Chembio Diagnostics Receives SAHPRA Approval for DPP SARS-CoV-2 Antigen Test

November 29, 2021

HAUPPAUGE, N.Y., Nov. 29, 2021 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced receipt on November 26, 2021, of South Africa Health Products Regulatory Authority (SAHPRA) approval for the DPP SARS-CoV-2 Antigen test, authorizing marketing and distribution of the test for use at the point-of-care by professional healthcare providers.

“We are pleased that independent evaluation of the DPP SARS-CoV-2 Antigen test again demonstrated strong sensitivity and specificity performance. This is another validation of the DPP technology that expands the regulatory approvals received by our COVID testing portfolio,” said Richard Eberly, Chembio’s President and Chief Executive Officer. “South Africa represents a large testing market opportunity. We are excited to provide our distributor, Patient Focus Africa (PFA), with another testing solution in addition to our DPP SARS-CoV-2 IgM/IgG Antibody test, to help manage the evolving needs of the pandemic in South Africa.”

The DPP SARS-CoV-2 Antigen test has been designed to detect SARS-CoV-2 antigens in only 20 minutes. The DPP SARS-CoV-2 Antigen test uses a minimally invasive nasal swab and is designed to be read visually or with a DPP Micro Reader 2 optical analyzer. Both the DPP SARS-CoV-2 Antigen test and the IgM/IgG Antibody test are authorized for import and distribution in South Africa by Chembio’s distributor, Patient Focus Africa, pursuant to licenses issued by SAHPRA. PFA is a World Health Organization accredited company for near patient testing, wellness, and professional point of care testing. PFA is partially owned by Discovery Health, the largest private healthcare Insurance provider in South Africa, and services both the public and private healthcare markets in the country.

“We have 22 years’ experience of using quality point of care and rapid tests in the Southern African market. We have conducted millions of tests over this period of time. Let me state unequivocally: the Chembio DPP platform/test is in a league of its own. The quality control built into the strip, the ease of collecting quality samples, and the receipt of results that you can trust time after time – this is truly lifesaving,” said Jacques du Toit, Founder and Manager Director of Patient Focus Africa. “These sentiments are expressed and shared by our customers. Thank you Chembio for adding life to days; days to life!”

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 for the rapid detection and diagnosis of 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 second paragraph with respect to Chembio’s belief and current expectations with respect to the potential distribution of the DPP SARS-CoV-2 Antigen test in South Africa are not historical facts and may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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, 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: actions taken by PFA, the sole distributor of DPP SARS-CoV-2 Antigen tests in South Africa, will determine the extent, if any, to which Chembio is able to generate revenue from the distribution of the tests in South Africa and those actions are outside Chembio’s control; the availability and cost of human, material and other resources required to build and deliver the tests, which factors are largely outside Chembio’s control; the ability of Chembio to maintain existing, and timely obtain any required additional, regulatory SAHPRA approvals for COVID-19 diagnostic tests, which approvals are subject to processes that can change recurringly without notice; Chembio’s dependence upon, and limited experience with, COVID-19 diagnostic tests; and the risks of doing business with foreign governmental entities, including geopolitical, international and other challenges as well as potential material adverse effects of tariffs and other 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, 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. All other trademarks appearing in this release are the property of their respective owners.

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Source: Chembio Diagnostics, Inc.