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Chembio Launches HIV Self-Testing Initiative in Europe

MEDFORD, N.Y., April 29, 2015 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, announced today that, for the first time, its SURE CHECK® HIV 1/2 testing device will be made available in self-test kits in Europe. Chembio's partners in this initiative, BioSure (UK) Ltd (U.K.) and AAZ (France), each received CE Mark approval for self-testing and will begin marketing a private label version of Chembio's SURE CHECK® HIV 1/2 Assay that each partner adapted for this application.

On April 27, BioSure launched sales of Chembio's SURE CHECK® HIV 1/2 testing device under the brand name BioSURE HIV Self Test, U.K.'s first HIV self-testing kit. There are approximately 110,000 people living with HIV in the U.K., and an estimated 26,000 are unaware of their positive HIV status.

On April 28, AAZ announced plans to launch an HIV self-testing initiative with sales of Chembio's SURE CHECK® HIV 1/2 testing device in France under the brand name autotest VIH®. There are approximately 160,000 people living with HIV in France, and an estimated 29,000 are unaware of their positive HIV status.

John Sperzel, Chembio's Chief Executive Officer, commented, "We are pleased that our European partners were the first to receive the CE Mark for HIV self testing, allowing them to market private label versions of our SURE CHECK® HIV 1/2 Assay. The European HIV testing landscape is changing and our product is well-suited for the self-testing segment, given its ability to provide simple, fast and reliable detection of antibodies to HIV 1 and HIV 2.

"Testing remains a critical tool in efforts to fight the spread of HIV. Through these newly launched self-test kits, people can manage their health with privacy and dignity. It is our hope that the option for self-care will increase testing and ultimately play an important role in reducing the incidence of HIV."

Chembio's SURE CHECK® HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview® Complete. Outside the U.S., Chembio markets the product through distributors, under the brands SURE CHECK® HIV 1/2 Assay and STAT-VIEW™ HIV 1/2 Assay. The SURE CHECK® HIV 1/2 Assay is Food & Drug Administration (FDA) approved, CLIA-waived, European CE-marked, and has been pre-qualified by the World Health Organization (WHO). Results are obtained in 15 minutes via a 2.5uL blood sample (i.e., fingerstick, serum, plasma, or venipuncture whole blood). The assay is stable at room temperature and provides 99.7% sensitivity and 99.9% specificity.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing $8.0 billion point-of-care testing market. Chembio markets its DPP® HIV 1/2 Assay and HIV 1/2 STAT-PAK® Assay in the U.S. and internationally. The Company's SURE CHECK® HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview® Complete. Outside the U.S., Chembio markets its SURE CHECK® HIV 1/2 Assay through distributors.

Chembio has developed a patented point-of-care test platform technology, the Dual Path Platform (DPP®) technology, which has significant advantages over lateral-flow technologies. This technology is providing Chembio with a significant pipeline of business opportunities for the development and manufacture of new products.

Headquartered in Medford, NY, Chembio is licensed by the U.S. Food and Drug Administration (FDA) as well as the U.S. Department of Agriculture (USDA), and is certified for the global market under the International Standards Organization (ISO) directive 13485. Chembio Diagnostic Systems, Inc. is a wholly-owned subsidiary of Chembio Diagnostics, Inc. For more information, please visit: www.chembio.com.

Forward-Looking Statements

Statements contained herein that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief or current expectations of the Company and its management. Such statements, which are estimates only, reflect management's current

views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from the above forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to Chembio's ability to obtain additional financing and to obtain regulatory approvals in a timely manner, as well as the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

CONTACT: Chembio Diagnostics

Susan Norcott

(631) 924-1135, ext. 125

snorcott@chembio.com

Vida Strategic Partners (investor relations)

Stephanie C. Diaz

(415) 675-7401

sdiaz@vidasp.com

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