



Lexicon Pharmaceuticals Completes Enrollment of Pivotal Phase 3 SONATA-HCM Study of Sotagliflozin in Symptomatic Non-Obstructive and Obstructive Hypertrophic Cardiomyopathy (HCM)

July 27, 2026

Study substantially exceeded enrollment target of 500 patients

Topline results anticipated in Q1 2027

THE WOODLANDS, Texas, July 27, 2026 (GLOBE NEWSWIRE) -- [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXXR) today announced that randomization of patients has been completed in the pivotal Phase 3 “**S**otagliflozi**N** in Patients with Symptom**A**Tic obstructive **A**nd non-obstructive **H**ypertrophic **C**ardio**M**yopathy (SONATA-HCM)” clinical trial evaluating sotagliflozin in patients with non-obstructive (nHCM) and obstructive (oHCM) hypertrophic cardiomyopathy.

The study substantially exceeded its enrollment target of 500 patients across more than 130 sites in 20 countries. The primary efficacy endpoint will assess improvement in symptoms for the entire population (nHCM and oHCM). The final study population included a substantial majority of patients with non-obstructive HCM, providing a robust opportunity to evaluate sotagliflozin in a patient group for whom effective treatment options remain limited, as well as a meaningful cohort of patients with obstructive HCM. Lexicon believes the final study population will enable a thorough assessment of sotagliflozin's potential across the spectrum of symptomatic HCM. Topline results are anticipated in the first quarter of 2027.

“Completion of patient enrollment in SONATA-HCM marks an important milestone for patients living with the symptoms of HCM, a chronic, progressive disease,” said Craig Granowitz, M.D., Ph.D., Lexicon’s senior vice president and chief medical officer. “We believe that sotagliflozin, a dual SGLT1 and SGLT2 inhibitor with a unique mechanism of action as compared to currently available treatments, has the potential to be a differentiated option for symptomatic HCM patients. We look forward to sharing topline results in the first quarter of 2027.”

SONATA-HCM is the only ongoing Phase 3 study in both non-obstructive and obstructive HCM and is the largest Phase 3 study including both nHCM and oHCM to date. SONATA-HCM is a randomized, double-blind, placebo-controlled, multinational trial that is evaluating the efficacy of sotagliflozin on symptoms, function, and other patient-reported outcomes, as well as safety, in patients with symptomatic 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). Patients with symptomatic HCM on a stable dose of guideline-directed therapy for HCM, including cardiac myosin inhibitors, were permitted to enroll in the study depending on certain criteria.

“For patients living with hypertrophic cardiomyopathy, there remains a significant need for additional treatment options that can help address persistent symptoms and improve daily function,” said Sharlene M. Day, M.D., co-principal investigator for SONATA-HCM, Presidential Professor, Director of Translational Research of the Penn Cardiovascular Institute, University of Pennsylvania. “Having a well-tolerated medication with a distinct mechanism of action that can complement other therapies would be an important advance for physicians and patients.”

“Completing enrollment in SONATA-HCM is a major achievement for the HCM community and reflects the commitment of investigators, study teams and participants,” said Carolyn Y. Ho, M.D., co-principal investigator for SONATA-HCM, Professor of Medicine at Harvard Medical School and Medical Director of the Cardiovascular Genetics Center at Brigham and Women’s Hospital. “We are grateful to the patients involved in this trial, whose partnership is essential to advancing research and hopefully bringing a novel treatment option to people living with HCM.”

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 hypertrophic cardiomyopathy (HCM).

About Lexicon Pharmaceuticals

Lexicon is a biopharmaceutical company with a mission of pioneering medicines that transform patients’ lives. Lexicon has a pipeline of drug candidates in discovery, preclinical, and clinical development in neuropathic pain, hypertrophic cardiomyopathy

(HCM), obesity and metabolic disorders, and other cardiometabolic indications. For additional information, please visit www.lexpharma.com.

Safe Harbor Statement

This press release contains “forward-looking statements,” including statements relating to the research, development and therapeutic and commercial potential of sotagliflozin in hypertrophic cardiomyopathy. In addition, this press release may also contain forward-looking 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, 2025, 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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