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Unicycive Issued Notice of Acceptance to Initiate Phase 1 Study of UNI-494 Following Review of Clinical Trial Application by the Medicines and Healthcare Products Regulatory Agency in the United Kingdom

Expects to dose patients in first-in-human Phase 1 study with UNI-494 in first quarter 2023

LOS ALTOS, Calif., Dec. 22, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, announced today that the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK) has completed review of the Clinical Trial Application (CTA) and has issued a notice of acceptance for UNI-494 first-in-human Phase 1 study in healthy volunteers.

“With this notice of acceptance from the MHRA, we look forward to proceeding to first-in-human clinical trials with our second drug, UNI-494,” stated Shalabh Gupta, MD, Chief Executive Officer of Unicycive. “We are studying UNI-494 initially in the UK as its active metabolite, nicorandil, has been extensively studied throughout Europe, including in the UK. We’ve selected a qualified UK-based Contract Research Organization (CRO) to conduct the Phase 1 study, which we expect will begin dosing patients in the first quarter of 2023. 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 with a background of CKD (Chronic Kidney Disease).”

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. The Company is on track to initiate the Phase 1 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 an investigational phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease (CKD patients on dialysis. 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.

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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