March 13, 2024

Unicycive Therapeutics Delivers Both an Oral and Poster Presentation on UNI-494 at the AKI and CRRT Conference

– Promising Preclinical Results in Delayed Graft Function of Acute Kidney Injury –

– UNI-494 Phase 1 Single Ascending Dose Portion of Clinical Trial Complete –

LOS ALTOS, Calif., March 13, 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 two presentations related to UNI-494 were presented on March 12, 2024 at the 29th International Conference on Advances in Critical Care Nephrology AKI and CRRT 2024.

"We are excited about the tremendous progress we have made with our second clinical development asset, UNI-494," said, Shalabh Gupta, MD, Chief Executive Officer of Unicycive. "Last week we announced that UNI-494 has been granted orphan drug designation by the FDA for the prevention of delayed graft function (DGF) after kidney transplantation which is a meaningful milestone for the program. The data presented at the CRRT conference demonstrates statistically significant results for UNI-494 in a preclinical model of DGF which provides additional evidence that UNI-494 may be a valuable asset for prevention of DGF and other acute kidney injury clinical conditions."

"In conjunction with these presentations, we are also excited to announce that our ongoing Phase 1 clinical trial in UNI-494 has successfully completed the single ascending dose (SAD) portion of the study. UNI-494 was well-tolerated up to 160 mg administered as a single dose. This dose was chosen as the go-forward dose based on promising safety, tolerability, and pharmacokinetic data. In the multiple ascending dose (MAD) portion of the study, 80 mg is now being administered twice-a-day to participants enrolled in the study. We expect to complete the Phase 1 trial and report the full results in the second half of this year," concluded Dr. Gupta.

The oral presentation, entitled, "Intravenous Administration of UNI-494 Ameliorates Acute Kidney Injury in Rat Model of Delayed Graft Function" was delivered by Satya Medicherla, Ph.D., Vice President, Preclinical Pharmacology, Unicycive Therapeutics. Dr. Medicherla presented results from the study evaluating the *in vivo* efficacy of intravenous (IV) UNI-494 in the unilateral renal ischemia-reperfusion rat model of acute kidney injury (AKI), which is a well-established model of DGF. In the study, a single IV dose of UNI-494 at 5 mg/kg/IV or 10 mg/kg/IV reduced specific kidney functional markers and tubular injury marker with statistically significant results ($p<0.01$). Importantly, UNI-494 prevented serum and urinary markers of AKI at 5 mg/kg, and proximal tubular injury scores improved in a dose-dependent manner. The study concluded that UNI-494 is a potential candidate for prevention of DGF and other AKI clinical conditions.

The poster, entitled, “UNI-494 Phase 1 Safety, Tolerability and Pharmacokinetics: Trial in Progress” was presented by Guru Reddy, PH.D., Vice President of Preclinical R&D, Unicycive Therapeutics. The poster describes the ongoing Phase 1 dose-escalating single-center, double-blind, placebo-controlled, randomized clinical trial in healthy volunteers. The trial consists of two parts: Part 1 is a single ascending dose (SAD) study to determine the maximum tolerated dose (n=40); Part 2 is a multiple ascending dose (MAD) study to understand the effect of multiple doses administered of UNI-494 (n=20). The trial is designed to evaluate the safety, tolerability, and pharmacokinetics of UNI-494 in healthy subjects. The SAD study was successfully completed, and a dose of 80 mg twice-a-day (BID) was carried over to the MAD study which is currently ongoing.

The publications will be available on the Unicycive websitehere.

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 clinical development for the treatment of conditions related

to 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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