Chembio Diagnostics Submits EUA Application for DPP SARS-CoV-2 Antigen Test System

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Rapid Test Provides Results in Only 20 Minutes

HAUPPAUGE, N.Y., Oct. 15, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced the submission of an application for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for the DPP SARS-CoV-2 Antigen test system, which has been designed to detect SARS-CoV-2 antigens in only 20 minutes. The DPP SARS-CoV-2 Antigen test system consists of a DPP SARS-CoV-2 Antigen test cartridge, a DPP Micro Reader optical analyzer and a minimally-invasive nasal swab.

“The antigen test system EUA submission is another example of the scientific expertise of our team and the flexibility of our DPP technology,” said Richard Eberly, Chembio’s President and Chief Executive Officer. “We are committed to leveraging this technology to offer a comprehensive COVID-19 testing portfolio. The DPP platform is ideally suited as a cost-effective system for rapid testing at the point of care and can help expand patient access to testing. Rapid antigen testing has proven to be one of the most effective methods for population screening and diagnosis available today. Offering both antibody and antigen testing using the same Micro Reader will enable clinicians to both diagnose and monitor COVID-19 infection status with Chembio products. Thank you to our team and to BARDA for their support throughout the development of the antigen system. We look forward to working with the FDA to achieve EUAs as soon as possible for the DPP SARS-CoV-2 Antigen test system and our previously submitted antibody test system.”

As defined by the U.S. Centers for Disease Control and Prevention, part of the U.S. Department of Health and Human Services (HHS), antigen tests are immunoassays that detect the presence of a specific viral antigen, which imply a current viral infection. Rapid antigen tests are commonly used in the diagnosis of respiratory pathogens, including influenza viruses and respiratory syncytial virus.

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, which can deliver 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 the Project
Chembio’s development of a COVID-19 point-of-care antigen system using DPP technology and its request for an EUA for the system has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures under Contract No. 75A50120C00138.

Forward-Looking Statements
Statements contained in the second paragraph of this release that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933. Forward-looking statements include statements regarding the intent, belief or current expectations of Chembio and its management with respect to the marketing and sale of the DPP SARS-CoV-2 Antigen system. Such statements reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from 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 research, development and commercialization efforts may not result in its successfully and timely developing and commercializing a COVID-19 antigen system; Chembio may be unable to anticipate or respond to changes in FDA regulatory requirements with respect to its proposed COVID-19 antigen system, or otherwise may be unable to obtain or maintain an EUA, or other necessary regulatory approvals, for its COVID-19 antigen system; potential customers in the United States may not adopt the DPP SARS-CoV-2 Antigen system to the extent expected by Chembio; Chembio may not succeed in obtaining a CLIA Waiver with respect to the DPP SARS-CoV-2 Antigen system; and Chembio may not be able to compete successfully with other companies that have developed, or develop in the future, COVID-19 antigen detection systems, some of which companies have substantially greater resources than Chembio. Chembio undertakes no obligation to publicly update forward-looking statements in this release to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to the forward-looking statements or the

occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's public filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and its subsequent Quarterly Reports on Form 10-Q, particularly under the heading “Risk Factors.” Readers should interpret many of the risks identified in these reports as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic.

DPP is Chembio’s registered trademark. For convenience, this trademark appears in this release without ® symbols, but that practice does not mean that Chembio will not assert, to the fullest extent under applicable law, its rights to the trademark.

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