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**IMMUNE MONITORING WITH IMMUKNOW® IN ISLET TRANSPLANTATION MAY PROVE USEFUL IN  
REDUCING THE POTENTIAL RISKS OF REJECTION, INFECTION AND OTHER COMPLICATIONS  
FOLLOWING TRANSPLANT**

*The results of these studies will be presented during the  
American Transplant Congress in Boston, MA, May 30 – June 3, 2009*

**Columbia, MD, May 30, 2009** – In an effort to improve the management of pancreatic islet recipients by managing graft stability and reducing immune system risk, Dr. Davide Mineo and colleagues at the Diabetes Research Institute at the University of Miami retrospectively studied 26 islet recipients to correlate ImmuKnow assay values with clinical outcomes over a 2-year period. Among transplant patients with functioning and stable islet grafts, the mean ImmuKnow ATP level was 216ng/mL. In contrast, the mean ImmuKnow ATP level in patients with graft dysfunction or failure was 370ng/mL and among those with infections or drug toxicity, the mean ImmuKnow value was 91ng/mL. In further support, fasting glucose and HbA1c as well as CD4+ T-lymphocytes positively correlated with ATP levels.

Dr. Mineo explained that monitoring immune function following pancreatic islet transplantation has been a complex procedure based on a variety of measures, such as reactive antibodies, drug levels, metabolic parameters and clinical status. “By themselves, none of these measures can be used to reliably predict clinical outcomes in these patients,” said Dr. Mineo. “The results of our study support the use of the ImmuKnow assay to reduce the risk of graft failure, infections or drug toxicity in islet transplant patients.”

These results are in agreement with a report from Baylor Research Institute’s study of patients at Baylor University Medical Center at Dallas and Baylor All Saints Medical Center at Fort Worth. Because diagnostic tests for pancreatic islet rejection are lacking, the appropriate level of immunosuppression required to prevent rejection has not been established. To assess the level of immune system competence and the potential of rejection or other complications related to over-immunosuppression, investigators prospectively monitored 5 patients with the ImmuKnow assay following islet transplantation. Three insulin-free patients maintained ImmuKnow levels of 180-450ng/ml. A fourth patient lost some graft function as ImmuKnow levels briefly decreased to 85-189ng/ml and the fifth had ImmuKnow levels <100ng/ml during a long period of infectious complications. That patient eventually gained insulin independence and the ImmuKnow levels increased to 258-374ng/ml.

Nicholas Onaca, MD, a transplant surgeon on the medical staff at Baylor University Medical Center at Dallas explains, “By using ImmuKnow, this study suggests that islet grafts can be maintained at lower levels of immunosuppression, but this raises the question whether graft loss from over-immunosuppression and drug toxicity is more prevalent than graft loss from rejection.” Onaca contends that further studies will be necessary to validate these observations over longer periods of time.



The use of the ImmuKnow assay as described in these studies has not been cleared by the U.S. Food & Drug Administration.

***About ImmuKnow***

**ImmuKnow** is a noninvasive biomarker of immune function that assesses cellular immune status by detecting cell-mediated immunity (CMI) in adult immunosuppressed patients. It measures the concentration of adenosine triphosphate (ATP) released from CD4 cells following cell stimulation. The ImmuKnow test is a qualitative assay and does not directly quantify the level of immunosuppression. Results of the ImmuKnow assay should be used in conjunction with clinical presentation, medical history, and other clinical indicators when assessing the immune status of any individual patient.

***About Cylex, Inc.***

**Cylex** is a privately held global life sciences company that is the leader in the development and manufacture of *in vitro* diagnostic products that are intended to illuminate immunity. ImmuKnow is the *in vitro* diagnostic utilized to detect cell-mediated immunity (CMI) in an immunosuppressed population, and is increasingly being adopted at organ transplant centers throughout the United States and abroad. The Company's patented technology provides an innovative platform allowing clinicians to simply and reproducibly assess CMI. The Company is based in Columbia, MD USA.