ProKidney Announces Positive Interim REGEN-007 Phase 2 Trial Data and Provides Clinical and Operational Updates

June 10, 2024

- *Interim results of REGEN-007 Phase 2 trial show stabilization of kidney function for 18 months*
- *Safety profile consistent with prior studies and comparable to kidney biopsy*
- *Resumed manufacturing and both PROACT 1 and PROACT 2 Phase 3 trials*
- *Management to host live webcast today at 8:00 a.m. ET*

WINSTON-SALEM, N.C., June 10, 2024 (GLOBE NEWSWIRE) -- **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today announced positive interim results from the Phase 2 REGEN-007 trial evaluating the Company's renal autologous cell therapy, rilparencel, in patients with CKD caused by diabetes and provided clinical and operational updates. Management will host a live webcast today at 8:00 a.m. ET to discuss the data.

REGEN-007 Phase 2 Trial Interim Efficacy & Safety Data

REGEN-007 is an ongoing multi-center Phase 2 open-label 1:1 randomized two-armed trial in patients with diabetes and CKD who have an estimated glomerular filtration rate (eGFR) of 20 - 50 mL/min/1.73m². At randomization, patients are allocated to two treatment groups using different dosing regimens. Group 1 replicates the dosing schedule for our Phase 3 clinical study program in which patients receive two rilparencel injections – one in each kidney, three months apart. Group 2 tests an exploratory dosing regimen to investigate whether physiological triggers, rather than a time-based trigger, could optimize multiple administrations of rilparencel. In Group 2, patients receive a single rilparencel dose in one kidney and a second dose in the contralateral kidney only if triggered by a sustained eGFR decline of ≥ 20%, and/or an increase in the urine albumin to creatinine ratio (UACR) from baseline of ≥ 30% and ≥ 30 mg/g.

In Group 1, as of May 7, 2024, patients with at least 12 months follow-up after the second injection of rilparencel (n=13) show stabilized kidney function for 18 months (average eGFR change from baseline to 18 months was -1.3 ml/min/1.73m^2). Importantly, similar results were observed in a subset of these patients (n=10) who met key inclusion criteria currently used in our Phase 3 clinical study program (average eGFR change from baseline to 18 months was -0.6 ml/min/1.73m^2). Additional analyses will be performed as Group 1 data matures.

Twenty-five patients received at least one rilparencel injection in Group 2; 12 patients received a second rilparencel injection based on eGFR criteria (n=3) or UACR criteria (n=9). Patients in Group 2 who received two injections are scheduled to have up to 18 months of follow-up after their second injection. No rilparencel-related serious adverse events were observed across all patients in the study who received at least one rilparencel injection (n=49).

Clinical and Operational Update

- Effective June 1, 2024, ProKidney resumed manufacturing for U.S. and non-European clinical study sites
- Anticipate a potential QP Declaration of Equivalence to EU GMPs to be received by the end of June 2024; this will allow ProKidney to ship rilparencel to clinical study sites in Europe
- In its PROACT 1 study, ProKidney has resumed screening patients under an amended protocol that has been enriched with higher risk patients
- In its PROACT 2 study, ProKidney recently activated sites in Spain in anticipation of receipt of the QP Declaration of Equivalence to EU GMPs

"These are critically important operational milestones for ProKidney. Manufacturing has restarted, and our Phase 3 clinical study program has resumed. Furthermore, the interim results from REGEN-007 are promising and reveal the potential of rilparencel to preserve kidney function in patients with moderate to severe CKD," said Bruce Culleton, Chief Executive Officer. "This is our first clinical study using bilateral kidney dosing and cryopreserved rilparencel replicating our approach in both PROACT 1 and PROACT 2 Phase 3 studies. I am very excited for the next phase of ProKidney's evolution as we endeavor to demonstrate preservation of kidney function using rilparencel in a patient population with limited therapeutic options."

Webcast Information
Management will host a live conference call and webcast at 8:00 a.m. ET today, June 10, 2024, to discuss the REGEN-007 data, the restart of manufacturing, and the resumption of the Phase 3 trials. The conference call can be accessed by dialing 1-877-407-0784 from the United States or 1-201-689-8560 internationally, followed by conference ID: 13747006. The live webcast will be available here and in the Events & Presentation section of ProKidney's website at www.prokidney.com , with an archived replay available for approximately 90 days following the event.

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, rilparencel (also known as REACT®), 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. Rilparencel has received Regenerative Medicine Advanced Therapy (RMAT) designation, as well as FDA and EMA guidance, supporting its ongoing Phase 3 clinical program. 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 potential of rilparencel to preserve kidney function in patients with moderate to severe CKD, the potential QP Declaration of Equivalence to EU GMPs, the potential benefits and impact of the Company's products, if approved, and potential regulatory approvals. 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 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 the 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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