# ProKidney Announces Strategic Updates to its Phase 3 Program to Accelerate Rilparencel's Registrational Path to Potential Approval in the U.S.

September 3, 2024

- *Refined the focus of the Phase 3 program to accelerate path to potential U.S. approval and commercial launch in the Company's highest priority market*
- *Discontinued the ex-U.S.-based PROACT 2 trial and focused Company resources on PROACT 1 to expedite enrollment and accelerate estimated topline data readout to Q3 2027*

WINSTON-SALEM, N.C., Sept. 03, 2024 (GLOBE NEWSWIRE) -- **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney" or the "Company"), a late clinical-stage biotech company focused on the development of a first-in-class cell therapy candidate for chronic kidney disease (CKD), today announced strategic updates to its Phase 3 program for rilparencel, an investigational treatment to potentially preserve kidney function in patients with type 2 diabetes and advanced CKD.

ProKidney recently completed a comprehensive internal and external review, including engaging with ex-FDA officials and seasoned regulatory experts, to determine the optimal path to bring rilparencel to patients in the U.S. with type 2 diabetes and advanced CKD – a market where there is high unmet clinical and economic need. An important conclusion of this review is that under the provisions of the Regenerative Medicine Advanced Therapy (RMAT) designation, the Company believes rilparencel is eligible for initial FDA approval under an expedited approval pathway based upon successful completion of the ongoing Phase 3 REGEN-006 (PROACT 1) trial. ProKidney believes that the Phase 3 REGEN-016 (PROACT 2) trial is not required for initial U.S. registration. Thus, the Company will discontinue PROACT 2, which was focused on enrollment outside the U.S. With the discontinuation of PROACT 2, ProKidney now expects current cash to support operating plans into Q1 2027. The Company estimates the revised Phase 3 program will deliver topline results by Q3 2027 and reduce expenses by approximately $150 to $175 million.

"We decided to prioritize PROACT 1 to accelerate potential U.S. registration and commercial launch. We are confident that this strategic shift in our Phase 3 program is the most expeditious and resource efficient approach to bring rilparencel to market in the U.S., our highest priority market," said Bruce Culleton, M.D., Chief Executive Officer. "The recent positive REGEN-007 interim data update in June further supports the urgency to bring our innovation to patients with advanced CKD. We look forward to continuing our engagement with the FDA, under the RMAT designation, to bring rilparencel to market."

Today's update follows a transformational period for ProKidney over the past 10 months. In November 2023, Bruce Culleton, M.D., a nephrologist and seasoned leader of kidney care organizations, was appointed Chief Executive Officer. Under Dr. Culleton's leadership, ProKidney has made significant progress, including the implementation of improved quality management systems to ensure compliance with global standards for commercial manufacturing and the Phase 3 program, the refinement and restart of the Phase 3 program with a renewed focus on patients with advanced CKD in the U.S., and the appointment of several key executive leaders across clinical operations, manufacturing, human resources, and business operations. The Company also released final data from the Phase 2 RMCL-002 trial and interim data from the Phase 2 REGEN-007 trial. Data from these trials suggest that rilparencel's greatest potential therapeutic impact is in advanced CKD patients at high risk of kidney failure. This patient population aligns with feedback from payors and providers who have emphasized the need for treatment options in this population.

Rilparencel was granted RMAT designation by the FDA in October 2021. RMAT designation can be granted to regenerative medicine therapies (including cell therapies) that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and have preliminary clinical evidence that indicate the drug candidate has the potential to address unmet medical needs for such disease or condition. This designation is intended to facilitate an accelerated development and review process similar to the breakthrough therapy designation. With an RMAT designation for rilparencel, ProKidney will continue to work with the FDA to receive guidance on its registrational program, including guidance on clinical trial design, manufacturing, and long-term patient follow-up, as appropriate.

**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 type 2 diabetes and advanced CKD. The study protocol was amended in 1H 2024 to focus on a subset of patients with stage 4 CKD (eGFR 20-30ml min/1.73m$^2$) and late stage 3b CKD (eGFR 30-35ml min/1.73m$^2$) with accompanying albuminuria (urine albumin-to-creatinine ratio, or UACR less than 5,000 mg/g for patients with eGFR 20-30ml min/1.73m$^2$ and 300-5,000 mg/g for patients with eGFR 30-35ml min/1.73m$^2$). 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. Subjects in the treatment group are to receive the first rilparencel injection within 18 weeks of kidney biopsy. After three months it is intended that a second rilparencel injection be given into the contralateral kidney. Subjects in the control group, who previously

underwent the sham biopsy procedure, are to receive two sham injections at similar time points as the treatment group. The primary objective is to assess the efficacy of up to two rilparencel injections 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-of-its-kind, patented, proprietary autologous cellular therapy being evaluated for its potential to preserve kidney function in diabetic patients at high risk of kidney failure.

**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 (i) rilparencel is eligible for initial FDA approval under an expedited approval pathway based upon the successful completion of the Phase 3 REGEN-006 (PROACT 1) trial, (ii) the Phase 3 REGEN-016 (PROACT 2) trial is not required for initial U.S. registration, and (iii) the revised Phase 3 program will accelerate estimated topline data readout and deliver topline results by Q3 2027, expectations with respect to financial results and expected cash runway, including the Company's expectation that current cash will support operating plans into Q1 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: 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 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.

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