Lexicon Announces Receipt of Complete Response Letter for Zynquista™ (sotagliflozin)

December 20, 2024

Confirms Previously Disclosed and Anticipated FDA Decision

THE WOODLANDS, Texas, Dec. 20, 2024 (GLOBE NEWSWIRE) -- Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) today announced it has received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for Zynquista™ (sotagliflozin) as an adjunct to insulin therapy for glycemic control in adults with type 1 diabetes and chronic kidney disease (CKD).

This expected communication from the FDA aligns with the company's previously disclosed strategic decision to discontinue launch preparations for Zynquista and focus solely on its clinical development pipeline.

"We are sincerely grateful to the patients and physicians who participated in our Zynquista™ clinical trials, and the broader diabetes community who strongly advocated for Zynquista's approval," said Mike Exton, Ph.D., chief executive officer and director of Lexicon. "Although this was not our desired outcome for sotagliflozin in this indication, we remain steadfast in our commitment to advancing our clinical pipeline, including our near-term focus on LX9211 for diabetic neuropathic pain (DPNP) with top line data from our PROGRESS Phase 2b study anticipated in Q1 2025, and pursuing innovations that we believe can profoundly benefit 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, growth and future operating results, discovery and development 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, conduct preclinical and clinical development and obtain necessary regulatory approvals of sotagliflozin, LX9211, LX9851 and 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 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, 2023 and other subsequent disclosure documents 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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