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Unicycive Therapeutics Announces Publication of Positive Comparison of Oxylanthanum Carbonate to Commercially Available Phosphate Binders in the American Journal of Nephrology

Newly Assigned USAN Name, Oxylanthanum Carbonate, replaces Lanthanum Dioxycarbonate

LOS ALTOS, Calif., July 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 that the peer-reviewed international journal the *American Journal of Nephrology* has published positive results on the phosphate binding capacity for oxylanthanum carbonate (OLC). The Company also announced the adoption of the non-proprietary name, oxylanthanum carbonate (OLC) by the United States Adopted Name (USAN) organization, replacing lanthanum dioxycarbonate (LDC) which has been used in previous publications and company presentations. OLC is Unicycive's investigational phosphate binding agent utilizing proprietary nanoparticle technology being developed as a lower pill burden option for the treatment of hyperphosphatemia in chronic kidney disease (CKD) patients on dialysis.

The publication, entitled, "High Phosphate-Binding Capacity of Oxylanthanum Carbonate with a Low Medication Volume: Comparison with Commercially Available Phosphate Binders," showed that OLC had the lowest daily phosphate binder dose volume and the lowest volume required to bind 1 g of phosphate compared to five other commercially available phosphate binders.

"The published data supports our other studies demonstrating that oxylanthanum carbonate has the potential to improve medication adherence and the quality of life for patients suffering from CKD," said Shalabh Gupta, MD, CEO of Unicycive. "A key focus for management of CKD is phosphate control, but currently available binders have suboptimal phosphate-binding capacity, and their characteristics often result in low adherence and suboptimal phosphate regulation. OLC has the potential to reduce the pill burden compared to commercially available products—a key point of differentiation in the phosphate binder market."

For patients with chronic kidney disease (CKD) and end-stage kidney disease (ESKD), regulation of phosphate levels between 3.0 and 4.5 mg/dl is crucial to preserve the proper function of many biological processes, including energy metabolism, skeletal development, and bone integrity. The development of hyperphosphatemia, a condition where serum phosphorus concentration rises above 4.5 mg/dL, is associated with significant

pathophysiology and increased mortality risk. Almost 75% of patients on dialysis in the United States have serum phosphorus concentrations greater than 4.5 mg/dL [7]; therefore, a key focus for CKD management is phosphate control.

Stuart Sprague, DO, FASN, Chief Emeritus of the Division of Nephrology and Hypertension at NorthShore University HealthSystem and Clinical Professor of Medicine at the University of Chicago Pritzker School of Medicine, and the lead author of the study commented, “The effective management of hyperphosphatemia in chronic kidney disease patients remains an elusive challenge despite the commercial availability of numerous phosphate binder options. Patients often find it difficult to adhere to their phosphate binder prescription due to issues of high pill burden, poor palatability, and side-effects. If approved, oxylanthanum carbonate may offer patients a welcome, low pill burden alternative.”

The objective of the study was to assess the volume of OLC required to bind 1 g phosphate and to compare it with other currently available phosphate binders, to determine which binder allows for the highest normalized potency with the lowest daily medication volume. The results of the study showed that the daily phosphate binder dose volume was lowest with oxylanthanum carbonate (OLC) (2.3 cm^3) and highest with sevelamer carbonate (9.7 cm^3).

Phosphate binder volumes by tablet

	Tablet volume, cm^3	**Daily medication volume, cm^3**	**Volume to bind 1g phosphate, cm^3**
Ferric citrate (1,000 mg)	0.92	7.4–8.3	46.5
Calcium acetate (667 mg)	0.75	7.7	25.0
Lanthanum carbonate (500 mg lanthanum)	1.33	4.0–8.0	19.8
Lanthanum carbonate (1,000 mg lanthanum)	2.67		
Oxylanthanum carbonate (500 mg lanthanum)	**0.35**	**2.3**	**5.6**
Oxylanthanum carbonate (1,000 mg lanthanum)	**0.75**		
Sevelamer carbonate (800 mg)	1.08	9.7	73.4
Sucroferric oxyhydroxide (2,500 mg)	1.83	5.5–7.3	NR

The full publication can be accessed here.

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.

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). 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 over 100 healthy volunteers. 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 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 www.unicycive.com.

Fosrenol® is a registered trademark of Shire International Licensing BV.
[1]Reason Research, LLC 2022 survey. Results here.

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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