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Unicycive Therapeutics Receives Confirmatory Guidance on Renazorb Regulatory Pathway

On-track to submit New Drug Application in Q4 2022

LOS ALTOS, Calif., Nov. 29, 2021 /PRNewswire/ -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today provided an update on the development and regulatory filing pathway for Renazorb (lanthanum dioxycarbonate). Renazorb is a second-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD).

In a recent Type C interaction with the U.S. Food and Drug Administration (FDA), Unicycive sought the FDA's feedback on the sufficiency of the Renazorb data package to support a 505(b)(2) new drug application (NDA) submission. Unicycive provided results from *in vitro* studies conducted to support the comparability of Renazorb and its active lanthanum moiety to the approved product Fosrenol®[1]. Based on these data, the FDA confirmed in their response that the phosphate-binding mechanism and stoichiometry of Renazorb is comparable to Fosrenol®.

The FDA also confirmed their previous guidance that Unicycive may support the NDA filing of Renazorb through a 505(b)(2) pathway based on a single clinical bioequivalence study performed in healthy volunteers demonstrating comparable changes in urinary phosphate excretion between Renazorb and Fosrenol®.

Renazorb has previously been studied in a similar healthy volunteer clinical trial in which Renazorb demonstrated significant changes in urinary phosphate excretion compared to placebo. The remaining bioequivalence clinical study will include a comparator arm with Fosrenol® to enable comparison of phosphate binding effectiveness of Renazorb against this approved drug in healthy volunteers.

Together with the previously agreed-upon 6-month mouse toxicology, the additional bioequivalence study will provide the necessary bridge to support the NDA submission. No

additional pre-clinical or clinical studies are currently expected to be required in support of an NDA submission for Renazorb.

"This Type C FDA feedback on Renazorb allows us to confirm our previous guidance to submit an NDA for Renazorb in the fourth quarter of 2022," said Shalabh Gupta, MD., Unicycive's Chief Executive Officer. "We are prepared and funded to complete the healthy volunteer urinary phosphate study for the Renazorb NDA submission. We look forward to working closely with the FDA and continuing our progress toward making this important medicine available to CKD patients and healthcare providers in search of new hyperphosphatemia treatments with the potential to lower the significant pill burden often associated with currently available phosphate binder therapy."

About Unicycive

Unicycive Therapeutics, Inc. is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead product candidate, 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. Investors should read the risk factors set forth in our registration statement on Form S-1 and our periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Unicycive does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

[1]*Fosrenol (lanthanum carbonate) is a registered trademark of Shire (now Takeda)*

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