Lexicon Pharmaceuticals Announces Update on Submission of Additional Data to U.S. FDA Supporting the Benefit-Risk Profile of Zynquista® in Type 1 Diabetes

September 22, 2025

Data obtained from ongoing third-party funded, investigator-sponsored trials have been submitted in effort to address the December 2024 complete response letter

Company seeks alignment on reasonable path forward for Zynquista NDA resubmission

FDA feedback from Type D meeting now expected during the fourth quarter

THE WOODLANDS, Texas, Sept. 22, 2025 (GLOBE NEWSWIRE) -- Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) today announced an update to the previous submission of additional clinical data to the U.S. Food and Drug Administration (FDA) from ongoing third-party funded, investigator-initiated studies supporting the potential resubmission of the New Drug Application for Zynquista® (sotagliflozin), an oral SGLT1/SGLT2 inhibitor, as an adjunct to insulin for glycemic control in adults with type 1 diabetes (T1D). The FDA has informed Lexicon that it requires additional time to review this data and now expects to provide feedback from the September Type D meeting in the fourth quarter, previously anticipated by end of September.

As previously disclosed, the submission of additional clinical data followed a complete response letter issued by the FDA in December 2024 that cited concerns of increased risk of diabetic ketoacidosis. Based on subsequent discussions with FDA regarding potential regulatory paths forward, Lexicon has been granted a Type D meeting and has submitted data from three ongoing studies of sotagliflozin conducted by the Steno Diabetes Center (STENO1)[1], the Joslin Diabetes Center (SUGARNSALT)[2] and the University of Dundee (SOPHIST)[3] supporting the benefit-risk profile of Zynquista in T1D.

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.

References
[1]"Multifactorial Intervention to Reduce Cardiovascular Disease in Type 1 Diabetes (Steno1)." *Clinicaltrials.Gov*, www.clinicaltrials.gov/study/NCT06082063. Accessed 4 Sept. 2025.
[2]"Sotagliflozin to Slow Kidney Function Decline in Persons With Type 1 Diabetes and Diabetic Kidney Disease (SUGARNSALT)." *Clinicaltrials.Gov*, www.clinicaltrials.gov/study/NCT06217302. Accessed 4 Sept 2025.
[3]"SOPHIST Clinical Trial." *University of Dundee*, www.sites.dundee.ac.uk/sophist-trial/. Accessed 4 Sept. 2025.

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, including sotagliflozin. 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, regulatory interactions relating to its drug candidates, 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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