



July 5, 2017

## **ChemBio's DPP® Zika System Including the DPP® Micro Reader Approved by Brazil's Health Regulatory Agency**

MEDFORD, N.Y., July 05, 2017 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced that it has received approval for commercial use in Brazil of its DPP® Micro Reader by the Brazilian health regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA), in collaboration with Bio-Manguinhos/Fiocruz.

With this latest ANVISA approval, ChemBio's DPP® Zika System, which includes the DPP® Zika IgM/IgG Assay and DPP® Micro Reader, is now approved for commercial use in Brazil.

The DPP® Zika IgM/IgG Assay detects antibodies using a tiny (10uL) drop of blood from the fingertip and provides quantitative results in 15 minutes, when used with the handheld, battery-operated DPP® Micro Reader.

Sharon Klugewicz, ChemBio's acting CEO, commented, "We are pleased to receive ANVISA approval for commercial use of the DPP® Micro Reader and look forward to commercializing our DPP® Zika System in Brazil. In recent months, we have achieved several important pre-commercial milestones. Previously, we received approval of the DPP® Zika IgM/IgG Assay by ANVISA, as well as a successful evaluation of the DPP® Zika System by Brazil's National Institute for Quality Control in Health (INCQS); and we now have received approval of the DPP® Micro Reader by ANVISA. In collaboration with Bio-Manguinhos, we can now shift our focus to commercial activities."

In 2016, ChemBio announced its Zika collaboration with Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation (Fiocruz), which is Brazil's Government unit responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system. Brazil has been the nation hardest hit by the Zika virus, where more than 2,300 cases of microcephaly, a devastating birth defect associated with Zika virus, have been confirmed and more than 3,000 cases are under investigation.

Zika virus is a mosquito-borne virus that was first identified in Uganda in 1947. While there are cases of sexual transmission of the Zika virus, it is believed that the virus is primarily transmitted to humans through the bite of an infected mosquito from the *Aedes* genus, mainly *Aedes aegypti*, the same mosquito that transmits dengue, chikungunya, and yellow fever. Since 2015, Zika outbreaks have been recorded in over 80 countries and territories.

### **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 each of its DPP® HIV 1/2 Assay, HIV 1/2 STAT-PAK® Assay, and SURE CHECK® HIV 1/2 Assay, with these ChemBio brand names, in the U.S. and internationally both directly and through third-party 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. Each of ChemBio Diagnostic Systems, Inc. and RVR Diagnostics Sdn Bhd, a Malaysia corporation, 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