



Data From Lexicon's RELIEF-DPN 1 Phase 2 Study of LX9211 Published Today in *Diabetes Care*, a Peer-Reviewed Journal of the American Diabetes Association

June 19, 2024

Clinical trial of LX9211, an investigational non-opioid investigational therapy, demonstrated clinically significant benefits for people with diabetic peripheral neuropathic pain (DPNP)

Investigators conclude that clinical outcomes of RELIEF-DPN 1 support commencement of Lexicon's dose-ranging Phase 2b PROGRESS trial, currently enrolling patients

The Woodlands, Texas, June 19, 2024 – [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXRX) today announced that *Diabetes Care*, the peer-reviewed journal of the American Diabetes Association, has published a research paper on the company's Phase 2 RELIEF-DPN-1 clinical trial investigating LX9211 for the treatment of diabetic peripheral neuropathic pain (DPNP).

In the proof-of-concept RELIEF-DPN-1 study, the effects of LX9211 were assessed over an 11-week evaluation period, which included a six-week double-blind treatment period and a 5-week single-blind safety follow-up period. The primary efficacy endpoint under evaluation was the change from baseline to week 6 in average daily pain score (ADPS), which was achieved for subjects participating in the low-dose LX9211 arm. Patient reported outcomes were improved in patients treated with LX9211 and LX9211 was generally well tolerated.

As noted by the study authors, currently available therapies for DPNP provide only modest pain relief, with fewer than half of individuals achieving 50% reduction in pain severity. Additionally, most people suffering from DPNP experience undesirable, dose-limiting adverse events with existing therapies. And despite a lack of supportive clinical evidence, many people with DPNP continue to be treated with opioids as first-line therapy, leading to very high associated risks and complications, including death.

"Results observed in this study show that LX9211 may become an efficacious treatment for moderate-to-severe pain due to DPNP. These findings reflect a promising breakthrough in the clinical management of DPNP, one of the strongest risk factors for mortality in people with diabetes, and the leading cause of non-traumatic amputation," said Rodica Pop-Busui, MD, PhD, Division of Metabolism, Endocrinology and Diabetes, Department of Internal Medicine, University of Michigan, Ann Arbor, MI, and the lead author of the research paper.

"We are grateful to the investigators, their research teams and the people suffering from DPNP who participated in this important study," said Craig Granowitz, M.D., Ph.D., Lexicon's senior vice president and chief medical officer. "Their contributions have enabled us to commence our large dose-ranging Phase 2b PROGRESS trial, currently enrolling patients throughout the United States."

To learn about the PROGRESS trial please visit diabeticpainstudy.com.

An abstract of a Lexicon-sponsored study entitled "**Patient-Reported Burden of Disease in Diabetic Peripheral Neuropathic Pain—Learnings from In-depth Patient Interviews—Substudy of RELIEF-DPN 1**" will be presented at the 84th Scientific Sessions of the American Diabetes Association on Sunday, June 23, 2024, 12:30 - 1:30 p.m. ET, in the Poster Hall (West A-4-B2), Board No. 484.

The research paper, "**Efficacy and Safety of LX9211 for Relief of Diabetic Peripheral Neuropathic Pain (RELIEF-DPN 1): Results of a Double-blind, Randomized, Placebo-Controlled, Proof-of-Concept Study**," can be accessed [here](#).

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 commercially launched one of these medicines, INPEFA® (sotagliflozin) in the United States, and has a pipeline of other promising drug candidates in discovery and clinical and preclinical development in neuropathic pain, diabetes and metabolism and other indications. For additional information, please visit www.lexpharma.com.

About LX9211

Discovered using Lexicon's unique approach to gene science, LX9211 is a potent, orally delivered, selective, investigational small molecule inhibitor of adaptor-associated kinase 1 (AAK1). Lexicon identified AAK1 in its target discovery efforts as a promising approach for the treatment of neuropathic pain and identified LX9211 and another development candidate in a neuroscience drug discovery alliance with Bristol-Myers Squibb from which Lexicon holds exclusive development and commercialization rights. Preclinical studies of LX9211 demonstrated central nervous system penetration and reduction in pain behavior in models of neuropathic pain without affecting opiate pathways. LX9211 has received Fast Track designation from the U.S. Food and Drug Administration for development in diabetic peripheral neuropathic pain.

Safe Harbor Statement

This press release contains "forward-looking statements," including statements relating to LX9211 and Lexicon's financial position and long-term outlook on its business, 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 INPEFA in heart failure, conduct preclinical and clinical development and obtain necessary regulatory approvals of sotagliflozin (in other indications), 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 products and 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.

For Investor Inquiries:

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

For Media Inquiries:

Alina Cocuzza
Lexicon Pharmaceuticals, Inc.
acocuzza@lexpharma.com