February 9, 2015

Chembio's DPP(R) HIV-Syphilis Assay Cleared for Launch in Brazil

Only Combination Assay Approved by Brazil's ANVISA for Point-of-Care Detection of HIV and Syphilis

MEDFORD, N.Y., Feb. 9, 2015 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, has received approval for commercial use of its DPP® HIV-Syphilis Assay by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). The Chembio Dual Path Platform (DPP®) HIV-Syphilis Assay is the only POC test cleared for commercialization in Brazil for rapid, POC detection of both HIV 1/2 and syphilis. Chembio developed this novel combination assay to address the growing concern among public health officials regarding co-infection rates of HIV and syphilis as well as mother-to-child transmission (MTCT) of HIV and syphilis.

John Sperzel, Chembio's Chief Executive Officer, commented, "Our DPP® HIV-Syphilis Assay was successfully launched in Mexico during 2014, including use to screen pregnant women for both HIV and syphilis. We believe the DPP® HIV-Syphilis Assay may have similar application in Brazil and may play a role in the global initiative to reduce MTCT of HIV and syphilis, as well as growing HIV and syphilis co-infection rates."

Co-infection rates of HIV and syphilis are on the rise and, according to the Centers for Disease Control and Prevention (CDC), there is an estimated two-to-five-fold increased risk of acquiring HIV if exposed to that infection when syphilis is present. Further, an estimated two million pregnancies annually are affected by MTCT of HIV and/or syphilis, resulting in high rates of stillbirth, spontaneous abortion, low birth weight and perinatal death. Congenital syphilis is a preventable disease, which could be eliminated through effective prenatal screening, and treatment of infected pregnant women.

Chembio developed this novel combination test using its DPP® technology. The Chembio DPP® HIV-Syphilis Assay is a single-use, immunochromatographic, rapid screening test for the detection of antibodies to HIV types 1 and 2 and syphilis Treponema pallidum in fingerstick whole blood, venous whole blood, serum, or plasma. The test requires a small 10 µl blood sample, is highly sensitive and specific, provides results in as little as 15 minutes, has a built-in procedural control, can be stored at room temperature, and has up to a 24-month shelf life.

"Chembio's overarching goal is to leverage its DPP® platform globally to deliver the specific diagnostics that are most needed in each corner of the world. This product approval in Brazil represents our latest success in achieving that goal. For the current DPP® HIV-Syphilis Assay, we also are working to obtain WHO pre-qualification, CE Mark for use in Europe, and approvals in certain Southeast Asia countries through our partner in Malaysia. We are also focused on developing a U.S. version of the DPP® HIV-Syphilis Assay," added Sperzel.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing $8.0 billion point-of-care testing market. Chembio markets its DPP® HIV 1/2 Assay and HIV 1/2 STAT-PAK® Assay in the U.S. and internationally. The Company's SURE CHECK® HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview® Complete. Outside the U.S., Chembio markets its SURE CHECK® HIV 1/2 Assays 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.

Headquartered in Medford, NY, 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 13485. Chembio Diagnostic Systems, Inc. is a wholly-owned subsidiary of Chembio Diagnostics, Inc. 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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