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IMMUNE FUNCTION IN ADULT HEART TRANSPLANT PATIENTS REFLECTS RISK FOR ORGAN REJECTION AND INFECTION

Data from 76 patients over 3 years confirms value of assay of cell-mediated immunity

Boston, MA, April 11, 2008 – Results of an analysis of three years of data on the monitoring of cell-mediated immunity (CMI) in adult patients undergoing heart transplantation at the University of California at Los Angeles (UCLA) Health System have demonstrated that ImmuKnow[®] values appear to closely reflect the immune function of the transplant recipient and patient risk for organ rejection and/or infection. These data were presented today by Dr. Jon Kobashigawa at the annual meeting of the International Society for Heart and Lung Transplantation (ISHLT) in Boston, MA.

“Based on our experience with the ImmuKnow assay we believe it is possible to assess the probability that specific patients are at risk for organ rejection or infection,” stated Dr. Kobashigawa.

Between 2005 and 2007 Dr. Kobashigawa and his colleagues studied the immune function of 76 adult heart transplant patients. A total of 170 ImmuKnow assays were carried out in these patients between 12 and 365 days after transplantation. Levels of cell-mediated immunity (CMI) were classified as low (<225 ng/mL ATP), moderate (225-525 ng/mL ATP) or strong (>525 ng/mL ATP). In these patients, the mean CMI was 305 ng/mL of ATP with a standard deviation of \pm 153 ng/mL ATP. All patients were treated with tacrolimus, mycophenolate, and corticosteroids to lower the potential risk of organ rejection.

In follow-up analysis of the available data, Kobashigawa et al. were able to document five biopsy-proven organ rejections in patients with stronger immune function (CMI > 300 ng/mL ATP; based on 74 assays) as compared to no rejections in patients with lower immune function (CMI < 300 ng/mL ATP; based on 96 assays). This difference was statistically significant ($p < 0.001$).

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The average measure of immune function during rejection was also significantly higher (average CMI = 438 ng/mL ATP) than the average measure among patients showing no signs of rejection (average CMI = 301 ng/mL ATP; $p = 0.05$).

The analysis also looked at the incidence of infections among the study population. A total of 30 infections were identified in patients with low CMI (<225 ng/mL ATP; based on 57 assays) as compared to only eight infections in patients with moderate or strong CMI (>225 ng/mL ATP; based on 113 assays). The average CMI in samples from patients with infection was 119 ng/mL ATP as compared to 336 ng/mL ATP in samples from patients with no sign of infection ($p < 0.001$). Identified infections included 13 with a viral etiology; 15 with bacterial etiology; and 10 with fungal etiology.

“Immune function monitoring of adult heart transplant patients using the ImmuKnow assay may have the potential to aid in the assessment of the immune status of the patient and the patient’s risk for organ rejection or infection,” concluded Dr. Kobashigawa. “We are currently conducting clinical studies using these data to manage immunosuppression in our heart transplant patients, with the goal of limiting risk for rejection and infection.”

Dr. Kobashigawa’s presentation was entitled, “Success of immune monitoring with ImmuKnow (Cylex™) to assess rejection/infectious risk in heart transplantation.” Dr. Kobashigawa is Clinical Professor of Medicine and Chief of the Division of Clinical Faculty Medicine at David Geffen School of Medicine at UCLA. He is also Medical Director of the UCLA Heart Transplant Program.

About ImmuKnow®

ImmuKnow is an immune cell function assay that can detect cell-mediated immunity (CMI) in adult immunosuppressed patients 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 use of the

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ImmuKnow assay as described in this study has not been cleared by the FDA. The company may use data from this study or similar studies to support a future FDA marketing application for a similar indication.

ImmuKnow is a product of Cylex™, a privately held global life sciences company and the leader in the development and manufacture of research and *in vitro* diagnostic products intended to assist in the assessment of immune function.

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 US and abroad. The Company's patented technology provides an innovative platform allowing clinical researchers to simply and reproducibly measure CMI for the development of new diagnostics, biomarkers and companion assays. The Company is based in Columbia, MD.