SONATA-HCM Study Design Presented at Heart Failure 2025, the Annual Congress of the Heart Failure Association of the European Society of Cardiology

May 19, 2025

Lexicon is evaluating the safety and efficacy of sotagliflozin in patients with both obstructive and non-obstructive hypertrophic cardiomyopathy (HCM)

Pivotal Phase 3 clinical trial is actively enrolling patients in 20 countries, with all sites expected to be operational by Q3 2025

THE WOODLANDS, Texas, May 19, 2025 (GLOBE NEWSWIRE) -- Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) today announced details of its "**SO**tagliflozi**N** in Patients with Symptom**AT**ic obstructive **A**nd non-obstructive **H**ypertrophic **C**ardio**M**yopathy (SONATA-HCM)" study were presented on Saturday, May 17. The study design was disclosed in Belgrade, Serbia at one of the premier international heart failure meetings: Heart Failure 2025, the Annual Congress of the Heart Failure Association of the European Society of Cardiology.

Enrollment is underway in SONATA-HCM, with all study sites in 20 countries expected to be operational by September 2025. Lexicon believes there is potential for the study results to support a supplemental new drug application (sNDA) for sotagliflozin for both obstructive and non-obstructive HCM.

SONATA-HCM is the only ongoing Phase 3 study in both obstructive and non-obstructive HCM. It is a randomized, double-blind, placebo-controlled multicenter trial that will evaluate the efficacy of sotagliflozin, a dual SGLT1 and SGLT2 inhibitor, on symptoms, function, and other patient-reported outcomes, as well as safety in patients with symptomatic HCM. The study is designed to enroll 500 patients worldwide, 250 with obstructive HCM and 250 with non-obstructive HCM. The primary efficacy endpoint is improvement in symptoms, as measured by change from baseline to week 26, in the Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ) CSS survey.

"There is a huge unmet need for people suffering from HCM, with no approved or effective therapies for non-obstructive HCM," said Sharlene M. Day, M.D., co-principal investigator for SONATA-HCM and Presidential Professor and Director of Translational Research in the Division of Cardiovascular Medicine and the Cardiovascular Institute at the University of Pennsylvania Perelman School of Medicine. "I'm very excited to be testing the potential for sotagliflozin to improve symptoms in a broad number of patients across the spectrum of HCM, as has previously been demonstrated in patients with heart failure with reduced and preserved ejection fraction. Sotagliflozin's tolerability profile and immediate benefits observed in patients with heart failure could potentially make it a very appealing option for patients with HCM if the benefits do indeed extend to this population."

As a chronic, progressive disease, HCM can worsen over time and lead to other complications, including heart failure and stroke. Sotagliflozin is a proven drug for the treatment of heart failure, with an established safety record and significant use in clinical practice. A growing body of evidence suggests that sotagliflozin's dual inhibition of SGLT1 and SGLT2 reduces the risk of major adverse cardiovascular events (MACE), including heart attack and stroke, as most recently published in *The Lancet* in February 2025.

"SONATA-HCM is an important study with the potential to support a broad label to enhance the care of patients with both obstructive and non-obstructive HCM," said Craig Granowitz, M.D., Ph.D., Lexicon's senior vice president and chief medical officer.

For more information on the study, visit the SONATA-HCM page on ClinicalTrials.gov.

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.

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, hypertrophic cardiomyopathy (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 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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