

TRACT Therapeutics, Inc. Received FDA Approval for a Phase 2 Trial Using a Patient's Immune Cells to Prevent Organ Rejection

CHICAGO--([BUSINESS WIRE](#))-- TRACT Therapeutics, Inc., a biotechnology company developing personalized regulatory T-cell (Treg) therapy, announced today that it received Food and Drug Administration (FDA) approval to initiate a Phase 2 clinical trial to investigate the efficacy and safety of its novel therapy for kidney transplant recipients. The therapeutic approach, utilizing a patient's own cells, expanded in the laboratory and infused back to the patient after an organ transplant, shows promise in restoring immune balance so the body will accept the foreign organ instead of rejecting it. Current standard of care practices for transplant patients to prevent rejection requires the lifetime use of toxic medications which weaken the immune system causing life-threatening effects and eventual rejection of the organ in approximately 50% of the patients receiving a transplant. A National Institute of Health study in the U.S. recently revealed that organ recipients have a high risk of developing 32 different types of cancer. TRACT's innovative approach aims to change the standard treatment for transplant recipients by reducing or eliminating the lifelong use of immunosuppressive drug therapy.

The Phase 2 study of 120 subjects will evaluate the efficacy and safety of a single Treg infusion in kidney transplant recipients and is projected to initiate enrollment in a few months. "The limitations of drug-based immunosuppression have significantly increased interest in the use of regulatory T-cells to restore balance to the immune system and avoid transplant rejection," stated Joseph R Leventhal, MD, PhD, Director of Kidney and Pancreas Transplantation at Northwestern University Feinberg School of Medicine.

Gretchen S Johnson, President and CEO of TRACT Therapeutics, commented, "We are pleased to continue on our path toward approval and commercialization of this novel Treg therapy with the goal of greatly enhancing the lives of transplant patients around the world."

About TRACT Therapeutics

TRACT Therapeutics, Inc. is a clinical-stage biotechnology company developing a novel therapeutic approach to restoring immune balance in organ transplantation and autoimmune disease. Its proprietary platform technology, using autologous polyclonally expanded regulatory T-cells was developed at Northwestern University by pioneer, Joseph R Leventhal, MD, PhD and his research colleagues. TRACT will file for Orphan Drug Designation for organ transplantation in 2016. For additional information, visit our website at: www.tracttherapeutics.com

This press release contains forward-looking statements that express the belief, potential anticipation or expectation, as well as other statements which are not historical fact, and statements related to clinical trials and their results, design, FDA product approvals or other marketing approvals, features, functionality and performance. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected in these forward-looking statements. These risks include, among others: the regulatory approval process in the U.S. for biologics, market acceptance of new products, the ability to obtain and maintain patent or other proprietary intellectual property protection and the actual impact of those patents and rights, general market and economic factors, ability to effect transition from pilot-scale to large-scale commercial production of products, and availability of additional manufacturing capacity on acceptable terms.

Contacts

TRACT Therapeutics, Inc.
Gretchen S Johnson
President and CEO
(312) 587-0087

Source: TRACT Therapeutics, Inc.

View this news release online at:
<http://www.businesswire.com/news/home/20160429005792/en>