

PROKIDNEY

Developing Solutions for Dialysis Prevention



Virtual KOL Event and Recap of RMCL- 002 Final Data

May 28, 2024



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Agenda

Opening Remarks

Bruce Culleton, MD

CEO, ProKidney

2024 Treatment
Landscape for
Patients with DKD

Steven G. Coca, DO, MS

Professor of Medicine (Nephrology) at the Icahn School of Medicine at Mount Sinai

Treating CKD: Current
and Future Trends

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Q&A

KOL Biographies



Steven G. Coca, DO, MS is a Professor of Medicine at the Icahn School of Medicine at Mount Sinai, the Associate Chair for Clinical and Translational Research for the Department of Internal Medicine, and the Director of Clinical Research for the Division of Nephrology. Dr. Coca's research focuses on the utility of blood and urine biomarkers for risk stratification of patients with acute kidney injury and chronic kidney disease. He has been a part of several large NIH funded consortia on biomarkers in kidney disease, including TRIBE-AKI, ASSESS-AKI, CKD Biocon, and the KPMP (Kidney Precision Medicine Project). He has over 300 publications, and has received several awards, including the Distinguished Researcher Award from the American Society of Nephrology in 2021. His work on prognostic biomarkers and risk models has led to the development of KidneyIntelX, a new bioprognostic test for patients with type 2 diabetes and CKD, that was recently approved by the FDA and is commercially in use in clinical practice at several large healthcare systems.



Arnold L. Silva, MD, PhD is the director of the Home Hemodialysis and Peritoneal Dialysis programs at Boise Kidney & Hypertension Institute. Dr. Silva received his bachelor's and master's degrees in Biology from California State University in Fresno, CA. He received his PhD from the University of Arizona in Tucson, studying the physiology of membrane transport and cell volume regulation. He received his MD from the University of Arizona, followed with residency training in internal medicine and nephrology fellowship at the University of Arizona affiliated hospitals. Dr. Silva has been appointed Clinical Assistant Professor of Medicine at the University of Arizona, and has taught in many areas of biology, biochemistry, and physiology for California State University and University of California. Dr. Silva has been very active as an independent investigator in the basic sciences and clinical research throughout his career, and currently acts as a Principal Investigator on projects for Boise Kidney.



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 chronic kidney disease caused by diabetes



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 (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 REGEN-007 interim results in mid-2024
Resume manufacturing and PROACT 1 Phase 3 trial, commence PROACT 2 Phase 3 trial in mid-2024

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 year¹

Total annual costs to Medicare for patients with CKD (including ESRD) exceed **\$138B²**

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**

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2024 Treatment Landscape for Patients with Diabetic Kidney Disease

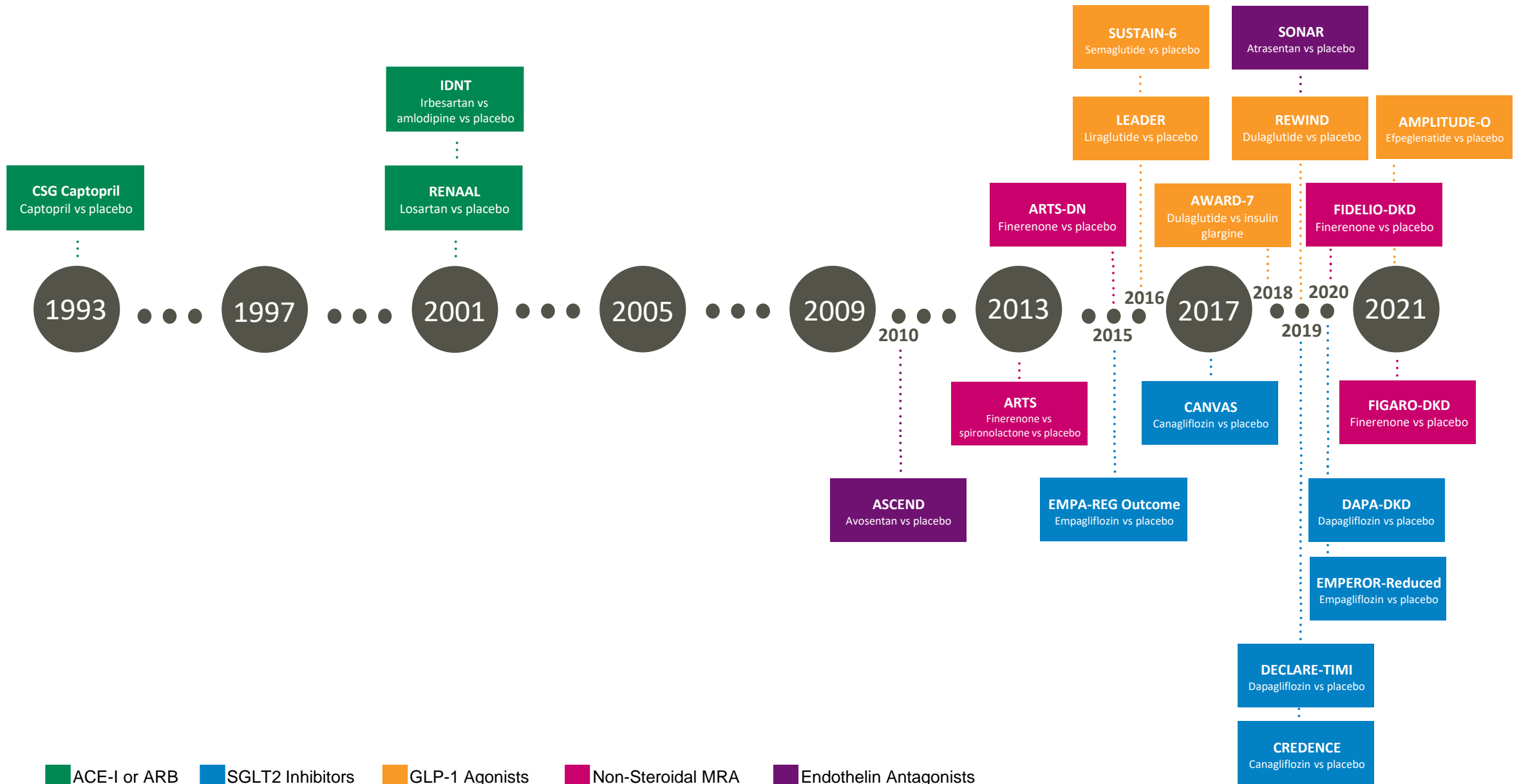
Steven Coca, DO, MS

Professor of Medicine (Nephrology)

Icahn School of Medicine at Mount Sinai, NY, NY



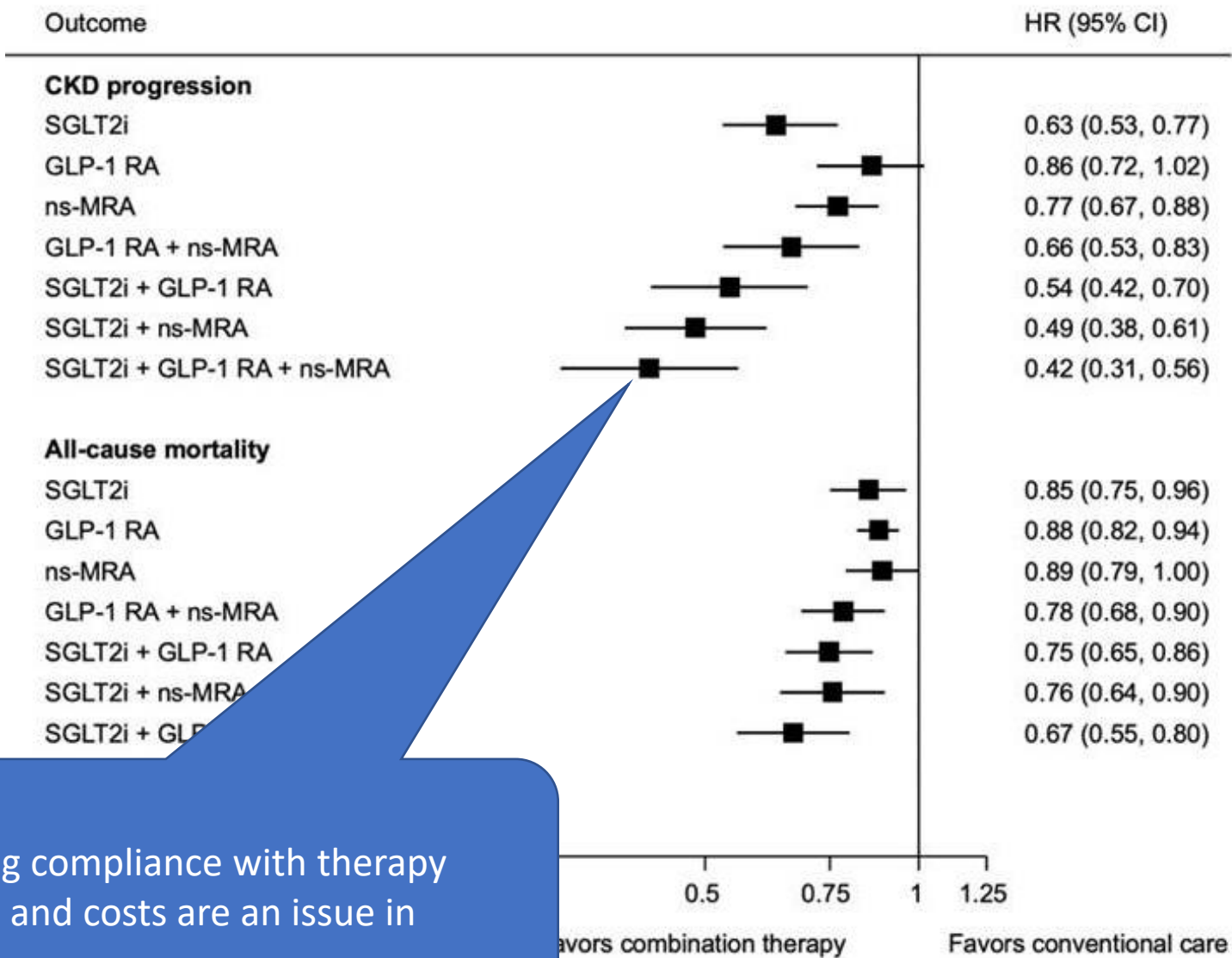
Timeline of Landmark Trials in Diabetic Kidney Disease



Multiple Pillars of DKD Therapy in 2024



Estimated Lifetime Benefits of Combination Therapy with SGLT2i, GLP1 RAs, and ns-MRA in DKD

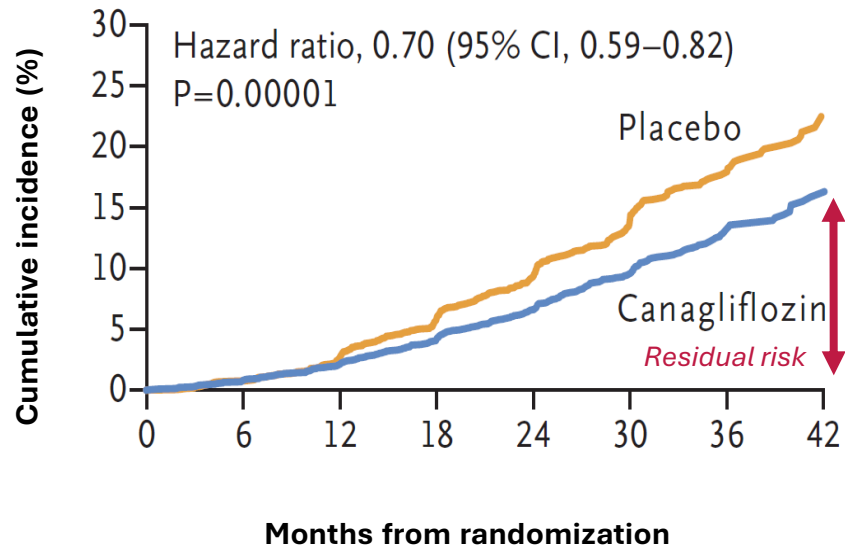


-Best case scenario
 -Assumes high lifelong compliance with therapy
 -Long-term tolerance and costs are an issue in practice

High Residual risk of CKD progression Despite Effectiveness of SGLT2i in Providing a Decrease in Risk Compared to Standard of Care

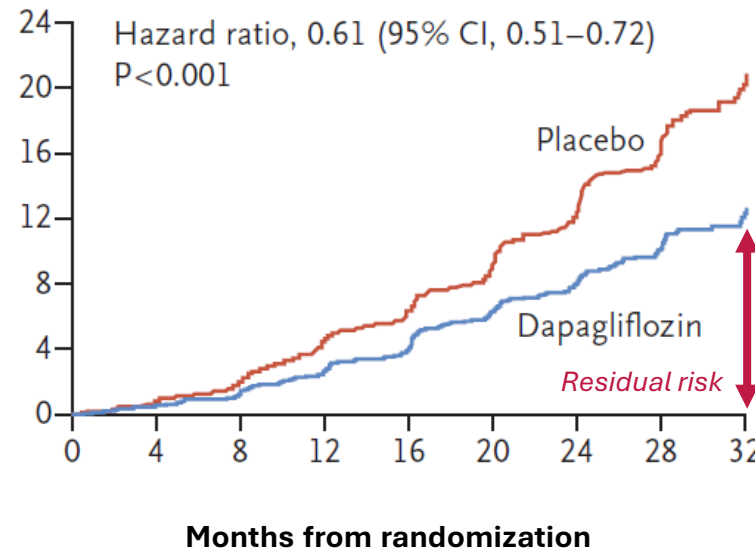
CRENDENCE¹

Primary outcome: Composite of ESRD, doubling of serum creatinine, or death for renal or CV disease



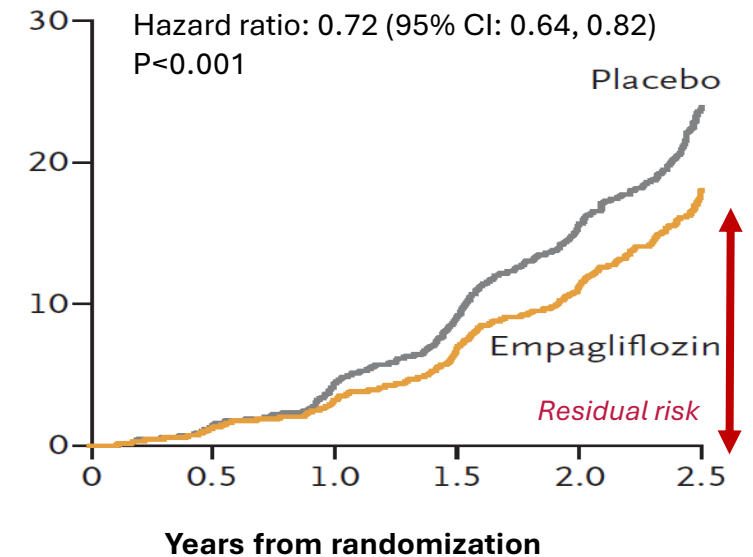
DAPA-CKD²

Primary outcome: $\geq 50\%$ eGFR decline, ESRD, or death from renal or CV causes



EMPA-KIDNEY³

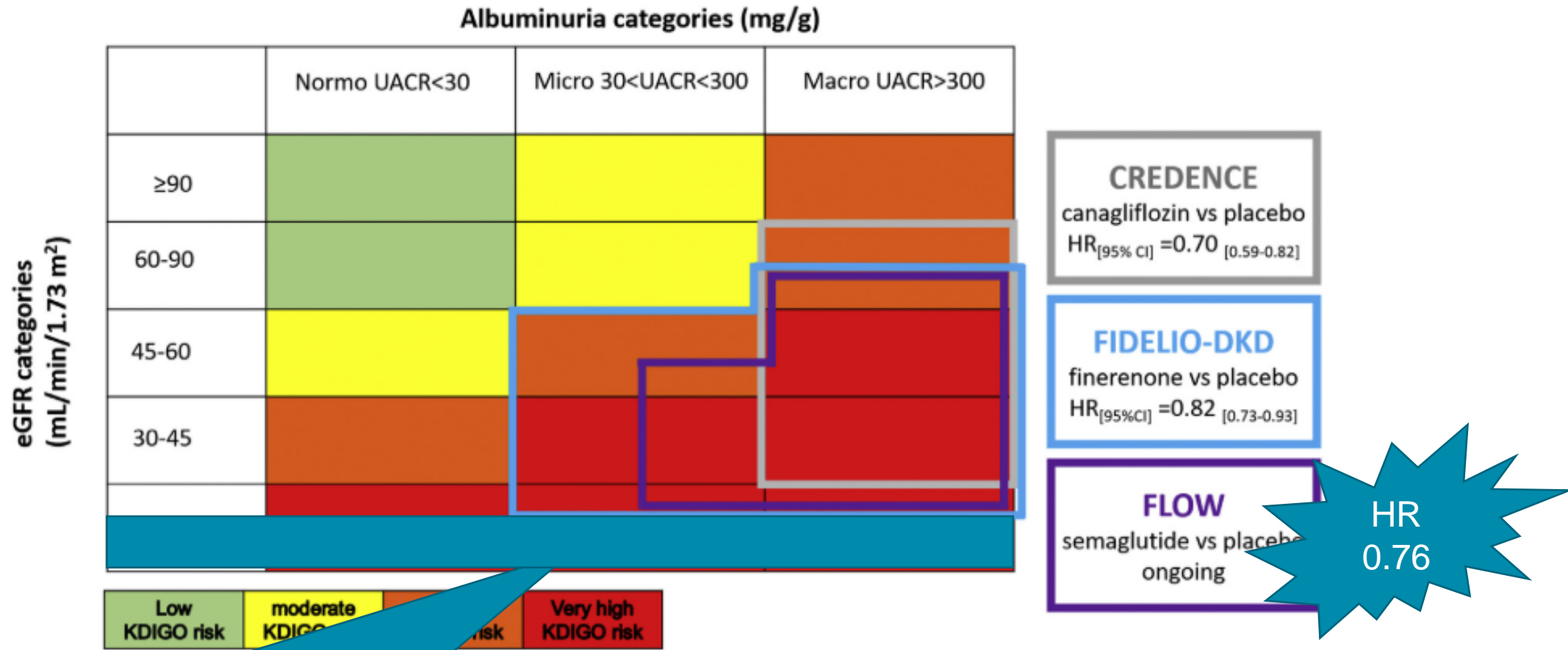
Primary outcome: Composite of ESRD, sustained decline in eGFR to <10 mL/min/1.73 m² or $\geq 40\%$, or death from renal causes



CI, confidence interval; CKD, chronic kidney disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; HR, hazard ratio

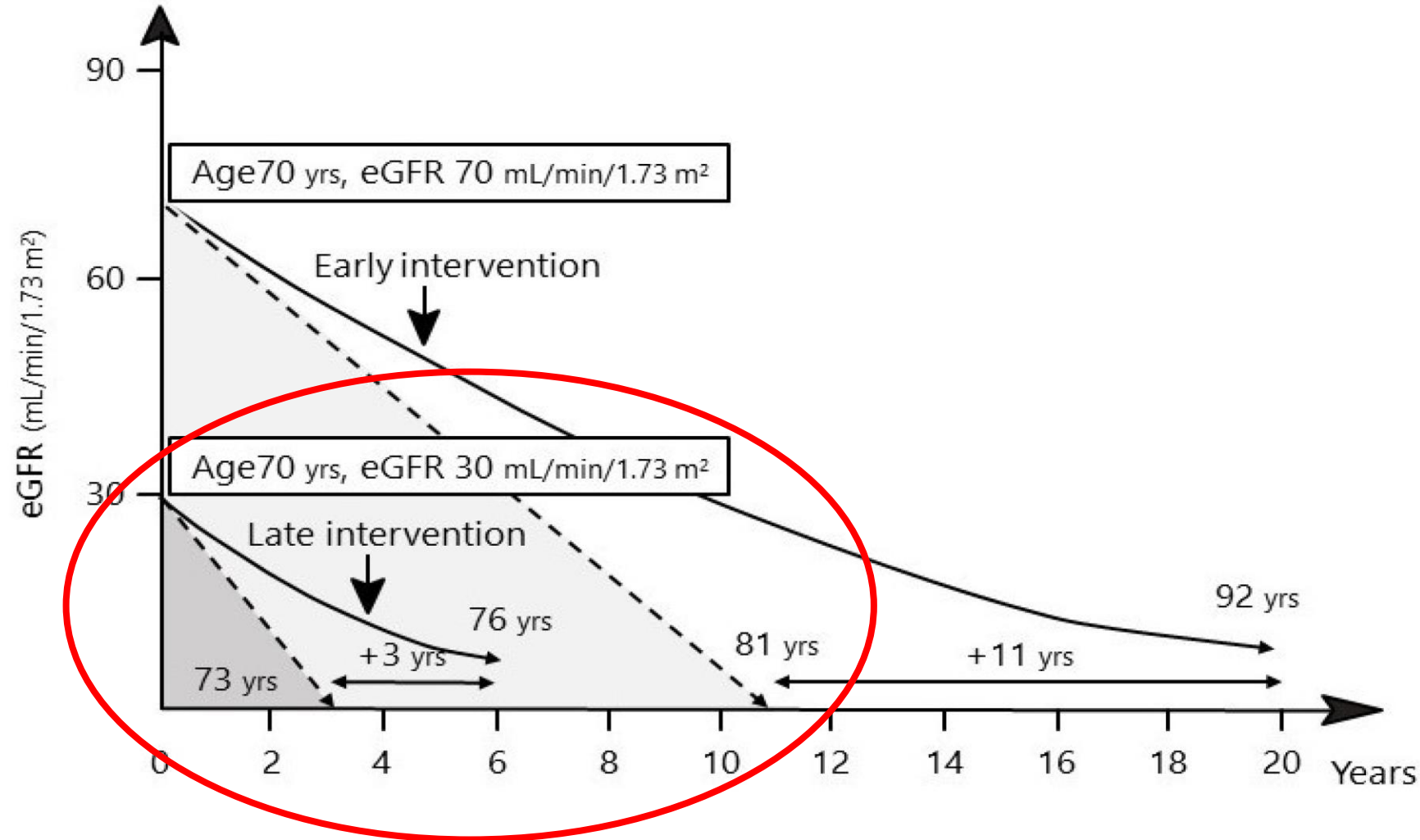
1. Perkovic V, et al. *N Engl J Med* 2019;380:2295-2306; 2. Heerspink HJL, et al. *N Engl J Med* 2020;383:1436-1446; 3. The EMPA-KIDNEY Collaborative Group. *N Engl J Med* 2023;388:117-127

SGLT2i, GLP1-RA, and Finerenone Trials Enrolled Higher Risk Patients off the KDIGO Heatmap and Down to eGFR ≈ 25 ml/min/1.73m²



Most of CKD G4 excluded from the major DKD trials

While early intervention can delay ESKD for many years, late interventions (more common) only allows for a small to moderate delay in ESKD



Conclusions

- Tremendous progress and treatment options in DKD over the last 5-7 years
- We can now SLOW the progression to ESKD
- We cannot completely stop progression
- There is still substantial residual risk of progression
 - Inability to treat all higher risk DKD with triple/quadruple therapies
 - Even on therapies, progression still occurs
 - Minimal data on efficacy in advanced DKD
- **There is a need for more treatment options for advanced stages of DKD to prevent progression to ESKD**

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Treating CKD: Current and Future Trends



BOISE KIDNEY
& HYPERTENSION INSTITUTE



CARE CARDIO
RENAL
INSTITUTE

Arnold L. Silva MD, PhD
Director of Clinical Research
Boise Kidney and Hypertension
CaRe Research Network

The Burden of CKD

- Affects over 40 million Americans
- Similar numbers in Europe
- CKD linked to CVD and Metabolic Disease
- ~90% of patients with CKD remain undiagnosed

CKD is a Progressive Disease

- Declining eGFR is associated with increased CVD risk
- Those who reach ESKD have high mortality
- Survival not improved in ESKD population over last 2 decades despite high investment in research
- Cost: ESKD patients are ~1% of the total Medicare population but consume ~7% of the Medicare budget

CKD: New Therapies

- SGLT2 agents and MRAs
- Both shown to reduced proteinuria
- Both attenuate eGFR decline
- BUT patients still progress with eGFR loss > 2 mL/min/1.73 m² per year
- Goal is to reduce eGFR decline to < 1 mL/min/1.73 m² per year to preserve renal function

Cell Therapy: REACT[®] (rilparencel)

- Autologous/Homologous Approach
- Safety profile established in > 100 patients
- No demonstrated immunogenic or tumorigenicity
- Phase 2 data demonstrates reduction in eGFR decline to < 1 mL/min/1.73 m² per year

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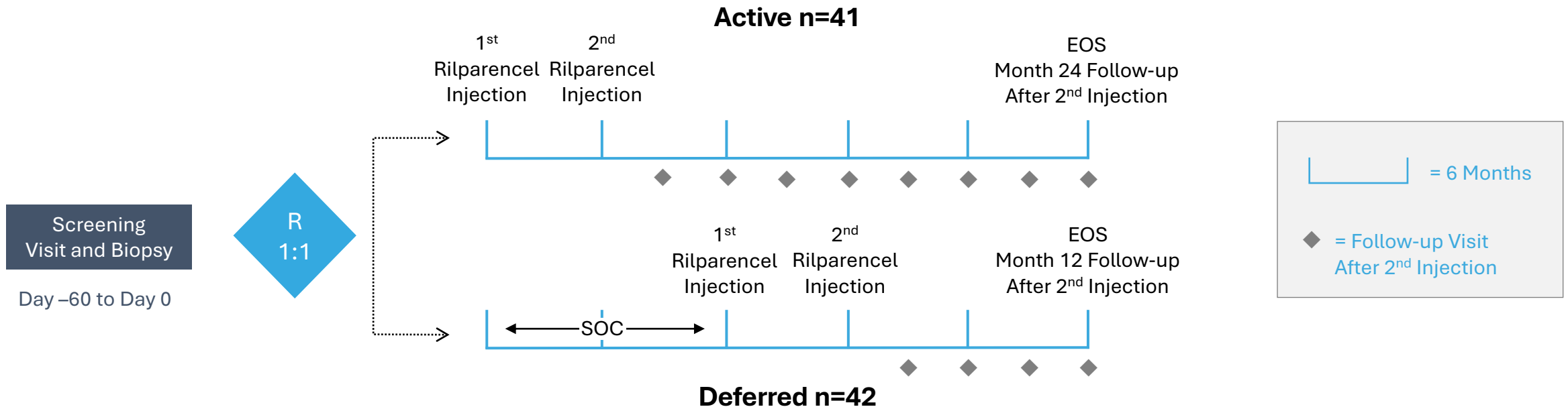
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RMCL-002: Trial Design



Key Entry Criteria

- Type 2 Diabetes Mellitus (DKD)
- Male or female 30-80 years of age
- eGFR ≥ 20 and ≤ 50 mL/min/1.73m²
- Not on kidney dialysis, HbA1c <10%

Study Endpoints

- Rilparencel and procedure related adverse events**
- Change in kidney function (assessed by eGFR)**

Study Timeframe

- First patient injected in 2017
- RMAT granted for Phase 3 program in January 2022

RMCL-002: Study Objectives and Endpoints

Study Objectives

- To assess the safety and efficacy of up to two rilparencel 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)

RMCL-002 Baseline Subject Characteristics are Balanced and Represent a High-Risk CKD Population

| | ACTIVE ARM (n=41) | DEFERRED ARM (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 | 2.5% | 14% |
| White | 95% | 74% |
| Other | 2.5% | 12% |
| Blood pressure, mm HG | 133 / 72 | 135 / 73 |
| eGFR, ml/min/1.73m² (mean +/- SD) | 33.9 +/- 8.6 | 31.7 +/- 7.4 |
| Stage 3A CKD, n (%) | 5 (12%) | 3 (7%) |
| Stage 3B CKD, n (%) | 21 (51%) | 18 (43%) |
| Stage 4 CKD, n (%) | 15 (37%) | 21 (50%) |
| UACR mg/g (median +/- interquartile range) | 740 (68, 1597) | 598 (58, 1985) |
| Geometric Mean of UACR mg/g | 389 | 330 |
| HbA1c, % (mean +/- SD) | 7.2 +/- 1.0 | 7.1 +/- 1.0 |

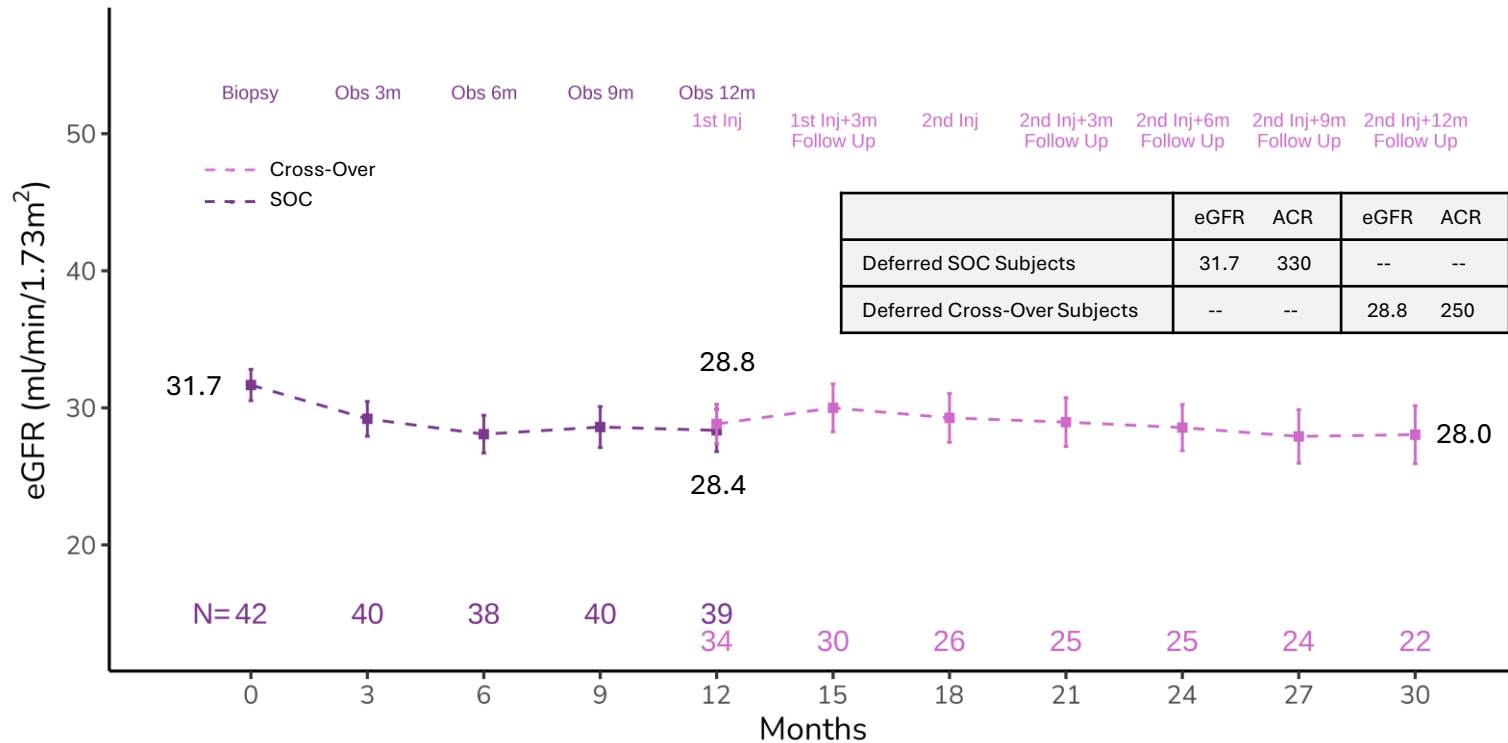
No Rilparencel-related SAEs Identified in RMCL-002

| ADVERSE EVENT | BIOPSY # of events (n=83)* | RILPARENCEL INJECTION # of events (n=132)* |
|---|----------------------------------|--|
| Hematoma (including Page Kidney during biopsy) | 2 | 2 |
| Pain | 0 | 2 |
| Acute Kidney Injury | 1 | 1 |
| CKD progression (eGFR progression) | 0 | 1 |
| Pyrexia | 0 | 1 |
| Anemia | 0 | 1 |
| Pneumonia | 0 | 1 |
| Creatinine increase | 0 | 1 |

Other events with possible-relatedness include kidney fibrosis and indeterminate renal vessel occlusion or vasospasm

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

Deferred Arm Subjects



| | eGFR | ACR | eGFR | ACR |
|------------------------------|------|-----|------|-----|
| Deferred SOC Subjects | 31.7 | 330 | -- | -- |
| Deferred Cross-Over Subjects | -- | -- | 28.8 | 250 |

Average eGFR of the Deferred cohort was 31.7 at baseline vs 28.4 at 12 months

[absolute difference of -3.3 ml/min/1.73m² over 12 months]

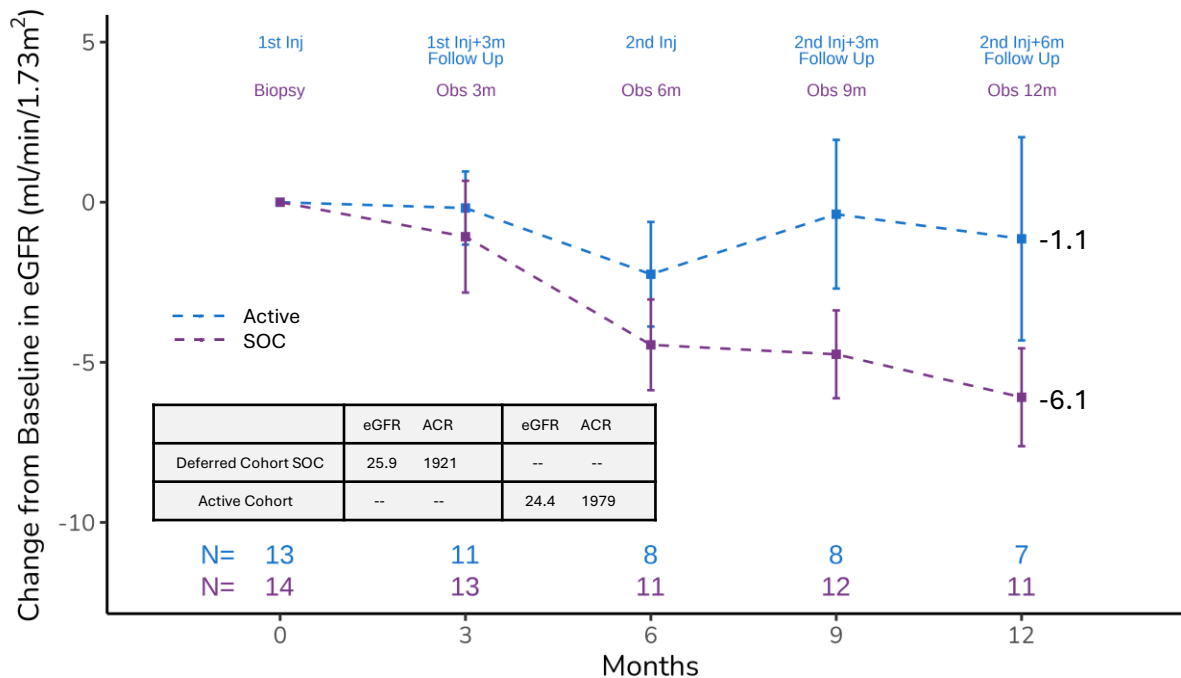
Average eGFR at 1st injection after cross-over was 28.8 vs 28.0 at 18 months

[absolute difference of -0.8 ml/min/1.73m² over 18 months]

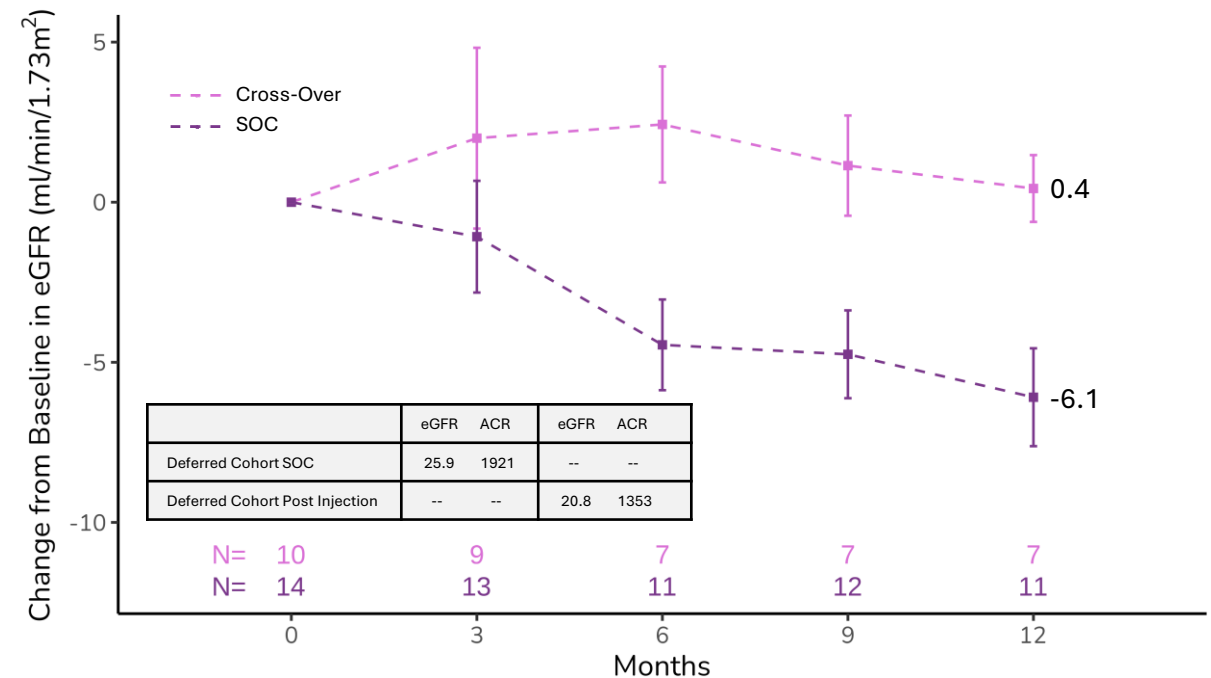
Subgroup Analysis of Diabetic Subjects with CKD Stage 4 and Class A3 Albuminuria*

Stabilization of Kidney Function in Active and Deferred Arm Subjects at 12 Months vs SOC

UACR Severe & CKD4 Subgroups in Active vs Deferred Arm



UACR Severe & CKD4 Subgroups in Deferred Arm



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

RMCL-002 Final Data Takeaways

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 subjects who had the **highest risk of kidney failure** (Stage 4 CKD with high UACR¹)
- Injections were **well tolerated** with a consistent safety profile comparable to kidney biopsy

Key Actions

We have **enriched** our Phase 3 PROACT 1 Study to include more subjects with the **highest risk of kidney failure**

PROACT 1 **amendment completed and submitted to the FDA** in late March

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 Stage 3/4 CKD (20-35 mL/min/1.73m ² , n=685) |  | 006/PROACT 1 | | | | | Ongoing |
| Diabetes Type II – Prevent/Delay ESRD in Stage 3/4 CKD (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 Stage 3/4 CKD (20-50 mL/min/1.73m ² , n=83 randomized) |  | 002 | | | | | Final Data Presented |
| Diabetes Type I & II – Prevent/Delay ESRD in Stage 3/4 CKD (20-50 mL/min/1.73m ² , n=53 randomized) |  | 007 | | | | | Fully Enrolled |
| Completed Trials | | | | | | | |
| Diabetes Type II – Delay ESRD in Stage 4/5 CKD (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

Q&A