ProKidney Announces Publication of Trial Design for Phase 2 Multicenter Clinical Trial of REACT for Late Stage 4 Diabetes-Related Chronic Kidney Disease

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WINSTON-SALEM, N.C., Jan. 10, 2023 (GLOBE NEWSWIRE) -- ProKidney Corp. (Nasdaq: PROK) ("ProKidney"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today announced the publication of the trial design and early data analysis from REGEN-003, a Phase 2 clinical study of Renal Autologous Cell Therapy (REACT®), in the *Journal of Blood Purification*. The paper, titled **Renal Autologous Cell Therapy (REACT) in Type 2 Diabetes with Late Stage 4 Diabetes-Related Chronic Kidney Disease: Trial Design and Early Analysis,** was published online and will appear later this year in the print edition of the Journal (DOI: doi.org/10.1159/000527582).

"In this study, we believe we have demonstrated the potential of REACT to delay the need for dialysis in patients with late CKD Stage 4 diabetic kidney disease (DKD)," said Joseph Stavas, M.D., ProKidney's SVP, Head of Global Clinical Development, and lead author of the manuscript. "This is a high-risk patient population with seriously reduced kidney function. The patients that took part in this study had an average estimated glomerular filtration rate (eGFR) of approximately 15.5 ml/min/1.73m^2 (eGFR CKD-EPI-sCr) These patients would be expected to progress to end stage renal disease (ESRD) requiring dialysis, and due to comorbidities, they do not typically qualify for a kidney transplant."

REGEN-003 is a single-arm, open-label, multicenter Phase 2 clinical trial that enrolled a total of ten adults with pre-renal failure resulting from type 2 DKD (kidney function measured by eGFR of 14-20 ml/min/1.73 m²). Following a percutaneous kidney biopsy and *ex vivo* expansion of Selected Renal Cells (SRCs) that form REACT, the REACT product was injected into the cortex of the biopsied kidney with CT image guidance. Nine participants received two doses of the REACT product at 6-month intervals; one participant received only one injection. A 6-month observation pre-trial was required to establish patients' "own" baseline and rate of DKD progression. No product-related serious adverse events occurred, and two procedure-related hematomas required observation without transfusion or angiographic interventions. At the time of this early analysis, dialysis was delayed a mean of 16 months (range 6-28 months). At 15 months, two patients (20%) had preservation of their kidney function and had not advanced to renal replacement therapy. One patient died due to complications related to COVID, and an additional subject died due to a myocardial infarction approximately 18 months after enrollment. Additional information on the study is available at https://www.clinicaltrials.gov/ct2/show/NCT03270956.

Dr. Stavas further commented, "The goal of REACT is to halt the progression of CKD and preserve kidney function in patients who would otherwise experience kidney failure and progress to dialysis. We believe that REACT has the potential to have a significant, positive impact on patients' health and quality of life. Publication of the 003-study design and results in this prestigious journal provides important recognition of the benefit REACT could have in the lives of these very sick patients."

ProKidney would like to thank the patients, their families and team members of the participating institutions for their contributions to this trial and their efforts to find a cure for CKD.

About ProKidney

ProKidney, a pioneer in the treatment of CKD through innovations in cellular therapy, was founded in 2015 after a decade of research. ProKidney's lead product candidate, REACT® (REnal Autologous Cell Therapy), is a first-of-its-kind, patented, autologous cellular therapy with the potential to not only slow and stabilize the progression of CKD, but in some cases possibly drive meaningful improvement in kidney function. Late-stage CKD, Stage 3b - 4, is a key target for REACT therapy. REACT has received Regenerative Medicine Advanced Therapy (RMAT) designation, as well as FDA and EMA guidance, supporting its ongoing Phase 3 clinical program, which launched in January 2022. For more information, visit www.prokidney.com.

About CKD

There are no therapies that effectively reverse late-stage CKD. CKD is a serious diagnosis with significant morbidity and mortality, notable for the 5-year mortality of a new diagnosis of CKD Stage 4 being higher than that of a new non-metastatic cancer diagnosis. CKD most often presents as a progressive decline in kidney function ultimately resulting in the failure of the kidneys and the need for renal replacement therapy, such as hemodialysis, or kidney transplant. One in three Americans is at risk for CKD which currently affects approximately 75 million people in the United States and Europe and over 400 million across Asia. CKD is among the largest single expenses incurred by the US health care system. One in five patients that progress to renal failure will die in the first year of dialysis.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. ProKidney's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, the company's expectations with respect to financial results, future performance, development and commercialization of products, if approved, the potential benefits and impact of the company's products, if approved, potential regulatory approvals, and the size and potential growth of current or future markets for the company's products, if approved. Most of these factors are outside of the company's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the inability to maintain the listing of the company's Class A ordinary shares on the Nasdaq; the inability to implement business plans, forecasts, and other expectations or identify and realize additional opportunities, which may be affected by, among other things, competition and the ability of the company to grow and manage growth profitably and retain its key employees; the risk of downturns and a changing regulatory landscape in the highly competitive biotechnology industry; the inability of the company to raise financing in the future; the inability of the company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of the company to identify, in-license or acquire additional technology; the inability of the company to compete with other companies currently marketing or engaged in the biologics market and in the area of treatment of kidney diseases; the size and growth potential of the markets for the company's products, if approved, and its ability to serve those markets, either alone or in partnership with others; the company's

estimates regarding expenses, future revenue, capital requirements and needs for additional financing; the company's financial performance; the company's intellectual property rights; uncertainties inherent in cell therapy research and development, including the actual time it takes to initiate and complete clinical studies, the fact that interim results of clinical trials may not be indicative of future results, and the timing and content of decisions made by regulatory authorities; the impact of COVID-19 or geo-political conflict such as the war in Ukraine on the company's business; and other risks and uncertainties indicated from time to time in the company's filings with the Securities and Exchange Commission. The company cautions readers that the foregoing list of factors is not exclusive and cautions readers not to place undue reliance upon any forward-looking statements, which speak only as of the date made. The company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based.

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