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Chembio Files for CLIA Waiver with FDA for Point-of-Care DPP(R) HIV 1/2 Assay

MEDFORD, N.Y., Dec. 2, 2013 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care ("POC") diagnostic tests for infectious diseases, has completed its Clinical Laboratory Improvement Amendment ("CLIA") waiver studies for its DPP® HIV 1/2 Assay (the "Assay"). The Company believes the study results meet CLIA waiver requirements and it has filed the CLIA waiver application with the U.S. Food and Drug Administration ("FDA").

In support of the application to the FDA Chembio sponsored studies at multiple sites evaluating the accuracy and simplicity of the Assay. The Assay is a rapid, POC assay for the detection of HIV 1/2 antibodies in either oral fluid or blood samples. Approximately 1,100 individuals infected with HIV, or at risk for infection with HIV, participated in the studies, which included testing on oral fluid, finger-stick whole blood and venous whole blood samples from each patient.

A CLIA waiver will allow Chembio to make the test available to customers addressing the widest possible range of at-risk individuals in the U.S., such as in outreach clinics, community-based organizations and physician offices (See "About CLIA Waiver" below). Although there is no statutory time in which the FDA must review a CLIA waiver application, Chembio anticipates that it will receive a CLIA waiver of the Assay from the FDA in order to launch this product in the U.S. during the second quarter of 2014, as planned.

"Despite a significant increase in awareness, there are still nearly 50,000 new HIV infections diagnosed every year in the U.S.," stated Lawrence Siebert, Chembio's chief executive officer. "The fact that nearly 1 in 5 people with HIV don't know they are infected contributes to the spread of this disease. Our DPP® HIV 1/2 Assay has several attractive and unique features, including oral fluid collection, a user-friendly collection swab, and enhanced sample retention and processing safety via the SampleTainer® processing device. Therefore a CLIA waiver of this product will provide an important new option in the United States rapid HIV testing market."

The announcement of Chembio's CLIA waiver application immediately follows yesterday's observance of World AIDS Day. World AIDS Day is held on December 1st each year and is dedicated to raising HIV awareness globally. While there have been many advances in the fight against HIV/AIDS, it has tragically claimed more than 25 million lives since 1981, and there are more than 35 million people currently living with the infection worldwide.

"All of us at Chembio commemorate World AIDS Day by renewing our commitment to develop and deliver high-quality, cost-effective HIV rapid tests worldwide, and to support prevention programs," added Siebert. "In light of the 2013 recommendations by the U.S. Preventive Services Task Force that HIV testing be an A-rated preventive service, it is anticipated that more of the estimated 250,000 HIV-positive Americans who are currently unaware of their disease, will be tested and referred to care to manage their disease with increasingly effective therapies. We believe that there will be an increased demand for testing in the U.S. as a result, and that Chembio is well positioned for serving this demand. As we continue to grow our presence in the U.S. market, Chembio remains the only U.S.-based manufacturer of cost-effective FDA-approved rapid HIV tests to private, governmental and non-governmental organizations and programs globally, many of which are funded by the United States through the President's Emergency Plan for AIDS Relief ("PEPFAR")."

About Chembio's DPP® HIV 1/2 Assay

The rapid POC DPP® HIV 1/2 Assay (the "Assay") was first approved by FDA's Center for Biologics Evaluation & Research ("CBER") in December 2012 as a Pre-Marketing Approval ("PMA") of a "moderately complex" biological product. With such approval a CLIA waiver application for this product could be filed with FDA's Center for Devices & Radiological Health ("CDRH"), which Chembio has now done. The Assay is based on Chembio's innovative and patented Dual Path Platform technology, or DPP®. The Assay detects antibodies to HIV-1 and HIV-2 in finger-stick whole blood, venous whole blood, serum, or plasma samples within approximately 15 minutes, and also has a number of differentiating performance features and claims, including the ability to use an oral fluid sample with the Assay. The Assay includes a proprietary SampleTainer® collection system, is easy to use, has a uniform procedure across all sample matrices, and provides the user with a clear read-out of results.

For more information about the Company's POC DPP® HIV 1/2 Assay, please visit http://chembio.com/products/human-

diagnostics/dpp-hiv-12-assay/.

About CLIA Waiver

CLIA waiver is granted by the CDRH for tests that are categorized as simple or low ("waived") complexity and that are demonstrated to have an insignificant risk of an erroneous result. Tests of "moderate" and "high" complexity may only be run by sophisticated laboratories that meet stringent requirements under CLIA. Most CLIA requirements are waived, however, if a laboratory only employs tests of low complexity.

More than 6.8 billion laboratory tests are performed each year in the United States. Waived labs account for roughly 60% of the 230,000 clinical laboratories in the United States. The vast majority of waived labs are in physicians' offices and other facilities in close proximity to patients and health-care providers. The closeness of these labs to patients allows for point-of-care testing ("POCT"), where health-care providers get results in real time as opposed to sending patient specimens to off-site laboratories and waiting days or weeks for results. POCT can provide faster diagnosis and treatment decisions, made while a patient is actually in a doctor's office. POCT for also may prevent situations where patients fail to return to their provider in order to get the information or treatment they need, and to reduce the risk of transmission to additional people in the event of a positive result. For sexually transmitted diseases such as HIV, this can contribute both to improved patient and public health outcomes.

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. 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 200 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: 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.

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