# ProKidney highlights key registrational program elements supporting advancement of REACT®

May 3, 2022

**Winston-Salem, NC,** May 3, 2022 — ProKidney LP (ProKidney), a leading clinical-stage cellular therapeutics company focused on the treatment of chronic kidney disease (CKD) and the prevention of both end-stage renal disease (ESRD) and the need for dialysis, today highlighted the key registrational program elements supporting development of its autologous cell therapy REACT® for diabetic CKD. The design of the Phase 3 program for REACT® is a result of our consultation with the Food & Drug Administration (FDA) for this first in class cellular therapy being developed to restore kidney function in patients with CKD.

REACT® is an autologous cell therapy produced from a patient's own kidney cells that is comprised of a proprietary mixture of progenitor cells that have been grown and purified, so they can be placed back into the patient's kidney. REACT does not require immunosuppression frequently given with other renal replacement therapies. REACT involves a minimally invasive procedure, starting with a standard biopsy, that allows the cells to harness the body's intrinsic ability to repair and restore damaged kidney tissue. The reinjection procedure has been shown to be better tolerated than contemporary biopsy.

In October 2021, the FDA granted ProKidney's REACT Regenerative Medicine Advanced Therapy (RMAT) designation, after reviewing more than seven years of data collected from over 100 REACT®–treated patients with stages 3/4 diabetic CKD and moderate-to-severe albuminuria. RMAT is a process designed by the FDA to expedite the development and review of a medicine candidate, if: a) the candidate is a regenerative medicine therapy (which includes cell therapies), b) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and c) preliminary clinical evidence indicates that the candidate has the potential to address unmet medical needs for such disease or condition. ProKidney's multi-center, randomized (1-to-1) Phase 2 trial enrolled 81 stage 3/4 CKD diabetic patients who received two injections in the same kidney six months apart and are being followed for up to two years. REACT's promising interim Phase 2 data has shown that a majority of patients achieved disease stabilization or improved kidney function.

With the grant of RMAT designation for REACT®, the FDA is providing ProKidney in-depth guidance on the REACT® registrational program. This guidance includes evaluation of clinical trial designs, manufacturing, and long-term clinical study follow-up. In addition, at a recent multi-disciplinary meeting, the FDA also provided guidance on Chemistry, Manufacturing, and Controls (CMC) evaluations directed toward assessments of comparability and potency, thereby providing a clear path for potential REACT® commercialization, if approved by the FDA. Collectively, this comprehensive development plan is designed to support North American and European marketing with regulatory submissions targeted for late 2025 or early 2026.

"ProKidney and our investors are excited to have brought forward REACT® to address a challenge never considered possible: restoration, and even reversal, of a patient's loss of kidney function," said Dr. Tim Bertram, CEO and Founder of ProKidney. "In alignment with FDA guidance, we've laid out the key elements for a potentially transformational new therapeutic approach. We intend to bring this first ever autologous cell therapy for CKD through regulatory review and out to patients as expeditiously as possible. We look forward to continuing the enrollment of patients in our Phase 3 trial, as we roll out the program to more than 300 clinical centers worldwide."

**FDA Confirms ProKidney's Design of The Phase 3 Clinical Program for REACT®**

The registrational clinical program is designed to generate efficacy and safety data in two randomized, sham-controlled, blinded studies with a three-component primary endpoint under a Time-to-Event design. The trials in total will include approximately 1,200 subjects globally, and a clinical evidence package based on this design may provide the necessary evidence of safety and effectiveness to support a Biologics License Application (BLA) for commercialization of REACT®.

The Phase 3 program will be conducted in multiple centers in the United States, Europe, Latin America, and Asia Pacific. Study subject demographics will be consistent with previous trials involving REACT®, including patients at high-risk-of-end-stage kidney disease: Type 2 diabetic mellitus, CKD stage 3/4, not on renal dialysis, eGFR 20-50 ml/min/1.73 $m^2$, and UACR ranging from 30-5000 mg/g. The robust safety profile of REACT® after two injections in the same kidney in clinical studies thus far supports an effort to enhance efficacy potential by injecting subjects in both kidneys in the Phase 3 program. This broader injection pattern holds the potential to achieve greater efficacy as the therapy will be delivered into the patients' two kidneys – 2x the kidney mass as compared to Phase 2.

Study subjects in the treatment arm will undergo a kidney biopsy and then be injected in each kidney once with a three-month interval in between injections. Study subjects randomized to the standard of care arm of the study will receive sham biopsies and injections. Following either the second REACT® or sham injections, subjects in the treatment or standard of care arms will be followed clinically until they reach one of the three components of the primary composite endpoint. Specifically, the primary composite endpoint for this Phase 3 clinical program is the time from the first injection to the earliest of:

- At least 40% reduction in estimated glomerular filtration rate (eGFR), which is a measure of how well the kidneys are working;
- eGFR<15mL/min/1.73m² sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- Death from renal or cardiovascular causes.

In addition to the primary endpoint, a set of key secondary endpoints will be included to evaluate trends in proteinuria, quality of life, other kidney associated laboratory parameters, and other metrics.

Subjects from the control standard of care arms of both Phase 3 trials, will be allowed to enroll into a new Phase 2 trial to allow them to be injected with REACT® after completing the Phase 3 trial or after experiencing one of the qualifying events highlighted above. This ability to cross over is expected to facilitate the recruitment of study subjects by allowing them to access the potential benefits of REACT®, and at the same time expand the clinical evidence for REACT's efficacy and safety profile.

**FDA Accepts ProKidney's Proposed Matrix Potency Assay for REACT ®**

In providing guidance for a commercial-ready manufacturing program, the FDA accepted ProKidney's proposed matrix potency assay characterizing the progenitor cell population in REACT® and cytokine profile supportive of the REACT® mechanism of action. This clarifies provision of quality assurance prior to delivery to patients. Proactive CMC review and evaluation supports ProKidney's plans for rapid manufacturing scale-out to support global market readiness, subject to receipt of regulatory approval.

Furthermore, the FDA accepted ProKidney's proposal for a long-term 5-year clinical follow-up program for all REACT® injected patients, to be enrolled with patients who have previously received REACT® injections in one or both kidneys. This long-term follow-up program could provide robust evidence in support of premium pricing and product durability for REACT®.

**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.

**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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