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Trinity Biotech Announces FDA Submission of High Sensitivity Troponin I Product

DUBLIN, Ireland (December 17, 2015).... Trinity Biotech plc. (Nasdaq: TRIB) is pleased to announce today that it has submitted to the U.S. Food and Drug Administration (FDA), for 510(k) clearance, its Meritas Point of Care Analyzer and Meritas cardiac troponin-I (cTnI) point-of-care assay for use in the diagnosis of myocardial infarction (MI). The cTnI assay will enable health care professionals to quickly determine patient cardiac status in Emergency Department settings, to accelerate patient care and to reduce overall costs of delivering health care.

The Meritas cTnI assay is run on the Meritas Point of Care Analyzer. The single-use, pre-calibrated cTnI assay is simple to use, and delivers cTnI results in about 15 minutes in both whole blood and plasma samples. The assay combines sensitive antibody reagents and the use of advanced injection moulding technologies to create high-fidelity micropillar structures to control sample fluidics. Clinical data was collected at 14 geographically dispersed locations across the United States and MIs were determined by a panel of independent adjudicators.

The following table outlines the clinical performance results of the product at the time of admission to the hospital emergency room.

	Sensitivity	Specificity
Whole Blood	66%	94%
Plasma	78%	95%

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, and other risks detailed in the Company's periodic reports filed with the Securities and Exchange Commission.

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