

June 10, 2025



Unicycive Provides Update on New Drug Application for Oxylanthanum Carbonate to Treat Hyperphosphatemia in Patients with Chronic Kidney Disease on Dialysis

- The U.S. Food and Drug Administration (FDA) identified deficiencies at a third-party manufacturing vendor
- FDA to provide final decision by PDUFA action date of June 28, 2025

LOS ALTOS, Calif., June 10, 2025 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY or the "Company"), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced an update on its New Drug Application (NDA) for oxylanthanum carbonate (OLC) to treat hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis.

The FDA communicated to the Company that it had identified deficiencies in cGMP compliance at a third-party manufacturing vendor (one of its CDMO's third-party subcontractors and not its Drug Substance vendor) following an FDA inspection.

The FDA indicated that, given the identified deficiencies, any label discussions between the FDA and the Company are precluded. The Company has responded to all FDA information requests and expects a final decision from the FDA by the PDUFA action date of June 28, 2025.

"We are discussing with our partners to help resolve FDA's concerns and remain confident in the promise of OLC based on the extensive clinical and preclinical data we've generated," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "We believe OLC is a promising new treatment option and we are eager to bring it as quickly as we can to patients with CKD on dialysis who are living with hyperphosphatemia."

About Oxylanthanum Carbonate (OLC)

OLC is an investigational oral phosphate binder that leverages proprietary nanoparticle technology to deliver high phosphate binding potency, reducing the number and size of pills that patients must take to treat hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. Its potential best-in-class profile may have meaningful patient adherence benefits over currently available treatment options as it requires a lower pill burden.

Unicycive is seeking FDA approval of OLC via the 505(b)(2) regulatory pathway. The NDA submission package is based on data from three clinical studies (a Phase 1 study in healthy volunteers, a bioequivalence study in healthy volunteers, and a tolerability study of OLC in CKD patients on dialysis), multiple preclinical studies, and the chemistry, manufacturing and controls (CMC) data. OLC is protected by a strong global patent portfolio including issued

patents on composition of matter with exclusivity until 2031, and with the potential for patent term extension until 2035.

About Hyperphosphatemia

Hyperphosphatemia is a serious medical condition that occurs in nearly all patients with End Stage Renal Disease (ESRD). Annually there are over 450,000 individuals in the U.S. that require medication to control their phosphate levels.² Uncontrolled hyperphosphatemia is strongly associated with increased death and hospitalization for CKD patients on dialysis. 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 investigational treatment is oxylanthanum carbonate, a novel phosphate binding agent currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of hyperphosphatemia in patients with chronic kidney disease who are on dialysis. Unicycive's second investigational treatment UNI-494 is intended for the treatment of conditions related to acute kidney injury. It has been granted orphan drug designation (ODD) by the FDA for the prevention of Delayed Graft Function (DGF) in kidney transplant patients and has completed a Phase 1 dose-ranging safety study in healthy volunteers. For more information, please visit [Unicycive.com](https://unicycive.com) and follow us on [LinkedIn](#) and [X](#).

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, 2024, 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.

¹ Block GA, Klassen PS, Lazarus JM, Ofsthun N, Lowrie EG, Chertow GM. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. *J Am Soc Nephrol*. 2004 Aug;15(8):2208-18. doi: 10.1097/01.ASN.0000133041.27682.A2. PMID: 15284307.

² Flythe JE. Dialysis-Past, Present, and Future: A Kidney360 Perspectives Series. *Kidney360*. 2023 May 1;4(5):567-568. doi: 10.34067/KID.0000000000000145. Epub 2023 Jun 29. PMID: 37229723; PMCID: PMC10371371.

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Source: Unicycive Therapeutics, Inc.