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

MEDFORD, N.Y., March 25, 2014 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care ("POC") diagnostic tests for infectious diseases, announced today that its HIV 1/2 STAT-PAK® Assay received CE Mark approval from European regulators. The ChemBio HIV 1/2 STAT-PAK® Assay is now cleared for commercialization within the European Union for rapid, POC detection of HIV.

According to the World Health Organization (WHO), more than 1.5 million people have been diagnosed with HIV in the European Region since the start of the epidemic, including 131,000 new HIV cases in 2012. The WHO reports that in 2012, 50% of newly diagnosed HIV infections in the European Region were diagnosed late (with CD4 cell counts below 350/mm<sup>3</sup>) and 30% even later (with CD4 cell counts of 200/mm<sup>3</sup> or lower), causing delayed initiation of antiretroviral therapy. Based on this data the WHO reports that an increase in HIV testing and counseling needs to be scaled up in the battle against this disease.

"We believe the ChemBio STAT-PAK® HIV 1/2 and SURE CHECK® HIV 1/2 Assays are important tools in the fight against HIV/AIDS. The simple test procedure, fast turnaround time, and reliable results make ChemBio STAT-PAK® HIV 1/2 and SURE-CHECK® HIV 1/2 uniquely suited for clinical and outreach settings, allowing immediate patient counseling and referral," stated John Sperzel, President and CEO of ChemBio.

"In the coming months, we expect to launch the ChemBio HIV 1/2 STAT-PAK® Assay and recently CE marked ChemBio [SURE CHECK® HIV 1/2 Assay](#) in Europe. In addition, we continue to work with regulators in Europe to obtain CE Marks for the ChemBio DPP® HIV 1/2 Oral Fluid test and the ChemBio DPP® HIV-Syphilis test," added Sperzel.

### **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. 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 200 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](http://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 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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