



CYLEX CORPORATE RELEASE: FINAL – May 29, 2008

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**MULTIPLE INDEPENDENT STUDIES REPORT ON USE OF CYLEX'S IMMUNE CELL FUNCTION ASSAY IN POSTOPERATIVE MONITORING OF KIDNEY, LIVER, AND HEART TRANSPLANT RECIPIENTS**

***Thirteen different studies, which included the use of ImmuKnow® to assess immune cell function, will be presented at the annual American Transplant Congress***

***Columbia, MD, May 30, 2008*** – On Saturday, May 31 through Tuesday, June 3, at the annual American Transplant Congress (ATC) in Toronto, Canada, a total of 13 presentations will either report specifically on studies of the use of the ImmuKnow assay or will include information on the use of this assay in monitoring kidney, liver, and heart transplant patients over time.

Since it was initially cleared as an *in vitro* diagnostic technique to detect cell-mediated immunity (CMI) in adult patient populations undergoing immunosuppressive therapy for organ transplantation, understanding of the possible applications of the Cylex™ ImmuKnow assay (in clinical practice and in the clinical research setting) has continued to expand. Selected institutions are expected to issue their own detailed media information about individual studies (highlighted in bold type below). However, the full list of studies that is known to either focus on or include explicit reference to use of the ImmuKnow assay for CMI is as follows:

***Saturday, May 31, 2008***

- **“Is infection in heart transplant patients related to low immune cell function or low white blood cell count or both?”** (B. Pavlovic-Surjancev, P. Lingam, N. Patel, et al.) – poster presentation, 5:30 p.m. – 7:00 p.m. (*Poster Session: Heart Transplantation I*)

*This study, from Loyola University Medical Center in Maywood, IL, assesses relative values of cell-mediated immunity, white blood cell count, and lymphocyte count in monitoring 26 heart transplant patients of whom 15 had various infections.*



- **“Sirolimus (SRL) blunts mitogen response at trough (C0) levels more than cyclosporine (CSA) or tacrolimus (TAC) — a safeguard for our many long-term noncompliant kidney transplant patients (KTPs)”** (X. Ye, N. Khosla, R. Batarese, et al.) – poster presentation, 5:30 p.m. – 7:00 p.m. (*Poster Session: Psychosocial and Compliance Issues*)  
*Mitogen response to three different immunosuppressive agents was assessed in 160 kidney transplant patients at an average of more than 6 years post-surgery using the Cylex ImmuKnow assay in this study from the University of California San Diego School of Medicine, San Diego, CA.*
- **“Anti-CD20 monoclonal antibody (Rituximab) clears persistent post transplant (TX) EBV viremia, but the effect may not be sustained”** (L. Jinadu, M. Toyoda, E. Kamil, et al.) – poster presentation, 5:30 p.m. – 7:00 p.m. (*Poster Session: Kidney: Pediatrics*)  
*This study, from Cedars Sinai Medical Center in Los Angeles, CA, includes reference to the use of ImmuKnow in serial monitoring of 5 pediatric renal transplant patients being treated for persistent Epstein-Barr viremia.*

**Sunday, June 1, 2008**

- **“Effect of induction agent on cellular and humoral responses to renal transplants in sensitized patients”** (M. S. Leffell, D. Kopchliiska, D. P. Lucas, et al.) – oral presentation, 3:35 p.m. (*Concurrent Session: Immunosuppression: Protocols for Sensitized and ABO Incompatible Renal Transplantation: A Period of Consolidation*)  
*CMI was one of three parameters assayed in monitoring the responses of renal transplant patients to two different induction agents in this study from Johns Hopkins University School of Medicine, Baltimore, MD.*
- **“411 living donor kidney transplants using alemtuzumab pre-conditioning and tacrolimus monotherapy: 5-year experience”** (H. P. Tan, J. Donaldson, A. Basu, et al.) – oral presentation, 4:20 p.m. (*Concurrent Session: Kidney Immunosuppression: Induction Therapy I*)  
*This study from the University of Pittsburgh Medical Center reports the 5-year results of the largest series (to date) of living kidney donor transplants with alemtuzumab preconditioning, including the role of the Cylex ImmuKnow assay in patient monitoring to assist in the weaning of recipients to tacrolimus monotherapy.*



- **“Monitoring of immune function for treatment of post-transplant de novo malignancy”** (T. Uemura, T. R. Riley III, A. Khan, et al.) – poster presentation, 5:00 p.m. – 6:00 p.m. (*Poster Session: PTLD/Malignancies: All Topics*)

*The Cylex ImmuKnow assay was used to compare outcomes of 52 kidney and liver transplant patients with de novo malignancies post transplant in this study from the Penn State Milton S. Hershey Medical Center, Hershey, PA.*

- **“New insights into the use of immune cell function monitoring in kidney transplant management”** (F. Benitez, A. Gautam, and N. Najafian) – poster presentation, 5:00 p.m. – 6:00 p.m. (*Poster Session: Non-Invasive Immune Monitoring II*)

*This pilot study from the Children’s Hospital, Brigham and Women’s Hospital, and Boston Medical Center, Boston, MA suggests three new findings related to the use of CMI in post-transplant monitoring of patients with kidney transplants.*

#### **Monday, June 2, 2008**

- **“Rejection characteristics of 200 living donor kidney transplants using alemtuzumab induction and tacrolimus monotherapy”** (H. P. Tan, J. Donaldson, A Basu, et al.) – oral presentation, 2:15 p.m. (*Concurrent Session: Kidney – Acute Rejection: Immunosuppressive Agents and Registry Data*)

*This study from the University of Pittsburg Medical Center reports the longest (3-year) follow-up of the largest series (to date) of living kidney donor transplants with alemtuzumab preconditioning and tacrolimus monotherapy, including the role of the Cylex ImmuKnow assay in patient monitoring.*

- **“Relationship between immune function and humoral sensitization in renal transplant recipients”** (A. Zeevi, C. Bentlejewski, A. Girnita et al.) – poster presentation, 5:00 p.m. – 6:00 p.m. (*Poster Session: Kidney Immunosuppression: Induction Therapy*)

*This study of 290 samples from 39 renal transplant recipients from the University of Pittsburg Medical Center and Cylex, Inc. suggests that cell-mediated immune function and anti-HLA antibody screening tests are independent measures of different arms of the immune response.*

- **“ATP levels (ATP) analyzed by Cylex ImmuKnow assay (ICF) are useful to guide management of CMV and BKV infection, but has limited utility for EBV”** (D. Thomas, A. Pao,



D. Puliyananda, et al.) – poster presentation, 5:00 p.m. – 6:00 p.m. (*Poster Session: Kidney: Complications IV*)

*The role of CMI in guiding the management of CMV and BKV infections in 194 kidney transplant patients over a period of 3 years is clarified in this study from the Cedars Sinai Medical Center, Los Angeles, CA.*

- **“Immune monitoring with Cylex ImmuKnow in the management of post kidney transplant recipients”** (M. R. Carreno, T. Cordovilla, Y Jin, et al.) – poster presentation, 5:00 p.m. – 6:00 p.m. (*Poster Session: Kidney: Complications IV*)

*The role of CMI in guiding the post-transplantation management of 339 kidney transplant patients is examined in this study of over 2,000 test specimens from the University of Miami Lawrence Miller School of Medicine, Miami, FL.*

- **“The ATP release assay in normal, dialysis and transplant patients, and its practical application”** (E. A. Santiago-Delpin, S. de Echegaray, D. M. Perez, et al.) – poster presentation, 5:00 p.m. – 6:00 p.m. (*Poster Session: Kidney: Complications IV*)

*This case-control approach to measuring CMI involved monitoring Hispanic kidney transplant patients together with CMI values in normal Hispanics and Hispanic patients on dialysis in this study from the University of Puerto Rico, San Juan, PR.*

#### ***Tuesday, June 3, 2008***

- **“Impact of Cylex immune cell function assay in predicting acute cellular rejection and recurrence of HCV in liver transplantation”** (K. Hashimoto, K. Hirose, T. Diago Usó, et al.) – poster presentation, 5:00 p.m. – 6:00 p.m. (*Poster Session: Liver: Hepatitis*)

*The role of CMI in monitoring 63 patients receiving orthotopic liver transplants, with a specific focus on the ability to distinguish acute cellular rejection from HCV recurrence, is examined in this study from The Cleveland Clinic, Cleveland, OH.*

The various studies report on the clinical use of the ImmuKnow immune function assay in adult and in pediatric patients. The use of the ImmuKnow assay for identification of patients at risk for organ rejection and/or infection, as described in some of these studies, has not been cleared by the U.S. Food & Drug Administration (FDA). The company may use data from these or similar studies to support future FDA marketing applications.



### ***About ImmuKnow®***

**ImmuKnow** is an immune cell function assay that can detect cell-mediated immunity 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 ImmuKnow assay has not been cleared by FDA for assessment of immune cell function in pediatric patients.

### ***About Cylex, Incorporated***

**Cylex™** is a privately held global life sciences company and a leader in the development and manufacture of research and in vitro diagnostic products intended to assist in the assessment of immune function. Cylex is the first and only company to offer a patent-protected in vitro diagnostic assay (ImmuKnow) used in the detection of cell-mediated immune function in immune-suppressed organ transplant patient populations. The ImmuKnow assay is increasingly being adopted for use by organ transplant centers throughout the USA and in other countries around the world.

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.