press release

Ozempic® receives EU recommendation in peripheral arterial disease, cementing the broad benefits of semaglutide for people with type 2 diabetes and comorbidities

- Pending a decision from the European Commission, Ozempic® (once-weekly semaglutide) will have the broadest approved label in the glucagon-like peptide-1 receptor agonist (GLP-1 RA) class, demonstrating improvements in blood sugar, weight, cardiovascular (CV) events, chronic kidney disease and peripheral arterial disease (PAD) functional outcomes[1].
- Ozempic® is the first and only glucose-lowering treatment with proven functional benefits in people with type 2 diabetes and PAD[1]. The positive opinion is based on results from the phase 3b STRIDE trial, which demonstrated an improvement in walking capacity in patients with type 2 diabetes and PAD[1].
- Additional data from STRIDE and SOUL (CV outcomes with Rybelsus® in type 2 diabetes) were presented today at the American Diabetes Association's (ADA) 85th Scientific Sessions[2,3].

Bagsværd, Denmark, 23 June 2025 – Novo Nordisk today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for an update of the Ozempic® (once-weekly semaglutide) label to reflect the positive data from the STRIDE peripheral artery disease (PAD) functional outcomes trial.

STRIDE is the only dedicated PAD functional outcomes trial with a glucagon-like peptide-1 receptor agonist (GLP-1 RA). PAD is a manifestation of atherosclerotic cardiovascular disease (ASCVD) where a build-up of fatty deposits in the artery walls restricts blood supply to muscles, which can cause debilitating symptoms, physical limitations and poor quality of life[4].

"People living with type 2 diabetes face multiple cardiometabolic challenges, yet there is a lack of treatments that address the full disease spectrum," said Ludovic Helfgott, executive vice president, Product & Portfolio Strategy at Novo Nordisk. "Pending a decision from the European Commission, a STRIDE label update would complete the picture for Ozempic®, making it the only GLP-1 RA to have proven risk reduction of cardiovascular death, heart attack, stroke, major kidney events and improvement in functional walking capacity in people with type 2 diabetes. Coupled with its extensive real-world evidence, Ozempic® offers best-in-class benefits for people

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living with type 2 diabetes and its comorbidities, helping to treat today's disease, while potentially reducing future complications."

Following the positive opinion from the CHMP, Novo Nordisk expects the European Commission to implement the label update within approximately two months. Novo Nordisk has also filed for a label expansion of Ozempic® in the US, and a decision is expected in last quarter of 2025.

Based on data from the SOUL trial, Novo Nordisk has also filed for a label expansion for Rybelsus® with the EMA and FDA. This could potentially make Rybelsus® the first and only oral GLP-1 RA with proven cardiovascular (CV) benefits. A decision is also expected in the second half of 2025.

At the American Diabetes Association's (ADA) 85th Scientific Sessions, secondary data from the STRIDE, SOUL and FLOW semaglutide trials were presented:

- **STRIDE:** Secondary results showed that once-weekly semaglutide 1.0 mg consistently improved maximum walking distance in people with type 2 diabetes with symptomatic PAD compared to placebo, regardless of their type 2 diabetes characteristics[2].
- **SOUL:** Secondary results showed that the CV benefits of oral semaglutide in people with type 2 diabetes and CV disease (CVD) and/or chronic kidney disease (CKD) appeared more pronounced in people with higher HbA_{1c} levels at baseline. CV benefits were consistent across BMI categories[3].
- **FLOW:** Secondary results showed that the CKD benefits of once-weekly semaglutide 1.0 mg in people with type 2 diabetes, and regardless of baseline BMI, did not seem to be explained by change in body weight[5]. An additional analysis demonstrated that adding semaglutide to standard of care was projected to be highly cost-effective over the longer term in people with type 2 diabetes and CKD in Denmark[6].

These results add to the body of evidence that supports semaglutide use across a spectrum of CV and metabolic conditions, including type 2 diabetes and CKD[7], metabolic dysfunction-associated steatohepatitis (MASH)[8], obesity and heart failure with preserved ejection fraction (HFpEF) with and without type 2 diabetes[9–12]. They also add to the well-established safety profile of semaglutide, with more than 33 million patient-years of exposure across indications since its launch in 2018[13].

About STRIDE

STRIDE is a double-blind, randomised, placebo-controlled phase 3b clinical trial assessing the benefit of once-weekly injectable semaglutide 1.0 mg, marketed as Ozempic®, on functional capacity. The trial enrolled 792 participants with type 2 diabetes and symptomatic PAD with walking-induced leg pain. The primary endpoint was maximum walking distance on a constant load treadmill for people treated with semaglutide compared to placebo at Week 52[1]. STRIDE is the only dedicated PAD functional outcomes trial with a GLP-1 RA.

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The STRIDE trial achieved its primary endpoint, with semaglutide 1.0 mg demonstrating a superior and clinically meaningful improvement of 13% in maximum walking distance and a mean treatment difference of 39.9 meters on a steep (12%) incline, compared to placebo at Week 52[1].

About SOUL

SOUL was a multicentre, international, randomised, double-blind, parallel-group, placebo-controlled, phase 3 CV outcomes trial with 9,650 participants enrolled. It was conducted to assess the effect of oral semaglutide vs placebo on CV outcomes in people with type 2 diabetes and established CVD and/or CKD. The SOUL trial was initiated in 2019. The key objective of SOUL was to demonstrate that oral semaglutide lowers the risk of major adverse CV events (MACE; a composite endpoint consisting of CV death, non-fatal myocardial infarction and non-fatal stroke) compared to placebo, when both added to standard of care in patients with type 2 diabetes and established CVD and/or CKD[14].

The SOUL trial demonstrated a significant 14% risk reduction compared to placebo in MACE in adults with type 2 diabetes and CVD and/or CKD, making Rybelsus® (oral semaglutide) the first and only oral GLP-1 RA with proven CV benefit[15].

About FLOW

FLOW was a randomised, double-blind, parallel-grouped, placebo-controlled, superiority trial comparing injectable semaglutide 1.0 mg with placebo as an adjunct to standard of care. The trial assessed the effect of the treatments on kidney outcomes for prevention of progression of kidney disease and risk of kidney and CV mortality in people with type 2 diabetes and CKD (defined as estimated glomerular filtration rate [eGFR] ≥50 and ≤75 mL/min/1.73 m^2 with urine albumin-to-creatinine ratio [UACR] >300 and <5,000 mg/g or eGFR ≥25 and <50 mL/min/1.73 m^2 with UACR >100 and <5,000 mg/g). A total of 3,533 people were enrolled in the trial, which was conducted in 28 countries at around 400 investigator sites[7].

The key objective of the FLOW trial was to demonstrate delay in progression of CKD and to lower the risk of kidney and CV mortality through a composite primary endpoint consisting of the following five components: onset of persistent ≥50% reduction in eGFR according to the CKD-Epidemiology Collaboration (EPI) equation compared with baseline; onset of persistent eGFR (CKD-EPI) <15 mL/min/1.73 m^2; initiation of chronic kidney replacement therapy (dialysis or kidney transplantation); death from kidney disease; or death from CVD. Confirmatory secondary endpoints included annual rate of change in eGFR (CKD-EPI), MACE (including non-fatal myocardial infarction, non-fatal stroke and CV death) and all-cause mortality[7].

The FLOW trial demonstrated a statistically significant and superior 24% risk reduction in kidney disease progression, and a reduction in MACE and all-cause mortality in those treated with semaglutide 1.0 mg vs placebo[7].

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About PAD

Lower extremity PAD is a severe form of ASCVD that is under-screened, under-diagnosed and impacts approximately 230 million people globally[16]. The classical symptom is intermittent claudication, associated with limited walking ability and poor health-related quality of life[4]. Type 2 diabetes is one of the leading risk factors for PAD; nearly one in three people with PAD has type 2 diabetes[17]. While anti-atherosclerotic therapies and lifestyle changes are recommended, there are no effective therapies to specifically improve functional outcomes in PAD and type 2 diabetes[18].

About Ozempic®

Ozempic® (semaglutide) injection 0.25 mg, 0.5 mg, 1.0 mg or 2.0 mg is a once-weekly GLP-1 RA indicated, along with diet and exercise, to improve blood sugar (glucose) in adults with type 2 diabetes and to reduce the risk of major CV events such as heart attack, stroke or death in adults with type 2 diabetes mellitus with known heart disease[19,20]. Ozempic® is the only GLP-1 RA indicated to reduce the risk of worsening kidney disease and risk of death from CV events in adults with type 2 diabetes and CKD[20]. Ozempic® is currently marketed in 72 countries, and 7 million people with type 2 diabetes are currently being treated with Ozempic® worldwide[21].

About Rybelsus®

Rybelsus® (oral semaglutide) is a GLP-1 RA indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise[22,23]. Rybelsus® is administered once daily and is approved for use in three therapeutic dosages: 3 mg, 7 mg and 14 mg[24,25]. Rybelsus® offers superior blood glucose lowering vs Januvia® and Jardiance®[24,25], together with consistent weight reduction[24–26] and reduction in cardiometabolic risk factors[26]. Rybelsus® is currently commercially marketed in 45 countries. More than 2.1 million people with type 2 diabetes are currently being treated with Rybelsus® worldwide[21].

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 77,400 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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