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Unicycive Announces Exclusive License and Development Agreement with Lee's Pharmaceutical Holdings Limited for Renazorb in China and Certain Other Asian Markets

Expands and accelerates Renazorb opportunity in important markets for patients with hyperphosphatemia through local partner with deep domain expertise

Agreement includes upfront payment, royalties and milestone payments

LOS ALTOS, Calif., July 18, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today announced that the Company has entered into an agreement granting exclusive rights to develop, market and commercialize Renazorb® (lanthanum dioxycarbonate) to Lee's Pharmaceutical (HK) Limited, a wholly-owned subsidiary of Lee's Pharmaceutical Holdings Limited ("Lee's Pharm") (SEHK: 950), in Mainland China, Hong Kong, and certain other Asian markets. Renazorb is Unicycive's novel phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease (CKD) patients.

"We are delighted to partner with Lee's Pharm for the development and marketing of Renazorb in China, one of the world's largest markets for end-stage renal disease (ESRD), where we believe our novel phosphate binding agent will bring significant benefit to patients with hyperphosphatemia," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Lee's Pharm has the clinical, regulatory and commercial expertise in these Asian markets and we are confident this relationship will maximize the market opportunity for our proprietary nanotechnology-based asset in these territories while bringing meaningful benefit to patients. Unicycive owns global rights for Renazorb and by partnering Renazorb in select Asian countries, we begin to unlock its value for patients, physicians and for our shareholders."

Under the terms of the agreement, Lee Pharm will be responsible for development, registration filing and approval for Renazorb in the licensed territories. In addition, Lee Pharm will have sole responsibility for the importation of the drug product from Unicycive and for the costs of commercialization of Renazorb in the licensed territories.

Unicycive will receive an upfront payment of $1.0 million upon signature and up to $1.0 million in milestone payments upon product launch in China and will be eligible for tiered royalties upon achievement of prespecified regulatory and commercial achievements.

“The global renal disease market in Asia is growing due to the rise in chronic kidney disease, and in turn, results in increased incidence of hyperphosphatemia. The need for an effective phosphate binder with reduced pill burden would be a welcome addition to the treatment armamentarium as patient compliance is an important factor to achieving target serum phosphorous levels. Uncontrolled hyperphosphatemia is a persistent challenge that results in increased hospitalizations and in a greater risk of mortality,” said Ms. Leelalertsuphakun Wanee, Managing Director of Lee’s Pharm. “Renazorb also provides Lee’s Pharm’s commercial team with another product in our portfolio to sell in Asian markets.”

The incidence and prevalence of ESRD in China was projected to increase by 1.19 and 1.95 % annually and was expected to reach 250.5 per million people (pmp) (95 % CI, 247.7-253.3) and 1505 pmp (95 % CI, 1450-1560) by 2025.[i] In patients with ESRD, the prevalence of hyperphosphatemia varies from 50% to 74%.[ii]

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 Lee’s Pharm

Lee’s Pharm is a research-driven and market-oriented biopharmaceutical company with more than 25 years of operation in the pharmaceutical industry in China. Lee’s Pharm is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing based in Mainland China with global perspectives. Lee’s Pharm has established extensive partnerships with over 20 international companies and

currently markets more than 25 proprietary, generic and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau and Taiwan. The Company focuses on several key disease areas such as cardio-renal, woman health, pediatrics, rare diseases, oncology, dermatology and obstetrics, and has more than 40 products under different development stages stemming from both internal research and development as well as from the licensing of development, commercialization, and manufacturing rights from various United States, European and Japanese companies. More information is available at www.leespharm.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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SOURCE: Unicycive Therapeutics, Inc.

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[i] BMC Nephrol. 2016 Jun 13;17(1):60. doi: 10.1186/s12882-016-0269-8.

[ii] Leaf DE, Wolf M. A physiologic-based approach to the evaluation of a patient with hyperphosphatemia. Am J Kidney Dis. 2013 Feb;61(2):330-6. [PMC free article] [PubMed]

Source: Unicycive Therapeutics, Inc.