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Trinity Biotech Announces Breakthrough Results From Pre-Pivotal Trial of Disruptive Continuous Glucose Monitoring (CGM) Technology

Trinity Biotech's patented technology represents a paradigm shift in the global CGM market, projected to exceed $20 billion by 2029

DUBLIN, Ireland (January 28, 2025) - Trinity Biotech plc (Nasdaq: TRIB), a commercial-stage biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors, today announced compelling results from its latest pre-pivotal clinical trial for its next-generation continuous glucose monitoring (CGM) system. The pre-pivotal clinical trial, which included 30 diabetic participants—primarily individuals with Type 1 diabetes—represents a significant milestone in Trinity's mission to deliver affordable, high-performance CGM technology.

Trinity Biotech's redesigned ergonomic modular device features a reusable applicator and a rechargeable wearable transmitter that eliminates costly disposable components while delivering a seamless user experience. By using more durable, reusable components, enabled by Trinity's proprietary self-inserting sensor technology, the Trinity CGM is designed to deliver care at a significantly lower cost than today's two largest manufacturers. By addressing affordability—a key barrier to adoption of this life changing technology —Trinity's innovative approach has the potential to bring CGM technology to millions of individuals who have been priced out of the market. This disruptive design not only expands access but also redefines sustainability in the CGM space, further differentiating Trinity's solution from current market leaders.

"We believe that our patented technology—featuring a modular, eco-friendly design and cutting-edge sensor performance—represents a paradigm shift in the CGM market, which is projected to exceed $20 billion by 2029. We are developing a CGM system that is not only highly accurate but also disruptively affordable and user-friendly," said John Gillard, CEO of Trinity Biotech. "The two largest CGM manufacturers currently generate approximately $11 billion in sales annually serving just 10 million users combined—less than 2% of the 800 million people living with diabetes worldwide. This reflects a market which is constrained by the high cost of existing technologies. By delivering a solution that drastically reduces costs while maintaining top-tier performance, we believe we can significantly expand access to CGM devices and unlock the full potential of this underserved market."

Study Results Underscore Breakthrough Performance

Trinity Biotech's latest pre-pivotal trial involved 30 diabetic participants, primarily individuals with Type 1 diabetes, each of whom wore multiple sensors over a 15-day period. The trial evaluated modifications made by Trinity's R&D team to technology acquired from Waveform Technologies, Inc. that enhance sensor design and performance, yielding exceptional results:

- **Superior Signal Quality**: Significant improvements in signal clarity compared to previously released Waveform CGM sensors.
- **Enhanced Reliability Post-Insertion**: Sensor performance immediately after placement demonstrated markedly improved consistency, reducing variability for users.
- **Breakthrough Accuracy**: A 25-30% improvement in the key accuracy metric—mean absolute relative difference (MARD)—over earlier Waveform CGM sensors.
- **Industry-Standard Low-Glucose Precision**: Accuracy for low blood sugar readings (measured by mean absolute difference, or MAD) is now aligned with industry benchmarks, a critical achievement for hypoglycemia management.

Next Steps: Advancing Toward Commercialization

These results significantly bolster confidence in Trinity's ability to deliver a calibration-free CGM system that meets FDA's iCGM standard, enabling seamless integration with insulin pumps. Building on this success, Trinity expects to complete further clinical trials on additional device enhancements and remains on track to file for regulatory approval in the European Union in 2025, followed by filing for U.S. FDA approval in 2026, setting the stage for commercial rollouts targeting both diabetes patients and the broader market of individuals seeking real-time glucose insights.

To keep up to date with Trinity Biotech's CGM developments please visit our dedicated CGM microsite - https://cgm.trinitybiotech.com

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, 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, continuing international government financial support for healthcare programs, 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 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.