Caris Life Sciences Publishes Study Showing Whole Exome Measurement of Tumor Mutational Burden Results in Increased Overall Survival Compared to Estimates from Targeted Gene Panels

May 11, 2026

Targeted gene panels miscalculate tumor mutational burden in 10–15% of patients, directly resulting in incorrect pembrolizumab eligibility determination

IRVING, Texas, May 11, 2026 /PRNewswire/ -- Caris Life Sciences® (NASDAQ: CAI), a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer, has published a study in *Cancer Immunology, Immunotherapy* demonstrating that measuring tumor mutational burden (TMB) using ultra-deep Whole Exome Sequencing (WES) provides superior prediction of pembrolizumab immunotherapy benefit compared to estimates of TMB from targeted gene panels. TMB is a pan-tumor biomarker used to determine patients' eligibility for pembrolizumab. These findings highlight the importance of testing all cancer patients with ultra-deep WES, the only truly comprehensive genomic profile for therapy selection.

The study used Caris' large-scale, real-world clinico-genomic database, containing 26,756 patients treated with pembrolizumab who were evaluable for this study. WES provides a true measurement of TMB by interrogating every protein-coding gene mutation that may create a neoantigen, in comparison to targeted panels that only estimate TMB with incomplete gene coverage.

Key findings include:

- The analysis compared WES-measured TMB with commercially available targeted panel estimates of TMB and found discordance in 10-15% of cases, with error rates correlating to panel size.
- In discordant cases, WES TMB more accurately predicted overall survival in pembrolizumab-treated patients than panel-based estimates.
- In a subset of 'TMB reliant' patients (n = 3,981), for example, patients with tumor types that lack disease-specific immune checkpoint inhibitor indications, the median overall survival in discordant cases was about five months longer for WES TMB-High and panel TMB-Low compared to WES TMB-Low and panel TMB-High cases treated with pembrolizumab.

"These findings underscore the critical importance of using Whole Exome Sequencing to guide immunotherapy decisions," said Milan Radovich, PhD, Senior Vice President, Chief Scientific Officer at Caris. "Whole Exome Sequencing is the gold-standard for determination of tumor mutational burden, ensuring that patients who stand to benefit from pembrolizumab are correctly identified and that those unlikely to respond are not exposed to unnecessary treatment."

The study concludes that WES-based TMB measurements are a superior predictor of pembrolizumab benefit than panel-based TMB estimates and more reliably identify both patients who may benefit from therapy and those unlikely to respond, particularly in tumor types where TMB is the primary biomarker guiding access to immune checkpoint inhibitors.

Caris received FDA approval in November 2024 for MI Cancer Seek. This tissue-based assay is the first and only simultaneous WES and Whole Transcriptome Sequencing (WTS)-based assay with FDA-approved companion diagnostic (CDx) indications for molecular profiling of solid tumors and includes quantitative reporting of TMB.

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-publishes-study-showing-whole-exome-measurement-of-tumor-mutational-burden-results-in-increased-overall-survival-compared-to-estimates-from-targeted-gene-panels-302768392.html

SOURCE Caris Life Sciences