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Chembio Announces Oral Presentation and Multiple Poster Presentations at 2012 HIV Diagnostics Conference

Company Highlights the Clinical Utility of Its Dual Path Platform Rapid, Point-of-Care Tests in HIV and Related Infectious Diseases including Syphilis and Hepatitis-C

MEDFORD, N.Y., Dec. 13, 2012 (GLOBE NEWSWIRE) -- **Chembio Diagnostics, Inc.** (Nasdaq:CEMI),a leader in point-of-care diagnostic tests for infectious diseases, announces that an oral presentation and multiple poster presentations underscoring the clinical utility of the Company's Dual Path Platform[®] rapid, point-of-care (POC) diagnostic tests are being presented at the 2012 HIV Diagnostics Conference being held December 12-14 at the Sheraton Atlanta Hotel.

An oral presentation entitled "Performance Evaluation of the DPP® HIV-SYPHILIS Assay: a novel, point-of-care rapid HIV 1/2, and Syphilis Treponema pallidum Antibody Combination Test" was delivered by Javan Esfandiari, Senior Vice President of Research and Development for Chembio. The presentation was made in conjunction with the "Testing for HIV/Hepatitis or HIV/Syphilis Co-infections" workshop moderated by Kelly Wroblewski, Association of Public Health Laboratories, which took place at 4:00 p.m. local time on December 12th.

In his presentation on Wednesday, Mr. Esfandiari showcased the Company's DPP[®] HIV-SYPHILIS, a single-use immunochromatographic, rapid screening test for the detection of antibodies to HIV 1/2 and Syphilis Treponema pallidum in fingerstick whole blood, venous whole blood, serum or plasma. Data have shown the test to have accurate results with documented sensitivity and specificity for both HIV 1/2 and Syphilis antibodies on one device.

Mr. Esfandiari noted, "In the U.S., approximately 16% of patients, as well as 28% of men, who are infected with syphilis are also co-infected with HIV. As a result, there is growing interest in an accurate, rapid POC test that can diagnose both HIV and syphilis antibodies. Moreover, syphilis facilitates HIV transmission, making an early and accurate syphilis diagnosis key to preventing continued transmission of both diseases. DPP[®] HIV-SYPHILIS requires minimal patient sample and provides

actionable results in 20 minutes, allowing for results and counseling at the point-of-care. Based on the market need and the strength of these data, we intend to work with the regulatory authorities to establish a pathway to approval for this much-needed diagnostic."

In addition, the Company has two posters being presented at the Conference today:

- "Performance Evaluation of a Novel HIV-1/2 Rapid Test for the Detection of HIV-1/2 Antibodies in Oral Fluid and Whole Blood," which demonstrated the diagnostic sensitivity of the DPP[®] HIV assay to detect HIV infection, currently pending FDA Pre-Marketing Application approval in point estimates ranging from 99.9% to 100% for fingerstick whole-blood specimens and 98.9% to 100% for oral-fluid specimens. The diagnostic specificity of the DPP[®] HIV tests was 100% in all sites for fingerstick whole-blood specimens and 99.9% to 100% for oral-fluid specimens. The sensitivity estimate on oral-fluid specimens was lower in the United States (98.9%) compared with Mozambique and Nigeria (100%) mainly due to the known HIV-positive population. Approximately 84% (731/868) in the United States and 60% (129/215) in Nigeria of the known HIV-positive population recruited were taking antiretroviral drug therapy.
- "Evaluation of the DPP® HIV-HCV-Syphilis Assay: a novel, point-of-care rapid HIV 1/2, HCV and Syphilis Treponema pallidum Antibody Combination Test," which indicated that DPP[®] HIV-HCV-Syphilis assay, a rapid, qualitative multiplex POC test for the detection of antibodies to HIV 1/2, HCV and Syphilis Treponema pallidum in fingerstick whole blood, venous whole blood, serum or plasma, can be used to screen for HIV, HCV and Syphilis Treponema pallidum antibodies. Compared with the FDA-approved HIV, HCV and Syphilis Treponemal tests, all selected blood, sera and plasma samples tested with DPP HIV-HCV-Syphilis assay had 100% specificity for HIV and Syphilis Treponemal bands, and 100% and 99.4% specificity with blood and sera/plasma for HCV band, respectively.

"We are delighted to have this solid body of clinical data presented at the 2012 HIV Diagnostics Conference including the outstanding performance of our HIV 1/2 test that is pending approval," stated Lawrence Siebert, Chembio's Chief Executive

Officer. "These data confirm the high sensitivity and specificity of our DPP[®] rapid assays in patients with HIV and HIV-related infectious diseases. The simultaneous detection of multiple antibodies offers the opportunity to increase diagnosis of and treatment for these highly infectious diseases, which is hoped to reduce their transmission. As a result, there continues to be a substantial interest in these products by public health groups in the U.S. and abroad."

About the 2012 HIV Diagnostics Conference

The 2012 HIV Diagnostics Conference, co-sponsored by the Centers for Disease Control and Prevention (CDC), the National Minority AIDS Council (NMAC), and the Association of Public Health Laboratories (APHL), provides an opportunity for clinicians, clinical and public health laboratorians, HIV/AIDS program managers and directors, and industry representatives to review developments in HIV diagnostics, share data and research findings, and establish collaborations. Since its inception in 2005, the HIV Diagnostics Conference has served as an opportunity for those interested in issues related to HIV diagnostic testing to gather and discuss new developments and related prevention and surveillance measures.

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 <u>www.chembio.com</u>.

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 success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

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