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ChemBio's DPP(R) HIV 1/2 Assay Receives CE Mark Approval for Rapid Point-of-Care Detection of HIV

Sales of DPP(R) HIV 1/2 Assay in Europe Anticipated in Q4 2015

MEDFORD, N.Y., June 3, 2015 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care ("POC") diagnostic tests for infectious diseases, announced today that it has received approval for a CE Mark for its DPP® HIV 1/2 Assay. The ChemBio DPP® HIV 1/2 Assay for rapid, POC detection of HIV is now cleared for commercialization and sale within the 28 member states of the European Union.

According to multiple international health and surveillance agencies, an estimated 2.3 million people are living with HIV in the member states of the European Union with at least one in three infected people being unaware of their status. According to recent reports, as many as 50% of those infected with HIV in the member states of the European Union are diagnosed late, after symptoms emerge, and approximately one-half of new infections annually are contracted from people who are not yet diagnosed. In an effort to reduce such transmissions, governments across Europe are working to provide increased access to HIV testing and early treatment.

"Early diagnosis of HIV provides a significant advantage to patients," stated John Sperzel, President and CEO of ChemBio. "It's been well-documented that people who are diagnosed early and who receive early treatment can expect nearly the same life expectancy as those who are HIV negative. With ChemBio's DPP® HIV 1/2 Assay, healthcare professionals in the member states of the European Union will have an exceptionally sensitive, specific and rapid diagnostic to support widespread testing and early treatment," added Sperzel.

ChemBio's DPP® HIV 1/2 Assay detects HIV antibodies in oral fluid or blood and uses the Company's patented Dual Path Platform (DPP®) technology, which offers excellent sensitivity and specificity. The product's unique SampleTainer® specimen collection bottle is a safe, closed system for collecting potentially infectious samples. The DPP® HIV 1/2 Assay is one of only two FDA-approved, CLIA-waived oral fluid HIV 1/2 rapid tests available in the U.S. The Company expects to launch sales of the product in the European Union in the fourth quarter of 2015.

About ChemBio Diagnostics

ChemBio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing \$8.0 billion point-of-care testing market. ChemBio markets its DPP® HIV 1/2 Assay and HIV 1/2 STAT-PAK® Assay in the U.S. and internationally. The Company's SURE CHECK® HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview® Complete by a single entity. Outside the U.S., ChemBio markets its SURE CHECK® HIV 1/2 Assay primarily through distributors.

ChemBio has developed a patented point-of-care (POC) 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.

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. ChemBio Diagnostic Systems, Inc. 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.

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