Spectral AI Completes Data Analysis for U.S. Burn Pivotal Study

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DALLAS, Feb. 07, 2025 (GLOBE NEWSWIRE) -- **Spectral AI (NASDAQ: MDAI) ("Spectral AI" or the "Company")**, developer of the AI-driven DeepView® System, which received Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") in 2018 and uses multi-spectral imaging and AI algorithms to predict burn healing potential, today announced the completion of its data analytics for its U.S. Burn Pivotal Study. One of the largest domestic burn studies ever conducted, the U.S. Burn Pivotal Study is designed to validate the AI-driven algorithm used by the Company's DeepView ® System for its burn indication. Spectral AI's DeepView® System is a predictive medical device and associated software that assesses the healing potential of burn wounds by combining multispectral imaging with an AI-driven algorithm trained and tested against a proprietary database of more than 340 billion clinically-validated data points. By distinguishing between healing and non-healing tissue, the DeepView® System provides an immediate and binary prediction of wound healing on the same day of injury, benefiting clinical decision-making regarding next step treatment.

The Company announced today that it has completed its data analytics and the results reflect strong metrics of the DeepView® System when compared to burn and emergency room physicians in determining the wound healing potential of burns. The Company also notes the following:

- The Company will pursue a De Novo classification request from the FDA for use of the DeepView® System in burn care and expects to submit its De Novo request by June 2025.
- It has worked with the FDA through numerous pre-submission meetings for guidance and the advancement of its DeepView AI®- Burn technology.

"After completing the image analysis and truthing of our U.S. Burn Pivotal Study, I am highly encouraged by the sensitivity and specificity results of our DeepView® System when compared to the wound healing potential as determined by treating physicians," stated Dr. J. Michael DiMaio, MD, Chairman of the Board at Spectral AI. "These results underscore the transformative impact of the DeepView ® System and its attendant use of artificial intelligence in burn wound care, offering clinicians an immediate, data-driven assessment tool that can improve treatment decisions and patient outcomes. The dedication of our team in reaching this critical FDA submission milestone cannot be overstated, and we remain committed to bringing this breakthrough technology to burn care institutions across the U.S."

About Spectral AI

Spectral AI, Inc. is a Dallas-based predictive AI company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, with initial applications involving patients with burns and diabetic foot ulcers. The Company is working to revolutionize the management of wound care by "Seeing the Unknown®" with its DeepView ® System. The DeepView® System is a predictive device that offers clinicians an objective and immediate assessment of a burn wound's healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal of exceeding the current standard of care in the future, the DeepView® System is expected to provide faster and more accurate treatment insight towards value care by improving patient outcomes and reducing healthcare costs. For more information about the DeepView® System, visit www.spectral-ai.com.

Forward-Looking Statements

Certain statements made in this release are "forward looking statements" within the meaning of the "safe harbor" provisions of the United States Private Securities Litigation Reform Act of 1995, including statements regarding the Company's strategy, plans, objectives, initiatives and financial outlook. When used in this press release, the words "estimates," "projected," "expects," "anticipates," "forecasts," "plans," "intends," "believes," "seeks," "may," "will," "should," "future," "propose" and variations of these words or similar expressions (or the negative versions of such words or expressions) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance, conditions or results, and involve a number of known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside Company's control, that could cause actual results or outcomes to differ materially from those discussed in the forward-looking statements. As such, readers are cautioned not to place undue reliance on any forward-looking statements.

Investors should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" sections of the Company's filings with the SEC, including the Registration Statement and the other documents filed by the Company. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

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