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

MAJOR INCLUSION
- Male, Female ages 30–80 years
- T2DM and Diabetic Kidney Disease
- No dialysis, eGFR 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

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

MATERIALS and METHODS

2. PRIMARY SAFETY ENDPNT

Assess safety and efficacy of up to 2 REACT injections

3. PRIMARY EFFICACY ENDPNT

Procedural and product related adverse events

4. QUALITY OF LIFE OBSERVATION

KDQOL Survey through 24 months

REFERENCES

A. Levey et. al. “Change in albuminuria and eGFR as end points for clinical trials in early stages of CKD: a scientific workshop sponsored by the NKF in collaboration with the US FDA and EMA”, AJKD 2020;75:84–104
L. Inker et. al. (2019) "GFR slope as a surrogate end point for kidney disease progression in clinical trials: a meta-analysis of treatment effects of randomized control trials" JASN 2018; 30:1753-1763.

Trial Contact

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CONCLUSIONS and FUTURE DIRECTIONS

- Trial enrollment completed for 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

OBJECTIVES/OUTCOMES/OBSERVATIONS

1. PRIMARY OBJECTIVE

Assess safety and efficacy of up to 2 REACT injections

2. PRIMARY SAFETY ENDPNT

Procedural and product related adverse events

3. PRIMARY EFFICACY ENDPNT

Improved renal function – eGFR chronic slope and ACR

4. QUALITY OF LIFE OBSERVATION

KDQOL Survey through 24 months

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