

# PROKIDNEY

*Developing Solutions for Dialysis Prevention*



## **REGEN-007 Interim Results & Updates**

*June 2024*



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This presentation 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 expectations with respect to financial results, future performance, development and commercialization of products, if approved, the potential benefits and impact of the Company’s products, if approved, potential regulatory approvals, and the size and potential growth of current or future markets for the Company’s products, if approved. 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 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 impact of COVID-19 or geo-political conflict such as the war in Ukraine on the Company’s business; and other risks and uncertainties indicated from time to time in the Company’s 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. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

# 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

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## 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

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## 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

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## 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

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# What is Rilparencel and Why is it Relevant?



## Unmet Needs

Over **35 million U.S. adults** have chronic kidney disease (CKD)<sup>1</sup>

More than **135,000 of these CKD patients progress to dialysis** every year<sup>1</sup>

Total annual costs to Medicare for patients with CKD (including ESRD) exceed \$138B<sup>2</sup>

## 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**

# Overview of the Rilparencel Clinical Program

		PRECLINICAL	IND	PHASE 1	PHASE 2	PHASE 3	STATUS
<b>Pivotal Trial Program</b>							
<b>Diabetes Type II – Prevent/Delay ESRD in Stage 3b/4 CKD</b> (20-35 mL/min/1.73m <sup>2</sup> , n=685)		006/PROACT 1					Ongoing
<b>Diabetes Type II – Prevent/Delay ESRD in Stage 3b/4 CKD</b> (20-44 mL/min/1.73m <sup>2</sup> , n=600)		016/PROACT 2					Ongoing
<b>Long term follow-up study for patients previously treated with rilparencel</b>		008					Ongoing
<b>Supportive Trials</b>							
<b>Diabetes Type II – Prevent/Delay ESRD in Stage 3/4 CKD</b> (20-50 mL/min/1.73m <sup>2</sup> , n=83)		002					Final Data Presented
<b>Diabetes Type I &amp; II – Prevent/Delay ESRD in Stage 3/4 CKD</b> (20-50 mL/min/1.73m <sup>2</sup> , n=53)		007					Fully Enrolled
<b>Completed Trials</b>							
<b>Diabetes Type II – Delay ESRD in Stage 4/5 CKD</b> (14-20 mL/min/1.73m <sup>2</sup> , n=10)		003					Trial Completed
<b>Congenital Anomalies – Prevent/Delay ESRD</b> (14-50 mL/min/1.73m <sup>2</sup> , n=5)		004					Trial Completed



Frozen product



Unilateral injections



Bilateral injections

ESRD = End-Stage Renal Disease

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

## Manufacturing Relaunch

- Effective June 1<sup>st</sup>, 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

Persistent albuminuria categories Description and range		
A1	A2	A3
Normal to mildly increased	Moderately increased	Severely increased
<30 mg/g <3 mg/mmol	30-300 mg/g 3-30 mg/mmol	>300 mg/g >30 mg/mmol

GFR categories (mL/min/1.73 m <sup>2</sup> ) Description and range			Risk for ESRD		
	GFR Category	GFR Range (mL/min/1.73 m <sup>2</sup> )	A1	A2	A3
G1	Normal or high	≥90	Low	Moderately Increased	High
G2	Mildly decreased	60-89	Low	Moderately Increased	High
G3a	Mildly to moderately decreased	45-59	Moderately Increased	High	Very High
G3b	Moderately to severely decreased	30-44	High	Very High	Very High
G4	Severely decreased	15-29	Very High	Very High	Very High
G5	Kidney failure	<15	Very High	Very High	Very High

**Risk for ESRD**

- Low
- Moderately Increased
- High
- Very High

**Standard of Care**

**Antihypertensives**

- ACEi
- ARB

**Glucose & Inflammation Reduction**

- SGLT2i
- DPP-4
- GLP-1

**Rilparencel's Target Population**

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



# 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 <sup>1</sup>	Canagliflozin (SGLT2 inhibitor)	0%
Dapagliflozin in Patients with CKD <sup>2</sup>	Dapagliflozin (SGLT2 inhibitor)	14%
Empagliflozin in Patients with CKD <sup>3</sup>	Empagliflozin (SGLT2 inhibitor)	34%
Effect of Finerenone on Cardiovascular and Kidney Outcomes in Patients with Type 2 Diabetes and CKD <sup>4</sup>	Finerenone (Selective MRA)	7%
Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes <sup>5</sup>	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

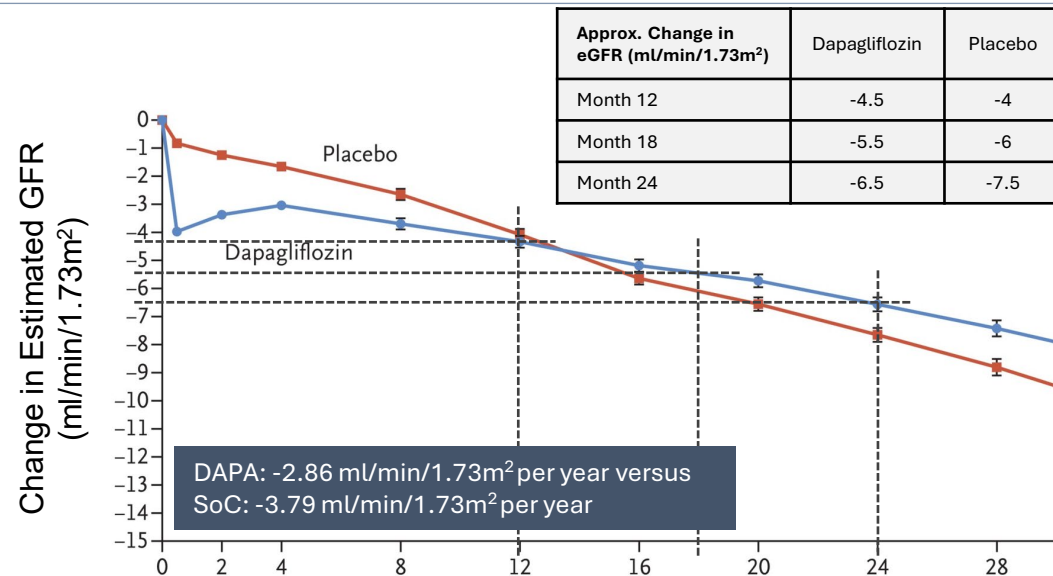
3. Herrington et al. N Engl J Med 2023  
 4. Agarwal. R et al. Eur Heart J. 2022;  
 Sarafidis. P et al. Clin J Am Soc Nephrol 2023

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

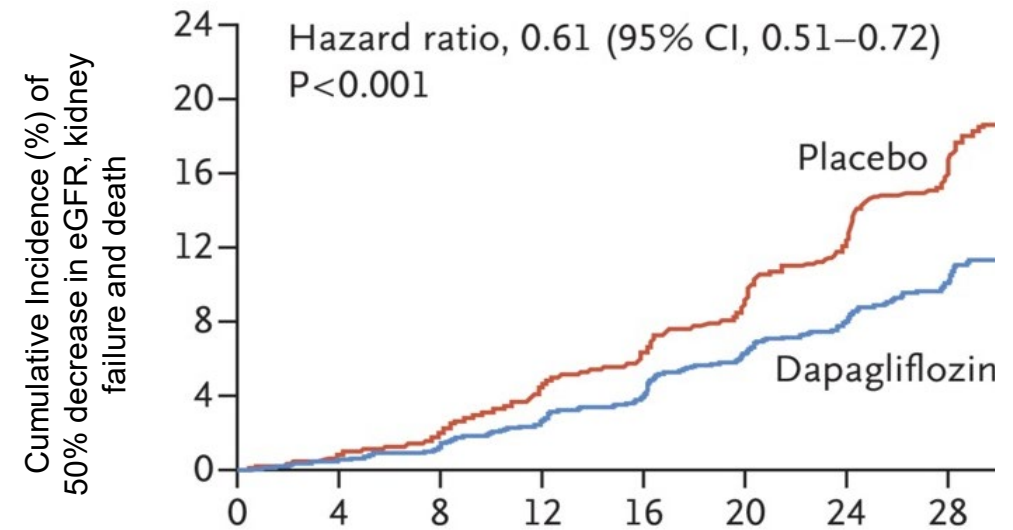
Patients continue to lose kidney function on SGLT2 inhibitors and progress to Stage 4/5 CKD



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<sup>1</sup> does not prevent events in ~50-75% of people with diabetic kidney disease<sup>2</sup>



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



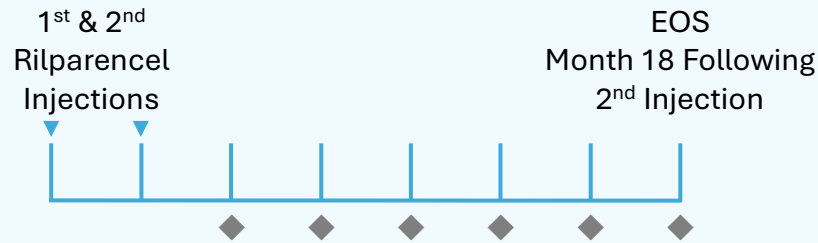
**REGEN-007 Interim  
Analysis**  
*May 7, 2024*



# REGEN-007 Trial Design

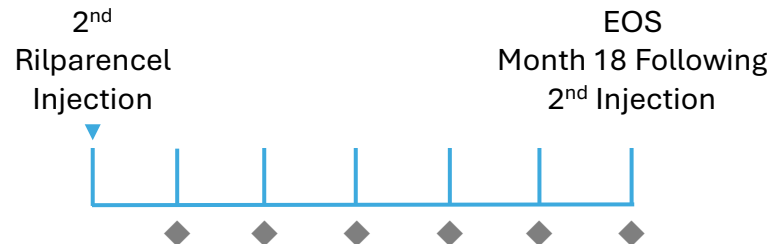
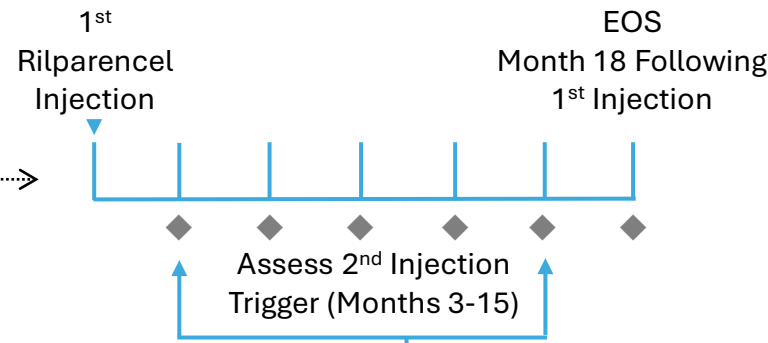
## Group 1 Dosing Regimen and Use of Cryopreserved Product Mirrors Phase 3 Program

**Group 1  
(Ph3 Dosing Regimen)  
n = 25**



**R  
1:1**

**Group 2  
(Exploratory Dosing Regimen)  
n = 25**



Screening Visit and Biopsy

Day -60 to Day 30

= 3 Months

= Follow-up Visit After Last Injection

### Key Entry Criteria

- CKD with type 1 or type 2 diabetes
- Subjects 30-80 years of age
- eGFR  $\geq 20$  and  $\leq 50$  mL/min/1.73m<sup>2</sup>
- UACR 30-5000 mg/g
- HbA1c <10%

### Group 2 Re-Dosing Trigger

Sustained 30-Day:

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

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



# 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](https://www.klinrisk.com/)<sup>1</sup> software and comparable usage of SGLT2 inhibitors

# 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



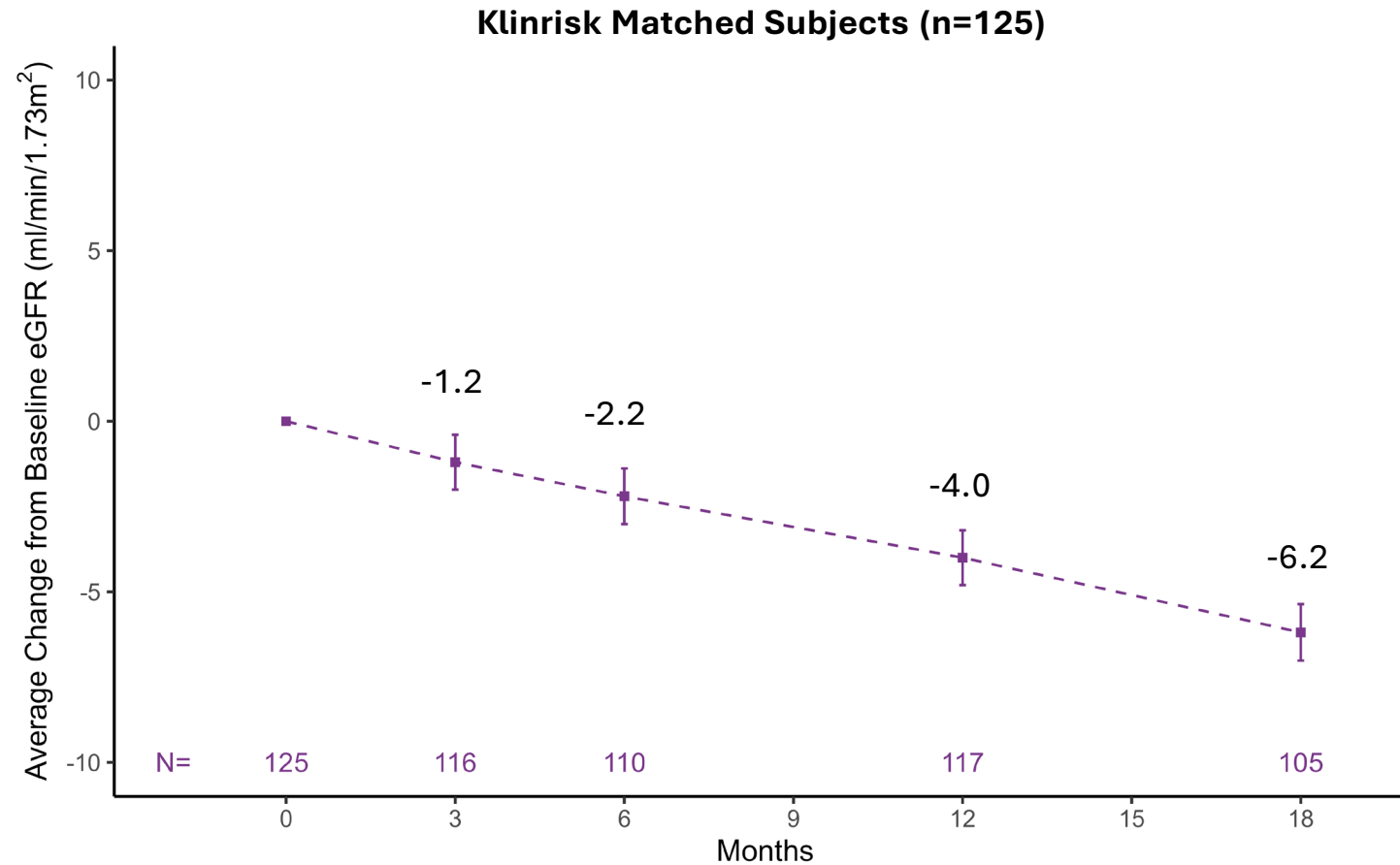
**J.D. McCullough**

- ◇ 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



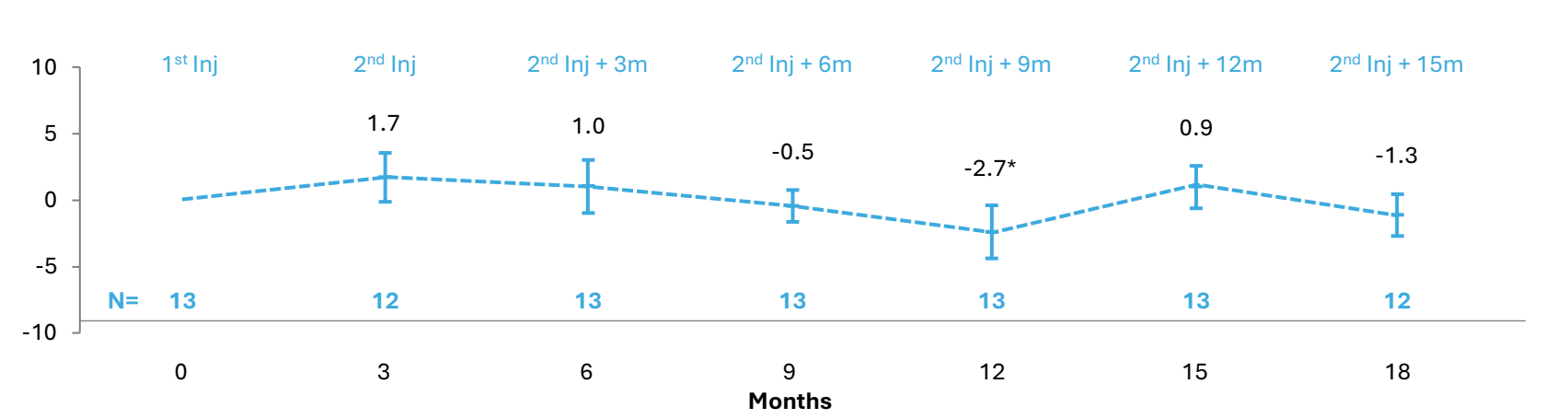
Average Change in eGFR from Baseline at 18 Months

**-6.2 ml/min/1.73m<sup>2</sup>**  
**(95% CI -7.8, -4.6)**

# Kidney Function Stabilizes for 18 Months After 1<sup>st</sup> Injection

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

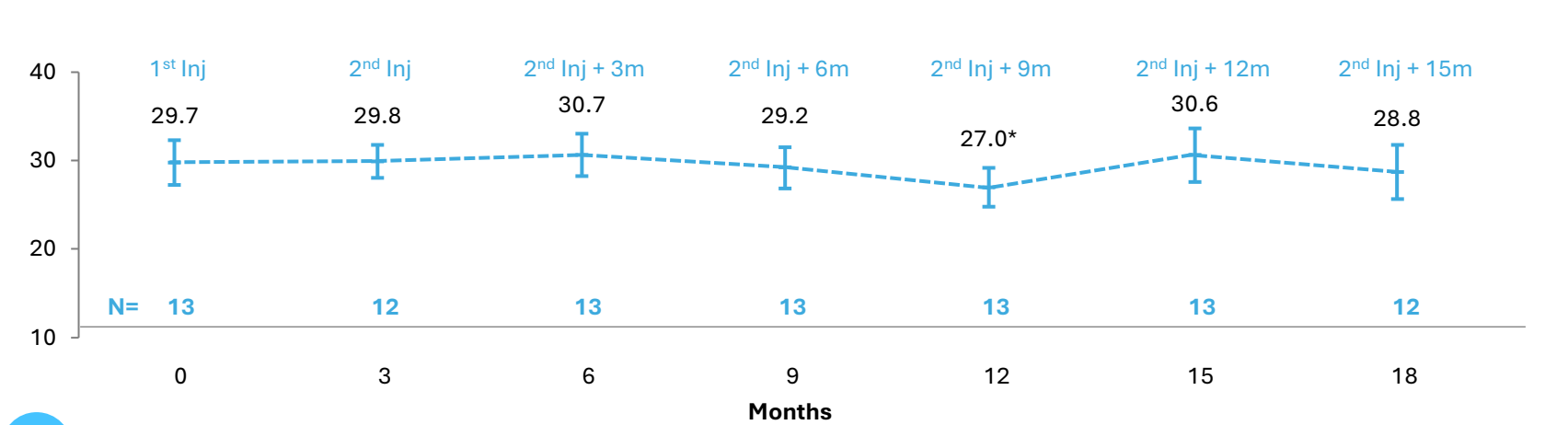
**Average Change from Baseline eGFR (mL/min/1.73m<sup>2</sup>)**



Average Change from Baseline with 18 Months Follow-up Post 1<sup>st</sup> Injection

**-1.3 mL/min/1.73m<sup>2</sup>**  
(95% CI -5.1, 2.5)

**Average eGFR (mL/min/1.73m<sup>2</sup>)**



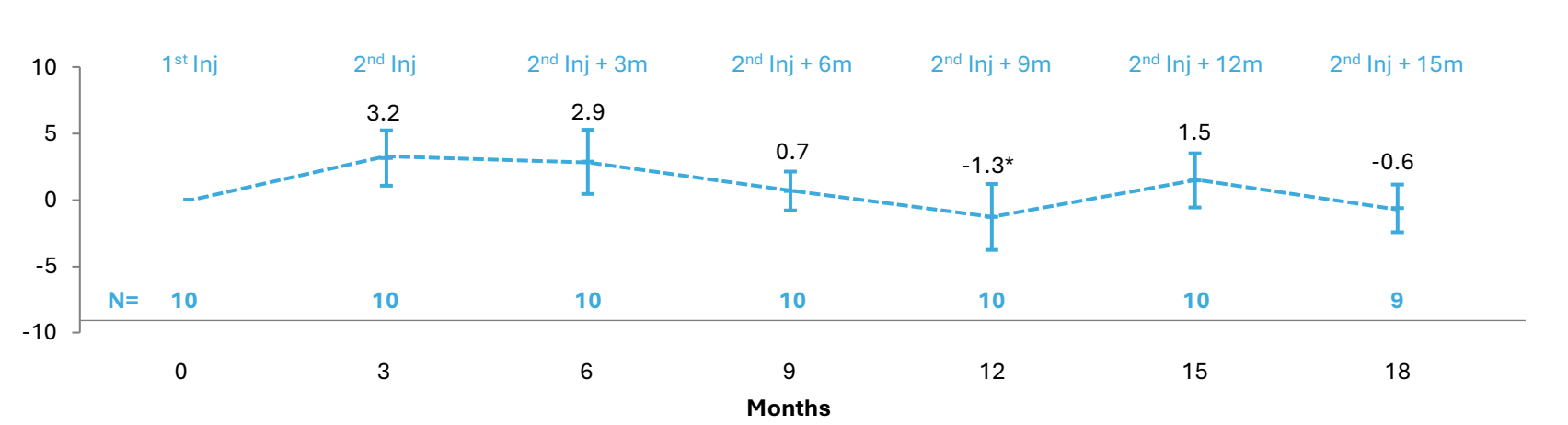
Average eGFR in Group 1 was 29.7 at Baseline vs 28.8 at 18 Months Post 1<sup>st</sup> Injection

**[absolute difference -0.9 mL/min/1.73m<sup>2</sup> at 18-months]**

# Kidney Function Stabilizes for 18 Months After 1<sup>st</sup> Injection in Subjects Meeting Phase 3 Criteria

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

**Average Change from Baseline eGFR (mL/min/1.73m<sup>2</sup>)**

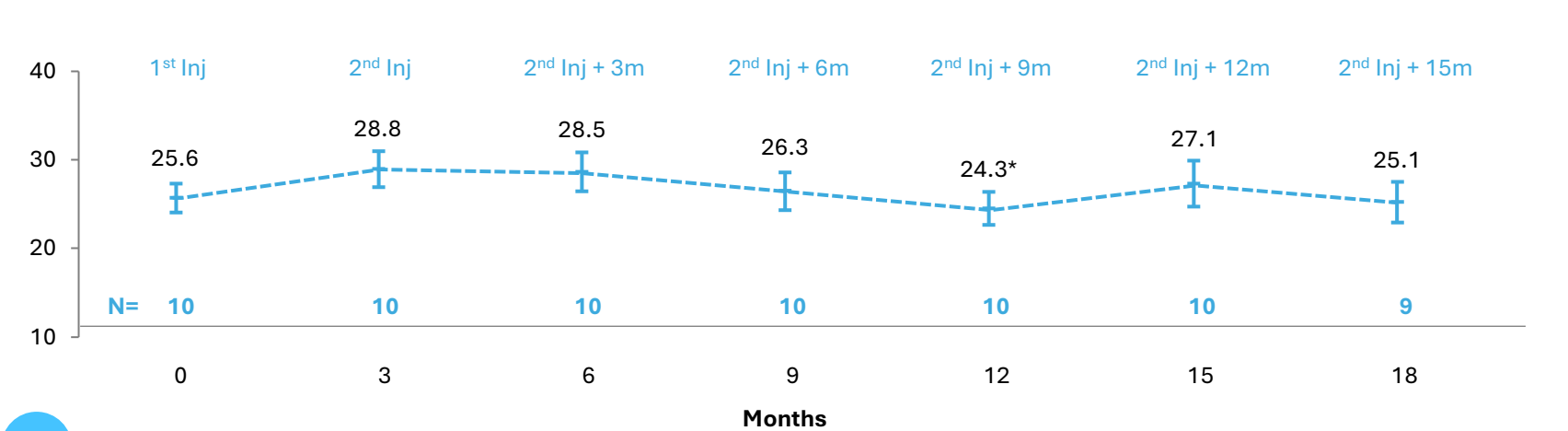


Average Change from Baseline with 18 Months Follow-up Post 1<sup>st</sup> Injection

**-0.6 mL/min/1.73m<sup>2</sup>**  
(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/1.73m<sup>2</sup>
  - Not on kidney dialysis, HbA1c <10%
  - UACR ≤5000 mg/g

**Average eGFR (mL/min/1.73m<sup>2</sup>)**



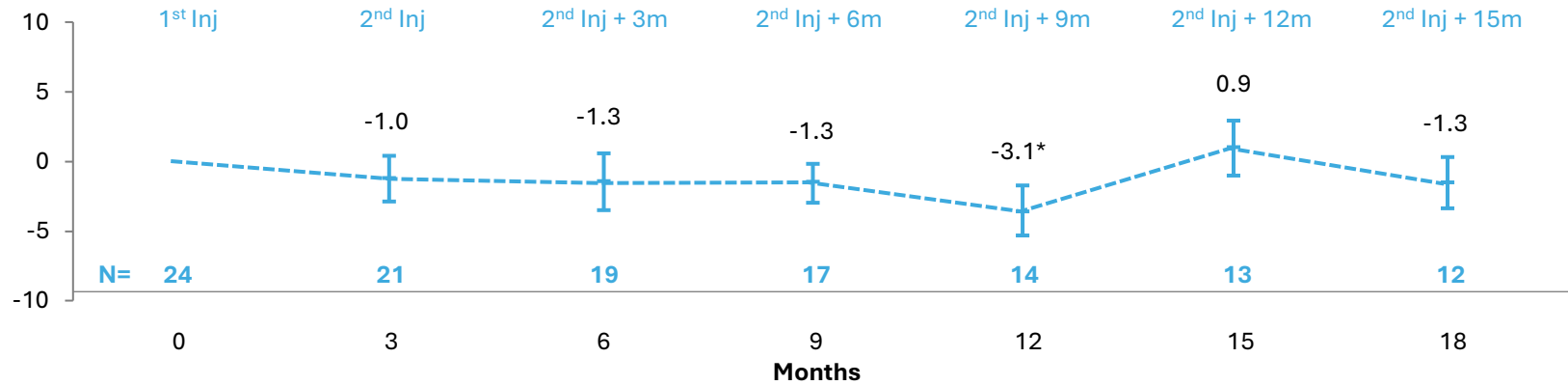
Average eGFR in Group 1 was 25.6 at Baseline vs 25.1 at 18 Months Post 1<sup>st</sup> Injection

**[absolute difference -0.5 mL/min/1.73m<sup>2</sup> at 18-months]**

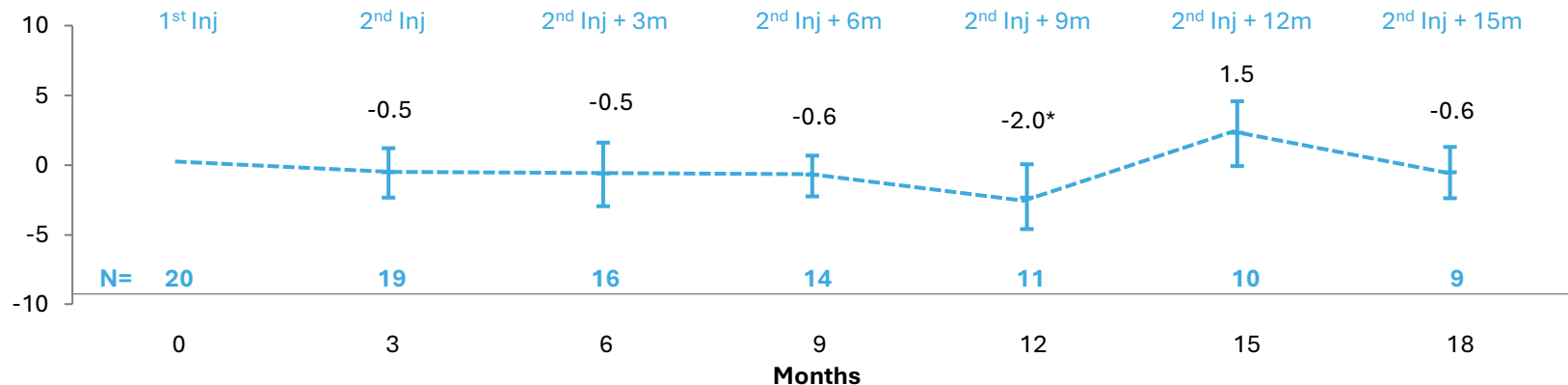
# Kidney Function After 1<sup>st</sup> Injection Across All Subjects

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

**Kidney Function After 1<sup>st</sup> Injection Across All Subjects (n=24): Avg Change from Baseline eGFR (mL/min/1.73m<sup>2</sup>)**



**Kidney Function After 1<sup>st</sup> Injection Across All Ph3 Eligible Subjects (n=20): Avg Change from Baseline eGFR (mL/min/1.73m<sup>2</sup>)**



Additional analyses will be performed as Group 1 data matures

# No Rilparencel-related Serious Adverse Events have been Observed

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



# 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

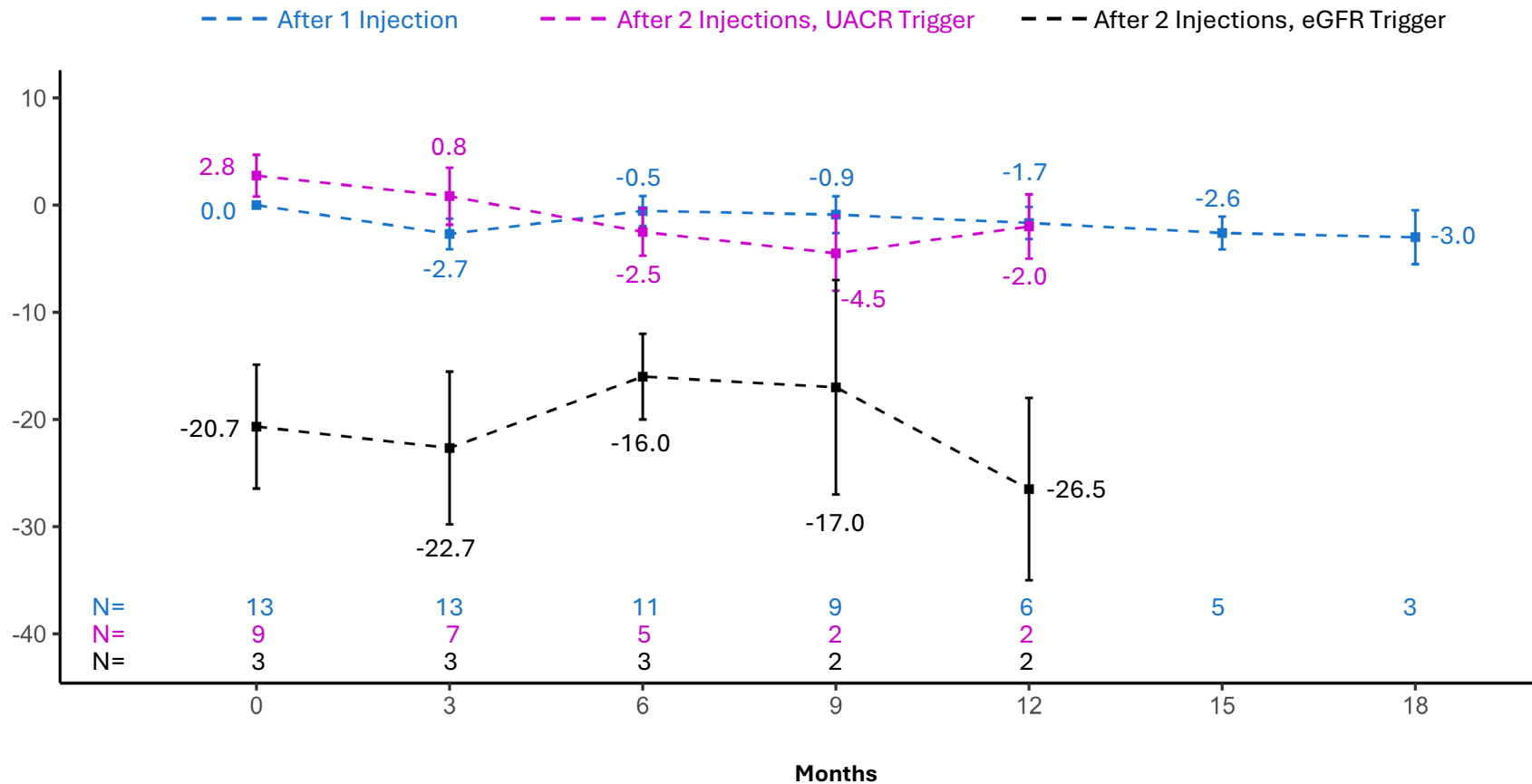
\*\*Cash, cash equivalents and marketable securities as of March 31, 2024

# Appendix

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

12 patients received a 2<sup>nd</sup> 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/1.73m<sup>2</sup>)



## Group 2 Re-Dosing Trigger

Sustained 30-Day:

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

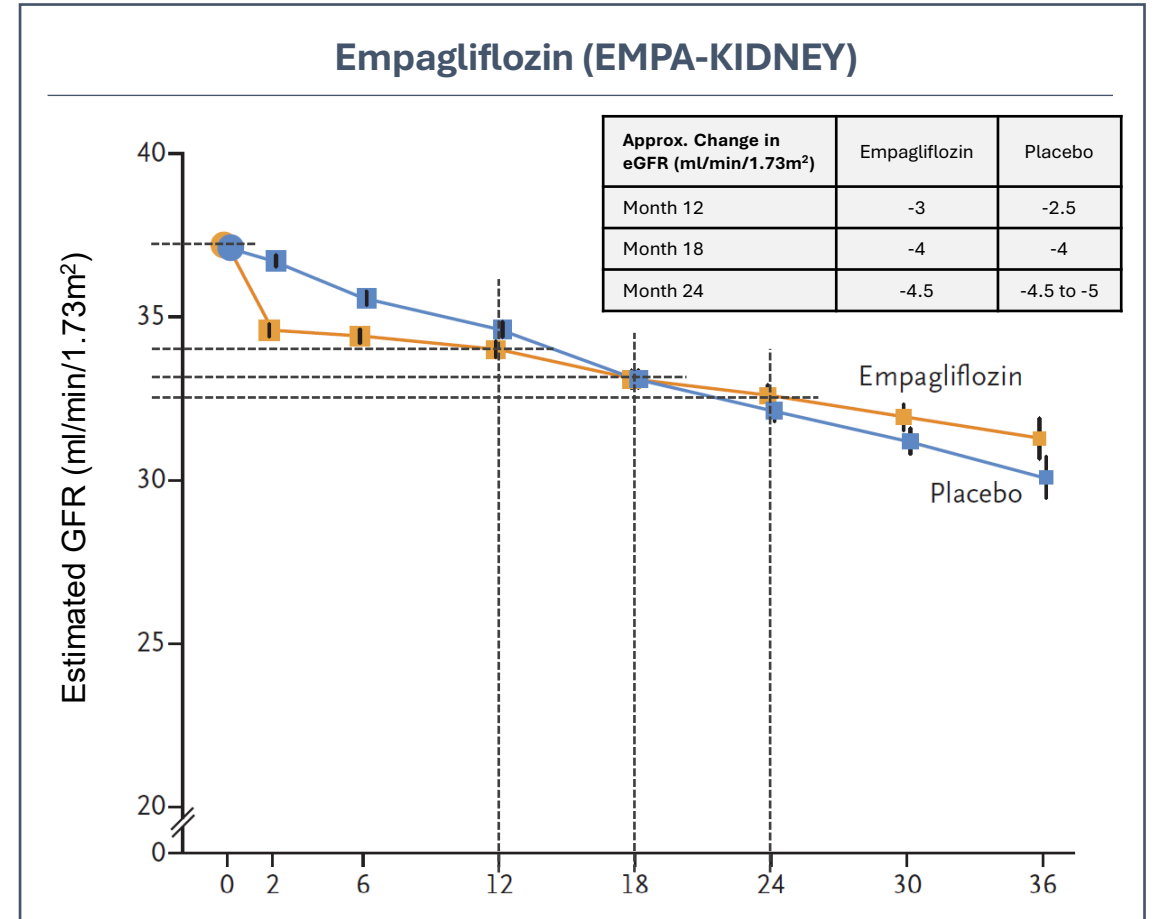
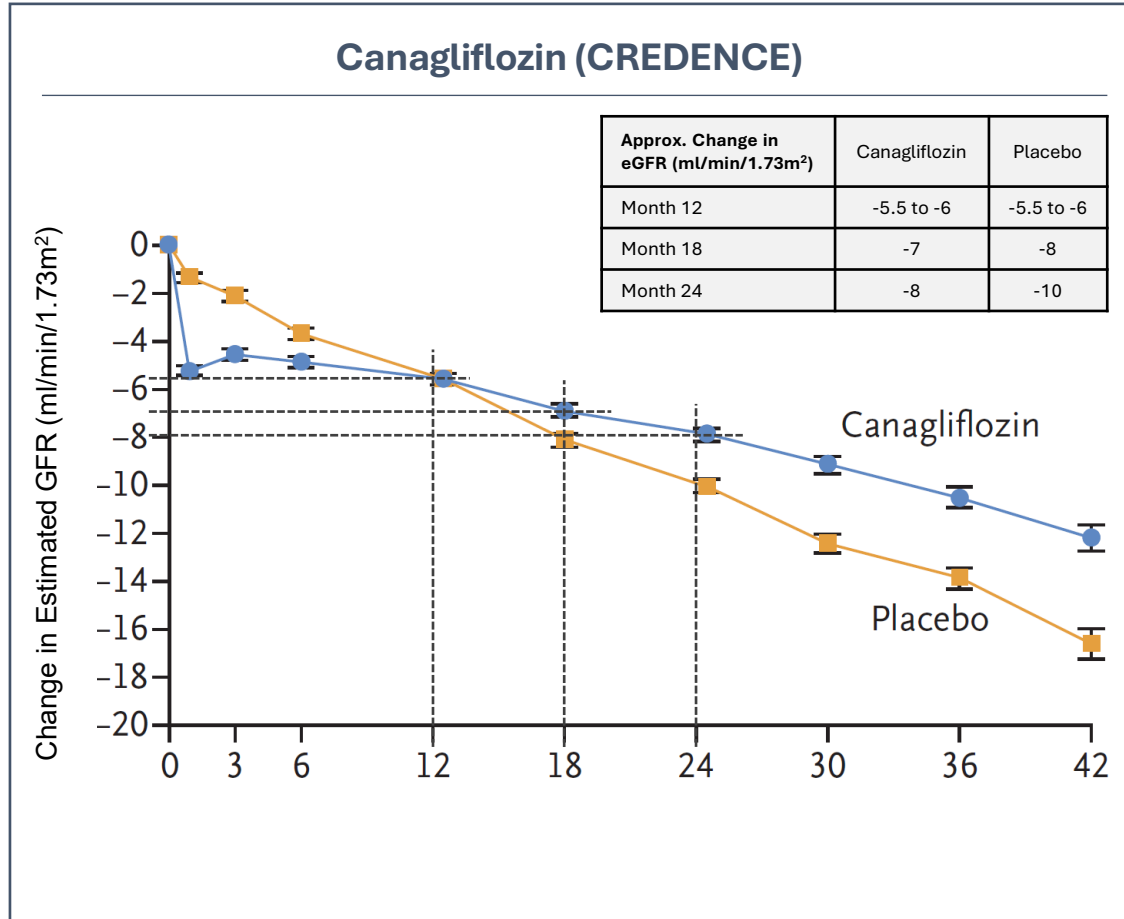
13 of 25 patients have received 1 injection

9 of 25 patients received a 2<sup>nd</sup> injection based on the UACR trigger

3 of 25 patients received a 2<sup>nd</sup> injection based on the eGFR trigger

# 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



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