Chembio Diagnostics Awarded $3.2 Million Contract from the CDC for Development and Clinical Validation of Dual-Path Platform Syphilis Screen & Confirm Assay

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HAUPPAUGE, N.Y., Sept. 06, 2022 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Chembio) (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced it was awarded a $3.2 million contract from the Centers for Disease Control and Prevention (CDC) for the development and clinical validation of a rapid point-of-care (POC) diagnostic test for syphilis.

Chembio will undertake to develop a syphilis test and confirm assay based on its Dual Path Platform (DPP) technology and proprietary DPP Micro Reader II. The assay will be intended to simultaneously and separately detect treponemal and nontreponemal IgM and IgG antibodies. The test should require only 10 µL of fingerstick blood, serum, or plasma and produce results in under 20 minutes.

Chembio has previous experience in the field of rapid syphilis diagnostics through its successful development, validation, and commercialization of DPP HIV-Syphilis. The Chembio DPP HIV-Syphilis Assay is a rapid serologic test for the detection of antibodies to HIV and/or the causative agent of syphilis, *Treponema pallidum*. Additionally, Chembio has worked to develop a DPP Syphilis Screen and Confirm test, using a CDC licensed reagent with improved liposomal preparation on the nontreponemal test line.

"We are excited to continue expanding our core sexually transmitted disease portfolio with the syphilis screen and confirm assay," commented Javan Esfandiari, Chembio's Chief Science and Technology Officer. "We look forward to developing a highly sensitive and highly specific test that will potentially enable physicians to diagnose and treat active syphilis in a timely manner. Early and reliable diagnosis and timely treatment can prevent transmission of syphilis as well as the development of severe complications. We are honored to have been selected by the CDC for this award."

Syphilis infections continue to be a significant health problem and are particularly threatening in high-risk groups and in people who are pregnant, where congenital syphilis can severely affect pregnancy outcome and infant morbidity. According to the CDC, the rate of primary and secondary syphilis (the most infectious stages of the disease) has increased almost every year since the historic low in 2001–2002, increasing 25.4% during 2020–2021, according to preliminary data. The timely identification and treatment of syphilis can decrease the transmission to others and result in better patient outcomes.

Serologic tests are currently available in clinical laboratories for the detection of active syphilis, which require shipping samples to perform tests of moderate or high complexity. There is no rapid point-of-care test currently available to accomplish both screening and confirmation of active syphilis. The development of such a test should allow for rapid diagnosis of an active infection and timely patient treatment, thus reducing the overall burden of syphilis in the U.S.

About the DPP Rapid Test Platform
Chembio's proprietary DPP technology platform provides high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. Through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, delivering greater clinical value than other rapid tests. For certain applications, Chembio's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzer then reports accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on-site. Objective results produced by the DPP Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

Chembio's portfolio of DPP-based point-of-care tests with FDA regulatory approvals include the DPP HIV-Syphilis System (PMA approved), DPP HIV 1/2 Assay (PMA approved and CLIA waived), DPP Zika IgM System (510(k)), and DPP Ebola Antigen System (EUA). Additionally, DPP-based tests have received regulatory approvals from the World Health Organization, CE-Mark, ANVISA, and other global organizations, where they aid in the detection and diagnosis of several other critical diseases and conditions.

All DPP tests are developed and manufactured in the United States and are the subject of a range of domestic and global patents and patents pending.

About Chembio Diagnostics
Chembio is a leading diagnostics company focused on developing and commercializing point-of-care tests used to detect and diagnose infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. Chembio's products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers. Learn more at www.chembio.com.

Forward-Looking Statements
Certain statements contained in the first, second, fourth and sixth paragraphs above are not historical facts and may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the intent, belief or current expectations with respect to the opportunity, timing and operational and financial success of Chembio's ability to develop and clinically validate a rapid point-of-care (POC) diagnostic test for the screening and confirmation of active syphilis, and its ability to develop such a syphilis screen and confirm assay that will simultaneously and separately detect treponemal and nontreponemal IgM and IgG antibodies, and require only 10 µL of fingerstick blood, serum, or plasma and produce results in under 20 minutes. Such statements, which are expectations 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 forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, many of which may

be outside the control of Chembio, including, but not limited to, the following, any of which could be exacerbated even further by the continuing COVID-19 outbreak in the United States and globally: the global need for a rapid test to detect and diagnose active syphilis; the success of Chembio's research, development and commercialization efforts, including Chembio's ability to make the necessary investment with respect to such efforts; Chembio's ability to maintain existing, and timely obtain additional, regulatory approvals; the potential development of competing rapid POC tests for active syphilis; Chembio's retention of key personnel; transportation delays, logistics disruptions and supply chain limitations; and changes in U.S. trade policy. Chembio undertakes no obligation to publicly update forward-looking statements in this release to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to the forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's periodic public filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and its Quarterly Report on Form 10-Q for the quarterly periods ended March 31, 2022 and June 30, 2022, particularly under the heading "Risk Factors."

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