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Chembio Commences CLIA Waiver Studies for DPP(R) HIV 1/2 Assay

MEDFORD, N.Y., April 18, 2013 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI) a leader in point-of-care diagnostic tests ("POCT"), announces that the Clinical Laboratory Improvement Amendments (CLIA) waiver studies for its DPP® HIV 1/2 Assay have commenced. In December 2012, Chembio received FDA approval for the DPP® HIV 1/2 assay, which detects antibodies to HIV 1 and 2 in oral fluid, finger-stick whole blood (fingerstick), venous whole blood, serum or plasma samples.

The CLIA waiver studies are required by the FDA to establish the quality standards for laboratory testing, which ensures the accuracy, reliability and timeliness of patient tests results regardless of where the tests are performed. Currently, there are more than 180,000 testing sites in the U.S. that are able to use CLIA-waived products.

Chembio's multi-site CLIA clinical study will test oral fluid, finger-stick blood and venous whole blood samples prospectively collected from approximately 1,000 subjects who are HIV positive and of unknown HIV status. The study is expected to be completed within three to four months. Upon completion of the required enrollment of subjects, Chembio plans to submit the conclusions of the clinical study as a CLIA Waiver Application to the FDA. We anticipate the FDA's review of the CLIA Waiver Application will be completed during the fourth quarter of 2013.

"We are very pleased to commence the CLIA clinical testing for our DPP® HIV 1/2 Assay. It is a key component for Chembio as we finalize our commercial strategy to launch the DPP® assay in the U.S.," noted Lawrence Siebert, Chembio's Chief Executive Officer. "With more than 1.2 million Americans estimated to be living with HIV and approximately 20% of them unaware they are infected with the virus, rapid HIV tests are playing a critical role in the U.S., as they have globally, to help identify those with HIV and to prevent disease transmission. The market for these tests is expected to grow significantly with the 2012 recommendations made by the U.S. Preventive Services Task Force that embrace the 2006 Center for Disease Control's recommendations that mandate insurance reimbursement for routine HIV testing."

About DPP® HIV 1/2 Assay

The DPP® HIV 1/2 assay detects antibodies to HIV 1 and 2 in oral fluid, finger-stick whole blood (fingerstick), venous whole blood, serum or plasma samples. The DPP® HIV 1/2 assay provides a simple "reactive/non-reactive" result. In a clinical evaluation of over 3,000 patients across three countries, the diagnostic sensitivity of the DPP® HIV 1/2 assay to detect HIV infection ranged from 99.9% to 100% for fingerstick specimens and 98.9% to 100% for oral fluid specimens. The diagnostic specificity of the DPP® HIV 1/2 assay was 100% for fingerstick specimens and 99.9% to 100% for oral fluid specimens. The test is intended to be used in the preliminary diagnosis of patients with HIV in point-of-care settings such as public health and other clinics, hospital emergency rooms and physician offices.

The DPP® HIV 1/2 Assay is the only rapid test in the U.S. that does not use lateral flow or other older flow-through technologies. DPP® HIV 1/2 delivers visual results within approximately 15 minutes, is simple to use, requires minimal sample size, has a shelf life of 24 months, and does not require refrigeration. Providing results at the point-of-care eliminates the chance that patients at risk would not return or call back for results, thereby improving prevention efforts of forward transmission.

DPP® HIV 1/2 features a comfortable swab for collection of oral fluid samples and provides sharp distinct test lines due to the proprietary DPP® technology. In addition, a proprietary sample collection system in this assay enables each sample to be contained in a convenient, closed collection vial, or Sampletainer™, which provides additional sample for repeat testing, allowing greater testing flexibility over other systems that do not have separate sample collection or that use open vials for stirring blood samples.

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.

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.

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