ProKidney Receives Allowance from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for proact 1 (REGEN-006) and EMA Scientific Advice on Phase 3 Protocols of REACT for Diabetic Chronic Kidney Disease

November 3, 2022 10:05 AM EDT

WINSTON-SALEM, N.C., Nov. 03, 2022 (GLOBE NEWSWIRE) -- **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today announced the allowance of the **proact 1** (REGEN-006) Phase 3 study protocol for its investigational candidate REACT® by the United Kingdom's (UK) MHRA. This follows submission of a clinical trial application for the **proact 1** Phase 3 study protocol previously allowed by the Food & Drug Administration (FDA) in the United States (US), where recruitment is actively underway, and now allows ProKidney to begin patient recruitment at clinical trial sites in the UK. In a related regulatory development, ProKidney also received favorable scientific advice from the European Medicines Agency (EMA) on the adequacy of its Phase 3 development program, consisting of **proact 1** and **proact 2,** to support an eventual marketing authorization application (MAA).

"We are extremely pleased to announce that the MHRA has granted allowance to ProKidney to open sites in the UK, accepting the **proact 1** study protocol that is already underway in the US and Canada. Our **proact** program of two pivotal phase 3 trials aims to proactively prevent the progression to renal failure," said Dr. Tim Bertram, CEO, of ProKidney. "This next step fits well into the execution plans to recruit a total of 600 REACT-treated patients into this first of two global Phase 3 studies. We are actively working toward submitting clinical trial applications for REACT to reach new clinical research sites, providing options to physicians and their patients who are potentially in need of CKD treatment."

Dr. Darin Weber, Senior Vice President of Regulatory Development, added "It is gratifying that we now have scientific advice from EMA that ProKidney's overall registrational clinical development program, consisting of Phase 3 studies **proact 1** and **proact 2**, if successful, can be the basis of an MAA to support commercialization in the European Union. The feedback from EMA is consistent with responses received from FDA following designation of REACT as a Regenerative Medicine Advanced Therapy (RMAT) product."

About the REACT™ Global proact Phase 3 Program

The global Phase 3 program for REACT® (**RE**nal **A**utologous **C**ell **T**herapy) is comprised of two studies: **proact 1** (REGEN-006), which is currently enrolling patients, and **proact 2** (REGEN-016), which will begin enrolling patients in early 2023. The trial names utilize the term "proact" to represent ProKidney's proactive approach to preventing the progression to renal failure and precluding the need for hemodialysis or transplant. The studies will be enrolling patients with diabetic CKD in the U.S. and rest of the world, including multiple centers anticipated in the United Kingdom, European Union, Latin America, and Asia Pacific regions. Each study aims to enroll 300 patients per arm (active or sham) resulting in a total of approximately 1,200 subjects. Targeted study subject demographics include Type 2 diabetic mellitus, CKD with eGFR 20-50 ml/min/1.73 m^2, and UACR ranging from 300-5000 mg/g and who are not on renal dialysis.

Study participants in the treatment arm will undergo a kidney biopsy and then be injected with REACT in each kidney once, with a three-month interval between injections. Study subjects randomized to the standard of care arm of the study will receive sham biopsies and injections. Following REACT or sham injections, subjects in both arms will be followed clinically until they reach one of the three components of the primary composite endpoint, which is the time from the first injection to the earliest of:

- At least 40% reduction in estimated glomerular filtration rate (eGFR), which is a measure of how well the kidneys are working; or
- eGFR<15mL/min/1.73m² sustained for 30 days; or
- Chronic dialysis; or
- Renal transplant; or
- Death from renal or cardiovascular causes.

In addition to the primary endpoint, key secondary endpoints will be included to evaluate trends in proteinuria, Quality of Life, other kidney associated laboratory parameters. Interim data from the global REACT Registrational Program including **proact 1** interim results in late 2024 and **proact 2** interim results in late 2025.

More information about the **proact 1** (REGEN-006; NCT05099770) and **proact 2** (REGEN-016; NCT05286853) studies can be found at clinicaltrials.gov.

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 by the FDA, as well as EMA, MHRA, and Health Canada guidance, supporting its ongoing **proact** 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.

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 combined company’s expectations with respect to financial results, future performance, development and commercialization of products, if approved, the potential benefits and impact of the combined company’s products, if approved, potential regulatory approvals, anticipated financial impacts and other effects of the business combination on the combined company’s business, and the size and potential growth of current or future markets for the combined company’s products, if approved. Most of these factors are outside of the combined 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 combined company’s Class A ordinary shares on the Nasdaq following the business combination; the inability to implement business plans, forecasts, and other expectations and to recognize the anticipated benefits of the business combination or identify and realize additional opportunities, which may be affected by, among other things, competition and the ability of the combined 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 combined company to raise financing in the future; the inability of the combined 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 combined company to identify, in-license or acquire additional technology; the inability of combined 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 combined company’s products, if approved, and its ability to serve those markets, either alone or in partnership with others; the combined company’s estimates regarding expenses, future revenue, capital requirements and needs for additional financing; the combined company’s financial performance; the combined 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 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 combined company’s business; and other risks and uncertainties indicated from time to time in the proxy statement relating to the business combination, including those under “Risk Factors” therein, and in the combined company’s other filings with the Securities and Exchange Commission. The combined 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 combined 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.

Contact Information

ProKidney Corp.
Clinical Trial Information
info@prokidney.com

Corporate:
Glenn Schulman, PharmD, MPH
SVP, Investor Relations
glenn.schulman@prokidney.com

Investors:
Burns McClellan
Lee Roth
Lroth@burnsmc.com

Media:
Burns McClellan
Selina Husain / Robert Flamm, Ph.D.
Shusain@burnsmc.com / rflamm@burnsmc.com