



## Observed Safety Profile Supports Bilateral Dosing of ProKidney's REACT™ – 007 Update

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*Potential for Amplified Therapeutic Effect of REACT™ with Bilateral Kidney Injections*

*Potential to report data from enhanced delivery approach 1Q 2023*

WINSTON-SALEM, N.C., June 07, 2022 (GLOBE NEWSWIRE) -- ProKidney LP ("ProKidney"), a leading clinical-stage cellular therapeutics company focused on therapies for chronic kidney disease ("CKD"), today announced an update on its REGEN-007 Phase 2 clinical study of REACT™.

**Background** - ProKidney's REGEN-002 trial is a multi-center, randomized (1-to-1) Phase 2 trial that enrolled 81 stage 3/4 CKD diabetic patients who received two injections in the same kidney six months apart. Patients are being followed for up to two years. Previously disclosed preliminary and interim data as of September 2021 showed promising results with a majority of patients achieving disease stabilization or improved kidney function.

Based on an observed favorable safety profile in REGEN-002 and other previous studies, and a signal of improved kidney function, in REGEN-007 ProKidney is proceeding with the injection of REACT™ into both kidneys. ProKidney expects that injecting both kidneys will result in increased therapeutic effect as compared to injecting a single kidney, as the systemic effects of Type-2 diabetes mellitus impact both kidneys. By injecting both kidneys, patients have maximal exposure to REACT™ cells, with the potential to impact a greater proportion of damaged renal tissue. The number of glomeruli (the filtering units of the kidney) that are amenable to regenerative therapy is effectively doubled by injecting both kidneys, thereby allowing both kidneys to initiate healing and repair to improve function. The main goal of REGEN-007 is to evaluate whether REACT™ injections in both kidneys, as compared to two injections in the same kidney in REGEN-002, will: (a) increase the improvement of kidney function over and above the mean estimated glomerular filtration rate (eGFR) improvement observed in REGEN-002, and/or (b) increase the number of patients in which kidney function stabilizes or improves.

REGEN-007 is an ongoing, prospective, randomized, open-label, repeat dose, double-arm, controlled safety and efficacy study of REACT™ in subjects with type 1 or 2 diabetes and CKD. The primary objective of this study is to assess the safety and efficacy of up to two REACT™ injections delivered into biopsied and non-biopsied contralateral kidneys using a minimally invasive percutaneous approach. This open-label trial uses the same dosing regimen used in the ongoing Phase 3 trial launched in January of this year and will involve dosing both kidneys with REACT™. ProKidney commenced enrollment for REGEN-007 in the third quarter of 2021 and has expanded target enrollment from 30 to up to 50 subjects as a result of strong investigator and patient interest. As of June 1, 2022, 24 subjects were enrolled with 12 subjects randomized to cohort 1 and 12 subjects randomized to cohort 2. As of June 1, four subjects in cohort 1 had received their first dose of REACT™, two of whom received a second dose into the contralateral kidney, and five subjects in cohort 2 had received their first dose of REACT™.

"This study is expected to provide valuable insights into the potential benefits of treatment with doses of REACT™ in each kidney, and together with the ongoing Phase 3 program, is expected to support our planned biologics license application submission to the FDA in 2025," said Tim Bertram, Ph.D., Chief Executive Officer of ProKidney. "We believe that dosing both kidneys with REACT™ can enhance our mission of sustaining renal function by augmenting the repair process over the course of a patient's life. We look forward to testing this hypothesis as we continue to recruit subjects, and to reporting data from our enhanced delivery approach in 1Q23."

The 50 subjects to be enrolled in REGEN-007 will be randomized (1-to-1) into one of two cohorts. The 25 patients to be randomized to Cohort 1 will receive two REACT™ injections in the biopsied and non-biopsied contralateral kidney 3 months apart. The 25 patients to be randomized to Cohort 2 will receive a single REACT™ injection into the biopsied kidney, with a second injection into the contralateral kidney if certain pre-defined laboratory triggers are met. For Cohort 2 patients, the triggers include a 30-day sustained decline in eGFR by at least 20% from the baseline value, confirmed with repeat laboratory testing, and/or an increase of  $\geq 30\%$  and of at least 30 mg/g in albuminuria from baseline, using a standard urine chemistry, sustained for at least 30 days with two repeat central laboratory testing 7 days apart at least 30 days after initial event for confirmation.

REGEN-007's primary efficacy endpoint is improvement in the rate of renal function decline as indicated by the change from pre-injection baseline value to post-injection total (acute + chronic) slope of eGFR. The primary safety endpoint is treatment-emergent adverse events through 24 months following the last REACT™ injection. ProKidney anticipates initial evaluation from this study from a limited number of patients in the first half of 2023, with topline data expected in 2025.

ProKidney's Phase 3 program is expected to enroll up to 1,200 patients into two randomized, multi-center and blinded studies, REGEN-006 (600 patients) and REGEN-016 (600 patients), each with patients randomized (1-to-1) into an active cohort and a sham injection cohort. In both studies, active cohort patients will be injected with REACT™ in each kidney once with a three-month interval between injections, and patients randomized to the standard of care (sham) arm of the study will receive sham biopsies and sham injections. REGEN-007 is an unblinded study in which Cohort 1 patients will receive the same treatment regimen as the patients in the Company's Phase 3 program who are randomized to the active arms. We anticipate that REGEN-007 may provide some insights regarding the magnitude of clinical benefit that might be observed in ProKidney's Phase 3 program.

### About ProKidney

ProKidney, a pioneer in the treatment of CKD through innovation 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, disease-modifying, autologous cellular therapy with the potential not only to slow and stabilize the progression of CKD, but in some cases drive meaningful improvement in kidney function. REACT™ has received Regenerative Medicine Advanced Therapy (RMAT) designation, as well as FDA and EMA guidance, supporting the Phase 3 clinical program that launched on schedule in January 2022. On January 18, 2022, ProKidney announced that it would become a publicly traded company via a business combination with Social Capital Suvretta Holdings Corp. III (Nasdaq: DNAC). For more information, visit [www.prokidney.com](http://www.prokidney.com).

### Additional Information and Where to Find It

In connection with the proposed transaction between Social Capital Suvretta Holdings Corp. III ("SCS") and ProKidney, SCS has filed a preliminary proxy statement with the U.S. Securities and Exchange Commission (the "SEC") and intends to file a definitive proxy statement with the SEC.

SHAREHOLDERS OF SCS ARE ADVISED TO READ THE PRELIMINARY PROXY STATEMENT, AS AMENDED FROM TIME TO TIME, THE DEFINITIVE PROXY STATEMENT AND ALL OTHER RELEVANT DOCUMENTS FILED OR THAT WILL BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION AS THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. HOWEVER, THESE DOCUMENTS WILL NOT CONTAIN ALL THE INFORMATION THAT SHOULD BE CONSIDERED CONCERNING THE PROPOSED TRANSACTION. THEY ARE ALSO NOT INTENDED TO FORM THE BASIS OF ANY INVESTMENT DECISION OR ANY OTHER DECISION IN RESPECT OF THE PROPOSED TRANSACTION. When available, the definitive proxy statement will be mailed to the shareholders of SCS as of a record date to be established for voting on the proposed transaction. Shareholders will also be able to obtain copies of the preliminary proxy statement, the definitive proxy statement and other documents filed with the SEC that will be incorporated by reference therein, without charge, once available, at the SEC's website at <http://www.sec.gov>.

The documents filed by SCS with the SEC also may be obtained free of charge at SCS's website at <https://socialcapitalsuvrettaholdings.com/dnac> or upon written request to 2850 W. Horizon Ridge Parkway, Suite 200, Henderson, NV 89052.

#### **Participants in the Solicitation**

SCS and ProKidney and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from SCS's shareholders in connection with the proposed transaction. A list of the names of such directors and executive officers and information regarding their interests in the proposed transaction between ProKidney and SCS will be contained in the definitive proxy statement when available. You may obtain free copies of these documents as described in the preceding paragraph.

#### **No Offer or Solicitation**

This communication shall not constitute a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the proposed transaction. This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any states or jurisdictions in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, or an exemption therefrom.

#### **Forward-Looking Statements**

This communication may contain certain forward-looking statements within the meaning of the federal securities laws, including with respect to the proposed transaction between ProKidney and SCS and the timing of enrollment of ProKidney's clinical trials, availability of clinical data and obtainment of regulatory approvals. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this communication, including but not limited to: (i) the risk that the proposed transaction may not be completed in a timely manner or at all, which may adversely affect the price of SCS's securities, (ii) the risk that the proposed transaction may not be completed by SCS's business combination deadline and the potential failure to obtain an extension of the business combination deadline if sought by SCS, (iii) the failure to satisfy the conditions to the consummation of the proposed transaction, including the adoption of the definitive agreement related to the business combination between SCS and ProKidney (the "Business Combination Agreement") by the shareholders of SCS and the satisfaction of the minimum cash condition, (iv) the lack of a third-party valuation in determining whether or not to pursue the proposed transaction, (v) the inability to complete the private placement entered into in connection with the transaction, (vi) the occurrence of any event, change or other circumstance that could give rise to the termination of the Business Combination Agreement, (vii) the effect of the announcement or pendency of the transaction on ProKidney's business relationships, operating results, and business generally, (viii) risks that the proposed transaction disrupts current plans and operations of ProKidney and potential difficulties in ProKidney employee retention as a result of the transaction, (ix) the outcome of any legal proceedings that may be instituted against ProKidney or against SCS related to the Business Combination Agreement or the proposed transaction, (x) the ability to maintain the listing of SCS's securities on a national securities exchange, (xi) the price of SCS's securities may be volatile due to a variety of factors, including changes in the competitive and highly regulated industries in which SCS plans to operate or ProKidney operates, variations in operating performance across competitors, changes in laws and regulations affecting SCS's or ProKidney's business, and changes in the combined capital structure, (xii) the ability to implement business plans, forecasts, and other expectations after the completion of the proposed transaction, and identify and realize additional opportunities, (xiii) the risk of downturns and a changing regulatory landscape in the highly competitive biotechnology industry, and (xiv) 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 foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" section of SCS's preliminary proxy statement on Schedule 14A (File No. 001-40560), as amended from time to time, filed with the SEC, SCS's annual report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 28, 2022, the definitive proxy statement of SCS, when available, including those under "Risk Factors" therein and other documents filed by SCS from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and ProKidney and SCS assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. Neither ProKidney nor SCS gives any assurance that either ProKidney or SCS, or the combined company, will achieve its expectations.

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