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Trinity Biotech Expands Global Rollout of High-Capacity Column System for FDA-Cleared HbA1c Testing Solution After Securing Regulatory Clearances

Company advances its mission to deliver next-generation diabetes management solutions and expand global market penetration

Next-generation column technology enhances efficiency, expands recurring revenue potential, and strengthens Trinity Biotech's competitive position in the \$2B+ HbA1c market

DUBLIN, Ireland (December 15, 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 it has secured regulatory clearances in multiple countries, enabling the expanded rollout of its next-generation high-capacity HbA1c column system for the Premier Hb9210 analyzer which is now available in more than 10 countries, including the United States. The upgraded system significantly increases testing throughput, improves operational efficiency, and supports greater recurring revenue opportunities and margin expansion as the company strengthens its leadership position in the growing global HbA1c market.

The global laboratory HbA1c market is estimated to be currently worth over \$2 billion annually and is expected to grow to exceed \$3.5 billion by 2030. This expected rise in the HbA1c market is primarily driven by the increasing prevalence of diabetes¹.

Designed for Trinity Biotech's Premier Hb9210 analyzer, the company's dedicated laboratory HbA1c solution, the upgraded column system delivers up to four times the testing capacity compared to the existing column system and minimizes instrument downtime through improved stability and reduced maintenance requirements. These operational gains create a more efficient workflow for clinical laboratories and support broader adoption of the platform.

Key Highlights:

- Reduced downtime and improved operational efficiency, enabling higher throughput.
- Increased column stability, minimizing maintenance interruptions and reducing operator workload.
- The latest software update delivers additional automation of routine tasks enabling greater productivity and cost savings.

Trinity Biotech's Premier Hb9210 solution continues to be recognized as a gold standard in HbA1c testing, with published peer-reviewed scientific comparative studies continuing to confirm the strong clinical performance of the company's HbA1c analyzer system². In addition, a recent article published

¹ <https://www.maximizemarketresearch.com/market-report/global-hba1c-laboratory-tests-market/81466/>

² <https://doi.org/10.1080/00365513.2023.2281400> and <https://doi.org/10.1080/03630269.2025.2524437>.

by the Association for Diagnostics and Laboratory Medicine states “*Still, BAC (Trinity Biotech) remains the method with the highest specificity for HbA1c currently on the market.*”

“Launching this advanced system in key markets, including the U.S., positions Trinity Biotech to capture further growth opportunities in the global diabetes care segment,” said John Gillard, CEO and President of Trinity Biotech. “The combination of higher capacity, reduced downtime, and automation creates a compelling value proposition for laboratories, and we expect strong adoption in key markets to drive long-term shareholder value.”

Trinity Biotech continues to work closely with customers and regulatory authorities to expand availability into additional countries, reinforcing its commitment to global market penetration and innovation in diabetes care.

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

³ https://myadlm.org/cln/articles/2025/septemberoctober/navigating-hemoglobin-a1c-measurements-for-diabetes-care?utm_campaign=september-cln-monthly-email&utm_medium=email&hsenc=p2ANqtz--H-b8nqWXfE5QzwxN7g7ng4LhJzv0dDYVj2Cvg-NZIV7uT8_-w9cxM7lAzfzVYdEg1c2ODGomD_hAXRIAHVcYtRVxNxLe4bPax9TWmCPC1IGjFkJO&hsmi=382763562&utm_content=382763562&utm_source=hs_email

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.