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Unicycive Therapeutics Successfully Completes UNI-494 Phase 1 Study in Healthy Volunteers

UNI-494 was Well-Tolerated as a Single Dose up to 160 mg and in Multiple Doses at 40 mg Twice-a-Day

LOS ALTOS, Calif., Oct. 09, 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 the successful completion of the UNI-494 Phase 1 study in healthy volunteers.

"We are pleased to announce the successful completion of the UNI-494 Phase 1 study that informs our next steps for advancement to a potential Phase 2 clinical trial in patients with acute kidney injury," said Shalabh Gupta, MD, Chief Executive Officer of Unicycive. "This is an important milestone for the clinical development of UNI-494 as it provides the necessary dosing and tolerability data to progress the program. We plan to request a meeting with the U.S. Food and Drug Administration (FDA) before the end of the year to review these Phase 1 results and a potential Phase 2 study design. We would like to extend our gratitude to the trial investigator and participants who committed their time and effort to the study."

Trial Design: The Phase 1 study was a single center, double-blind, placebo-controlled, randomized single ascending dose (Part 1) and multiple ascending dose (Part 2) study in healthy volunteers conducted in the United Kingdom. Dosing in both arms was completed in a stepwise fashion. The objective of the study was to assess the safety, tolerability and pharmacokinetics of UNI-494.

Single Ascending Dose: Part 1 of the study enrolled 40 participants in 5 cohorts with 30 participants dosed with UNI-494 and 10 participants dosed with placebo. UNI-494 was well-tolerated in healthy participants as a single dose ranging from 10 mg to 160 mg. There were no serious adverse events (SAEs) or adverse events (AEs) leading to withdrawal. Headache was the most common adverse event reported. Most of the adverse events were mild, and all participants dosed with UNI-494 completed the study.

Multiple Ascending Dose: Part 2 of the study enrolled 19 participants in two cohorts with 15 participants dosed with UNI-494 and 4 dosed with placebo. In Cohort One (n=9), participants were dosed with 40 mg two times a day (BID) for 5 days with UNI-494 or matching placebo. In Cohort Two (n=10), participants were dosed with 80 mg BID for 5 days. There were no serious adverse events (SAEs) in Part 2 of the study, and UNI-494 was safe and well-tolerated at the 40 mg BID dose for 5 days. Most common adverse events reported included headache, nausea, and vomiting. In Cohort One, the majority of the adverse events reported were mild and all but one participant completed the study. In Cohort Two, UNI-494 was not well-tolerated with 4 participants withdrawing from the study due to adverse events.

Pharmacokinetics of UNI-494 were also evaluated in the study. The absorption of UNI-494 was fast, and UNI-494 was rapidly metabolized to release nicorandil and the linker as expected. Plasma concentration of nicorandil increased in a slightly greater than proportional manner as the dose increased.

Collectively, these results will help determine the dose and schedule of UNI-494 for a potential Phase 2 clinical trial in patients with acute kidney injury.

Unicycive intends to present additional details of the study at an upcoming scientific conference.

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. 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. UNI-494 has completed a Phase 1 dose-ranging safety study in healthy volunteers.

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, end stage renal disease.

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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