Chembio Diagnostics Evaluates Monkeypox Rapid Point-of-Care Test Development

August 16, 2022

HAUPPAUGE, N.Y., Aug. 16, 2022 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Chembio) (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced it is evaluating the potential to develop a monkeypox rapid point-of-care (POC) test. Chembio is exploring the technical requirements for test development leveraging its multiple technology platforms, DPP, SURE CHECK, and STAT PAK, along with funding partners and the broader market opportunity.

"We are in dialogue with leading health organizations at the federal and state level to evaluate the need for a rapid test to detect and diagnose monkeypox. We are assessing the market needs, timing, regulatory pathway and investment required to develop a test," said Richard Eberly, Chembio's President and Chief Executive Officer. "Current tests available for monkeypox are PCR based, and given our history of developing rapid POC tests for infectious disease outbreaks, we believe we may be positioned to leverage our technology to provide a differentiated rapid solution. Based on our findings we will determine if this is a viable future opportunity for Chembio."

Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus is part of the same family of viruses as variola virus, the virus that causes smallpox with symptoms similar to smallpox symptoms, but milder, and rarely fatal. Monkeypox can spread from person to person through direct contact with the infectious rash, scabs, or body fluids. It also can be spread by respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact. There are now over 11,000 total confirmed monkeypox cases in the United States.

Chembio has a track record of delivering testing solutions for three recent infectious disease outbreaks with the expedited development rapid point-of-care tests. This includes the rapid development of a Zika product for the U.S. market, when the Zika outbreak was impacting the United States in 2017. The company also developed a DPP Ebola test to help with the outbreak with Ebola in 2018. This was followed by the development of COVID tests when the pandemic hit the U.S. in 2020. Additionally, Chembio has developed rapid point-of-care DPP diagnostic tests for HIV 1/2 and Syphilis with the introduction of STAT PAK and SURE CHECK.

Currently, the FDA has cleared one test to detect monkeypox, offered through the U.S. Centers for Disease Control and Prevention (CDC) as a lab developed test (LDT). The test utilizes a swab sample from a monkeypox lesion, creating the need for earlier detection to limit the spread of the disease and expedite treatment.

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, 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 diagnostics company focused on developing and commercializing point-of-care tests used to detect and diagnose infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment. 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

Certain statements contained in the first and second 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 opportunity, timing and operational and financial success of Chembio's desire and ability to research, develop and manufacture a rapid POC test to detect monkeypox. 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, many of which may be outside the control of Chembio, 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: the global need for a rapid test to detect and diagnose monkeypox; the success of Chembio's research, development and commercialization efforts, including Chembio's ability to make the necessary investment with respect to such efforts; Chembio's ability to maintain existing, and timely obtain additional, regulatory approvals; the potential development of competing rapid POC tests for monkeypox; Chembio's retention of key personnel;

transportation delays, logistics disruptions and supply chain limitations; and changes in U.S. trade policy. 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and its Quarterly Report on Form 10-Q for the quarterly periods ended March 31, 2022 and June 30, 2022, particularly under the heading "Risk Factors."

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 trademarks.

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

Source: Chembio Diagnostics, Inc.