Chembio Diagnostics Awarded $12.7 Million by BARDA for Development of Rapid DPP Respiratory Antigen Panel and 510(k) Submission of the Rapid DPP SARS-CoV-2 Antigen Test System

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HAUPPAUGE, N.Y., Dec. 02, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI) a leading point-of-care diagnostic company focused on infectious diseases, today announced it has been awarded a contract from the Biomedical Advanced Research and Development Authority (BARDA), which is part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. The contract will support the development and pursuit of U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for a rapid, multiplex DPP Respiratory Antigen Panel point-of-care test system using Chembio's proprietary DPP technology for the upcoming flu season.

The contract also supports preparation of a submission in pursuit of FDA 510(k) clearance for the rapid DPP SARS-CoV-2 Antigen test system that was recently submitted to the FDA for an EUA. The award totals $12,691,726.

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

The U.S. Centers for Disease Control and Prevention has recognized that contemporaneous testing for the three viruses will provide public health officials with information to help limit the spread of the viruses while conserving scarce resources.

A second portion of the contract will support the verification, process validation, and production of clinical validation data to be included in a submission to the FDA for 510(k) clearance and CLIA-waiver for the DPP SARS-CoV-2 Antigen test system. This system consists of a DPP SARS-CoV-2 Antigen test cartridge and a DPP Micro Reader analyzer and is designed to use a minimally invasive nasal swab to detect SARS-CoV-2 viral antigens in only 20 minutes. The system was developed by Chembio and submitted to the FDA for an EUA on October 15, 2020, with support from BARDA under contract number 75A50120C00138.

"We are honored to again partner with BARDA and appreciate their support as we endeavor on the shared mission to expand and decentralize COVID-19 testing," stated Richard Eberly, Chembio's President and Chief Executive Officer. "The DPP technology is highly versatile, and these new product and regulatory objectives illustrate our commitment to offering virus detection for diagnosis at the point-of-care. We believe rapid, point-of-care tests can improve clinical outcomes and play a major role in combating this ongoing pandemic, especially during the upcoming flu season."

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 the Project
Chembio will use the 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
Statements contained in this release 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 Chembio and its management with respect to the development of, and obtaining an EUA for, a COVID-19 point-of-care 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 the DPP Respiratory Antigen Panel point-of-care test system or the DPP SARS-CoV-2 Antigen test system; 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 DPP SARS-CoV-2 Antigen test system, or otherwise may be unable to obtain or maintain an EUAor other necessary regulatory approvals; potential customers may not adopt point-of-care antigen systems to the extent expected by Chembio; 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 U.S. 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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