Trinity Biotech subsidiary, Primus Corporation Receives FDA Warning Letter

DUBLIN, Ireland, Aug. 17, 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 its subsidiary Primus Corporation has received a warning letter from the U.S. Food and Drug Administration (FDA) following an inspection of its Kansas City, Missouri manufacturing facility that took place in January 2020. The issues identified in this letter primarily relate to the company's Ultra2 product range.

Trinity Biotech is fully committed to the highest standards of quality and compliance, has full confidence in the quality of the products manufactured at the Primus facility and will work in an urgent and collaborative manner with the FDA to resolve all of the issues addressed in the warning letter. As requested by the FDA, the company will provide a response outlining the actions it will take within 15 business days from receipt of the letter.

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.

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