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THREE INDEPENDENT STUDIES INCLUDE THE IMMUKNOW® ASSAY TO MANAGE AND OPTIMIZE IMMUNOSUPPRESSION THERAPY IN TRANSPLANT PATIENTS

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

Columbia, MD, May 31, 2009 – A study conducted at Westchester Medical Center in Valhalla, NY examined liver transplant recipients to determine whether the use of the ImmuKnow assay to guide immunosuppression therapy would reduce drug toxicity and drug-related adverse events.

According to Dr. Patricia Sheiner, the lead investigator in this study, “using ImmuKnow in liver transplant recipients may help minimize renal injury by providing a more individually-adjusted immunosuppression therapy.” Dr. Sheiner added that “ImmuKnow may lead to improved immunosuppression therapy management that benefits transplant patients by reducing adverse effects.” In 20 patients, clinical decision-making during the management of immunosuppression therapy was based on ImmuKnow assay levels. In 32 other patients, changes in immunosuppression therapy were based on immunosuppressive drug levels. Although it did not reach statistical significance, the use of the ImmuKnow assay resulted in substantially lower mean serum creatinine levels at 5 months.

In a study to determine whether ImmuKnow can guide adjustment of immunosuppressive medications to lower risks of infection and/or graft loss, Dr. Abubakr A. Imam and co-investigators at the Akron Children's Hospital in Ohio conducted a retrospective study to assess the role of the ImmuKnow assay in viral surveillance and immune function monitoring in 35 pediatric renal transplant patients.

“Among the 5 patients who became positive for EBV or BK virus,” explained Dr. Imam, “each event was preceded by a deviation in baseline ImmuKnow status. Immunosuppression was adjusted in each case, accordingly, without evidence of graft loss or clinical symptoms.” He concluded by saying “viral surveillance together with ImmuKnow can be useful to prevent infection or organ rejection by tailoring immunosuppressive therapy.” For each patient, viral studies and ImmuKnow results were routinely obtained and immunosuppressive drug dosing was adjusted based on positive viral studies using ImmuKnow results as an adjunct tool.

In a related study, researchers at the University of North Carolina at Chapel Hill and Ohio State University prospectively studied the use of the ImmuKnow assay together with various viral markers in 93 renal transplant recipients. Lead study investigator, Dr. Kenneth A. Andreoni, summarized the results of the study by saying, “we collected ImmuKnow data along with viral monitoring. From our



data, we feel we may be able to prevent some viral infections by decreasing immunosuppression when ImmuKnow assay values are <100ng/ml or when post-transplant baseline ImmuKnow values decrease by >50%." Among patients who developed elevated viral levels, the majority either displayed an ImmuKnow value <100ng/ml or >50% decrease in baseline ATP value. In several of these patients, low ImmuKnow results led directly to immunosuppression medication decreases and subsequent increases in ImmuKnow with no infections or rejections.

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.