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Unicycive Reports Key Findings of UNI-494 Efficacy in Preclinical Animal Model of Geographic Atrophy

Treatment with UNI-494 improved contrast vision in animal models of geographic atrophy (GA)

GA is an advanced form of Age-related Macular Degeneration (AMD) and there are currently no FDA-approved drugs to slow the progression of AMD

LOS ALTOS, Calif., Nov. 21, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with unmet medical needs, today announced key findings of UNI-494 efficacy from a preclinical study in animal models of Geographic Atrophy (GA).

UNI-494 is a mitochondrial potassium channel (mitochondrial K_{ATP}) activator in development for treating diseases affected by mitochondrial dysfunction, such as kidney, liver, and ocular diseases. Mitochondrial dysfunction is implicated in Age-related Macular Degeneration (AMD) progression. GA is an advanced form of AMD. The Company evaluated the effect of UNI-494 in preventing visual function loss in a rat model of GA.

The study evaluated four groups (n=8 per group): untreated, vehicle control, low dose of UNI-494, and high dose of UNI-494. GA was induced by bilateral subretinal injection of sodium iodate in experimental animals. UNI-494 was administered orally twice a day (BID) for 20 days, with the first administration of UNI-494 starting before sodium iodate injection. Contrast vision was measured by optokinetic tracking. Treatment of animals with the high dose of UNI-494 resulted in 150% and 200% improvement in contrast vision compared to vehicle and untreated animals. Further preclinical studies are planned to investigate these promising findings of the effect of UNI-494 in improving visual function.

“We are excited to report that UNI-494 improved visual function in well-established rat models of GA, which is responsible for 10-20% of blindness in AMD, a disease that affects five million people globally. Contrast sensitivity is widely accepted as a critical aspect of visual function and has been shown to correlate with ability to perform instrumental activities of daily living,” said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive.

“Importantly, these data support UNI-494’s mechanism of action, which holds promise for indications in which mitochondrial dysfunction is implicated, such as kidney disease, liver disease and other ophthalmic diseases. Our goal is to remain focused and advance UNI-494 in kidney disease, and to explore partnerships for other indications in order to maximize the potential of this promising new therapeutic. Toward that end, we remain on track to initiate a Phase I study in healthy volunteers during the first quarter of 2023 in the UK following

clearance by the Medicines and Healthcare products Regulatory Agency (MHRA)," concluded Dr. Gupta.

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 mitoK_{ATP} 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 I study in healthy volunteers. The Company is on track to initiate the Phase I healthy volunteer study.

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 late preclinical development for the treatment of acute kidney injury. For more information, please visit www.unicycive.com.

Forward-looking statement

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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