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Trinity Biotech Secures Major Regulatory Approval for Offshored and Outsourced Manufacturing of Its Market Leading Uni-Gold Rapid HIV Test, Further Accelerating Financial Performance Transformation

Strategic Offshore Manufacturing Move Expected to Drive Gross Margin Expansion, EBITDA Accretion and Cashflow Generation

DUBLIN, Ireland (November 18, 2025) - Trinity Biotech plc (Nasdaq: TRIB), a commercial-stage biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors, today announced it has received World Health Organization (WHO) approval for the offshored and outsourced upstream manufacturing activities of its market leading Uni-Gold™ HIV rapid test, a well-established and cornerstone diagnostic product used in HIV screening programs internationally. This regulatory approval marks a further critical milestone in the Company's comprehensive transformation plan aimed at driving sustainable profitability.

This major regulatory approval enables Trinity Biotech to transition upstream production of Uni-Gold™ from its legacy in-house operations to a more cost-effective outsourced model, while maintaining the highest levels of product integrity and regulatory compliance.

The initiative is part of a complex, multifaceted project that has been in development for approximately two years. It reflects the ability of Trinity Biotech's current leadership team to envision and execute high-value, strategic business transformation projects to drive long-term capital value. This transformation capability creates a long-term value creation driver in the business as it focuses on future growth opportunities.

"This achievement underscores our commitment to executing a profitability-focused transformation strategy. By strategically partnering with world-class manufacturing providers, we are ensuring that Trinity Biotech remains competitive, agile, and well-positioned for long-term growth," said John Gillard, President & Chief Executive Officer of Trinity Biotech.

The transition to outsourced offshore upstream manufacturing is expected to deliver substantial improvements in gross margin, EBITDA and cashflow generation. The move is part of a broader strategic initiative to streamline operations, reduce fixed costs, and focus internal resources on innovation and market expansion.

Trinity Biotech will implement this next phase of this new Uni-Gold™ HIV manufacturing model in the coming months.

Key Highlights:

- WHO approval granted for offshored and outsourced upstream manufacturing activities of Uni-Gold™ HIV.
- Supports transformation plan focused on financial turnaround and sustainable growth.
- Expected to improve gross margins, EBITDA and cashflow generation.

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.