



ChemBio Announces EUA Submission for DPP Respiratory Antigen Panel

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Test Provides Simultaneous Detection of Flu A, Flu B, and SARS-CoV-2

HAUPPAUGE, N.Y., Sept. 22, 2021 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced the submission of an Emergency Use Authorization (EUA) application to the Food and Drug Administration (FDA) for the company's DPP Respiratory Antigen Panel test system.

The DPP Respiratory Antigen Panel test system is designed to provide simultaneous, discrete, and differential detection of Influenza A, Influenza B, and SARS-CoV-2 antigens from a single patient sample using a simple nasal swab. The test system is expected to provide results in approximately 20 minutes and be read on ChemBio's DPP Micro Reader analyzer. The system is intended to enable appropriate clinical management of patients with suspected respiratory infections and to assist in the containment of COVID-19 cases during the flu season.

"Our DPP Respiratory Antigen Panel test system represents an additional differentiated offering among our COVID testing portfolio that can help clinicians at decentralized testing locations gain essential information about a patient's infection status in only 20 minutes. COVID-19 infection rates are rising as we approach the flu season, and it is critical for clinicians to be able, at the point of care, to quickly triage respiratory infection patients with symptoms common to both COVID and flu infections and then administer the proper treatment regimen," said Richard L. Eberly, ChemBio's President and Chief Executive Officer. "We believe this approach, as recommended by the U.S. Centers for Disease Control and Prevention, can save both time and resources. We are thankful for BARDA's support and guidance throughout the development and evaluation of this test system."

The DPP Respiratory Antigen Panel test system was developed with funds and support as part of a \$12.7 million contract awarded by Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. The contract also supports preparation of a submission to the FDA in pursuit of 510(k) clearance for the DPP SARS-CoV-2 Antigen test system.

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 such as respiratory 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 the Project

This project 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, under Contract No. 75A50121P00012.

Forward-Looking Statements

Certain statements contained in the second and third paragraphs above are not historical facts and may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the intent, belief or current expectations with respect to the regulatory approval, distribution and sale of ChemBio's DPP Respiratory Antigen Panel test system, and the availability, timing, functionality and regulatory approval of the test systems. Such statements, which are expectations 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 forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to, the following, any of which could be exacerbated even further by the continuing COVID-19 outbreak in the United States and globally: ChemBio may be unable to anticipate or respond to changes in FDA regulatory requirements with respect to its proposed DPP Respiratory Antigen Panel point-of-care test system, or otherwise may be unable to obtain or maintain an EUA or other necessary regulatory approvals; ChemBio's development and commercialization efforts may not result in it successfully and timely developing and commercializing the DPP Respiratory Antigen Panel point-of-care test system; potential customers may not adopt point-of-care antigen systems to the extent expected by ChemBio; ChemBio business plans depend significantly upon, but ChemBio has limited experience with, COVID-19 diagnostic tests; 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 periodic public filings with the U.S. Securities and Exchange Commission, including its Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2021 and June 30, 2021, and its Current Report on Form 8-K filed with the Securities and Exchange Commission on July 19, 2021, particularly under the heading "Risk Factors" or similar headings.

DPP is Chembio's registered trademark, and the Chembio logo is Chembio's trademark. For convenience, these trademarks appear in this release without © or ™ 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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