Chembio Diagnostics Receives Emergency Use Authorization for DPP COVID-19 System for IgG and IgM Antibodies

April 15, 2020

First Shipments of the COVID-19 Serological Test have been Released

HAUPPAUGE, N.Y., April 15, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced receipt of Emergency Use Authorization (EUA) for its DPP COVID-19 System. The DPP COVID-19 System is a serological test and analyzer that provides numerical readings for both IgM and IgG levels within 15 minutes from a simple finger stick drop of blood. Both Chembio's Micro Reader 1 and Micro Reader 2 analyzers are compatible with the test.

"We are very pleased with the continued progress our teams are making to address the market demands with our DPP COVID-19 serological system," stated Rick Eberly, Chembio's Chief Executive Officer. "The flexibility of having two analyzers and a system that provides high sensitivity and specificity that is generally consistent with the performance of Chembio's other DPP platform tests as part of our offering places us in a unique position to serve a variety of markets. Additionally, we are pleased to announce that our manufacturing team has produced and shipped our first lots of the COVID-19 Systems, and we look forward to providing further product within the US and abroad."

About Chembio Diagnostics
Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. The company's patented DPP technology platform, which uses a small drop of blood from the fingertip, 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, a number of which applications are under active development with collaboration partners. 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
The second paragraph of this press release contain statements concerning the intent, belief and current expectations of Chembio and its management that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements reflect management's current views based on certain assumptions, and they involve risks and uncertainties. Actual results, events, or performance may differ materially from the 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 success of Chembio's research, development and commercialization efforts; Chembio's ability to maintain existing, and timely obtain additional, regulatory approvals; the potential development of competing diagnostic tests for COVID-19; the unpredictability associated with the COVID-19 pandemic; Chembio's retention of key personnel; and other changes in U.S. trade policy; and other risks described in public reports filed by Chembio with the Securities and Exchange Commission, including under the caption "Risk Factors" in Chembio's Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Chembio undertakes no obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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..

Contact:
Philip Taylor
Gilmartin Group
(415) 937-5406
investor@chembio.com

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This is a correction of the initial announcement to remove the term "point-of-care" from the description of the DPP COVID-19 System, based on advice from the Food and Drug Administration that use of "point-of-care" in this context implied that the test are deemed to waived under the Emergency Use Authorization of Medical Products and Related Authorities. Apr 15, 2020