press release

Ozempic® (once-weekly semaglutide 1.0 mg) shown to improve walking distance and quality of life in adults with type 2 diabetes and peripheral artery disease (PAD) at ACC 2025

- Ozempic® improved maximum walking distance by 13% vs placebo in adults with type 2 diabetes and peripheral artery disease (PAD) in the phase 3 STRIDE trial[1].
- Data were presented at the American College of Cardiology's (ACC) Annual Scientific Session and Expo in Chicago, US, while simultaneously published today in *The Lancet*[2].
- Approximately 230 million people globally have PAD, a severe form of atherosclerotic cardiovascular disease[3], and nearly one in three people with PAD have type 2 diabetes[4].

Bagsværd, Denmark, 29 March 2025 – Novo Nordisk today presented the full results from STRIDE, a phase 3b peripheral artery disease (PAD) outcomes trial investigating the effects of once-weekly injectable Ozempic® (semaglutide 1.0 mg) in adults with type 2 diabetes and PAD, at the American College of Cardiology's (ACC) Annual Scientific Session and Expo in Chicago, US[1]. These new data from the phase 3 trial were featured during a late-breaking clinical trial session at the ACC and simultaneously published today in *The Lancet*[2].

The double-blind, randomised, placebo-controlled 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 incline, compared to placebo at week 52. The trial also demonstrated superiority to placebo for all confirmatory secondary outcomes assessed, including pain-free walking distance at week 52, health-related quality of life (Vascular Quality of Life Questionnaire-6) at week 52, and maximum walking distance at week 57[1].

“Peripheral artery disease (PAD) may cause severe symptoms, physical limitations, and a diminished quality of life, often making even short walks, such as retrieving the mail challenging. In individuals with PAD and diabetes, the disease can be even more severe, affecting small blood vessels and limiting the effectiveness of revascularization procedures and other treatments. Semaglutide 1.0 mg is the first medication in over two decades to show improvements in cardiometabolic and cardiovascular outcomes as well as meaningful improvements in functional capacity and quality of life, which could address a critical unmet

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need for those with both PAD and type 2 diabetes," said Marc P. Bonaca, MD, Director of Vascular Research, University of Colorado School of Medicine, Lead Investigator of the STRIDE trial. “The significant improvements in walking distance and patient-reported quality of life observed with semaglutide 1.0 mg in the STRIDE trial are promising and represent an important step forward on the path to advancing treatment options for this patient population.”

PAD is a severe form of atherosclerotic cardiovascular disease that is under-screened and underdiagnosed and impacts approximately 230 million people globally[3]. Type 2 diabetes is one of the leading risk factors for PAD, and nearly one in three people with PAD have type 2 diabetes[4]. There are limited therapies available to specifically improve functional limitations in PAD, representing a significant unmet need in this population[5].

“Novo Nordisk continues to evolve its focus beyond diabetes and obesity towards a broader spectrum of metabolic and cardiovascular health,” said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “These data, alongside other data being presented at ACC, reinforce the comprehensive set of health benefits of semaglutide, making it a strong option for healthcare professionals addressing the spectrum of metabolic and cardiovascular health – and our continued leadership in the space.”

The safety results from the STRIDE trial are consistent with the well-established safety and tolerability profile of once-weekly semaglutide[1], supported by long-term safety data with more than 33 million patient-years of exposure[6]. Serious adverse events (SAEs) were reported in fewer participants in the semaglutide group than in the placebo group (74 [19%] vs 78 [20%]). SAE probably related to treatment occurred in 2 participants (1%) in the semaglutide group and in 2 participants (1%) in the placebo group. SAE possibly related to treatment occurred in 3 (1%) and 4 (1%) participants, respectively. SAEs leading to permanent treatment discontinuation of semaglutide or placebo were less common in the semaglutide group than in the placebo group (11 [3%] vs 13 [3%]). SAEs led to the death of 3 (1%) and 8 (2%) participants in the semaglutide and placebo arms, respectively; however, no SAEs leading to death were treatment-related[1].

Based on data from the STRIDE clinical trial, Novo Nordisk submitted a label extension application for Ozempic® to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). A decision is anticipated in 2025.

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. It 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. STRIDE is the only dedicated PAD functional outcomes trial with a GLP-1 RA.

About PAD

Lower extremity PAD is a severe form of atherosclerotic cardiovascular disease. The classical symptom is intermittent claudication, associated with limited walking ability and poor health-related quality of life[7]. Type 2 diabetes is one of the leading risk factors for PAD; nearly one in three people with PAD have type 2 diabetes[4]. 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[8].

About Ozempic®

Ozempic® (semaglutide) injection 0.25, 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 mellitus and to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes mellitus with known heart disease[9,10]. Ozempic® is currently marketed in 75 countries and 7 million people with type 2 diabetes are currently being treated with Ozempic® worldwide[11].

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 76,300 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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