



Lexicon Pharmaceuticals Presents Additional Pilavapadin Data in Diabetic Peripheral Neuropathic Pain at 19th Annual Pain Therapeutics Summit

October 14, 2025

– Results support advancement of 10 mg dose into Phase 3 development –

– End-of-Phase 2 meeting request accepted by U.S. FDA; partnership discussions progressing –

THE WOODLANDS, Texas, Oct. 14, 2025 (GLOBE NEWSWIRE) -- [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXRX) today announced the Company presented additional clinical data and program updates from its Phase 2 pilavapadin program at the 19th Annual Pain Therapeutics Summit.

These data follow the [topline results](#) from the Phase 2b PROGRESS study of pilavapadin in diabetic peripheral neuropathic pain (DPNP) announced in March of 2025, which identified 10 mg once daily as the most clinically meaningful and appropriate dose to advance into Phase 3 development.

“Following the release of topline results from our PROGRESS study earlier this year, we performed additional analyses of the Phase 2 program data that support Phase 3 readiness of the 10mg dose of pilavapadin for DPNP. With these additional analyses, we have submitted an end-of-Phase 2 meeting with the U.S. FDA,” said Mike Exton, Ph.D., chief executive officer and director of Lexicon. “Our request has been accepted by the FDA and, in tandem, we are actively progressing discussions with potential partners.”

The additional analyses from the Phase 2 program resulted in four primary conclusions by the company with respect to the 10mg dose of pilavapadin:

1. **Validated biological activity**, as evidenced by a linear relationship between increased plasma levels of pilavapadin and pain reduction.
2. **Clinically meaningful efficacy**, with a 2-point average daily pain score (ADPS) reduction from baseline at 12 weeks.
3. **Acceptable tolerability profile**, with placebo-like treatment completion rates.
4. **Acceptable safety profile** in line with standard of care, further bolstered by subsequent studies showing no prolonged QTc interval with pilavapadin treatment and no significant impact on the pharmacokinetics (PK) of pilavapadin from mild to moderately impaired renal function.

The data presentation included results from a post-hoc, pooled analysis of the Phase 2 RELIEF-DPN 1 and Phase 2b PROGRESS studies, which collectively enrolled more than 600 patients, designed to investigate the exposure-response relationship across the two Phase 2 studies, investigate the lack of efficacy of the 20 mg dose in the PROGRESS study, and confirm the robustness of the 10 mg dose for Phase 3 studies. Participants in the PROGRESS 20 mg dose arm were less adherent than participants in the other study arms, potentially driven by increased tolerability symptoms among patients receiving the 20mg dose and potentially driving the lack of observed dose response in that arm.

The slide presentation from the 19th Annual Pain Therapeutics Summit is available on the Events page of the Company's website at <https://investors.lexpharma.com/>.

About Pilavapadin

Discovered using Lexicon's unique approach to gene science, pilavapadin (LX9211) 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.

For Investor and Media Inquiries:

Lisa DeFrancesco

Lexicon Pharmaceuticals, Inc.

lexinvest@lexpharma.com