



Lexicon Pharmaceuticals Provides Update on Baseline Patient Characteristics for Pivotal Phase 3 SONATA-HCM Study of Sotagliflozin in Symptomatic Hypertrophic Cardiomyopathy

October 23, 2026

-- Patient demographics consistent with prior studies of other agents in HCM and reflect real-world clinical practice --

-- Mean baseline KCCQ-CSS of 59 shows considerable symptom burden at study entry --

-- Substantial over enrollment strengthens statistical power and provides robust dataset to evaluate the efficacy and safety of sotagliflozin --

THE WOODLANDS, Texas, Oct. 23, 2026 (GLOBE NEWSWIRE) -- [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXRX), a leading cardiometabolic biopharmaceutical company, today provided an update on the baseline characteristics of the patients randomized into the ongoing 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 symptomatic hypertrophic cardiomyopathy. The data will be presented in detail by Dr. Sharlene Day, M.D., Presidential Professor, Director of Translational Research of the Penn Cardiovascular Institute, University of Pennsylvania and co-chair of the SONATA-HCM steering committee, on Saturday, October 24, 2026, at 4:05 p.m. ET at the International HCM Summit in Boston, MA.

The patient enrollment profile of SONATA-HCM is consistent with the study's inclusive design, which aimed to reflect real-world clinical practice. Patients were permitted to remain on stable background therapies, including cardiac myosin inhibitors, allowing evaluation of sotagliflozin in patients receiving currently available HCM treatments. Importantly, baseline demographic and clinical characteristics within both the non-obstructive (nHCM) and obstructive HCM (oHCM) cohorts were generally consistent with those reported in previous clinical studies of other agents in those respective patient populations, supporting the relevance of the SONATA-HCM study population to the broader HCM community.

In total, SONATA-HCM enrolled 542 patients across more than 130 sites in 20 countries, substantially exceeding the study's target enrollment of 500 patients and a providing larger dataset that may further enhance the statistical power of the study to detect meaningful treatment effects on its primary efficacy endpoint. Among enrolled patients, 440 have nHCM and 102 have oHCM, positioning SONATA-HCM to evaluate sotagliflozin in a broad HCM population while emphasizing patients with non-obstructive disease, who currently have no FDA-approved disease-specific treatments.

The overall study population had a mean baseline Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS) of 59, reflecting a considerable burden of symptoms and limitations in daily activities at study entry. KCCQ-CSS ranges from 0 to 100, with higher scores indicating better health status and fewer symptoms, demonstrating that the SONATA-HCM study population began the trial with substantial opportunity for improvement. The primary efficacy endpoint of the pivotal study is improvement in symptoms, as measured by change from baseline in KCCQ-CSS at Week 26.

"We designed SONATA-HCM to evaluate sotagliflozin in a broad and clinically relevant HCM population reflective of real-world clinical practice, and we are very pleased that the final study population met that objective," said Craig Granowitz, M.D., Ph.D., senior vice president and chief medical officer of Lexicon. "The demographic and clinical characteristics of both the obstructive and non-obstructive HCM cohorts were generally consistent with those reported in previous studies of other agents, while the baseline KCCQ score reflects a population with meaningful symptom burden. Combined with the substantial over enrollment and representation of both major HCM subtypes, we believe SONATA-HCM is well positioned to evaluate sotagliflozin across the broad spectrum of symptomatic HCM patients."

SONATA-HCM is the only ongoing Phase 3 study in both nHCM and oHCM and is the largest Phase 3 study including both nHCM and oHCM to date. Topline results are anticipated in the first quarter of 2027.

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 and the heart. 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 Pharmaceuticals is a biopharmaceutical company pursuing novel medicines for patients with serious cardiometabolic diseases. Building on a proven legacy in genetic target discovery, Lexicon is advancing a clinical pipeline in areas of significant and often underserved need, with programs in hypertrophic cardiomyopathy (HCM), type 1 diabetes (T1D), obesity and other related metabolic conditions. Lexicon is committed to developing differentiated therapies that can be integrated broadly into clinical practice, with the goal of expanding treatment options for patients. Its capabilities extend from early-stage target discovery through clinical development and commercialization, strategically paired with high-impact collaborations to maximize the global reach of its medicines.

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.

For Media Inquiries:

Dave Belian
Lexicon Pharmaceuticals, Inc.
lexinvest@lexpharma.com

For Investor Inquiries:

Lisa DeFrancesco
Lexicon Pharmaceuticals, Inc.
lexinvest@lexpharma.com