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Unicycive to Highlight Potential of UNI-494 to Restore Mitochondrial Function and Reduce Oxidative Stress at Two Upcoming Medical and Scientific Meetings

Data from two abstracts supporting UNI-494's potential to treat acute and chronic kidney injury accepted for presentation at the 28th International Conference on Critical Care in Nephrology: the Acute Kidney Injury & CRRT 2023 Conference

Highlights key role mitochondria play in disease progression in both acute and chronic kidney injury at 5th Annual Chronic Kidney Disease Drug Development Summit

LOS ALTOS, Calif., Feb. 27, 2023 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced that the potential of UNI-494, the Company's proprietary drug that selectively binds to the SUR2B subunit of the mitochondrial K_{ATP} channel, will be the focus of several presentations at two upcoming medical and scientific meetings in March 2023.

Shalabh Gupta, M.D., Chief Executive Officer of Unicycive, will lead a discussion on UNI-494 at the upcoming 5th Annual Chronic Kidney Disease Drug Development Summit taking place in Boston, MA from March 7-9, 2023.

- Data elucidating how and why mitochondria play a key role in disease progression in both acute and chronic kidney diseases will be highlighted in a presentation titled, "Two Sides of the Same Coin: Targeting AKI in the Framework of CKD," on Tuesday, March 7, 2023, at 12:00 pm Eastern time.
- Dr. Gupta's presentation will include a discussion on predicting patients most likely to develop AKI and those most likely to respond to treatment, along with how to design efficient trials in AKI to optimize therapeutic response.

Two abstracts were accepted for presentation at the 28th International Conference on Critical Care in Nephrology: the Acute Kidney Injury & CRRT Conference taking place in San Diego, CA from March 29- April 1, 2023. The following data will be presented at AKI & CRRT:

- Efficacy data from a study of UNI-494 in an animal model of AKI will be presented in a poster titled, "UNI-494 Lowers Urine 2-microglobulin in Rats."
- Safety data from the 28-day oral toxicity study of UNI-494 will be presented in a poster titled "Orally administered UNI-494 is well-tolerated in dogs."

"We are delighted to have the potential of UNI-494 as a treatment for kidney diseases

highlighted in multiple medical meetings before audiences of leading kidney disease experts,” said Dr. Gupta. “We are studying UNI-494 in Phase 1 clinical trial in the United Kingdom (UK). We also plan to file a corresponding Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in 2023 for a Phase 2 proof-of-concept trial in acute kidney injury (AKI) patients.”

About UNI-494

UNI-494 is a novel proprietary drug that selectively binds to the SUR2B subunit of the mitochondrial K_{ATP} channel and activates it to restore mitochondrial function and reduce oxidative stress. UNI-494 is cleaved by esterase enzymes to form nicorandil, the active metabolite. Nicorandil has extensive safety, and efficacy data from multiple clinical trials, including a 5,000-patient randomized controlled trial (IONA Study) and there is a consensus in the literature that the activation of mitoKATP channel is the biological basis for the observed cardio-protection and reno-protection in multiple clinical trials.

Unicycive has completed all non-clinical safety assessment studies required for regulatory filing to initiate a Phase 1 study in healthy volunteers in the UK.

UNI-494 is protected by issued patent(s) in the U.S. and Europe and a wide range of patent applications worldwide.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive’s lead drug, Renazorb, is a novel phosphate binding agent being developed for the treatment of hyperphosphatemia. UNI-494 is a patent-protected new chemical entity in clinical development for the treatment of acute kidney injury. For more information, please visit www.unicycive.com.

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, including the outbreak of COVID-19 coronavirus, 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, 2021, 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.

Investor Contact:

ir@unicycive.com
(650) 900-5470

Anne Marie Fields
Stern Investor Relations
annemarie.fields@sternir.com
212-362-1200

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