

For Immediate Release



Caris Life Sciences Publishes Study Featuring the Largest Real-World Cohort of Tissue-Agnostic Indications Revealing Over 20 Percent of Patients Are Eligible for “Pan-Cancer” Therapies

A 295,000+ patient study revealed variable efficacy among cancers for patients treated with tissue-agnostic drugs and uncovered the potential for expanding approvals to other drugs of the same class

IRVING, Texas, March 20, 2025 – [Caris Life Sciences](#)® (Caris), a leading next-generation AI TechBio company and precision medicine pioneer, today announced the publication of “[Real-world evidence provides clinical insights into tissue-agnostic therapeutic approvals](#)” in *Nature Communications*. Utilizing the largest real-world clinical and genomic dataset of tissue-agnostic indications reported to date across more than 295,000 patients, the study provides a comprehensive evaluation of real-world outcomes for patients eligible for these powerful “pan-cancer” therapies, such as pembrolizumab and larotrectinib. These drugs are categorized as tumor-agnostic therapies, targeting specific genetic or molecular features of tumors rather than their anatomical location or histology.

The study focused on the use and clinical benefits of tissue-agnostic therapies, which target specific molecular biomarkers across numerous cancer types. Key findings include:

- More than 20 percent of patients are candidates for a tissue-agnostic drug.
- Approximately five percent of patients who lacked any tumor-specific indication were found to carry a tissue-agnostic indication and became eligible for tissue-agnostic drug treatment.
- Tissue-agnostic therapy uptake was poor for rare indications, illustrating the need for enhanced clinical education.
- Current tissue-agnostic indications could potentially be expanded, as evidenced by clinical benefits in tumor types and drugs of the same class that were not investigated in the original clinical trials.

“By harnessing the power of Caris’ large clinico-genomic dataset, we have shown that tissue-agnostic drugs produce different outcomes in different tissues,” said [George W. Sledge, Jr., MD](#), EVP and Chief Medical Officer of Caris and study author. “We additionally found evidence of clinical benefit beyond approved indications, illustrating the enormous potential of real-world data to inform the clinical use of tissue-agnostic drug approvals, potentially improving patient outcomes.”

“Caris has generated one of the most extensive clinico-genomic datasets in oncology through years of comprehensive molecular profiling,” said Caris President and study author [David Spetzler, MS, PhD, MBA](#). “Our advanced analyses of real-world data now enable us to uncover findings of clinical value for large patient populations. One in five patients in our study were eligible for a tissue-agnostic drug, which demonstrates the widespread impact of our findings.”

Detailed Scientific Information

This study used a real-world database of 295,316 molecularly profiled tumor samples with associated clinical outcomes data across 57 tumor types to investigate the utility and uptake of six tissue-agnostic therapies (pembrolizumab, larotrectinib, entrectinib, dostarlimab, dabrafenib and selpercatinib). At least one current FDA-approved tissue-agnostic indication (TMB-High, MSI-High/dMMR, *BRAF*^{V600E} mutations, and *NTRK* and *RET* fusions) was detected in 21.5% of patients, including 5.4% lacking any tumor-specific indication. In patients with rare *NTRK* fusions, there was poor clinical uptake of the clinically successful targeted therapies larotrectinib and entrectinib, underlining the need for oncologist education on rare indications.

Strikingly, significant differences in pembrolizumab-associated outcomes were observed across tumor types for the most common indications (TMB-High and MSI-High/dMMR), demonstrating that the effects of these therapies are not tissue-agnostic. Clinical benefits were also observed in tumor types and drugs of the same class (such as nivolumab) that were not investigated in pivotal clinical trials. This suggests the possible expansion of therapeutic avenues for a given tissue-agnostic indication.

These findings demonstrate the power of Caris' extensive real-world dataset for generating valuable clinical insights to inform the clinical implementations of tissue-agnostic drug approvals and improve outcomes for patients with cancer.

Designed to capture and analyze molecular information from tissue and blood in a comprehensive manner, the proprietary Caris Platform is a powerful set of precision medicine solutions, providing Whole Exome Sequencing (WES) and Whole Transcriptome Sequencing (WTS) as standard practice. Caris sequences at sector-leading depth of coverage, which directly correlates to increased accuracy and detection of low-frequency biomarkers of relevance. Caris also evaluates protein biomarkers through an extensive menu of immunohistochemical (IHC) tests analyzed in a tumor-type specific manner, which in combination with WES and WTS, provides a comprehensive view of a patient's disease across DNA, RNA and proteins. The Caris approach reveals an individualized molecular blueprint of a patient's disease, providing actionable, personalized treatment pathways and driving superior clinical outcomes for patients.

About Caris Life Sciences

Caris Life Sciences® (Caris) is a leading next-generation AI TechBio company and precision medicine pioneer that is actively developing and delivering innovative solutions to revolutionize healthcare and improve the human condition. Through comprehensive molecular profiling (Whole Exome and Whole Transcriptome Sequencing) and the application of advanced AI and machine learning algorithms, Caris has created the large-scale, multimodal database and computing capability needed to analyze and further unravel the molecular complexity of disease. This convergence of sequencing power, big data and AI technologies provides a differentiated platform to deliver the next generation of precision medicine tools for early detection, diagnosis, monitoring, therapy selection and drug development.

Caris was founded with a vision to realize the potential of precision medicine in order 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. To learn more, please visit [CarisLifeSciences.com](https://www.CarisLifeSciences.com).