Clinical Data Demonstrating Efficacy of Sotagliflozin in Preserved Ejection Fraction Heart Failure (HFpEF) without Diabetes Presented at American Heart Association (AHA) Annual Scientific Sessions 2025

November 8, 2025

Oral presentation highlights sotagliflozin's unique benefits to HFpEF patients in significantly improving cardiac and physical performance, and quality of life

THE WOODLANDS, Texas, Nov. 08, 2025 (GLOBE NEWSWIRE) -- Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) today announced that new sotagliflozin clinical data was presented at the AHA Annual Scientific Sessions 2025. The data highlighted benefits observed from sotagliflozin treatment in heart failure patients with preserved ejection fraction (HFpEF), and without diabetes, across a range of measures, including cardiac structure and function, quality of life and functional capacity.

Conducted under the direction of Dr. Juan J Badimon, PhD, FACC, FAHA, director, Atherothrombosis Research Unit, professor of Medicine/Cardiology at Mount Sinai Medical Center in New York City, “SOTA P CARDIA: A Randomized Trial of Sotagliflozin in HFpEF Patients without Diabetes” was a prospective, randomized, double-blind, placebo-controlled trial that exclusively enrolled patients with HFpEF, the most rapidly increasing form of heart failure.

The objective of the study was to compare treatment with sotagliflozin to placebo on a number of cardiac functional and structural measures, such as left ventricular mass, diastolic function, standard six-minute walk test, and KCCQ. The study enrolled 88 participants who were racially diverse and 70 percent female. Patients were treated with sotagliflozin or placebo for six months, and comparisons were made between groups during and after completion of treatment.

Treatment with sotagliflozin resulted in statistically significant improvements in left ventricular mass, diastolic function, capacity for a six-minute walk test, and KCCQ measurements. In addition, though peak VO_2 improvement did not achieve statistical significance, there was a notable improvement after treatment with sotagliflozin.

“The benefits observed with sotagliflozin treatment in the study include significant improvements in cardiac structure and function, symptom relief and, most importantly, quality of life and functional capacity,” said Dr. Badimon. “Although sotagliflozin was approved more than two years ago for heart failure patients with or without diabetes, our study is the first to demonstrate important clinical benefits for patients with preserved ejection fraction without diabetes.”

According to the American College of Cardiology, nearly 6.7 million Americans have heart failure, more than half with preserved ejection fraction. This condition often leads to frequent hospitalizations and has a one-year risk of death of roughly 25 percent.

“When you combine these study results with previously reported data on reductions among patients treated with sotagliflozin in the risks for MACE and rehospitalization following previous hospitalization for acute heart failure events, the potential for sotagliflozin to be considered a different class of medication starts to come into focus,” said Craig Granowitz, M.D., Ph.D., Lexicon’s senior vice president and chief medical officer.

Click here and search for “SOTA P CARDIA” to access the study abstract.

About Sotagliflozin
Discovered using Lexicon’s unique approach to gene science, sotagliflozin is an oral inhibitor of two proteins responsible for glucose regulation known as sodium-glucose cotransporter types 2 and 1 (SGLT2 and SGLT1). SGLT2 is responsible for glucose and sodium reabsorption by the kidney and SGLT1 is responsible for glucose and sodium absorption in the gastrointestinal tract. Sotagliflozin has been studied in multiple patient populations encompassing heart failure, diabetes, and chronic kidney disease in clinical studies involving approximately 20,000 patients. Sotagliflozin is also currently under investigation for another cardiac condition, hypertrophic cardiomyopathy (HCM).

About Lexicon Pharmaceuticals
Lexicon is a biopharmaceutical company with a mission of pioneering medicines that transform patients’ lives. Through the Genome5000™ program, Lexicon’s unique genomics target discovery platform, Lexicon scientists studied the role and function of nearly 5,000 genes and identified more than 100 protein targets with significant therapeutic potential in a range of diseases. Through the precise targeting of these proteins, Lexicon is pioneering the discovery and development of innovative medicines to treat disease safely and effectively. Lexicon has a pipeline of promising drug candidates in discovery and clinical and preclinical development in neuropathic pain, HCM, obesity, metabolism and other indications. For additional information, please visit www.lexpharma.com.

Safe Harbor Statement

This press release contains "forward-looking statements," including statements relating to Lexicon's financial position and long-term outlook on its business, including the commercialization of its approved products and the clinical development of, regulatory filings for, and potential therapeutic and commercial potential of sotagliflozin and its other drug candidates. In addition, this press release also contains forward looking statements relating to Lexicon's growth and future operating results, discovery, development and commercialization of products, strategic alliances and intellectual property, as well as other matters that are not historical facts or information. All forward-looking statements are based on management's current assumptions and expectations and involve risks, uncertainties and other important factors, specifically including Lexicon's ability to meet its capital requirements, successfully commercialize its approved products, successfully conduct preclinical and clinical development and obtain necessary regulatory approvals of its other drug candidates on its anticipated timelines, achieve its operational objectives, obtain patent protection for its discoveries and establish strategic alliances, as well as additional factors relating to manufacturing, intellectual property rights, and the therapeutic or commercial value of its approved products and other drug candidates. Any of these risks, uncertainties and other factors may cause Lexicon's actual results to be materially different from any future results expressed or implied by such forward-looking statements. Information identifying such important factors is contained under "Risk Factors" in Lexicon's annual report on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission. Lexicon undertakes no obligation to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

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