# Trinity Biotech Announces Application for Early Sjogrens Syndrome Test Panel PLA Code

DUBLIN, Ireland, Feb. 07, 2024 — Trinity Biotech Plc. (Nasdaq: TRIB) (the "Company") today announced that its New York based reference laboratory, Immco Diagnostics, has applied for a Proprietary Laboratory Analyses (PLA) code for its Early Sjögrens Syndrome Test Panel, to allow for an optimised market access strategy to deliver broader patient access and improved profitability.

It is estimated that up to approximately 3 million people in the US have Sjögrens Syndrome, making it one of the most prevalent autoimmune syndromes. Individuals with Sjögrens Syndrome suffer most notably from dry eyes and dry mouths, as well as difficulty swallowing, increased dental cavities, joint pain and swelling, among other ailments. There is an acute shortage of evidence-based standardized screening tools for Sjögren's Syndrome, contributing to a prolonged diagnostic journey and an overall trend of underdiagnosis. The provision of effective diagnostic tools can significantly improve clinical outcomes and reduce the cost burden of care in Sjögrens Syndrome disease management for payors and health systems.

The Early Sjögrens Syndrome Test Panel is a valuable immunological tool for clinicians to both identify patients earlier, when therapeutic intervention is most effective, and to also identify patient cohorts most at risk of progression to Sjögren's Syndrome.

A PLA code is a distinct, specific code assigned to a particular test and approved by the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel. PLA codes must be requested by the clinical laboratory or manufacturer that offers the test. The PLA code allows the clinical lab or manufacturer to preferentially differentiate the test in terms of payor pricing and avoid the utilization of multiple generic lower value CPT codes, ultimately incentivising Immco Diagnostic's commercial partners to provide broader patient access to this key diagnostic tool.

Subject to approval, we expect the PLA code for the Early Sjögrens Syndrome Test Panel to become effective in Q3 2024, which should allow Immco Diagnostics to implement a further optimised market access strategy, aimed at delivering better patient access, while affording improved profitability for both Immco Diagnostics and our commercialization partners.

Immco Diagnostic's laboratory provides specialised autoimmune diagnostic solutions to health networks including the largest lab chains in the US.

**About Trinity Biotech Plc**

*Trinity Biotech 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. The 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, Germany, France and the U.K. 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*.

**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 presentation may be affected by risks and uncertainties, including, but not limited to, our ability to capitalize on our purchase of the assets of Waveform, 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, 2022 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.*


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