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Trinity Biotech announces EUA submission for Covid-19 ELISA Antibody test

DUBLIN, Ireland (August 20, 2020)....Trinity Biotech plc (Nasdaq: TRIB), a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets announced that it has filed its submission for an Emergency Use Authorization (EUA) for its Covid-19 IgG ELISA antibody test with the FDA. This test will determine which individuals within the population have been exposed to the SARS-CoV-2 virus. The transfer of production to our facility in Jamestown, New York is complete, our manufacturing capability is very significant and the instrumentation platforms that perform ELISA testing are available in virtually every testing laboratory in the world.

The product demonstrates specificity in excess of 98% and sensitivity in excess of 95%, in samples of 14 days or more from symptom onset. EUA submission allows us to begin marketing the product immediately.

In addition, the Company is developing a rapid point-of-care Covid-19 test to detect antibodies to the virus that can be run in 12 minutes using one drop of blood procured by finger prick. This test will have utility similar to that outlined above for the ELISA antibody test. Once development and transfer to manufacturing of this rapid test is complete we intend to avail of the FDA's EUA pathway to expedite its approval for sale in the USA.

This pipeline of Covid-19 products complements our existing Viral Transport Media (VTM) product, which is used in the Covid-19 sample collection process for PCR molecular testing. We have scaled up the manufacture of VTM to meet increased levels of demand over the past months and we expect demand to continue as Covid-19 testing remains critical to the management of the pandemic.

Ronan O'Caoimh, Chief Executive Offer commented "We are very pleased to announce the submission of our Covid-19 ELISA antibody test for FDA Emergency Use Authorization (EUA). The test demonstrates both impressive specificity and sensitivity. Meanwhile, the ELISA testing platform with its excellent reputation for quality and widespread adoption makes it an ideal format for large scale antibody testing."

Forward-looking statements in this release are made pursuant to the "safe harbor" provision of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including, but not limited to, the results of research and development efforts, the effect of regulation by the United States Food and Drug Administration and other agencies, the impact of competitive products, product development commercialisation and technological difficulties. In addition, there is uncertainty about the spread of the COVID19 virus and the impact it will have on the Company's operations, the demand for Company's products, global supply chains and economic activity in general. These and other risks and uncertainties are detailed in the Company's Securities and Exchange Commission filings.

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.