April 18, 2012

Chembio Reports Completion of Enrollment in Pivotal Trial for DPP® Point-of-Care HIV 1/2 Test

Expects to File Final PMA Module With the FDA in June

Chembio Reports Completion of Enrollment in Pivotal Trial for DPP® Point-of-Care HIV 1/2 Test

Expects to File Final PMA Module With the FDA in June

MEDFORD, NY, Apr 18, 2012 (MARKETWIRE via COMTEX) --Chembio Diagnostics, Inc. (OTCQB: CEMI) (PINKSHEETS: CEMI), a company that develops, manufactures, markets and licenses point-of-care diagnostic tests, today announced completion of enrollment in a 3,000-patient clinical trial in support of a Pre-Marketing Approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the Company's DPP® HIV 1/2 Assay. This product 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 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.

"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. Anti-retroviral medications allow many individuals to effectively manage their disease and have increased patients' desire to know their status," said Lawrence Siebert, Chief Executive Officer of Chembio. "Now that enrollment in our pivotal trial is complete, reference lab testing will be completed and the clinical sites will be closed by early May; within approximately 30 days thereafter we expect to finalize and submit the third and final module of our PMA application to the FDA. This final module is principally comprised of this study's data. We believe that the product will meet the required performance on all sample matrices."

The 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. In addition to clinical data from this study to support field performance, the other principal components required for PMA approval are non-clinical data, manufacturing data and a pre-approval inspection of the manufacturing facility.

The FDA accepted Chembio's shell application for DPP HIV 1/2, 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. The Company expects the pre-approval inspection of its manufacturing facility to occur during the second or third quarter of 2012.

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 North America, 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, N.Y. with approximately 160 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. For more information, please visit: www.chembio.com.

Forward-Looking Statements

Statements contained here in 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. Actual revenue may differ materially from those anticipated in this press release. 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. 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.

Contacts:
Chembio Diagnostics
Susan Norcott
631-924-1135 x125
snorcott@chembio.com

Investor Relations
LHA
Anne Marie Fields
(212) 838-3777
afields@lhai.com
@LHA_IR_PR

SOURCE: Chembio Diagnostics, Inc.

mailto:snorcott@chembio.com
mailto:afields@lhai.com