

PROKIDNEY

Developing Solutions for Dialysis Prevention



Corporate Presentation

March 2024



Forward-looking Statements

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Disrupting the CKD Treatment Landscape

Renal Autologous Cell Therapy:

Rilparencel (REACT[®]) proprietary autologous cellular therapy being evaluated to **preserve kidney function** in moderate to severe diabetic kidney disease



An Introduction to ProKidney

Goal

Preserve kidney function in advanced CKD patients

An opportunity to preserve kidney function in the moderate to severe diabetic kidney disease population 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 (PROACT1) and REGEN-016 (PROACT2)
Supported by three Phase 2 clinical trials in advanced CKD patient populations

Leadership

Leadership Team with Clinical Development & Regulatory Experience

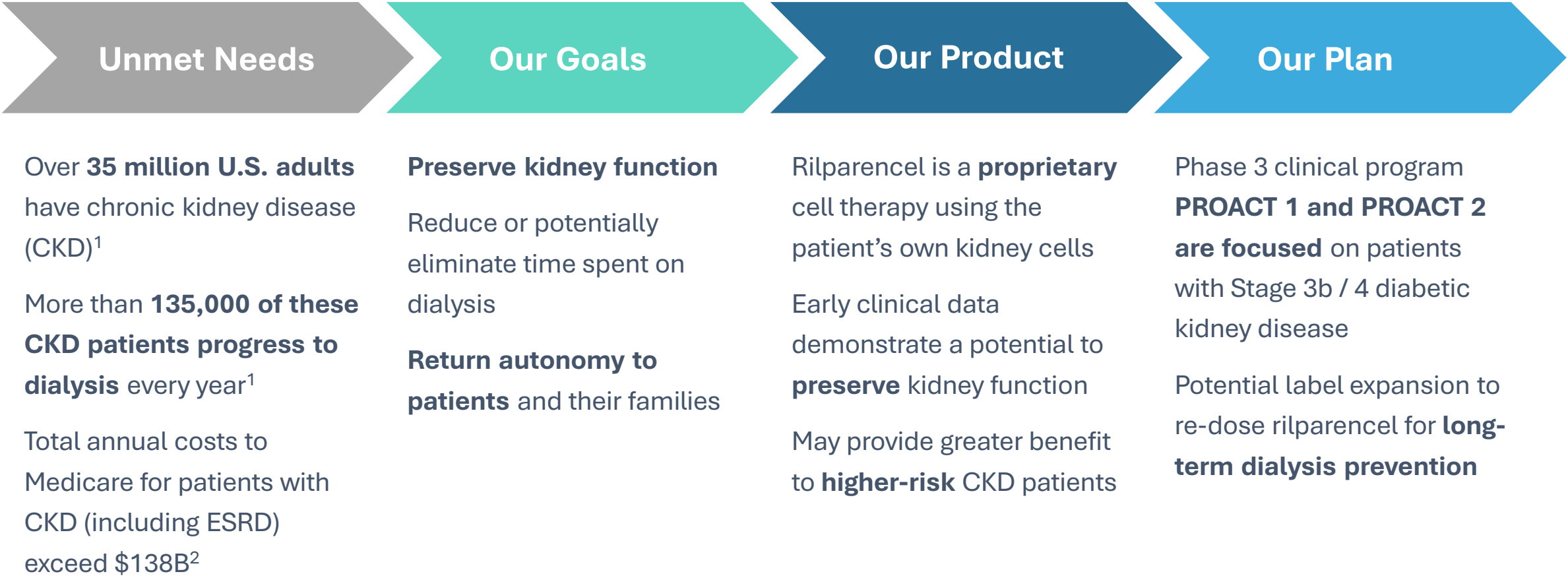
Together the team brings over 150 years cumulative experience in the discovery, development, manufacturing and commercialization of biotechnology, pharmaceutical, and device products.

Milestones

Meaningful Near-Term Milestones

Phase 2 RMCL-002 full results expected 1H 2024
Phase 2 REGEN-007 interim results Mid-2024

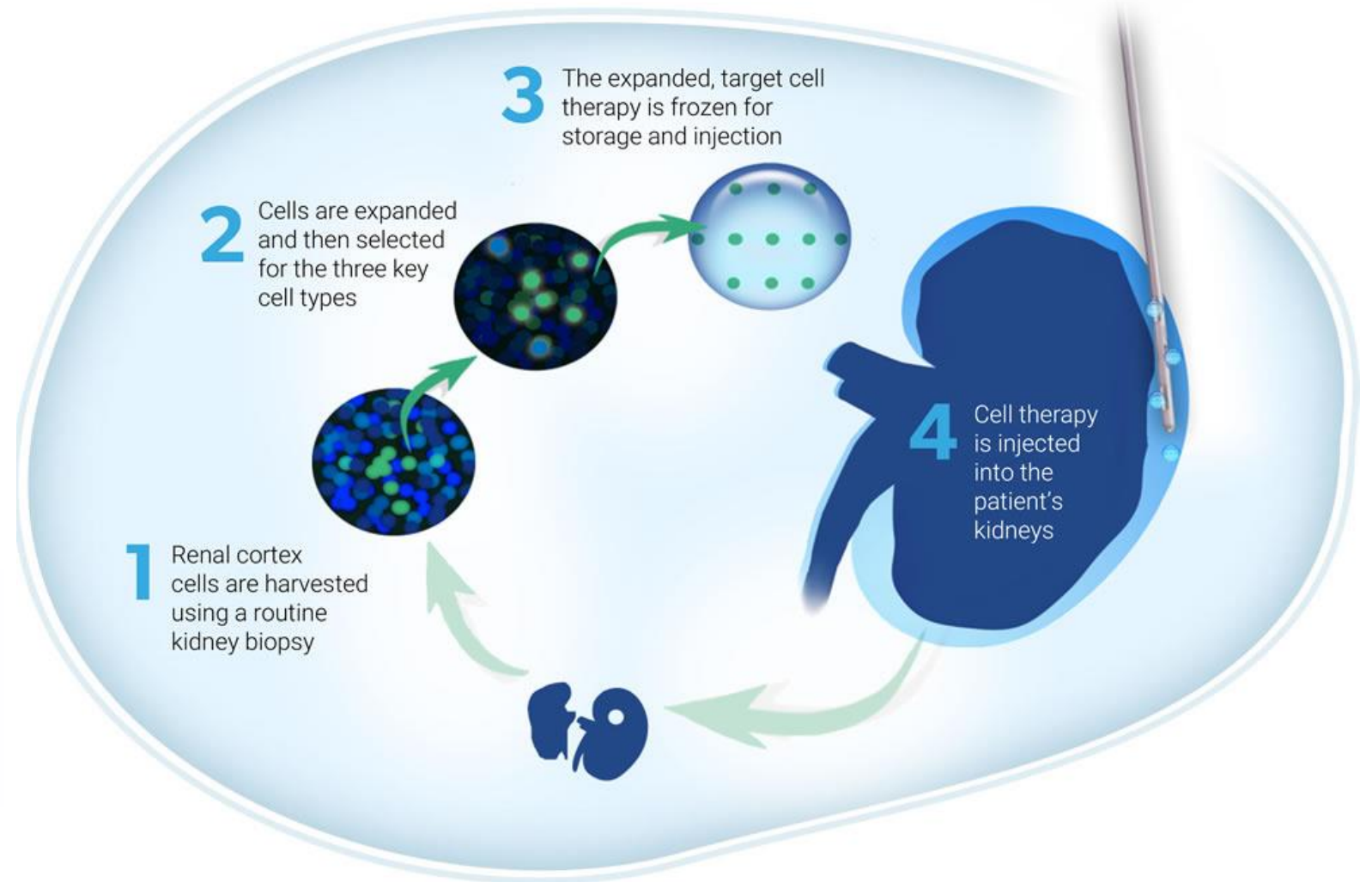
What is Rilparencel and Why is it Relevant?








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

Rilparencel Goal: Preservation of Kidney Function

ProKidney's Autologous Cell Therapy



Overview of the Rilparencel Clinical Program

		PRECLINICAL	IND	PHASE 1	PHASE 2	PHASE 3	STATUS
Pivotal Trial Program							
Diabetes Type II – Prevent/Delay ESRD in CKD 3/4 (20-35 ml/min/1.73m ² , N = 600)		006/PROACT 1					Ongoing
Diabetes Type II – Prevent/Delay ESRD in CKD 3/4 (20-44 ml/min/1.73m ² , N = 600)		016/PROACT 2					Enrollment Mid-2024
Long term follow-up study for patients previously treated with rilparencel		008					Ongoing
Supportive Trials							
Diabetes Type II – Prevent/Delay ESRD in CKD 3/4 (20-50 ml/min/1.73m ² , N = 83 randomized)		002					Fully Enrolled
Diabetes Type I & II – Prevent/Delay ESRD in CKD 3/4 (20-50 ml/min/1.73m ² , N= 53 randomized)		007					Fully Enrolled
Completed Trials							
Diabetes Type II – Delay ESRD in CKD 4/5 (14-20 ml/min/1.73m ² , N = 10)		003					Trial Completed
Congenital Anomalies – Prevent/Delay ESRD (14-50 ml/min/1.73m ² , N= 5)		004					Trial Completed



Frozen product



Unilateral injections



bilateral injections

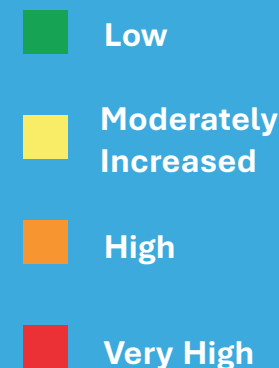
ESRD = End-Stage Renal Disease

Unmet Clinical and Payer Need in High-Risk CKD Patients

Rilparencel May Preserve Kidney Function and Delay Need for Dialysis in Highest-Risk Progressors

- 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

Risk for ESRD



				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 ²) Description and range	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

**Rilparencel's
Target Population**

Standard of Care

Antihypertensives

- ACEi
- ARB

Glucose & Inflammation Reduction

- SGLT2i
- DPP-4
- GLP-1

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 to 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 CKD Outcomes in Type 2 Diabetes ⁴	Finerenone (Selective MRA)	< 10%
Rationale, Design, and Baseline Data of FLOW – a Kidney Outcomes Trial with Once Weekly Semaglutide in People with Type 2 Diabetes and CKD ⁵	Semaglutide (GLP-1RA)	10%

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

1. Perkovic V et al. N Eng J Med 2019
2. Heerspink H et al. N Engl J Med 2020

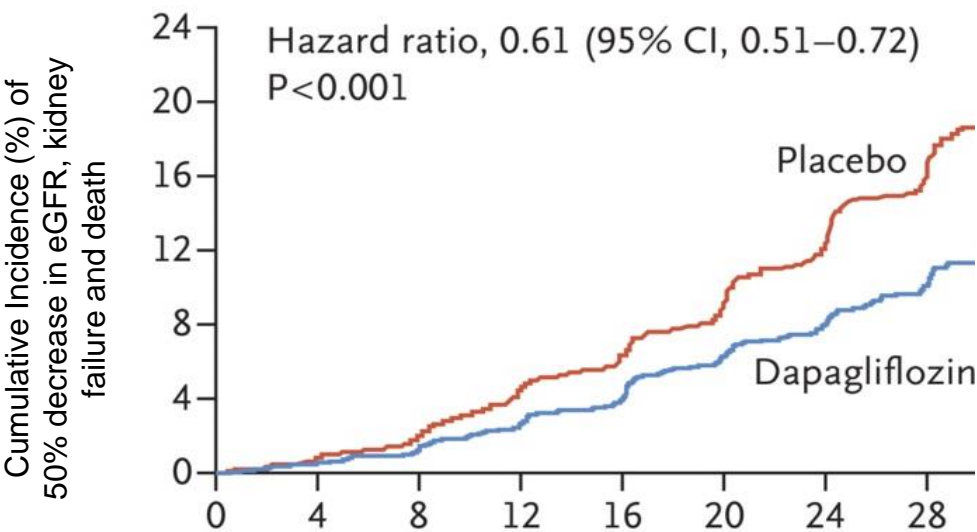
3. Herrington et al. N Engl J Med 2023
4. Bakris G et al. N Engl J Med 2020

5. Rossing P et al. Nephrol Dial Transplant 2023

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

Standard of Care has Limitations

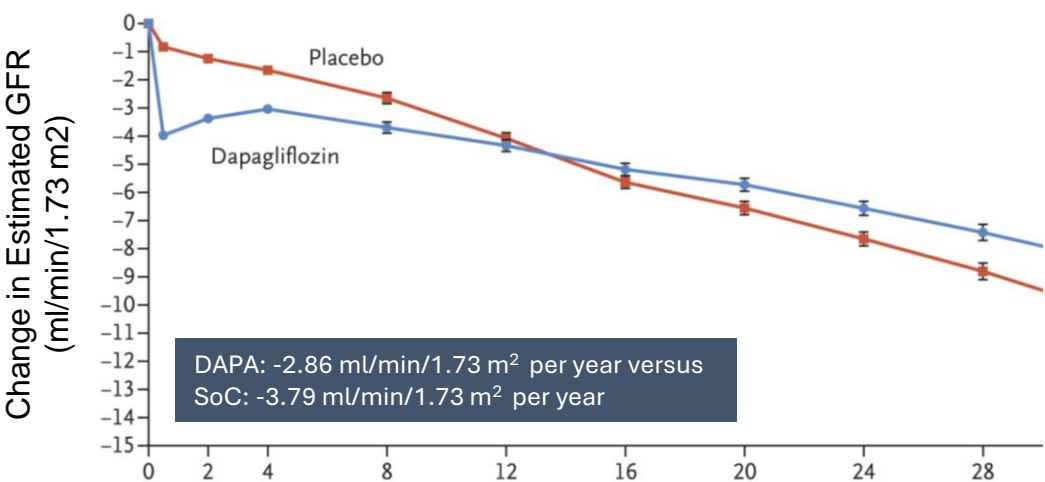
Current standard of care¹ does not prevent events in ~ 50-75% of people with diabetic kidney disease²



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

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

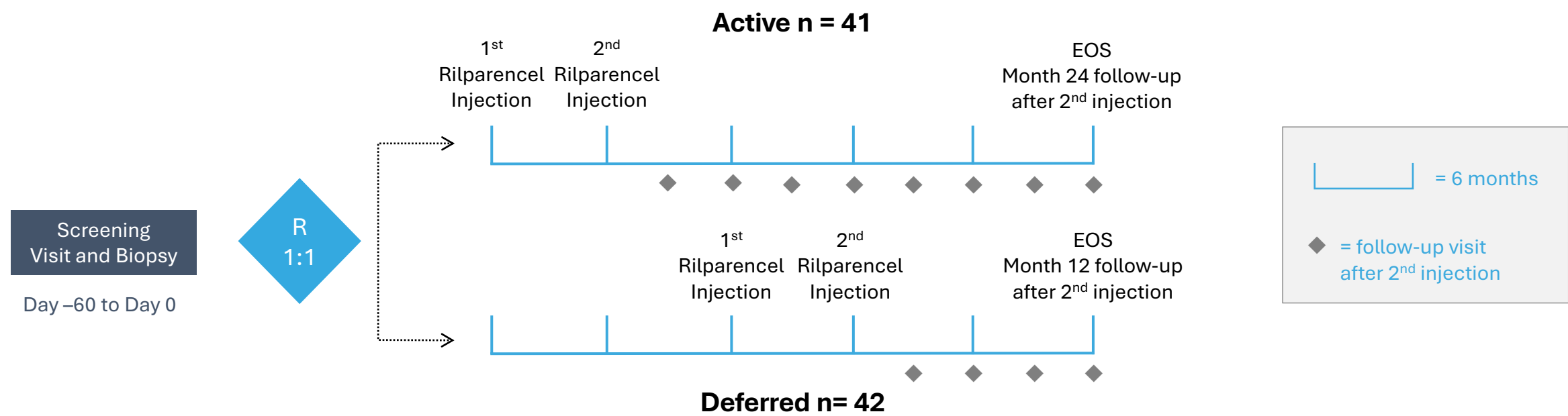
1. Standard of care includes ACE inhibitors, angiotensin receptor blockers and SGLT2 inhibitors
2. Heerspink HJL et al. N Eng J Med 2020



RMCL-002 Interim Analysis



RMCL-002: Trial Design



Key Entry Criteria	Study Endpoints	Study Timeframe
Type 2 Diabetes Mellitus (DKD) Male or female 30-80 years of age eGFR ≥ 20 and ≤ 50 mL/min/1.73m ² Not on kidney dialysis, HbA1c <10%	Rilparencel and procedure related adverse events Change in kidney function (assessed by eGFR)	RMAT granted for Phase 3 program in January 2022

Study Demographics are Balanced and Represent a High-Risk CKD Population

	ACTIVE (n=41)	DEFERRED (n=42)
Age, years (<i>mean +/- SD</i>)	66.1 +/- 9.9	64.6 +/- 8.9
Female : Male, %	29% : 71%	36% : 64%
Hispanic or Latino, %	17%	10%
Race, %		
Black or African American	2%	14%
White	93%	71%
Other	5%	14%
Blood pressure, mm HG	133 / 72	135 / 73
eGFR, ml/min/1.73m ² (<i>mean +/- SD</i>)	33.9 +/- 8.6	31.8 +/- 7.4
Stage 3A CKD, n (%)	4 (10%)	3 (7%)
Stage 3B CKD, n (%)	21 (51%)	19 (45%)
Stage 4 CKD, n (%)	16 (39%)	20 (48%)
UACR mg/g (<i>median +/- interquartile range</i>)	740 (68, 1597)	598 (58, 1985)
Geometric Mean / Median of UACR mg/g	251 / 250	308 / 567
HbA1c, % (<i>mean +/- SD</i>)	7.2 +/- 1.0	7.1 +/- 1.0

No Rilparencel-related SAEs Identified in RMCL-002

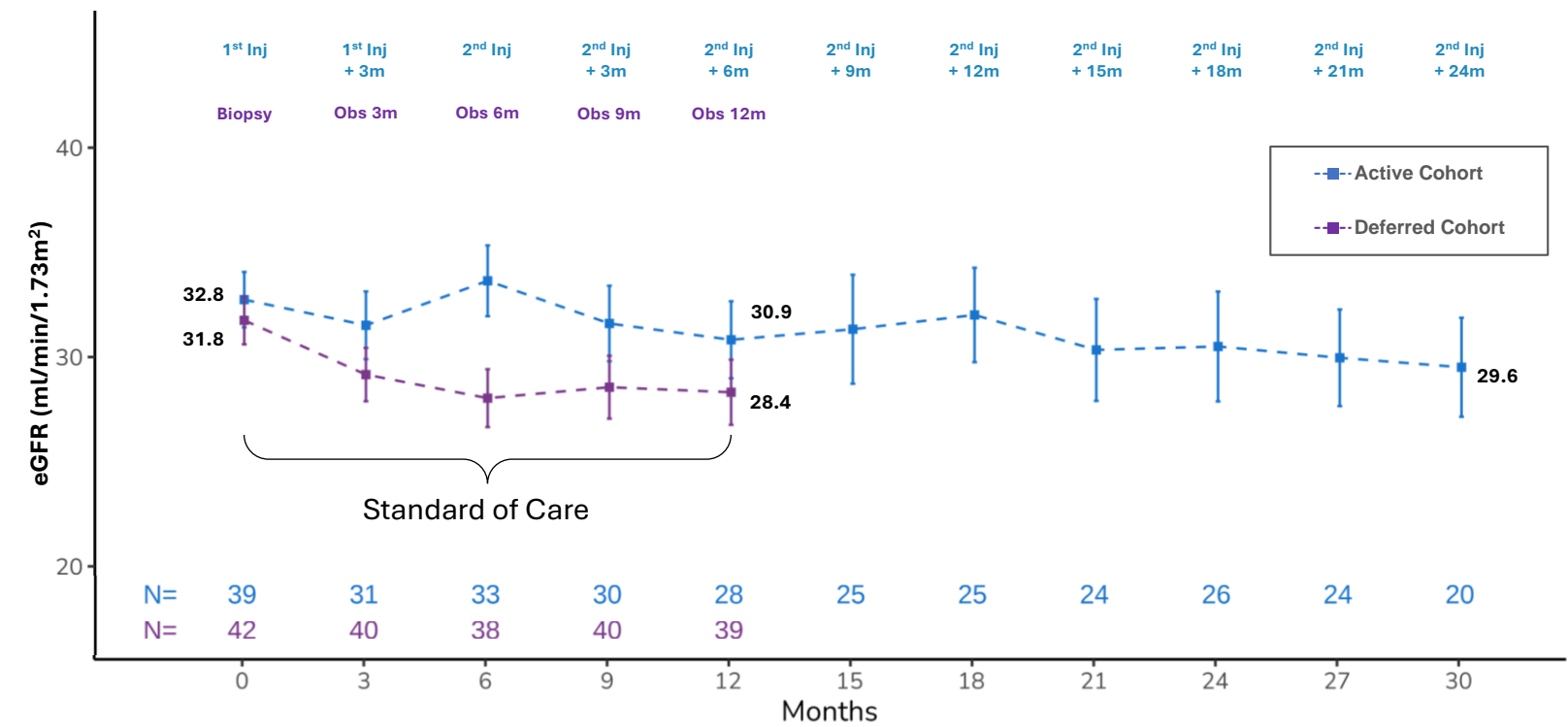
ADVERSE EVENT	BIOPSY # of events (%) (N=83)*	RILPARENCEL INJECTION # of events (%) (N=132)*
Hematoma	1(1.2)	1(0.8)
Pain	0	3(2.3)
Hematuria	0	0
Transfusion	0	1 (0.8)
Surgical Intervention	0	0
Death	0	0
Acute Kidney Injury	0	1(0.8)
CKD progression	0	1(0.8)
Renal vascular disorder	0	1(0.8)
Kidney fibrosis	0	1(0.8)

Data as of August 1, 2023

*All events are based on sponsor assessment of causality. No rilparencel-related serious adverse events were observed. Procedure-related serious adverse events were observed in 6/83 subjects including 1 participant who experienced a hematoma, transfusion, and acute kidney injury. A needle design change was implemented after this event

Active Cohort Patients Showed No Clinically Meaningful eGFR Decline Over 30 Months

Change in Average eGFR in Active Cohort vs Deferred Cohort on SOC

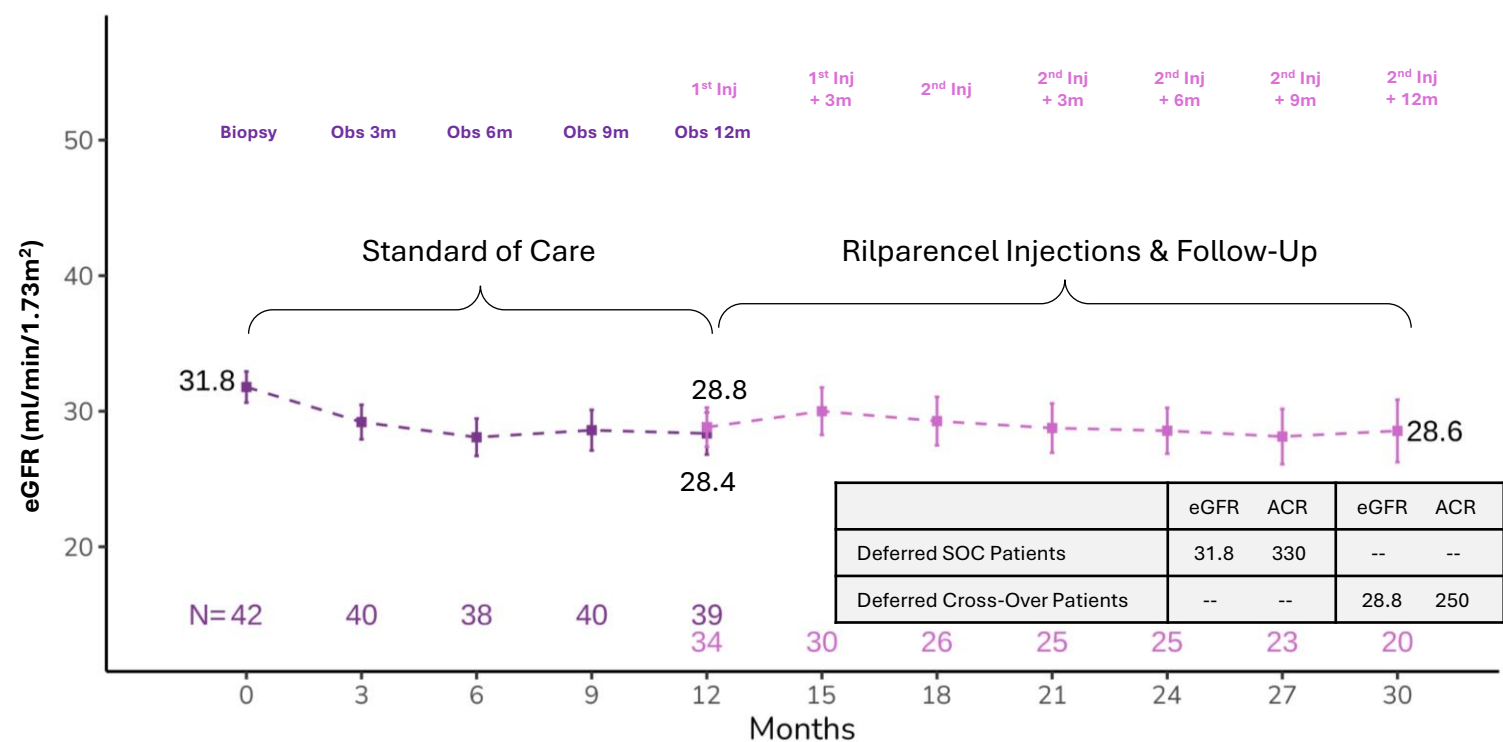


The Active Cohort showed a cumulative change in average eGFR of **-3.2 mL/min/1.73m² after 30-months;**

The Deferred Cohort, receiving standard of care, showed a cumulative change in average eGFR of **-3.4 mL/min/1.73m² after 12-months.**

Deferred to Cross-Over Patients Showed Preservation of eGFR after Rilparencel Injection

Average eGFR in Deferred Cohort: SOC followed by Rilparencel Treatment



Average eGFR of the Deferred cohort was 31.8 at baseline vs 28.4 at 12 months

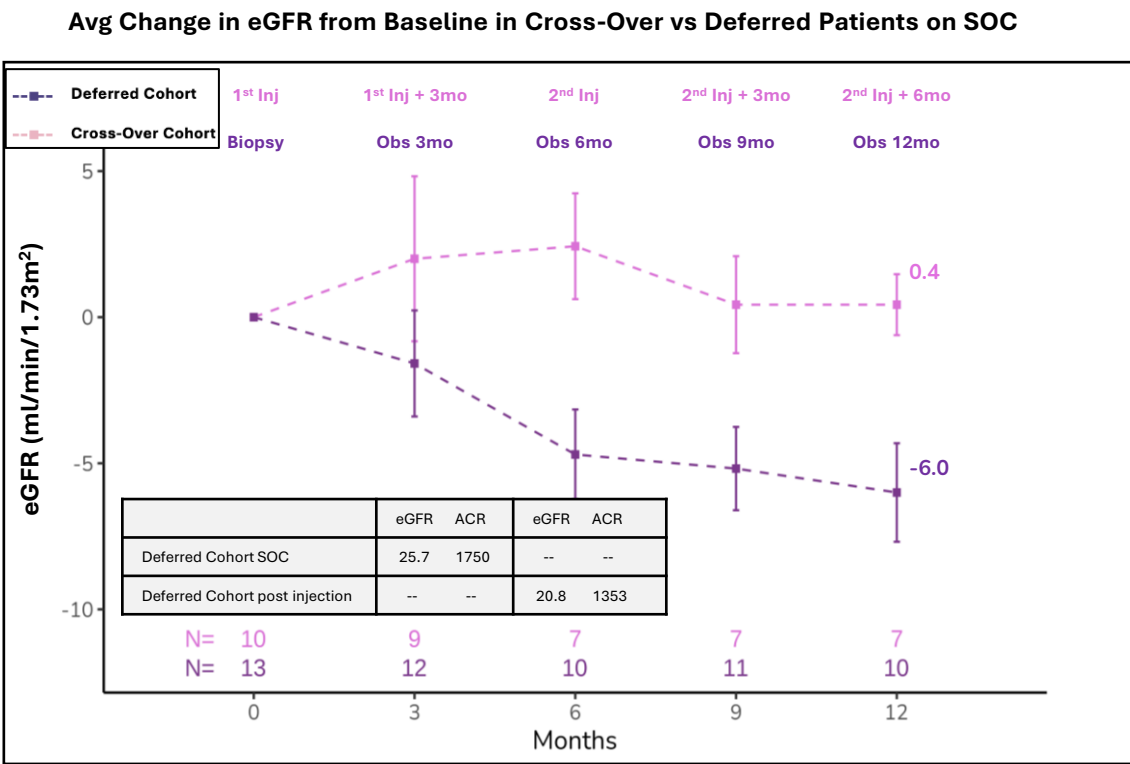
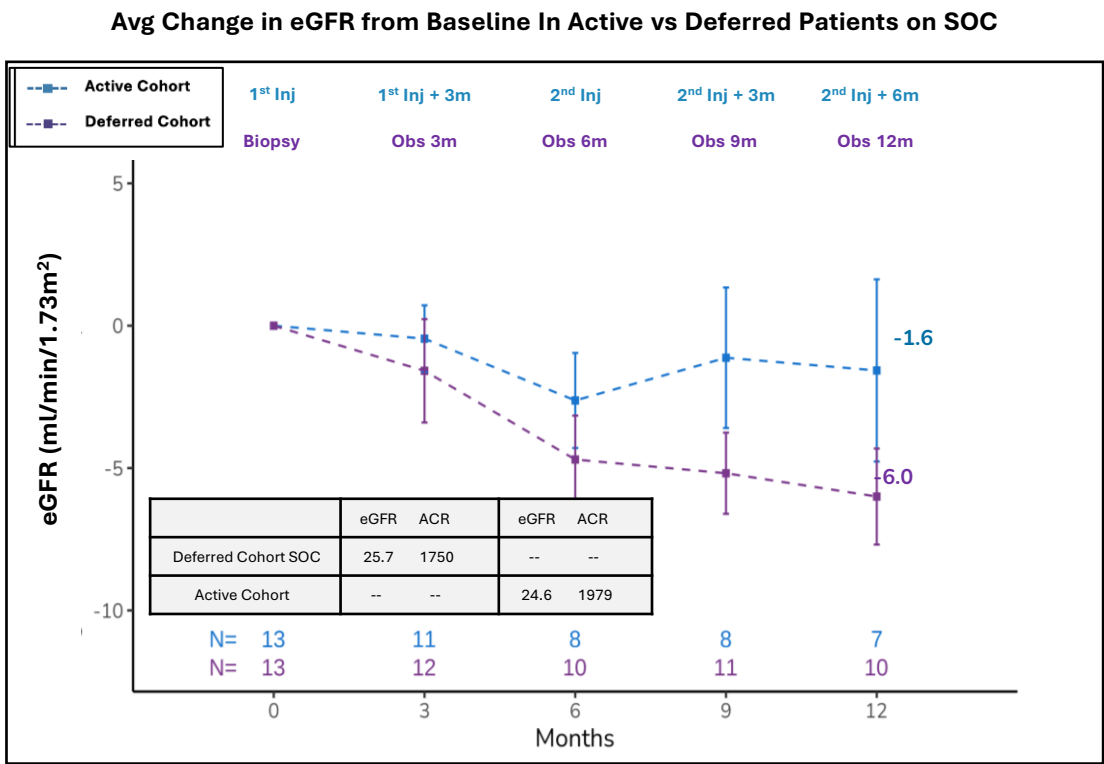
[absolute difference of -3.4 ml/min/1.73m² over 12 months]

Average eGFR at 1st injection after cross-over was 28.8 vs 28.6 at 18 months

[absolute difference of -0.2 ml/min/1.73m² over 18 months]

Subgroup Analysis of Diabetic Patients with CKD Stage 4 and Class A3 Albuminuria*

Stabilization of Kidney Function in Active (n=13) and Deferred (n=10) Patients at 12 months vs SOC



***Patients with Stage 4 CKD & Class A3 (Severe Albuminuria, >300 mg/g) are one of the fastest progressing CKD patient populations¹**

Rilparencel Demonstrates the Potential for Preservation of Kidney Function in Patients with Diabetes and Advanced Kidney Disease

Key Findings

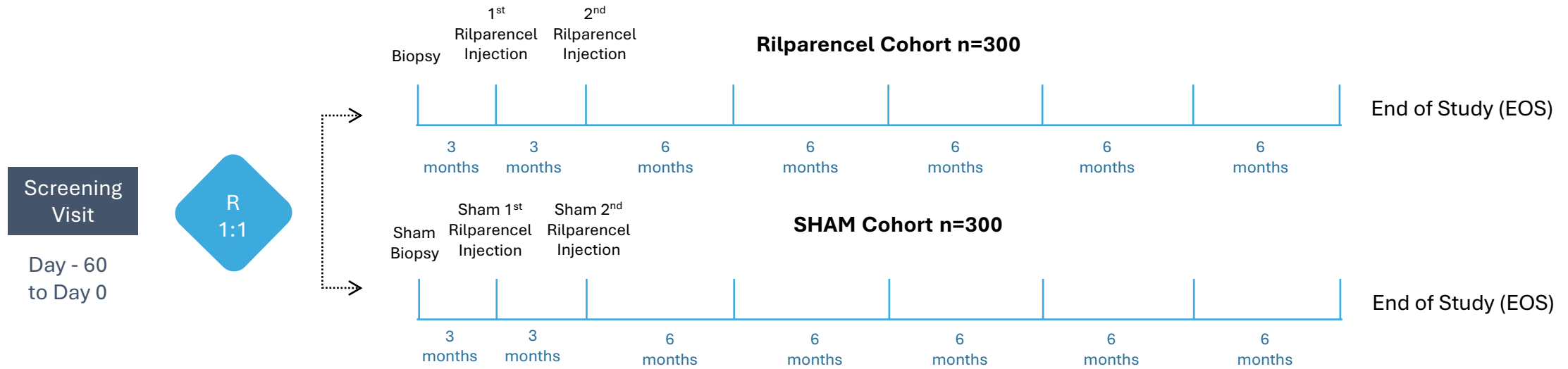
- Showed potential to **preserve kidney function** for up to 30 months in several patient groups
- Benefit to kidney function was most notable in patients who had the **highest risk of kidney failure** (CKD 4 with high UACR¹)
- Injections were **well tolerated** with a consistent safety profile comparable to kidney biopsy

Next Steps

We are **enriching** our Phase 3 PROACT 1 Study to include more patients with the **highest risk of kidney failure**

Rilparencel Registrational Program: proact 1 (REGEN-006)

Modifying PROACT 1 eGFR enrollment criteria from current range of ≥ 20 to ≤ 50 mL/min/1.73m² to new range of ≥ 20 to ≤ 35 mL/min/1.73m² to better align with RMCL-002 results and Payer / Clinical Feedback



Existing Key Entry Criteria

- CKD caused by Type II Diabetes
- Male or Female 30-80 years of age
- **eGFR ≥ 20 and ≤ 50 mL/min/1.73m²**
- Not on renal dialysis, HbA1c $< 10\%$
- UACR 300 - 5,000 mg/g

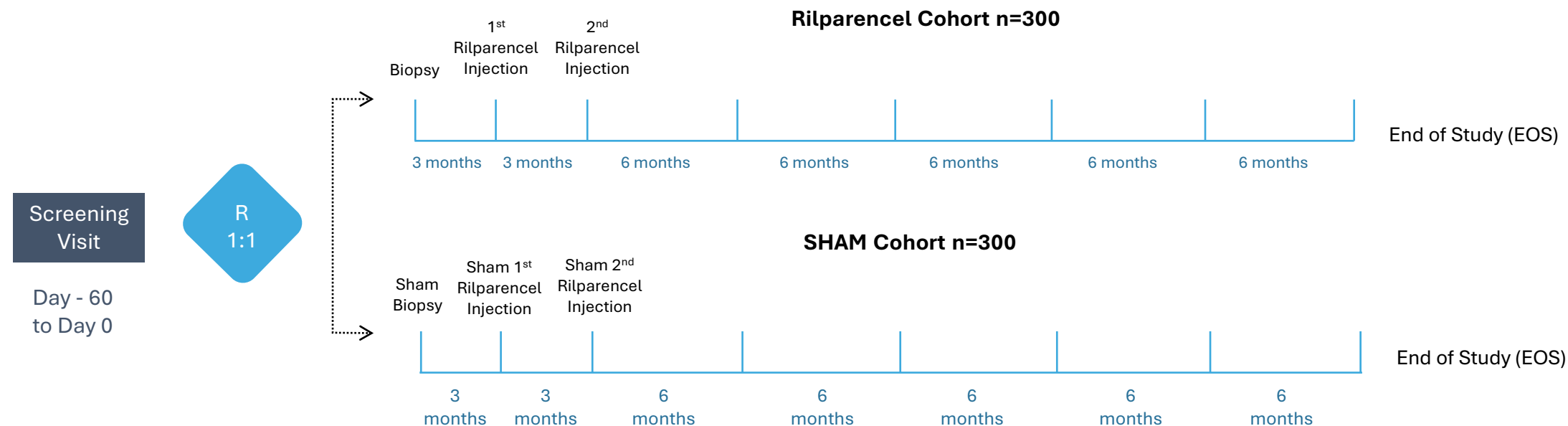
New Protocol Modifications

- **eGFR ≥ 20 and ≤ 35 mL/min/1.73m²**
- UACR 300 - 5,000 mg/g for eGFR 30-35
- Updating standard of care expectations
- 600 patients in addition to ~50 currently enrolled patients who meet new eGFR criteria

Time-to-Event Primary Composite Endpoint (Unchanged)

- At least 40% reduction in eGFR;
- eGFR < 15 mL/min/1.73m² sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- Death from renal or cardiovascular causes

Rilparencel Registrational Program: proact2 (REGEN-016)



Key Entry Criteria

- CKD caused by Type II Diabetes
- Male or Female 30-80 years of age
- eGFR ≥ 20 and ≤ 44 mL/min/1.73m²
- Not on renal dialysis, HbA1c <10%
- UACR 300 - 5,000 mg/g

Protocol

- No protocol modifications planned

Time-to-Event Primary Composite Endpoint

- At least 40% reduction in eGFR;
- eGFR <15mL/min/1.73m² sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- Death from renal or cardiovascular causes

Advancing a Comprehensive Clinical Plan

1H 2023

REGEN-003 Phase 2 Trial; Results published 1Q23

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

2H 2023

RMCL-002 Phase 2 enrollment complete; Interim results 2H23

- Open label safety & efficacy of rilparencel
- Stage 3b/4 Diabetic CKD (eGFR 20-50)
- Potential to preserve kidney function for up to 30 months in several patient groups
- **Final results in 1H 2024**

2024 and beyond

REGEN-007 Phase 2 enrollment complete

- Open-label trial Diabetic CKD Stage 3/4 (eGFR 20-50)
- Bi-lateral kidney injections
- Cryopreserved commercial formulation
- **Interim Results mid-2024**
- **Full 12 month data from cohort 1 in 1H 2025**

Rilparencel Phase 3 Diabetic CKD Trials

PROACT 1 – Enrollment focused on U.S. / PROACT 2 – Enrollment focused outside U.S.

- Enriching proact 1 with high-risk patients to align with 002 data and meet clinical and payer needs
- Manufacturing temporarily paused while company amends PROACT 1 protocol and concurrently, in response to QP audit, optimizes capabilities to meet EU and Global manufacturing and quality management system standards for Phase 3 studies, and prepares for transition to commercial manufacturing. NO SAFETY EVENTS are responsible for this pause
- **Expect PROACT 1 will resume, and PROACT 2 will commence, enrollment in mid-2024**
- **Completion of both studies anticipated in 2027**

Regulatory

FDA / EMA agreement on pivotal study design / RMAT designation in U.S.

Financial Highlights



NASDAQ: PROK

229,343,531 shares
outstanding*

\$363M 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
Colin Bristow	UBS
Kelly Shi	Jefferies

*As of March 21, 2024
**Cash, cash equivalents and marketable securities as of 12/31/2023