July 10, 2024

Unicycive Therapeutics Announces Initial Positive Patient Satisfaction Findings from Pivotal Clinical Trial of Oxylanthanum Carbonate (OLC)

– Patients preferred OLC more than 4 to 1 over their prior phosphate binder therapy –

– Median daily pill burden reduced by half after switch to OLC –

LOS ALTOS, Calif., July 10, 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 announced the initial results from the patient reported outcome survey conducted during the UNI-OLC-201 pivotal clinical trial. The positive top-line results from the oxylanthanum carbonate (OLC) trial in patients with hyperphosphatemia who have chronic kidney disease on dialysis were reported on June 25, 2024.

The patient reported outcomes are being evaluated from a satisfaction questionnaire that was a pre-specified exploratory objective of the study. The questionnaire surveyed patients in the UNI-OLC-201 trial to assess characteristics of their current phosphate binder as compared to OLC after switching medications. The questions included patient satisfaction, ease of use, and preferred therapy and were taken at the start and conclusion of the study. In the survey, OLC consistently outperformed the other phosphate binders in all categories: 79% of patients preferred OLC while 18% preferred their prior therapy, 98% of patients said that OLC was easy to take compared to 55% for their prior therapy, 89% of patients said they were satisfied with OLC while 49% were satisfied with their prior therapy.

"We are gratified by the encouraging patient reported findings from our pivotal trial that mirror the better-than-expected topline clinical results that we reported last month," said, Shalabh Gupta, MD, Chief Executive Officer of Unicycive. "In the design of our pivotal clinical trial for OLC, we believed that it was important to consider the patient perspective and the personal challenges that they face in managing their hyperphosphatemia. Importantly, the results showed that patients preferred OLC greater than 4 to 1 over their prior phosphate binder therapy. Our focus is now directed toward filing our New Drug Application and making OLC available to patients who may benefit from its potential best-in-class profile, if approved."

Pablo Pergola, MD, PhD, Research Director, Clinical Advancement Center, Renal Associates, P.A., and principal investigator for the UNI-OLC-201 trial, commented, "In this clinical study, our patients stated a clear preference for OLC over their prior phosphate lowering therapies. This positive patient reported experience with OLC is encouraging because hyperphosphatemia outcomes are often negatively impacted by non-adherence to phosphate lowering prescriptions due to side effects and high pill burden. At the end of the

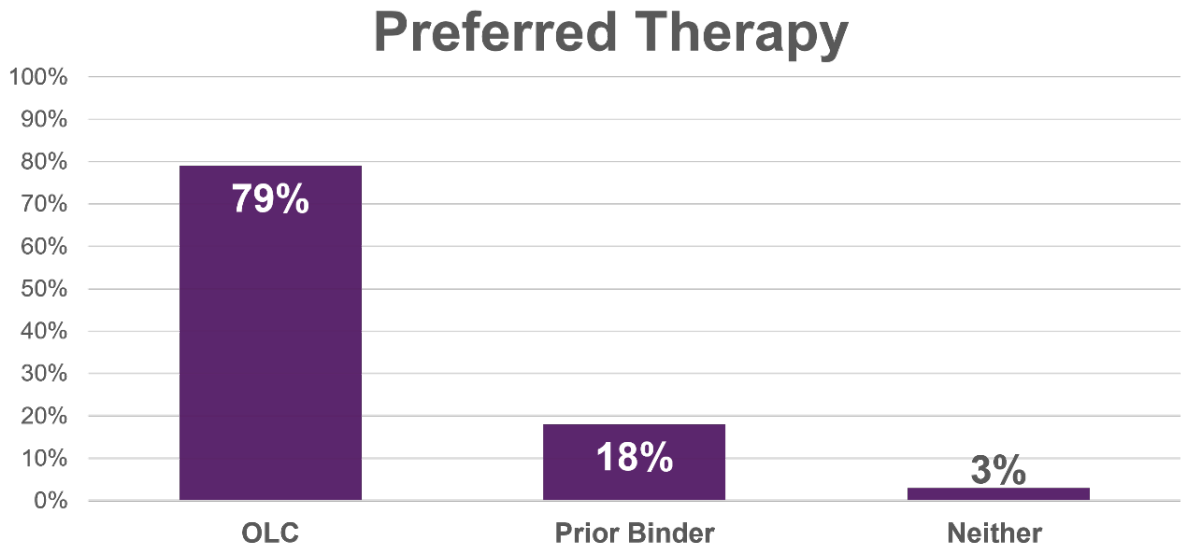
study, several of my patients asked not to be put back on their prior phosphate binder."

Background

Patients screened to enter the trial were taking the following phosphate binder therapies (n=128): 52% Renvela® (sevelamer carbonate), 19% PhosLo® (calcium acetate, 15% Auryxia® (ferric citrate), 13% Velphoro® (sucroferric oxyhydroxide, and 1% Other. Once patients were enrolled into the trial, they went through a washout period for two weeks to clear their current phosphate binder from the body.

Key Findings

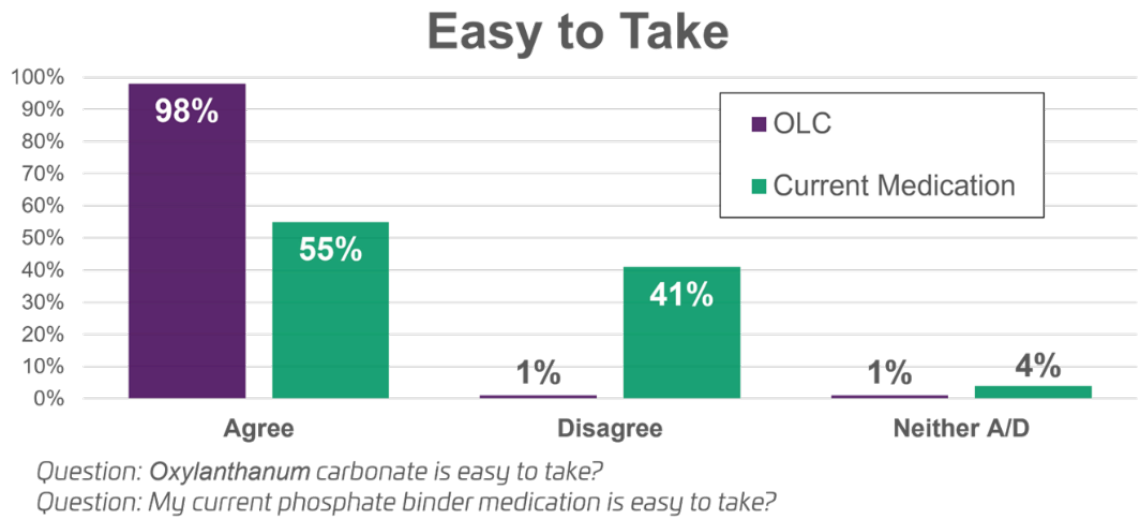
Preferred Therapy: In response to the question: *Based on your experience in this clinical trial, do you prefer your current phosphate binder or OLC,* 79% preferred OLC, 18% preferred their prior phosphate binder, and 3% preferred neither.



Question: Based on your experience in this clinical trial, do you prefer your current phosphate binder or OLC?

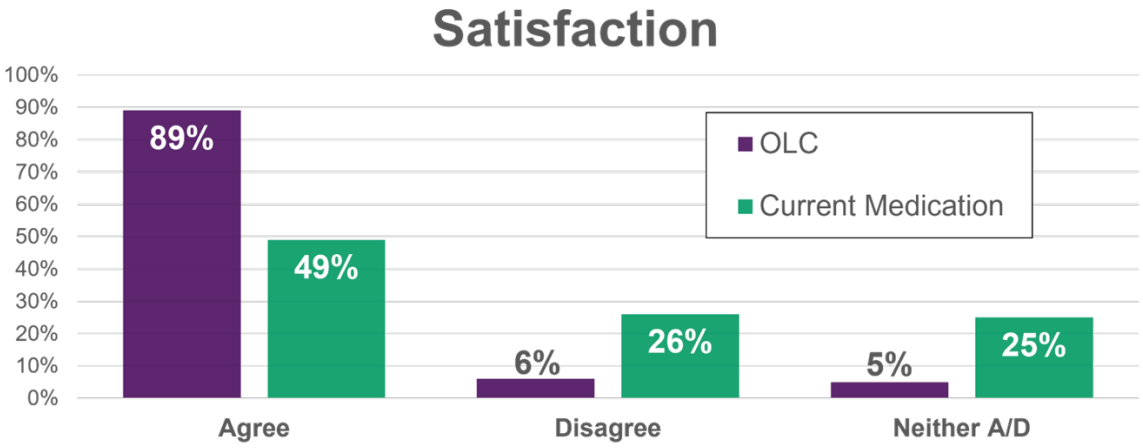
Ease of Use: In the trial, the median patient pill burden on OLC was reduced by half compared to their prior phosphate binder therapy. The pill burden on prior therapy at screening was a median of 6 (mean 6.5) pills per day. On OLC, the pill burden at the end of the study was a median of 3 (mean 3.9) pills per day.

In response to the question: *My current phosphate binding medication is easy to take*, 55% of patients agreed, 41% disagreed, and 4% neither agreed nor disagreed. In response to the question: *Oxylanthanum carbonate (OLC) is easy to take*, 98% of patients agreed, 1% disagreed, and 1% neither agreed nor disagreed.



Question: Oxylanthanum carbonate is easy to take?
Question: My current phosphate binder medication is easy to take?

Patient Satisfaction: At screening, less than half of the patients in the study agreed with the statement, *I am satisfied with my current phosphate binder medication* At the end of the study and after switching to OLC, 89% of patients agreed with the statement, *I am satisfied with oxylanthanum carbonate.* Only 6% expressed dissatisfaction with OLC.



Question: I am satisfied with oxylanthanum carbonate (OLC)?
Question: I am satisfied with my current medication?

The initial findings from the Oxylanthanum carbonate (OLC) pivotal trial satisfaction questionnaire are preliminary and subject to change based on further detailed analysis. Full survey results are expected to be presented at a future medical conference.

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 results of the bioequivalence study, pharmacodynamic (PD) bioequivalence of OLC to Fosrenol was established. A pivotal clinical trial was also conducted in CKD patients on hemodialysis that achieved the study objective and established favorable tolerability of OLC at clinically effective doses.

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 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 clinical development for the treatment of conditions related to acute kidney injury. For more information, please visit Unicycive.com and follow us on LinkedIn, X, 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, 2023, 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.

Renvela® is a registered trademark of Sanofi.
Phoslo® and Velphoro® are registered trademarks of Vifor Fresenius
Auryxia® is a registered trademark of Akebia Therapeutics
Fosrenol® is a registered trademark of Takeda Pharmaceutical Company Limited
[1]Reason Research, LLC 2022 survey. Results here.

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Photos accompanying this announcement are available at:
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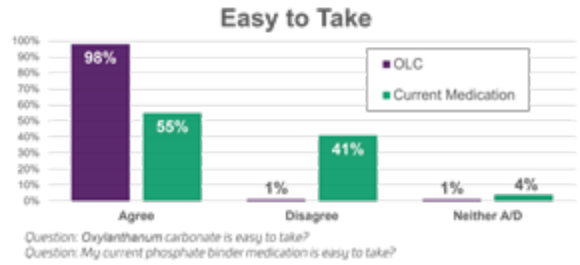
Preferred Therapy

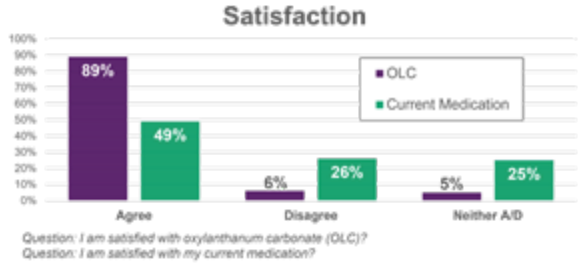
Question: Based on your experience in this clinical trial, do you prefer yur current phosphate binder or OLC?

Easy to Take



Question: Oxylanthanum carbonate is easy to take? Question: My current phosphate binder medication is easy to take?

Satisfaction



Question: I am satisfied with oxylanthanum carbonate (OLC)? Question I am satisfied with my current medication?

Source: Unicycive Therapeutics, Inc.