Chembio Diagnostics Receives WHO Prequalification Approval for Malaysia Facility

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Expands Manufacturing of HIV Tests for International Markets

MEDFORD, N.Y., Oct. 17, 2019 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced its manufacturing facility in Malaysia has been qualified by the World Health Organization (WHO) Prequalification program to produce Stat-Pak HIV 1/2 tests.

The WHO Prequalification of In Vitro Diagnostics (IVD) is a comprehensive assessment of individual IVDs through a standardized assessment process that includes inspection of the manufacturing site, review of a product dossier, performance evaluation including operational characteristics, and labelling review.

“Our investment in Malaysia is a key element of our growth strategy, commercially and operationally, and the WHO Prequalification approval represents a major milestone,” said John Sperzel, Chembio’s Chief Executive Officer. “This approval allows the company to manufacture our Stat-Pak HIV 1/2 test in Malaysia and supply it to international markets, which we plan to commence during the fourth quarter of 2019. We plan to expand Malaysia production to include other innovative Chembio products, which will also expand capacity and enhance product gross margins.”

Chembio’s investment in Malaysia began in January 2017 with the acquisition of RVR Diagnostics, which had previously received funding from the Malaysian Technology Development Corporation and the Malaysian Investment Development Authority, government agencies that oversee and drive investment into the manufacturing and services sectors in the country. Malaysia has a well-developed infrastructure, high-quality workforce and pro-business government policies, all of which offer significant strategic benefits for Chembio’s operations in the region.

About World Health Organization Prequalification
WHO Prequalification aims to ensure that diagnostics, medicines, vaccines and immunization-related equipment and devices for high burden diseases meet global standards of quality, safety and efficacy, in order to optimize use of health resources and improve health outcomes. The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers. This information, in conjunction with other procurement criteria, is used by UN and other procurement agencies to make purchasing decisions regarding diagnostics, medicines and/or vaccines. For more information, visit www.who.int/topics/prequalification/en/.

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
Statements contained in the third paragraph of this release that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief and current expectations of the company and its management with respect to the timing of production and supply of Stat-Pak HIV 1/2 tests manufactured in Malaysia and the expansion of manufacturing in Malaysia. Such statements, which are estimates 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 the above 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 manufacturing and commercialization efforts and Chembio’s retention and attraction of key personnel. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

DPP and STAT-PAK are Chembio’s registered trademarks. For convenience, these trademarks appear 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 trademarks.

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