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Chembio Diagnostics Obtains CE Mark for Its DPP(R) Syphilis Screen & Confirm Assay

MEDFORD, NY, Oct 11, 2011 (MARKETWIRE via COMTEX) --

Chembio Diagnostics, Inc. (OTCQB: CEMI) (PINKSHEETS: CEMI), which develops, manufactures, markets and licenses point-of-care diagnostic tests, announces that its DPP® Syphilis Screen & Confirm Assay has received a CE marking. The CE marking declares that a product has met all relevant European Union consumer safety, health or environmental requirements, and can therefore be sold within the European Economic Area.

The DPP® Syphilis Screen & Confirm Assay provides the most conclusive evidence available at the point-of-care (POC), of an active, previously untreated case of syphilis, thereby enabling diagnosis and treatment in a single visit to a clinic.

According to the World Health Organization, there will be 140,000 new cases of the disease in Europe this year alone, and 12 million new cases worldwide. Standard diagnosis of syphilis is currently analyzed using two different laboratory-based serologic tests, namely a non-treponemal screening test, usually either the Rapid Plasma Reagin (RPR) or Venereal Disease Research Laboratory (VDRL), followed by a more specific treponemal confirmatory assay. Chembio has developed the first dual non-treponemal & treponemal POC syphilis test that can be used in the European Union.

Utilizing Chembio's patented Dual Path Platform technology, DPP® Syphilis Screen & Confirm permits the simultaneous yet separate detection of both markers at the point of care, eliminating the need and resulting cost of two separate laboratory tests. The Company has recently begun clinical trials at the first of three sites in the United States in support of an application to the FDA for a 510(k) clearance, which the Company anticipates submitting in 2012. The Company also anticipates that this test will be eligible for a CLIA waiver (Clinical Laboratory Improvement Act waiver) which, if granted, would allow use of the test in point-of-care settings such as public health testing clinics and physician (i.e., OB-GYN) offices for screening of pregnant women. Accordingly, the Company believes that the DPP® Syphilis Screen & Confirm represents a considerable advance in cost-effective, timely and simple diagnosis.

Lawrence Siebert, CEO of Chembio Diagnostics, commented, "Now that we have received CE certification, we intend to focus our efforts in the EU market in order to aggressively ramp up sales of our DPP® Syphilis Screen & Confirm Assay to meet that need, while we also move forward on our United States FDA regulatory pathway."

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing $7 billion point-of-care testing market. Chembio's two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S. by Alere, Inc., formerly named Inverness Medical Innovations, Inc. Chembio markets its HIV STAT-PAK® line of rapid HIV tests internationally to government and donor-funded programs directly and through distributors. Chembio has developed a patented point-of-care 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 based on DPP®. Headquartered in Medford, NY, with approximately 130 employees, 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 13.485.

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 are estimates only, as the Company has not completed the preparation of its financial statements for those periods, nor has its auditor completed a review or audit of those results. Such statements 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, to obtain regulatory approvals in a timely manner and the demand for Chembio's products. In addition, actual revenue may differ materially from any amount referenced or otherwise anticipated in this press release. 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 set forth in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

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