LeukoDx Inc. Receives European CE Mark Approval and ISO Certification for Accellix™

Towson, MD & Jerusalem, IL, January 25, 2015 – LeukoDx Inc., an emerging leader in the field of innovative medical diagnostic technology, today announced that it has completed all requirements to receive the European CE ("Conformite Europeene") mark approval for the Accellix™ automated flow cytometry platform. Accellix™ is a fully-automated, cartridge-based flow cytometer with a novel menu of assays for in-vitro diagnosis. The CE mark, certifying that a product has met European Union (EU) requirements for marketing in Europe, applies to the company's 25 minute CD64 Assay. Independent clinical studies have demonstrated that the CD64 assay is superior to other common tests (CRP, PCT, leukocyte count) in sensitivity and specificity in the diagnosis of sepsis.

LeukoDx recently initiated a clinical trial at two leading medical centers in Israel to evaluate the diagnosis of sepsis using the CD64 marker on the Accellix System. With the CE mark, the company will now conduct additional clinical trials at a number of European sites, in departments supervised by key opinion leaders.

The company's Jerusalem facility has also received ISO 13485:2003 certification, an international standard governing the requirements of a quality-management system for medical devices and related services. The ISO certification is for "design, development, manufacturing, distribution and servicing of in-vitro diagnostic flow cytometry readers and cartridges."

"The ISO certification and CE mark approval are key milestones that position LeukoDx and our Accellix System for a commercial launch in 2015," said Julien Meissonnier, President and Chief Executive Officer of LeukoDx. "Our goal is to make Accellix the global gold-standard for sepsis diagnosis, and the CE Mark testifies to our commitment to quality, safety and performance."

"Sepsis causes millions of deaths globally each year, and is simply the most common cause of death in people who have been hospitalized," added Walter Drimer, Chairman of LeukoDx. "The worldwide incidence of sepsis is estimated to be 18 million cases per year and in the United States sepsis affects approximately 3 in 1,000 people — about a million cases per year. With such a life-saving opportunity, we are excited to introduce our innovative solution to the European market and to expand access to quick and reliable diagnosis of sepsis."

About LeukoDx Inc.

LeukoDx's mission is to deliver cost-effective, highly sensitive and actionable diagnostic information at the point of care via a novel automated IVD flow cytometry platform. Founded in 2009, LeukoDx's technology is based on technology initially developed for NASA at CalTech. To date, the Company has developed a compact reader for single use test-specific cartridges, and an application for the rapid confirmation of sepsis, a condition associated with high morbidity and mortality with no existing reliable diagnostic solution.

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