November 10, 2022

Unicycive Completes Enrollment of Pivotal Bioequivalence Study for RENAZORB™ (lanthanum dioxycarbonate), an Investigational Treatment for Hyperphosphatemia in Chronic Kidney Disease (CKD) Patients on Dialysis

Topline Data Expected by Year End 2022

On Track to File the NDA in 2023

LOS ALTOS, Calif., Nov. 10, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced that it has completed the enrollment of subjects in the RENAZORB bioequivalence (BE) study. RENAZORB (lanthanum dioxycarbonate) is an investigational phosphate binding agent utilizing proprietary nanoparticle technology that is being developed to treat hyperphosphatemia in CKD patients on dialysis.

The study is a randomized, open-label, two-way crossover BE study to establish pharmacodynamic bioequivalence between RENAZORB (lanthanum dioxycarbonate) and Fosrenol® (lanthanum carbonate)—the reference listed drug (RLD). Unicycive previously received confirmatory guidance from the U.S. Food and Drug Administration (FDA) that this single BE study in healthy volunteers would satisfy the requirements and that no other clinical studies are required for a New Drug Application (NDA) filing through the 505(b)(2) pathway.

The study enrolled 40 subjects per treatment arm (a total of 80 subjects enrolled) for 64 evaluable subjects. The study design, including the dose, primary endpoint, and sample size, was reviewed by, and aligned with the FDA before the initiation of the study. The primary endpoint of the study is LS (least square) mean change in urinary phosphate excretion from baseline to the evaluation period.

"The completion of enrollment of this pivotal clinical study is an important milestone for Unicycive, and we look forward to reporting the topline data from this study by the end of this year," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Based on the results of our pivotal BE study, Unicycive will seek a pre-NDA meeting with FDA subsequently to file the NDA in 2023. We remain confident that an advanced phosphate binder with the unique product profile of RENAZORB will be a welcome option for patients with hyperphosphatemia and represents a significant global market opportunity for Unicycive."

About RENAZORB (lanthanum dioxycarbonate)

RENAZORB is an investigational next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. Its potential best-in-class profile may have meaningful patient adherence benefits over currently available treatment options as it requires a smaller and fewer number of pills per dose and is swallowed instead of chewed.

About Hyperphosphatemia

Hyperphosphatemia is a serious medical condition that occurs in nearly all patients with End Stage Kidney Disease (ESKD). If left untreated, hyperphosphatemia leads to secondary hyperparathyroidism (SHPT), which then results in renal osteodystrophy (a condition like osteoporosis and associated with significant bone disease, fractures, and bone pain); cardiovascular disease with associated hardening of arteries and atherosclerosis (due to deposition of excess calcium-phosphorus complexes in soft tissue). Importantly, hyperphosphatemia is independently associated with increased mortality for patients with chronic kidney disease on dialysis. Based on available clinical data to date, over 80% of patients show signs of cardiovascular calcification by the time they become dependent on dialysis.

Dialysis patients are already at an increased risk for cardiovascular disease (because of underlying diseases such as diabetes and hypertension), and hyperphosphatemia further exacerbates this. Treatment of hyperphosphatemia is aimed at lowering serum phosphate levels via two means: (1) restricting dietary phosphorus intake; and (2) using, on a daily basis, and with each meal, oral phosphate binding drugs that facilitate fecal elimination of dietary phosphate rather than its absorption from the gastrointestinal tract into the bloodstream.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive’s lead drug, RENAZORB, is a novel phosphate binding agent being developed for the treatment of hyperphosphatemia. UNI-494 is a patent-protected novel drug candidate in late preclinical development for the treatment of acute kidney injury. For more information, please visit www.unicycive.com.

Forward-looking statement

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified using words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Unicycive's expectations, strategy, plans or intentions. These forward-looking statements are based on Unicycive's current expectations and actual results could differ materially. There are several factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side

effects or other safety risks that could preclude approval of our product candidates; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses; dependence on key personnel; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled 'Risk Factors' in Unicycive's Annual Report on Form 10-K for the year ended December 31, 2021, and other periodic reports filed with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Unicycive specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor Contact:

ir@unicycive.com
(650) 900-5470

Anne Marie Fields
Stern Investor Relations
annemarie.fields@sternir.com
212-362-1200

SOURCE: Unicycive Therapeutics, Inc.

Source: Unicycive Therapeutics, Inc.