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Unicycive Reports Key Findings of UNI-494 Efficacy in Preclinical Animal Model of Acute Kidney Injury (AKI)

Established animal model of AKI showed a statistically significant reduction of a key biomarker of kidney injury when treated with UNI-494

AKI remains a serious unmet medical need with no FDA approved drugs for its treatment

On track to file regulatory submission by year end 2022 to initiate first-in-humans Phase 1 study with UNI-494

LOS ALTOS, Calif., Sept. 07, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today announced key findings of UNI-494 efficacy from a preclinical study in rodent model of Acute Kidney Injury.

UNI-494 is a mitochondrial ATP sensitive potassium (mitoK_{ATP}) channel activator that is in development for the treatment of AKI. The Company evaluated the effect of UNI-494 on ischemia-reperfusion induced acute kidney injury (IR-AKI) in rats. Animals (n=10/group) were divided into 4 groups: sham, vehicle control, low dose of UNI-494 and high dose of UNI-494. Kidney injury was induced by 45-minute ischemia of bilateral kidneys. UNI-494 was administered orally 1-hour before the induction of ischemia and kidney function was monitored by measuring urinary creatinine, total urinary albumin, and β -2 microglobulin (β -2 MG). Treatment of animals with the higher dose of UNI-494 resulted in a statistically significant reduction of β -2 MG levels in urine.

"We are excited to report this key finding from the IR-AKI model showing treatment with UNI-494 significantly reduced this key biomarker of kidney injury that is a well-accepted biomarker of proximal renal tubule damage. We look forward to presenting these data, along with other data from the study, at an upcoming scientific meeting," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "We remain on track to file a regulatory submission by the end of 2022 that will allow us to initiate our Phase 1 study with UNI-494."

"These are very encouraging results for UNI-494. The rat IR-AKI model is a widely published model of AKI and β -2 MG is an established clinical biomarker of proximal renal tubule damage in AKI. The ability of UNI-494 to significantly reduce β -2 MG in these animals provides compelling support for the clinical development of this new drug for AKI," said Ravi Mehta, M.D., Prof. Emeritus of Medicine at University of California San Diego School of Medicine, and a world-renowned expert in AKI research.

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 which is 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 pharmacokinetic, safety pharmacology, genetic toxicity and ADME studies on UNI-494. Repeat dose toxicity studies in two species are on track to be completed in the third quarter. The Company is on track to file a regulatory submission in the second half of 2022 to initiate the Phase I healthy volunteer study.

While Unicycive's initial focus is on acute kidney injury (AKI), UNI-494's novel mechanism of action may also hold promise for indications in which mitochondrial dysfunction is implicated such as chronic kidney disease, liver disease (alcoholic hepatitis, hepatic encephalopathy) and ophthalmic disease (dry AMD, macular degeneration, etc).

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.

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