



## **Lexicon Voluntarily Withdraws Sotagliflozin New Drug Application and Plans Prompt Resubmission Targeted Early Q2 2022**

February 28, 2022

### **Resubmission to Correct Recently-Identified Technical Issue**

#### **Conference Call and Webcast at 8:00 am Eastern Time**

**The Woodlands, Texas, February 28, 2022** - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) today announced the voluntary withdrawal and planned near-term resubmission of the company's New Drug Application (NDA) for sotagliflozin to correct a technical issue with the submission recently identified by the company. The company promptly notified the U.S. Food and Drug Administration (FDA) about the issue and has been in discussions with the agency to correct the submission. Due to the proximity to the conclusion of the 60-day filing review period, Lexicon determined, after consultation with the FDA, that the withdrawal of the NDA and a subsequent resubmission would be the most appropriate action to provide a complete submission for review.

"The NDA resubmission is our top priority," said Lonnel Coats, Lexicon's chief executive officer. "We consider our ongoing dialogue with the FDA to be encouraging and are targeting a resubmission early in the second quarter of 2022."

Lexicon management will hold a live conference call and webcast today at 8:00 am ET / 7:00 am CT. The dial-in number for the conference call is 888-645-5785 (U.S./Canada) or 970-300-1531 (international). The conference ID for all callers is 8051406. The live webcast and replay may be accessed by visiting Lexicon's website at [www.lexpharma.com/investors](http://www.lexpharma.com/investors). An archived version of the webcast will be available on the website for 14 days.

### **About Sotagliflozin**

Discovered using Lexicon's unique approach to gene science, sotagliflozin is an oral dual inhibitor of two proteins responsible for glucose regulation known as sodium-glucose co-transporter types 1 and 2 (SGLT1 and SGLT2). SGLT1 is responsible for glucose absorption in the gastrointestinal tract, and SGLT2 is responsible for glucose reabsorption by the kidney. Sotagliflozin is approved in the European Union (EU) for use as an adjunct to insulin therapy to improve blood sugar (glycemic) control in adults with type 1 diabetes with a body mass index  $\geq 27$  kg/m<sup>2</sup>, who could not achieve adequate glycemic control despite optimal insulin therapy, but has not yet been commercially launched.

### **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](http://www.lexpharma.com).

### **Safe Harbor Statement**

*This press release contains "forward-looking statements," including statements relating to Lexicon's financial position and long-term outlook on its business, including the clinical development of, regulatory filings for, and potential therapeutic and commercial potential of sotagliflozin, LX9211 and its other potential 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 resubmit its NDA for sotagliflozin on its anticipated timelines and gain FDA acceptance of such resubmission. Additional important factors include 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, 2020, 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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