March 25, 2024

Unicycive Therapeutics to be Featured in Multiple Presentations at the Upcoming European Renal Association Congress

LOS ALTOS, Calif., March 25, 2024 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease (the "Company or "Unicycive"), today announced that multiple presentations will be delivered on the Company's product candidates, oxylanthanum carbonate (OLC) and UNI-494, at the 61st European Renal Association (ERA) Congress taking place May 23-26, 2024, in Stockholm, Sweden.

Shalabh Gupta, MD, Chief Executive Officer of Unicycive, commented, "The ERA Congress is one of the most prominent nephrology meetings of the year, and we are excited to deliver presentations on both OLC and UNI-494. In addition to presenting preclinical data supporting both of our programs, we will also be reporting on our two clinical trials in progress. We look forward to participating in this important event."

Oxylanthanum Carbonate (OLC)

Title:	**Enhanced Urinary Phosphorous Reduction: Comparative Study of Oxylanthanum Carbonate and Tenapanor in Rats**
Lead Author:	Satya Medicherla, Ph.D., Vice President, Preclinical Pharmacology, Unicycive
Type:	Focused Oral Presentation
Dates/Times:	May 25, 2024 from 12:10 p.m. – 12:15 p.m. CEST

Title:	**Oxylanthanum Carbonate for Hyperphosphatemia in End Stage Kidney Disease (ESKD): Tolerability Trial in Progress**
Lead Author:	Pablo E. Pergola, M.D., Ph.D., Renal Associates, P.A.
Type:	ePoster
Date/Time:	Available throughout the conference

UNI-494

Title:	**Oral Administration of UNI-494 Ameliorates Acute Kidney Injury in a Rat Model of Delayed Graft Function**
Lead Author:	Satya Medicherla, Ph.D., Vice President, Preclinical Pharmacology, Unicycive
Type:	Focused Oral Presentation
Dates/Times:	May 25, 2024 from 12:00 p.m. – 12:05 p.m. CEST

Title:	**UNI-494 Phase I Tolerability and Pharmacokinetics: Trial in Progress**
Lead Author:	Guru Reddy, Ph.D., Vice President of Preclinical R&D, Unicycive
Type:	Focused Oral Presentation
Dates/Times:	May 25, 2024 from 12:45 p.m. – 12:50 p.m. CEST

About Oxylanthanum Carbonate (OLC)

Oxylanthanum carbonate is a 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). OLC has over forty issued and granted patents globally. Its potential best-in-class profile may have meaningful patient adherence benefits over currently available treatment options as it requires a lower pill burden for patients in terms of number and size of pills per dose that are swallowed instead of chewed. Based on a survey conducted in 2022, Nephrologists stated that the greatest unmet need in the treatment of hyperphosphatemia with phosphate binders is a lower pill burden and better patient compliance.[1] The global market opportunity for treating hyperphosphatemia is projected to be in excess of $2.5 billion in 2023, with the United States accounting for more than $1 billion of that total. Despite the availability of several FDA-cleared medications, 75 percent of U.S. dialysis patients fail to achieve the target phosphorus levels recommended by published medical guidelines.

Unicycive is seeking FDA approval of OLC via the 505(b)(2) regulatory pathway. As part of the clinical development program, two clinical studies were conducted in over 100 healthy volunteers. The first study was a dose-ranging Phase I study to determine safety and tolerability. The second study was a randomized, open-label, two-way crossover bioequivalence study to establish pharmacodynamic bioequivalence between OLC and Fosrenol. Based on the topline results of the bioequivalence study, pharmacodynamic (PD) bioequivalence of OLC to Fosrenol was established.

Fosrenol® is a registered trademark of Shire International Licensing BV.
[1]Reason Research, LLC 2022 survey. Results here.

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.

About UNI-494

UNI-494 is a novel nicotinamide ester derivative and a selective ATP-sensitive mitochondrial potassium channel activator. Mitochondrial dysfunction plays a critical role in the progression

of acute kidney injury and chronic kidney disease. UNI-494 has a novel mechanism of action that restores mitochondrial function and may be beneficial for the treatment of several diseases including kidney disease. Unicycive is currently conducting a Phase 1 dose-ranging safety study in healthy volunteers in the United Kingdom that is expected to complete in 2H of 2024. UNI-494 is protected by issued patent(s) in the U.S. and Europe and a wide range of patent applications worldwide. UNI-494 has been granted orphan drug designation (ODD) by the U.S. Food and Drug Administration (FDA) for the prevention of Delayed Graft Function (DGF) in kidney transplant patients.

About Delayed Graft Function

Delayed Graft Function (DGF) refers to the acute kidney injury (AKI) that occurs in the first week after kidney transplantation, which necessitates dialysis intervention. As the name indicates, DGF can result in sub-optimal or impaired graft function and is one of the most common and serious complications of kidney transplantation. Poor kidney function in the first week of graft life is detrimental to the longevity of the allograft. DGF is also associated with higher rates of tissue rejection and decreased patient survival. Currently, there are no FDA approved drugs for the treatment of DGF.

Ischemia/reperfusion injury (IRI) is known to be a major causative factor for the AKI that results in DGF during kidney transplantation. Ischemic preconditioning, that works by activating K_{ATP} channels in mitochondria, is a natural endogenous mechanism which protects cells from IRI in the heart, kidney, liver, and other organs. UNI-494 is a pharmacological approach that emulates and enhances this natural phenomenon of ischemic preconditioning.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug candidate, oxylanthanum carbonate (OLC), is a novel investigational phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis. 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 Unicycive.com and follow us on LinkedIn and YouTube.

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, 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, 2022, 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.

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SOURCE: Unicycive Therapeutics, Inc.

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