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Unicycive Announces Exclusive License and Development Agreement with Lotus for Renazorb in the Republic of Korea

Develops Renazorb opportunity in new market for patients with hyperphosphatemia

Agreement includes upfront payment, royalties, and milestone payments

LOS ALTOS, Calif., Feb. 02, 2023 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today announced that it has entered into an exclusive license agreement with Lotus Pharmaceutical (“Lotus”, Taiwan TWSE ticker: 1795) , a leading global pharmaceutical company, for the development and commercialization of Renazorb® (lanthanum dioxycarbonate) in the Republic of Korea. Renazorb is Unicycive’s novel phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease (CKD) patients.

"We are especially pleased to announce our second partnership for Renazorb in Asia and are delighted to be working with Lotus, a renowned global pharmaceutical leader. We believe this collaboration provides the optimal infrastructure for the further development and commercialization of Renazorb in the Korean market,” said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. “Hyperphosphatemia continues to be a serious problem for end stage renal patients around the world, particularly as compliance with currently available phosphate binders is challenging. There remains a need for a new treatment with a product profile that has meaningful patient adherence benefits, such as Renazorb.”

“At Unicycive, one of our key goals is to bring Renazorb to hyperphosphatemia patients around the world and this latest partnership underscores our commitment to that mission. We continue to advance discussions with potential partners in other key geographies and look forward to building on the foundation of global partnerships we have initiated in Asia,” added Dr. Gupta.

“The partnership with Unicycive is a testament to our efforts to bring novel treatment options for patients with chronic diseases. Nephrology is one of the key therapeutic areas for Lotus, and Alvogen Korea, an affiliate of Lotus group has been dominant and has contributed to the nephrology market with its other blockbuster products, such as Epoetin for CKD treatment, which has leading market share (45% based on 3Q 2022 IQVIA data). Renazorb® is expected to provide another high value of clinical benefits to CKD patients in Korea,” said Petar Vazharov, Chief Executive Officer of Lotus.

Under the terms of the agreement, Lotus will be responsible for development, registration filing and approval of Renazorb in the Republic of Korea. In addition, Lotus will have sole responsibility for the importation of the drug product from Unicycive and for the costs of

commercialization of Renazorb in the Republic of Korea.

Unicycive will receive an upfront payment of $750,000 and may receive up to $4.45 million in milestone payments and tiered royalties upon achievement of prespecified regulatory and commercial achievements.

About Renazorb (lanthanum dioxycarbonate)

Renazorb 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). Its potential best-in-class profile has meaningful patient adherence benefits over currently available treatment options as it requires smaller and fewer number of pills per dose and is swallowed instead of chewed.

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 Lotus

Lotus (1795: TT) is an international pharmaceutical company with a global presence that is focused on commercializing novel and generic pharmaceuticals, offering patients better, safer and more accessible medicines. The Company has a recognized best-in-class R&D and manufacturing platform in Asia and has established partnerships in nearly every global market including the U.S., Europe, Japan, China, and Brazil. Lotus runs over 100 strategically selected pharmaceutical projects in development and registrations across Asia and the US, with over 250 commercial products. The Company invests in diversified best portfolio consisting of high-barrier oncology, complex generics as well as 505(b)2 and NCE via internal R&D investment and licensing-in partnership, and also strengthens its portfolio competitiveness by adding biosimilar products with support from strategic partners. Its industry-leading infrastructure certified by most of the advanced regulatory authorities

around the world, including US FDA, EU EMA, Japan PMDA, China FDA, and Brazil ANVISA.

More information is available at www.lotuspharm.com

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug, Renazorb, is a novel phosphate binding agent being developed for the treatment of hyperphosphatemia. 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.

Forward-looking statement

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, including the outbreak of COVID-19 coronavirus, 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, 2021, 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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