ProKidney Reports Statistically and Clinically Significant Topline Results for the Phase 2 REGEN-007 Trial Evaluating Rilparencel in Patients with Chronic Kidney Disease and Diabetes

July 8, 2025

- *Full results from REGEN-007 are being held and will be submitted to the American Society of Nephrology 2025 Kidney Week as a late-breaking clinical trial*
- *In Group 1 (n=24), kidney function stabilized in patients randomized to receive two rilparencel injections (one in each kidney). The annual decline in eGFR slope improved by 78% from -5.8 mL/min/1.73m^2 in the pre-injection period to -1.3 mL/min/1.73m^2 in the period following the last rilparencel injection. This 4.6 mL/min/1.73m^2 per year difference was statistically significant (p<0.001) and clinically meaningful*
- *In Group 2 (n=25), patients were randomized to receive a single rilparencel injection followed by a second injection only if kidney function worsened and a re-dosing trigger was met. The annual decline in eGFR slope improved by 50% from -3.4 mL/min/1.73m^2 in the pre-injection period to -1.7 mL/min/1.73m^2 in the period following the last rilparencel injection. This 1.7 mL/min/1.73m^2 per year difference was not statistically significant (p=0.085) but suggests evidence of a dose response*
- *No rilparencel-related serious adverse events were observed; the safety profile was consistent with previously reported study results and comparable to a kidney biopsy*
- *FDA Type B meeting set for this summer to confirm ProKidney's approach to using eGFR slope as the surrogate endpoint in the ongoing Phase 3 PROACT 1 study for accelerated approval*

WINSTON-SALEM, N.C., July 08, 2025 (GLOBE NEWSWIRE) -- **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney" or the "Company"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today reported statistically significant and clinically meaningful positive topline results from the full Group 1 modified intent-to-treat (mITT) population of the Phase 2 REGEN-007 trial evaluating rilparencel in patients with CKD and diabetes. Rilparencel is an autologous cellular therapy that has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food & Drug Administration (FDA) and is currently being evaluated in the ongoing Phase 3 REGEN-006 (PROACT 1) trial to demonstrate the therapy's potential to preserve kidney function in patients with advanced CKD and type 2 diabetes.

"We are very encouraged by the REGEN-007 topline results that demonstrated a robust improvement in eGFR slope following treatment with rilparencel in Group 1 as well as evidence of a dose response in Group 2. These data bolster our confidence in the design of our ongoing Phase 3 PROACT 1 study given the similarity between the dosing regimen in REGEN-007 Group 1 and PROACT 1. It is also worth noting that 15 of the 24 patients in Group 1 (63%) met key Phase 3 PROACT 1 inclusion criteria, and similar efficacy results were observed in this subgroup compared to the full Group 1 results. We plan to submit the full results from REGEN-007 to ASN's 2025 Kidney Week as a late-breaking clinical trial and are excited to share more details at that time with investors and the medical community," said Bruce Culleton, M.D., CEO of ProKidney. "We also look forward to our upcoming FDA Type B meeting in the coming weeks to confirm our approach to eGFR slope as a surrogate endpoint for accelerated approval. This meeting represents an important step toward our goal of expediting rilparencel's potential path to market in the U.S. where there remains a significant unmet clinical need in patients with advanced CKD and diabetes."

Phase 2 REGEN-007 Overview and Topline Results

REGEN-007 is a multi-center Phase 2 open-label 1:1 randomized two-arm trial in patients with diabetes, CKD, and an estimated glomerular filtration rate (eGFR) of 20-50 mL/min/1.73m². At randomization, patients were assigned to one of two treatment groups using different dosing regimens. Group 1 replicated the dosing schedule of the ongoing Phase 3 PROACT 1 study in which patients received two scheduled rilparencel injections (one in each kidney), approximately three months apart. Group 2 tested an exploratory dosing regimen to investigate whether disease progression triggers, rather than a time-based trigger, could optimize multiple administrations of rilparencel. In Group 2, patients received a single rilparencel injection in one kidney and a second injection in the contralateral kidney only if triggered by a sustained eGFR decline from baseline of ≥ 20%, and/or an increase in the urine albumin to creatinine ratio (UACR) from baseline of ≥ 30% and ≥ 30 mg/g.

The prespecified primary endpoint for REGEN-007 is the difference in annual eGFR slope (calculated using a linear mixed effects model) in the pre-injection period versus the period following the last rilparencel injection. The pre-injection period included all historical eGFR values collected up to 24 months before the screening visit as well as the on-study central laboratory eGFR results prior to first rilparencel injection. The period following the last injection included eGFR values from the last rilparencel injection to the end of study (EOS) visit. Median follow-up after the last injection was approximately 18 months in both Group 1 and Group 2.

Fifty-three patients were randomized in the study, of whom 49 patients (mITT population) received at least one rilparencel injection. Four patients did not receive any rilparencel injections. The majority of patients were male (69%), and the mean age was 60 years. At baseline, 38 of 49 patients (78%) had type 2 diabetes mellitus and 11 (22%) had type 1 diabetes. Thirty-nine (80%)

patients were receiving an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB), and 18 (37%) were receiving a sodium-glucose cotransporter-2 inhibitor (SGLT2i). At baseline, the mean (SD) eGFR was 33±10 mL/min /1.73m^2. Notably, the median UACR was higher in Group 1 (792 mg/g) compared to Group 2 (229 mg/g).

		Annual eGFR Slope (mL/min/1.73m^2)			
Group	**N (mITT)**	**Pre inj**	**Post last inj**	**Absolute benefit**	**Relative benefit**
1	24	-5.8	-1.3	**4.6**	**78%**
2	25	-3.4	-1.7	**1.7**	**50%**

In Group 1 (n=24), kidney function stabilized after receiving rilparencel. The annual decline in eGFR slope improved by 78% from -5.8 mL/min/1.73m^2 in the pre-injection period to -1.3 mL/min/1.73m^2 in the period following the last rilparencel injection. This 4.6 mL/min/1.73m^2 per year difference[1] was statistically significant (p<0.001) and clinically meaningful. Of the 24 patients in Group 1, 15 (63%) met key Phase 3 PROACT 1 inclusion criteria, and similar efficacy results were observed in this subgroup compared to the full Group 1 results. As a reminder, the Phase 3 PROACT 1 protocol was amended in 1H 2024 after a similar eGFR efficacy signal was observed in the Phase 2 RMCL-002 study subgroup analysis (n=23) of high-UACR, Stage 4 CKD patients with type 2 diabetes.

In Group 2 (n=25), the annual change in kidney function as measured by eGFR slope was -3.4 mL/min/1.73m^2 in the pre-injection period versus -1.7 mL/min/1.73m^2 in the period following the last rilparencel injection, resulting in an improvement of 50%, or 1.7 mL/min/1.73m^2 per year. This difference was not statistically significant (p=0.085) but suggests evidence of a dose response. Out of the 25 patients in Group 2, 15 (60%) met the re-dosing trigger and received a second rilparencel injection. The median time between the first and second injections in these 15 patients was approximately 11 months.

No rilparencel-related serious adverse events were observed across all patients in the study who received at least one rilparencel injection (n=49). The safety profile was consistent with previously reported study results and comparable to a kidney biopsy.

Full results from REGEN-007 are being held and will be submitted to the American Society of Nephrology (ASN) 2025 Kidney Week as a late-breaking clinical trial.

Phase 3 PROACT 1 Regulatory Progress
As previously communicated, the FDA confirmed during a Type B meeting in Q4 2024 that the accelerated approval pathway is available for rilparencel if an acceptable surrogate endpoint, such as eGFR slope, is used. ProKidney has an upcoming FDA Type B meeting this summer to confirm the approach to using eGFR slope as the surrogate endpoint for accelerated approval. Additional details are expected in mid-2025.

About Chronic Kidney Disease
CKD is a progressive condition characterized by the gradual decline of kidney function, which can ultimately lead to end-stage kidney disease (ESKD) requiring dialysis or transplantation. An estimated 37 million adults in the U.S. have CKD, though many remain undiagnosed in the early stages. Diabetes is the leading cause of CKD, and individuals with both conditions face significantly elevated risks of cardiovascular events, hospitalization, and mortality. ProKidney is developing rilparencel for patients with Stage 3b/4 CKD and diabetes, a population that includes 1 to 2 million people in the U.S. While current treatment options aim to slow disease progression, there remains a substantial unmet need for therapies that can stabilize kidney function and delay or prevent the need for dialysis in patients with advanced CKD.

About the Phase 3 REGEN-006 (PROACT 1) Clinical Trial
REGEN-006 is an ongoing Phase 3, randomized, blinded, sham controlled safety and efficacy study of rilparencel in subjects with advanced CKD and type 2 diabetes. The study protocol was amended in 1H 2024 to focus on a subset of patients with Stage 4 CKD (eGFR 20-30 mL/min/1.73m²) and late Stage 3b CKD (eGFR 30-35 mL/min/1.73m²) with accompanying albuminuria (UACR less than 5,000 mg/g for patients with eGFR 20-30 mL/min/1.73m² and 300-5,000 mg/g for patients with eGFR 30-35 mL/min /1.73m²). The total planned enrollment is approximately 685 subjects. Subjects are randomized (1:1) to the treatment group and the sham control group prior to kidney biopsy or a sham biopsy procedure, respectively. The primary objective is to assess the efficacy of up to two rilparencel injections (one in each kidney) using a minimally invasive percutaneous approach. The primary composite endpoint is the time from first injection to the earliest of: at least 40% reduction in eGFR; eGFR <15 mL/min/1.73m², and/or chronic dialysis, and/or renal transplant; or renal or cardiovascular death.

About ProKidney Corp.
ProKidney, a pioneer in the treatment of chronic kidney disease through innovations in cellular therapy, was founded in 2015 after a decade of research. ProKidney's lead product candidate, rilparencel (also known as REACT ®), is a first-in-class, patented, proprietary autologous cellular therapy being evaluated for its potential to preserve kidney function in diabetic patients at high risk of kidney failure. Rilparencel has received RMAT designation from the FDA. 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 beliefs that the FDA agrees that the Company’s Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval and that the Company could consider using eGFR slope as a surrogate endpoint on an accelerated approval pathway for rilparencel, expectations with respect to financial results and expected cash runway, including the Company’s expectation that current cash will support operating plans into 2027, 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 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: disruptions to our business or that may otherwise materially harm our results of operations or financial condition as a result of our recent domestication to the United States; the inability to maintain the listing of the Company’s Class A common stock on Nasdaq; the inability of the Company’s Class A common stock to remain included in various indices and the potential negative impact on the trading price of the Class A common stock if excluded from such indices; 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 risk that results of the Company’s clinical trials may not support approval; the risk that the FDA could require additional studies before approving the Company’s drug candidates; 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 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 geo-political conflict 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.

Investor Contacts:

ProKidney
Ethan Holdaway
Ethan.Holdaway@prokidney.com

LifeSci Advisors, LLC
Daniel Ferry
Daniel@lifesciadvisors.com

---

[1] Difference in values is due to rounding.