Akoya Announces Publication of New Immunotherapy Biomarker Signature in Science, Leveraging Principles of Astronomy and Pathology

June 10, 2021

Investigators at Johns Hopkins University (JHU) used AstroPath to identify and validate biomarkers for accurate prediction of long-term response to immune checkpoint inhibitors in advanced melanoma

AstroPath combines JHU's famed 3D sky mapping algorithms for managing astronomical-scale datasets with Akoya's cutting-edge Phenoptics ™spatial biology platform

MARLBOROUGH, Mass., June 10, 2021 (GLOBE NEWSWIRE) -- Akoya Biosciences Inc., (NASDAQ: AKYA), The Spatial Biology Company®, announced today that its Phenoptics solution contributed to the successful development of a novel platform, titled AstroPath, enabling researchers at Johns Hopkins University (JHU) to discover and validate a first-of-its-kind biomarker signature to predict immunotherapy response in advanced melanoma cases. The groundbreaking work, which is part of the ongoing collaboration between Akoya and JHU, and could have potential applications in other tumor types, was published June 11 in *Science*.

Immunotherapies utilize the immune system to combat cancer and are revolutionizing the treatment landscape, but they are effective only in a subset of patients. Biomarkers have the potential to identify those individuals who are most likely to benefit from treatment and improve the effectiveness of immunotherapy; however, there is a paucity of accurate biomarkers that can effectively predict long-term outcomes. In melanoma, this gap is particularly acute because there are no FDA-approved predictive tests for determining whether anti-PD-1 checkpoint inhibitors, a type of cancer immunotherapy, will be effective in a patient or not. A multi-institutional study of immuno-oncology biomarker modalities, published in *JAMA Oncology* in 2019, demonstrated that spatial biomarkers outperformed other biomarker testing approaches— such as gene expression profiling, tumor mutational burden (TMB) assessment, and PD-L1 immunohistochemistry (IHC) — for predicting response to immunotherapy treatment.

Researchers at The Mark Foundation Center for Advanced Genomics and Imaging at JHU and The Bloomberg-Kimmel Institute for Cancer Immunotherapy combined the Phenoptics multiplex immunofluorescence (mIF) platform with sky-mapping algorithms derived from astronomy to create AstroPath for deep whole slide imaging and spatially mapping microscopic sections of tumors. The lead investigators Dr. Janis Taube, a pathology expert, and Dr. Alexander Szalay, an astrophysicist and data science expert, are, respectively, Director of the Division of Dermopathology, and the Bloomberg Distinguished Professor in the Department of Computer Science at JHU. "Akoya's Phenoptics solution, one of the underlying technologies of AstroPath, enables researchers to study how tumor and immune cells are spatially organized in a tissue sample and gives deep insights on how they interact to influence cancer progression and treatment response," said Sneha Berry, PhD, a co-author of the paper, who is now a lead clinical research scientist at Akoya.

Study results

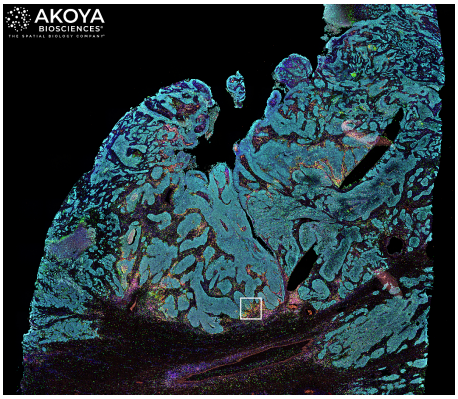
Through this study, the researchers identified a composite spatial phenotypic signature that is highly predictive of response to anti-PD-1 agents and of long-term outcomes for metastatic melanoma, and potentially other cancers. The researchers leveraged Akoya's Opal™ chemistry and the Vectra® mIF system (collectively part of the Phenoptics solution) to image six protein markers, PD-1, PD-L1, CD8, CD163, FOXP3, and SOX10, across the tumor microenvironment and spatially map different cell phenotypes. The team took a combinatorial approach to identify key determinants of therapy response, including specific cell phenotypes such as CD8+FoxP3+PD-1$^{(low/mid\ expression)}$ T-cells, which are correlated to positive response, and CD163+PD-L1^{negative} myeloid phenotype, which is associated with non-response. The combination of these features resulted in a highly predictive composite biomarker with an area under the curve (AUC)* of 0.91, the authors concluded. AUC reflects the biomarker assay's potential to be a future diagnostic tool. A perfect predictive test would have an AUC of 1.0 and the closer the AUC value is to 1.0, the higher the predictive accuracy. The team also validated the results in an independent cohort of samples, from another institution, resulting in an AUC value of 0.88. The biomarker signature also demonstrated the ability to predict overall survival in both the training and independent cohorts.

In the *Science* paper, the authors also laid out an integrated, multi-step process for biomarker

Astronomy Meets Pathology for Immunotherapy Research

The Johns Hopkins AstroPath™ team used Akoya's Phenoptics technology to image tumor tissue samples and analyzed spatial interactions between tumor and immune cells using astronomy algorithms.

Lung Cancer Whole Tissue Phenoptics Image



Akoya's Phenoptics™ platform captures high resolution images of whole tumor sections from patients, enabling researchers to study the spatial biology of the sample – i.e., how tumor and immune cells interact within the tumor microenvironment and influence response to immunotherapy. Different colors represent different cell types and biomarkers. The white box represents a zoomed in area for deeper microscopic analysis.

Lung Cancer Zoomed In Phenoptics Image

development from discovery to translation, which they hope can be the framework for standardizing the application of mIF and image handling across institutions, thus enabling clinical implementation in the future. The depth of validation in the study, for example, verifying the results in an independent cohort of samples, serves as a template for cancer researchers to discover novel spatial biomarkers with high predictive potential.

Solving the big data challenge with AstroPath

The analysis engine for AstroPath is the Sloan Digital Sky Survey, a 3D digital map of the universe built by Dr. Szalay. The survey's telescope shares some similarities with the Phenoptics platform because they both capture multicolor images of objects; in the case of the former it is celestial objects and in the case of the latter it is different cell types in a tumor sample. In the field of astronomy, the survey database can be rapidly queried at a massive scale to spatially map and analyze stars and galaxies across the universe. Each tumor sample imaged with the Phenoptics platform generates a map of millions of cells with billions of different data points, posing a data analysis challenge. This challenge is compounded for translational studies that require researchers to study large cohorts of samples to discover new biomarkers. Dr. Taube and Dr. Szalay joined forces to solve this challenge by applying celestial object mapping algorithms to the study of the tumor microenvironment, enabling rapid probabilistic studies of how tumor and immune cells organize and interact to influence treatment response.

"We're honored to have supported the JHU team in such a seminal study," said Akoya Biosciences CEO Brian McKelligon. "We believe the unique approach to spatial biomarker discovery, applied through AstroPath, will have a tremendous impact on the scientific community and takes us one step closer to realizing a future with precision immunotherapy."

About Akoya Biosciences

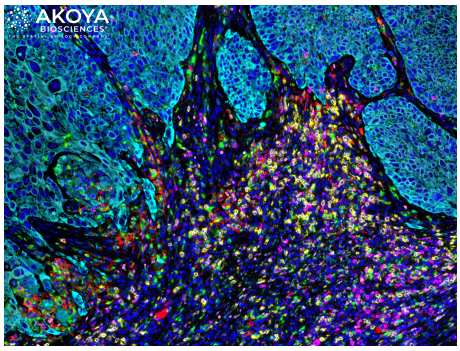
As The Spatial Biology Company®, Akoya Biosciences' mission is to bring context to the world of biology and human health through the power of spatial phenotyping. The company offers comprehensive single-cell imaging solutions that allow researchers to phenotype cells with spatial context and visualize how they organize and interact to influence disease progression and treatment response. Akoya offers two distinct solutions, the CODEX® and Phenoptics™ platforms, to serve the diverse needs of researchers across discovery, translational and clinical research. For more information, please visit https://www.akoyabio.com/.

Cautionary Note Regarding Forward Looking Statements

This press release contains "forward-looking statements" under applicable securities laws. In some cases, such statements can be identified by words such as: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements include express or implied statements regarding our ability to achieve our business strategies, growth, or other future events or conditions. Such statements are based on our current beliefs, expectations, and assumptions about future events or conditions, which are subject to inherent risks and uncertainties, including the risks and uncertainties discussed in the filings we make from time to time with the Securities and Exchange Commission. Actual results may differ materially from those indicated in forward-looking statements, and you should not place undue reliance on them. All statements herein are based only on information currently available to us and speak only as of the date hereof. Except as required by law, we undertake no obligation to update any such statement.

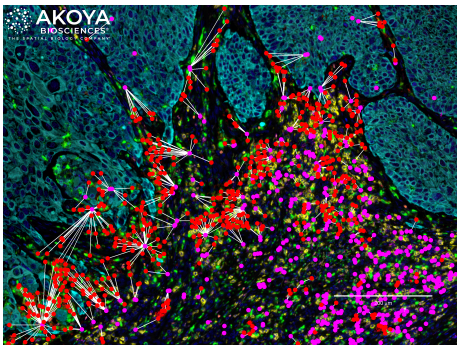
Investor Contact:
David Deuchler
Gilmartin Group LLC
investors@akoyabio.com

Media contact:
Michelle Linn
Bioscribe Inc
774-696-3803
michelle@bioscribe.com



The zoomed in area from image 1 allows a deeper analysis of specified 'hotspots'. Different colors represent different cell types and biomarkers e.g., PD-1, PD-L1 (checkpoint targets in pink and red respectively), cytotoxic T cells (a type of immune cell, in yellow), regulatory T cells (in orange), macrophages (another type of immune cell, in green), and tumor cells (in cyan). The cellular composition and distribution reveals immune engagement with the tumor, evidenced by the immune cells (in yellow, green

Lung Cancer Phenoptics Spatial Analysis Image



Scientists then use Akoya's Spatial Analysis software for visualizing and making proximity measurements for different cell types. Shown here are PD-1+ cells (magenta) within 25µm of tumor-associated macrophages (TAMs, in red). The presence of TAMs are associated with inflammation, immunosuppression, and drug resistance. Furthermore, in certain cancers the level of TAM infiltration can serve as a prognostic indicator of overall survival.

References:

Berry S, et al. Analysis of multispectral imaging with the AstroPath platform informs efficacy of PD-1 blockade. Science 2021

Luke JJ, Ascierto PA. Biology confirmed but biomarkers elusive in melanoma immunotherapy. Nat Rev Clin Oncol. 2020

Lu S, Stein JE, Rimm DL, et al. Comparison of Biomarker Modalities for Predicting Response to PD-1/PD-L1 Checkpoint Blockade: A Systematic Review and Meta-analysis. JAMA Oncol. 2019

Photos accompanying this announcement are available at

https://www.globenewswire.com/NewsRoom/AttachmentNg/b1cd7de8-9ca6-4ce2-8627-5595ede98f5a

https://www.globenewswire.com/NewsRoom/AttachmentNg/49379c39-d73e-4b81-9125-2caf281aa0d9

https://www.globenewswire.com/NewsRoom/AttachmentNg/6f3d5921-bccd-466b-a15d-1ab7cb49b7c0

https://www.globenewswire.com/NewsRoom/AttachmentNg/b0b257b2-66a8-4a99-b512-9b7acdce995f