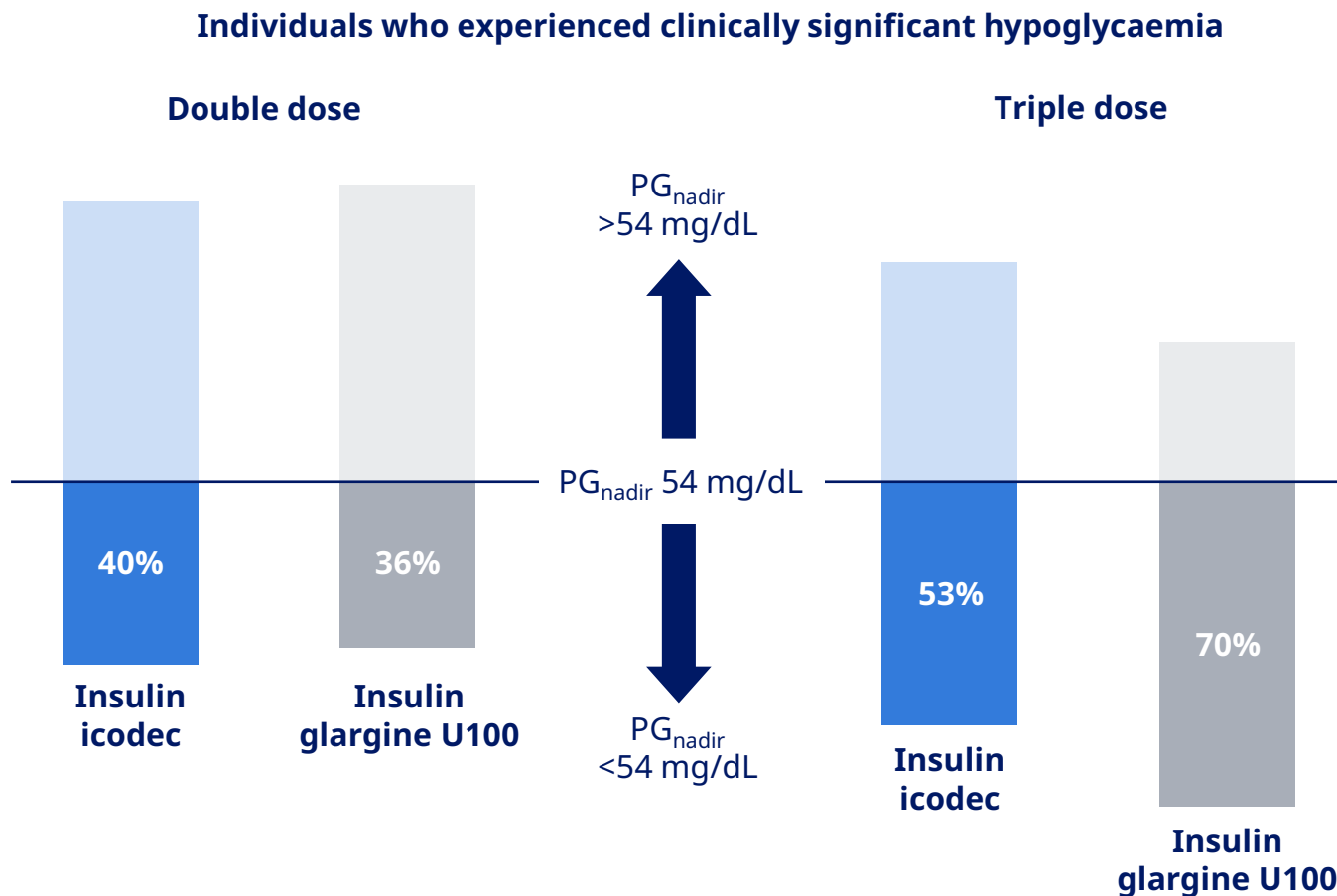
- **Hypoglycaemia frequency** after double or triple doses
- **Physiological response to hypoglycaemia** after a triple dose in patients with plasma glucose <54 mg/dL and/or hypoglycaemia symptoms

## Inclusion criteria

- **43 people with T2D** on basal insulin ± OAD
- **Age:** 18-72 years
- **HbA<sub>1c</sub>:** ≤9.0%
- **BMI :** 18.5-37.9 kg/m<sup>2</sup>

T2D: Type 2 diabetes; OAD: Oral anti-diabetic; BMI: Body mass index  
 Source: Pieber T, Arfelt K, Cailleateau R, et al. Hypoglycaemia Frequency and Physiological Response to Double or Triple Doses of Once-Weekly Insulin Icodec vs Once-Daily Insulin Glargine in Type 2 Diabetes. American Diabetes Association 82nd Session. Session: Insulins. Oral presentation 216-OR; 2022 Jun 3-7. New Orleans, LA.

# Comparable clinically significant hypoglycaemia for insulin icodec vs insulin glargine U100 in the trial



**Key findings**

**Hypoglycaemia frequency**

Comparable proportions of individuals experienced clinically significant hypoglycaemia with once-weekly insulin icodec vs once-daily insulin glargine U100 after double and triple doses

**Physiological response to hypoglycaemia after 3x dose**

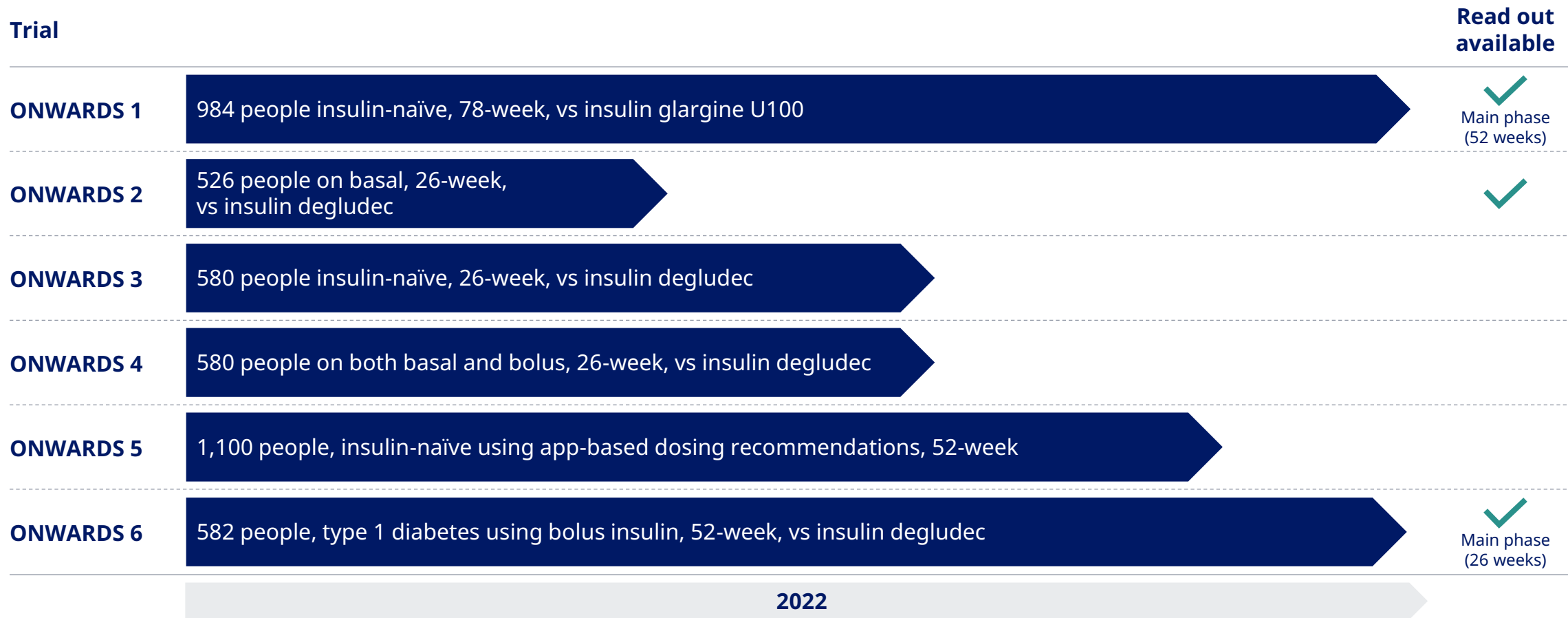
During hypoglycaemia, a comparable symptomatic response and a moderately greater endocrine response were seen for insulin icodec

**Overall safety**

No severe hypoglycaemic episodes during the treatment periods and no serious AEs following the induced hypoglycaemic episodes or during the trial overall

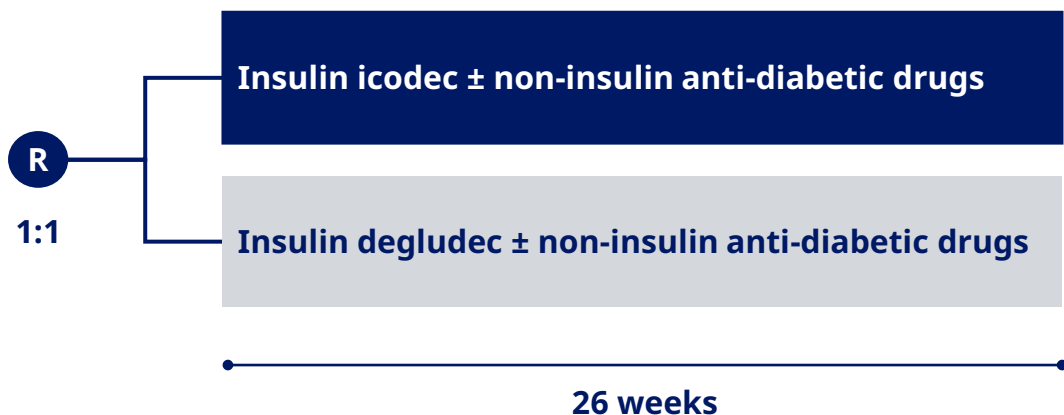
AE: Adverse events; PG: Plasma glucose  
 Source: Pieber T, Arfelt K, Cailleateau R, et al. Hypoglycemia Frequency and Physiological Response to Double or Triple Doses of Once-Weekly Insulin Icodec vs Once-Daily Insulin Glargine in Type 2 Diabetes. American Diabetes Association 82nd Session. Session: Insulins. Oral presentation 216-OR; 2022 Jun 3-7. New Orleans, LA.

# The first three trials of the ONWARDS programme have read out



# ONWARDS 2 was completed as the first of six trials in the phase 3 programme for once-weekly insulin icodec

The ONWARDS 2 phase 3a trial has been completed




Included 526 people with type 2 diabetes

### Objective

To confirm the efficacy (non-inferiority on HbA<sub>1c</sub>) and safety of once-weekly insulin icodec in patients with type 2 diabetes treated with basal only insulin

### Primary endpoint

- Change in HbA<sub>1c</sub> from baseline to week 26

### Inclusion criteria

- T2D treated with basal insulin ± OADs\* ± GLP-1 s.c.
- Age ≥18 years
- HbA<sub>1c</sub> 7-10%
- BMI ≤ 40 kg/m<sup>2</sup>

\*Pre-trial all OADs including oral GLP-1s are allowed but SU and glinides are to be discontinued at randomisation  
T2D: Type 2 diabetes; OAD: Oral anti Diabetics; s.c.: subcutaneous; BMI: Body mass index, SU: Sulfonylurea

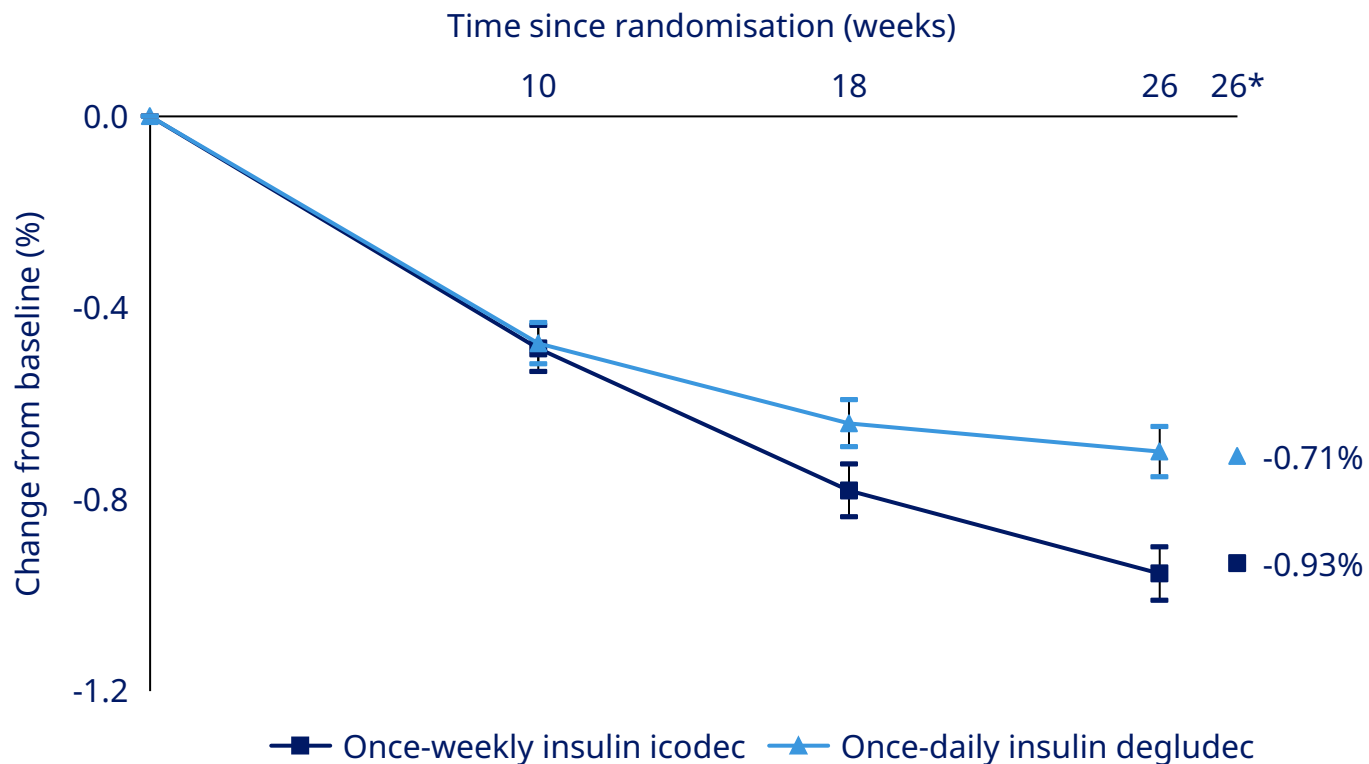
# Simple and easy titration for insulin icodec in the ONWARDS programme

	Pre-breakfast SMPG		Dose adjustment insulin icodec	Dose adjustment comparator
	mmol/L	mg/dL		
Lowest of the SMPG values	<4.4	<80	-20	-3
Mean of the SMPG values	4.4–7.2	80–130	0	0
	>7.2	>130	+20	+3

SMPG: Self-measured plasma glucose; mmol/L: Millimoles per litre  
 Note: Starting dose: 70U weekly (Ico) and 10U daily (IGlar) Dose adjustment based on the three pre-breakfast SMPG values measured on two days prior to titration and on the day of the titration

# ONWARDS 2 met its primary endpoint and demonstrated superiority on HbA<sub>1c</sub> reduction compared to insulin degludec

Superior change in HbA<sub>1c</sub> from baseline over time 26 weeks



Note: Overall baseline HbA<sub>1c</sub> of 8.13%

## Key highlights

### Primary endpoint:

- From an overall baseline HbA<sub>1c</sub> of 8.13%, once-weekly insulin icodec achieved a superior reduction in estimated HbA<sub>1c</sub> compared to insulin degludec
- Estimated treatment difference: -0.22%

\* Lines are based on observed data where the value denoted after 26 weeks is estimated mean value derived based on multiple imputation

# No statistically significant difference in hypoglycaemic events in ONWARDS 2

Overall hypoglycaemic episodes in the trial

On treatment	Insulin icodec				Insulin degludec			
	N	(%)	E	R	N	(%)	E	R
<b>Level 2:</b> Clinically significant hypo	37	(14.1)	1.13	0.73	19	(7.2)	0.41	0.27
<b>Level 3:</b> Severe hypo	0				1	(0.4)	0.01	0.01
<b>Level 3 or 2:</b> Severe or clinically significant hypo	37	(14.1)	1.13	0.73	19	(7.2)	0.42	0.27

## Key highlights

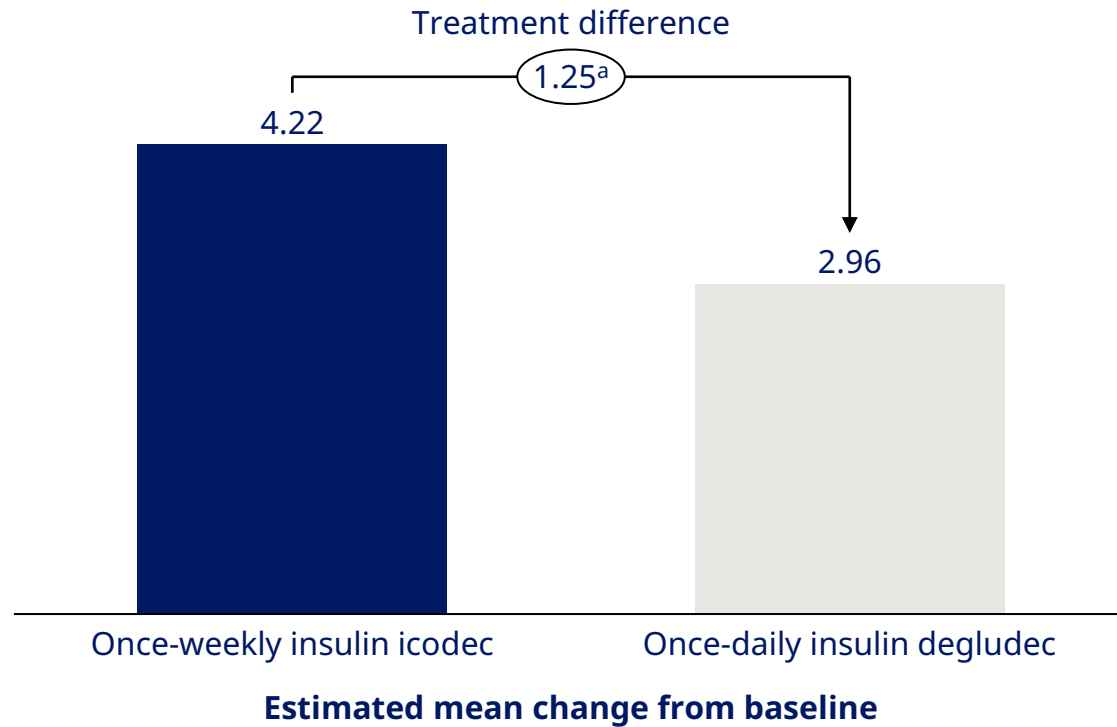
- No statistically significant difference in estimated rates of severe or clinically significant hypoglycaemia events
- 0.73 events<sup>1</sup> for insulin icodec and 0.27 events for insulin glargine
- In the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile

<sup>1</sup> Events measured as per patient year  
 Hypo: hypoglycaemia; N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of events, R: Rate (number of events per patient year of exposure, hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by blood glucose meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Note: Lines in graph 1 are based on observed data where the value denoted after 26-week is estimated mean value

# ONWARDS 2 showed a statistically significant improvement in quality of life compared to insulin degludec

## ONWARDS 2 quality of life assessment

Treatment satisfaction score



## ONWARDS 2 treatment satisfaction

Patient reported clinical outcome assessments via a Diabetes Treatment Satisfaction Questionnaire (DTSQ) without assistance of site personnel

The DTSQs were measured at baseline and end of treatment and the treatment satisfaction is evaluated across six dimensions including:

- Convenience
- Flexibility
- Satisfaction
- Recommend treatment

### Conclusion

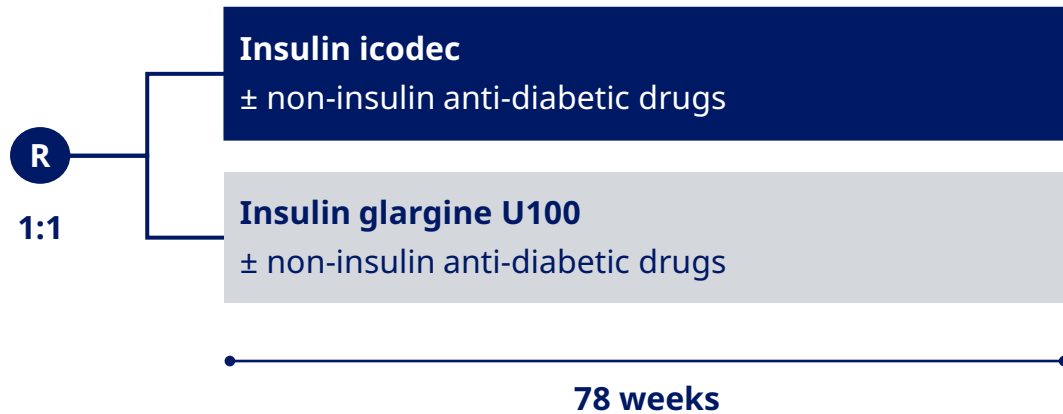
- Statistically significant improvement of treatment satisfaction score in favour of insulin icodec

<sup>a</sup> Treatment difference = 1.25 [0.41;2.10]95% CI,, P value: 0.0036



# ONWARDS 1 comparing insulin icodec in insulin-naïve patients with insulin glargine U100

## ONWARDS 1 trial design



 **Included 984 people with type 2 diabetes**

### Objective

To confirm the efficacy (non-inferiority on HbA<sub>1c</sub>) and safety of once-weekly insulin icodec in insulin-naïve patients with type 2 diabetes

### Primary endpoint

- Change in HbA<sub>1c</sub> from baseline to week 52

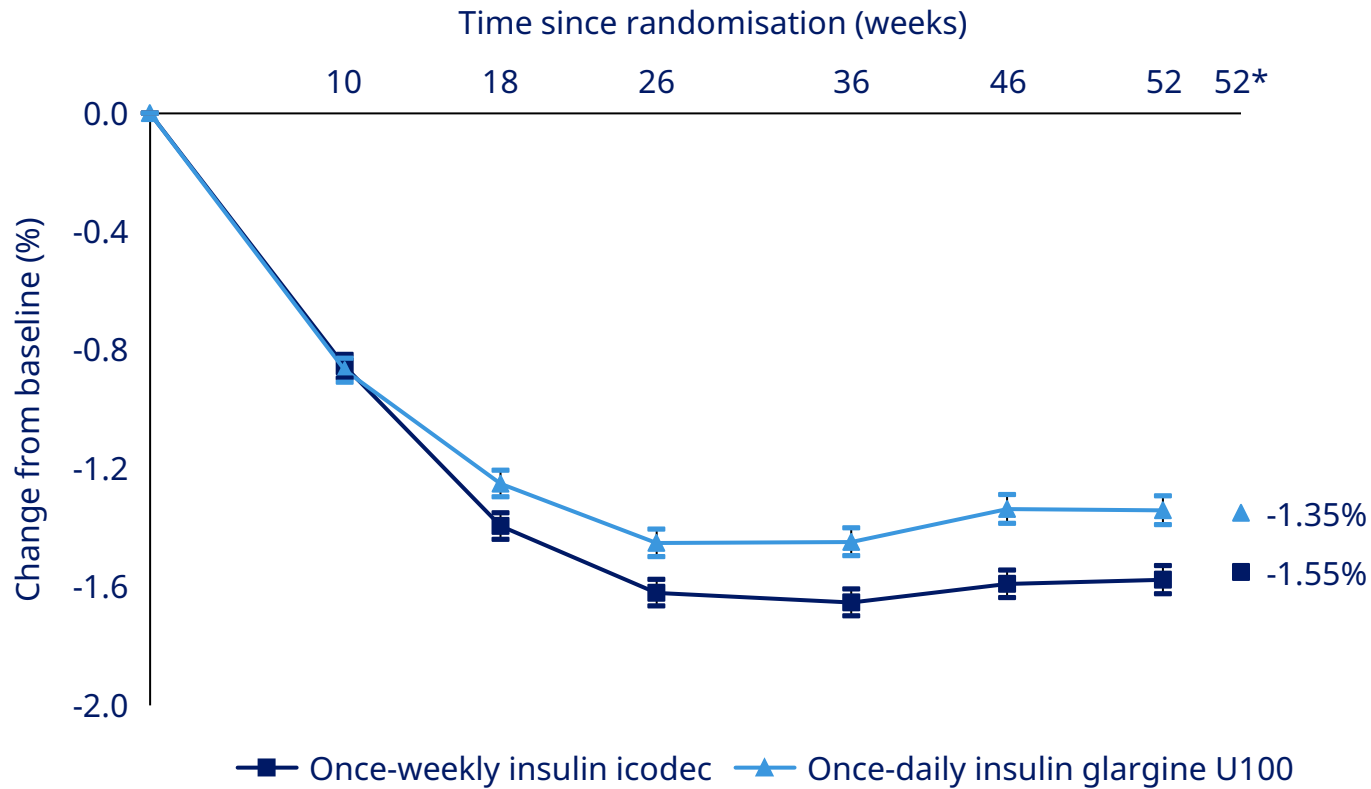
### Inclusion criteria

- T2D treated with OADs\* ± GLP-1 s.c.
- Age ≥ 18 years
- HbA<sub>1c</sub> 7.0-11.0%
- BMI ≤ 40 kg/m<sup>2</sup>

\*Pre-trial all OADs including oral GLP-1s are allowed but SU and glinides are to be discontinued at randomisation  
T2D: Type 2 diabetes; OAD: Oral anti Diabetics; s.c.: Subcutaneous; BMI: Body mass index, SU: Sulfonylurea

# ONWARDS 1 met its primary endpoint and demonstrated superior HbA<sub>1c</sub> reduction compared to insulin glargine U100

Superior change in HbA<sub>1c</sub> from baseline over time 52 weeks



Note: Overall baseline HbA<sub>1c</sub> of 8.5%

## Key highlights from main phase

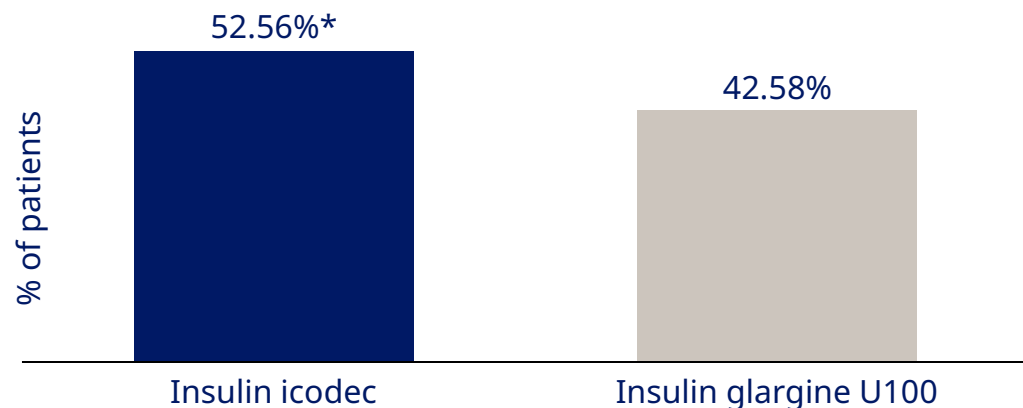
### Primary endpoint:

- 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 -1.55% compared to -1.35% for insulin glargine U100
- Estimated treatment difference: -0.19%

\*Lines are based on observed data where the value denoted after 52 weeks is estimated mean value derived based on multiple imputation

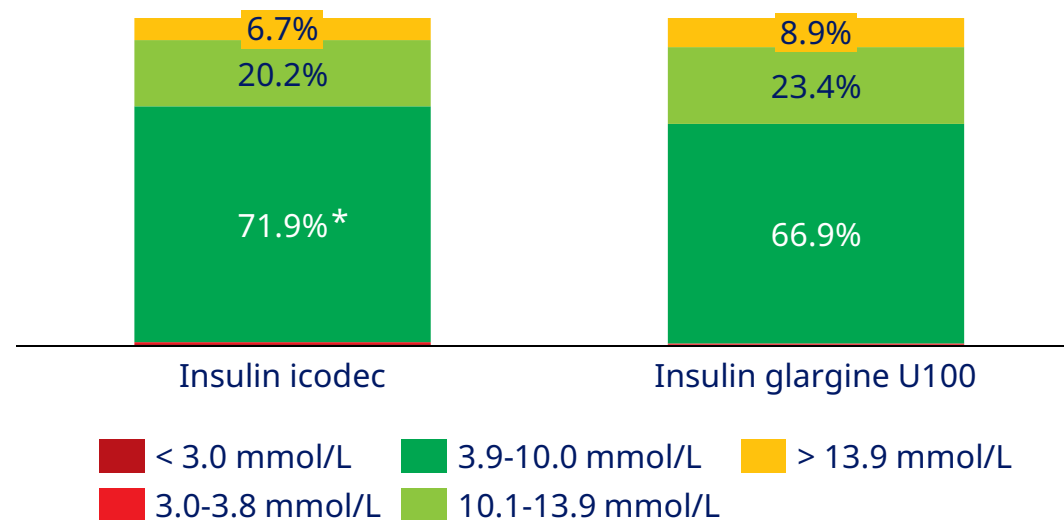
# With insulin icodec, more patients reached HbA<sub>1c</sub> target without hypoglycemia and achieved superior time in range

**Achievement of HbA<sub>1c</sub> target after 52 weeks without hypoglycemia<sup>1</sup>**



EOR = 1.49 [1.15, 1.94] 95% CI

**Superior time in range for insulin icodec vs insulin glargine U100**



■ < 3.0 mmol/L    ■ 3.9-10.0 mmol/L    ■ > 13.9 mmol/L  
■ 3.0-3.8 mmol/L    ■ 10.1-13.9 mmol/L

## Achievement of HbA<sub>1c</sub> target <7.0%

- More participants achieved the HbA<sub>1c</sub> target without any severe or clinically significant hypoglycaemia when treated with insulin icodec compared to insulin glargine U100

## Time in range

- 3.9–10.0 mmol/L from week 48 to week 52 was 71.94% with insulin icodec and 66.90% with insulin glargine U100, confirming superiority of insulin icodec vs insulin glargine U100
- Broadly equal to one additional hour in range per day

<sup>1</sup> Specifically an HbA<sub>1c</sub> <7% without level 2 or 3 hypoglycaemic episodes; \* Statistically significant difference in favour of insulin icodec. CI: Confidence interval, No correction for multiplicity. HbA<sub>1c</sub>: Haemoglobin A<sub>1c</sub>. The binary response after 52 weeks is analysed using a binary logistic regression model (logit link) with treatment and region as fixed factors, and the baseline HbA<sub>1c</sub> value as covariate. Missing HbA<sub>1c</sub> measurements are imputed using the same method as specified for the primary analysis before the target achievement criterion is applied; EOR: Estimated odds ratio

# No statistically significant difference in hypoglycaemic events in ONWARDS 1

Overall hypoglycaemic episodes in the trial

On treatment	Insulin icodec				Insulin glargine U100			
	N	(%)	E	R	N	(%)	E	R
<b>Level 2:</b> Clinically significant hypo	48	(9.8)	1.43	0.29	49	(10.0)	0.75	0.15
<b>Level 3:</b> Severe hypo	1	(0.2)	0.01	0.00	3	(0.6)	0.03	0.01
<b>Level 3 or 2:</b> Severe or clinically significant hypo	48	(9.8)	1.44	0.30	52	(10.6)	0.78	0.16

Key highlights from main phase

**Safety**

- No statistically significant difference in estimated rates of severe or clinically significant hypoglycaemia events
  - 0.30 events<sup>1</sup> for insulin icodec and 0.16 events for insulin glargine U100
- Insulin icodec appeared to have a safe and well-tolerated profile

<sup>1</sup> Events measured per patient year  
 Hypo: hypoglycaemia; N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of events, R: Rate (number of events per patient year of exposure, hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by blood glucose meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery.

# ONWARDS 6 in type 1 diabetes patients on bolus insulin and insulin icodec or insulin degludec

## ONWARDS 6 trial design



 **Included 582 people with type 1 diabetes**

### Objective

To confirm the efficacy (non-inferiority on HbA<sub>1c</sub>) and safety of once-weekly insulin icodec + bolus insulin in patients with type 1 diabetes

### Primary endpoint

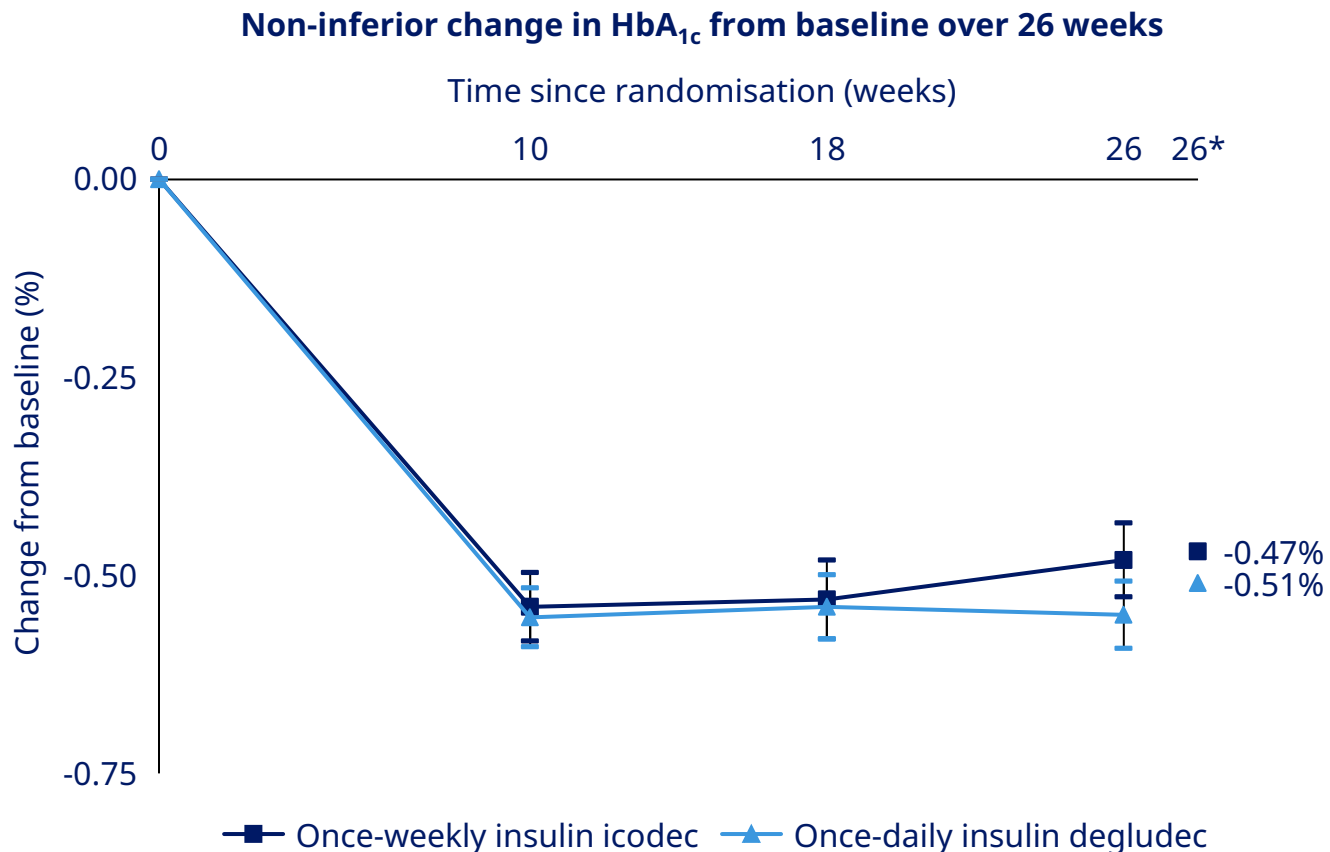
- Change in HbA<sub>1c</sub> from baseline to week 26

### Inclusion criteria

- T1D treated with basal-bolus insulin
- Age ≥ 18 years
- HbA<sub>1c</sub> < 10%

\*Pre-trial all OADs including oral GLP-1s are allowed but SU and glinides are to be discontinued at randomisation  
T1D: Type 1 diabetes

# ONWARDS 6 met its primary endpoint of demonstrating non-inferiority in reducing HbA<sub>1c</sub> compared to insulin degludec



Note: Overall baseline HbA<sub>1c</sub> of 7.6%

## Key highlights from main phase

### Primary endpoint:

- From an overall baseline HbA<sub>1c</sub> of 7.6%, once-weekly insulin icodec achieved a reduction in estimated HbA<sub>1c</sub> of -0.47% compared to -0.51% for insulin degludec in a T1D population
- Estimated treatment difference: 0.05%

\* Lines are based on observed data where the value denoted after 26-week is estimated mean value 26 derived based on multiple imputation  
T1D: Type 1 diabetes

# Statistically significant difference in hypoglycaemic events in people with type 1 diabetes in ONWARDS 6 trial

## Overall hypoglycaemic episodes in the trial

On treatment	Insulin icodec				Insulin degludec			
	N	(%)	E	R	N	(%)	E	R
<b>Level 2:</b> Clinically significant hypo	246	(84.8)	27.89	19.60	223	(76.4)	14.78	10.26
<b>Level 3:</b> Severe hypo	9	(3.1)	0.47	0.33	9	(3.1)	0.17	0.12
<b>Level 3 or 2:</b> Severe or clinically significant hypo	247	(85.2)	28.36	19.93	223	(76.4)	14.95	10.37

## Key highlights

- A statistical difference in the estimated rates of severe or clinically hypoglycaemia events<sup>1</sup>
  - 19.93 events for insulin icodec vs 10.37 events for insulin degludec
- Insulin icodec appeared to have a safe and well-tolerated profile

<sup>1</sup> Events measured as per patient year  
 Hypo: hypoglycaemia; N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of events, R: Rate (number of events per patient year of exposure, hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by blood glucose meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery.

# Insulin: Key take-aways

In a dedicated hypoglycemia study, no difference in hypoglaecemic events for insulin icodec vs insulin glargine U100 at double or triple dose

ONWARDS 1 and ONWARDS 2 met primary endpoints and demonstrated superior HbA<sub>1c</sub> reductions compared to insulin glargine U100 and insulin degludec, respectively

ONWARDS 6 met its primary endpoint of demonstrating non-inferiority in HbA<sub>1c</sub> reduction compared to insulin degludec

Once-weekly insulin icodec has the potential to be the ideal starting insulin for people with type 2 diabetes






# R&D milestones for 2022

Clinical milestones<sup>1</sup>
 Regulatory milestones<sup>1</sup>

Project		Q1 2022	Q2 2022	Q3 2022	Q4 2022
<b>Diabetes care</b>	<b>Ozempic® 2.0 mg</b>	US decision ✓			
	<b>FDC Sema – OW GIP</b>		Phase 1 results		
	<b>CagriSema T2DM</b>			Phase 2 results	
	<b>Higher doses inj. sema</b>			Phase 2 initiation	
	<b>Rybelsus®</b>		CN submission		
	<b>Icodec</b>			Phase 3a results	
	<b>Ideal Pump insulin</b>	Phase 1 results ✓			Phase 1 results
	<b>Oral GLP-1/GIP co-agonist</b>	Phase 1 initiation ✓			
<b>Obesity care</b>	<b>SELECT CVOT</b>			Potential interim analysis	
	<b>CagriSema</b>				Phase 3 initiation
	<b>LA-GDF15</b>			Phase 1 results	
<b>Rare disease</b>	<b>Sogroya® (somapacitan)</b>		US/EU/JP submission (GHD)		
	<b>Mim8</b>	Phase 1/2 results ✓			Phase 3 treatment <sup>2</sup>
<b>Other serious chronic diseases</b>	<b>Concizumab</b>	Phase 3a results (HwI) ✓	US submission (HwI)	Phase 3a results (HA/HB)	
	<b>Eclipse/Ndec</b>			Phase 2 initiation	
	<b>PRX004 (ATTR-CM)</b>		Phase 2 initiation		


<sup>1</sup> Expected to be published in the given quarter or in the subsequent quarterly company announcement. <sup>2</sup> First patient first visit in Q4 2021, which is solely for baselining purposes  
 Note: Trial initiations could be impacted by COVID-19; GHD: Growth Hormone Deficiency; sema: semaglutide; HwI: Haemophilia with inhibitors; ATTR-CM: Transthyretin Amyloid Cardiomyopathy; CVOT: Cardiovascular Outcomes Trial; Inj.: Injectible; Sema: Semaglutide

# Strategic aspirations 2025




**Purpose and sustainability (ESG)**

- Progress towards zero environmental impact
- Being respected for adding value to society
- Being recognised as a sustainable employer




**Innovation and therapeutic focus**

- Further raise the innovation-bar for diabetes treatment
- Develop a leading portfolio of superior treatment solutions for obesity
- Strengthen and progress the Rare disease pipeline
- Establish presence in Other serious chronic diseases focusing on CVD, NASH and CKD



**Commercial execution**

- Strengthen Diabetes leadership - aim at global value market share of more than 1/3
- More than 25 billion DKK in Obesity sales by 2025
- Secure a sustained growth outlook for Rare disease



**Financials**

- Deliver solid sales and operating profit growth
  - Deliver 6-10% sales growth in IO
  - Transform 70% of sales in the US<sup>1</sup>
- Drive operational efficiencies across the value chain to enable investments in future growth assets
- Deliver free cash flow to enable attractive capital allocation to shareholders

<sup>1</sup> From 2015 to 2022, 70% of sales to come from products launched from 2015. IO: International Operations; CVD: Cardiovascular disease; NASH: Non-alcoholic steatohepatitis; CKD: Chronic kidney disease.  
 Note: The strategic aspirations are not a projection of Novo Nordisk's financial outlook or expected growth.

# Agenda

## Introduction

Karsten Munk Knudsen

## Obesity care

*Post hoc analysis of STEP 1 and 4,  
STEP TEENS results and SELECT-LIFE*

Martin Holst Lange

## GLP-1 Diabetes

*Semaglutide in chronic kidney disease and  
peripheral artery disease*

Mads Frederik Rasmussen

## Insulin

*Insulin icodec hypoglycaemia frequency, results from  
ONWARDS 1, ONWARDS 2, and ONWARDS 6*

Martin Holst Lange

## Q&A

All

# Investor contact information

## Share information

Novo Nordisk’s B shares are listed on the stock exchange in Copenhagen under the symbol ‘NOVO B’. Its ADRs are listed on the New York Stock Exchange under the symbol ‘NVO’.

For further company information, visit Novo Nordisk on: [www.novonordisk.com](http://www.novonordisk.com)

## Upcoming events

- 04 August 2022 Financial statement for the first six months of 2022
- 02 November 2022 Financial statement for the first nine months of 2022
- 01 February 2023 Financial statement 2022

## Investor Relations contacts

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