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## **NEW DATA SUPPORT ROLE FOR MONITORING OF CELL-MEDIATED IMMUNITY IN ADULT PATIENTS FOLLOWING RENAL TRANSPLANTATION**

### **Cylex's ImmuKnow<sup>®</sup> assay shows clinical potential in independent study of adult kidney transplant patients**

**COLUMBIA, MD, August 21, 2008** – A recently published article by Sánchez-Velasco et al.\* in *Clinical Transplantation* has expanded our understanding of the clinical potential of monitoring cell-mediated immunity in adult patients at risk for organ rejection or infection subsequent to kidney transplantation.

Pablo Sánchez-Velasco and his colleagues in the Cantabria Health System and at the University of Cantabria, in Santander, Spain, used the Cylex ImmuKnow assay to prospectively monitor intracellular adenosine triphosphate (ATP) concentrations following CD4 cell activation as a measure of cell-mediated immune function in 81 immunosuppressed adults who underwent kidney transplantation. The objective of their study was to examine the association between cell-mediated immunity and risk for organ rejection (in under-immunosuppressed patients) or systemic infection (in over-immunosuppressed patients). Their data were also compared to intracellular ATP levels in 52 (non-transplanted) healthy controls.

Their results demonstrated a clear correlation between intracellular ATP levels for the healthy control group, a group of stable transplant patients, and infected transplant patients, with a statistically significant difference between the median ATP levels for these three groups:

- Infected transplant group (n = 24): mean ATP level = 197 ± 114 ng/mL
- Stable transplant group (n = 54): mean ATP level = 313 ± 193 ng/mL
- Healthy control group (n = 52): mean ATP level = 409 ± 177 ng/mL

These ATP levels correlate relatively closely to the three categories of cell-mediated immunity defined for adult transplant patients in the product's package insert.



Only three patients in this trial underwent an acute rejection episode during the course of this study. The authors state that this was an insufficient number of patients to validate the role of the ImmuKnow assay in monitoring risk for organ rejection. The mean ATP level of the three patients who underwent acute organ rejection was  $247 \pm 193$  ng/mL.

“We are pleased to see the data from this study support earlier published data on the use of the ImmuKnow assay in monitoring adult patients after a renal transplant,” stated Brad L. Stewart, president of Cylex. “Clearly there is further research needed to elucidate the appropriate standards for use of cell-mediated immunity to monitor risk for infection and rejection in selected patient categories. However, this publication further illustrates the potential risks for infection associated with over-immunosuppression in renal transplant patients, and the potential value of the ImmuKnow assay in monitoring immune status.”

\*Sanchez-Velasco P, Rodrigo E, Valero R, et al. Intracellular ATP concentrations of CD4 cells in kidney transplant patients with and without infection. *Clin Transplant*. 2008;22:55-60.

### **About ImmuKnow®**

**ImmuKnow** is the immune cell function assay cleared by the FDA to detect cell-mediated immunity (CMI) in adult patient populations undergoing immunosuppressive therapy for organ transplantation by measuring 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 ImmuKnow assays should be used in conjunction with clinical presentation, medical history, and other clinical indicators when assessing the immune status of any individual patient. The uses of the ImmuKnow assay as described in these studies have not been approved or cleared by the FDA. The Company may use data from these or similar studies to support future FDA marketing applications for similar indications.

### **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 intended to illuminate immunity. The Company's patented technology provides an innovative platform allowing clinical researchers to simply and reproducibly



measure immune cell function for the development of new diagnostics, biomarkers, and companion assays. The Company is based in Columbia, MD, USA.