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Unicycive Achieves Primary Endpoint in Pivotal Bioequivalence Study of Renazorb

Renazorb demonstrates pharmacodynamic bioequivalence to Fosrenol

Renazorb's enhanced product profile features reduced pill burden and small, swallowable tablets, which may improve patient compliance

On track to file New Drug Application mid-2023

LOS ALTOS, Calif., Dec. 28, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced that the primary endpoint was met in the Company's pivotal bioequivalence (BE) study comparing Renazorb to Fosrenol®. Based on the topline results, pharmacodynamic (PD) BE of Renazorb to Fosrenol was established and met the regulatory criteria for PD BE in the healthy volunteer BE study.

Renazorb is an investigational phosphate binding agent utilizing proprietary nanoparticle technology that is being developed to treat hyperphosphatemia in chronic kidney disease (CKD) patients on dialysis. If approved, Renazorb may dramatically reduce the pill burden that patients endure with currently available medications. The global market opportunity for treating hyperphosphatemia is projected to be in excess of $2.5 billion in 2022, with the United States accounting for more than $1 billion of that total. Despite the availability of several U.S. Food and Drug Administration (FDA)-cleared medications, 75 percent of U.S. dialysis patients fail to achieve the target phosphorus levels recommended by published medical guidelines. Market research indicates that the top reason for this significant unmet medical need is related to the high pill burden, which leads to poor patient compliance.

Unicycive previously received confirmatory guidance from the FDA that this single BE study in healthy volunteers would satisfy all clinical regulatory requirements and that no other clinical studies would be required for a New Drug Application (NDA) filing through the 505(b)(2) pathway.

Today's positive results are from a randomized, open-label, two-way crossover BE study to establish PD BE between Renazorb and Fosrenol. The study enrolled 40 subjects per treatment arm. The study design, including the dose, primary endpoint, and sample size, was reviewed, and aligned by the FDA before the initiation of the study.

"We are delighted with the successful outcome of our registrational BE study of Renazorb. This is a major milestone for Unicycive that brings us one step closer to obtaining market approval for Renazorb to treat hyperphosphatemia," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Our R&D team has extensive experience filing NDA submissions and a demonstrated track record of multiple product approvals from the FDA. We look forward to filing the NDA for Renazorb in mid-2023 and for its potential approval in

order to benefit the multitude of hyperphosphatemia patients who are not well served by current treatment options."

The primary outcome measure of the BE study was Least Square (LS) mean change in urinary phosphate excretion (in mg/day) from baseline to the evaluation period (PD variable). Based on the mixed-effect linear model, the 90% Confidence Interval (CI) was constructed for the difference in PD variable for Renazorb and Fosrenol. In addition, the acceptable range was defined as ± 20% of the LS mean of the PD variability for Fosrenol. PD BE was achieved because the 90% CI was completely contained within the acceptable range.

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). Its potential best-in-class profile has meaningful patient adherence benefits over currently available treatment options as it requires 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 Renal Disease (ESRD). If left untreated, hyperphosphatemia leads to secondary hyperparathyroidism (SHPT), which then results in renal osteodystrophy (a condition similar to 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.

Fosrenol is a registered trademark of Shire International Licensing BV.

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 new chemical entity in late preclinical development for the treatment of acute kidney injury. For more information, please visit www.unicycive.com.

Forward-looking statements

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

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