



Lexicon Pharmaceuticals Receives Fast Track Designation from the FDA for LX9211 for Diabetic Peripheral Neuropathic Pain

December 12, 2020

The Woodlands, Texas, December 11, 2020 – Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), announced today that it has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the development of LX9211 in diabetic peripheral neuropathic pain.

“The FDA’s Fast Track designation of LX9211 reflects the serious unmet medical need of people suffering from diabetic peripheral neuropathic pain,” said Praveen Tyle, Ph.D., executive vice president of research and development. “We look forward to working closely with the FDA throughout the clinical development process to bring this potential new innovative treatment to patients as quickly as possible.”

Lexicon is currently enrolling patients with diabetic peripheral neuropathic pain in a Phase 2 proof-of-concept study of LX9211 and is preparing to initiate a second Phase 2 clinical trial of LX9211 in post-herpetic neuralgia.

The FDA’s Fast Track designation is designed to facilitate the development and expedite the review of drugs that are being developed to treat serious conditions and fill unmet medical needs. The purpose of the designation is to expedite the timeline for bringing important new drugs to patients. Programs receiving Fast Track designation may benefit from early and frequent interactions with the FDA over the course of drug development. In addition, the Fast Track designation program provides eligibility for accelerated approval and priority review if relevant criteria are met and enables sponsors to submit individual sections of a New Drug Application (NDA) for review on a rolling-submission basis.

About LX9211

LX9211 is a potent, orally delivered, selective small molecule inhibitor of adapter-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.

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 neuropathic pain, heart failure, 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 Lexicon’s financial position, long-term outlook on its business and the clinical development and 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 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 LX9211, sotagliflozin and its other potential 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, 2019, 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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