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## **CYLEX™ RECEIVES ISO 13485:2003 AND 9001:2000 QUALITY CERTIFICATIONS**

**ISO certification confirms implementation of quality systems in product design and development, manufacture, and distribution for Cylex's ImmuKnow® immune cell function assay**

**COLUMBIA, MD, OCTOBER 1, 2008** – Cylex has announced receipt of certification to ISO 13485:2003 and 9001:2000. The 13485:2003 certification includes compliance with the Canadian Medical Devices Conformity Assessment System (CMDCAS). These certifications signify compliance with internationally recognized standards in design, development, and manufacturing of medical products. The certifications were issued by TÜV Rheinland of North America.

“This is a major achievement for the Company,” stated Brad L. Stewart, president of Cylex. “ISO certification confirms that quality systems have been implemented in product design and development, manufacture, operations, shipping, and service and will support CE marking of Cylex products that will be labeled for *in vitro* diagnostic use for sale within the European Community. In addition, the certification confirms that Cylex meets global quality design and manufacturing requirements for Canada.”

ISO 13485:2003 provides Cylex's customers with a “Quality Pledge” in regard to the Company's ongoing dedication to quality manufacturing, as well as demonstrating our readiness to take on the demanding challenges of building medical devices that are robust and reliable.

“In addition to the ISO 13485:2003 certificate, Cylex voluntarily elected to obtain certification to ISO 9001:2000 as well,” Stewart went on to say. “We did this to demonstrate our commitment to customer focus, customer satisfaction, and continuous quality improvement. And I want to take this opportunity to clearly recognize all Cylex's employees for the dedication, focus, and hard work that has made this certification possible.”



Certification to ISO standards is a baseline quality system requirement in many key markets for approval to sell a medical device and therefore supports the Company's plans to market its ImmuKnow immune cell function assay to customers around the world.

***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.

***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. Cylex has received certification to ISO 13485:2003 and 9001:2000 for its quality system for "design and development, manufacture and distribution of *in vitro* diagnostic products related to immune function testing". The Company is based in Columbia, MD USA.

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