Chembio Submits EUA Application for New DPP SARS-CoV-2 IgM/IgG Test System

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New Antibody Test System Provides Results in 15 Minutes from Finger Stick, Venous Whole Blood, Plasma, or Serum Samples

HAUPPAUGE, N.Y., Sept. 08, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced its initiation of the notification process and submission of an application for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for its new rapid antibody test system, DPP SARS-CoV-2 IgM/IgG.

"We are pleased to have accomplished all of our objectives in the development and validation of the new DPP SARS-CoV-2 IgM/IgG test system," stated Richard Eberly, Chembio's President and Chief Executive Officer. "Submission of the EUA application for this test system has been the top priority for our organization because we understand there is a large need in the market for additional rapid tests – especially ones that offer the ability to decentralize testing locations. We are excited to offer a solution to patients and clinicians across the healthcare system that addresses these needs."

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, battery-powered Micro Reader 1 or Micro Reader 2 analyzers that are produced by Chembio Germany. The DPP platform's ability to provide objective, numerical 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 the management of individual patients, as a population surveillance tool, and to potentially evaluate immune responses to anticipated vaccine administration.

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. The company's proprietary DPP technology platform, which uses a small drop of blood from the fingertip or alternative sample types, provides high-quality, cost-effective results in approximately 15 minutes. 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.

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 obtaining an EUA for a COVID-19 antibody 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 antibody system; Chembio may be unable to anticipate or respond to changes in FDA regulatory requirements with respect to its proposed COVID-19 antibody 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 may not adopt antibody 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 antibody 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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