



## Lexicon Pharmaceuticals Receives December 20, 2024 PDUFA Goal Date for Sotagliflozin Type 1 Diabetes NDA Resubmission

July 16, 2024

**Launch Preparations Actively Underway; Launch Planned for Early 2025**

**Lexicon Seeks Approval for Zynquista™ (sotagliflozin) as an Adjunct to Insulin Therapy for Glycemic Control in Adults with Type 1 Diabetes and Chronic Kidney Disease**

**The Woodlands, Texas, July 16, 2024** - [Lexicon Pharmaceuticals, Inc.](https://www.lexpharma.com) (Nasdaq: LXRX), today announced that the U.S. Food and Drug Administration (FDA) has acknowledged the resubmission of its New Drug Application (NDA) for Zynquista™ (sotagliflozin) as an adjunct to insulin therapy for glycemic control in adults with type 1 diabetes and chronic kidney disease (CKD). The FDA indicated that it considers the resubmission to be a complete response to the FDA's 2019 action letter regarding the sotagliflozin NDA for type 1 diabetes, providing a Prescription Drug User Fee Act (PDUFA) goal date of December 20, 2024.

"Lexicon has continued confidence in the favorable benefit/risk profile of sotagliflozin for adults with type 1 diabetes and CKD. With a PDUFA date now in hand, we can begin the next phase of launch preparation for Zynquista," said Dr. Mike Exton, chief executive officer and director. "If approved, this will mark Lexicon's second NDA approval and commercial launch in two years of products that originated from our novel discovery platform and advanced to regulatory approval and commercialization. With an exciting and diverse portfolio of assets, Lexicon is well-positioned for strong future value creation for all stakeholders."

### 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](https://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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