August 26, 2024

Unicycive Therapeutics to Present Three Posters at the American Society of Nephrology (ASN) Kidney Week 2024

LOS ALTOS, Calif., Aug. 26, 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 three poster presentations will be delivered on the Company’s product candidates at the American Society of Nephrology (ASN) Kidney Week 2024 taking place October 24-27, 2024 in San Diego, CA.

“Data from both oxylanthanum carbonate (OLC) and UNI-494 continue to garner strong interest from the medical community, and we look forward to presenting our data at Kidney Week, one of the most prominent meetings in our field,” said Shalabh Gupta, MD, Chief Executive Officer of Unicycive.

Title:	**Intravenous UNI-494 Slows the Progression or Halts/Reverses Acute Kidney Injury When Administered After Ischemia/Reperfusion in Rats**
Lead Author:	Satya Medicherla, Ph.D., Vice President, Preclinical Pharmacology, Unicycive
Session Title:	AKI: Mechanisms
Poster Board:	#FR-PO155
Date/Time:	Friday, October 25, 2024 from 10:00 a.m. – 12:00 p.m. PT

Title:	**Combination Oxylanthanum Carbonate and Tenapanor Lowers Urinary Phosphate Excretion in Rat**
Lead Author:	Satya Medicherla, Ph.D., Vice President, Preclinical Pharmacology, Unicycive
Session Title:	CKD-MBD: Basic and Translational
Poster Board:	#SA-PO243
Date/Time:	Saturday, October 26, 2024 from 10:00 a.m. – 12:00 p.m. PT

Title:	**UNI-494 Phase I Safety, Tolerability, and Pharmacokinetics**
Lead Author:	Guru Reddy, PH.D., Vice President of Preclinical R&D, Unicycive
Session Title:	AKI: Clinical, Outcomes, and Trials - Management
Poster Board:	#SA-PO036
Date/Time:	Saturday, October 26, 2024 from 10:00 a.m. – 12:00 p.m. PT

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 results of the bioequivalence study, pharmacodynamic (PD) bioequivalence of OLC to Fosrenol was established. A pivotal clinical trial was also conducted in CKD patients on hemodialysis that achieved the study objective and established favorable tolerability of OLC at clinically effective doses.

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 has completed enrollment in the UNI-494 Phase 1 dose-ranging safety study in healthy volunteers in the United Kingdom, and expects to report results in the third quarter 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 Acute Kidney Injury

Acute kidney injury (AKI) is defined as a sudden loss of kidney function that is determined based on increased serum creatinine levels and decreased urine output and is limited to a duration of 7 days. The primary causes of AKI include sepsis, ischemia, hypoxia, and drug-induced nephrotoxicity. Delayed Graft Function is a type of acute kidney injury that occurs in the first week after kidney transplantation. AKI is estimated to occur in 20-200 per million population in the community, 7-18% of patients in the hospital, and approximately 50% of patients admitted to the intensive care unit. Importantly, AKI is associated with morbidity and mortality; an estimated 2 million people die of AKI worldwide every year whereas survivors of AKI are at increased risk of chronic kidney disease and end stage renal disease.

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 clinical development for the treatment of conditions related to acute kidney injury. For more information, please visit Unicycive.com and follow us on LinkedIn, X, 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, 2023, 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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