December 29, 2025

Unicycive Therapeutics Announces Resubmission of New Drug Application (NDA) for Oxylanthanum Carbonate (OLC)

New PDUFA date expected in 1H 2026 within 30 days of NDA resubmission

LOS ALTOS, Calif., Dec. 29, 2025 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. ("Unicycive" or the "Company") (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced that it has resubmitted its 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for oxylanthanum carbonate (OLC), the Company's investigational oral phosphate binder for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis.

"Our original third-party manufacturing vendor has made significant progress toward regaining FDA compliance, allowing us to resubmit the OLC NDA as planned," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "With a cash runway into 2027, we are well-positioned to complete the regulatory approval process for OLC so we can prepare to bring this important treatment option to dialysis patients with hyperphosphatemia as soon as possible."

The NDA for OLC was resubmitted based on continued progress by the original third-party manufacturing vendor in resolving FDA-cited deficiencies and demonstrating inspection readiness. Unicycive previously discussed these milestones during a Type A meeting with the FDA in September 2025, which was held to obtain feedback and alignment on resolving the single deficiency identified in the Company's Complete Response Letter (CRL) related to the compliance status of the vendor. No additional issues were raised by the FDA. Following receipt of the CRL in June 2025, European Union regulatory authorities inspected the original third-party manufacturing vendor and identified no deficiencies.

The Prescription Drug User Fee Act target guidelines for NDA resubmissions include acknowledgment of acceptance for review within 30 days of submission, and completion of submission review within 6 months.

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.[1] 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.

[1]Flythe JE. Dialysis-Past, Present, and Future: A Kidney360 Perspectives Series. *Kidney360*. 2023 May 1;4(5):567-568. doi: 10.34067/KID.0000000000000145.

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 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 about Unicycive, visit 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; our need to raise substantial additional capital in the future to fund our continuing operations and the development and commercialization of our current product candidates and future product candidates; dependence on key personnel; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; risks related to delays in obtaining or failure to obtain FDA clearances or

approvals and noncompliance with FDA regulations; and our failure, or the failure of our third-party manufacturers, or their subcontractors, to comply with cGMPs or other applicable regulations, which could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations. 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.

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