Embargoed until June 22, 2025 at 4:30 PM CT

Oral Semaglutide Significantly Improves Cardiovascular Outcomes in Individuals with Type 2 Diabetes

Oral formulation demonstrates comparable cardiovascular benefits to injectable GLP-1s

CHICAGO, IL (JUNE 22, 2025) – A recent study found that oral semaglutide offers meaningful cardiovascular benefits for people with type 2 diabetes, lowering risk by 14%. Results from the Semaglutide Cardiovascular Outcomes Trial (SOUL) were unveiled as a late-breaking symposia at American Diabetes Association's® (ADA) 85th Scientific Sessions in Chicago.

Adults with diabetes have 2-4 times increased cardiovascular risk compared with adults without diabetes, and the risk rises with worsening glycemic control. In fact, people living with type 2 diabetes are more likely to develop and die from cardiovascular diseases, such as heart attacks, stroke, and heart failure than people who don't have diabetes. By eliminating the need for injections, oral semaglutide may improve adherence and support earlier initiation of therapy – broadening access to cardiovascular protection for patients who might otherwise delay or avoid treatment due to reluctance toward injectables.

The double-blind, placebo-controlled, event-driven superiority trial included 9,650 participants who were 50 years of age or older. All had type 2 diabetes with an A1C level between 6.5% and 10.0%, meaning elevated blood glucose (blood sugar), and had either known atherosclerotic cardiovascular disease, a form of heart disease caused by plaque buildup in the arteries, chronic kidney disease, or both. Participants were randomly assigned to receive either once-daily oral semaglutide (maximum dose of 14 mg) or a placebo, in addition to standard care. The primary outcome was major adverse cardiovascular events (a composite of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke), assessed in a time-to-first-event analysis. The confirmatory secondary outcomes included major kidney disease events (a five-point composite outcome). The mean (±SD) follow-up was 47.5±10.9 months, and the median follow-up was 49.5 months.

Initial results were published in the *New England Journal of Medicine in March* showing a 14% reduction in major adverse cardiovascular events (MACE). A primary-outcome event occurred in 579 of the 4,825 participants (12.0%; incidence, 3.1 events per 100 person-years) in the oral semaglutide group, as compared with 668 of the 4,825 participants (13.8%; incidence, 3.7 events per 100 person-years) in the placebo group (hazard ratio, 0.86; 95% confidence interval, 0.77 to 0.96; P=0.006). The results for the confirmatory secondary outcomes did not differ significantly between the two groups. The incidence of serious adverse events was 47.9% in the oral semaglutide group and 50.3% in the placebo group and the incidence of gastrointestinal disorders was 5.0% and 4.4%, respectively. The new results will expand on these findings.

“When treating patients with type 2 diabetes, it’s also important to address dangerous co-morbidities such as lowering the risk of heart disease,” said Darren K. McGuire, MD, MHSc; Professor of Medicine at UT Southwestern Medical Center and lead author of the study. “Our findings indicate that oral semaglutide could be a promising option in need of treatment for diabetes and cardiovascular risk.”

Looking ahead, the researchers will look to implement findings in a real-world setting to better inform clinical next steps.

Research presentation details:

Dr. McGuire will present the findings during the Symposium Presentation:

- *Effects of Oral Semaglutide on Cardiovascular (and Other) Outcomes in People with Type 2 Diabetes at High CV Risk*
- Sunday, June 22 at 4:30 - 6:00 PM CT

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About the ADA’s Scientific Sessions

The ADA's 85th Scientific Sessions, the world's largest scientific meeting focused on diabetes research, prevention, and care, will be held in Chicago, IL on June 20-23. Thousands of leading physicians, scientists, and health care professionals from around the world are expected to convene both in person and virtually to unveil cutting-edge research, treatment recommendations, and advances toward a cure for diabetes.

Attendees will receive exclusive access to thousands of original research presentations and take part in provocative and engaging exchanges with leading diabetes experts. Join the Scientific Sessions conversation on social media using #ADASciSessions.

About the American Diabetes Association

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to end diabetes and helping people thrive. This year, the ADA celebrates 85 years of driving discovery and research to prevent, manage, treat, and ultimately cure —and we're not stopping. There are 136 million Americans living with diabetes or prediabetes. Through advocacy, program development, and education, we're fighting for them all. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (800-342-2383). Join us in the fight on Facebook (American Diabetes Association), Spanish Facebook (Asociación Americana de la Diabetes), LinkedIn (American Diabetes Association), and Instagram (@AmDiabetesAssn). To learn more about how we are advocating for everyone affected by diabetes, visit us on X (@AmDiabetesAssn).