PRESS RELEASE

Study Shows Spatial Biology Is Essential for Predicting Response to Immuno-Oncology Treatment

In JAMA Oncology *report, multiplex immunofluorescence technology preserves critical data missed by other biomarker strategies*

MENLO PARK, CA — July 18, 2019 — Akoya Biosciences, Inc., The Spatial Biology Company™, announced today that an in-depth comparison of immuno-oncology biomarker types conducted by scientists at Johns Hopkins University, Yale University, and other institutions determined that multiplex immunofluorescence with spatial characterization significantly outperformed other biomarker testing approaches — such as gene expression profiling, tumor mutational burden assessment, and immunohistochemistry — for predicting patient response to treatments targeting PD-1/PD-L1. The study was published today in *JAMA Oncology*.

Multiplex immunofluorescence, a new type of biomarker assay, allows investigators to simultaneously analyze the expression of many proteins in individual cells within the tumor microenvironment, preserving critical information about which cells are active and how they are spatially distributed relative to each other. This type of analysis is made possible with the end-to-end solutions offered by Akoya: the CODEX® System, an ultra-high multiplexing platform for biomarker discovery, and Phenoptics™, a high-throughput multiplexing platform for translational and clinical research.

Immunotherapies targeting PD-1 or PD-L1 have proven remarkably effective for treating cancer in some patients, but there remains a paucity of accurate biomarkers that can differentiate responders from non-responders. Identifying the patients most likely to respond to these therapies is an important step in ensuring optimal outcomes for all patients. To date, several assays have been developed with the potential to predict response based on genetic signatures, gene expression, and immunohistochemistry. Although these assays are helpful in limited situations, there is a need for options that are better at predicting response across a larger percentage of cases.

The study, conducted in collaboration with leading scientists at Johns Hopkins University, Yale University, Vanderbilt University, and Northwestern University, reviewed published data from more than 50 studies covering more than 10 types of cancer and over 8,000 patients. Statistical analyses were performed to assess the performance and predictive value of each type of biomarker. While tumor mutational burden, gene expression profiling, and immunohistochemistry had comparable performance to each other for differentiating between responders and non-responders, multiplex immunofluorescence had considerably better performance metrics. Specifically, it had fewer false positives, meaning it was less likely to predict positive response in a patient who would not ultimately respond to therapy.

"This meta-analysis of previous studies clearly demonstrates the potential for using multiplex immunofluorescence to generate more comprehensive and reliable data to better predict response to anti-PD-1/PD-L1 treatments," said Cliff Hoyt, Vice President of Translational and Scientific Affairs at Akoya and a co-author of the paper. "This contributes to growing evidence that spatial resolution of tumor biomarkers is essential for an accurate view of cancer biology, and the Akoya team is excited to help researchers continue down this promising avenue of investigation."

By performing an sROC curve evaluation, the authors of the *JAMA Oncology* publication cited multiplex immunofluorescence and multiplex immunohistochemistry (AUC of 0.79) as having significantly higher diagnostic predictive accuracy when compared to PD-L1 immunohistochemistry (AUC of 0.65, P<.001). Additionally, it outperformed both gene expression profiling (AUC of 0.65, P=.003) and tumor mutation burden (AUC of 0.69, P=.049).

"Immunotherapies represent the latest advance in cancer treatment, and this important study shows that the multiplex immunofluorescence technology underlying our systems can serve to more accurately stratify patients for optimal outcomes," said Brian McKelligon, Chief Executive Officer of Akoya. "Of the approaches available for spatially resolving biomarkers, the Phenoptics platform is uniquely suited to fulfill the most critical needs in translational research and clinical applications. Our end-to-end solutions put researchers in the best position to drive precision immuno-oncology forward in the coming years."

Paper reference: Steve Lu *et al*. Comparison of Biomarker Modalities for Predicting Response to PD-1/PD-L1 Checkpoint Blockade. *JAMA Oncology*. doi: 10.1001/jamaoncol.2019.1549

To learn more about the results of this seminal study, please attend the upcoming webinar presentation on August 21 from first author Dr. Steve Lu, hosted by Akoya Biosciences.

About Akoya Biosciences

Akoya Biosciences, The Spatial Biology Company™, offers the most comprehensive, end-to-end solutions for high-parameter tissue analysis from discovery through clinical and translational research, enabling the development of more precise therapies for immuno-oncology and other drug development applications. The company has two industry-leading platforms that empower investigators and researchers to gain a deeper understanding of complex diseases such as cancer, and other immune system or neurological disorders. The CODEX® system is the only benchtop platform that can efficiently quantify more than 40 biomarkers and is ideally suited for biomarker discovery. The Phenoptics™ platform is the only end-to-end multiplexed immunofluorescence solution with the robustness and high throughput necessary for translational research and clinical trials. For more information, please visit https://www.akoyabio.com/.

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