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

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INTRODUCTION

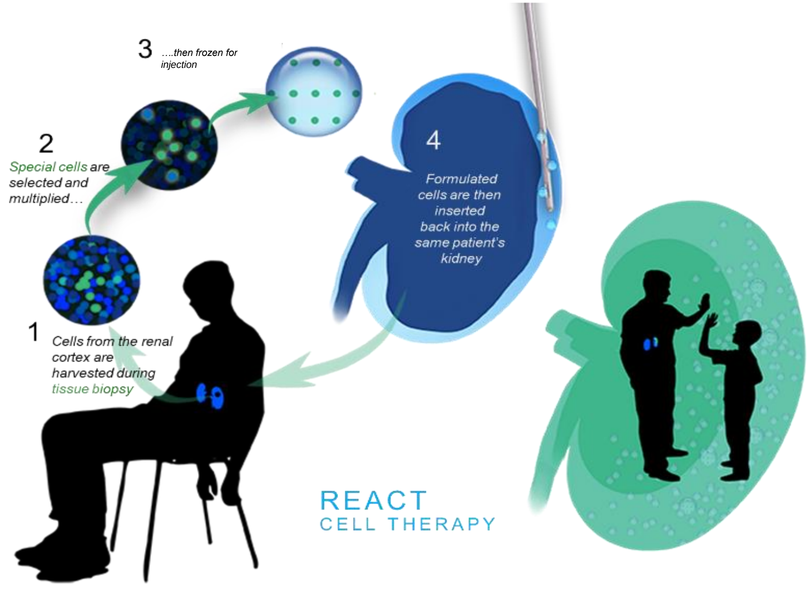
Progenitor Cell-based Phase II Trial of Renal Autologous Cell Therapy™ (REACT) to prevent or delay T2DM Stage 3b/4 CKD RRT (NCT 02836574)

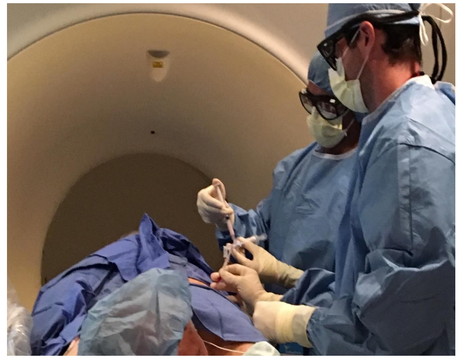
Multiple renal therapies have entered the clinical development pipeline for diabetic kidney disease. Most target a biochemical or genetic aspect of various disease pathways of CKD. Few CKD cell-based therapies are under investigation to avert RRT.

MATERIALS and METHODS

- Ongoing multi-center, prospective, open-label
- RCT with Active and Deferred Cohorts
- Randomization 1:1 (80 subjects)
- Percutaneous kidney biopsy and injection
- 2nd dose after 6 months in same kidney

- Deferred Cohort: SOC for 12 mo.
- CKD, glycemic, lipidemic, coagulation control
- Cross-over @12 months to Active Cohort
- 2 yr. follow-up for each Cohort then 5 year LTFU





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

Atraumatic small gauge needle tip (arrow) in cortex of Stage 4 CKD Kidney

INCLUSION and EXCLUSION CRITERIA

MAJOR INCLUSION

- Male, Female ages 30-80 years
- T2DM and Diabetic Kidney Disease
- No dialysis, eGRF 20-50 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

OBJECTIVES/OUTCOMES/OBSERVATIONS

1. PRIMARY OBJECTIVE
Assess safety and efficacy of up to 2 REACT injections
2. PRIMARY SAFETY ENDOPOINT
Procedural and product related adverse events
3. PRIMARY EFFICACY ENDPOINT
Improved renal function – eGFR chronic slope and ACR
4. QUALITY OF LIFE OBSERVATION
KDQOL Survey through 24 months

CONCLUSIONS and FUTURE DIRECTIONS

- *Trial enrollment completed by 2H2020*
- *Interim analysis supports:*
  - *Product safety*
  - *Procedure safety*
- *Global Phase III trial design underway*
- *Phase III efficacy endpoints:*
  - *eGFR slope/ACR reduction*
  - *Delay in RRT/Death*
- *REACT™ offers options to delay RRT for late stage CKD*

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Trial Contact

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TWIN CITY BIO

RESEARCH STUDY CONDUCTED at 16 Major Academic Research Centers and Internationally recognized investigators