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Unicycive Therapeutics Announces Enrollment of First Patient in Pivotal Clinical Trial for Oxylanthanum Carbonate (OLC) in Patients with Chronic Kidney Disease on Dialysis

Study will Evaluate 60 Participants with Results Expected in Q2 2024

LOS ALTOS, Calif., Dec. 18, 2023 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease (the "Company or "Unicycive"), today announced the enrollment of the first patient in its open-label, single-arm, multicenter, multidose pivotal clinical trial with Oxylanthanum Carbonate (OLC). OLC is a next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis.

"The initiation of patient enrollment in our OLC pivotal clinical trial is a critical milestone as we strive to reduce the pill burden and improve quality of life for individuals with chronic kidney disease on dialysis," said, Shalabh Gupta, MD, Chief Executive Officer of Unicycive. "OLC's novel characteristics have the potential to make it the best-in-class phosphate binder in the billion-dollar hyperphosphatemia market. Data from this pivotal trial is the last major component to complete our data package to file a New Drug Application (NDA) and will be informative for physicians as they consider a new potential therapy for their patients. We expect to report data from the trial in the second quarter of 2024 and file the NDA shortly thereafter."

The primary endpoint for the study will evaluate the tolerability of clinically effective doses of OLC in patients with CKD on dialysis. The secondary endpoints will evaluate safety and pharmacokinetics. There is no statistical analysis required to demonstrate efficacy as bioequivalence to Fosrenol® was previously established; and there is no other clinical study required to submit an NDA under the 505(b)(2) regulatory pathway.

The trial is expected to enroll 60 evaluable participants. Once participants are enrolled into the trial, they will go through a washout period for two weeks to clear their current phosphate binder from their system. Participants will initially be dosed at 500 mg of OLC three times a day (TID) and be titrated to a clinically effective dose that is defined as the dose required to achieve a serum phosphate range of ≤5.5 mg/dL. The maximum dose of OLC tested will be 3000 mg/day (1000 mg TID). As a reminder, all approved phosphate binders, including Fosrenol, are administered on a dose titration schedule based on the control of serum phosphate. Once titrated to a clinically effective dose, participants will then be treated for four weeks to evaluate serum phosphate levels.

About Oxylanthanum Carbonate (OLC)

Oxylanthanum carbonate is a next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. OLC has over forty issued and granted patents globally. Its potential best-in-class profile may have meaningful patient adherence benefits over currently available treatment options as it requires a lower pill burden for patients in terms of number and size of pills per dose that are swallowed instead of chewed. Based on a survey conducted in 2022, Nephrologists stated that the greatest unmet need in the treatment of hyperphosphatemia with phosphate binders is a lower pill burden and better patient compliance.[1] The global market opportunity for treating hyperphosphatemia is projected to be in excess of $2.5 billion in 2023, with the United States accounting for more than $1 billion of that total. Despite the availability of several FDA-cleared medications, 75 percent of U.S. dialysis patients fail to achieve the target phosphorus levels recommended by published medical guidelines.

Unicycive is seeking FDA approval of OLC via the 505(b)(2) regulatory pathway. As part of the clinical development program, two clinical studies were conducted in more than 100 healthy subjects. The first study was a dose-ranging Phase I study to determine safety and tolerability. The second study was a randomized, open-label, two-way crossover bioequivalence study to establish pharmacodynamic bioequivalence between OLC and Fosrenol. Based on the topline results of the bioequivalence study, pharmacodynamic (PD) bioequivalence of OLC to Fosrenol was established.

About Hyperphosphatemia

Hyperphosphatemia is a serious medical condition that occurs in nearly all patients with End Stage Renal Disease (ESRD). If left untreated, hyperphosphatemia leads to secondary hyperparathyroidism (SHPT), which then results in renal osteodystrophy (a condition similar to osteoporosis and associated with significant bone disease, fractures and bone pain); cardiovascular disease with associated hardening of arteries and atherosclerosis (due to deposition of excess calcium-phosphorus complexes in soft tissue). Importantly, hyperphosphatemia is independently associated with increased mortality for patients with chronic kidney disease on dialysis. Based on available clinical data to date, over 80% of patients show signs of cardiovascular calcification by the time they become dependent on dialysis.

Dialysis patients are already at an increased risk for cardiovascular disease (because of underlying diseases such as diabetes and hypertension), and hyperphosphatemia further exacerbates this. Treatment of hyperphosphatemia is aimed at lowering serum phosphate levels via two means: (1) restricting dietary phosphorus intake; and (2) using, on a daily basis, and with each meal, oral phosphate binding drugs that facilitate fecal elimination of dietary phosphate rather than its absorption from the gastrointestinal tract into the bloodstream.

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

[1]Reason Research, LLC 2022 survey. Results here.

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.

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