Chembio Announces FDA CLIA Waiver Submission for DPP HIV-Syphilis System

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HAUPPAUGE, N.Y., Nov. 28, 2022 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced the submission to the U.S. Food and Drug Administration (FDA) for a Clinical Laboratory Improvement Amendments (CLIA) waiver for the DPP HIV-Syphilis System.

“We are pleased to communicate that our DPP HIV-Syphilis System has been submitted to FDA for CLIA waiver. Upon receipt of CLIA waiver, we believe this will represent a large step forward in rapid testing for sexually transmitted infections. We appreciate the collaboration with the FDA on this submission and look forward to continued dialog regarding our CLIA waiver application,” said Richard L. Eberly, Chembio’s President and Chief Executive Officer.

Co-infection rates of HIV and syphilis are on the rise, according to the CDC, and individuals with an active syphilis infection have an estimated two- to five-fold increased risk of contracting HIV if exposed to that virus. The CDC has also reported that untreated syphilis in pregnant women who contracted the disease during the four years prior to delivery can lead to infection of the fetus in up to 80% of cases and may result in stillbirth or infant death in up to 40% of cases. Congenital syphilis is a preventable disease that could be significantly reduced through effective prenatal testing of women of childbearing age and treatment of infected pregnant women.

Chembio’s DPP HIV-Syphilis System assists clinicians in diagnosing both HIV and syphilis while patients are still under care at the testing location. The System is a multiplex, single-use, 15-minute test that is designed, in combination with our Micro Reader analyzer, to simultaneously detect antibodies to HIV types 1 and 2 and *Treponema pallidum*, the bacteria that causes syphilis. The test uses a small, 10-microliter sample of fingerstick whole blood, venous whole blood, or plasma.

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 second and third 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 regulatory approval, distribution and sale of Chembio’s DPP products and the availability, timing and functionality. 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, 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 ability of Chembio to timely obtain additional regulatory approvals for such test system, which approvals are subject to processes that can change recurringly without notice; and Chembio’s dependence upon, and limited experience with, COVID-19 diagnostic tests. 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, its Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2022, June 30, 2022 and September 30, 2022 and in subsequent filings, particularly under the headings “Risk Factors.”

Contact:
Philip Taylor
Gilmartin Group
415-937-5406
investor@chembio.com

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