Proposed Clinical Study Protocol for KidneyCell

A Phase II, Randomized, Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of Intravenous (IV) Infusion of KidneyCell in Patients with Moderate to Severe Chronic Kidney Disease (CKD)

Proposed DRAFT

Study Description

This is a Phase II, randomized, open-label, multicenter study designed to evaluate the safety and efficacy of KidneyCell, an investigational cell-based therapy, in patients with moderate to severe chronic kidney disease (CKD). Chronic kidney disease is a progressive condition characterized by the gradual loss of kidney function, which can lead to end-stage renal disease (ESRD) and the need for dialysis or kidney transplantation. Current treatments focus on managing symptoms and slowing disease progression, but there is a significant unmet medical need for therapies that can promote tissue repair and improve kidney function.
KidneyCell consists of [Insert Brief Description of Cell Source and Mechanism of Action, e.g., mesenchymal stromal cells (MSCs) derived from [Source] that have been shown to possess anti-inflammatory and regenerative properties]. This study will evaluate the safety and efficacy of two different dose levels of KidneyCell compared to standard of care (SOC) in patients with CKD Stage 3b or 4.

Condition or disease	Intervention/treatment	Phase
Chronic Kidney Disease Kidney Failure, Chronic	Drug: KidneyCell - Low Dose (1 x 10^6 cells/kg body weight) Drug: KidneyCell - High Dose (2 x 10^6 cells/kg body weight) Other: Standard of Care (SOC) including blood pressure control, ACE inhibitors or ARBs, and management of CKD complications	Phase 2 Phase 2

Study Design

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	120 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open-Label)
Primary Purpose:	Treatment
Official Title:	A Phase II, Randomized, Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of Intravenous (IV) Infusion of KidneyCell in Patients with Moderate to Severe Chronic Kidney Disease (CKD)
Estimated Study Start Date:	October 2026
Estimated Primary Completion Date:	October 2028
Estimated Study Completion Date:	December 2028

Arms and Interventions

Arm	Intervention/treatment
Experimental: KidneyCell - Low Dose Single IV infusion of KidneyCell at a dose of 1 x 10^6 cells/kg	**Drug: KidneyCell - Low Dose** Cell Therapy product (IV Infusion)
Experimental: KidneyCell - High Dose Single IV infusion of KidneyCell at a dose of 2 x 10^6 cells/kg	**Drug: KidneyCell - High Dose** Cell Therapy product (IV Infusion)
Active Comparator: Standard of Care (SOC) Standard medical management for CKD as per current clinical guidelines	**Drug: SOC for CKD** Blood pressure management, ACE inhibitors/ARBs, etc.

Outcome Measures

Primary Outcome Measure:

- Change from baseline in estimated Glomerular Filtration Rate (eGFR) at 12 months post-infusion [Time Frame: Baseline to 12 months]
- Incidence of Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs) [Time Frame: From infusion through 12 months]

Secondary Outcome Measures:

- Change from baseline in eGFR at 3, 6, and 24 months post-infusion [Time Frame: Baseline to 24 months]

- Change from baseline in Urine Albumin-to-Creatinine Ratio (UACR) [Time Frame: Baseline to 12 and 24 months]
- Change from baseline in serum creatinine levels [Time Frame: Baseline to 12 and 24 months]
- Time to progression to End-Stage Renal Disease (ESRD) or need for dialysis [Time Frame: Up to 24 months]
- Changes in health-related quality of life (HRQoL) as measured by the KDQOL-36 questionnaire [Time Frame: Baseline to 12 and 24 months]

Eligibility Criteria

Ages Eligible for Study: 18 Years to 75 Years (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No
Inclusion Criteria:
- Diagnosis of Chronic Kidney Disease (CKD) Stage 3b or 4.
- Estimated GFR (eGFR) between 15 and 44 mL/min/1.73m² (using the CKD-EPI equation).
- Stable medical management of CKD for at least 3 months prior to screening.
- Subject must be willing and able to provide informed consent and comply with all study procedures.

Exclusion Criteria:
- Kidney transplant recipient or currently on dialysis.
- History of malignancy within the last 5 years (excluding non-melanoma skin cancer).
- Active systemic infection or known HIV, Hepatitis B, or Hepatitis C infection.
- Uncontrolled hypertension (Systolic BP > 160 mmHg or Diastolic BP > 100 mmHg).
- Current pregnancy or breastfeeding.
- Any other medical condition that, in the opinion of the investigator, would make the subject unsuitable for the study.

Contacts and Locations

Information from the Sponsor: KidneyCell Medical Affairs
For more information on this study, please contact: clinicaltrials@kidneycell.com
Locations:
- **United States, New York:** NYU Langone Health, New York, NY
- **United States, California:** UCLA Medical Center, Los Angeles, CA
- **United States, Texas:** Houston Methodist Hospital, Houston, TX

More Information

Responsible Party:	KidneyCell Therapeutics Inc.
ClinicalTrials.gov Identifier:	NCT[Pending]
Other Study ID Numbers:	KC-2026-02

Study First Submitted:	May 11, 2026
Last Update Posted:	May 11, 2026

Note: This is a proposed protocol and is subject to change based on regulatory feedback and further internal review.
