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# Chembio and Bio-Manguinhos Announce Plans to Introduce a Point-of-Care Diagnostic Test for Zika Virus in Brazil

MEDFORD, NY, May 05, 2016 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced the status of its plans with Bio-Manguinhos/Fiocruz to obtain regulatory approval and to introduce a POC diagnostic test for Zika virus in Brazil. The announcement coincides with the 40th anniversary of Bio-Manguinhos, which was recognized at the Third International Symposium of Immunobiologicals, held May 2-5, 2016 in Rio de Janeiro, Brazil.

Bio-Manguinhos is the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system. Over the last 12 years, Chembio and Bio-Manguinhos have successfully collaborated to develop and commercialize a number of POC diagnostics, including tests for HIV, Syphilis, and Leishmania.

Since announcing its initial Zika collaboration with Bio-Manguinhos in March 2016, Chembio has made significant progress toward the commercialization of the DPP® Zika IgM/IgG Assay in Brazil, including the following:

- Developed DPP® Zika IgM/IgG Assay in Chembio's Research & Development facilities.
- Conducted tests of DPP® Zika IgM/IgG Assay with nearly a thousand clinical samples from Brazil, Colombia, Dominican Republic, El Salvador, Malaysia, Mexico and the United States.
- Submitted application for approval of DPP® Zika IgM/IgG Assay and DPP® Micro Reader with the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA).
- Established commercial terms with Bio-Manguinhos, to supply DPP® Zika IgM/IgG Assay to Brazil's Ministry of Health.
- Initiated third-party discussions for funding to accelerate further development and commercialization opportunities for DPP® Zika IgM/IgG Assay and related DPP® assays.

John Sperzel, Chembio's Chief Executive Officer, commented, "The Zika virus is a global health emergency and continues to pose a serious threat to the people in Brazil. We are pleased with the rapid development of our DPP® Zika IgM/IgG Assay and the results of clinical testing to date, which includes blood samples from approximately 600 pregnant women. Our progress has been accelerated by the initial grant from the Paul G. Allen Family Foundation and the collaborative efforts of government, industry and regulators. In addition to our plans concerning the DPP® Zika IgM/IgG Assay, our collaboration with Bio-Manguinhos includes plans to develop and introduce a family of related POC DPP® assays, including DPP® Dengue IgM/IgG Assay, DPP® Chikungunya IgM/IgG Assay, DPP® Zika/Dengue/Chikungunya IgM/IgG Combo Assay, DPP® Dengue NS1 Antigen Assay, and DPP® Zika/Dengue/Chikungunya Antigen Combo Assay."

**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 its 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. Outside the U.S., Chembio markets its SURE CHECK® HIV 1/2 Assays 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.

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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