



ProKidney Announces Alignment with the FDA on the Accelerated Approval Pathway for Rilparencel

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- FDA confirmed that eGFR slope is an acceptable surrogate endpoint for accelerated approval of rilparencel in patients with CKD and type 2 diabetes
- FDA also confirmed that the ongoing Phase 3 PROACT 1 study can be used for both accelerated approval and for full approval
- Nearly half of the patients required for the accelerated approval analysis using eGFR slope have been enrolled
- Topline data to support an application for accelerated approval is anticipated in Q2 2027

WINSTON-SALEM, N.C., July 15, 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 announced confirmation of alignment with the U.S. Food and Drug Administration (FDA) on the accelerated approval pathway for rilparencel. Rilparencel is an autologous cellular therapy that received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA and currently is 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.

In a recent Type B meeting, the FDA confirmed that the slope of estimated glomerular filtration rate (eGFR) in patients from the ongoing Phase 3 PROACT 1 study can serve as the surrogate endpoint and primary basis for a Biologics License Application (BLA) submission of rilparencel under the accelerated approval pathway. The FDA agreed that a rilparencel effect size (versus sham controls) of at least 1.5 mL/min/1.73m²/year improvement would be an acceptable demonstration of efficacy in the setting of patients receiving appropriate standard of care therapies. ProKidney anticipates topline data readout of eGFR slope as the surrogate endpoint to support an application for accelerated approval in Q2 2027. To date, ProKidney has enrolled nearly half of the patients required for the accelerated approval analysis. The FDA also confirmed that the ongoing Phase 3 PROACT 1 study may serve as the confirmatory study to support full approval of rilparencel based on the primary time-to-event composite endpoint specified in the protocol. Updated guidance on the expected timing of the confirmatory readout will be provided in 1H 2026.

"We are very encouraged by the FDA's support of the accelerated approval pathway for rilparencel using eGFR slope, marking a critical regulatory milestone for ProKidney," said Bruce Culleton, M.D., CEO of ProKidney. "This alignment allows us to move forward with clarity and conviction as we advance enrollment in our pivotal Phase 3 PROACT 1 study on the heels of the positive Phase 2 REGEN-007 topline results announced last week. We look forward to our ongoing dialogue with the FDA, under RMAT designation, to bring rilparencel to patients with advanced CKD and diabetes, a patient population with high unmet clinical and societal needs."

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 surrogate endpoint for accelerated approval is eGFR slope, and 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. 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 its Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval, eGFR slope can be used 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.

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