press release

Novo Nordisk's oral semaglutide demonstrates potential to be the first oral GLP-1 RA therapy for children and adolescents with type 2 diabetes

- PIONEER TEENS is the first clinical trial of an oral GLP-1 RA therapy in children and adolescents aged 10–17 years with type 2 diabetes, addressing a significant unmet need.
- The trial demonstrated a statistically significant and superior reduction in blood sugar by 0.83% vs placebo at 26 weeks.
- Novo Nordisk expects to file for regulatory approval of a label expansion for Ozempic® pill and Rybelsus® in the US and EU in the second half of the year.

Bagsværd, Denmark, 23 April 2026 – Novo Nordisk today announced positive topline results from PIONEER TEENS, a phase 3a trial evaluating oral semaglutide for type 2 diabetes in children and adolescents aged 10–17 years with type 2 diabetes. Oral semaglutide demonstrated a superior reduction in HbA_{1c} (a measure of blood sugar control) over placebo in the trial and showed a well-tolerated safety profile consistent with previous Novo Nordisk semaglutide trials. Oral semaglutide is available today as Rybelsus® in the EU and US and will be available in the US as Ozempic® pill soon.

"Over the past two decades, the prevalence of type 2 diabetes among children and adolescents has increased substantially, yet treatment options for this population remain limited, underscoring a significant unmet need. Oral semaglutide has already demonstrated clinically meaningful glycaemic efficacy and a well-established safety profile in adults with type 2 diabetes, alongside proven cardiovascular benefits unique to this molecule," said Martin Holst Lange, chief scientific officer and executive vice president, Research & Development, at Novo Nordisk. "These results from the PIONEER TEENS trial confirm that oral semaglutide is an effective treatment option for children and adolescents with type 2 diabetes who require glycaemic control beyond that provided by the current standard of care."

Type 2 diabetes in children and adolescents is a severe and progressive condition that is strongly associated with increased risks of early mortality in adulthood. Current management for glycaemic control in youth-onset type 2 diabetes remains constrained, and there is an

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unmet need for more treatment options. In 2021, 14.6 million adolescents were living with type 2 diabetes globally. By 2030, this number is projected to increase to 20.9 million[1-3].

Current guidelines recommend metformin and insulin as first-line treatments[4,5]; however, metformin is associated with failure in glycaemic control in approximately half of adolescents[13], and insulin is associated with hypoglycaemia and weight gain[4,5]. This is the first clinical trial of an oral GLP-1 RA therapy in this age group, addressing a critical unmet need. Pending regulatory approvals, oral semaglutide has the potential to be the first and only oral GLP-1 RA to demonstrate superior glycemic efficacy versus placebo in children and adolescents with type 2 diabetes, while maintaining the well-established safety profile seen across the semaglutide portfolio.

About the PIONEER TEENS Trial

PIONEER TEENS (NCT04596631) was a 52-week, randomised, double-blind, placebo-controlled phase 3a trial evaluating oral semaglutide at maximum tolerated doses (3 mg, 7 mg, or 14 mg once daily) vs placebo in 132 children and adolescents aged 10–17 years with type 2 diabetes. The participants received background treatment with metformin, basal insulin or both. The primary endpoint was change from baseline to week 26 in HbA_{1c}[6].

About oral semaglutide in type 2 diabetes

Oral semaglutide in type 2 diabetes (available today as Rybelsus® in the EU and US; launching in the US as Ozempic® pill later in Q2 2026) 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. Oral semaglutide in type 2 diabetes is administered once daily. Two bioequivalent tablet formulations exist: 1.5 mg, 4 mg, and 9 mg (round tablets, second generation) and 3 mg, 7 mg, and 14 mg (oval tablets, first generation). In addition, 25 mg and 50 mg tablets are approved in the EU for type 2 diabetes[7,8]. Oral semaglutide offers superior blood glucose lowering versus multiple comparators[9,10], together with consistent weight reduction[9,10,11], reduction in cardiometabolic risk factors[11] and reduction in major adverse cardiovascular events (MACE).[12] Oral semaglutide is not currently approved for use in children or adolescents.

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 68,800 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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