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Chembio Files Final Module of Premarket Approval Application With FDA for DPP(R) Point-of-Care HIV 1/2 Rapid Test

MEDFORD, NY, Jun 07, 2012 (MARKETWIRE via COMTEX) --Chembio Diagnostics, Inc. (NASDAQ: CEMI) (OTCQB: CEMID) (PINKSHEETS: CEMI), which develops, manufactures, markets and licenses point-of-care diagnostic tests, reports it has filed the final module of its Premarket Approval (PMA) application with the U.S. Food and Drug Administration (FDA) for the Company's DPP® HIV 1/2 Assay. This module contains clinical data from the Company's 3,000-patient pivotal clinical trial for the product.

"We are delighted to submit the final module of our PMA, and look forward to a favorable response from the FDA by year end in order to attain our ultimate goal to bring our DPP® HIV 1/2 Assay to market. Our pivotal study involved five clinical sites across the U.S. and was designed to include various patient groups as required by the FDA to support the sensitivity and specificity of the product across various demographics," commented Lawrence Siebert, Chembio's Chief Executive Officer. "With more than 1.1 million Americans estimated to be living with HIV and approximately 20% of them unaware they are infected with the virus, rapid HIV tests are playing a critical role in the U.S., as they have globally, to help identify those with HIV and to prevent disease transmission."

Chembio's DPP® HIV 1/2 Assay is a rapid point-of-care test for the detection of antibodies to HIV 1 and 2 in oral fluid, finger-stick whole blood, venous whole blood, serum or plasma samples that provides a simple "reactive/non-reactive" result. The test is intended to be used in the preliminary diagnosis of patients with HIV in point-of-care settings such as public health and other clinics, hospital emergency rooms and physician offices. The DPP® HIV 1/2 Assay delivers visual results within approximately 15 minutes, is simple to use, has a shelf life of 24 months and does not require refrigeration.

The DPP® HIV 1/2 Assay is based on Chembio's patented Dual Path Platform (DPP®) technology. The DPP® enables samples to directly bind with target analytes before detection reagents are introduced to visualize the test results and can improve accuracy compared with the current lateral flow HIV test technologies. In addition, a proprietary sample collection system in this assay enables each sample to be contained in a convenient, closed collection vial, or Sampletainer™, which provides more testing flexibility over other systems that do not have separate sample collection or that use open vials for stirring blood samples.

The FDA accepted Chembio's shell application for DPP® HIV 1/2 Assay, proposing a modular PMA submission plan containing three sections or "modules." This approach divides the PMA application into modules filed at different times that together form the complete submission. This approach allows the FDA to review each module separately as soon as it is received, making it possible for manufacturers to receive timely feedback during the review process, and perhaps shortening the time to a regulatory determination. Chembio submitted the first two modules containing the preclinical data, prior clinical testing and a quality manufacturing system review to the FDA in April and October 2011, respectively.

About Chembio Diagnostics Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing $10 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, 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 170 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. 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 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.

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