Lexicon Pharmaceuticals Resubmits Sotagliflozin NDA for Type 1 Diabetes

June 21, 2024

Lexicon Seeks Approval for Sotagliflozin as an Adjunct to Insulin Therapy for Glycemic Control in People with Type 1 Diabetes and Chronic Kidney Disease

Company Anticipates Six Month Review and Potential Launch in Early 2025

The Woodlands, Texas, June 21, 2024 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today announced that, following multiple interactions with and recent feedback from the U.S. Food and Drug Administration (FDA), it has resubmitted its New Drug Application (NDA) for sotagliflozin as an adjunct to insulin therapy for glycemic control in people with type 1 diabetes and chronic kidney disease (CKD).

"We are confident in the benefit/risk profile of sotagliflozin for people with type 1 diabetes and CKD, and our team has been resolute in identifying and pursuing a regulatory path forward," said Lonnel Coats, director and chief executive officer. "We are now one step closer to bringing this important potential therapy to market for the many people who suffer from type 1 diabetes and CKD, and who could benefit from an adjunct to insulin therapy for glycemic control."

In 2019, the FDA issued a complete response letter (CRL) regarding the NDA for sotagliflozin for type 1 diabetes. In 2021, at Lexicon's request, the FDA issued a public Notice of Opportunity for Hearing (NOOH) on whether there were grounds for denying such approval. Lexicon and FDA subsequently agreed in late 2023 to hold the NOOH proceedings in abeyance in order to engage in discussions regarding a path forward for resubmission and potential approval of the NDA. The application remains in "filed" status at the FDA and the company expects to receive a formal communication from FDA within 30 days of today's submission establishing the action date and anticipates a six-month regulatory review period.

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.

Safe Harbor Statement

This press release contains "forward-looking statements," including statements relating to the therapeutic and commercial potential, research and clinical development and regulatory status of sotagliflozin in type 1 diabetes. In addition, this press release may also contain forward looking statements relating to 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 commercialize INPEFA® (sotagliflozin) in heart failure, conduct preclinical and clinical development and obtain necessary regulatory approvals of sotagliflozin in type 1 diabetes and 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 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.

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