ProKidney Announces Positive Interim Data from RMCL-002 Phase 2 Clinical Trial of Renal Autologous Cell Therapy (REACT®) for Diabetic CKD and Provides Corporate Updates

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Updated positive interim Phase 2 data demonstrate potential efficacy of REACT® to preserve kidney function in moderate and high-risk diabetic CKD patients

Focusing Phase 3 development program on patients with Stage 3b and 4 diabetic CKD at highest risk of advancing to kidney failure and need for renal replacement therapy

Dr. Bruce Culleton appointed ProKidney CEO following Dr. Tim Bertram's transition to advisory role

Sufficient capital to fund operations into fourth quarter 2025

ProKidney to host conference call and webcast tomorrow at 8:00 a.m. ET

WINSTON-SALEM, N.C., Nov. 13, 2023 (GLOBE NEWSWIRE) -- ProKidney Corp. (Nasdaq: PROK) ("ProKidney"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today announced updated positive interim diabetic CKD data from its RMCL-002 Phase 2 study that support the Company's evolution into late-stage development and position the Company to change the treatment paradigm in high-risk diabetic CKD patients with its REACT® (rilparencel) renal autologous cell therapy.

Positive interim Phase 2 data demonstrate the potential of REACT® to preserve kidney function in moderate and high-risk diabetic CKD patients. Updated interim REACT RMCL-002 study data support continued investigation of REACT's potential to benefit patients with moderate and high-risk diabetic CKD. The updated data include information from 83 patients enrolled in the RMCL-002 study. All patients had Stage 3 or 4 CKD caused by type 2 diabetes. The ongoing Phase 2 clinical study assessed adverse events and changes in kidney function as measured by estimated glomerular filtration rate (eGFR), as primary study endpoints. The dataset revealed a safety profile in line with previous Phase 1 & 2 REACT trials, with REACT showing a safety profile similar to that of a kidney biopsy. Overall, the updated Phase 2 trial data showed preservation of kidney function in several patient groups with advanced CKD caused by type 2 diabetes, with the most notable potential benefit shown in patients who had the highest risk of kidney failure (CKD Stage 4 with severe albuminuria), where there remains a significant unmet clinical need.

Pablo Legorreta, Chairman of ProKidney's Board of Directors, said "We are excited to report more mature interim data for ProKidney's RMCL-002 Phase 2 study which suggests that REACT ® was able to preserve kidney function for up to 30 months in a meaningful proportion of the patients treated in the study. When I got involved with ProKidney, I hoped that if REACT could slow the decline of kidney function in a meaningful proportion of patients, it could become an important and differentiated therapy. It is exciting to see that REACT appears to have exceeded my expectations of preservation of kidney function in this population that faces significant unmet medical needs."

Focusing ongoing Phase 3 development program on patients with Stage 3b and 4 diabetic CKD at highest risk of advancing to kidney failure and need for renal replacement therapy. Based on these emerging results, the Company plans to update its ongoing **proact 1** Phase 3 clinical study (REGEN-006) protocol to focus on patients with higher risk of kidney failure. In the **proact 1** Phase 3 clinical study we will modify the eGFR enrollment range from the **current range of ≥20 to ≤ 50 ml/min /1.73m^2** to **a new range of ≥20 to ≤ 35 ml/min/1.73m^2**, to focus on the most severe patients, to better align with RMCL-002 results and clinical feedback. The Company does not intend to modify the eGFR enrollment range for its second Phase 3 trial, **proact 2** (REGEN-016), which is currently **≥20 to ≤ 44 ml/min/1.73m^2**. Maintaining the eGFR enrollment range of **proact 2**, which includes the CKD Stage 3B population, will enable the Company to seek a broader commercial label. The modification to the eGFR enrollment range to our **proact 1** Phase 3 clinical study will cause a delay in enrollment of this study, and we expect to resume enrollment during the first half of 2024.

ProKidney to temporarily pause manufacturing to address Qualified Person Audit - No safety events are responsible for this pause. A recent audit performed by the Company's contracted qualified person (QP) to evaluate its readiness for release and distribution of REACT to the EU, while still in process, identified certain deficiencies in the documentation of the quality management systems to be addressed prior to release and distribution of product for EU clinical sites. Many of these improvements to GMP systems and control activities were ongoing but had not yet been completed at the time of the audit.

The Company is temporarily pausing manufacturing until the first half of 2024, while the Company optimizes its capabilities to meet EU and global standards for its Phase 3 program and future commercial manufacturing. The Company will work to implement these manufacturing and documentation improvements concurrently with the 006 pause for protocol changes such that it expects proact 1 will resume, and proact 2 will commence enrollment in the first half of 2024.

Dr. Bruce Culleton, EVP Clinical Development and Commercialization, to be appointed ProKidney CEO upon Dr. Tim Bertram's transition to an advisory role. As the Company progresses into pivotal development and commercialization, ProKidney is pleased to announce the appointment of Dr. Bruce Culleton as the Company's CEO, effective November 15, 2023. Dr. Culleton will also join the ProKidney board of directors. Dr. Tim Bertram will transition from his current role as director and CEO to a scientific advisory role.

"We're leveraging a novel renal autologous cell therapy to improve care in a population of CKD patients with little to no options other than dialysis, and Dr. Culleton is uniquely qualified as a physician and business leader to guide ProKidney through the pivotal trials of REACT®, said Dr. Bertram. "I look forward to supporting the Company and helping ensure a smooth transition for the organization."

Commenting on his new role, Dr. Culleton stated, "I am honored to accept the role of CEO at ProKidney and to build upon the foundation laid by Dr. Bertram. I am excited by the opportunity to bring a life-changing solution to patients who are on a path to dialysis. ProKidney is well positioned to execute on a successful Phase 3 program, and I look forward to working with the team on this next phase while staying true to putting patients first in everything we do."

Mr. Legorreta added "We are thrilled to welcome Dr. Culleton into his new role as CEO, as he builds upon Dr. Betram's successes at ProKidney. Bruce's clinical, regulatory and commercial expertise will be invaluable as ProKidney navigates its Phase 3 studies towards completion, prepares for regulatory submission both in the U.S. and abroad, and prepares REACT for commercialization. We are thankful for Dr. Bertram's development of REACT and his decades-long perseverance and dedication to bringing the therapy forward to patients with kidney disease. Dr. Bertram's significant contribution has been instrumental in advancing ProKidney from its inception and into clinical development."

Dr. Culleton joined ProKidney in July 2023 as Executive Vice President of Clinical Development and Commercialization. Dr. Culleton has dedicated his 25-year professional career to improving the health and quality of life of patients with kidney disease. Over this time his responsibilities have included direct patient care, clinical research, product development, and executive leadership positions at Baxter Healthcare and CVS Kidney Care, a wholly owned subsidiary of CVS Health.

Dr. Culleton earned a Doctor of Medicine degree from Memorial University of Newfoundland, and a Master's Degree in Business Administration from Northwestern University, Kellogg School of Management. He completed specialization in Internal Medicine and Nephrology through the Royal College of Physicians and Surgeons of Canada, as well as a fellowship in Clinical Epidemiology at Boston University, Framingham Heart Study.

Sufficient capital to fund operations into fourth quarter 2025. ProKidney reported it has $396 million in cash, cash equivalents and marketable securities as of September 30, 2023. With the changes the Company announced today, including protocol modifications and manufacturing improvements, the Company expects to be able to fund operations into the fourth quarter of 2025.

The Company expects to provide full data of its RMCL-002 Phase 2 study in the first half of 2024 and interim results on its ongoing RMCL-007 Phase 2 study in mid- 2024 and full results in the first half of 2025. The Company will provide additional guidance regarding the timing of its Phase 3 programs during the conference call on November 14, 2023.

Investor Conference Call

ProKidney management will be hosting a webcast and investor conference call tomorrow, November 14, 2023, at 8:00 a.m. ET. The live webcast presentation may be accessed here. Further, you may listen to the presentation by dialing 1-877-407-0784 (US) or 1-201-689-8560 (International) and entering the Conference ID: 13742672. Following the completion of the presentation, a replay of the webcast will also be accessible on the investor relations section of ProKidney website here.

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, proprietary autologous cellular therapy being evaluated to potentially preserve kidney function in diabetic patients at high risk of kidney failure. REACT® has received Regenerative Medicine Advanced Therapy (RMAT) designation, as well as FDA and EMA guidance, supporting its ongoing Phase 3 clinical program that launched in January 2022. For more information, please visit www.prokidney.com.

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 and expected cash runway, future performance, development and commercialization of products, if approved, the potential benefits and impact of the Company's products, if approved, potential regulatory approvals, the size and

potential growth of current or future markets for the Company's products, if approved, the advancement of the Company's development programs into and through the clinic and the expected timing for reporting data, the making of regulatory filings, updating clinical trial protocols, or achieving other milestones related to the Company's product candidates, and the advancement and funding of the Company's developmental programs generally. 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 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 clearances or approvals 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 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 and the timing and content of decisions made by regulatory authorities; the fact that interim results from our clinical programs may not be indicative of future results; 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 included under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other 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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