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Chembio's DPP® HIV-Syphilis Assay Receives CE Mark for Simultaneous Point-of-Care Detection of HIV and Syphilis

DPP® HIV-Syphilis Assay on Track for U.S. Regulatory Submission in 2017

MEDFORD, N.Y., Jan. 17, 2017 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced that it has received a CE mark for its DPP® HIV-Syphilis combination assay. The Chembio DPP® HIV-Syphilis Assay is now cleared to be marketed and sold within the member states of the European Union and the Caribbean region, except for Puerto Rico.

The Chembio DPP® HIV-Syphilis Assay is a single-use, rapid screening test for the detection of antibodies to HIV types 1 and 2 and syphilis *Treponema pallidum* using 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.

John Sperzel, Chembio's Chief Executive Officer, commented, "We are pleased to receive a CE mark for our DPP® HIV-Syphilis Assay, which allows us to market and sell the test in Europe and the Caribbean region, except for Puerto Rico. We believe the DPP® HIV-Syphilis Assay can play a role in the global initiative to reduce transmission of HIV and syphilis to unborn children, as well as to screen certain populations to address 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, there is an estimated two-to-five-fold increased risk of contracting HIV if exposed to that infection when syphilis is present. Further, an estimated two million pregnancies annually are affected by mother-to-child-transmission 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 significantly reduced through effective prenatal screening, and treatment of infected pregnant women.

"We intend to leverage our patented DPP® platform to deliver diagnostic tests that are most needed in each corner of the world. In the U.S., our goal is to bring our DPP® HIV-Syphilis Assay to market as quickly as possible, as there currently are no other such combination tests available in the U.S. market. We plan to complete a U.S. clinical trial for our DPP® HIV-Syphilis Assay and file for U.S. regulatory approval in early 2017. In addition to our receipt of a CE mark for the DPP® HIV-Syphilis Assay, we have previous regulatory approvals in Mexico and Brazil, and we are working to obtain approvals in certain Southeast Asia countries, following our recent acquisition of Malaysia-based RVR Diagnostics," 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 each of its DPP® HIV 1/2 Assay, HIV 1/2 STAT-PAK® Assay, and SURE CHECK® HIV 1/2 Assay, with these Chembio brand names, in the U.S. and internationally both directly and through third-party distributors. The Company's SURE CHECK® HIV 1/2 Assay previously has been exclusively sold in the U.S. as Clearview® Complete HIV 1/2 Assay.

Chembio has developed a patented point-of-care (POC) 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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