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**PATENTED IMMUKNOW® IMMUNE CELL FUNCTION ASSAY
TO BE STUDIED IN ITALIAN LIVER TRANSPLANT PATIENTS**

Cylex committed to exploring the full potential of the ImmuKnow assay

COLUMBIA, MD, August 28, 2008 – In association with its Italian distributors, ADA SRL, Cylex, Inc. today announced that the value of its patented ImmuKnow assay will be investigated in one part of a major, three-part, Italian trial of aspects of immunosuppression in patients undergoing liver transplantation subsequent to hepatitis C virus (HCV)-related cirrhosis of the liver.

“Cylex is honored to be working with Prof. Antonio Daniele Pinna, MD, and his colleagues at the University of Bologna and other centers in exploring the potential value of ImmuKnow in monitoring the cell-mediated immunity of patients following liver transplantation, “ stated Brad Stewart, president of the Company. “Professor Pinna is a renowned authority in this field, and we look forward to supporting his team as necessary through the course of this trial.”

Under the leadership of Prof. Pinna, the ImmuKnow assay will be used in one part of this three-part, multi-center trial in patients undergoing initial transplantation for hepatitis C virus (HCV)-related cirrhosis of the liver (with or without hepatocellular carcinoma). The three-part trial is designed to evaluate several primary research objectives:

- To compare the incidence of acute rejection and HCV recurrence between the study group (receiving an investigational immunosuppressive regimen) and a control group (receiving a standard regimen)
- To reduce infection and acute rejection in a population of liver transplant recipients assessed using the Cylex ImmuKnow assay compared to a control group, allowing an earlier intervention able to reduce hospitalizations secondary to infection or transplant rejection



- To develop novel diagnostic tools to distinguish acute HCV recurrence from acute rejection and to identify specific parameters able to predict severity of recurrence and rapidity of evolution of HCV re-infection

The value of the ImmuKnow assay as a method to monitor cell-mediated immunity and evaluate the need to modify the level of immunosuppression of individual patients will be addressed in the second part of this three-part trial, as specified above. A sample size of 103 patients will be required to assess the value of ImmuKnow in this study. Patients enrolled in the first-mentioned section of the study will be eligible for enrollment in the ImmuKnow evaluation study.

Patients in this study will be classified according to standard ImmuKnow criteria for cell-mediated immunity, as defined in the product's package insert. All patients will have blood drawn and tested on a regular schedule immediately prior to and following surgery for a period of 1 year. Tests will be conducted according to the following schedule:

- Immediately before transplantation
- On study day 1 after transplantation
- Once weekly for weeks 1-4
- Once each in week 6 and week 8
- Once a month during months 3-6
- Once each during months 9 and 12

A total of 14 ImmuKnow tests per patient will be carried out (for each patient without complications).

"Evolving data strongly suggest the value of Cylex's cell-mediated immune function assay in monitoring patients undergoing liver transplantation," stated Prof. Pinna. "Our intent is to investigate whether these data can be replicated in an Italian clinical trial population, thereby confirming the potential of the ImmuKnow assay as a standard monitoring technology for long-term follow-up of liver transplant patients."

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.

About ADA SRL

ADA, based in Padova with offices throughout Italy, is highly experienced in the development and delivery of diagnostic equipment and services to support the management and rehabilitation of individual patients, and is a supplier of diagnostic goods and services to Italian healthcare providers. ADA is a member of Assobiomedica (www.assobiomedica.it).

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