



ChemBio Diagnostics Receives WHO Prequalification Approval for HIV Self-Test

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Innovative HIV Self-Test Uses the World's Smallest Blood Sample

MEDFORD, N.Y., Nov. 04, 2019 (GLOBE NEWSWIRE) -- November 4, 2019 - ChemBio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced its SURE CHECK HIV Self-Test has received World Health Organization (WHO) Prequalification approval.

The WHO Prequalification of In Vitro Diagnostics (IVD) is a comprehensive assessment of individual IVDs through a standardized process that includes inspection of the manufacturing site, review of a product dossier, performance evaluation including operational characteristics, and labelling review. It signifies that the product meets global standards of quality, safety and performance, and is used by United Nations and other procurement agencies such as PEPFAR, UNITAID, and the Global Fund to make purchasing decisions.

The SURE CHECK HIV Self-Test provides unparalleled ease of use -- using the world's smallest blood sample required by any rapid HIV test -- and provides results in 15 minutes. The unique design of the SURE CHECK HIV Self-Test integrates the capillary device and buffer solution, eliminating the need for separate collection devices and buffer solution bottles required by other HIV self-tests. The SURE CHECK HIV Self-Test, which detects antibodies to HIV 1 and HIV 2, demonstrated sensitivity of 99.4% and specificity of 100%, when comparing untrained HIV self-test users to trained professionals.

"We are pleased to receive WHO Prequalification approval for our innovative HIV self-test, as it paves the way for commercialization in a high-growth HIV testing segment," said John Sperzel, ChemBio's Chief Executive Officer. "The approval of this test allows global funders and national ministries of health to confidently expand access to HIV self-testing, enabling diagnosis and treatment. It is estimated that 21% of the world's population living with HIV are unaware of their positive status, and the WHO strongly recommends HIV self-testing as a mechanism to expand access to HIV treatment."

The essential element of ChemBio's newly WHO Prequalified HIV Self-Test is the company's SURE CHECK HIV 1/2 Assay that is FDA approved, CLIA waived, CE marked, WHO Prequalified, and trusted by health care professionals across the globe. ChemBio's SURE CHECK HIV 1/2 Assay was also incorporated into two CE marked private label versions of HIV self-tests that both commenced European commercialization in 2015.

In 2016, the WHO published global HIV self-testing guidelines, recommending that HIV self-testing be offered as an additional approach to HIV testing services. ChemBio's SURE CHECK HIV Self-Test was evaluated by the HIV Self-Testing Africa Initiative (STAR) that is funded by UNITAID, with the goal of accelerating self-test adoption by addressing market, regulatory and policy barriers. SURE CHECK HIV Self-Test was found to have superior acceptability and performance, facilitating widespread adoption.

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 fourth and sixth paragraphs 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 or current expectations of the company and its management. 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 research, development 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 SURE CHECK 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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