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Unicycive Therapeutics Granted Patent on UNI-494 to Treat Acute Kidney Injury by the United States Patent and Trademark Office (USPTO)

Ensures Intellectual Property Protection Until 2040

LOS ALTOS, Calif., July 17, 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 issuance of U.S. Patent No. 12,036,211 by the United States Patent and Trademark Office (USPTO) for UNI-494.

The patent, valid until 2040, secures protection of a method of treating a disease or a condition selected from acute kidney injury or contrast induced nephropathy by administering the UNI-494 compound. The UNI-494 compound covered in the method of use claims is not limited to a particular salt, dose or type of administration. 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.

"We are pleased to receive this patent from the USPTO, which ensures intellectual property protection for many years to come,” said Shalabh Gupta, MD, Chief Executive Officer of Unicycive. “This Method of Use patent for UNI-494 is an important component of our strategy to become a leader in the development of drugs that target kidney disease. UNI-494 is currently in an ongoing Phase 1 clinical trial and recently received Orphan Drug Designation in Delayed Graft Function, a form of acute kidney injury. This patent helps protect our approach and expands our portfolio as we look to develop novel treatments for kidney diseases.”

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 the second half 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 on the basis of 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 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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