



Akoya Biosciences and Shanghai KR Pharmtech Announce Chinese Regulatory Agency Premarket Approval for KR-HT5 in China to Support Next Generation Pathology Clinical Workflows

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KR-HT5 is based on Akoya's Phenolmager® HT Platform

MARLBOROUGH, Mass. and SHANGHAI, China, May 02, 2024 (GLOBE NEWSWIRE) -- Akoya Biosciences, Inc. (Nasdaq: AKYA), The Spatial Biology Company®, and Shanghai KR Pharmtech, a leading company providing molecular diagnostic solutions in China, have jointly announced that KR-HT5, which Akoya Biosciences co-developed with Shanghai KR Pharmtech utilizing the Phenolmager HT technology as its foundation, has received premarket approval from China's National Medical Products Administration (NMPA) to support next generation pathology clinical workflows.

The NMPA serves as the national regulatory body in China, overseeing the safety, quality, and efficacy of medical products, encompassing pharmaceuticals and medical devices. Obtaining NMPA approval indicates that the regulatory authority has examined and sanctioned the product for sale or utilization in the Chinese clinical market.

The KR-HT5 is a product jointly developed by Akoya Biosciences and Shanghai KR Pharmtech for Chinese clinical needs. Built on the Phenolmager HT core technologies, specifically Akoya's Multispectral Imaging (MSI) and spectral unmixing technologies, KR-HT5 will provide clinicians with a high-throughput platform to enable analysis for multiplex biomarker workflows. Shanghai KR Pharmtech will offer the KR-HT5 as part of its [Next Generation Pathology \(NGP\) solutions](#).

"We are honored and excited to collaborate with Shanghai KR Pharmtech to develop KR-HT5 with our Phenolmager HT core technology and launch the Next Generation Pathology initiative," expressed Brian McKelligon, CEO of Akoya Biosciences.

"We are very pleased to see that KR-HT5 has received NMPA premarket approval, and we will leverage Akoya's research capabilities and experience in spatial omics, combined with our understanding and work in the Chinese domestic market, to promote the clinical utilization of Next Generation Pathology solutions," said Lingbin Bu, CEO of Shanghai KR Pharmtech.

Forward-Looking Statements

This press release contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements concerning our expectations about the potential, utility and safety of our products and services, our ability to market, sell and achieve market acceptance of our current and planned products and services and other matters regarding our business strategies, future performance, collaborations and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "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. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the Securities and Exchange Commission from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

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 response to therapy. Akoya offers a full continuum of spatial phenotyping solutions to serve the diverse needs of researchers across discovery, translational and clinical research: PhenoCode™ Panels and PhenoCycler®, Phenolmager® Fusion and Phenolmager HT Instruments. To learn more about Akoya, visit www.akoyabio.com.

About Shanghai KR Pharmtech

Shanghai KR Pharmtech is a company based in Shanghai, China that specializes in translational research and applications in precision medicine, aiming to provide comprehensive molecular diagnostic solutions for various applications. It provides services to over 500 hospitals and research institutions in China through CAP-accredited medical laboratory, three high-tech enterprises, two research and development centers in Shanghai and Xuzhou, a precision Medicine Technology Research institution, an IVD production factory, and a thirty-thousand square meters Smart Medical Industry Park. Shanghai KR Pharmtech has pioneered the clinical services of NGP (Next Generation Pathology) and NGS (Next Generation Sequencing) within China.

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