# Lexicon Pharmaceuticals Highlights Scientific and Medical Presentations Relating to Its Successful Phase 2 Proof-of-Concept Study of LX9211 in Painful Diabetic Neuropathy

September 20, 2022

***Poster and Oral Presentation at PAINWeek Describing a Novel Mechanism of Action for Neuropathic Pain***

***Poster at International Association for the Study of Pain (IASP) World Congress on Pain Describing Design Elements of the RELIEF-DPN-1 Study***

***Podium Presentation at 16th Annual Pain Therapeutics Summit Discussing Full Results From the RELIEF-DPN-1 Study***

**The Woodlands, Texas, September 20, 2022** - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) today announced a series of scientific and medical presentations describing the progression of its investigational drug LX9211 from discovery to translation in a clinical proof-of-concept study.

- A poster was presented and an oral presentation was given on September 8th and 9th, respectively, at the **PAINWeek 2022 National Conference on Pain Management** in Las Vegas, Nevada
  - The poster and presentation, each titled *"LX9211, a Novel Therapeutic Approach to Treatment of Neuropathic Pain,"* described the mechanism of action of LX9211's novel target, adaptor-associated protein kinase 1 (AAK1), as well as results from multiple preclinical models of neuropathic pain after treatment with the potent AAK1 inhibitor LX9211.
- A poster will be presented today at 3:15pm ET at the **IASP World Congress on Pain** in Toronto, Canada. (https://iaspworldcongress2022.org/)
  - The poster, titled *"Efficacy, Safety, and Pharmacokinetics of LX9211 in the Treatment of Diabetic Peripheral Neuropathic Pain (RELIEF-DPN 1),"* outlines the unique study design, baseline patient characteristics, and the positive results of the primary endpoint of the study.
- An oral presentation will be given on November 14th at 3:35pm ET at **Arrowhead's Annual Pain Therapeutics Summit** in Washington, D.C. (https://www.paintherapeuticsummit.com/)
  - The presentation, titled *"A Phase 2 Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of LX9211 in the Treatment of Diabetic Peripheral Neuropathic Pain (RELIEF-DPN 1),"* will discuss the framework of the trial, the preclinical basis for the program, and a full analysis of the results from this positive proof-of-concept study.

"We believe the successful translation of a novel mechanism for the potential treatment of neuropathic pain could be transformational for patients," said Dr. Craig Granowitz, Lexicon's senior vice president and chief medical officer. "We are excited to present these findings to the medical and scientific community and expect to communicate additional LX9211 clinical and preclinical data as they become available. Based on these results, we will expeditiously advance the clinical development of LX9211 for the treatment of neuropathic pain, an area of significant unmet clinical need."

**About the RELIEF-DPN-1 Study**

RELIEF-DPN-1 was a Phase 2 randomized, double-blind, placebo-controlled, parallel-group, multicenter study evaluating the efficacy, safety and pharmacokinetics of LX9211 in the treatment of painful diabetic neuropathy, also referred to as diabetic peripheral neuropathic pain. The study enrolled 319 patients at approximately 40 U.S. clinical sites, evaluating three treatment groups receiving placebo or one of two dosing regimens of LX9211 (an initial dose of 100 mg followed by once-daily doses of 10 mg or an initial dose of 200 mg followed by once-daily doses of 20 mg). The primary efficacy endpoint under evaluation was the change from baseline to week 6 in ADPS, based on the 11-point numerical rating scale. The results of the study on the primary endpoint showed a reduction from baseline in ADPS of 1.39 points (p=0.007 versus placebo) in the low dose arm and 1.27 points (p=0.030 versus placebo) in the high dose arm, compared to 0.72 in the placebo arm. Under the statistical analysis plan for the study, a p-value of less than 0.028 was considered statistically significant.

The RELIEF-DPN-1 study was the first of two Phase 2 proof-of-concept studies evaluating LX9211 in neuropathic pain. LX9211 is also under evaluation in RELIEF-PHN-1, a study in patients with post-herpetic neuralgia, from which Lexicon is targeting top-line results around the end of the fourth quarter of 2022.

**About LX9211**

Discovered using Lexicon's unique approach to gene science, LX9211 is a potent, orally delivered, selective 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 the development in diabetic peripheral neuropathic pain.

**About Lexicon Pharmaceuticals**

Lexicon is a biopharmaceutical company with a mission of pioneering medicines that transform patients' lives. Through its Genome5000™ program, 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 safely and effectively treat disease. Lexicon advanced one of these medicines to market and has a pipeline of promising drug candidates in discovery and clinical and preclinical development in heart failure, neuropathic pain, diabetes and 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 the clinical development of and potential therapeutic and commercial potential of LX9211. In addition, this press release also contains forward looking statements relating to the clinical development of, regulatory filings for and potential therapeutic and commercial potential of sotagliflozin and Lexicon's other potential drug candidates, as well as 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, successfully conduct preclinical and clinical development and obtain necessary regulatory approvals of sotagliflozin, LX9211 and its other potential drug candidates on its anticipated timelines, successfully commercialize any products for which it obtains regulatory approval, 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, 2021, 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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