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IMMUNE TOLERANCE NETWORK TO FUND EXPANDED CLINICAL TRIAL OF EDMONTON ISLET TRANSPLANT TECHNIQUE

CHICAGO, IL - June 6, 2000 - The Immune Tolerance Network (ITN), one of the flagship clinical research projects of the US National Institutes of Health and Juvenile Diabetes Foundation announced today that it will begin a multicenter clinical trial of the “Edmonton Protocol” for islet transplantation. The trial, a first in islet transplantation, is slated to begin in the fall of this year and will perform approximately thirty-two new transplants at up to eight clinical centers across North America and Europe. The trial will attempt to further assess the effectiveness of the technique and identify any long-term risks associated with immunosuppressive therapies. Researchers hope the technique will serve as a platform for testing new treatments in which the permanent reversal of diabetes can be achieved without the need for immune suppressing therapies.

The new technique, developed by Dr. James Shapiro and colleagues at the University of Alberta, garnered international headlines last week after it was announced that all 8 patients they treated remain free from the need for daily insulin injections for up to 14 months following treatment. Published today for the July 27 issue of the *New England Journal of Medicine*, the Edmonton group’s methods have been hailed by researchers as a major breakthrough in the fight against diabetes, which affects an estimated 16 million Americans.

“Dr. Shapiro’s work represents one of the most significant breakthroughs we have seen to date in islet transplantation”, said Dr. Jeffrey Bluestone, Director of the Immune Tolerance Network.

Despite their obvious excitement, many scientists have noted that there remain several obstacles to the widespread application of the technique. Donor islet cells, removed from the pancreases of cadavers, are difficult to acquire. Furthermore, transplant recipients are required to take immunosuppressive drugs that prevent rejection of the islets and the long-term effects of these drugs are ill-defined, with potential harmful side-effects.

According to Bluestone, “The Immune Tolerance Network hopes this breakthrough will act as a launch pad for further advances that will allow us to free transplant recipients from the immune suppressive therapies.”

The mission of the ITN is the development of new immune tolerance therapies, highly specific treatments that reprogram the immune system to inhibit disease-causing immune responses while keeping beneficial, disease-fighting immune responses intact. The trial marks the first approved clinical trial in the ITN’s effort to develop more effective therapies for diseases such as diabetes, kidney disease, autoimmune diseases and allergy and asthma. The 144 million dollar research effort is led by a consortium of 70 world leaders in immune tolerance from over 40 institutions around the globe.

“The ITN is an intellectual powerhouse,” commented Dr. Robert Goldstein, Chief Scientific Officer of the Juvenile Diabetes Foundation. “It is exciting to see so many world-leaders working together with a single goal in mind.”

The participating clinical centers selected by the ITN will be announced in the coming months, following successful tests of each center's capabilities. The ITN will also open the trial on a self-funding basis to any other centers meeting stringent requirements. The Network will provide each center with support for additional studies designed to examine the effectiveness of the procedure and to investigate the underlying immunologic mechanisms at work following islet transplantation.

For more information visit the ITN website at www.immunetolerance.org or the JDF website at www.jdfcure.org.

The Immune Tolerance Network is a seven year, \$144 million dollar clinical research program headquartered at the University of Chicago and founded in October 1999 to solicit, develop, implement and assess clinical strategies and biological assays for the purposes of inducing, maintaining and monitoring tolerance in humans for kidney and islet transplantation, autoimmune diseases and allergy & asthma. The ITN is jointly sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) and the Juvenile Diabetes Foundation International. The NIAID and NIDDK are the funding institutes of the National Institutes of Health.

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