

August 24, 2022



Unicycive Announces Multiple Abstracts Selected for Presentation at American Society of Nephrology's Kidney Week 2022

Data support the Company's pipeline of innovative product candidates aimed at improving the quality-of-life for patients battling kidney disease

LOS ALTOS, Calif., Aug. 24, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today announced the acceptance of two abstracts to be presented as posters and one publication in the Abstract Supplement at the American Society of Nephrology's (ASN) Kidney Week 2022 taking place November 3-6, 2022 in Orlando, Fla.

UNI-494 is a novel proprietary drug targeting the SUR2 subunit of the mitochondrial KATP channel activator that reduces oxidative stress and restores mitochondrial function. 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).

Renazorb is an advanced phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD).

"Kidney Week 2022 offers an ideal opportunity to share the favorable results from two of Unicycive's important product candidates with the nephrology community," said Shalabh Gupta, M.D., Chief Executive Officer. "We continue to build on the body of clinical and scientific evidence to support the potentially best-in-class product profiles for Renazorb to treat hyperphosphatemia and for UNI-494 to reduce oxidative stress and restore mitochondrial function in a number of potential indications, including Acute Kidney Injury."

The following abstracts have been accepted for presentation at the NKF Spring Clinical Meeting:

Poster Title: "Preclinical Pharmacokinetics of a Novel Nicorandil Prodrug"
Session Title: Pharmacology (PO1900)
Poster # 3760757
Date/Time: Friday, November 4, from 10:00 am – 12:00 pm Eastern Time
Poster Board #: FR-PO220

Poster Title: "Lanthanum Dioxycarbonate Effectively Reduces Urinary Phosphate Excretion in Healthy Volunteers"
Session Title: Vascular Calcification, Nephrolithiasis, Bone (PO0402)
Poster # 3760842
Date/Time: Saturday, November 5, from 10:00 am – 12:00 pm Eastern Time

In addition, Abstract #3764498, which is titled "Daily Medication Volume of Phosphate Binder Therapies," was accepted for publication in ASN 2022's Abstract Supplemental.

All abstracts for ASN's Kidney Week 2022 will be available via the ASN website (www.asn-online.org/education/kidneyweek) by October 14, 2022.

About Renazorb (lanthanum dioxycarbonate)

Renazorb is a non-aluminum, non-calcium, phosphate binder manufactured using a patent-protected nanotechnology process. Renazorb has been shown to offer unique phosphate binding characteristics, which have the potential to treat hyperphosphatemia in chronic kidney disease patients. It also has meaningful patient adherence benefits as it requires smaller and fewer number of pills per dose than the current standard of care and is swallowed instead of chewed. Unicycive is preparing a clinical bioequivalence study performed in healthy volunteers in order to submit a 505(b)(2) new drug application to the U.S. Food and Drug Administration.

About UNI-494

UNI-494 is a novel proprietary drug targeting the SUR2 subunit of the mitochondrial KATP channel activator that reduces oxidative stress and restores mitochondrial function. 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 KATP channel is the biological basis for the observed cardio-protection and reno-protection in multiple clinical trials. In preclinical studies, UNI-494 showed improvement on the pharmacokinetic profile resulting in substantially higher exposure of nicorandil that may allow for less frequent and lower dosing.

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 patent protected by issued patent(s) in the US 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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