CARDIO inCode-Score® collaboration with Thermo Fisher Scientific

Commercialisation agreement to sell, distribute and manufacture CARDIO inCode-Score® for the genetic risk prediction and prevention of coronary heart disease

OXFORD, UNITED KINGDOM, December 4, 2025 /EINPresswire.com/ -- GENinCode Plc (AIM: GENI), the Oxford based predictive genetics company focused on the prevention of cardiovascular disease ("CVD") and risk assessment of ovarian cancer, announces today a collaboration with Thermo Fisher Scientific to sell, distribute and manufacture the CARDIO inCode-Score® Polygenic Risk Score ("PRS") test for the prediction and prevention of coronary heart disease ("CHD" or "heart disease").

Collaboration

The GENinCode and Thermo Fisher Scientific collaboration includes manufacturing of CARDIO inCode-Score® and sale and distribution across the US and Europe, Middle East and Africa (EMEA) regions. Prior to US FDA approval, laboratories will be introduced to CARDIO inCode-Score® as a Lab Developed Test (LDT) for the prevention of heart disease. Following FDA Medical Device approval, the collaboration will extend to manufacturing and sale of the device to laboratories and test centres across the US. A similar approach will be adopted in the EMEA market.

With the US and EU cardiovascular devices market estimated at US$22.8 billion and Euro€12.5 billion respectively, and 80% of heart disease and stroke being preventable, the collaboration will provide the CARDIO inCode-Score® test to assess an individual's genetic risk of heart disease. The test process will use GENinCode's proprietary 'SITAB' system for clinical testing, AI bioinformatics and risk reporting.

Thermo Fisher Scientific has been chosen as the preferred partner based on the design and development of the CARDIO inCode-Score® test on the QuantStudio™ 5 Dx Real-Time PCR System. The QuantStudio™ 5 Dx Real-Time PCR System is globally available with significant coverage across the US and EMEA region. Increasing demand for CARDIO inCode-Score® will be met by Thermo Fisher Scientific scale up of the test manufacturing.
The CARDIO inCode-Score® test recently received New York State licensure to complete its US Centers for Medicare and Medicaid Services (CMS) state coverage with the test included in the 2025 Clinical Laboratory Fee Schedule at an average reimbursement of ~$500.00 per test.

GENinCode continues to progress discussions with the FDA and expects to submit additional data requested to complete its De Novo assessment in Q1. 2026.

CARDIO inCode-Score® (PRS)

CARDIO inCode-Score® is a clinically validated, commercially available polygenic risk score (PRS) based on DNA extracted from a simple saliva or blood sample. The extracted DNA is scored to identify an individual's inherited genetic risk of heart disease thereby enabling prevention through lifestyle change and/or therapeutic treatment. The test has been designed and optimized for population-based risk prediction and primary prevention of heart disease and is being made available at affordable pricing to international healthcare systems.

By integrating CARDIO inCode-Score® into existing clinical pathways, healthcare providers can more accurately identify individuals at heightened 'lifetime risk' of heart disease and personalise treatment and prevention strategies. This preventive approach reduces the incidence of severe cardiovascular events, such as heart attacks and strokes, and mitigates the economic costs associated with long-term heart disease care.

It represents a significant step to improving public health outcomes and particularly in addressing the global burden of cardiovascular disease.
CARDIO inCode-Score® has amassed significant clinical evidence across multi-ancestry populations with the tests now being clinically adopted in EU, UK and US. Recent peer-reviewed studies using CARDIO inCode-Score® have demonstrated genetic risk significantly influences the relationship between LDL-cholesterol and heart disease, with the combination of elevated LDL-cholesterol and a high CARDIO inCode-Score® conferring substantially greater lifetime risk.

Matthew Walls, GENinCode Chief Executive Officer said; "We are delighted to announce this milestone collaboration with Thermo Fisher Scientific to scale CARDIO inCode-Score across the US and EMEA markets. The collaboration advances our commercial pathway and will accelerate the adoption of CARDIO inCode-Score well beyond our current capabilities. The collaboration also underpins our US-FDA and EU-IVDR Medical Device 2026 expansion plans."

For more information visit www.genincode.com

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