



January 26, 2016

## **ChemBio to Sell Its SURE CHECK® HIV 1/2 Assay in the United States Beginning June 1, 2016**

### **Exclusive U.S. Distribution Agreement With Alere to Terminate May 31, 2016**

MEDFORD, N.Y., Jan. 26, 2016 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, will begin selling its SURE CHECK® HIV 1/2 Assay in the U.S. market on June 1, 2016. The product is currently distributed in the U.S. by Alere, Inc. under Alere's Clearview® COMPLETE brand ("Alere"), and ChemBio has notified Alere that ChemBio will not renew or extend the U.S. SURE CHECK® HIV 1/2 Assay distribution agreement when the agreement terminates, effective May 31, 2016.

In 2006, ChemBio granted Alere the exclusive right to distribute ChemBio's SURE CHECK® HIV 1/2 assays in the U.S. market, under Alere's Clearview® brand. Effective May 31, 2016, Alere's U.S. distribution rights for SURE CHECK® (Clearview® COMPLETE) will terminate in accordance with the terms of the agreement. Effective June 1, 2016, ChemBio will begin selling the SURE CHECK® HIV 1/2 assay in the U.S. market through its existing U.S. sales force and distribution channels. Outside the U.S., ChemBio currently markets the SURE CHECK® HIV 1/2 Assay, primarily through distributors.

The SURE CHECK® HIV 1/2 Assay is Food & Drug Administration (FDA) approved, CLIA-waived, European CE-marked, and has been pre-qualified by the World Health Organization (WHO). Assay results are obtained in 15 minutes using only a 2.5uL blood sample (i.e., fingerstick, serum, plasma, or venipuncture whole blood). The assay is stable at room temperature and provides 99.7% sensitivity and 99.9% specificity.

John Sperzel, ChemBio's Chief Executive Officer, commented, "Today's announcement concerning termination of the U.S. distribution agreement with Alere, effective May 31, 2016, affirms our intent to gain full global rights related to the SURE CHECK® HIV 1/2 Assay, including sales, marketing, distribution and trademark rights. The SURE CHECK® HIV 1/2 Assay is a high-quality, well-respected product and we look forward to marketing and selling the product in the U.S. market, effective June 1, 2016."

### **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](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.*

CONTACTS:

Chembio Diagnostics  
Susan Norcott  
(631) 924-1135, ext. 125  
snorcott@chembio.com

Vida Strategic Partners (investor relations)  
Stephanie C. Diaz  
(415) 675-7401  
sdiaz@vidasp.com