

Press release

LEUKOCARE licenses biomarker cell-free DNA to Trillium Diagnostics

Trillium to develop a commercial IVD assay kit for early diagnosis of infection/sepsis

Munich, Germany, and Bangor, Maine, USA, 10.10.2012

LEUKOCARE AG, a German biotech company, and Trillium Diagnostics, LLC, an US-based diagnostic company, announced today that both partners have formed a strategic alliance regarding the development and marketing of LEUKOCARE's patented method for the detection of inflammatory activity using the novel biomarker circulating cell-free DNA (cf-DNA). Trillium will use the technology to develop a commercial assay for the diagnosis of sepsis.

Neutrophil-derived DNA is the major component of cf-DNA, which has recently been recognized as an important predictive biomarker in severely ill patients with acute or chronic inflammatory disorders.

LEUKOCARE has granted to Trillium an exclusive, royalty-bearing license of its patent and know-how for the method of measuring the quantity of cf-DNA to develop a commercial IVD assay kit for the worldwide market. Trillium intends to establish a cf-DNA test as a simple and cost effective tool for healthcare professionals to obtain clinically informative data on patients with suspected infection/sepsis.

The development process is expected to return an approved and marketable assay in about 2 years' time.

"A prognostic assay for sepsis will represent a tremendous improvement in intensive care medicine," said Bruce Davis, M.D., CEO and President of Trillium Diagnostics. "It clearly would fulfil an unmet medical need to help identify sepsis patients at early stage and to initiate rapid treatment actions." Dr Davis added, "cf-DNA is an important addition to our patented infection/sepsis diagnostic assays of neutrophil CD64 expression (Leuko64 assay) and soluble CD163 (Macro163 assay). We hope these three assays

used in parallel will provide unparalleled sensitivity and specificity in diagnosis.”

Michael Scholl, CEO of LEUKOCARE, said: ”We have found a strong and competent partner in Trillium. Its pertinent expertise in developing and marketing diagnostic assays will make the best use of the potential of the cf-DNA biomarker. LEUKOCARE will participate in the future success of the product by significant royalties.”

Notes for editors:

About LEUKOCARE

LEUKOCARE is a leading provider of technologies for stabilizing proteins to extend shelf-life and to enable terminal sterilization. Based on these technologies, LEUKOCARE can improve biopharmaceutical products and vaccines as well as functionalize a wide variety of surfaces including implant surfaces, wound dressings, stents, catheters and others.

LEUKOCARE developed and successfully brought to clinic a Leukocyte Inhibition Module (LIM) which applies antibodies coupled to the membrane of a filter device to inactivate Leukocytes, thus avoiding inflammation in patient undergoing heart surgery. In this context, LEUKOCARE further developed and patented a fluorescence based assay to monitor the activity of the immune system by measuring the concentration of cell-free DNA (cf-DNA).

LEUKOCARE leverages its comprehensive expertise in product-focused industrial partnerships. The company offers its know-how in biofunctional coatings, formulation of biologics and product development to interested parties ranging from service-based collaborations to co-development partnerships. LEUKOCARE was founded in 2003 and is headquartered in Martinsried near Munich, Germany.

For further information, please visit: www.LEUKOCARE.com.

About Trillium

Trillium Diagnostics LLC, based in Bangor Maine (U.S.A.), develops, manufactures and markets niche products that address unmet medical needs. Trillium has focused on improved proteomic and cytomics methods using patented approaches to understand the immunologic response to infection/sepsis, thereby leading to the development of novel and improved IVD assays for infectious disease. Additionally Trillium products (anti-HbF, FETALtrol and FMH QuikQuant) have become recognized for improved detection and monitoring of fetomaternal hemorrhage in the modern

management of pregnancy. Founded in 1996, Trillium Diagnostics is based on a foundation of recognized expertise in laboratory hematology, assay development and flow cytometry. Trillium Diagnostics is dedicated to improving healthcare outcomes by providing proteomic and cell-based assay products that are innovative, robust and reliable.

For more information visit: www.trilliumdx.com

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