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Unicycive Initiates Pivotal Clinical Bioequivalence Study of Renazorb to Treat Hyperphosphatemia

On track to complete study by year end 2022

LOS ALTOS, Calif., June 02, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease today announced the initiation of its pivotal clinical bioequivalence (BE) study of Renazorb® (lanthanum dioxycarbonate.) Renazorb is a novel phosphate binding agent utilizing proprietary nanoparticle technology that is being developed by Unicycive for the treatment of hyperphosphatemia.

Unicycive previously received confirmatory guidance from the U.S. Food and Drug Administration (FDA) that this single BE study in healthy volunteers demonstrating the comparability of pharmacological efficacy of Renazorb to the reference listed drug, Fosrenol® would satisfy the requirements for a New Drug Application filing through the 505(b)(2) pathway.

"The initiation of this clinical study is an important milestone for Unicycive that brings us one step closer to advancing this novel phosphate binding agent toward market approval and demonstrates our experienced team's ability to execute on our development strategy," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive.

About the BE Study Design

The study is a randomized, open label, two-way crossover BE study to establish pharmacodynamic bioequivalence between Renazorb and Fosrenol. The study will enroll 32 individuals per treatment arm for a total of 64 evaluable subjects. The primary endpoint of the study is LS (least Square) mean change in urinary phosphate excretion from baseline to the evaluation period. The study will consist of a screening period, 2 dosing periods, a washout period, and a follow-up period.

The Renazorb program is supported by a previously completed clinical trial that studied Renazorb in 32 healthy volunteers. In this study, Renazorb was minimally absorbed to the systemic circulation and was safe and well-tolerated at doses up to 6000 mg/day. Renazorb significantly reduced urine phosphate excretion and significantly increased fecal phosphate excretion at doses at and above 3000 mg/day.

The Unmet Need in Hyperphosphatemia

Renazorb is intended to be administered as a tablet to be swallowed whole at mealtimes. CKD patients typically have co-morbidities, often requiring them to be on strict pill schedules.

Current phosphate binders such as Fosrenol, Renagel/Renvela® and Phoslo® involve patients needing to take multiple and/or larger pills (on average, 9 pills/day), in addition to other, non-phosphate binder pills they sometimes need to take, resulting in poor adherence to the prescribed drug therapy. Potential strategies to improve adherence to phosphate binders in patients with ESRD include: (i) a reduction in pill size and number, (ii) improvement of palatability, and (iii) a reduction in associated adverse effects as published in a study by Covic and Rastogi in 2013. Consequently, Unicycive believes there is a significant need for a better phosphate binder, such as Renazorb, that has high and rapid phosphate binding, alongside a reduced pill burden for better medication compliance.

The hyperphosphatemia treatment market exceeds one billion dollars in the U.S. and is more than double that in the rest of the world. The Unicycive team is preparing to capitalize on this substantial opportunity by offering patients and providers an attractive treatment alternative.

In tandem with the clinical development program, the Company is focused on its commercialization plans for Renazorb in the U.S. and around the world. Unicycive is conducting important market research to inform its brand and market access strategy and comprehensive launch plan for Renazorb.

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.

Fosrenol is a Registered Trademark of Takeda Pharmaceuticals Company Ltd.
Renagel is a Registered Trademark of Genzyme Corporation
Phoslo is a Registered Trademark of Fresenius Medical Care

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.

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