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ChemBio Awarded Grant to Develop First Oral Fluid/Saliva Point-of-Care Diagnostic Test for Malaria

MEDFORD, N.Y., April 25, 2016 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, has been awarded a \$678,000 grant from the Bill & Melinda Gates Foundation to expedite the feasibility testing and development of the world's first oral fluid/saliva POC diagnostic test to simply and accurately identify individuals infected with all species of malaria.

ChemBio's DPP[®] technology has been selected for this grant due to its exceptional sensitivity and potential to aid in the goal of eliminating malaria. To achieve this goal, diagnostics must be capable of detecting asymptomatic individuals with low parasite densities that contribute to the transmission of the disease, and allow detection using easy-to-collect oral fluid/saliva samples, rather than blood samples required by currently available rapid malaria tests.

Javan Esfandiari, ChemBio's Chief Science & Technology Officer, commented, "We are honored that ChemBio was selected for this important endeavor. Under a prior feasibility grant from the Bill & Melinda Gates Foundation, our DPP[®] technology demonstrated the ability to detect malaria in individuals with low parasite densities using whole blood. These results, combined with our success using oral fluid to develop the DPP[®] HIV 1/2 Assay, provides optimism that we can apply the patented DPP[®] technology toward the detection of malaria using oral fluid/saliva. Our DPP[®] HIV 1/2 Assay is FDA-approved and CLIA-waived."

According to the World Health Organization (WHO), malaria occurs in nearly 100 countries and in five of six WHO regions. Globally, an estimated 3.2 billion people are at risk of being infected with malaria and developing the disease. In 2015, there were an estimated 214 million new cases of malaria and 438,000 deaths worldwide. The burden is heaviest in the WHO African Region, where an estimated 90% of all malaria deaths occur, and where children under 5 years of age account for approximately 70% of all malaria deaths.

John Sperzel, ChemBio's Chief Executive Officer, commented, "Malaria continues to exact an enormous toll on human health and to impose a heavy social and economic burden. POC diagnostic tests to detect malaria, orders of which have increased from 46 million in 2008 to 314 million in 2015, are an increasingly important tool in the diagnosis and treatment of malaria. Further progress requires innovation, and we are pleased that the Bill & Melinda Gates Foundation chose ChemBio to develop the next generation of POC tests to detect malaria."

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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