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ChemBio Expands Exclusive Distribution Agreements with Isla Lab to Include Puerto Rico and U.S. Virgin Islands

MEDFORD, N.Y., Sept. 23, 2016 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced that the Company has entered into an exclusive distribution agreement with Isla Lab LLC that includes both Puerto Rico and the U.S. Virgin Islands. ChemBio recently announced that it had entered into an exclusive distribution agreement with Isla Lab Caribbean that included the 25 Caribbean nations. With today's announcement, Isla Lab becomes ChemBio's exclusive distribution partner throughout the Caribbean region, including Puerto Rico and the U.S. Virgin Islands.

The exclusive distribution agreements with Isla Lab LLC include current products of ChemBio that have met the regulatory requirements established by the U.S. Food & Drug Administration (FDA) that allow the products to be marketed and sold in Puerto Rico and the U.S. Virgin Islands: DPP[®] HIV 1/2 Assay, HIV 1/2 STAT-PAK[®] Assay, and SURE CHECK[®] HIV 1/2 Assay. The agreements also provide for inclusion of ChemBio products that may obtain the required regulatory approvals in the future, such as DPP[®] Zika IgM/IgG Assay, DPP[®] Chikungunya IgM/IgG Assay, DPP[®] Dengue IgM/IgG Assay, DPP[®] Zika/Chikungunya/Dengue IgM/IgG Combination Assay, DPP[®] HIV-Syphilis Assay, DPP[®] Syphilis Screen & Confirm Assay, and DPP[®] Micro Reader.

John Sperzel, ChemBio's CEO, commented, "Isla Lab is the leading diagnostics distributor in the Caribbean region and we are pleased to expand our exclusive distribution agreements to include Puerto Rico and the U.S. Virgin Islands. We believe ChemBio's U.S. FDA-approved point-of-care HIV Assays will become important tools in Puerto Rico's fight against HIV/AIDS, where over 20,000 people are living with HIV and approximately one in six people are unaware of their positive HIV status. Nearly 20% of the newly diagnosed HIV cases in Puerto Rico have advanced to AIDS, a sign that current HIV testing methods are either not sufficiently widespread or not sufficiently effective in identifying acute or chronic HIV cases.

"Puerto Rico and the U.S. Virgin Islands are experiencing widespread Zika virus transmission. ChemBio is actively engaged with the U.S. FDA, and we hope to obtain FDA Emergency Use Authorization, which will allow the Company to introduce our POC DPP[®] Zika IgM/IgG Assay and DPP[®] Micro Reader in Puerto Rico and the U.S. Virgin Islands," added Mr. Sperzel.

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.

About Isla Lab Products

Isla Lab Products, LLC was founded in 1977, in San Juan, Puerto Rico and is a leader in the distribution of innovative

technology for clinical laboratories, hospitals and other healthcare institutions. For more information, please visit: www.islalab.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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