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PROSPECTIVE MICROBIAL ANALYSIS OF BRONCHOALVEOLAR LAVAGE FLUIDS WITH IMMUNE FUNCTION TESTING CAN DISTINGUISH BETWEEN FUNGAL COLONIZATION AND FUNGAL DISEASE IN LUNG TRANPLANT RECIPIENTS

Data from 150 lung transplant patients demonstrates potential to improve management of risk for infection

Boston, MA, April 10, 2008 – A prospective analysis of data collected from 170 patients receiving lung transplantation at the University of Pittsburgh Medical Center (UPMC) has suggested that the ImmuKnow® assay of cell-mediated immunity (CMI), when combined with microbial analysis of bronchoalveolar (BAL) fluids in immunosuppressed patients, can help to differentiate between patients with fungal colonization and those patients with active fungal infections. These data were presented in an oral session today by Shahid Husain, MD at the annual meeting of the International Society for Heart and Lung Transplantation (ISHLT) in Boston, MA.

“Our hypothesis was that global immunoreactivity, as measured prospectively using the ImmuKnow assay of CMI, would be different for patients with fungal colonization as compared to patients with true fungal infections,” said Dr. Husain. “This hypothesis appears to have been borne out by our preliminary results.”

“Our study has shown that ImmuKnow values are significantly different for patients with fungal colonization as compared to patients with true fungal infections six months after transplantation,” Husain continued.

Data were collected prospectively from 170 lung transplant recipients at UPMC between 2003 and 2006. These patients provided a total of 712 blood samples for analysis, while also being prospectively monitored and classified for episodes of infection according to standardized criteria.

All patients received alemtuzumab induction and tacrolimus suppression to prevent organ rejection.

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Results of ImmuKnow assays of CMI were included in the analysis if and when they were obtained within 30 days of a documented episode of clinical syndrome (fungal colonization/ fungal disease).

In the initial 6-month period following T-cell depletion (while patients were still receiving prophylaxis), the investigators observed no statistical differences between measures of CMI and clinical condition of the patients. However, beginning six months after transplantation, when prophylaxis was stopped, there were significant differences in CMI between clinically stable patients (188 ng/mL ATP) and those with evident infections documented by microbial analysis of BAL (91 ng/mL ATP; $p < 0.001$). The median ImmuKnow measure of CMI based on samples from 45 patients diagnosed with fungal colonization (but no clinical infection) was 188 ng/mL ATP, which was not significantly different from the median value of samples from all clinically stable patients. However, this CMI value was significantly higher than the value in the six transplant patients with fungal disease (78 ng/mL ATP; $p < 0.01$).

“This study expands our understanding of the applicability of the ImmuKnow immune function assay in effective management of lung transplant recipients in the post-transplant setting,” stated Dr. Husain. “While we had demonstrated an association between infection and low ImmuKnow values in an earlier study, we now have specific preliminary prospective evidence that will guide us in predicting risk for fungal infection in these immune-suppressed patients over time.”

Dr. Husain’s presentation was entitled, “Use of an immune monitoring assay to distinguish between fungal colonization and fungal disease in lung transplant recipients.” Dr. Husain is currently Assistant Professor of Medicine and Director of Transplant Infectious Diseases in the Division of Infectious Diseases and Multi-Organ Transplantation, Toronto General Hospital-University Health Network, Toronto, Canada.

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.

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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 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.