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Trinity Biotech Announces the World Health Organisation Approval Of TrinScreen™ HIV

DUBLIN, Ireland (February 14, 2022). Trinity Biotech plc (Nasdaq: TRIB) has received approval for its new HIV screening product, TrinScreen™ HIV, from the World Health Organisation (WHO).

TrinScreen™ HIV

Trinity Biotech's Uni-Gold™ HIV product has been the main confirmatory test provider for the detection of the HIV virus on the African continent over many years. Trinity Biotech has developed this new product, TrinScreen™ HIV, specifically for the screening market, a market that is significantly larger than the confirmatory market, with an estimated market size of over USD150m.

TrinScreen™ HIV is a rapid test providing results in less than 12 minutes from a finger stick drop of blood and the test has demonstrated excellent performance in both an independent evaluation sponsored by the WHO and in a multi-centre clinical evaluation conducted in Africa in 2020 by the Company. The Company believes the TrinScreen™ HIV product has a number of key advantages compared to the current main incumbent product.

Having been the main confirmatory test provider for the detection of HIV in Africa over many years, the Company has strong relationships with key opinion leaders in this area as well as with the Non-Government Organisations who fund HIV testing in Africa. In anticipation of the WHO approval of TrinScreen™ HIV, the Company has expanded the sales and marketing team serving the African continent through the appointment of senior and experienced sales executives with a demonstrated track record in the HIV market.

This WHO approval coupled with the excellent product performance, Trinity Biotech's brand equity and an experienced sales and marketing team should allow Trinity Biotech to expedite the adoption of TrinScreen™ HIV into recurring multi-year national screening algorithms across Africa and as a result, the Company expects to capture a significant share of the HIV screening market in Africa.

Opportunities also exist for TrinScreen™ HIV in emerging countries on other continents.

The Company will manufacture TrinScreen™ HIV at its automated manufacturing plant in Bray, Ireland.

Comments

Commenting, Ronan O'Caoimh, Chief Executive Officer stated, "We are excited to have received WHO approval for our new HIV screening product, TrinScreen HIV. This product has been a strategic priority for Trinity Biotech over several years and this approval is a very positive development for the company's future. We have already earned a strong reputation in the HIV testing market in Africa with our HIV confirmatory test, Uni-Gold HIV. We believe that with TrinScreen HIV, we are 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.