



Chembio Diagnostics Provides Update on FDA Submission of DPP HIV-Syphilis Test

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Anticipates FDA Approval of Multiplex Test and Micro Reader During Q1 2020

MEDFORD, N.Y., Jan. 02, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today provided an update on its Premarket Approval application submission to the U.S. Food and Drug Administration (FDA) for the DPP HIV-Syphilis System. The company anticipates FDA approval of the DPP HIV-Syphilis System, which includes the DPP HIV-Syphilis test and DPP Micro Reader, during the first quarter of 2020.

"Our clinical study, which included the prospective enrollment of over 2,500 subjects, demonstrated that the DPP HIV-Syphilis System met the performance requirements established with the FDA," said John Sperzel, Chembio's Chief Executive Officer. "We provided the additional studies requested, which included data on pregnant women, and expect a decision from the FDA within two months."

Chembio's DPP HIV-Syphilis System is a single-use, 15-minute screening test for the simultaneous detection of antibodies to HIV types 1 and 2 and the bacteria that causes syphilis, *Treponema pallidum*. It uses a 10 microliter sample of fingerstick of whole blood, venous whole blood, or plasma. The test is highly sensitive and specific, has a built-in procedural control, can be stored at room temperature, and has up to a 24-month shelf life.

Co-infection rates of HIV and syphilis are on the rise and, according to the U.S. Centers for Disease Control and Prevention, individuals with an active syphilis infection have an estimated two-to-five-fold increased risk of contracting HIV if exposed to that virus. 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 that could be significantly reduced through effective prenatal screening and treatment of infected pregnant women.

About Chembio Diagnostics

Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. The company's patented DPP technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in approximately 15 minutes. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease, a number of which applications are under active development with collaboration partners. 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

Statements contained in the first and third paragraphs of this release with respect to the receipt of FDA approval of the DPP HIV-Syphilis test and DPP Micro Reader, and the anticipated timing of receipt of such approvals, are not historical facts and constitute forward-looking statements within the meaning of the Securities Act of 1933, as amended. 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 there can be no assurance that FDA approval of the DPP HIV-Syphilis test or the DPP Micro Reader will be received by March 2020 or at all. 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.

DPP is Chembio's registered trademark and Micro Reader is Chembio's trademark. For convenience, these trademarks appear in this release without ® or TM symbols, but that practice does not mean that Chembio will not assert, to the fullest extent under applicable law, its rights to the trademarks.

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