

October 31, 2013

## Chembio Launches DPP(R) HIV-Syphilis Test

## **Receives First Purchase Order from Mexican Distributor**

## Multiplex HIV-Syphilis Assay Approved for USAID Waiver List, Now Eligible for U.S. Global Aid Procurements

MEDFORD, N.Y., Oct. 31, 2013 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI) a leader in the development, manufacture and marketing of point-of-care diagnostic tests ("POCT") for infectious diseases, announced today that the company received its first purchase order for its DPP® HIV-Syphilis Assay from its distributor in Mexico . The DPP® HIV-Syphilis Assay is based on the company's patented Dual Path Platform (DPP®), a POCT platform that is well suited for multiplexing, and that in this case adds a syphilis biomarker to the company's already FDA-approved DPP® HIV 1/2 test. The addition of this marker has resulted in a unique finger-stick whole blood test that can help reduce the transmission of both HIV and syphilis from mother to child. Globally, more pregnant women are infected with syphilis than HIV, and pre-natal testing is an essential tool to help prevent transmission of both diseases to the unborn child.

The DPP® HIV-Syphilis Assay has also been approved for inclusion on the United States Agency for International Development ("USAID") waiver list, which to the Company's knowledge is the first HIV-Syphilis product to be included on this list according to the USAID's most recently published waiver list. This approval makes this product eligible for procurements by U.S. government-funded global health programs such as the President's Emergency Plan for AIDS Relief (PEPFAR) and its affiliated programs and stakeholders. USAID approval involves laboratory studies of product performance performed by the International Laboratory Branch of the United States Centers for Disease Control ("CDC") across multiple production lots to ensure consistent performance. The Company anticipates that the results from the CDC's evaluation will be published in due course. Chembio is also pursuing CE Marking and FDA approval of this product.

The purchase order from Mexico follows the previously reported favorable evaluation of the sensitivity and specificity of this test by Mexico's Institute of Epidemiological Diagnosis and Reference (InDRE). In the InDRE's testing, the Chembio DPP® HIV-Syphilis test performed with 100% sensitivity and 100% specificity on all samples.

"We believe the results of InDRE's tests together with the USAID waiver list approval provide a compelling validation of the Chembio DPP® HIV-Syphilis product for global health programs," stated Javan Esfandiari, Chembio's Senior Vice President of Research & Development. "We also look forward to developing many opportunities for this product around the world where there is a great need for detecting both HIV and syphilis in prenatal testing programs, and the USAID approval will help facilitate these opportunities."

To facilitate product expansion into other markets worldwide, Chembio continues to make good progress toward having this product also approved by the World Health Organization for procurement by other large donor-funded global health screening programs. The company is also working directly in several regions of the world to develop and inform stakeholders about the availability of this innovative product. Information concerning this product can be viewed at <a href="http://chembio.com/products/human-diagnostics/dpp-hivsyphilis-assay/">http://chembio.com/products/human-diagnostics/dpp-hivsyphilis-assay/</a>.

## **About Chembio Diagnostics**

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing \$10 billion point-of-care testing market. Chembio's two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S. by Alere, Inc. (formerly, Inverness Medical Innovations, Inc.). Chembio markets its HIV STAT-PAK® line of rapid HIV tests internationally to government and donor-funded programs directly and 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 based on DPP®. Headquartered in Medford, NY, with approximately 170 employees, 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 13.485. For more information, please visit: <a href="https://www.chembio.com">www.chembio.com</a>.

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.

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