Chembio Diagnostics Receives ANVISA Approval for DPP SARS-CoV-2 Antigen System in Brazil

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HAUPPAUGE, NY, November 13, 2020 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced that its subsidiary Chembio Diagnostics Brazil Ltda. has received regulatory approval from Agência Nacional de Vigilância Sanitária (ANVISA) to market the DPP SARS-CoV-2 Antigen System in Brazil.

The DPP SARS-CoV-2 Antigen test system is designed to detect SARS-CoV-2 antigen in only 20 minutes. The detection of specific SARS-CoV-2 viral antigen implies a current infection by the virus responsible for COVID-19 cases. The DPP SARS-CoV-2 Antigen System consists of a DPP SARS-CoV-2 Antigen test cartridge, a DPP Micro Reader 1 or DPP Micro Reader 2 analyzer, and a minimally invasive nasal swab.

Clinical trial data demonstrates sensitivity of 96.0% at zero to six days from the onset of symptoms and specificity of 98.7% on symptomatic population as compared to PCR tests.

“We are grateful for the approval of our DPP SARS-CoV-2 Antigen System by ANVISA. The exceptional performance of this assay highlights again the value and flexibility of our DPP technology,” stated Javan Esfandiari, Chembio’s Executive Vice President and Chief Science & Technology Officer. “We believe helping people understand their infection status has shown to be one of the most effective methods for controlling the spread of COVID-19. Enabling patients and providers to know this information at the point-of-care in 20 minutes can help further reduce the risk of virus transmission and improve patient outcomes. We are very proud to offer this System in Brazil and assist in efforts to manage the global pandemic.”

Chembio Diagnostics Brazil, formerly Orangelife Comercio e Industria Ltda., is Chembio’s Brazilian commercial subsidiary that Chembio acquired in November 2019. Offering leading point-of-care tests to Brazilian state, private, and pharmacy markets, Chembio Diagnostics Brazil also provides local support to the Company’s long-time partner Bio-Manguinhos.

“Combined with ANVISA’s prior Approval for Emergency Use of the DPP COVID-19 IgM/IgG assay, we are now able to offer the Brazilian healthcare sector Systems that detect active infections and provide antibody status that both run on the same Micro Reader analyzers. Our test systems are rapid, accurate, and ideal for decentralized testing which can help expand access to testing across communities,” stated Charles Caso, Chembio’s Vice President, Sales and Marketing. “We view Brazil as one of the most attractive infectious disease testing markets in the world, and we plan to expand the commercial team at Chembio Diagnostics Brazil to leverage our growing portfolio of approved tests in the country.”

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, Agência Nacional de Vigilância Sanitária (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 point-of-care diagnostics company focused on detecting and diagnosing infectious diseases, including COVID-19, sexually transmitted disease, and fever and tropical disease. 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.

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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