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Chembio Receives FDA Approval for DPP(R) Point-of-Care HIV 1/2 Rapid Test

MEDFORD, N.Y., Dec. 21, 2012 (GLOBE NEWSWIRE) -- **Chembio Diagnostics, Inc.** (Nasdaq:CEMI),a leader in point-of-care diagnostic tests for infectious diseases, announces receipt of approval from the U.S. Food and Drug Administration (FDA) to market the Company's Dual Path Platform® (DPP®) HIV 1/2 assay for the rapid, point-of-care (POC) detection of HIV-1/2 antibodies in either oral fluid or blood samples. This determination follows a review of Chembio's Premarket Approval (PMA) application and marks the first FDA approval of a diagnostic assay utilizing the Company's patented Dual Path Platform® technology. DPP® enables samples to bind directly with target analytes before detection reagents are introduced to visualize the test results, and can improve accuracy compared with the current lateral flow HIV test technologies.

"We are very proud to receive FDA approval to market our DPP® HIV 1/2 Assay, which allows us to commercialize a POC oral fluid rapid diagnostic test that we believe has superior performance compared with the only other oral fluid HIV rapid test on the market," 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. In addition, the market for these tests is expected to grow significantly with the recent recommendations by the U.S. Preventive Services Task Force to mandate insurance reimbursement for routine HIV testing."

Chembio's DPP® point-of-care HIV 1/2 Assay detects antibodies to HIV-1 and HIV-2 in oral fluid, fingerstick whole blood, venous whole blood, serum or plasma samples, and provides a simple "reactive/non-reactive" result. In a multi-site clinical study of approximately 2,800 patients across five clinical settings, including a pediatric hospital, the diagnostic sensitivity of the assay to detect HIV infection resulted in sensitivity of 99.8% for fingerstick samples; 99.9% for venous whole blood, serum and plasma samples; and 98.9% for oral fluid samples. The specificity of the assay was 100% for fingerstick specimens; and 99.9% for oral fluid, venous whole blood, plasma and serum samples. 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® point-of-care 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 is approved to detect HIV in patients two years of age and older, which is also a differentiating feature compared with all other rapid assays that are approved only to detect HIV in patients 13 years of age and older. DPP® HIV 1/2 delivers visual results within 15 minutes, is simple to use, requires minimal sample size, has a shelf life of 24 months and does not require refrigeration. DPP® HIV 1/2 features a comfortable swab for collecting oral fluid samples and provides sharp, distinct test lines due to the DPP® technology. In addition, a proprietary sample collection system enables each sample to be contained in a convenient, closed collection vial, or Sampletainer™, which may provide 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.

"As we finalize our commercial strategy for the launch of this new DPP® assay in the U.S, we will be conducting and submitting our Clinical Laboratory Improvement Amendments (CLIA) waiver trials in order to establish the quality standards for our laboratory testing that provide for the accuracy, reliability and timeliness of patient tests results regardless of where the tests are performed," added Mr. Siebert. "We plan to make this submission during the first half of 2013 and expect to launch DPP® HIV 1/2 in the U.S. during the second half of 2013."

For more information about the Company's DPP® point-of-care HIV 1/2 Rapid Assay, Chembio has animated video, poster presentations and publications available on its website at: http://chembio.com/products/human-diagnostics/dpp-hiv-12-assay/.

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 additional information, please visit the Company's website at 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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