January 23, 2024

Unicycive Therapeutics Issues Shareholder Letter to Highlight Corporate Progress and Key Upcoming Milestones

– Topline Data from OLC Pivotal Trial Expected in Q2 2024 –
– OLC will target the multibillion-dollar hyperphosphatemia market –

LOS ALTOS, Calif., Jan. 23, 2024 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease (the "Company or "Unicycive"), today issued a letter to shareholders.

Dear Shareholders:

As I sit down to write this letter, I am filled with a profound sense of gratitude and excitement, energized for the year ahead. I remain as confident as ever that the work we're doing at Unicycive will change the treatment paradigm in kidney disease and leave a lasting impact for patients, physicians, and for you, our shareholders.

When I founded Unicycive in 2016 I knew the journey we were embarking on was ambitious —to offer hope to the millions of patients suffering from chronic kidney diseases who continue to go underserved. Thanks to your unwavering support and the steadfast commitment of our small but mighty team, I am constantly amazed at how we're able to tackle obstacles head on, solve problems efficiently, and continue to move closer to our goal.

In this letter, I am pleased to recap for you another year of great accomplishments. We've made significant advancements in our clinical programs which will propel us to new heights in 2024**.**

Addressing a Critical Need

Today, dialysis patients experience an excessive pill burden that is among the highest across various chronic disease states including HIV/AIDS, diabetes mellitus, and congestive heart failure. Phosphate binders to treat hyperphosphatemia account for half of the problem.[1]

Importantly, uncontrolled hyperphosphatemia is strongly associated with increased hospitalization and mortality.[2]

Our lead program, Oxylanthanum Carbonate, or OLC, is a next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology with two key advantages. First, only three tablets are required per day (versus as many as 12) and each are meaningfully smaller in size compared to the currently approved phosphate

binders. Second, the tablets are swallowed whole with water and not chewed, making it easier for patients to take.[3]

The novel characteristics of OLC show its potential to be a best-in-class product to treat hyperphosphatemia by reducing the pill burden volume by more than 4-fold compared to the most prescribed phosphate binder.

During 2023 we made significant progress with OLC under the FDA's 505(b)(2) regulatory pathway which allows us to reference the already approved drug, lanthanum carbonate (Fosrenol®[4]) to streamline our submission package. As reported in December 2022, OLC was evaluated in a previous bioequivalence study that measured efficacy in healthy volunteers (n=80) in which OLC has found to be equivalent to the reference drug, Fosrenol.

Last year, we gained alignment with the FDA on the overall data package required (preclinical, clinical and CMC) to file a New Drug Application (NDA). The Agency agreed with our proposed clinical study design including sample size, duration of treatment, and primary endpoint of the study. Last month, we initiated the pivotal clinical trial (NCT06218290) to evaluate the tolerability of OLC in chronic kidney disease (CKD) patients on dialysis (n=60) and expect to report topline data in the second quarter of this year. This is the last major component to complete our data package to file an NDA with the FDA, which we intend to submit mid-year**.**

If approved, OLC will target the multibillion-dollar hyperphosphatemia market and will be a new potential therapy for physicians to administer to their patients.

Strong Scientific Leadership with OLC

This year we continued to publish scientific data on OLC at national and international conferences. We presented five posters on OLC at conferences including at the National Kidney Foundation (NKF), International Society of Nephrology (ISN) and European Renal Association (ERA).

We also published two manuscripts on OLC in peer reviewed journals.The *American Journal of Nephrology* publication highlighted the phosphate binding capacity of OLC showing that OLC had the lowest daily phosphate binder dose volume and the lowest volume required to bind one gram of phosphate compared to five other commercially available phosphate binders.

Increasing Market Awareness

A top priority for us in 2023 was growing market awareness of OLC's potential best-in-class product profile. We conducted live and virtual advisory board meetings with some of the country's most influential nephrologists. Also, for the first time, Unicycive exhibited at the American Society of Nephrology Kidney Week, the world's premier nephrology conference where we showcased the high unmet need in the management of hyperphosphatemia and the urgent need for new therapies like OLC (https://www.lesspillburden.com). We are encouraged by the overwhelmingly positive reception to the OLC story and are planning continued market-shaping activities for 2024.

Portfolio Expansion

In addition to OLC, we continue to advance our second compound UNI-494 for the treatment of acute kidney injury and chronic kidney disease. UNI-494 is a novel nicotinamide ester derivative and a selective ATP-sensitive mitochondrial potassium channel activator. Mitochondrial dysfunction plays a critical role in the progression of acute kidney injury and chronic kidney disease. UNI-494 has a novel mechanism of action that restores mitochondrial function and may be beneficial for the treatment of several diseases including kidney disease. The asset is currently in a Phase 1 dose-ranging safety study in healthy volunteers in the United Kingdom that is expected to complete this year.

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

Looking Ahead

We believe 2024 will be a transformational year for Unicycive. We will report out our pivotal data for OLC next quarter and plan to complete our data package and submit an NDA mid-year. We continue to work closely with the medical community to publish data on our programs and plan for future commercialization of OLC.

As a company, all of our stakeholders are vital to our success. I would like to express my deep appreciation to the physician investigators, study participants, and especially to our dedicated Unicycive employees. The progress we have made demonstrates what's possible when we believe in the work we are doing and come together to make a meaningful difference.

Thank you for your support,

Shalabh Gupta, MD, Chief Executive Officer of Unicycive

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug candidate, oxylanthanum carbonate (OLC), is a novel investigational phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease 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 Unicycive.com and follow us on LinkedIn and YouTube.

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, 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, 2022, 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.

References:

[1] Chiu YW, et al. Clin J Am Soc Nephrol. 2009

[2] Block GA, et al. J Am Soc Nephrol. 2004

[3] Dosing information: www.accessdata.fda.gov

[4] Fosrenol® is a registered trademark of Shire International Licensing BV.

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SOURCE: Unicycive Therapeutics, Inc.

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