ProKidney

RMCL-002 Interim Results & Updates

November 14, 2023

Developing Solutions for Dialysis Prevention

REACT® [**RE**nal **A**utologous **C**ell **T**herapy]

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Agenda

01 Opening Remarks

02 REACT Phase 2 RMCL-002 Data

03 Plans for Phase 3 Program (Studies REGEN-006 and REGEN-016)

04 Advancing a Comprehensive Clinical Plan

Disrupting the CKD Treatment Landscape

Renal Autologous Cell Therapy:

REACT® (rilparencel) proprietary autologous cellular therapy being evaluated to **preserve kidney function** in diabetic patients at high risk of kidney failure

What is REACT® 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[2]

Total annual costs to Medicare for patients with CKD (including ESRD) exceed $138B[1]

Our Goals

Preserve kidney function

Reduce or potentially eliminate time spent on dialysis

Return autonomy to patients and their families

Our Product

REACT® 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

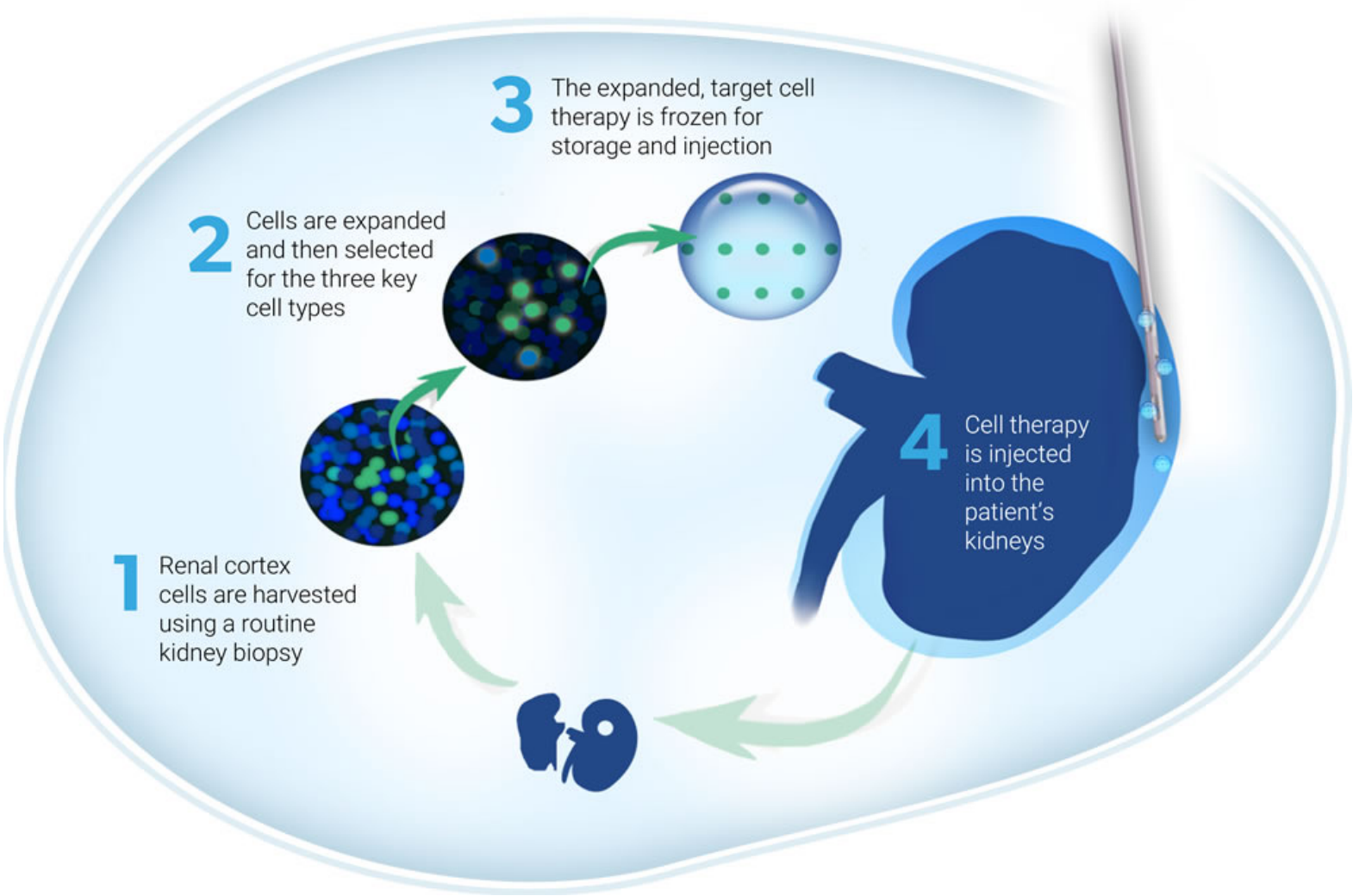
Phase 3 clinical program **proact 1 and proact 2 are underway** in patients with Stage 3b / 4 diabetic kidney disease

Potential label expansion to re-dose REACT 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*

REACT® Goal: Preservation of Kidney Function

ProKidney's REACT® Autologous Cell Therapy



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Overview of the REACT® Clinical Program

Lead Platform Programs*	PRECLINICAL	IND	PHASE 1	PHASE 2	PHASE 3	STATUS
Pivotal Trial Program						
Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m^2, N = 600)				006/proact 1		Ongoing
Diabetes Type II – Prevent/Delay CKD 3/4 stratified for SGLT2i (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 REACT				008		Enrollment 4Q 2023
Supportive Trials						
Diabetes Type II – Delay CKD 4/5 (14-20 ml/min/1.73m^2, N = 10)				003		Trial Completed
Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m^2, N = 81)				002		Fully Enrolled
Diabetes Repeat Dose Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m^2, N= 50)				007		Fully Enrolled
Multi / extended-dosing for previously REACT-treated patients				015		Fully Enrolled
Congenital Anomalies – Prevent/Delay (14-50 ml/min/1.73m^2, N= 5)				004		Trial Completed

*As of October 2023

Frozen product

Unilateral injections

bilateral injections

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Unmet Clinical and Payer Need in High-Risk CKD Patients

REACT® May 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

- Low
- Moderately Increased
- High
- Very High

GFR categories (mL/min/1.73 m²) Description and range			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
G1	Normal or high	≥90			
G2	Mildly decreased	60-89			
G3a	Mildy to moderately decreased	45-59			
G3b	Moderately to severely decreased	30-44			
G4	Severely decreased	15-29			
G5	Kidney failure	<15			

REACT'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%
Dapaglifozin in Patients with CKD[2]	Dapaglifozin (SGLT2 inhibitor)	14%
Empaglifozin in Patients with CKD[3]	Empaglifozin (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%

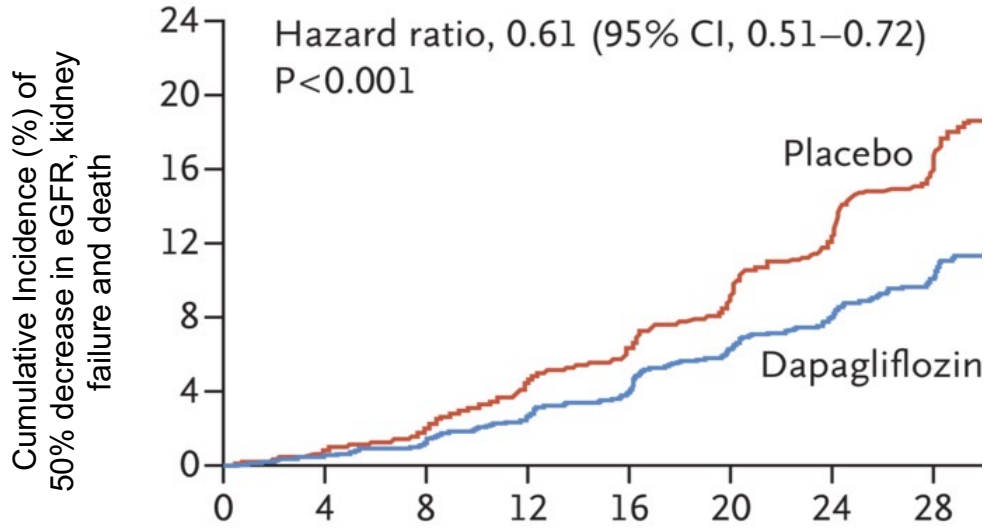
All recent landmark clinical trials in CKD focus on Stage 2/3 CKD

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

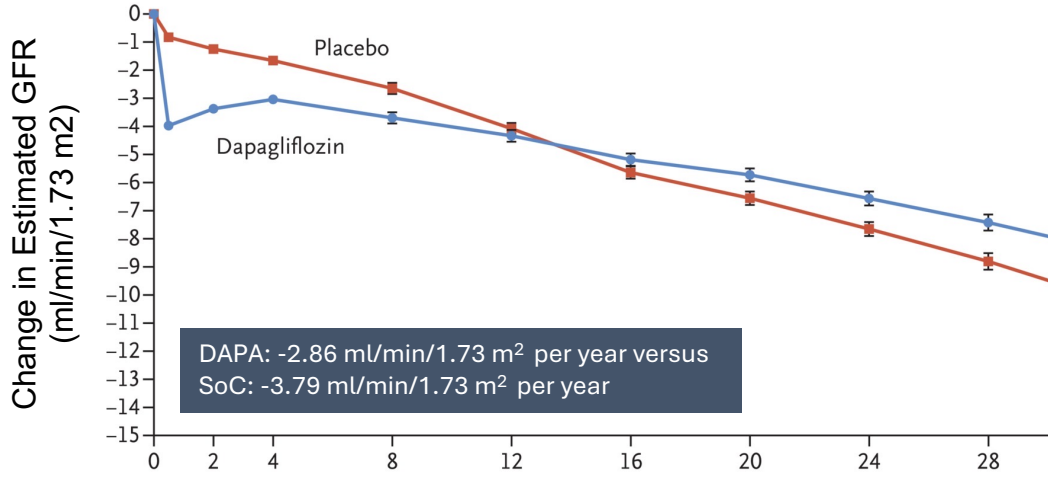
Current standard of care[1] does <u>not</u> prevent events in ~ 50-75% of people with diabetic kidney disease[2]



Dapagliflozin: <u>19 patients</u> required treatment to prevent <u>one</u> primary outcome event

Current SGLT2 Inhibitors are Blockbusters

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*

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RMCL-002 Interim Analysis

August 2023 Data Cut

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In this Phase 2 Study, REACT® Demonstrates the Potential for Preservation of Kidney Function in Patients with Diabetes and Advanced Kidney Disease

Key Findings

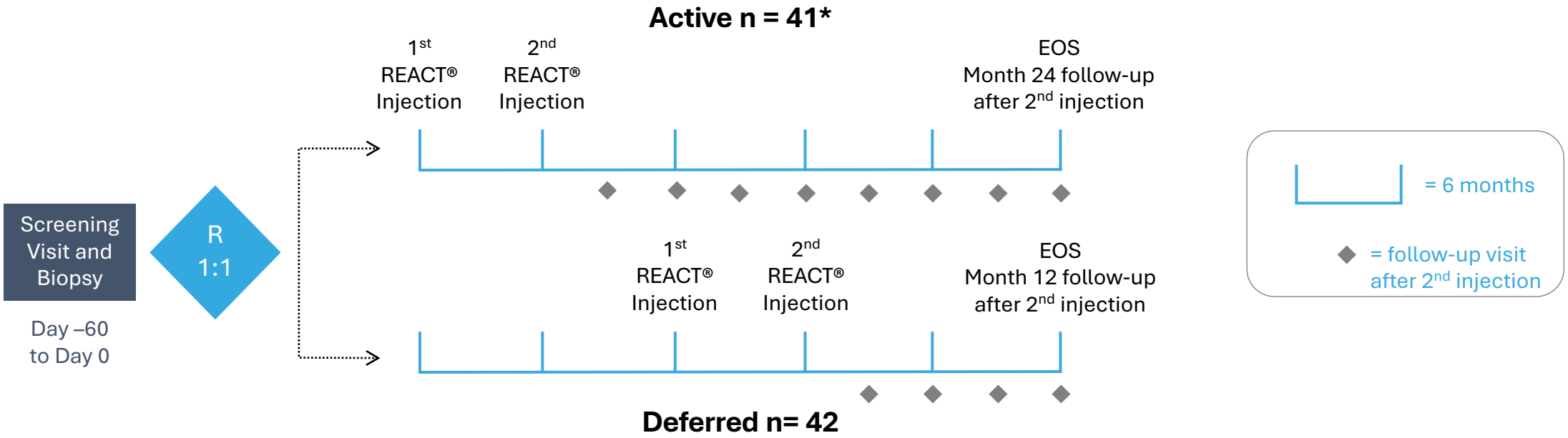
- REACT showed potential to preserve kidney function for up to 30 months in several patient groups
- REACT's benefit on kidney function was most notable in patients who had the highest risk of kidney failure (CKD 4 with high UACR[1])
- REACT injections were well tolerated with a consistent safety profile 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

1. *UACR = urine albumin-to-creatinine ratio (a measure of albuminuria)*

RMCL-002: Trial Design



Key Entry Criteria

- 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%

Study Endpoints

- **REACT and Procedure Related Adverse Events**
- **Change in kidney function (assessed by eGFR)**

Study Timeframe

- RMAT granted for Phase 3 program in January 2022
- 13 subjects remaining on study (n= 9 in Deferred arm) and will complete by YE 2023

RMAT = Regenerative Therapy Advanced Medicine

Study Objectives and Endpoints

Study Objectives

- To assess the safety and efficacy of up to two REACT injections given 6 months apart and delivered into the biopsied kidney using a percutaneous approach

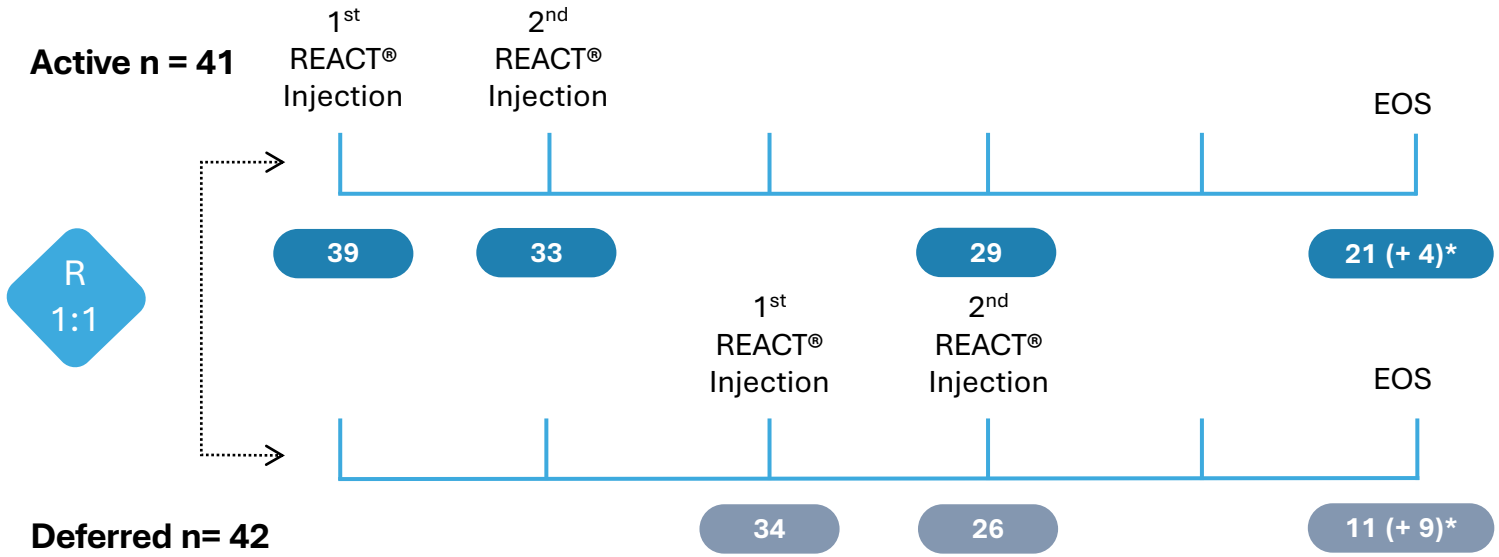
Study Endpoints

- Procedural- and investigational product-related adverse events
- Change in kidney function as measured by serial measurements of estimated glomerular filtration rate (eGFR)

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

	ACTIVE (n=41)	DEFERRED (n=42)
Age, years *(mean +/- SD)*	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 *(mean +/- SD)*	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 *(median +/- interquartile range)*	740 (68, 1597)	598 (58, 1985)
Geometric Mean / Median of UACR mg/g	251 / 250	308 / 567
HbA1c, % *(mean +/- SD)*	7.2 +/- 1.0	7.1 +/- 1.0

Current Enrollment Status & Completion Expectations



- Rates of drop-out due to death or dialysis are typical for advanced CKD
- 13 patients remain on study (4 in Active cohort, 9 in Deferred cohort)
- All patients expected to complete the study by end of 2023
- Final study results anticipated in 1H 2024

ACTIVE COHORT

39	Before 1st Injection: 2 subjects withdrew
33	Before 2nd Injection: 4 subjects EOS** as per protocol, 1 subject expired, 1 started dialysis
29	Before 12-month follow-up after 2nd injection: 2 subjects expired, 2 subjects withdrew
21	Before 24-month follow-up after 2nd injection: 3 subjects EOS as per protocol, 1 subject started dialysis, 4 subjects remain enrolled but have not reached 24-month follow-up

DEFERRED COHORT

34	Before cross-over: 7 subjects EOS as per protocol, 1 subject started dialysis
26	Before 2nd injection: 4 subjects EOS as per protocol, 1 subject expired, 3 started dialysis
11	Before 12-month follow-up after 2nd injection: 2 subjects EOS as per protocol, 2 subjects expired, 2 subjects started dialysis, 9 subjects remain enrolled but have not reached 24-month follow-up

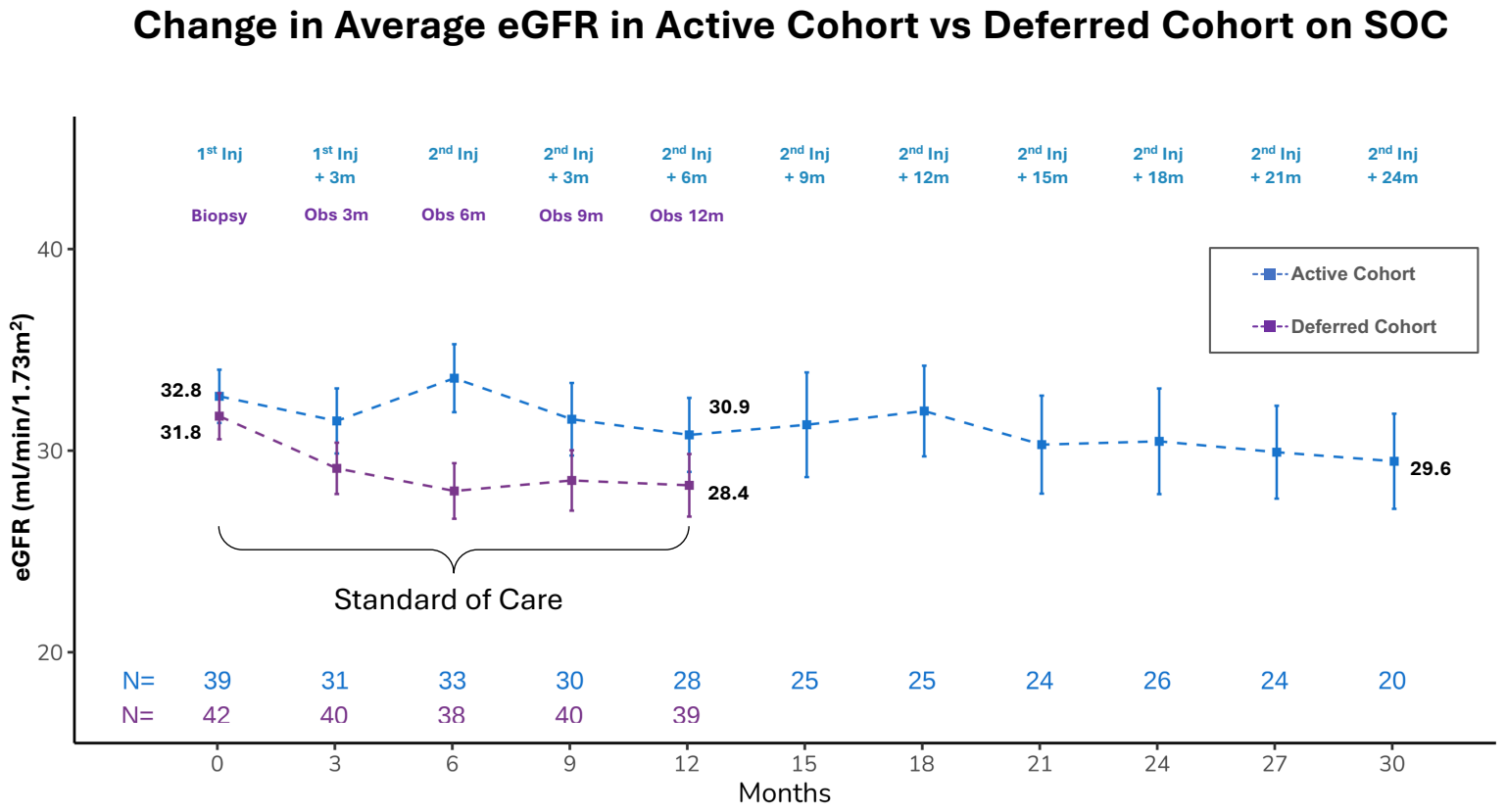
* Subjects pending last eGFR measurement. EOS = End of Study

No REACT-related SAE's Identified in RMCL-002

ADVERSE EVENT	BIOPSY # of patients (%) (N=83)*	REACT INJECTION # of patients (%) (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)

*All events are based on sponsor assessment of causality
No REACT-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



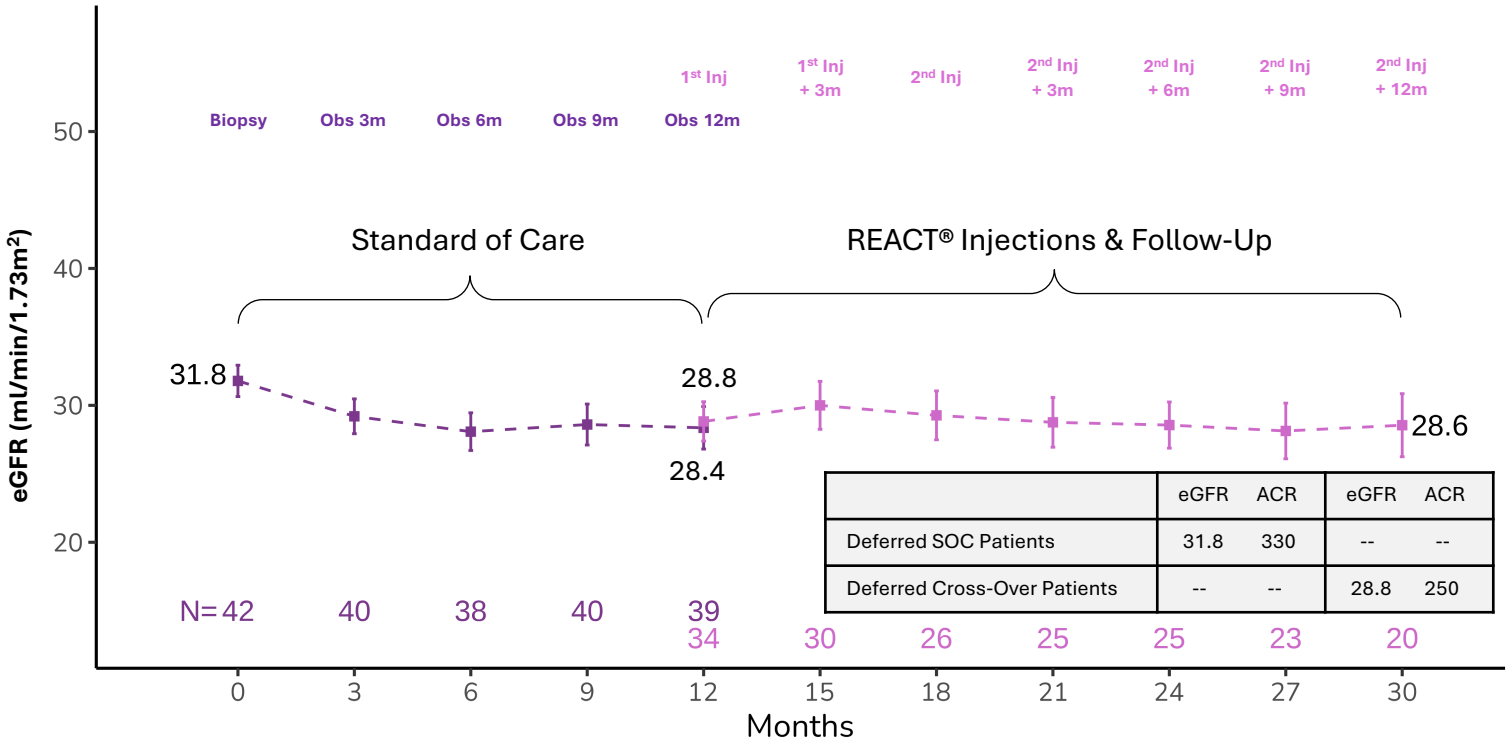
The Active Cohort showed a cumulative change in average eGFR of **-3.2 ml/min/1.73m^2 after 30-months**;

The Deferred Cohort, receiving standard of care, showed a cumulative change in average eGFR of **-3.4 ml/min/1.73m^2 after 12-months.**

Data points are mean +/- SEM ; Data as of August 1, 2023

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

Average eGFR in Deferred Cohort: SOC followed by REACT® Treatment



	eGFR	ACR	eGFR	ACR
Deferred SOC Patients	31.8	330	--	--
Deferred Cross-Over Patients	--	--	28.8	250

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]

Data as of August 1, 2023

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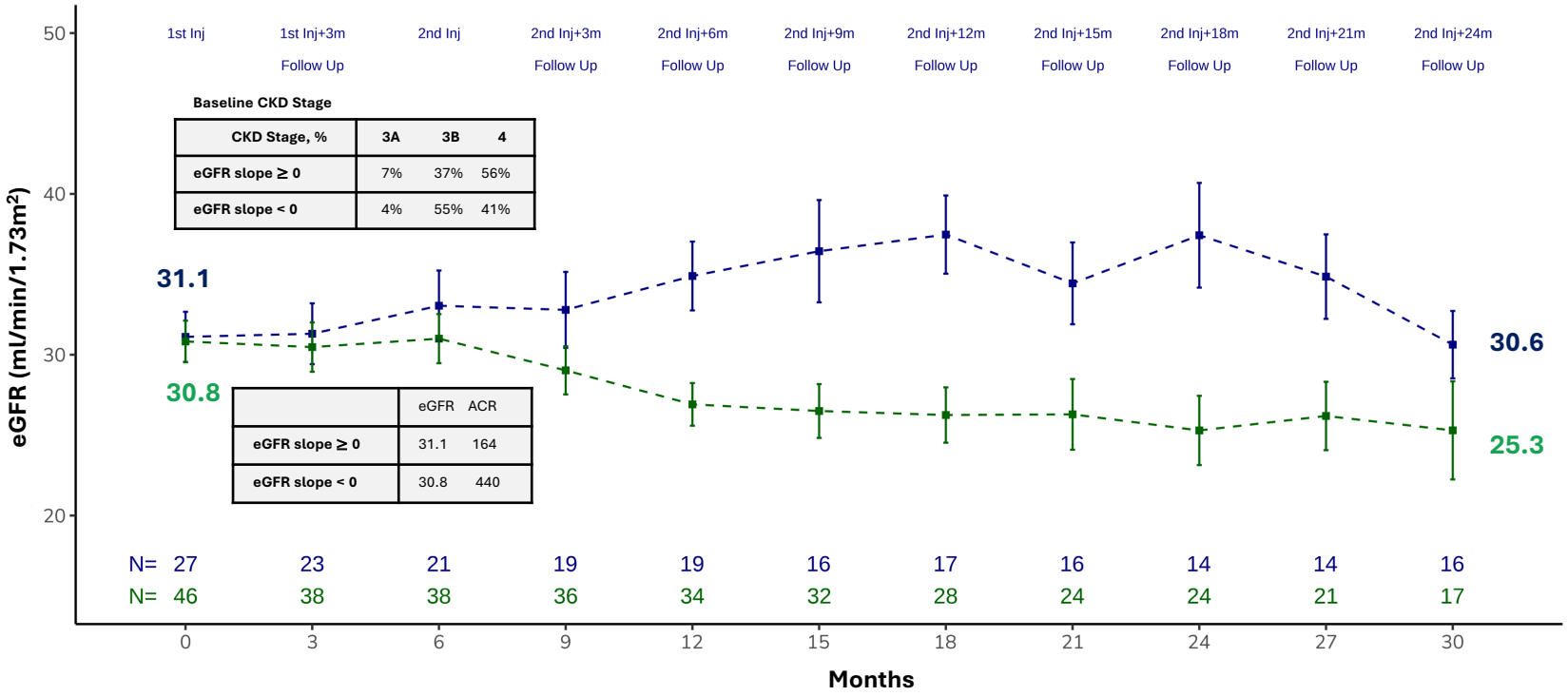
Post-Hoc Analysis of All Subjects who Received at Least One Injection

37% of subjects (27 / 73) had preservation of eGFR during 30 months of follow-up

All Subjects who Received at Least One Injection with REACT
Grouped into Subjects with an 18-month individual slope in eGFR ≥ 0 (n=27) versus
Subjects with an 18-month individual slope in eGFR < 0 (n=46)

Average eGFR in REACT® Treated Subjects



Data as of August 1, 2023

REACT treated subjects with 18-month individual eGFR Slope ≥ 0 had a change in average eGFR of

-0.5 ml/min/1.73m²

[56% of these subjects had Stage 4 CKD]

REACT treated subjects with 18-month individual eGFR Slope < 0 had change in average eGFR of

-5.5 ml/min/1.73m²

[41% of these subjects had Stage 4 CKD]

ProKidney

Post-Hoc Analysis of All Subjects who Received at Least One Injection

37% of subjects (27 / 73) had preservation of eGFR during 30 months of follow-up

All Subjects who Received at Least One Injection with REACT
Grouped into Subjects with an 18-month individual slope in eGFR ≥ 0 (n=27) versus
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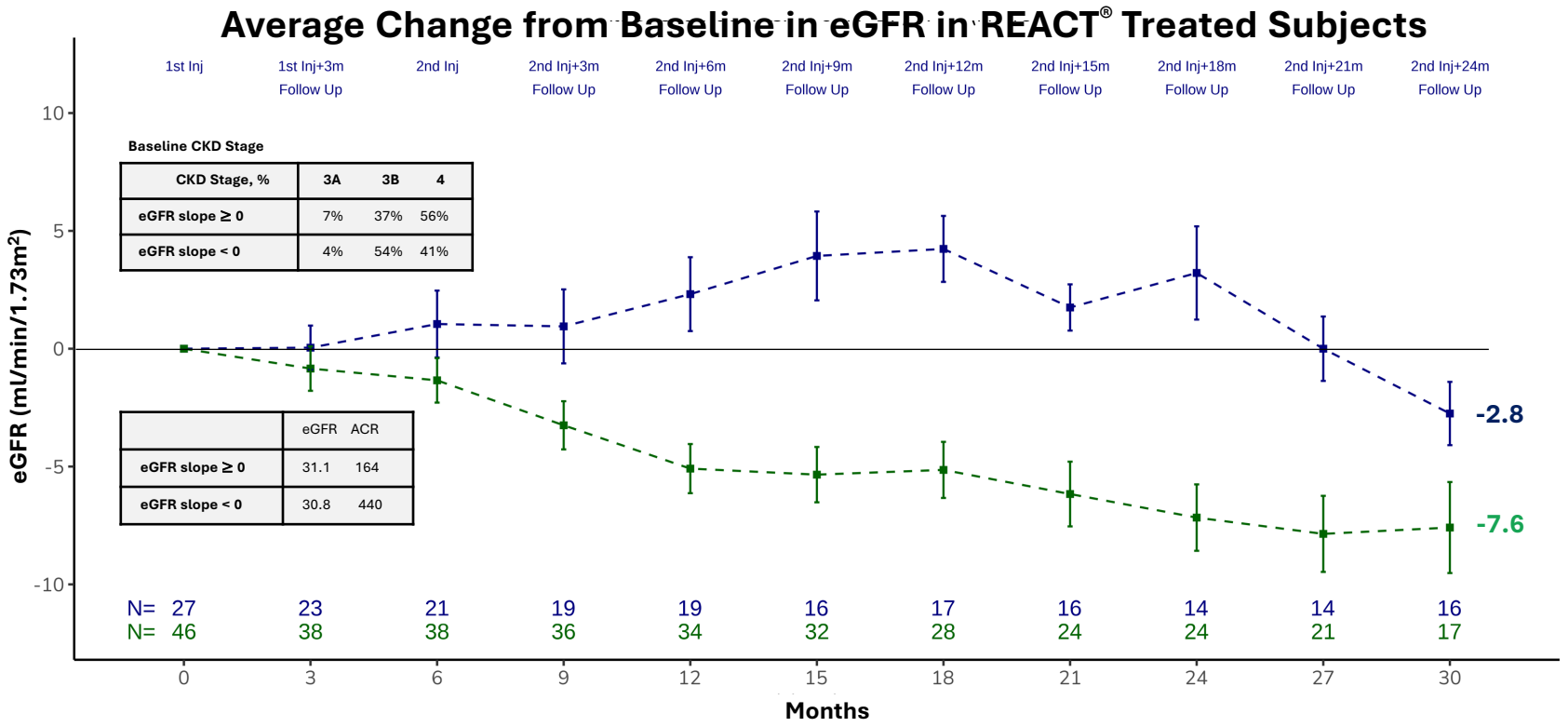

Data as of August 1, 2023

REACT treated subjects with 18-month individual eGFR Slope ≥ 0 had an average change from baseline in eGFR of

-2.8 ml/min/1.73m²
at 30 months

REACT treated subjects with 18-month individual eGFR Slope < 0 had an average change from baseline in eGFR of

-7.6 ml/min/1.73m²
at 30 months

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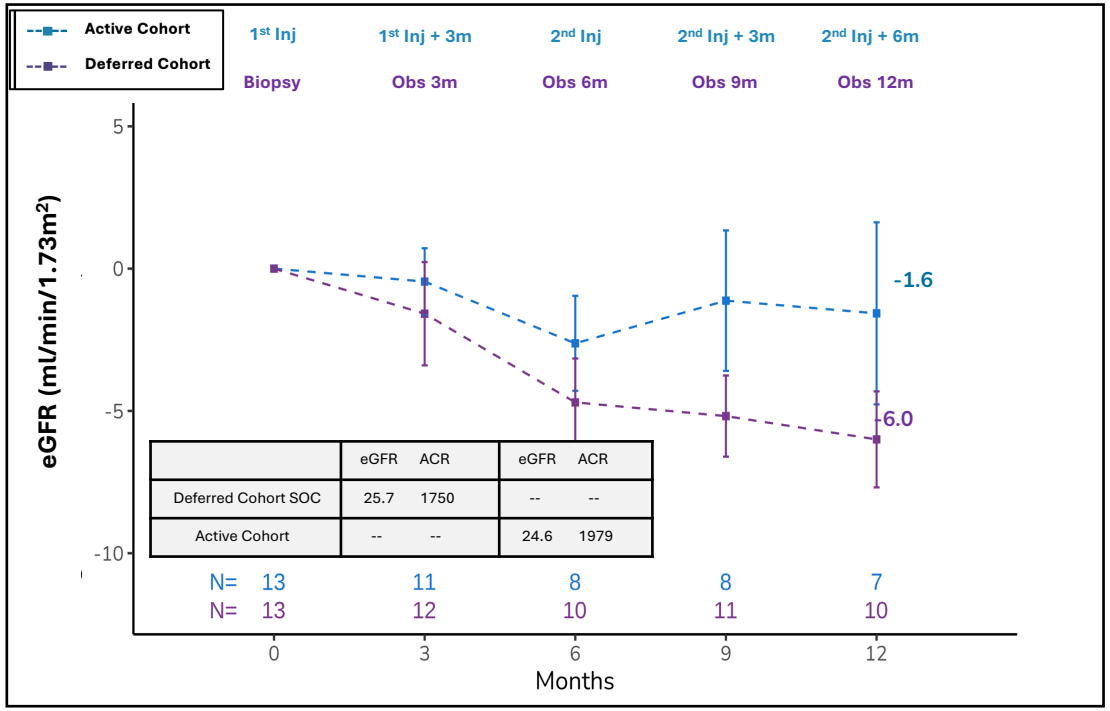
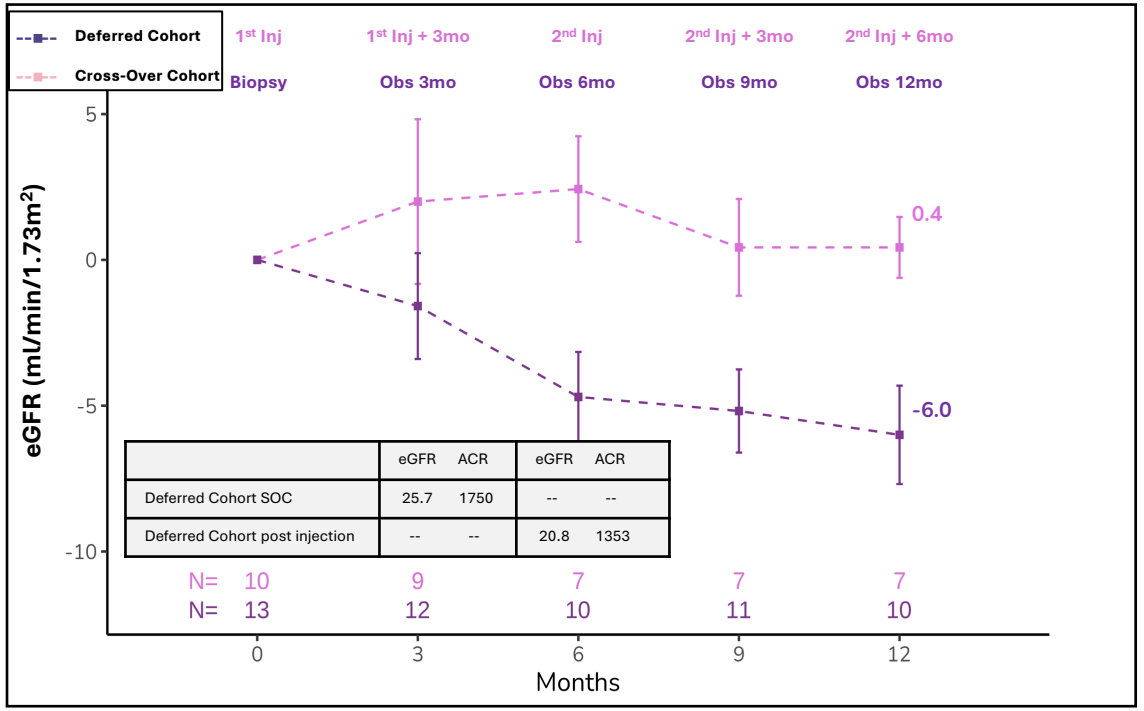
Subgroup Analysis of Diabetic Patients with CKD Stage 4 and Class A3 Albuminuria*

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

Avg Change in eGFR from Baseline In Active vs Deferred Patients on SOC



Avg Change in eGFR from Baseline in Cross-Over vs Deferred Patients on SOC



***Patients with Stage 4 CKD & Class A3 (Severe Albuminuria, >300 mg/g) are one of the fastest progressing patient populations[1]**

Data as of August 1, 2023

1. *Oshima M, Shimizu M, Yamanouchi M, et al. Trajectories of kidney function in diabetes: a clinicopathological update. Nat Rev Nephrol. 2021;17(11):740-750. doi:10.1038/s41581-021-00462-y*

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- REACT's benefit on kidney function was most notable in patients who had the highest risk of kidney failure (CKD 4 with high UACR[1])
- REACT injections were well tolerated with a consistent safety profile comparable to kidney biopsy

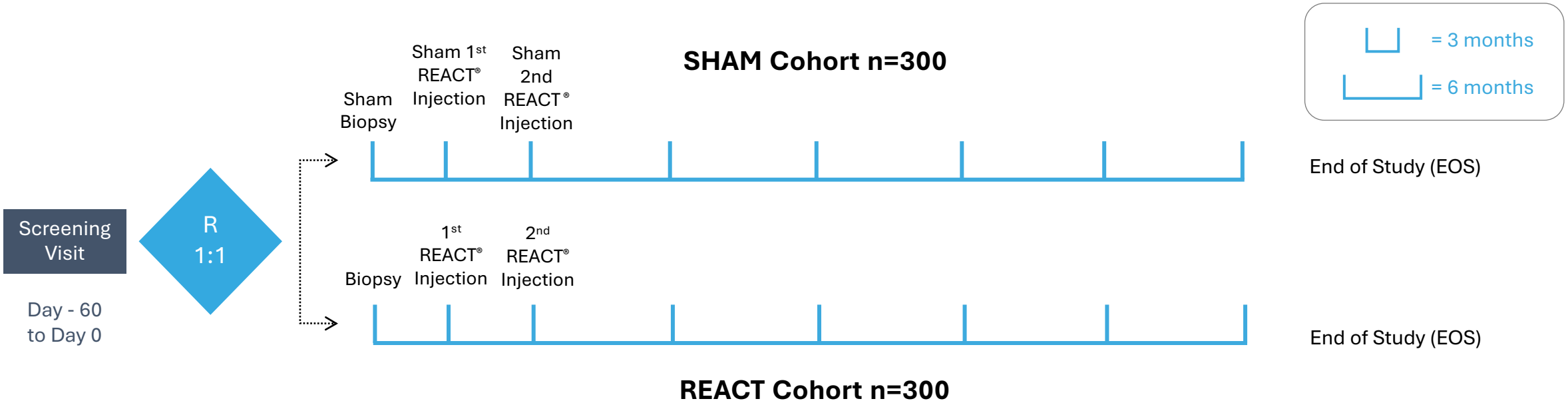
Next Steps

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

1. *UACR = urine albumin-to-creatinine ratio (a measure of albuminuria)*

REACT® Registrational Program: proact 1 (REGEN-006)

Modifying proact 1 eGFR enrollment criteria from current range of ≥20 to ≤ 50ml/min/1.73m^2 to new range of ≥20 to ≤ 35 ml/min/1.73m^2 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/1.73m^2**
- Not on renal dialysis, HbA1c <10%
- UACR 300 - 5,000 mg/g

New Protocol Modifications

- **eGFR ≥20 and ≤ 35 ml/min/1.73m^2**
- 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<15mL/min/1.73m^2 sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- Death from renal or cardiovascular causes

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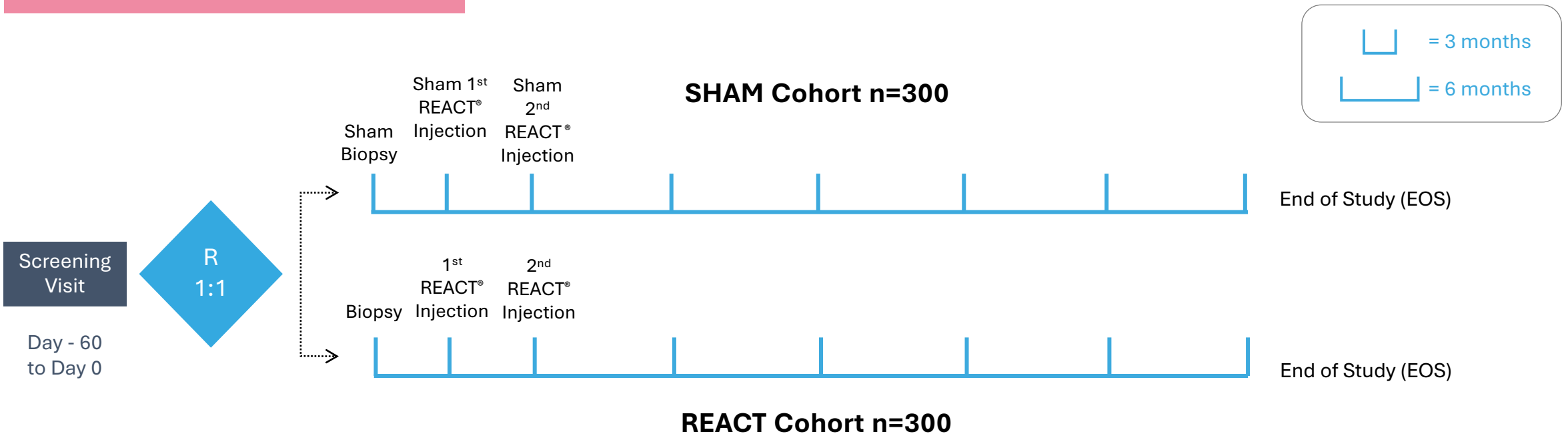
REACT® Registrational Program: proact2 (REGEN-016)

NO MODIFICATIONS PLANNED



Key Entry Criteria

- CKD caused by Type II Diabetes
- Male or Female 30-80 years of age
- eGFR ≥ 20 and ≤ 44 mL/min/1.73m^2
- 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/1.73m^2 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	2H 2023	2024 and beyond
☑ **REGEN-003 Phase 2 Trial; Results published 1Q23** • Safety & efficacy of REACT® • Stage 4/5 Diabetic CKD (eGFR 14-20) • Assess impact on progression and time to dialysis in patients with imminent risk of dialysis	☑ **RMCL-002 Phase 2 Enrollment complete Interim results 2H23** • Last patient last visit December 2023 • Stage 3b/4 Diabetic CKD (eGFR 20-50) • 2 injections into biopsied kidney • Open label safety & efficacy of REACT • **Full results in 1H 2024**	**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 results in 1H 2025**

REACT® Phase 3 Diabetic CKD Trials

proact 1 – Enrollment focused on U.S.

proact 2 – Enrollment focused ex-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**

Cash Position (9/30/2023)

$396M cash provides runway into 4Q 2025

Regulatory

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

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Appendix

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Annualized eGFR Slopes using Linear Mixed Effects Modeling

Subject Group	Number of Subjects	Duration of Follow-up	Annualized eGFR Slope (ml/min/1.73m^2)
Active Cohort	39	12-months after 1st injection	-3.6
Deferred Cohort during standard of care (SOC)	42	12-months after biopsy	-3.4
Deferred Cohort after Cross-over and injection with REACT	34	12-months after 2nd injection	-0.8
Active Cohort, Stage 4 and UACR > 300 mg/g	13	12-months after 1st injection	-2.4
Deferred Cohort during SOC, Stage 4 and UACR > 300 mg/g	13	12-months after biopsy	-5.8
Deferred Cohort after Cross-over, Stage 4 and UACR > 300mg/g	10	12 months after 1st injection	-0.4