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ChemBio's DPP[®] Zika Test Approved by Brazil's Health Regulatory Agency

MEDFORD, N.Y., Nov. 01, 2016 (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 of its DPP[®] Zika IgM/IgG Assay by the Brazilian health regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA).

ChemBio's DPP[®] Zika IgM/IgG Assay detects antibodies using a tiny (10uL) drop of blood from the fingertip and provides semi-quantitative results in 15 minutes, using ChemBio's patented DPP[®] technology platform and handheld, battery-operated DPP[®] Micro Reader.

In March 2016, ChemBio announced its initial Zika collaboration with Bio-Manguinhos, 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. In May 2016, ChemBio and Bio-Manguinhos/Fiocruz announced plans to obtain regulatory approval and to introduce a POC diagnostic test for the Zika virus in Brazil.

John Sperzel, ChemBio's CEO, commented, "We are pleased to receive approval from Brazil's health regulatory agency and look forward to initiating sales of our DPP[®] Zika IgM/IgG Assay, which we expect to occur after we have obtained successful INCQS evaluation of the DPP[®] Zika IgM/IgG Assay and ANVISA approval of the DPP[®] Micro Reader. We are currently involved with INCQS, Brazil's National Institute for Quality Control in Health, and ANVISA to accomplish these final steps."

Mr. Sperzel further commented, "Brazil has been hardest hit by the Zika virus, where it is estimated that 1.5 million people have been infected with Zika virus and 2,000 babies have been born with microcephaly, a devastating birth defect linked to the Zika virus. We are hopeful that our DPP[®] Zika IgM/IgG Assay will assist in dealing with the health emergency posed by the Zika virus, especially as we approach December and the start of summer in Brazil."

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, Aedes aegypti and Aedes albopictus, the same mosquitos that transmit Dengue, Chikungunya and Yellow Fever. In January 2016, the Centers for Disease Control and Prevention (CDC) activated its Emergency Operations Center (EOC) to respond both to outbreaks of Zika occurring in the Americas and to increased reports of microcephaly and Guillain-Barré syndrome in areas affected by Zika. In February 2016, the World Health Organization (WHO) declared a Public Health Emergency of International Concern (PHEIC) because of clusters of microcephaly and other neurological disorders in some areas affected by Zika. Since 2015, Zika outbreaks have been recorded in approximately 60 countries and territories, with symptoms similar to other arbovirus infections such as Dengue. Those symptoms include fever, skin rashes, conjunctivitis, muscle and joint pain, malaise and headache.

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. The Company's SURE CHECK[®] HIV 1/2 Assay previously has been exclusively sold in the U.S. as Clearview[®] Complete HIV 1/2 Assay.

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.

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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