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Trinity Biotech Announces CE Mark of its 10-Minute Covid-19 Antigen Test

DUBLIN, Ireland, May 20, 2022 (GLOBE NEWSWIRE) -- Trinity Biotech plc (Nasdaq: TRIB) has achieved a CE Mark for its 10-minute Covid-19 antigen test. This CE mark allows for use by healthcare professionals and trained users. The Company intends to launch the test throughout the European Union as well as other countries that recognise the CE Mark designation.

In addition to its ease-of-use and impressive speed to result, in extensive clinical trials the test has demonstrated excellent 99% sensitivity and 99% specificity which are accuracy levels superior to many of the tests currently on the market.

The test uses an anterior nasal swab sample rather than the more invasive nasopharyngeal swab, providing a more comfortable patient experience. The test also has several features that benefit the user including a convenient pre-filled extraction buffer and a run time of 10 minutes which is faster than many competitor products. This speed to result and pre-filled buffer allows a higher throughput of patients for healthcare professionals and trained users performing the test, while also providing a more comfortable patient experience without compromising on diagnostic performance.

In many instances, antigen tests have replaced PCR as the go-to method for Covid-19 testing and we expect antigen tests to be an important tool for the management of Covid-19 for many years to come.

The rapid Covid-19 antigen test has been developed by Trinity Biotech on the same lateral flow test platform as the recently World Health Organisation (WHO) approved Trinscreen HIV™ test and will be manufactured at the Company's high volume automated lateral flow manufacturing site in Bray, Ireland.

The Company will continue to examine regulatory approval pathways in other countries in deciding what further regulatory approvals to seek for this product.

The Company intends to continue to expand its rapid test portfolio in infectious disease using the existing lateral flow test platform and high-volume automated manufacturing.

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.