



Lexicon Pharmaceuticals Announces Successful End-of-Phase 2 Meeting with FDA For Pilavapadin in the Treatment of Diabetic Peripheral Neuropathic Pain

January 21, 2026

– No objections raised by FDA to advancement of pilavapadin into Phase 3 development utilizing two-arm registrational studies of 10 mg daily dose compared to placebo –

THE WOODLANDS, Texas, Jan. 21, 2026 (GLOBE NEWSWIRE) -- [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXRX) today announced the successful completion of the End-of-Phase 2 (EOP2) Meeting with the U.S. Food and Drug Administration (FDA) for pilavapadin in diabetic peripheral neuropathic pain (DPNP). During the meeting, the FDA raised no objections to the advancement of pilavapadin into Phase 3 development, which would include two placebo-controlled, 12-week, two arm registrational studies comparing the 10 mg daily dose to placebo. The primary endpoint of the Phase 3 studies will be the change in average daily pain score (ADPS) from baseline to Week 12.

"Our End-of-Phase 2 meeting with FDA was productive and provided Lexicon with the insights needed to design a robust Phase 3 program, with the goal of making the first non-opioid DPNP medicine available to patients in over two decades," said Mike Exton, Ph.D., chief executive officer and director of Lexicon. "Furthermore, the FDA did not require any unanticipated preclinical or clinical studies that would be expected to complicate or delay the advancement of this program into Phase 3 development and a potential regulatory submission."

About Pilavapadin

Discovered using Lexicon's unique approach to gene science, pilavapadin is a potent, once-daily, orally delivered, selective, investigational small molecule inhibitor of AAK1, a novel target for neuropathic pain which inhibits reuptake and recycling of neurotransmitters involved in pain signaling without affecting opiate pathways. Lexicon identified AAK1 in its target discovery efforts as a promising approach for the treatment of neuropathic pain. Preclinical studies of pilavapadin demonstrated central nervous system penetration and reduction in pain behavior in models of neuropathic pain without affecting opiate pathways.

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 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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