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

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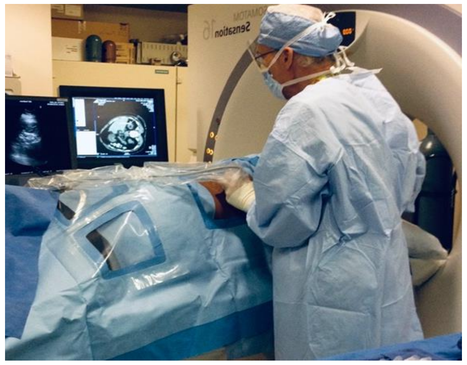
INTRODUCTION

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

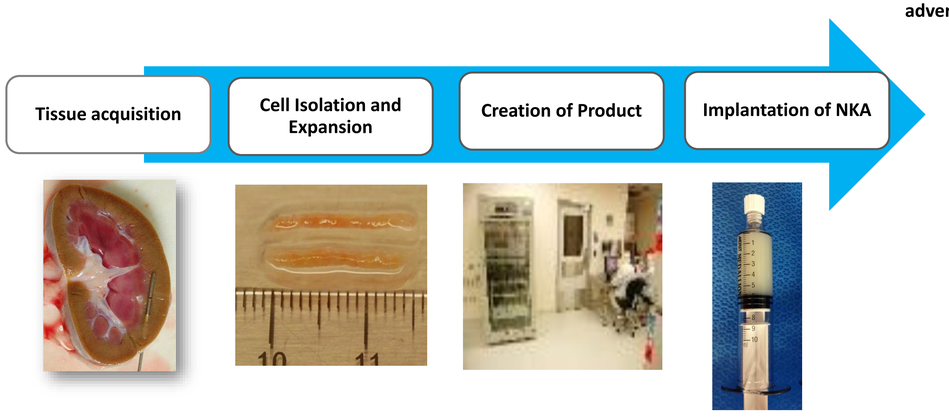
Multiple renal therapies have appeared in the clinical development pipeline for diabetic kidney disease. Most trials focus on biochemical or genomic aspects of various disease pathways of CKD. There are limited cell-based therapies under investigation in pre-stage 5 CKD to delay Renal Replacement Therapy.

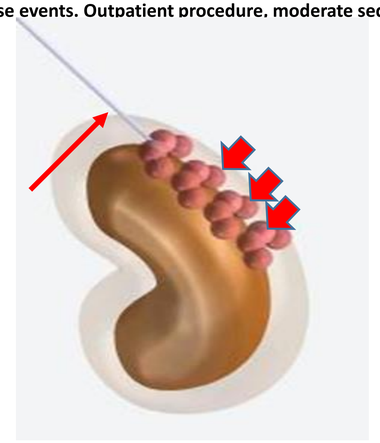
MATERIALS and METHODS

- 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



CT real-time precision implant of REACT™ & observation for adverse events. Outpatient procedure, moderate sedation.





Atraumatic small gauge needle tip (arrow) in kidney Cortex showing REACT injection deposits (arrowheads).

INCLUSION and EXCLUSION CRITERIA

MAJOR INCLUSION

- Male, Female ages 30-65 years
- T2DM and Diabetic Kidney Disease
- No dialysis, eGRF 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 ASA, NSAIDS, warfarin
- Refrain from fish oil & anti-platelet agents
- Able to sign informed consent

MAJOR EXCLUSION

- Type 1 DM and other glomerular disease
- Renal transplantation
- HbA1c > 10% at screening
- Metabolically unstable diabetes
- Hgb < 9 g/dl prior to NKA implantation
- Small kidneys, single kidney by US or MRI
- AKI 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

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