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## **ChemBio Launches U.S. Sales of its SURE CHECK® HIV 1/2 Assay and Reduces Prices of HIV Tests for U.S. Public Health Market**

MEDFORD, N.Y., June 01, 2016 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced the launch of U.S. sales of its ChemBio-branded SURE CHECK® HIV 1/2 Assay. In connection with this launch, the Company is implementing a new pricing strategy for its POC HIV products for the U.S. public health market with the goal of increasing testing frequency and reducing rates of HIV infection. Effective immediately, the Company will begin selling its HIV tests in the U.S. public health market at a price of five dollars (\$5.00) per test, which represents a significant discount from current pricing.

Products to be offered under this new pricing initiative include ChemBio's three FDA-approved, CLIA-Waived HIV assays (DPP® HIV 1/2, SURE CHECK® HIV 1/2, and HIV 1/2 STAT-PAK®). This product portfolio provides customers with multiple POC HIV testing options, as well as the ability to use either fingerstick or venous whole blood or oral fluid samples. The Company's SURE CHECK® HIV 1/2 Assay was previously sold in the U.S. as Clearview® COMPLETE HIV 1/2 Assay. Beginning today, the easy-to-use POC HIV test will be marketed under ChemBio's brand name, SURE CHECK® HIV 1/2 Assay.

The Centers for Disease Control and Prevention (CDC) estimates that approximately 1.2 million people are living with HIV infection in the U.S., including approximately 156,000 (12.8%) who are unaware of their positive HIV status. Over the past decade, the number of people living with HIV infection in the U.S. has increased, while the annual number of new HIV infections has remained relatively stable at approximately 50,000 per year. Still, the pace of new infections continues at far too high a level.

John Sperzel, ChemBio's Chief Executive Officer, commented, "According to the CDC, there are approximately 50,000 new HIV infections annually in the U.S., a number that has not declined despite the availability of numerous laboratory and POC tests to detect HIV antibodies or antigens. Building on the foundation of the CDC's three-year HIV Expanded Testing Initiative, and supporting the 2015-2020 National HIV/AIDS Strategy, which includes 'widespread testing and linkage to care' as one of the four key areas of critical focus, our newly-launched price reduction in the U.S. public health market seeks to facilitate increased POC HIV testing with ChemBio's high-quality HIV assays, demonstrating our corporate commitment to reduce the number of annual HIV infections in the U.S."

Mr. Sperzel further commented, "Historically, ChemBio's U.S. sales and marketing efforts for SURE CHECK® HIV 1/2 and HIV 1/2 STAT-PAK® Assays were controlled by an exclusive marketing partner. This relationship ended for our HIV 1/2 STAT-PAK® Assay in 2014 and for our SURE CHECK® HIV 1/2 Assay on May 31, 2016. To mark the beginning of a new era, ChemBio has announced a major price reduction in the U.S. public health market.

"Our POC HIV assays are effective in identifying HIV infections, including early detection. According to a CDC evaluation of HIV assays, ChemBio's DPP® HIV 1/2, SURE CHECK® HIV 1/2, and HIV 1/2 STAT-PAK® Assays all identified infections earlier than OraQuick ADVANCE® HIV 1/2 (OraSure Technologies, Inc.) and Uni-Gold™ Recombigen® HIV 1/2 (Trinity Biotech plc).<sup>1</sup> By selling our high-quality HIV assays in the U.S. public health market at five dollars (\$5.00) per test, we believe we can play a role in reducing the number of annual HIV infections in the U.S. through increased POC testing."

<sup>1</sup>[http://www.cdc.gov/hiv/pdf/testing\\_Advantages&Disadvantages.pdf](http://www.cdc.gov/hiv/pdf/testing_Advantages&Disadvantages.pdf)

### **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, HIV 1/2 STAT-PAK® Assay and SURE

CHECK<sup>®</sup> HIV 1/2 Assay, with these Chembio brand names, in the U.S. and internationally both directly and through third-party distributors. SURE-CHECK<sup>®</sup> HIV 1/2 Assay previously has been sold in the U.S. exclusively as Clearview<sup>®</sup> COMPLETE HIV 1/2 Assay.

Chembio has developed a patented point-of-care test platform technology, the Dual Path Platform (DPP<sup>®</sup>) 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](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, 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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