

Oral semaglutide (14 mg) demonstrates superior reduction in cardiovascular events

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Oral Semaglutide is currently commercially marketed in 45 countries



Novo Nordisk recently presented the full results from the SOUL cardiovascular outcomes trial, demonstrating that oral semaglutide significantly reduced the risk of major adverse cardiovascular events in adults with type 2 diabetes and cardiovascular disease (CVD) and/or chronic kidney disease (CKD).

These new data from the phase 3b trial were featured during a late-breaking clinical trial session at the American College of Cardiology's (ACC) Annual Scientific Session and Expo in Chicago, US and simultaneously published in New England Journal of Medicine.

The SOUL trial achieved its primary endpoint, demonstrating a 14% reduction in risk of major adverse cardiovascular events (MACE) in adults with type 2 diabetes and CVD and/or CKD when treated with oral semaglutide compared to placebo.

Each component of MACE, being nonfatal myocardial infarction (26%) and nonfatal stroke (12%), CV death (7%) contributed to the risk reduction. Notably, among trial participants from the Asian region, the risk of major adverse cardiovascular events (MACE) reduction was even more pronounced at 27%.

Based on data from the SOUL clinical trial, Novo Nordisk submitted a label extension application for oral semaglutide, which

has been accepted for review by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). A decision is anticipated in 2025.

Dr V. Mohan, Chairman, Dr. Mohan's Diabetes Specialities Centre, said "This data reinforces oral semaglutide's groundbreaking role as the first and only approved oral glucagon-like peptide-1 receptor agonist (GLP-1 RA) to achieve a significant reduction in cardiovascular risk within this high-risk population. This achievement enhances the existing standards of care for managing both T2DM and CVD, offering patients an innovative and effective therapeutic intervention. The observed impact of oral semaglutide on cardiovascular outcomes underscore its potential to address a critical unmet need in type 2 diabetes and cardiometabolic disease management."