press release

EU approval makes Novo Nordisk's oral semaglutide the first and only oral GLP-1 RA to reduce cardiovascular death, heart attack and stroke

- Oral semaglutide (Rybelsus®) is now the first and only oral GLP-1 RA approved for type 2 diabetes, with proven cardiovascular benefits[1]
- This approval is based on results from the SOUL clinical trial, where oral semaglutide (Rybelsus®) reduced cardiovascular death, heart attack and stroke by 14% versus placebo, when added to standard of care, in adults with type 2 diabetes at high cardiovascular risk[1]
- In addition, new results from SOUL will be presented at one of the largest diabetes conferences (EASD) later this week, showing that oral semaglutide significantly reduced hospitalisations compared with placebo[2]

Bagsværd, Denmark, 15 September 2025 – Novo Nordisk today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has approved an update to the Rybelsus® (oral semaglutide) label to reflect the cardiovascular benefits seen in the SOUL trial. SOUL was a phase 3b trial carried out to evaluate the effect of Rybelsus® on cardiovascular outcomes in people with type 2 diabetes and atherosclerotic cardiovascular disease (ASCVD) and/or chronic kidney disease (CKD)[1]. Rybelsus® is now the first and only oral glucagon-like peptide 1 receptor agonist (GLP-1 RA) – mimicking a natural hormone in your body that helps regulate blood sugar, appetite, and digestion – available in the EU for type 2 diabetes with a proven cardiovascular benefit[1].

"Heart problems are the leading cause of disability and death for people living with type 2 diabetes. Therefore, treatments that also address heart problems are key to improving not only health outcomes, but also quality of life – and this approval will help do just that," said Emil Kongshøj Larsen, executive vice president, International Operations at Novo Nordisk. "This milestone makes semaglutide the only oral GLP-1 RA with proven blood glucose and body weight reduction, as well as cardiovascular benefits."

New results from the SOUL trial will be shared later this week at the European Association for the Study of Diabetes (EASD) 2025 Annual Meeting, 15–19 September. These include findings that treatment with oral semaglutide significantly reduced hospitalisations related to serious adverse events compared with placebo[2]. Additional SOUL results will be presented at the same

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meeting, which highlight that the cardiovascular benefits of oral semaglutide were consistent regardless of body mass index (BMI) and body weight of participants[3].

In the US, a decision is expected later this year for a label extension for the cardiovascular indication for Rybelsus®. Novo Nordisk has also submitted an application in the US for a once-daily 25 mg oral formulation of semaglutide (Wegovy® in a pill) in adults living with obesity or overweight and cardiovascular disease. A decision is expected at the turn of this year, and if approved, Wegovy® would become the first oral GLP-1 RA indicated for chronic weight management.

Rybelsus® is the first and only oral GLP-1 RA approved for the treatment of type 2 diabetes, following its launch in 2019. It is supported by a strong clinical and real-world evidence base, demonstrating superior blood glucose reduction and body weight reduction versus multiple comparators, as well as an established safety profile in people with type 2 diabetes[4-8].

About SOUL
SOUL was a multicentre, international, randomised, double-blind, parallel-group, placebo-controlled, phase 3 cardiovascular outcomes trial, with 9,650 participants enrolled. It was conducted to assess the effect of oral semaglutide versus placebo, when added to standard of care, on cardiovascular outcomes in people with type 2 diabetes and established cardiovascular disease and/or chronic kidney disease (CKD). The SOUL trial was initiated in 2019. The primary outcome was time-to-first occurrence of major adverse cardiovascular events (MACE; a composite objective consisting of cardiovascular death, heart attack and stroke)[1].

The SOUL trial demonstrated a superior reduction in MACE of 14% for people treated with oral semaglutide compared to placebo in people with type 2 diabetes and cardiovascular disease and/or CKD, making Rybelsus® (oral semaglutide) the first and only oral GLP-1 RA with a proven cardiovascular benefit[1].

About Rybelsus®
Rybelsus® (oral semaglutide) is a glucagon-like peptide 1 receptor agonist (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[7, 9]. Rybelsus® is administered once daily and is approved for use in the following therapeutic dosages: 1.5 mg, 3 mg, 4 mg, 7 mg, 9 mg, 14 mg, 25 mg and 50 mg[4, 5]. Rybelsus® offers superior blood glucose lowering versus multiple comparators[4, 5], together with consistent weight reduction[4, 5, 10], reduction in cardiometabolic risk factors[10] and reduction in major adverse cardiovascular events (MACE)[1]. Rybelsus® is now the first and only oral GLP-1 RA available in the EU for type 2 diabetes with a proven cardiovascular benefit[1]. It is currently available in 48 countries[11], and more than 2.4 million people with type 2 diabetes are currently being treated with Rybelsus® worldwide[12].

About Wegovy®
Semaglutide 2.4 mg is marketed under the brand name Wegovy®. In the EU, Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults with a BMI of 30 kg/m^2 or greater (obesity) or adults with a BMI of 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition. In the EU, Wegovy® is also indicated for paediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and gender (obesity) and body weight above 60 kg. The clinical section of the label also includes data on Wegovy® major adverse cardiovascular events (MACE) risk reduction, improvements in heart failure with preserved ejection fraction (HFpEF)-related symptoms and physical function, as well as pain reduction related to knee osteoarthritis[13].

In the US, Wegovy® is indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of MACE in adults with established cardiovascular disease and either obesity or

overweight, to reduce excess body weight and maintain weight reduction long term in paediatric patients aged 12 years and older with obesity and in adults with obesity or with overweight in the presence of at least one weight-related comorbid condition, as well as for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in adults with moderate to advanced liver scarring (fibrosis), but not with cirrhosis of the liver, in combination with a reduced calorie diet and increased physical activity[14].

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 78,400 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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