

Trinity Biotech Welcomes TrinScreen HIV's Inclusion In The New Kenyan HIV Testing Algorithm

DUBLIN, Ireland, March 22, 2023 — Trinity Biotech plc (Nasdaq: TRIB) (the “Company”), a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets, today welcomed the announcement by the Kenyan Ministry of Health of the adoption of a new HIV rapid testing algorithm. This new algorithm establishes Trinity Biotech’s TrinScreen HIV as the screening test (A1 = screen test under World Health Organisation (“WHO”) guidelines).

The Kenyan HIV screening programme is one of the largest in Africa, with an estimated annual number of screening tests of between 7 million and 9 million. The Company understands that the Kenyan Ministry of Health is moving to rapidly deploy the new HIV testing algorithm with testing expected to begin in Quarter 2, 2023.

Trinity Biotech developed TrinScreen HIV specifically for the African screening market, which has an estimated market size of approximately USD150m, and received WHO pre-qualification approval in February 2022.

The Kenyan HIV testing algorithm was the first testing algorithm for which TrinScreen HIV was submitted. The adoption of TrinScreen HIV by the Kenyan Ministry of Health is a significant vote of confidence in the performance of TrinScreen HIV and a recognition of Trinity Biotech’s track record of supporting HIV testing in Africa with quality products over the last twenty-five years.

Trinity Biotech is currently working with ministries of health in several other African countries regarding the future adoption of TrinScreen HIV as the screening test in their respective HIV testing algorithms.

Trinity Biotech has been preparing for large scale manufacturing of TrinScreen HIV at its automated WHO standard, ISO13485 certified lateral flow test facility in Bray, Ireland and the Company expects to scale workforce capacity at the facility in the second quarter as orders ramp up.

Comments

Commenting on the announcement, Mícheál Roche, Vice President of Global Health, stated “The Kenyan Ministry of Health is regarded as a leader in the early adoption of innovations around HIV care. That they have chosen TrinScreen HIV as the screening test for Kenya demonstrates the quality of the product. I believe the fact that TrinScreen HIV has been adopted in Kenya will greatly assist the product being adopted into HIV algorithms in other countries”.

Commenting on the announcement, Aris Kekedjian, Chief Executive Officer stated, “TrinScreen HIV is a strategically important product for Trinity Biotech and Kenya was identified early on as the key launch market for TrinScreen HIV given its size and influence across Africa as a thought leader in HIV care. This announcement demonstrates Trinity Biotech’s ability to disrupt well-established incumbents with world-class, high-quality point of care solutions. This is a core milestone in the company’s transformation into a focused, high-growth innovator in decentralised diagnostics and diabetes care”.

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.

About Trinity Biotech Plc

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.

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