Clinical Trial Collaborations: The Mathews Center for Cellular Therapy (MCCT) & the Comprehensive Transplant Center

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Solid organ transplantation has achieved success over the past twenty years. However, there are limitations that hold this treatment modality from achieving truly great success. Currently, patients who have a solid organ transplant must be maintained on drugs that ‘suppress’ their immune system and prevent their immune system from recognizing the transplanted organ as ‘foreign’ and rejecting the organ. These immunosuppressive drugs are usually effective in preventing the rejection of the organ but this comes with a steep price. These patients often times have poor quality of life due to the side-effects of taking these drugs for the rest of their lives, these patients are hospitalized more often, have a great rate of infection and also have a much greater rate of other organ failure. The MCCT, in conjunction with several clinical investigator groups within the Comprehensive Transplant Center, is developing and evaluating various forms of cellular therapy to induce tolerance after solid organ transplantation. Northwestern University and Northwestern Memorial Hospital are spearheading the use of cellular therapy to induce tolerance – made possible by the existence of the MCCT.

Dr. Leventhal was one of the first recipients of the Mathews Regenerative Medicine Endowment grants for FY2013. These funds were used to develop and validate the GMP (good manufacturing practices)-manufacturing of regulatory T cells (T-regs) for clinical use. While there is substantial literature that indicates that T-regs could be beneficial in eliciting tolerance in the transplant setting, their use has not been evaluated clinically due to the previous inability to generate T-regs in sufficient number and under GMP conditions to make this modality clinically feasible.

The data obtained by Dr. LeFever and the MCCT staff, under the auspices of this endowment, was submitted to the FDA for review which has resulted in FDA approval of our clinical trial and our manufacturing of the T-regs as therapy for patients undergoing kidney transplantation.

Dr. Leventhal seeks to harness the immunosuppressive activities of T-regs in order to induce tolerance and improve the outcomes in the kidney transplant patient population. He applied for additional funds for FY2014 from the endowment and these were granted as well. These funds will pay for the manufacture of T-regs for the first two patients in our clinical trial. These patients will receive their kidney transplant and their infusion of T-regs sometime during the summer of 2014.