Caris Life Sciences Receives MolDX Approval for Caris ChromoSeq, Advancing Access to Comprehensive Genomic Profiling for Myeloid Malignancies

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IRVING, Texas, May 4, 2026 /PRNewswire/ -- Caris Life Sciences® (NASDAQ: CAI), a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer, today announced that Caris ChromoSeq™ has received MolDX approval, a key milestone supporting broader clinical access to Caris' comprehensive whole genome tumor profiling assay for myeloid malignancies.

The Molecular Diagnostic Services (MolDX) program, administered by Palmetto GBA on behalf of the Centers for Medicare & Medicaid Services (CMS), evaluates molecular diagnostic tests to determine whether they demonstrate clinical validity and utility to support coverage and reimbursement decisions. MolDX approval reflects a rigorous review of the test performance and medical usefulness, helping ensure that high-value molecular diagnostics are accessible to appropriate patients.

Caris ChromoSeq is the world's first and only ultra-deep whole genome sequencing (WGS) assay for myeloid malignancies. The assay sequences at unprecedented depth, up to eight times deeper than what is typically considered a deep whole genome sequencing run, enabling highly sensitive and comprehensive detection of clinically relevant genomic alterations.

"Securing MolDX approval for Caris ChromoSeq represents an important step in expanding access to highly informative genomic testing for patients with complex myeloid cancers," said Matthew Oberley, MD, PhD, Senior Vice President, Chief Clinical Officer and Pathologist-in-Chief at Caris. "Our goal is to replace fragmented diagnostic workflows with a single, comprehensive assay that delivers clear, actionable insights to clinicians when time and accuracy matter most."

Caris ChromoSeq is designed to support the comprehensive clinical genomic evaluation of acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), myeloproliferative neoplasms (MPN) and other suspected myeloid malignancies. By utilizing ultra-deep whole genome analysis, ChromoSeq enables detection of single-nucleotide variants, insertions and deletions, copy number alterations, structural variants and gene fusions that are critical for diagnosis, risk stratification and clinical decision-making.

Unlike traditional diagnostic workflows that rely on multiple separate assays, Caris ChromoSeq is designed to replace serial testing with one integrated approach, reducing complexity and minimizing delays in care. Results are consolidated into a single, easy-to-interpret clinical report to support timely treatment decisions.

For clinicians, this milestone reinforces confidence in the test's clinical performance and evidentiary foundation. For patients, this approval represents progress toward broader access to comprehensive genomic insights that can inform diagnosis and management of genetically complex myeloid diseases.

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

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