UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 10, 2024

PROKIDNEY CORP.
(Exact name of Registrant as Specified in Its Charter)

Cayman Islands	**001-40560**	**98-1586514**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2000 Frontis Plaza Blvd. **Suite 250** **Winston-Salem, North Carolina** **(Address of Principal Executive Offices)**	**27103** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 336 999-7019

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A ordinary shares, $0.0001 par value per share	PROK	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 10, 2024, ProKidney Corp. (the "Company") issued a press release titled "ProKidney Announces Positive Interim REGEN-007 Phase 2 Trial Data and Provides Clinical and Operational Updates". A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On June 10, 2024, the Company announced REGEN-007 Phase 2 Trial Interim Efficacy & Safety Data as well as certain clinical and operational updates. On June 10, 2024, the Company also updated its corporate presentation for use in meetings with investors, analysts and others. A copy of this presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the presentation.

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 chronic kidney disease (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/1.73m2). 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/1.73m2). 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

Forward Looking Statements

This disclosure in this report contains 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release dated June 10, 2024
99.2	Investor Presentation dated June 10, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROKIDNEY CORP.

Date: June 10, 2024

By: /s/ James Coulston
James Coulston
Chief Financial Officer

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

- *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 — **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

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"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

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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.

Investor Contacts:

ProKidney
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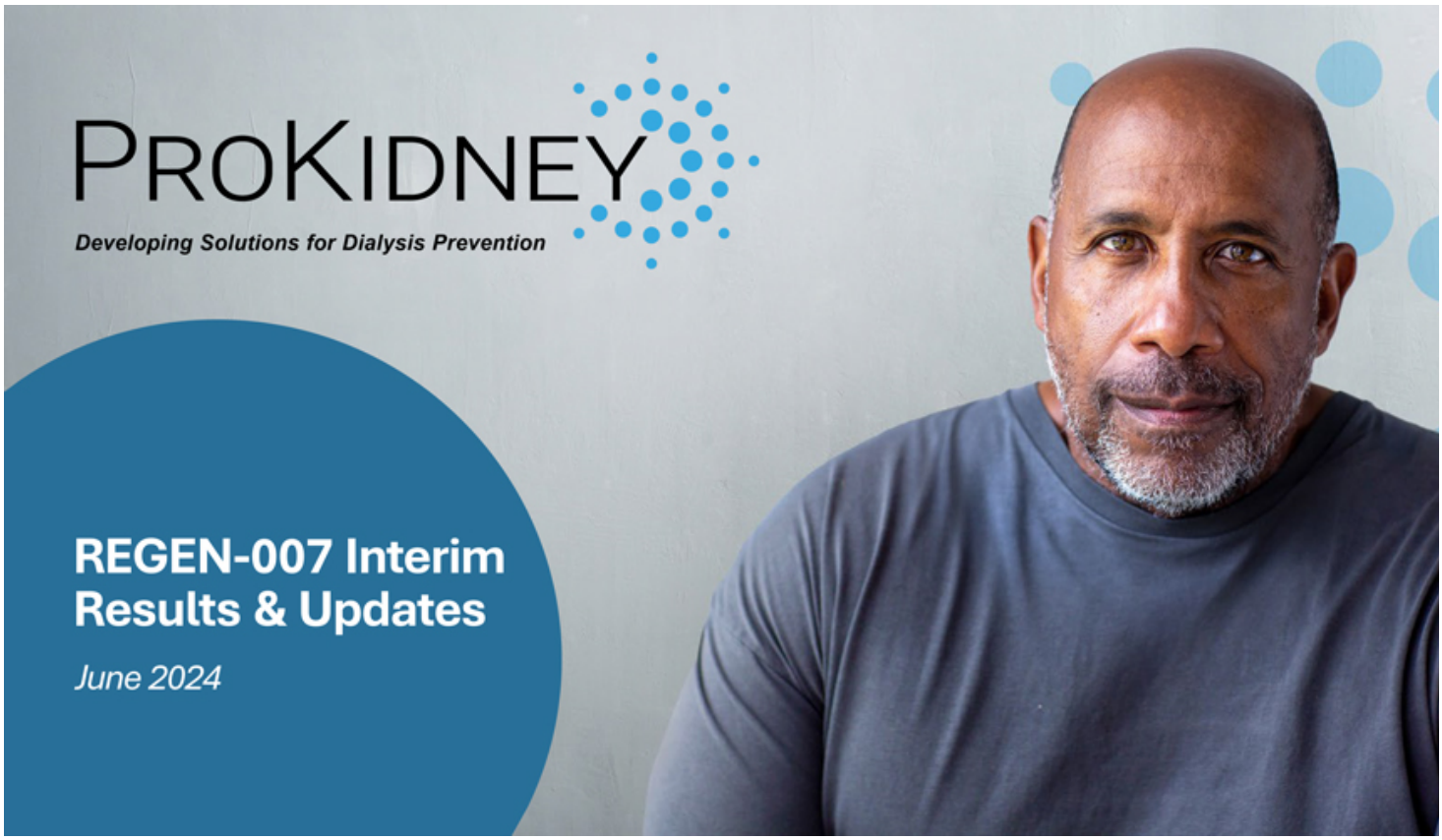
Ethan.Holdaway@prokidney.com

LifeSci Advisors, LLC
Daniel Ferry
Daniel@lifesciadvisors.com

Exhibit 99.2


PROKIDNEY
Developing Solutions for Dialysis Prevention
REGEN-007 Interim Results & Updates
June 2024

Forward-looking Statements

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An Introduction to ProKidney

Goal

Preserve kidney function in advanced CKD patients

Preserve kidney function in patients with moderate to severe chronic kidney disease caused by diabetes who are faced with limited options for care beyond transplantation or dialysis

Rilparencel

A proprietary autologous cellular therapy with RMAT designation

Currently in pivotal Phase 3 clinical development with REGEN-006 (PROACT 1) and REGEN-016 (PROACT 2)

Supported by three Phase 2 clinical trials in advanced CKD patient populations

Leadership

Leadership Team with Clinical Development & Regulatory Experience

Together the team brings over 150 years cumulative experience in the discovery, development, manufacturing and commercialization of biotechnology, pharmaceutical, and device products

Recent Developments

Meaningful Recent Developments

Phase 2 REGEN-007 interim results published in June 2024

Resumed PROACT 1 and PROACT 2 Phase 3 trials; resumed manufacturing for our clinical studies

CKD = chronic kidney disease RMAT = regenerative medicine advanced therapy

What is Rilparencel and Why is it Relevant?

Unmet Needs

Over **35 million U.S. adults** have chronic kidney disease (CKD)[1]

More than **135,000 of these CKD patients progress to dialysis** every year[1]

Total annual costs to Medicare for patients with CKD (including ESRD) exceed $138B[2]

Our Goals

Preserve kidney function

Reduce or potentially eliminate time spent on dialysis

Return autonomy to patients and their families

Our Product

Rilparencel is a **proprietary** cell therapy using the patient's own kidney cells

Early clinical data demonstrate a potential to **preserve** kidney function

May provide greater benefit to **higher-risk** CKD patients

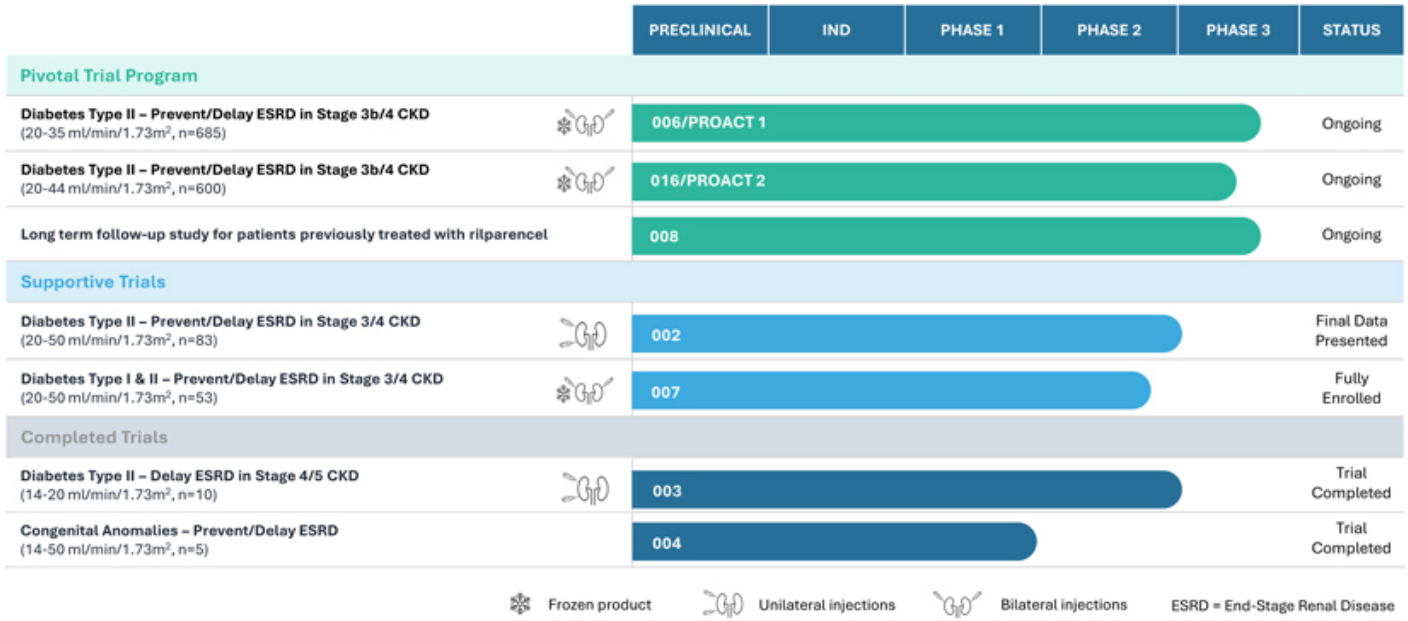
Our Plan

Phase 3 clinical program **PROACT 1 and PROACT 2 are focused** on patients with Stage 3b/4 CKD caused by type 2 diabetes

Potential label expansion to re-dose rilparencel for **long-term dialysis prevention**

1. CDC Fact Sheet. https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html
2. USRDS 2023 Annual Report

Overview of the Rilparencel Clinical Program



As of June 2024

With Relaunch of Manufacturing and Phase 3 Studies, We Look Forward to Advancing our Clinical Program

Manufacturing Relaunch

- Effective June 1st, we **restarted manufacturing** for our clinical studies
- We anticipate QP Declaration of Equivalence to EU GMPs to be received by the end of June 2024

Resumption of Phase 3 Program

- In our PROACT 1 study, we filed a protocol amendment with the FDA in March, 2024; Central IRB approval has been received; **sites are now open for enrollment under the amended protocol**
- In our PROACT 2 study, we initiated sites in Spain in anticipation of receipt of our QP Declaration of Equivalence to EU GMPs

Advancing a Comprehensive Clinical Plan

2023

REGEN-003 Phase 2 Trial; Results published 1Q 2023

- Safety & efficacy of rilparencel in Stage 4/5 CKD caused by type 2 diabetes (eGFR 14-20)
- Assessed impact on progression and time to dialysis in patients with imminent risk of dialysis

2024

RMCL-002 Phase 2 Trial; Results published 2Q 2024

- Open-label safety & efficacy of rilparencel in Stage 3/4 CKD caused by type 2 diabetes (eGFR 20-50)
- Potential to preserve kidney function for up to 30 months in several patient groups

REGEN-007 Phase 2 Trial; Enrollment complete; Interim results published 2Q 2024

- Open-label safety & efficacy of rilparencel in Stage 3/4 CKD caused by diabetes (eGFR 20-50)
- Bilateral kidney injections & cryopreserved commercial formulation

Phase 3 Randomized Controlled Clinical Trials – Stage 3b/4 CKD caused by type 2 diabetes

- **PROACT 1** resumed enrollment in 2Q 2024
- **PROACT 2** commenced site activations in 2Q 2024

2025 and beyond

REGEN-007 Phase 2 Trial; Full 12 month data from Group 1 expected in 1H 2025

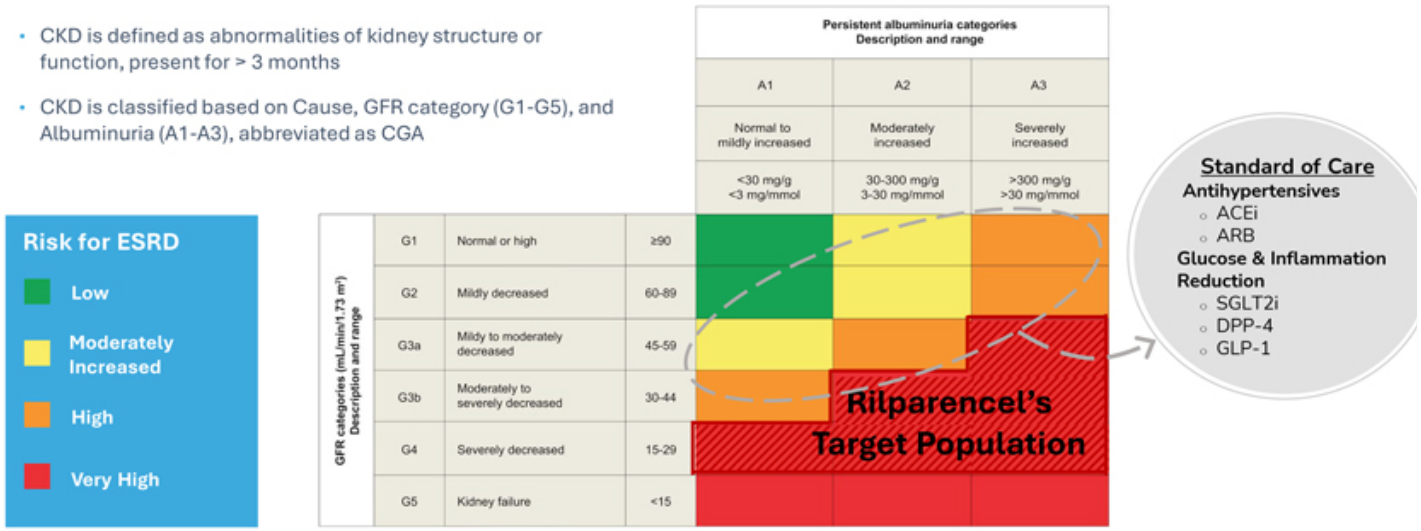
Update on Mechanism of Action in 2H 2025

Phase 3 Randomized Controlled Clinical Trials – Stage 3b/4 CKD caused by type 2 diabetes

- Completion of both studies anticipated in 2027

Unmet Clinical and Payer Need in High-Risk CKD Patients

- CKD is defined as abnormalities of kidney structure or function, present for > 3 months
- CKD is classified based on Cause, GFR category (G1-G5), and Albuminuria (A1-A3), abbreviated as CGA



Today, clinical priorities for patients with Stage 4 CKD (G4) are largely focused on treating co-morbidities and preparing patients for transplantation or dialysis

Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 clinical practice guideline for diabetes management in chronic kidney disease. *Kidney Int* 2020;98:S1–115.

Therapeutic Options that Delay the Need for Dialysis in Patients with Stage 4 Chronic Kidney Disease are Limited

Study	Active Product	Subjects with Stage 4 CKD
Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy[1]	Canagliflozin (SGLT2 inhibitor)	0%
Dapagliflozin in Patients with CKD[2]	Dapagliflozin (SGLT2 inhibitor)	14%
Empagliflozin in Patients with CKD[3]	Empagliflozin (SGLT2 inhibitor)	34%
Effect of Finerenone on Cardiovascular and Kidney Outcomes in Patients with Type 2 Diabetes and CKD[4]	Finerenone (Selective MRA)	7%
Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes[5]	Semaglutide (GLP-1RA)	11%

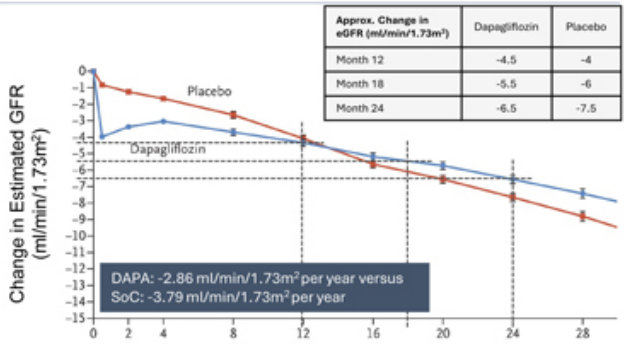
All recent landmark clinical trials in CKD primarily focus on Stage 2 and 3 CKD

1. Perkovic V et al. N Eng J Med 2019
2. Heerspink H et al. N Engl J Med 2020
3. Herrington et al. N Engl J Med 2023
4. Agarwal. R et al. Eur Heart J. 2022; Sarafidis. P et al. Clin J Am Soc Nephrol 2023
5. Perkovic V et al. N Engl J Medicine 2024

While New Therapies Are a Step Forward, Patients Still Lose Kidney Function and Experience Clinically Significant Events

SGLT2 inhibitors Do Not Prevent Progression of Advanced CKD

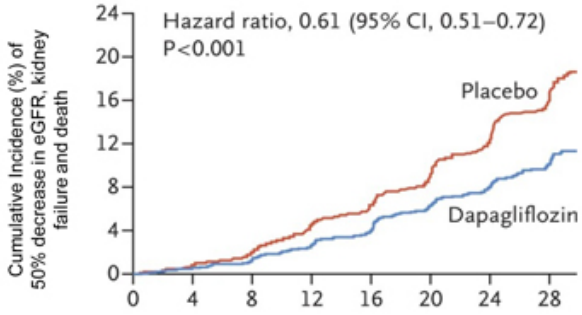
Patients continue to lose kidney function on SGLT2 inhibitors and progress to Stage 4/5 CKD



While dapagliflozin demonstrated <1.0 ml/min/yr difference in eGFR, it was able to achieve a reduction in clinically important events

Standard of Care has Limitations

Current standard of care[1] does not prevent events in ~50-75% of people with diabetic kidney disease[2]



Dapagliflozin: 19 patients required treatment to prevent one primary outcome event

1. Standard of care includes ACE inhibitors, angiotensin receptor blockers and SGLT2 inhibitors
2. Heerspink HJL et al. N Eng J Med 2020

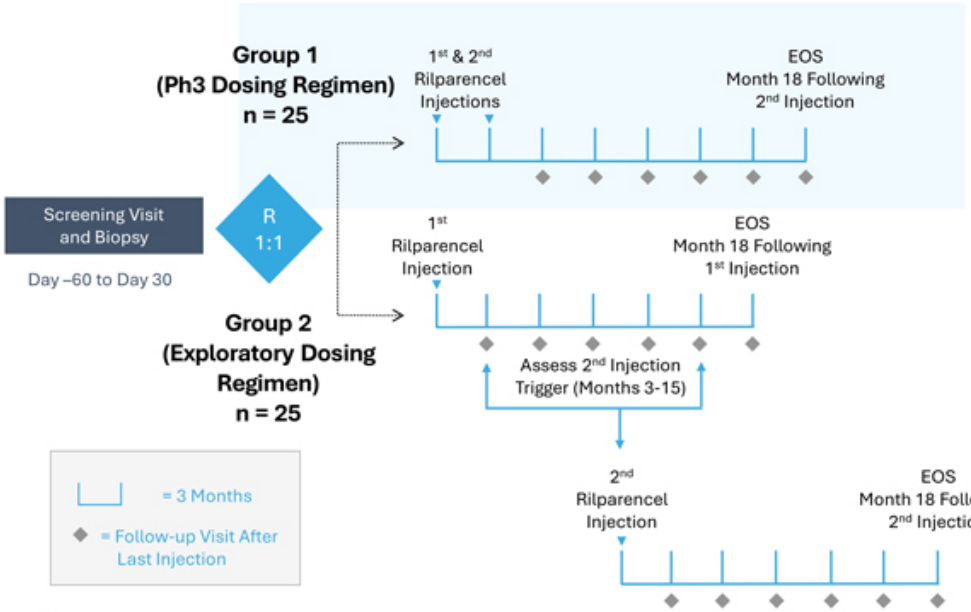
ProKidney

REGEN-007 Interim Analysis

May 7, 2024

REGEN-007 Trial Design

Group 1 Dosing Regimen and Use of Cryopreserved Product Mirrors Phase 3 Program



Key Entry Criteria

CKD with type 1 or type 2 diabetes

Subjects 30-80 years of age

eGFR ≥20 and ≤50 mL/min/1.73m^2

UACR 30-5000 mg/g

HbA1c <10%

Group 2 Re-Dosing Trigger

Sustained 30-Day:

- Decline in eGFR of ≥20% from baseline, and/or
- Increase of ≥30% and ≥30 mg/g in UACR from baseline

eGFR = estimated glomerular filtration rate; UACR = urine albumin-to-creatinine ratio (a measure of albuminuria)

REGEN-007 Interim Analysis Objectives and Endpoints in Group 1

Objectives

- In subjects with at least 12 months follow-up after 2 injections, assess the safety and efficacy of cryopreserved rilparencel delivered into the biopsied and non-biopsied contralateral kidney using a percutaneous approach

Endpoints

- Procedural and investigational product-related adverse events
- Change in kidney function as measured by eGFR

Current Enrollment Status & Completion Expectations

53 Subjects were Randomized in REGEN-007 with 27 Subjects Randomized to Group 1
(1 Subject Withdrew Consent Pre-Biopsy)

26 Subjects in Group 1

Of the 26 Subjects who were Biopsied, 24 Subjects Received at-least 1 Injection (2 Subject's Biopsies had Insufficient Cells for Injection)

24 Subjects

Of the 24 Subjects, 1 Subject had a Contra-indication (Bleeding Risk) for a 2nd Injection & 1 Subject Died before 12 Months Follow-up

22 Subjects Expected to Receive 2 Injections with 12 Months Follow-up

As of May 7, 2024: 13 Subjects Have Received 2 Injections with a Minimum of 12 Months Follow-up post 2nd Injection

Baseline Characteristics in Group 1 Subjects with a Minimum of 12 Months Follow-up after Two Rilparencel Injections

	SUBJECTS WITH MINIMUM 12 MONTHS FOLLOW-UP AFTER 2ND INJECTION (n=13)	SUBJECTS WITH MINIMUM 12 MONTHS FOLLOW-UP AFTER 2ND INJECTION AND COMPARABLE TO PHASE 3 INCLUSION CRITERIA (n=10)
Age, years *(mean +/- SD)*	62.8 +/- 8.2	63.9 +/- 8.7
Female : Male, %	54% : 46%	60% : 40%
Hispanic or Latino, %	0%	0%
Race, %		
Black or African American	0%	0%
White	100%	100%
Other	0%	0%
Blood pressure, mm HG	135 / 72	138 / 74
eGFR, ml/min/1.73m² *(mean +/- SD)*	29.7 +/- 9.5	25.6 +/- 4.9
UACR mg/g *(median, min max)*	239 (4, 2392)	390 (35, 2392)
HbA1c, % *(mean +/- SD)*	7.3 % +/- 1.6	7.3 % +/- 1.6
ACE/ARB Use, %	69%	60%
SGLT2 Use, %	31%	20%
GLP-1 Use, %	46%	60%

HbA1c = hemoglobin A1c; SGLT2 = sodium glucose cotransporter 2 protein inhibitor; ACE = angiotensin converting enzyme; ARB = angiotensin II receptor blockers

Externally Developed Control Arm to Contextualize REGEN-007 Interim Data

Objective

- Explore how 18 month change in kidney function in subjects enrolled in REGEN-007 might compare against matched contemporaneous controls

Methods

- In partnership with Dr. Navdeep Tangri (University of Manitoba), 13 subjects from REGEN-007 were matched 10:1 with diabetic subjects from recent CKD clinical trials
- Matching was independently performed based upon 2-year risk of kidney failure using Klinrisk[1] software and comparable usage of SGLT2 inhibitors

1. https://www.klinrisk.com/

Klinrisk Founding Team

Navdeep Tangri

- Co-Founder and CEO
- Founder and Scientific Director, Chronic Disease Innovation Centre
- Professor of Medicine, University of Manitoba

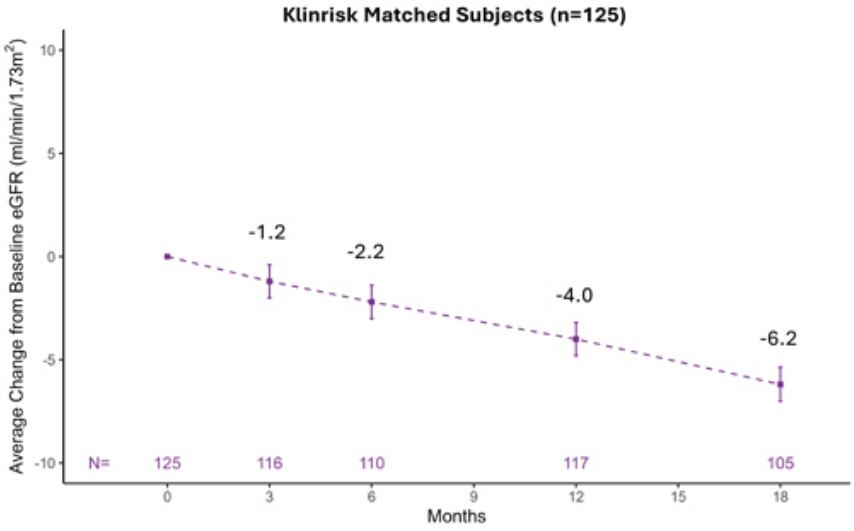
- Global leader in risk prediction who developed the most widely used algorithms in nephrology worldwide
- Published more than 380 manuscripts
- Risk equations have been integrated in electronic health records (Epic), laboratory information systems, and national & international clinical practice guidelines
- Strong track record of leading international clinical trials, developing trial endpoints with FDA and participating FDA discussions on drug approval and labeling
- Relationships with large pharmaceutical companies – considered a key opinion leader internationally in the CKD space

J.D. McCullough

- Chief Operating Officer
- Health tech executive specializing in regulated AI commercialization

- First autonomous AI FDA clearance and SaMD reimbursement including CMS coverage at Digital Diagnostics
- Closed seven figure deals with health systems, payors, labs, and biopharma companies
- Led FDA strategy and engagement for 10+ SaMD products, including Breakthrough, PMA, De Novo, and 510(k)
- Licensed over 50M patient records globally to drive AI & drug development
- Strategic advisor to Top 20 Biopharma, regulatory & reimbursement firms, and venture-backed startups
- Previous Commercial & Product Executive positions at Aegis Ventures, Arcturis Data, Digital Diagnostics

Matched Controls Showed a Continuous Decline in Kidney Function over 18 Months



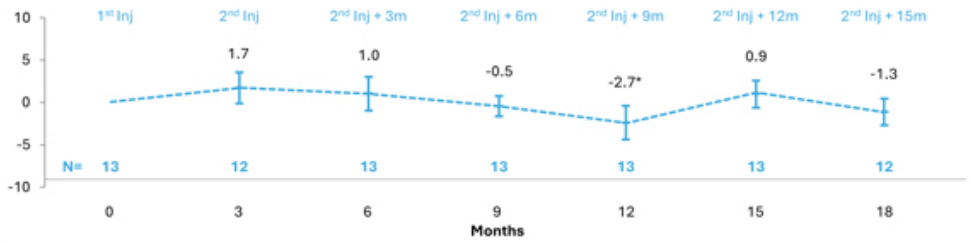
Average Change in eGFR from Baseline at 18 Months

-6.2 ml/min/1.73m²
(95% CI -7.8, -4.6)

Kidney Function Stabilizes for 18 Months After 1st Injection

Group 1 Subjects (n=13) with Minimum 12 Months Follow-up Data Post 2nd Injection

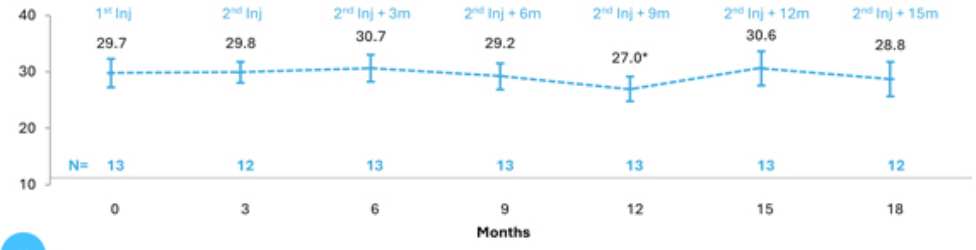
Average Change from Baseline eGFR (ml/min/1.73m²)



Average Change from Baseline with 18 Months Follow-up Post 1st Injection

-1.3 ml/min/1.73m² (95% CI -5.1, 2.5)

Average eGFR (ml/min/1.73m²)



Average eGFR in Group 1 was 29.7 at Baseline vs 28.8 at 18 Months Post 1st Injection

[absolute difference -0.9 ml/min/1.73m² at 18-months]

Interim analysis; Data points are mean +/- SEM ; Data as of May 7, 2024

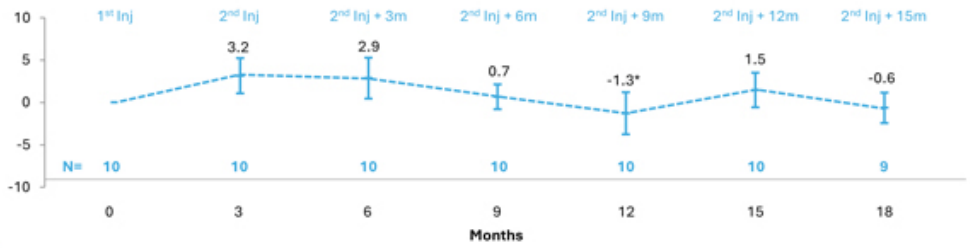
*eGFR highly influenced by 1 patient that recovered on measurements at month 15 and month 18

ProKidney

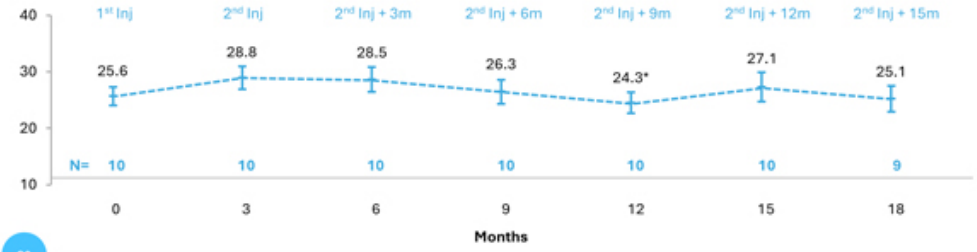
Kidney Function Stabilizes for 18 Months After 1st Injection in Subjects Meeting Phase 3 Criteria

Group 1 Subjects Ph 3 Eligible Subgroup (n=10) with Minimum 12 Months Follow-up Data Post 2nd Injection

Average Change from Baseline eGFR (ml/min/1.73m²)



Average eGFR (ml/min/1.73m²)



Average Change from Baseline with 18 Months Follow-up Post 1st Injection

-0.6 ml/min/1.73m² (95% CI -4.7, 3.6)

Phase 3 Criteria:

- CKD caused by type 2 diabetes
- Subjects 30-80 years of age
- eGFR ≥20 and ≤44 mL/min/1.73m²
- Not on kidney dialysis, HbA1c <10%
- UACR ≤5000 mg/g

Average eGFR in Group 1 was 25.6 at Baseline vs 25.1 at 18 Months Post 1st Injection

[absolute difference -0.5 ml/min/1.73m² at 18-months]

Interim analysis; Data points are mean +/- SEM ; Data as of May 7, 2024

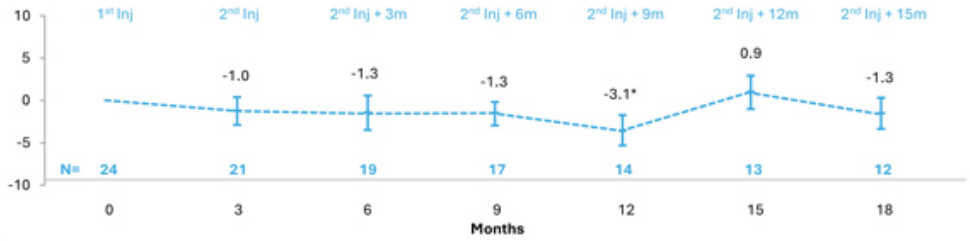
*eGFR highly influenced by 1 patient that recovered on measurements at month 15 and month 18

ProKidney

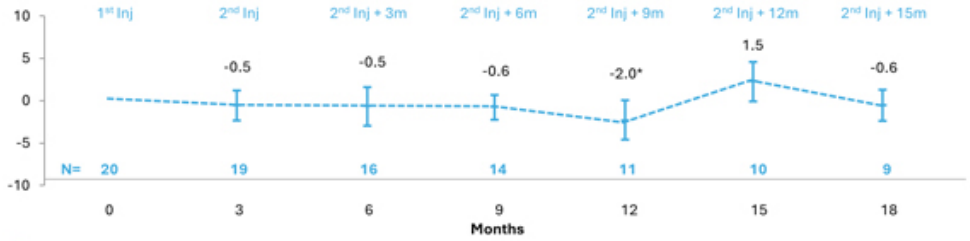
Kidney Function After 1st Injection Across All Subjects

All Subjects (n=24) and All Phase 3 Eligible Subjects (n=20) Treated in Group 1

Kidney Function After 1st Injection Across All Subjects (n=24): Avg Change from Baseline eGFR (ml/min/1.73m²)



Kidney Function After 1st Injection Across All Ph3 Eligible Subjects (n=20): Avg Change from Baseline eGFR (ml/min/1.73m²)



Additional analyses will be performed as Group 1 data matures

Interim analysis; Data points are mean +/- SEM ; Data as of May 7, 2024

*eGFR highly influenced by 1 patient that recovered on measurements at month 15 and month 18

No Rilparencel-related Serious Adverse Events have been Observed

ADVERSE EVENT	BIOPSY # of SAEs (n=51)	RILPARENCEL INJECTION # of SAEs (n=49)
Hematoma	2	1
Thrombosis	1	0
Hematuria	1	0
Hydronephrosis	1	0
Death	0	0
Acute Kidney Injury	2	0

Data as of May 7, 2024

REGEN-007 Interim Analysis Summary

Key Findings

- In Group 1 participants who had at least 12 months follow up after a second rilparencel injection, **kidney function was preserved for 18 months**. Similar results were observed **in participants who were evaluated under Phase 3 inclusion criteria**
- Bilateral dosing of cryopreserved product showed safety profile consistent with prior studies and comparable to kidney biopsy

Next Steps

- We look forward to providing **full results in 1H 2025**
- We have **enriched** our Phase 3 PROACT 1 Study to include more subjects with the **highest risk of kidney failure**
- We have **resumed PROACT 1 and PROACT 2** and look forward to enrolling new subjects in the near future

Financial Highlights

NASDAQ: PROK
231,698,039 shares outstanding*

$329M Cash** on hand, funds operations into 4Q25

Headquarters:
Boston, MA
Winston-Salem, NC

Covering Research Analysts

Jason Gerberry	Bank of America Global Research
Justin Zelin	BTIG
Yigal Nochomovitz	Citigroup Inc.
Jonathan Miller	Evercore ISI
Judah Frommer	Morgan Stanley
Eliana Merle	UBS
Kelly Shi	Jefferies

*As of May 10, 2024
**Cash, cash equivalents and marketable securities as of March 31, 2024

ProKidney

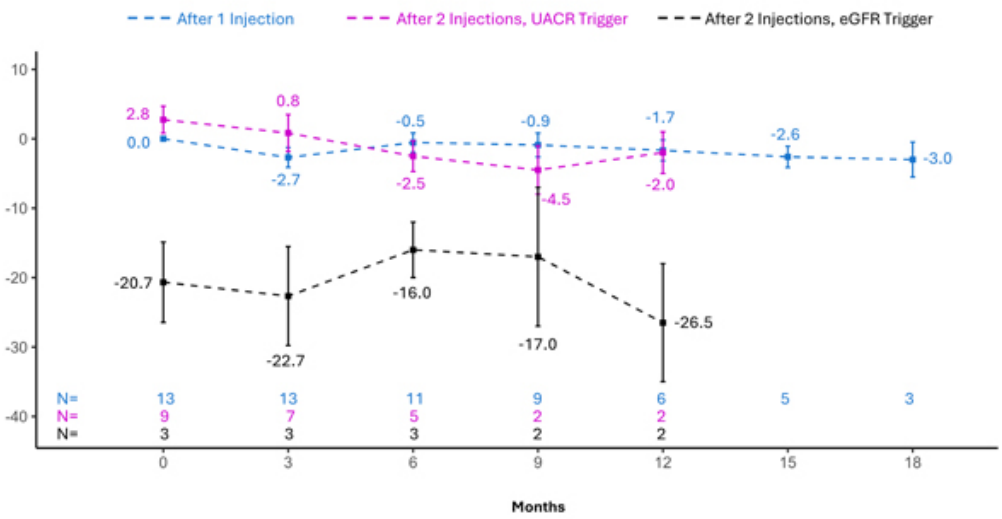
Appendix

ProKidney

Group 2 Patients After Receiving At Least One Injection (n=25)

12 patients received a 2nd rilparencel injection based on eGFR criteria (n=3) or UACR criteria (n=9)

Group 2 Patients After Receiving At Least One Injection (n=25): Average Change from Baseline eGFR (mL/min/1.73m²)



Group 2 Re-Dosing Trigger

Sustained 30-Day:

- Decline in eGFR of ≥20% from baseline, and/or
- Increase of ≥30% and ≥30 mg/g in UACR from baseline

13 of 25 patients have received 1 injection

9 of 25 patients received a 2nd injection based on the UACR trigger

3 of 25 patients received a 2nd injection based on the eGFR trigger

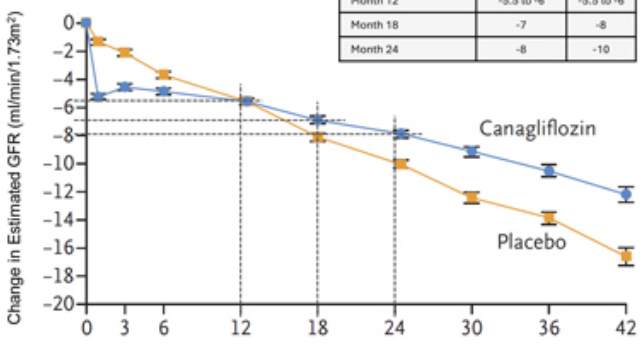
Interim analysis; Data points are mean +/- SEM ; Data as of May 7, 2024

Approximate Change in eGFR in Canagliflozin and Empagliflozin Clinical Trials

SGLT2 Inhibitors Do Not Prevent Progression of Advanced CKD and Patients Lose ~4 to 7 eGFR in the First 18 Months

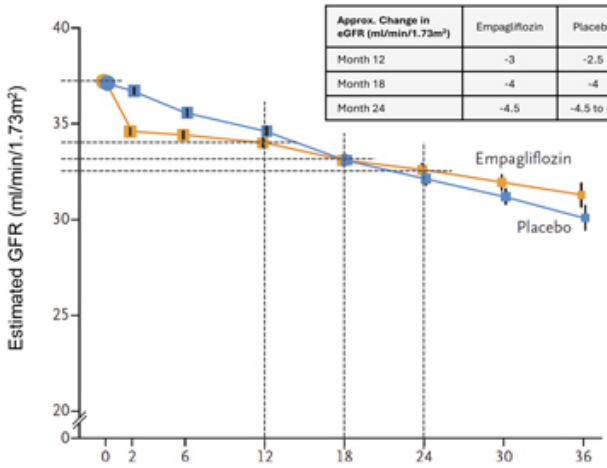
Canagliflozin (CREDENCE)

Approx. Change in eGFR (ml/min/1.73m²)	Canagliflozin	Placebo
Month 12	-5.5 to -6	-5.5 to -6
Month 18	-7	-8
Month 24	-8	-10



Empagliflozin (EMPA-KIDNEY)

Approx. Change in eGFR (ml/min/1.73m²)	Empagliflozin	Placebo
Month 12	-3	-2.5
Month 18	-4	-4
Month 24	-4.5	-4.5 to -5



1. Standard of care includes ACE inhibitors, angiotensin receptor blockers and SGLT2 inhibitors
2. Perkovic V et al. N Eng J Med 2019
3. Herrington et al. N Engl J Med 2023