Lexicon Announces FDA Acceptance of New Drug Application for Sotagliflozin to Treat Heart Failure

July 27, 2022

NDA supported by SOLOIST-WHF and SCORED Global Phase 3 Program Evaluating Sotagliflozin in Almost 12,000 People

The Woodlands, Texas, July 27, 2022 – Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review and filed its New Drug Application (NDA) for sotagliflozin, an investigational dual SGLT1 and SGLT2 inhibitor, for the treatment of heart failure. The FDA assigned a standard review for the NDA filing with a Prescription Drug User Fee Act (PDUFA) target action date in May 2023.

"This is an important step in potentially bringing sotagliflozin to market as a new treatment for heart failure," said Lonnel Coats, Lexicon's chief executive officer. "Informed by our regulatory discussions, we are seeking a broad heart failure label in the NDA encompassing heart failure patients with and without diabetes, and believe that the results of SOLOIST-WHF in patients admitted for recent worsening heart failure will be an important element distinguishing our proposed label. We look forward to engaging with the FDA during the review process to bring this potential new treatment to market by the middle of next year."

The NDA is supported by the results from the Phase 3 SOLOIST-WHF clinical study in patients with type 2 diabetes who had recently been hospitalized for worsening heart failure and the Phase 3 SCORED clinical study in patients with type 2 diabetes, chronic kidney disease and risks for cardiovascular disease. In the NDA, Lexicon is seeking that sotagliflozin be indicated to:

- Reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure, including those with acute or worsening heart failure.
- Reduce the risk of cardiovascular death, hospitalization for heart failure, urgent heart failure visit, nonfatal myocardial infarction, and nonfatal stroke in adults with type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors, including a history of heart failure.

About the SOLOIST-WHF and SCORED Studies

SOLOIST-WHF was a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluating the cardiovascular efficacy of sotagliflozin versus placebo when added to standard of care in 1,222 people with type 2 diabetes who had recently been hospitalized for worsening heart failure. The primary endpoint was the total number of events comprised of deaths from cardiovascular causes, hospitalizations for heart failure, and urgent visits for heart failure in people treated with sotagliflozin compared with placebo.

SCORED was a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluating the cardiovascular efficacy of sotagliflozin versus placebo when added to standard of care in 10,584 people with type 2 diabetes, chronic kidney disease with eGFR of 25 to 60 ml per minute per 1.73 m2 of body-surface area, and risks for cardiovascular disease. The primary endpoint was the total number of events comprised of deaths from cardiovascular causes, hospitalizations for heart failure, and urgent visits for heart failure in people treated with sotagliflozin compared with placebo.

Both SOLOIST-WHF and SCORED achieved their respective primary endpoints, with overall tolerability similar to placebo across both trials. Results from both studies were presented at the Late-Breaking Science Session of the American Heart Association (AHA) Scientific Sessions 2020 and simultaneously published in The New England Journal of Medicine (NEJM) in two separate articles titled: "Sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure" and "Sotagliflozin in Patients with Diabetes and Chronic Kidney Disease."

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 has been studied in multiple patient populations encompassing heart failure, type 1 and type 2 diabetes, and chronic kidney disease in fourteen Phase 3 clinical studies involving approximately 20,000 patients.

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," within the meaning of the federal securities laws, including, but not limited to, statements relating to the timing, clinical development of, regulatory filings and proposed label for, and potential therapeutic and commercial potential of sotagliflozin. 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, 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, quarterly report on Form 10-Q for the quarter ended March 31, 2022 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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