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Regulatory Approval Granted for Commencement Of Trinity Biotech's Offshored and Outsourced Manufacturing of its Flagship Rapid HIV Test, Facilitating Strategic and Financial Performance Transformation

Approval Facilitates Immediate Offshored and Outsourced Manufacturing

Strategic Offshore Manufacturing Move Expected to Drive Gross Margin Expansion, Free Up Working Capital, and Enhance Scalability

Transition to Outsourced Production Reduces Fixed Costs and Supports Trinity's Broader Profitability and Growth Objectives

DUBLIN, Ireland (August 20, 2025) - Trinity Biotech plc (Nasdaq: TRIB), a commercial-stage biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors, today announced that the in-country healthcare product regulatory authority has granted the key approval to initiate offshore and outsourced manufacturing of its flagship World Health Organization (WHO) prequalified TrinScreen™ HIV rapid test.

This key approval now enables Trinity Biotech to transition upstream production from its legacy in-house operations to a more cost-effective and scalable outsourced model, while maintaining the highest levels of product integrity and regulatory compliance. Trinity Biotech has now begun manufacturing under this new model, marking a critical milestone in the Company's transformation strategy. The strategic shift is expected to:

- Expand gross margins.
- Free up working capital.
- Reduce fixed costs, supporting broader profitability and growth objectives.

This latest approval builds on the previously announced WHO approval for the offshored and outsourced upstream manufacturing activities of Trinity Biotech's high-volume TrinScreen™ HIV rapid test.

"This key regulatory approval is a major step forward in our transformation journey," said John Gillard, President and Chief Executive Officer of Trinity Biotech. "It builds on our earlier WHO authorization and allows us to fully operationalize our offshore manufacturing model for TrinScreen™ HIV. This transition unlocks significant cost efficiencies, enhances scalability, and positions the Company for long-term financial health."

Forward-Looking Statements

This release includes statements that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 (the “Reform Act”), including but not limited to statements related to Trinity Biotech’s cash position, financial resources and potential for future growth, market acceptance and penetration of new or planned product offerings, and future recurring revenues and results of operations. Trinity Biotech claims the protection of the safe harbor for forward-looking statements contained in the Reform Act. These forward-looking statements are often characterized by the terms “may,” “believes,” “projects,” “expects,” “anticipates,” or words of similar import, and do not reflect historical facts. Specific forward-looking statements contained in this release may be affected by risks and uncertainties, including, but not limited to, our ability to capitalize on the Waveform transaction and of our recent acquisitions, our continued listing on the Nasdaq Stock Market, our ability to achieve profitable operations in the future, the impact of the spread of COVID-19 and its variants, the possible pause and/or disruption in U.S. Government funding for HIV tests produced by Trinity Biotech, potential excess inventory levels and inventory imbalances at the company’s distributors, losses or system failures with respect to Trinity Biotech’s facilities or manufacturing operations, the effect of exchange rate fluctuations on international operations, fluctuations in quarterly operating results, dependence on suppliers, the market acceptance of Trinity Biotech’s products and services, the continuing development of its products, required government approvals, risks associated with manufacturing and distributing its products on a commercial scale free of defects, risks related to the introduction of new instruments manufactured by third parties, risks associated with competing in the human diagnostic market, risks related to the protection of Trinity Biotech’s intellectual property or claims of infringement of intellectual property asserted by third parties and risks related to condition of the United States economy and other risks detailed under “Risk Factors” in Trinity Biotech’s annual report on Form 20-F for the fiscal year ended December 31, 2024 and Trinity Biotech’s other periodic reports filed from time to time with the United States Securities and Exchange Commission. Forward-looking statements speak only as of the date the statements were made. Trinity Biotech does not undertake and specifically disclaims any obligation to update any forward-looking statements.

About Trinity Biotech

Trinity Biotech is a commercial stage biotechnology company focused on diabetes management solutions and human diagnostics, including wearable biosensors. The Company 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 and has recently entered the wearable biosensor industry, with the acquisition of the biosensor assets of Waveform Technologies Inc. and intends to develop a range of biosensor devices and related services, starting with a continuous glucose monitoring product. Our 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 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.