
Cellular Immunotherapy for Induction of Immune Tolerance in HLA Matched Living Donor Kidney Transplant Recipients

Grant Award Details

Cellular Immunotherapy for Induction of Immune Tolerance in HLA Matched Living Donor Kidney Transplant Recipients

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-10411

Project Objective: Complete a Phase 1 clinical trial of combined kidney and hematopoietic stem cells transplants from HLA - matched living donors.

Investigator:

Name:	Daniel Brennan
Institution:	Medeor Therapeutics, Inc.
Type:	PI

Disease Focus: Kidney Disease, Kidney Failure

Human Stem Cell Use: Adult Stem Cell

Cell Line Generation: Adult Stem Cell

Award Value: \$11,217,155

Status: Active

Grant Application Details

Application Title: Cellular Immunotherapy for Induction of Immune Tolerance in HLA Matched Living Donor Kidney Transplant Recipients

Public Abstract: **Therapeutic Candidate or Device**

MDR-101 is cellular therapy consisting of kidney donor-derived CD34+ HSCs and CD3+ T-cells.

Indication

Maintenance of kidney allograft function after withdrawal of post-transplant immunosuppressant (IS) drugs in HLA matched kidney transplants recipients

Therapeutic Mechanism

Following infusion and engraftment of MDR-101, the progeny cells establish a state of mixed lympho-hematopoietic chimerism. This leads to a condition known as immune tolerance in which the transplanted kidney is no longer viewed as foreign by the recipient. This allows the gradual withdrawal of all immunosuppressive (IS) drugs that were previously required to prevent rejection of the transplanted kidney

Unmet Medical Need

It is well established the current IS drugs are directly nephrotoxic and have increased risks of diabetes, heart disease, and cancers and contribute to increased transplant recipient morbidity and mortality and coincident transplant organ loss. Elimination of IS drugs should minimize these risks.

Project Objective

Completion of P3 study and BLA submission to FDA

Major Proposed Activities

- cGMP manufacturing of MDR-101 product
- Demonstrate predictive value of donor mixed chimerism testing in recipients of HLA matched HSCs
- Demonstrate the ability to achieve durable immune tolerance

Statement of Benefit to California:

The proposed Phase 3 clinical study, will include several clinical sites within California, the state with more kidney transplants in 2016 than any other state. If successful, this clinical study, will lead to commercial availability of this therapy, which would improve the health status of California residents who have received an HLA-matched, living donor kidney transplants. The MDR-101 product is intended to eliminate the life long need for immunosuppressive drugs and known side effects.

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