December 21, 2017

Chembio Diagnostics Announces Completion of U.S. Clinical Trial Evaluating DPP® HIV-Syphilis System

U.S. Regulatory Submission for DPP® HIV-Syphilis System Expected in Q1 2018

MEDFORD, N.Y., Dec. 21, 2017 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced completion of the U.S. clinical trial evaluating its DPP® HIV-Syphilis System. The Company plans to file a Pre-Market Approval (PMA) submission with the Food and Drug Administration (FDA) during the first quarter of 2018 to support commercialization of the first POC HIV-Syphilis assay in the U.S.

The Chembio DPP® HIV-Syphilis System, which includes the DPP® HIV-Syphilis Assay and DPP® Micro Reader, is a single-use, rapid screening test for the detection of antibodies to HIV types 1 and 2 and syphilis *Treponema pallidum (the causative agent for syphilis)* using fingerstick whole blood, venous whole blood, or plasma. The test is performed using a small 10 µl fingerstick 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.

The U.S. clinical trial designed to evaluate the accuracy of the DPP® HIV-Syphilis System resulted with sensitivity and specificity that met the study objectives of the clinical protocol. The results of the clinical trial will be filed with the PMA submission for review by the FDA.

John Sperzel, Chembio's Chief Executive Officer, commented, "Chembio is aggressively pursuing a three-pronged growth strategy, which includes the strengthening of our sexually transmitted disease business, continued development of our fever disease portfolio, and additional pursuit and development of new and existing technology collaborations. Commercialization of the DPP® HIV-Syphilis Assay in the U.S. is a key element of our strategy, and completion of the U.S. clinical trial brings this novel product closer to the market. During the first quarter of 2018, we plan to file a PMA submission with the FDA, and we look forward to launching the DPP® HIV-Syphilis System in the U.S. market following FDA approval."

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.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets rapid diagnostic tests in the growing $8.0 billion POC testing market. The Company markets its products directly and through third-party distributors under the brand names: DPP®, STAT-PAK®, SURE CHECK®, and STAT-VIEW®.

Chembio has developed and patented the DPP® technology platform, which offers significant advantages over traditional POC lateral-flow technologies and provides the Company with a significant pipeline of business opportunities in the area of sexually transmitted disease, tropical and fever disease, and technology collaborations.

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. Each of Chembio Diagnostic Systems Inc. and Chembio Diagnostics Malaysia Sdn Bhd 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.

Contact:

Vida Strategic Partners (investor relations)
Stephanie C. Diaz
(415) 675-7401
sdiaz@vidasp.com