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Additional analysis from the SOLOIST study shows that sotagliflozin demonstrated a favorable effect on days alive and out of hospital (DAOH) compared to placebo in patients with diabetes and worsening heart failure.

Aurora, CO, June 24, 2021 – New published findings from the Effect of Sotagliflozin on Cardiovascular Events in Patients with Type 2 Diabetes Post Worsening Heart Failure, or SOLOIST trial, have been published in Annals of Internal Medicine, a journal of the American College of Physicians.

Michael Szarek, PhD, MS, a visiting professor in the division of cardiology at the University of Colorado School of Medicine, and Academic Research-Scientist at CPC Clinical Research, an academic research organization affiliated with the University of Colorado Anschutz Medical Campus, is the first author of this ground-breaking publication. He says that, “Among patients with diabetes who were recently hospitalized for worsening heart failure, the SGLT2 inhibitor sotagliflozin demonstrated a favorable effect on days alive and out of hospital (DAOH), a patient-centered outcome that is a comprehensive measure of total disease burden. Specifically, for every 100 days of follow-up, patients in the sotagliflozin group were alive and out of the hospital

2.9 days more than patients in the placebo group. This translates to over 10 days per year, which is a meaningful benefit to patients.”

It was unknown prior to the SOLOIST study if, in patients with diabetes recently hospitalized for worsening heart failure, initiation of treatment with a SGLT2 inhibitor prior to or shortly after discharge would be beneficial. Patients of this significant disease burden have high risk for recurrent hospitalization and death. This coupled with the high prevalence of these conditions world-wide means advancing research in this patient population has potentially important consequences for public health.

The full publication can be found at <https://www.acpjournals.org/doi/10.7326/M21-0651>

Media coverage of this includes: <https://www.healio.com/news/primary-care/20210621/sotagliflozin-reduces-deaths-time-spent-in-hospital-for-some-patients-with-diabetes>

ABOUT THE SOLOIST Trial

The Effect of Sotagliflozin on Cardiovascular Events in Patients with Type 2 Diabetes Post Worsening Heart Failure, or SOLOIST trial, was a randomized, double-blind, placebo-controlled trial. It observed 1222 patients across 306 sites in 32 countries. Patients were randomized to receive the intervention of 200 mg of sotagliflozin once daily (with a possible dose increase to 400 mg) or matching placebo.

According to Deepak L. Bhatt, MD, MPH, executive director of interventional cardiovascular programs at Brigham and Women's Hospital and professor of medicine at Harvard Medical School, in the primary efficacy analysis of the study, researchers observed 245 primary endpoint events in the sotagliflozin group and 355 events in the placebo group, for an event rate of 51 vs. 76.3 per 100 patient-years, an HR of 0.67 (95% CI, 0.52-0.85; $P < .001$). This translates to only needing 4 patient-years of treatment to avoid 1 event. The primary endpoint results of the SOLOIST study were published in the New England Journal of Medicine.

ABOUT CPC

CPC Clinical Research, an academic research organization and affiliate of the University of Colorado Anschutz Medical Campus, has led innovative research in cardiovascular disease and particularly peripheral artery disease and cardiometabolic disease for more than 30 years. Founded in 1989 to lead the Appropriate Blood Pressure Control in Diabetes (ABCD) trial (www.ncbi.nlm.nih.gov/pubmed/8960857), CPC is recognized for its expertise in scientific leadership in study design and comprehensive clinical trial management for both national and international clinical research. Over the past three decades, the organization's services have evolved to stay at the forefront of the everchanging landscape of clinical research.

CPC also leads innovative programs to help vulnerable populations across Colorado to achieve health without disparities. As a result of these efforts, CPC Community Health has provided health education and/or coaching to over 82,000 individuals and made

significant improvements in the lives of those at risk for cardiovascular disease. The results of these Community Health programs, focused on rural and urban Latino populations, have been recognized by the CDC.

CPC offers full-service clinical trial design, oversight, and management with rapid access to Key Opinion Leaders in a variety of therapeutic areas. These individuals are on the cutting edge of scientific, clinical and regulatory developments. Many of CPC's leadership team have chaired and/or served on FDA advisory committees including the Cardiovascular and Renal, Endocrine and Metabolism, and Reproductive Health committees. For more information, go to <https://cpcclinicalresearch.org> and www.cpccommunityhealth.org

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