

EMBARGOED UNTIL JUNE 29, 2021 at 12:15 p.m. ET

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EARLY USE OF SOTAGLIFLOZIN PROVIDES BENEFITS FOR PEOPLE WITH TYPE 2 DIABETES WITH CHRONIC KIDNEY DISEASE OR HEART FAILURE

Update on SCORED and SOLOIST trials shows reduction in cardiovascular events and stroke using glucose-lowering agents

WASHINGTON, DC (June 29, 2021) – Results from two large clinical trials show significant and early benefits from sotagliflozin, a drug that inhibits sodium-glucose transport protein 2 (SGLT2) and sodium-glucose transport protein 1 (SGLT1) in reducing heart failure, heart attack, and stroke—major problems in people with diabetes. The findings were presented at the virtual 81st Scientific Sessions of the American Diabetes Association® (ADA).

Patients with diabetes are at an increased risk of life-threatening conditions such as chronic kidney disease and heart failure. In fact, diabetes is the [leading cause](#) of kidney failure and the rate of heart failure for patients with diabetes is [four times](#) higher than the general population—highlighting the need to address these comorbidities within standard of care.

Less than a decade ago, the Food and Drug Administration (FDA) approved drugs for treating type 2 diabetes in an entirely new way using SGLT2 inhibitors to help the body eliminate blood sugar via urine, offering enhanced blood sugar (blood glucose) control, cardiovascular benefits, and weight loss for people with diabetes taking the drug. Another effective and complementary mechanism of action uses SGLT1 inhibition to reduce blood sugar via the digestive tract. Combination SGLT2 and SGLT1 inhibitors are currently being studied and none have been approved by the FDA.

Building on the evidence of this new class of drugs, the SCORED and SOLOIST trials evaluate the benefits of a combination drug that inhibits both SGLT2 and SGLT1 in patients experiencing kidney failure or heart failure.

Trial data come from SOLOIST, which randomized 1,222 people with type 2 diabetes who had been recently hospitalized for worsening heart failure. SCORED, a much broader 10,584 patient trial, studied the drug's ability to prevent cardiovascular events in people with diabetes and chronic kidney disease. Both studies were published in *The New England Journal of Medicine* and demonstrate the benefit of using an SGLT1/2 inhibitor drug for people with type 2 diabetes.

Paired analysis of SCORED and SOLOIST found:

- **SCORED:** SGLT1/2 inhibitors provide benefits across the full range of albuminuria, a sign of kidney disease that involves an excess of protein in urine, and decrease the chance of heart attack by 32% and of stroke by 34%.
- **SOLOIST:** SGLT1/2 inhibitors are safe and effective when initiated in patients hospitalized with acute heart failure and early, in-hospital initiation of SGLT2 inhibitors is safe and effective for people with type 2 diabetes and heart failure, reducing the risk of death from cardiovascular causes and hospitalization or urgent visits for heart failure by 33%.

“The results presented today add to the growing body of evidence demonstrating the overall benefit of this new class of glucose-lowering agents. It is now clear that most patients with type 2 diabetes and either kidney disease or heart failure should be assessed for initiation of an SGLT inhibitor,” said **Deepak L. Bhatt, MD, MPH, Executive Director of Interventional Cardiovascular Programs, Brigham and Women’s Hospital, and Professor of Medicine, Harvard Medical School.** “Our findings are the first of their kind, with this investigational drug demonstrating a benefit in people with diabetes across all the different types of heart failure.”

The authors indicate that sotagliflozin is not FDA approved and that if it is brought to the market, it would signify a major advance in the care of patients with diabetes, especially those with heart failure or kidney disease.

Research presentation details:

- Dr. Bhatt and other study investigators presented an update on SCORED and SOLOIST during a symposium listed below (Dr. Bhatt will speak at 10:15 a.m. ET):
- [Symposium - Update on SCORED and SOLOIST Cardiovascular and Kidney Outcomes Trials](#)
- **Date:** Tuesday, June 29, 10:15 a.m.–12:15 p.m. ET (all sessions will be recorded and accessible for 90 days)
- Dr. Bhatt will be providing an overview of the study findings and is available for virtual media interviews on Tuesday, June 29 from 2:00–3:00 p.m. ET
 - If interested in speaking with Dr. Bhatt [register here](#).

For more information or to request an interview with Dr. Bhatt, please contact the ADA Scientific Sessions media team at SciSessionsPress@diabetes.org.

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About the ADA’s Scientific Sessions

The ADA’s 81st Scientific Sessions, the world’s largest scientific meeting focused on



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diabetes research, prevention, and care, will be held virtually June 25–29. Leading physicians, scientists, and health care professionals from around the world will unveil cutting-edge research, treatment recommendations, and advances toward a cure for diabetes. Though the conference will be remote this year, attendees will receive exclusive access to nearly 2,000 original research presentations and take part in provocative and engaging exchanges with leading diabetes experts. Learn more and register at scientificsessions.diabetes.org and join the Scientific Sessions conversation on social media using #ADA2021.

About the American Diabetes Association

Every day, more than 4,000 people are newly diagnosed with diabetes in America. More than 122 million Americans have diabetes or prediabetes and are striving to manage their lives while living with the condition. The ADA is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For 80 years, the ADA has been driving discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. We help people with diabetes thrive by fighting for their rights and developing programs, advocacy, and education designed to improve their quality of life. Diabetes has brought us together, what we do next will make us Connected for Life. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383). Join the fight with us on Facebook ([American Diabetes Association](https://www.facebook.com/AmericanDiabetesAssociation)), Twitter ([@AmDiabetesAssn](https://twitter.com/AmDiabetesAssn)), and Instagram ([@AmDiabetesAssn](https://www.instagram.com/AmDiabetesAssn)).