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STOCKHOLM & VIRTUAL
MAY 23-26, 2024

Rilparencel Renal Autologous Cell Therapy for Patients with Stage 3-4 CKD and Type 2 Diabetes: Results from a Phase 2 Clinical Trial

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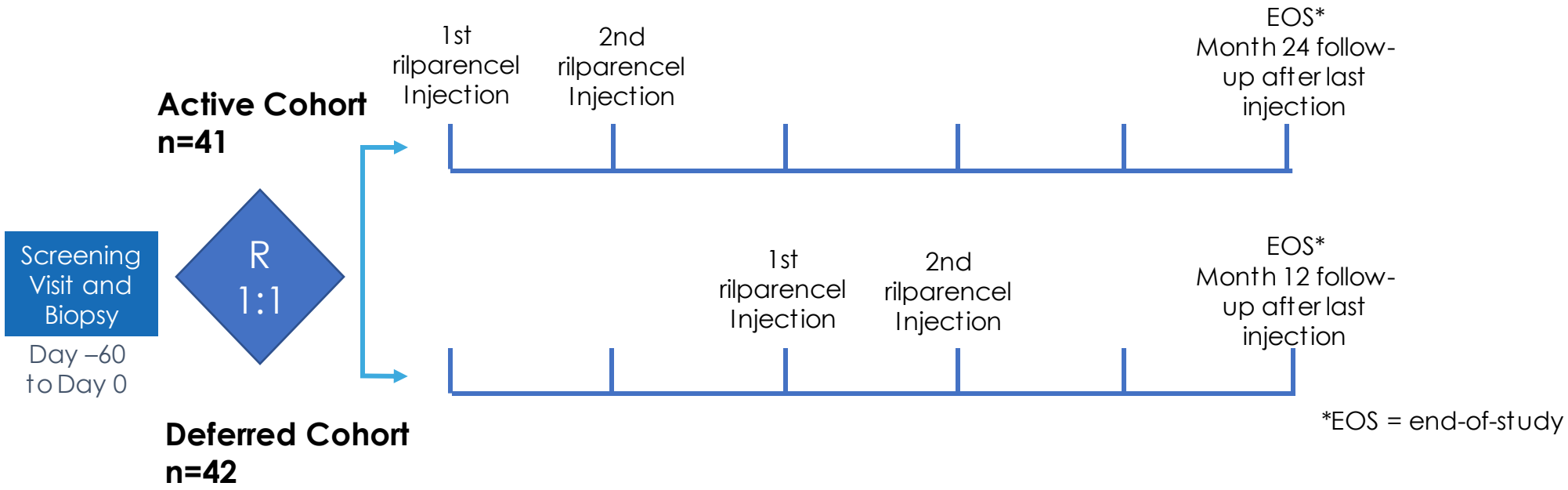
About ProKidney

- Cell-based biotechnology company located in the United States
- 18+ years of proprietary discovery in kidney disease cell therapy
- 11+ years Phase 1-3 clinical trials in subjects with moderate to severe CKD
- Company owned manufacturing and operations
- Investigational product, rilparencel (REACT®), is an autologous cell-based therapy currently in phase 3 trials

Trial Objectives and Endpoints

Trial Objective	• To assess the safety and efficacy of rilparencel in subjects with type 2 diabetes (T2DM) and moderate-to-severe chronic kidney disease (CKD)
Primary Efficacy Endpoint	• Change in kidney function, determined by serial measurements of eGFR
Primary Safety Endpoint	• Procedural- and product-related adverse events related to kidney biopsy, cell injection procedure, and investigational product

Study Design



Key Inclusion Criteria

- Type 2 diabetes mellitus with CKD
- Male or Female 30-80 years of age
- eGFR ≥20 and ≤50 mL/min/1.73m2
- BP<150/90 mmHG, A1c<10%, Hgb>9mg/dl @Bx
- Not on renal dialysis

- Time between 1st and 2nd rilparencel injections = 3-6 months
- Follow-up visits conducted at 3-month intervals

Methods

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Trial Timeline

- First Subject, First Visit
  - February 2017
- Last Subject, Last Visit
  - December 2023
- Database Lock
  - March 2024

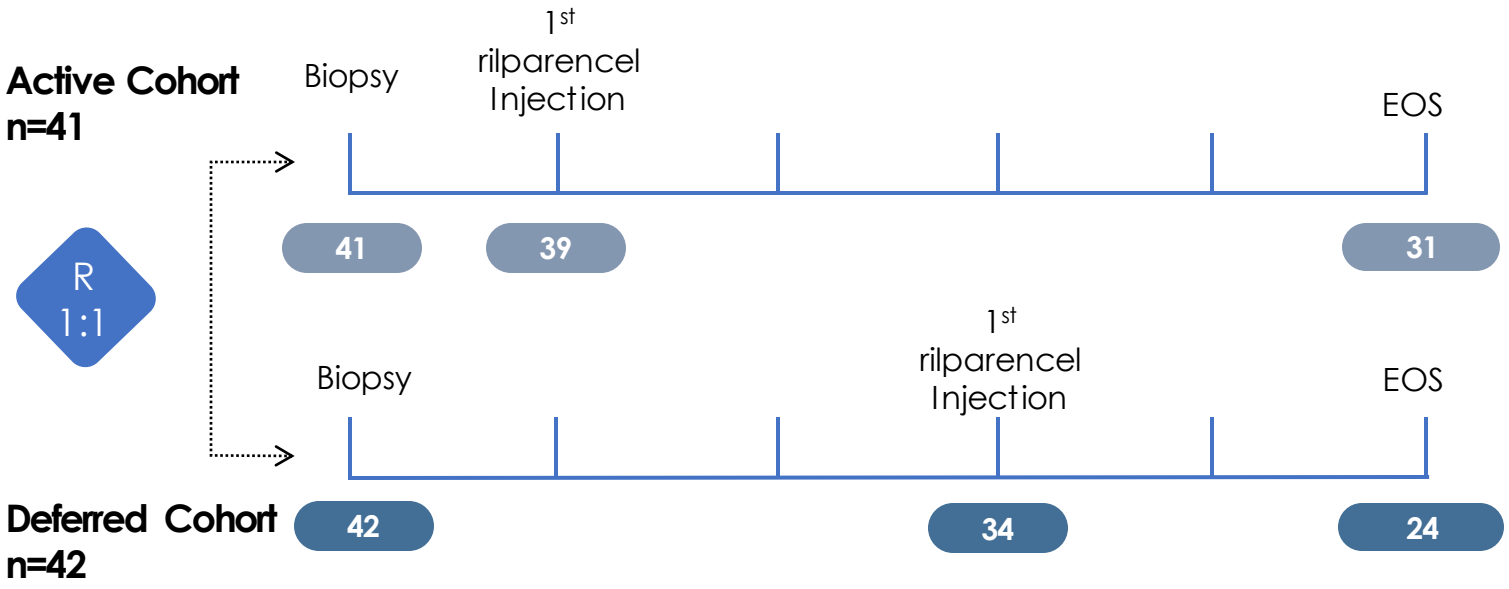
Rilparencel Procedures

- Ex vivo cultured expansion of cells from percutaneous kidney cortex biopsy
- Selected Renal Cells are formulated in gelatin-based hydrogel
- Concentration 100x10^6 cells/mL
- Up to 2 injection are performed in the same kidney as biopsy
- Cells are injected into the kidney cortex with CT guidance as an out-patient procedure
- Subject care after kidney biopsy and cell injection followed local standards of care

Statistical Analysis

- Analyses were performed on subjects who were randomized and biopsied
- The primary efficacy endpoint is summarized as average change (SEM) in eGFR from baseline
- eGFR slope is summarized using a linear mixed effects model
- Imputation was used for missing adverse event (AE) dates; windows around scheduled visits were used for efficacy analyses in lieu of imputation

Subject Flow



- 158 subject screenings occurred with 75 screen fails
- Death
  - 3 deaths occurred in the Active Cohort prior to end of study
  - 4 deaths occurred in the Deferred Cohort prior to end of study
- Dialysis
  - 3 subjects in the Active Cohort started dialysis
  - 6 subjects in the Deferred Cohort started dialysis. 1 subject began dialysis during SoC

ACTIVE COHORT

41	41 subjects were randomized to the Active Cohort and biopsied
39	Before 1st Injection: 2 subjects withdrew
31	Before End of Study: 3 subjects withdrew consent, 3 subjects died, 2 were lost to follow up

DEFERRED COHORT

42	42 subjects were randomized to the Deferred Cohort and biopsied
34	Before receiving rilparencel: 8 subjects withdrew
24	Before End of Study: 4 subjects died, 3 were lost to follow up, 2 withdrew consent, and 1 was non-compliant

Screening Demographics

Characteristics	Group 1 (Active Treatment, n=41)	Group 2 (Deferred Treatment, n=42)
Age, years (mean +/- SD)	66.0 +/- 10.0	64.5 +/- 8.9
Male (n)	29	27
Race (n)		
White	39	31
African American, Black, Asian, Other	2	11
Body Mass Index, kg/m^2	33.4 +/- 6.1	33.7 +/- 5.5
Systolic blood pressure, mmHg	127.6 +/- 17.0	133.4 +/- 14.9
Diastolic blood pressure, mmHg	72.1 +/- 9.7	73.4 +/- 10.3
eGFR, ml/min/1.73 m^2	34.3 +/- 8.5	31.6 +/- 8.1
UACR, mg/g median, [IQR]	740 [68-1694]	584 [56-2016]
Hemoglobin A1c, %	7.2 +/- 1.0	7.1 +/- 1.0
Concomitant Medications (n, %)		
SGLT2i	4 (9.8)	2 (4.8)
GLP-1	10 (24.4)	9 (21.4)
ACEi/ARB	34 (82.9)	32 (76.2)

Procedure and Product Safety Results

3 SAEs Related to Biopsy (n=83)

- 1 hematoma
- 1 Page Kidney
- 1 AKI

10 SAEs Related to Injection (n=132)

- 2 hematoma
- 2 pain (back & abdominal)
- 1 AKI
- 1 anaemia
- 1 pyrexia
- 1 pneumonia
- 1 blood creatinine increase
- 1 eGFR decrease

0 SAEs Related to Product (n=132)

- none

- This safety data reflects the clinically significant serious adverse events (SAE)

- Other adverse events with possible relatedness include:
  - Kidney fibrosis
  - Indeterminate renal vessel occlusion or vasospasm

Non-Procedure Related SAEs

Area of Interest	n (%)
Cardiac Death	2 (2.7)
Serious cardiac disorders	14 (19.2)
Acute myocardial infarction	7 (9.6)
Cardiac arrest	5 (6.8)
Coronary artery disease	4 (5.5)
Serious Renal and Urinary Disorders	19 (26.0)
Acute kidney injury	11 (15.1)
End stage renal disease	5 (6.8)
Serious Respiratory, thoracic and mediastinal disorders	11 (15.1)
Serious Infections and Infestations	19 (26.0)
Serious Metabolism and Nutrition Disorders	5 (6.8)

Primary Efficacy Result - Change in eGFR

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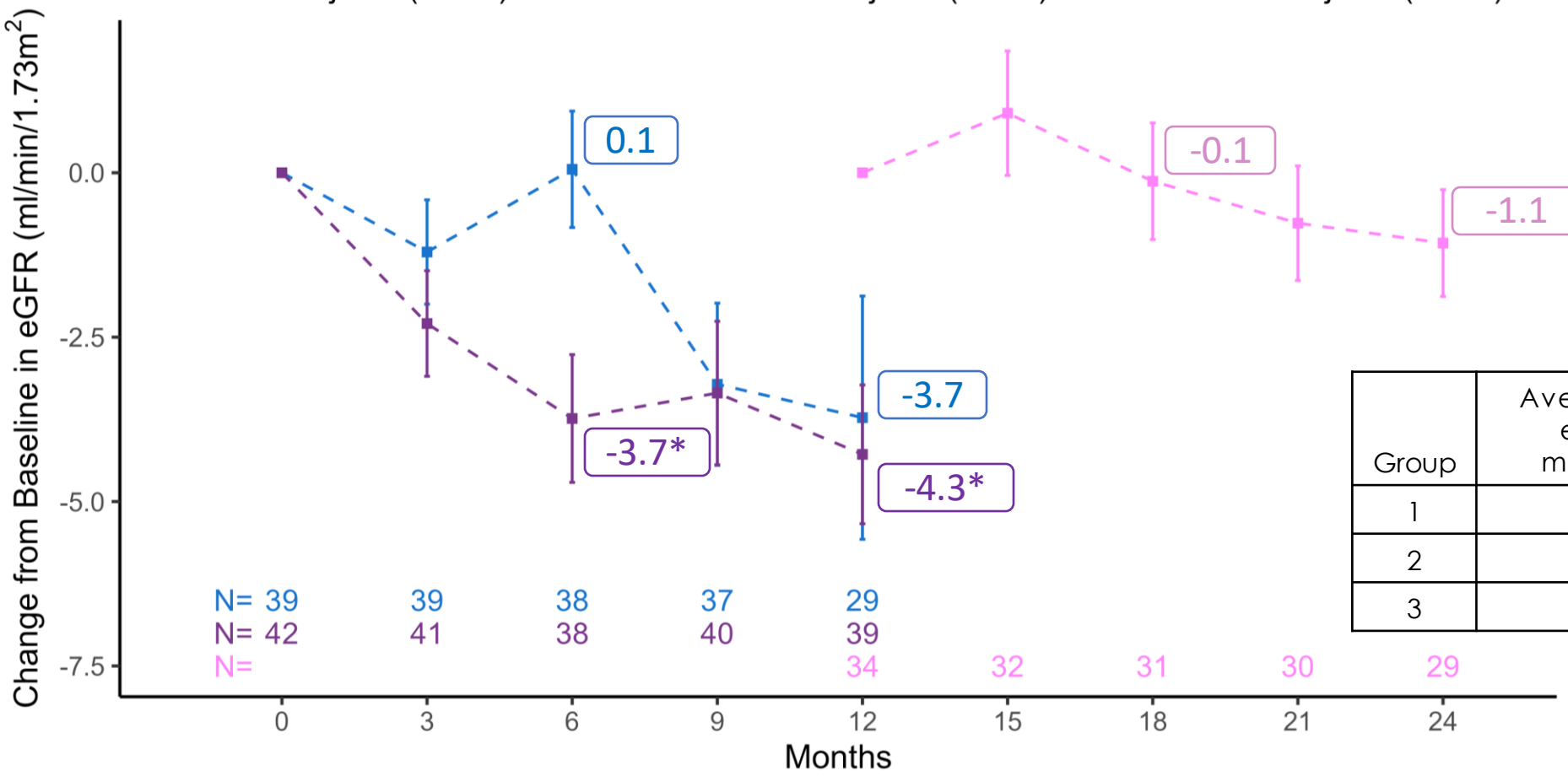
Active Subjects (N=39) v. Standard of Care Subjects (N=42) v. Cross Over Subjects (N=34)



Group	Average baseline eGFR (SEM) ml/min/1.73m²
1	32.8 (1.4)
2	31.7 (1.2)
3	28.8 (1.4)

*T-Test of Change from Baseline: P-value <0.05

Long Term eGFR Change from Baseline

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Average Change from Baseline in eGFR ml/min/1.73m^2

	18 Months	24 Months	30 Months
Group 1 (Active Treatment)	-3.1 (n=26)	-4.5* (n=29)	-7.0* (n=24)
Group 3 (Deferred Treatment: rilparencel injection)	-1.8* (n=24)	-0.1 (n=15)	-2.8 (n=12)

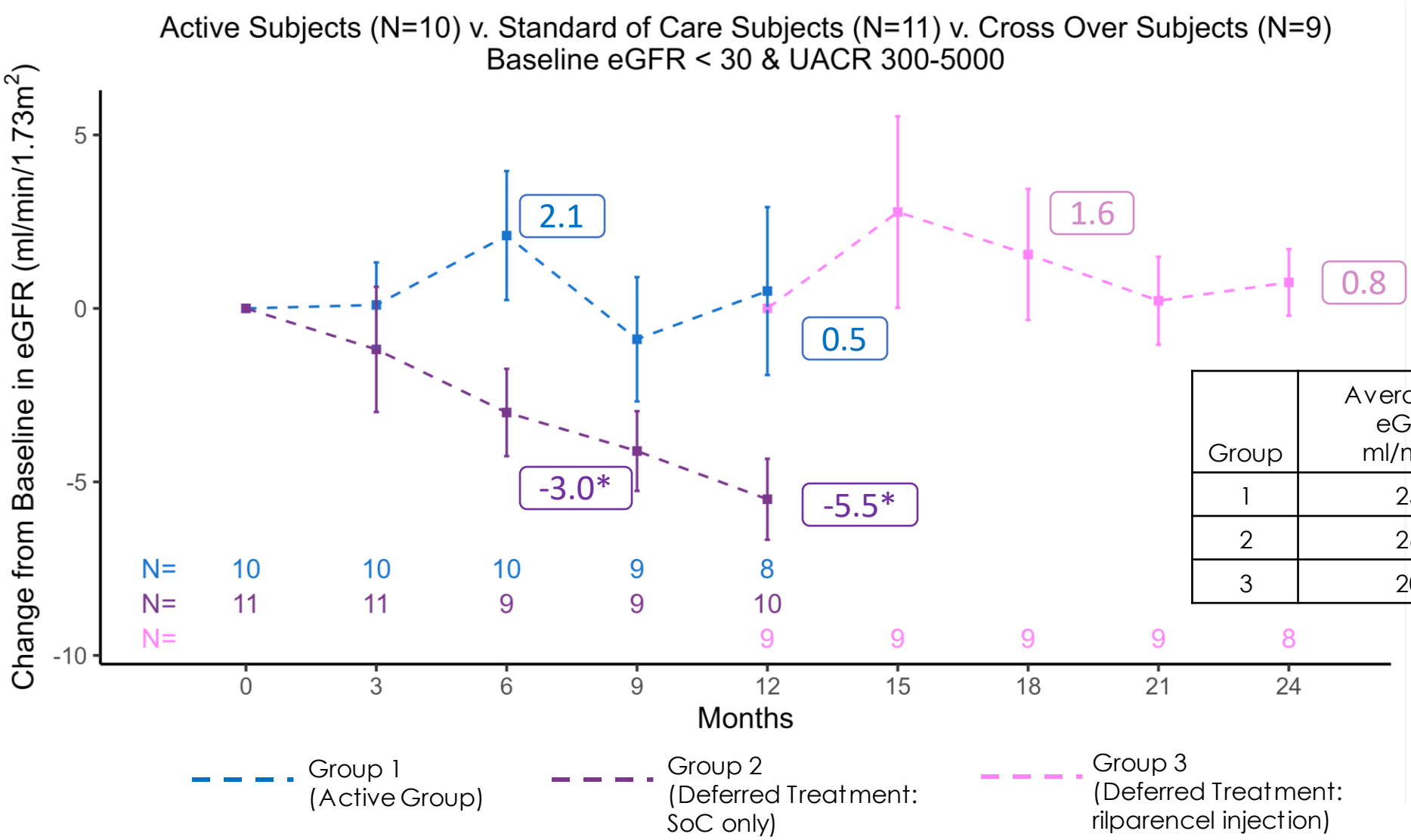
*T-Test of Change from Baseline: P-value <0.05

eGFR Slope Change

	Annualized eGFR Slope* (95% CI) Over 12 months ml/min/1.73m²/year	**Annualized eGFR Slope* (95% CI) Through End of Study ml/min/1.73m²/year**
Group 1 (Active Treatment)	-3.0 (-5.7, -0.2)	-3.0 (-4.3, -1.8)
Group 2 (Deferred Treatment: SoC Only)	-2.3 (-4.5, -0.1)	-2.8 (-4.5, -1.1)
Group 3 (Deferred Treatment: rilparencel injection)	--	-1.5 (-2.5,-0.4)

*Slope Calculated using a Linear Mixed Effects Model

Post-hoc Subgroup Analysis



Group	Average baseline eGFR (SEM) ml/min/1.73m^2
1	25.4 (1.4)
2	26.1 (0.8)
3	20.9 (0.9)

*T-Test of Change from Baseline: P-value <0.05

Key Study Limitations

- Open label trial design
- Randomized control group (SoC comparator) had only 12-month follow-up
- No upper threshold on UACR inclusion criteria
- Limited subject diversity
- COVID pandemic - reduced clinical site visits, lab assessments and limited facility access for procedures

Summary and Conclusion

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Key Findings

- Subjects randomized to the deferred treatment arm experienced less decline in kidney function after rilparencel treatment versus standard of care
- Kidney function stabilized in a subgroup of subjects with Stage 4 CKD and severe UACR
- Observed procedure and product related SAEs were tolerable and consistent with expected events from percutaneous kidney interventions

Conclusion

- Rilparencel, an autologous cell-based therapy, may preserve kidney function in subjects with type 2 diabetes and moderate-to-severe CKD
- Rilparencel is under further investigation in a global phase 3 study program

Thank you to our RMCL-002 Sites and Investigators

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