## Trinity Biotech Announces Positive Pre-Pivotal Trial Results for Its Next-Generation Continuous Glucose Monitor Technology

DUBLIN, Oct. 07, 2024 — Trinity Biotech plc (Nasdaq: TRIB), a commercial-stage biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors, today announced the successful completion of its first prepivotal clinical trial in Europe for its next-generation continuous glucose monitor (CGM) technology. The study assessed the analytical performance of CGM technology enhancements implemented by Trinity Biotech since acquiring the technology from Waveform Technologies in January 2024.

"We have made significant progress in the development of our next generation factory-calibrated CGM, combining a high degree of accuracy with a unique modular design that simplifies and enhances user experience, while significantly reducing cost and waste," stated John Gillard, President and Chief Executive Officer of Trinity Biotech. "The outcome of this pre-pivotal study confirms the effectiveness of the R&D plan executed since the acquisition of the Waveform Technologies assets earlier this year and will be used to guide further sensor design optimisations."

Trinity Biotech implemented a research and development plan aimed at improving both the performance and usability of the CE-marked, 15-day wear CGM device. Key design modifications introduced in this study include a significant reduction in the biosensor wire length, a change aimed at enhancing in-body performance. The trial results demonstrated that the refined sensor achieved a mean absolute relative difference (MARD) that compares favourably to the previous Waveform device.

Trinity Biotech's Chief Technology Officer, Dr Gary Keating, added, "Our next phase of refinements, guided by this study's positive results, will be tested in a second European prepivotal trial, which is scheduled to take place in the fourth quarter of this year and will set the stage for our pivotal trial in 2025."

For a deeper understanding of Trinity Biotech's CGM technology and its potential to transform diabetes management, visit the dedicated CGM microsite at <a href="https://cgm.trinitybiotech.com">https://cgm.trinitybiotech.com</a>. The microsite features a new vision video that highlights the design approach of the next-generation CGM device and the innovative features that make it a transformative solution for users and payors.

CGMs are small patch-like wearable medical devices that use biosensor wires under the skin to measure glucose in real-time. These devices are increasingly popular in diabetes management and health monitoring, with the global CGM market estimated to be over \$11 billion already and expected to surpass \$20 billion by 2029 due to the rising prevalence of diabetes and the growing demand for user-friendly, accurate monitoring solutions. Trinity

Biotech is well-positioned to capture a significant share of this market with its next-generation CGM technology expected to offer an affordable, factory-calibrated solution designed for ease of use and sustainability.

## **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 characterised 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 our purchase of the assets of Waveform Technologies, 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, 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, 2023 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 human diagnostics and diabetes management solutions, 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: <a href="https://www.trinitybiotech.com">www.trinitybiotech.com</a>.

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