Renal Autologous Cell Therapy/Neo-Kidney Augment™ (REACT/NKA): Phase II study of REACT/NKA implantation in Type 2 Diabetes with Pre-Stage 5 Chronic Kidney Disease

Joseph Stavas1, Tim Bertram1, Deepak Jain1, Ashely Johns1, David Gerber2, Prabir Roy-Chaudhury3, George Bakris4

inRegen/Twin City Bio, Cayman Islands/USA1, University of North Carolina School of Medicine, Division of Transplant Surgery, Chapel Hill, NC2, University of North Carolina School of Medicine, Division of Nephrology, Chapel Hill, NC3, University of Chicago School of Medicine, Division of Nephrology, Chicago, IL USA

INTRODUCTION

Progenitor Cell-based Phase II Trial of Renal Autologous Cell Therapy™ (REACT) to delay T2DM Pre-Stage 5 CKD RRT (NCT03270956)

Multiple renal therapies have appeared in the clinical development pipeline for diabetic kidney disease. Most trials focus on biochemical or genomic aspects of various disease pathways of CKD. There are limited cell-based therapies under investigation in pre-stage 5 CKD to delay Renal Replacement Therapy.

MATERIALS and METHODS

- Completed enrollment Q1 2020
- Multi-center, prospective, open-label
- Single group study assignment
- Nonrandomization (10 subjects)
- Percutaneous kidney biopsy and injection
- 2nd dose after 6 months in same kidney
- If unqualified for 2nd dose, will stay in trial FU
- 2 yr. follow-up for each Cohort then 5 year LTFU

MAJOR INCLUSION

- Male, Female ages 30-65 years
- T2DM and Diabetic Kidney Disease
- No dialysis, eGFR 14-20 ml/min/1.73m2
- Blood pressure stable and < 150/90 mm Hg
- > 2 values of eGFR or sCr @ 3 months prior
- Rate of CKD progression over last 18 months
- Refrain from fish oil & anti-inflammatory agents
- Delay in RRT/Death
dose,

INCLUSION and EXCLUSION CRITERIA

MAJOR EXCLUSION

- Type 1 DM and other glomerular disease
- Renal transplantation
- hHbA1c > 10% at screening
- Metabolically unstable diabetes
- Hgb < 9 g/dl prior to NKA implantation
- Small kidneys, single kidney by US or MRI
- A1c or rapid decline in renal function
- Renal masses, large cysts, APCKD, anatomy
- Cancer within 3 years

OUTCOMES/ OBSERVATIONS

1. PRIMARY OUTCOME
   Procedure and/or product adverse events to 24 mos.

2. SECONDARY OUTCOME
   Renal specific adverse events

3. OTHER OUTCOMES
   Renal function assessment; eGFR slope, sCr, proteinuria

CONCLUSIONS and FUTURE DIRECTIONS

- Trial enrollment completed Q1 2020
- Early interim analysis supports:
  - Product safety
  - Procedure safety
- Planned Phase III efficacy endpoints:
  - eGFR slope/ACR reduction
  - Delay in RRT/Death
- Global Phase III trial design pending
- REACT™ offers options to delay RRT for eGFR range 14-20 ml/min.

REFERENCES

A. Lewy et al. "Change in albuminuria and GFR as end points for clinical trials in early stages of CRD: a meta-analysis sponsored by the NET in collaboration with the US FDA and EMSA". AKD 2020;75:84-104
L. Imker et al. (2019) "GFR slope as a surrogate end point for kidney disease progression in clinical trials: a meta-analysis of treatment effects of randomised controlled trials". AKD 2019; 30:1753-1765

CONTACT

Contact: Joseph Stavas MD, MPH, FACR, FSIR
jstavas@inregen.com
inRegen/Twin City Bio, LLC
8200 Arco Corporate Drive, Suite 118
Raleigh, NC USA 27617