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NEW DATA SUPPORT EARLIER SUGGESTED GUIDANCE FOR LEVELS OF CELL-MEDIATED IMMUNITY IN PEDIATRIC LIVER TRANSPLANT PATIENTS

Cylex's ImmuKnow® assay suggests clinical potential in independent study of pediatric liver transplant patients

COLUMBIA, MD, August 21, 2008 – Israeli et al.,* in an article just published in the peer-reviewed journal *Liver Transplantation,* have further developed our understanding of the clinical potential of monitoring cell-mediated immunity in pediatric liver-transplant patients post-transplantation.

Working in a cooperative group involving several institutions in Petach-Tikva and Tel Aviv in Israel, Israeli and his colleagues focused on the use of the Cylex ImmuKnow assay to monitor cell-mediated immunity post-transplant in pediatric patients between 1 and 18 years of age who had undergone liver transplantation.

In adult transplant patients, cell-mediated immunity as measured using the ImmuKnow assay is classified into three categories, as defined in the product's package insert. However, a prior study in pediatric renal transplant patients reported that ATP levels defining equivalent categories among these pediatric patients were significantly lower than among comparable adult patients, and recommended the following pediatric categories:

- a pediatric "low" of <175 ng ATP/mL
- a pediatric "moderate" of between 175 and 395 ng ATP/mL
- a pediatric "strong" of >395 ng ATP/mL

Data from the study by Israeli et al. support these lower categories for cell-mediated immunity in pediatric transplant patients, and in liver transplant patients in particular:

- The median ATP level in this group of 28 samples from pediatric liver transplant patients was 300 ± 102 ng/mL.
- Half of the patient assays (between the 25th and 75th percentiles) were found to be between 251 and 387 ng ATP/mL.
- There was no significant difference between the immune function of stable pediatric liver transplant patients who were <12 years of age as opposed to those >12 years of age.
- During clinical quiescence, ImmuKnow assay results correlated with clinical status of the patients for 23/28 samples (82 percent), with correlation being defined as within a normal range of 195-395 ng ATP/mL.

"Cylex continues to be interested in understanding the categorization of cell-mediated immune status in the pediatric transplant patient community," stated Brad L. Stewart, president of Cylex. "Although the appropriate categorization of immune status is well-defined in the adult community, there are fewer data available on the application of the ImmuKnow assay in pediatric patients. Cylex will continue to support studies that seek to resolve questions about the use of ImmuKnow as a tool to monitor pediatric transplant patients and their levels of cell mediated immunity."

* Israeli M, Klein T, Sredni B, et al. ImmuKnow: a new parameter in immune monitoring of pediatric liver transplantation recipients. Liver Transplant. 2008;14:893-898.

About ImmuKnow®

ImmuKnow is the immune cell function assay cleared by the FDA to detect cell-mediated immunity (CMI) 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 uses of the ImmuKnow assay as described in these studies have not been approved or cleared by the FDA. The Company may use data from these or similar studies to support future FDA marketing applications for similar indications.

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 intended to illuminate immunity. 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, USA.