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Contact: **Trinity Biotech plc**
Terence Dunne
(353)-1-2769800
E-mail: terence.dunne@trinitybiotech.com

Trinity Biotech Announces the Submission of TrinScreen™ HIV to the World Health Organisation for Approval

DUBLIN, Ireland (March 30th, 2021). Trinity Biotech plc (Nasdaq: TRIB) has submitted its new HIV screening product, TrinScreen™ HIV, to the World Health Organisation (WHO) for approval.

This product, once approved, will allow the Company to build on its strong presence in HIV testing in Africa, with the Company having been the main confirmatory test provider over many years with its Uni-Gold™ HIV test.

It is expected that the WHO will take a number of months to consider the submission. The Company intends to use that time to prepare for automated manufacturing of the test at the Company's facility in Ireland.

Test Overview

The product is designed to test for the presence of HIV antibodies from a finger stick sample of blood, in less than 12 minutes. The test has been designed to maximise assay sensitivity and ease of use in the field. A high assay sensitivity indicates the potential risk of a false negative result is very low - a critical parameter in screening programmes where the objective is to identify those with HIV infection. Ease of use in the field allows for broad dissemination of testing which is of critical importance in the African HIV testing market.

Performance Evaluation

As part of the WHO approval process the product has already undergone an evaluation sponsored by the WHO with 1,200 clinical samples at an independent laboratory. The results of this evaluation were excellent. In addition to this, the full submission for pre-qualification also includes the data from a multi-centre clinical evaluation which concluded in Africa in 2020.

Comments

Commenting, Ronan O’Caoimh, Chief Executive Officer stated, “We are excited to have submitted our new HIV screening product, TrinScreen HIV, to the WHO for approval. The development of this product has been a strategic priority for Trinity Biotech over several years. It is very positive to see this project reach such a key milestone, especially given the challenges caused by COVID-19 to the clinical evaluation process. Trinity Biotech has already earned a strong reputation in the HIV testing market in Africa with our HIV confirmatory test, Uni-Gold HIV. We expect that on approval by the WHO of TrinScreen HIV, Trinity Biotech will be ideally positioned to take a significant share of the HIV screening market in Africa given the excellent clinical performance of the product and our existing strong reputation in the HIV testing market in Africa.”

Forward Looking Statements

Certain statements made in this release that are not historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words “estimate”, “project”, “intend”, “expect”, “believe” and similar expressions are intended to identify forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties. Many factors could cause the actual results, performance or achievements of Trinity Biotech to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements, including, but not limited to, the results of research and development efforts, risks associated with the outbreak and global spread of the coronavirus (COVID-19), the effect of regulation by the U.S. Food and Drug Administration and other agencies, the impact of competitive products, product development commercialization and technological difficulties. For additional information regarding these and other risks and uncertainties associated with Trinity Biotech’s business, reference is made to our reports filed from time to time with the U.S. Securities and Exchange Commission. We undertake no obligation to update or revise any forward-looking statements for any reason.

About Trinity Biotech

Trinity Biotech develops, acquires, manufactures and markets diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market. The products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood. Trinity Biotech sells direct in the United States, Germany, France and the U.K. and through a network of international distributors and strategic partners in over 75 countries worldwide. For further information please see the Company's website: www.trinitybiotech.com.