



Toronto General Hospital
University Health Network

MEDIA RELEASE: For Immediate Release

North America's first insulin-producing and 'protected' islet cell transplant performed at TGH

(Toronto, March 9, 2005) – Physicians at Toronto General Hospital, part of University Health Network successfully performed North America's first transplantation of specially coated insulin-producing islet cells into a patient with Type 1 diabetes on Tuesday Feb 22, 2005. The special coating on the islet cells protects the transplanted cells from the body's immune system reacting against them.

The patient was released from hospital three days after the procedure and is resting at home.

The procedure is part of a Phase I/II study to determine the safety and effectiveness of specially coated human pancreatic islets in improving the health and quality of life of diabetes patients without the need for long-term anti-rejection therapy. The clinical study's primary endpoints are safety assessments of the procedure at 180 days, with secondary endpoints examining the function of the transplanted insulin-producing islet cells.

The islet cells, encased in biocompatible microcapsules, are implanted into the abdominal cavity in a 20-minute surgical procedure. The capsules are permeable so that nutrients and glucose can get to the islets, and secreted insulin from the islets can get out into the blood.

Islets are insulin-producing cell clusters found within the pancreas. In diabetic patients, the pancreas does not produce enough insulin to regulate the body's blood sugar level. The study's goal is to have the transplanted cells produce enough insulin to control blood sugar levels to allow patients to either reduce or stop taking insulin entirely. Up to three million Canadians live with some level of diabetes and 200,000 need to take insulin.

Additionally, since the coating or capsule on the islets blocks the antibodies and T-cells of the immune system from reaching and destroying the transplant, there is no need for the patient to be on a long-term immune suppression regimen. To date, all transplant patients receive potent immunosuppressive medications for the rest of their lives after receiving a transplant.

Toronto General Hospital (TGH) physicians emphasize that many additional patients will have to be tested in clinical trials to determine how effective and long-term this treatment will be. This will take several more years, and the procedure is currently not a treatment option for patients with diabetes. Islet transplants are still experimental and are available only to people who participate in a clinical trial and meet specific criteria in the study protocol. TGH is the only hospital involved in this study and will enter only patients who have already been selected.

The clinical trial represents a new generation of islet transplantation technology by Amcyte Inc. of Santa Monica, California, who are the sponsors of this study.

"One of the aims of the Multi-Organ Transplant Program at TGH is to take advantage of the best technologies available in our efforts to make the lives of our patients better," said Dr. Gary Levy, Medical Director of the Multi Organ Transplant Program at TGH, "We believe that this clinical trial represents the next stage of islet transplantation technology that will allow us to explore a potential treatment consisting of a simple surgical procedure without exposing the patients to the health risks of long-term immune suppressive regimens."

Toronto General Hospital is a partner in University Health Network, along with Toronto Western and Princess Margaret Hospitals. The scope of research and complexity of cases at Toronto General Hospital has made it a national and international source for discovery, education and

patient care. It has one of the largest hospital-based research programs in Canada, with major research projects in transplantation, cardiology, surgical innovation, diabetes, infectious diseases, and genomic medicine. Toronto General Hospital is a teaching hospital affiliated with the University of Toronto.

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