Chembio Ebola Virus Diagnostic Test Receives U.S. FDA Emergency Use Authorization

November 9, 2018

MEDFORD, N.Y., Nov. 09, 2018 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care ("POC") diagnostics company focused on infectious diseases, today announced the receipt of U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for its DPP® Ebola Antigen System for use with human capillary “fingerstick” whole blood, EDTA venous whole blood, and EDTA plasma. The DPP® Ebola Antigen System includes the DPP® Ebola Assay and DPP® Micro Reader.

The DPP® Ebola Antigen System utilizes Chembio's patented DPP® technology platform, which is the same proven technology used in the Company's FDA approved HIV antibody tests and FDA authorized DPP® Zika System. The test detects viral antigens and provides qualitative results in 15-20 minutes, when used with the hand-held, battery-operated DPP® Micro Reader to reduce the risk of human error during test interpretation.

The test is authorized for the presumptive detection of Ebola virus (species *Zaire ebolavirus* and hereafter referred to as Ebola virus) in individuals with signs and symptoms of Ebola virus disease (EVD) in conjunction with epidemiological risk factors (including geographic locations with high prevalence of EVD). The DPP® Ebola Antigen System is intended for use in laboratories or facilities adequately equipped, trained and capable of such testing (including treatment centers and public health clinics).

Ebola virus disease was first discovered in 1976 near the Ebola River, in what is now the Democrat Republic of the Congo (DRC). EVD is an acute, severe and often fatal illness which initially presents with sudden onset of fever, fatigue, muscle pain, headache and sore throat. While there have been numerous EVD outbreaks including an ongoing outbreak in the DRC, the 2014-2016 outbreak in West Africa accounted for more cases and deaths than all others combined, making it the largest and most complex EVD outbreak. According to the World Health Organization, it can be difficult to clinically distinguish EVD from other infectious diseases such as malaria.

"We are pleased to receive FDA Emergency Use Authorization for our DPP® Ebola System as we believe it will be a valuable tool to address the global threat posed by Ebola virus, including the ongoing outbreak in the DRC," said John Sperzel, Chembio’s Chief Executive Officer. "Our patented DPP® technology continues to serve as a robust platform for the rapid detection of infectious diseases, and we hope to receive support and funding as we pursue additional regulatory approvals for our rapid Ebola test."

The DPP® Ebola Antigen System has not been FDA cleared or approved and has been authorized only for the diagnosis of EVD and not for any other viruses or pathogens. The DPP® Ebola Antigen System is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Ebola virus and/or diagnosis of EVD under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

About Chembio Diagnostics
Chembio Diagnostics, Inc. 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 15-20 minutes. Coupled with Chembio’s extensive scientific expertise, its novel DPP® technology offers broad market applications beyond infectious disease, a number of which 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.

Headquartered in Medford, NY, Chembio is registered with the U.S. Food and Drug Administration (FDA) as well as the U.S. Department of Agriculture (USDA), and is certified for the global market under the International Standards Organization (ISO) directive 13485. Learn more at www.chembio.com.

Media contact:
Lynn Pieper Lewis
Gilmartin Group
(415) 937-5402
investor@chembio.com

Source: Chembio Diagnostics, Inc.