July 26, 2022

Unicycive Reports Key Findings from Independent Renal Dietitian Survey

Hyperphosphatemia ranked as area of greatest unmet need

Highlights most appealing benefits of Renazorb as efficacy/potency and lower pill burden

Confirms patient preference for pills that are swallowed vs chewed

LOS ALTOS, Calif., July 26, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today announced the results from an independent survey of renal dietitians conducted by Spherix Global Insights, an independent business intelligence firm that leverages its own independent data and expertise to provide strategic guidance. The survey canvassed 100 U.S. renal dietitians regarding a variety of topics related to the treatment of their chronic kidney disease and dialysis patients.

Key findings from the Spherix survey:
https://www.spherixglobalinsights.com/nephrology/bone-and-mineral-metabolism/

- Renal Dietitians (RDs) report the highest degree of influence on phosphate binder choice compared to other drug categories
  - 9.2/10 vs. 7.8/10 for calcimimetics (2nd highest), and 1.9/10 for erythropoiesis-stimulating agents (ESAs)
- RDs indicate a high level of interest in the Renazorb product profile
  - 66% indicate “high” interest
  - 96% indicate “high” or “moderate” interest
  - Most appealing aspects of Renazorb are Efficacy/Potency (47%) and Lower Number of pills (34%)
  - 65% agree that patients prefer phosphate binders they can swallow as opposed to having to chew
- 65% of RDs rate hyperphosphatemia as the therapeutic area with the greatest unmet need for new products in dialysis patients

“As renal dietitians indicate they have high influence on brand selection for phosphate binders, the results of this survey are an important barometer that further support the potential for Renazorb to be the phosphate binder of choice,” said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. “Renazorb, with its high and rapid phosphate binding and reduced pill burden for better medication compliance, should offer patients an enhanced treatment option while presenting significant commercial potential. Moving forward, we are focused on establishing our global commercial strategy for Renazorb as hyperphosphatemia is a growing medical need worldwide.”

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, Renagel/Renvela®, Phoslo®, and Fosrenol® 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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