



Akoya Biosciences Secures CLIA Lab Certification, a Milestone for Applying Its Spatial Biology Technologies to Accelerating Precision Cancer Therapies

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Certification ensures Akoya's cutting-edge spatial biology tools meet the highest standards for translational medicine and clinical research, with longer term potential for companion diagnostics.

MARLBOROUGH, Mass., Nov. 30, 2021 (GLOBE NEWSWIRE) -- Akoya Biosciences, Inc. (Nasdaq: AKYA), The Spatial Biology Company[®], today announced that its Advanced Biopharma Solutions (ABS) laboratory, located in Marlborough, Massachusetts, has received its Certificate of Registration from the Clinical Laboratory Improvement Amendments (CLIA) program, following the receipt of a Massachusetts Department of Public Health clinical laboratory license. This certification enables Akoya's ABS lab to support later stage clinical trial studies with its biopharmaceutical partners.

CLIA certification affirms that Akoya's ABS lab processes and services operate under high quality standards and provides a framework for assay development and validation that consistently meets guidelines for accuracy, precision, specificity, sensitivity, and reproducibility. This milestone is an important step towards advancing the company's platforms toward clinical use. It further positions Akoya Biosciences as an attractive partner for biopharmaceutical companies seeking to incorporate its ground-breaking spatial biology technologies into their clinical research, most notably in the expanding field of cancer immunotherapy.

"Securing CLIA certification for ABS demonstrates our commitment to meeting the highest quality standards," said Brian McKelligon, Chief Executive Officer of Akoya Biosciences. "This is an important step in support of our effort to work with our biopharmaceutical partners to identify biomarkers that lead to better clinical decision making and improved patient outcomes."

Spatial biology, a rapidly emerging field of science, allows researchers to discover and validate biomarker signatures that map the interactions of tumor and immune cells across an entire tumor tissue section by retaining the spatial context. Published studies have demonstrated that spatial phenotypic signatures, based on Akoya's platform, are more accurate at predicting response to immunotherapy than biomarkers currently being used in the clinic.

The certification will enable Akoya to expand its collaborations with [key partners like AstraZeneca](#) and other biopharmaceutical companies working with Akoya's ABS Program. The goal of this program is to enable biopharma partners to leverage Akoya's deep spatial biology expertise and technological innovations from the early stages of clinical trials, potentially, through full companion diagnostic approval.

The CLIA certification is the latest milestone in Akoya's ongoing efforts to ensure consistency and standardization of its laboratory processes and results. Important prior milestones include a recent publication in the *Journal of Immunotherapy for Cancer* on the [MITRE Study](#), demonstrating for the first time a spatial biology workflow with the throughput, accuracy and reproducibility required to serve the translational and clinical markets.

For more information about Akoya's Advanced Biopharma Solutions offerings, please visit: akoyabio.com/advanced-biopharma-solutions.

About Akoya Biosciences

As The Spatial Biology Company[®], Akoya Biosciences' (Nasdaq: AKYA) 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. To learn more about Akoya, visit 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.

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