Chembio Announces Plans to Seek EUA Approval from FDA for Revised DPP COVID-19 IgM/IgG System and New DPP COVID-19 Antigen System

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HAUPPAUGE, N.Y., July 06, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading global point-of-care diagnostic company focused on infectious diseases, today announced its plans to submit applications to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) for a revised version of the DPP COVID-19 IgM/IgG System, a COVID-19 point-of-care serology system, and the DPP COVID-19 Antigen System, a new COVID-19 point-of-care antigen system.

Revised DPP COVID-19 IgM/IgG System

The DPP COVID-19 IgM/IgG System consists of Chembio's serology test for COVID-19 and a DPP Micro Reader analyzer. On April 15, 2020, the DPP COVID-19 IgM/IgG System was granted an EUA. Subsequently, the FDA announced performance review based in part on a National Institutes of Health/National Cancer Institute (NCI) process for the evaluation of COVID-19 serology tests. The NCI report acknowledges that this process, which evaluates COVID-19 serology test sensitivity and specificity using a panel of pre-selected samples, may not be indicative of either performance in the real-world or performance of finger stick blood as used in the Chembio system.

On June 16, 2020, the FDA revoked the EUA for the DPP COVID-19 IgM/IgG System. As a result, Chembio is revising its system with the objective of meeting the FDA's new criteria, including the use of the NCI process. The versatility of Chembio's proprietary DPP platform was critical to Chembio's ability to initially develop the DPP COVID-19 IgM/IgG System expeditiously, which enabled the system to become one of the first COVID-19 antibody tests to receive an EUA. The flexibility of the DPP platform will facilitate Chembio's objective of revising the system to meet the new FDA performance criteria, and Chembio expects, based on its development efforts to date, to apply for an EUA for the revised system during the third quarter of 2020.

"We believe recent positive feedback from a number of customers confirms that our rapid DPP COVID-19 IgM/IgG System can add tremendous value in quickly evaluating patient COVID-19 IgM and IgG antibody values in a variety of settings. We remain confident that the unique features and benefits of our test platform will make it one of the preferred solutions for antibody testing worldwide," stated Rick Eberly, Chembio's President and Chief Executive Officer. "In modifying our serology system, we are seeking to respond to the FDA's new performance criteria, as well as the rapidly evolving scientific and clinical understanding of the virus that led to the adoption of those criteria."

Chembio continues to offer the DPP COVID-19 IgM/IgG System outside the United States.

DPP COVID-19 Antigen System

After having recently obtained positive results from feasibility work, Chembio is pursuing development of a point-of-care DPP COVID-19 Antigen System. The DPP COVID-19 Antigen System is expected to consist of a DPP COVID-19 Antigen Assay and a DPP Micro Reader analyzer and to use a respiratory specimen, such as a nasal or nasopharyngeal swab, to detect COVID-19 antigens. The new system will be developed using the DPP platform, with the objective of offering COVID-19 detection for diagnosis at the point of care, to improve clinical outcomes.

"We intend to bring an antigen system to market to help with the rapid and direct detection of the COVID-19 virus," stated Mr. Eberly. "As with other DPP-based systems, we expect it to run in approximately 15 minutes without requiring the significant up-front investment and infrastructure needed for molecular detection systems. We believe a simpler, point-of-care design based on our DPP technology will be able to help identify infection rates closer to real time, where and when needed."

In a separate press release issued today entitled "Chembio Diagnostics Awarded BARDA Grant for Development of DPP COVID-19 Point-of-Care Antigen System," Chembio announced it had been awarded a contract from the Biomedical Advanced Research and Development Authority, known as BARDA, intended to assist Chembio in developing its COVID-19 point-of-care antigen system and in submitting an EUA for the system.

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 the development of, and obtaining an EUA for, a revised COVID-19 serology system and 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 either or both of the proposed COVID-19 systems; Chembio may be unable to anticipate or respond to FDA regulatory requirements, or changes in those requirements, with respect to one or both of the proposed COVID-19 systems, or otherwise may be unable to obtain or maintain an EUA, or other necessary regulatory approvals, for either or both of such COVID-19 systems, including approvals for

use of the COVID-19 antigen system as a point-of-care solution; potential customers may not adopt antibody or 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 antibody or 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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