Chembio Diagnostics Announces CE Mark for DPP SARS-CoV-2 Antigen and IgM/IgG Test Systems

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Enters Exclusive U.K. and Ireland Distribution Agreement with Luas Diagnostics

HAUPPAUGE, N.Y., Jan. 14, 2021 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced the CE mark for the DPP SARS-CoV-2 Antigen and IgM/IgG test systems, providing regulatory approval to register and market both test systems in the European Union and other geographies that accept the CE mark. The Company also announced that it has entered into a distribution agreement with Luas Diagnostics, which will commence system sales immediately while serving as the exclusive commercial partner for all of Chembio's products in the United Kingdom and Ireland.

"Having the CE mark for both COVID-19 test systems is indicative of the strong performance and reliability of the DPP system. These tests can assist clinicians across Europe with the diagnosis and management of patients and understanding virus exposure levels in their communities through testing in a variety of point-of-care settings," stated Richard Eberly, Chembio's President and Chief Executive Officer. "Partnering with Luas Diagnostics expands our global commercial footprint in the important markets of the United Kingdom and Ireland. We are very excited to offer our entire portfolio of products through this highly respected and connected organization."

The DPP SARS-CoV-2 Antigen test system utilizes a DPP SARS-CoV-2 Antigen test cartridge, a DPP Micro Reader optical analyzer and a minimally-invasive nasal swab to detect SARS-CoV-2 antigens in only 20 minutes. Rapid antigen tests are commonly used in the diagnosis of respiratory pathogens.

The DPP SARS-CoV-2 IgM/IgG test system detects antibodies to the Spike Receptor Binding Domain in the blood that the body produces in response to a COVID-19 infection. Objective results can be obtained within 15 minutes using finger stick, venous whole blood, plasma, or serum samples, and Chembio's cost-effective, highly portable, DPP Micro Reader analyzers. The DPP platform's ability to provide objective results can aid clinicians in avoiding the human interpretation errors associated with visual readings of traditional lateral flow tests.

IgM and IgG antibody test results assist clinicians in determining current or past exposure to the COVID-19 virus. The results and data from the test can contribute to improved clinical outcomes through management of individual patients, use as a population surveillance tool, and potentially evaluation of immune responses to vaccine administration.

Brendan Farrell, Chief Executive Officer of Luas Diagnostics, commented, "We are excited to form a partnership with Chembio and look forward to marketing and selling their range of rapid tests into the United Kingdom and Irish markets. We see enormous potential for Chembio's rapid antigen and antibody products and DPP multiplex solutions, where testing can be performed rapidly, accurately, and with limited training."

About the DPP Rapid Test Platform
Chembio's proprietary DPP technology platform provides high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. Through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, delivering greater clinical value than other rapid tests. For certain applications, Chembio's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzer then reports accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on-site. Objective results produced by the DPP Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

Chembio's portfolio of DPP-based point-of-care tests with FDA regulatory approvals include the DPP HIV-Syphilis System (PMA approved), DPP HIV 1/2 Assay (PMA approved and CLIA waived), DPP Zika IgM System (510(k)), and DPP Ebola Antigen System (EUA). Additionally, DPP-based tests have received regulatory approvals from the World Health Organization, CE-Mark, Agência Nacional de Vigilância Sanitária (ANVISA), and other global organizations, where they aid in the detection and diagnosis of several other critical diseases and conditions.

All DPP tests are developed and manufactured in the United States and are the subject of a range of domestic and global patents and patents pending.

About Chembio Diagnostics
Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases, including COVID-19, sexually transmitted disease, and fever and tropical disease. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. Chembio's products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers. Learn more at www.chembio.com.

About Luas Diagnostics:
Luas Diagnostics is based in Guildford, Surrey and is a UK registered private company, which was founded in 2020. Using enzymes, Luas Diagnostics has developed a new class of sensors that generate electric current upon encountering their molecular target, allowing the development of biomarker assays that are an order of magnitude faster, more versatile, and cheaper to build than current systems in the market. Because Luas Diagnostics' diagnostic tests do not require preparation, washing steps, or complex reading mechanisms, the tests can be miniaturized and coupled to a smartphone via Bluetooth for easy readout and uploading of data to repositories in the cloud.

Contact:
Philip Taylor
Gilmartin Group
(415) 937-5406
investor@chembio.com

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