Trinity Biotech Provides A Business Development Update For Q2 2021

DUBLIN, Ireland, July 16, 2021 — Trinity Biotech plc (Nasdaq: TRIB) provides a business development update for Q2 2021.

HIV Testing (TrinScreen™ HIV)

Trinity Biotech 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 a new product, TrinScreen™ HIV, specifically for the screening market, a market that is significantly larger than the confirmatory market.

TrinScreen™ HIV has already undergone an independent evaluation sponsored by the World Health Organisation (WHO), yielding excellent results. The final part of the approval process includes WHO review of the multi-site clinical evaluation which concluded in Africa in 2020. This final part of the submission dossier was submitted to the WHO in March 2021. In June 2021, the Company received an update from the WHO on the approval process. The WHO confirmed that their screening of the submission dossier is complete and the dossier will now move forward to the final assessment phase.

This is an important milestone in the approval process for TrinScreen™ HIV. This product, once approved, will allow the Company to build on its strong brand presence in HIV testing in Africa. The Company believes the TrinScreen™ HIV product has a number of key advantages compared to the current main incumbent product and expects a positive response from the WHO and the opportunity to expand its market share in the African HIV market.

The Company is preparing for the automated manufacture of TrinScreen™ HIV at its facility in Ireland in anticipation of WHO approval.

COVID-19 Rapid Antigen Test

Trinity Biotech is at an advanced stage in the development of a SARS-CoV-2 antigen test. This test will use the Company’s core lateral flow technology. The test can be run without any specialised equipment, provides a result in 12 minutes and utilises an easy-to-use anterior nasal swab sample.

As the COVID-19 pandemic and associated public health responses have developed, antigen tests have continued to play an important role in the overall diagnostic response. Even as the roll out of vaccines continues, the role of antigen tests in providing assurance around active infection remains important and Trinity Biotech expects antigen testing to have a continuing place in the overall public health response to COVID-19, even as vaccinations continue.

COVID-19 Rapid Antibody Test

In June 2021, the Company made an Emergency Use Authorisation (EUA) application to the FDA for the UniGold™ SARS-CoV-2 rapid antibody test. The test detects IgG antibodies against the SARS-CoV-2 virus and demonstrated sensitivity of 100% and specificity of 95% during validation studies when measured against a comparator PCR method that established a confirmed prior infection.

In July 2021 the FDA informed the Company that given the volume of EUA requests it has received, it is not currently prioritising this type of serological test for review and thus will not review an EUA application for the test at this time. The Company has examined other potential pathways to regulatory approval to allow US sales of this test, but it is expected that these would require significant additional investment.

Due to the advent and widespread adoption of COVID-19 vaccines since this antibody test was envisaged and the focus of public health authorities on using evidence of vaccination rather than the presence of antibodies as proof of immunity, the Company now expects that the use for such tests will be limited and thus the potential revenues from the sales of this product to be minimal. Given this current limited market demand for antibody tests, the Company has decided to not devote additional investment to this test and instead is focusing its resources on the aforementioned COVID-19 antigen test for which we expect a much larger market.

Expansion of Clinical Laboratory Testing Services

The Company continues to expand the range of services offered at its New York reference laboratory through a series of senior appointments. These appointments include a Designate Deputy Lab Director to support the laboratory's core Autoimmune testing services, as well as an additional Assistant Director with certifications of qualification previously not held at the reference lab. These appointments are designed to enable the build out of lab services into new clinical and consumer wellness markets beyond the core Autoimmune and Immunogenetic testing services on which the reference lab has established a reputation of scientific and customer service excellence over the last 10+ years.

The laboratory currently provides a broad range of diagnostic services across Diagnostic Immunology, Oral Pathology, Immunogenetics and Andrology.

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 (COVID19), 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

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