July 27, 2016

Chembio's DPP® Zika IgM/IgG Assay Obtains CE Mark for Rapid Point-of-Care Detection of Zika Virus

Sales of DPP® Zika IgM/IgG Assay Anticipated in Second Half of 2016

MEDFORD, N.Y., July 27, 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 obtained a CE mark for its DPP® Zika IgM/IgG Assay. The Chembio DPP® Zika IgM/IgG System, which includes an assay utilizing the patented DPP® technology, as well as a digital reader, the DPP® Micro Reader, are now cleared for commercialization and for sale in 17 European countries, including the United Kingdom, Germany, and France, as well as a majority of the Caribbean nations, not including Puerto Rico.

Chembio's DPP® Zika IgM/IgG Assay detects antibodies from a 10uL fingerstick sample and provides quantitative results in 20 minutes, using the Company's patented Dual Path Platform (DPP®) technology. The DPP® Zika IgM/IgG Assay is the first POC Zika test to obtain CE mark, and the Company expects to launch sales of the product in the eligible European and Caribbean nations during the second half on 2016.

Zika virus is a mosquito-borne virus that was first identified in Uganda in 1947. It is believed that the virus is 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. On January 22, 2016, the Centers for Disease Control and Prevention (CDC) activated its Emergency Operations Center (EOC) to respond to outbreaks of Zika occurring in the Americas and increased reports of microcephaly and Guillain-Barré syndrome in areas affected by Zika. On February 1, 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. On February 8, 2016, CDC elevated its EOC activation to a Level 1, the highest level. Since 2015, Zika outbreaks have been recorded in more than 60 countries and territories, with symptoms similar to other arbovirus infections such as dengue, and include fever, skin rashes, conjunctivitis, muscle and joint pain, malaise, and headache.

John Sperzel, Chembio's Chief Executive Officer, commented, "We are pleased to report our obtaining of the CE mark, and we look forward to initiating sales of our DPP® Zika IgM/IgG Assay and DPP® Micro Reader, which we anticipate in both the eligible European and Caribbean nations during the second half of 2016. We are hopeful that our DPP® Zika IgM/IgG Assay and DPP® Micro Reader become valuable tools to address global health emergencies posed by emerging fever diseases such as Zika virus. The DPP® Zika IgM/IgG Assay has been on an accelerated product development schedule, and our early success is in large measure the result of initial funding from the Paul G. Allen Family Foundation, a versatile DPP® technology platform, Chembio's scientific expertise, a global network of collaborations which enabled access to clinical specimens, and the positive interaction with regulatory agencies."

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

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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