Caris Life Sciences Launches Caris MI Clarity, the First and Only AI-Powered Test to Predict Both Early and Late Distant Recurrence Risk in Breast Cancer at the Time of Diagnosis

May 5, 2026

Caris MI Clarity leverages AI to transform how recurrence risk is understood and applied in postmenopausal patients with HR-positive/HER2-negative, node-negative early-stage breast cancer

IRVING, Texas, May 5, 2026 /PRNewswire/ -- Caris Life Sciences® (NASDAQ: CAI), a leading patient-centric next-generation AI TechBio company and precision medicine pioneer, today announced the launch of Caris MI Clarity™, the first prognostic test designed to deliver insight into both early and late distant recurrence risk for postmenopausal patients with HR-positive/HER2-negative, node-negative early-stage breast cancer at the time of diagnosis. Results are typically provided to the ordering physician within 3 business days of receiving the tissue sample, compared to a few weeks for historical tests.

The test was developed by leveraging Caris' proprietary multi-modal dataset, which contains tens of thousands of breast cancer samples, to train a series of models to analyze genetic features from digitized hematoxylin and eosin (H&E) slides for key markers of recurrence. These features were then used to train and evaluate a model to assess both early and late recurrence risk. The model was validated through a multi-year public-private research partnership with ECOG-ACRIN Cancer Research Group, utilizing samples and associated data from well-characterized national clinical trials, including ECOG-ACRIN's TAILORx and NSABP B-42 conducted by NRG Oncology. The model's focus on distant recurrence directly addresses the outcomes most closely associated with breast cancer mortality and long-term patient management.

For patients with early-stage breast cancer, accurately assessing the risk of distant recurrence is essential, as distant recurrence is the primary driver of mortality and a key factor in systemic treatment decisions. Distant recurrence risk is not static, but evolves over time, shaped by tumor biology, disease subtype, and treatment. In HR-positive disease, risk can persist for many years. Notably, the biological factors that drive distant recurrence in the first five years differ from those that contribute to recurrence five to fifteen years after diagnosis and a patient's early and late risks often do not align.

"Breast cancer clinicians have long been forced to make some of the most consequential treatment decisions with an incomplete picture of how recurrence risk changes over time," said George W. Sledge, Jr., MD, Chief Medical Officer at Caris. "Caris MI Clarity is designed to bring early and late distant recurrence risk together in a single test at diagnosis, when treatment decisions matter most. By leveraging AI on routine pathology and clinical data, Caris MI Clarity has the potential to fundamentally improve how we personalize care for postmenopausal patients with HR-positive/HER2-negative, node-negative breast cancer."

Current risk assessment tools provide valuable but partial insight, often focusing on only one phase of distant recurrence risk. As a result, clinicians frequently evaluate early and late distant recurrence risk separately, relying on different tools and datasets. This fragmented approach adds complexity to treatment planning and increases the challenge of balancing overtreatment, which can expose patients to unnecessary toxicity, with undertreatment, which may miss opportunities to meaningfully reduce distant recurrence risk, particularly in HR-positive disease, where risk can remain clinically relevant long after initial therapy.

The Caris MI Clarity model analyzes digitized H&E whole-slide pathology images together with clinical inputs using computational pathology and AI-driven machine learning. By identifying subtle histologic and clinical patterns associated with distant recurrence, Caris MI Clarity generates clinically relevant prognostic insight without requiring genomic sequencing. The test leverages standard pathology specimens that are already collected as part of routine care, ensuring accessibility and scalability without additional tissue requirements.

Caris MI Clarity provides distinct risk stratification into Low- or High-risk categories for both early (0–5 years) and late (5–15 years) distant recurrence, enabling clinicians to understand how distant recurrence risk may unfold over time from a single test performed at diagnosis.

The launch of Caris MI Clarity underscores Caris Life Sciences' continued expansion into advanced AI-driven, multimodal risk assessment. By integrating pathology and clinical data, Caris leverages its proprietary multi-modal dataset to advance a more comprehensive approach to understanding cancer biology and patient risk across the continuum of disease.

About Caris Life Sciences

Caris Life Sciences® (Caris) is a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer

actively developing and commercializing innovative solutions to transform healthcare. Through comprehensive molecular profiling (Whole Genome, Whole Exome and Whole Transcriptome Sequencing), advanced AI and machine learning, Caris has created the large-scale, multimodal clinico-genomic database and computing capability needed to analyze and further unravel the molecular complexity of disease. This convergence of next-generation sequencing, AI and machine learning technologies and high-performance computing provides a differentiated platform for developing the latest generation of advanced precision medicine diagnostic solutions for early detection, diagnosis, monitoring, therapy selection and drug development.

Caris was founded with a vision to realize the potential of precision medicine to improve the human condition. Headquartered in Irving, Texas, Caris has offices in Phoenix, New York, Cambridge (MA), Tokyo, Japan and Basel, Switzerland. Caris or its distributor partners provide services in the U.S. and other international markets.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities laws. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding our business, solutions, plans, objectives, goals, industry trends, financial outlook and guidance. In some cases forward-looking statements can be identified by words such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or similar expressions.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in these forward-looking statements are reasonable based on information currently available to us, we cannot guarantee that the future results, discoveries, levels of activity, performance or events and circumstances reflected in forward-looking statements will be achieved or occur. Forward-looking statements involve known and unknown risks and uncertainties, some of which are beyond our control. Risks and uncertainties that could cause our actual results to differ materially from those indicated or implied by the forward-looking statements in this press release include, among other things: developments in the precision medicine industry; our future financial performance, results of operations or other operational results or metrics; development, analytical and clinical validation, timing and performance of future solutions by us and our competitors; commercial market acceptance for our solutions, including acceptance of preventive as well as diagnostic testing paradigms, and our ability to meet resulting demand; the rapidly evolving competitive environment in which we operate; third-party payer reimbursement and coverage decisions related to our solutions; risks related to data management, storage, and processing capabilities and our ability to integrate and deploy artificial intelligence and advanced data analytics technologies; our ability to protect and enhance our intellectual property; regulatory requirements, decisions or approvals (including the timing and conditions thereof) related to our solutions; reliance on third-party suppliers; risks related to data security, patient privacy, and compliance with healthcare data protection regulations as well as potential cybersecurity threats to our data platforms; our compliance with laws and regulations; the outcome of government investigations and litigation; risks related to our indebtedness; and our ability to hire and retain key personnel as well as risks, uncertainties, and other factors described in the section titled "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 3, 2026, and in our other filings we make with the SEC from time to time. We undertake no obligation to update any forward-looking statements to reflect changes in events, circumstances or our beliefs after the date of this press release, except as required by law.

Caris Life Sciences Media:
Corporate Communications
CorpComm@CarisLS.com
214.294.5606

View original content to download multimedia:https://www.prnewswire.com/news-releases/caris-life-sciences-launches-caris-mi-clarity-the-first-and-only-ai-powered-test-to-predict-both-early-and-late-distant-recurrence-risk-in-breast-cancer-at-the-time-of-diagnosis-302762431.html

SOURCE Caris Life Sciences