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SERIAL MONITORING WITH IMMUKNOW® IS USEFUL IN THE RISK ASSESSMENT OF KIDNEY TRANSPLANT RECIPIENTS

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

Columbia, MD, May 30, 2009 – Lead investigator, Dr. Manuel R. Carreno, along with his colleagues from the University of Miami, evaluated whether single or serial ImmuKnow assessments are most useful in determining rejection or infection in kidney transplant recipients. Patients were randomly selected after 30-60 days (N=134) or 335-395 days posttransplant (N=91) and tested with ImmuKnow.

Based on the results of this study, Dr. Carreno commented, “pre-transplant baseline readings and serial monitoring with ImmuKnow are crucial for posttransplant risk assessments. Our results suggest that an isolated ImmuKnow test is insufficient to aid in the management of posttransplant recipients.” In addition, Dr. Carreno said, “serial posttransplant ImmuKnow values are useful because patients with ‘immunological quiescence’ have fewer complications compared to patients with erratic ImmuKnow values.”

“We believe that ImmuKnow is a valuable, noninvasive tool for helping clinicians manage their transplant patients,” added Dr. Phillip Ruiz, author and Medical Director of the Transplant Laboratories. “We recognize that the immune system responds quickly to change and that regular patient monitoring is critical to understanding these changes, which is why we test weekly in the first month posttransplant, followed by weeks 6 and 8 testing in the second month, monthly testing during months 3-12, and then as needed when circumstances suggest the immune function is affected.”

Risk assessment was performed within 3 study groups: The first group utilized single ImmuKnow measures alone, the second group compared posttransplant vs. pre-transplant ImmuKnow results and the third group compared posttransplant ImmuKnow results with other prior serial posttransplant ImmuKnow results taken during immunological quiescence.

The use of the ImmuKnow assay as described in this study 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.