Caris Life Sciences Expands Precision Oncology in Metastatic Prostate Cancer with PTEN IHC Testing

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IRVING, Texas, July 14, 2026 /PRNewswire/ -- Caris Life Sciences® (NASDAQ: CAI), a leading patient-centric next-generation AI TechBio company and precision medicine pioneer, today announced it will offer in-house PTEN immunohistochemistry (IHC) testing following the recent FDA approval of a biomarker-guided therapy and companion diagnostic assay. This testing is designed to help identify patients with PTEN-deficient metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer (previously known as metastatic hormone-sensitive prostate cancer) who are eligible for the newly approved biomarker-guided therapy, representing a significant advancement in precision oncology for this disease.

Prostate cancer remains one of the most prevalent malignancies in men, with more than 300,000 new cases diagnosed annually in the United States. The FDA approval of capivasertib, in combination with abiraterone and prednisone, for adults with PTEN-deficient mAPMN/S prostate cancer marks a critical turning point for this disease, enabling a more personalized approach to treatment. Historically, therapy selection in mAPMN/S prostate cancer has relied primarily on clinical characteristics rather than changes in protein expression.

Caris' PTEN IHC testing expands the company's already extensive menu of IHC assays and will enable oncologists to identify patients whose tumors exhibit PTEN protein loss, a key molecular alteration associated with activation of the PI3K/AKT pathway and potential therapeutic relevance. One in four patients with mAPMN/S prostate cancer have PTEN-deficient tumors, which are associated with faster progression and worse outcomes.

"For patients with metastatic hormone-sensitive prostate cancer, treatment decisions have historically been driven largely by clinical factors rather than biomarker-defined molecular alterations," said George W. Sledge, Jr., MD, EVP and Chief Medical Officer at Caris. "The ability to identify PTEN loss through IHC testing brings a new level of precision to treatment selection, helping ensure that the right patients can be matched with biomarker-driven therapies at a critical point in their disease."

Key Highlights of Caris PTEN IHC Testing:

Expanded IHC Capabilities: Caris continues to build one of the most comprehensive IHC testing portfolios in the industry, supporting critical biomarker identification across tumor types.

Support for Biomarker-Driven Therapy Selection: PTEN IHC testing enables identification of PTEN-deficient tumors, supporting treatment decisions in mAPMN/S prostate cancer where FDA-approved biomarker-targeted therapy is now available.

In-House Testing for Faster Results: By performing testing within Caris' CAP-accredited, CLIA-certified laboratories, results can be delivered efficiently to help inform timely clinical decision-making.

Advancing Personalized Care: Integration of PTEN IHC with Caris' broader multi-platform molecular profiling approach including next-generation sequencing (NGS) provides a more complete understanding of tumor biology to guide therapy selection.

The introduction of PTEN IHC testing reflects a broader evolution in prostate cancer care, as the field transitions toward biomarker-driven treatment strategies that align therapy with the molecular drivers of disease. By enabling identification of patients who are eligible for these therapies, Caris is helping advance more precise, individualized treatment decisions that may improve clinical outcomes.

Caris' comprehensive molecular profiling portfolio includes MI Cancer Seek®, Caris Assure®, Caris MI Clarity™, Caris Chromoseq™ and Caris Detect™. MI Cancer Seek is a tissue-based assay with FDA-approved companion diagnostic indications for molecular profiling of solid tumors, while Caris Assure is a blood-based assay designed to identify tumor-derived alterations through comprehensive sequencing approaches. Caris MI Clarity is 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. Caris Chromoseq is a Whole Genome Sequencing (WGS) assay designed to support the comprehensive clinical genomic evaluation of myeloid malignancies. Caris Detect™, is a groundbreaking multi-cancer early detection blood test designed to accurately find cancer signals early, at stage I and stage II, when treatment is more effective.

Caris remains committed to advancing precision medicine through innovative diagnostics, robust molecular data and clinically actionable insights that help transform cancer care.

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 Private Securities Litigation Reform Act of 1995 and other 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," "potential," "contemplate," "believe," "estimate," "predict," 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: 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, including our application for New York State Department of Health approval for Caris Assure; 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 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.

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