Spectral AI Completes Pediatric Enrollment in Emergency Departments for U.S. Burn Pivotal Study

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DALLAS, Jan. 28, 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. FDA in 2018, that uses multi-spectral imaging and algorithms to predict burn healing potential, today announced the completion of its pediatric enrollment at U.S. emergency departments 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 burn indication.

Using data from these burn center patients, the Company will pursue a De Novo classification from the U.S. Food and Drug Administration ("FDA") for use of the DeepView™ System and expects to submit the request in the first half of 2025.

Spectral AI's DeepView™ System for burn indication is a predictive medical device that assesses the healing potential of burns 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 at examination that can support clinical decision-making regarding next step treatment plans.

"I am proud of the continuing work by our investigators, their dedicated staff and most critically study enrollees," stated Dr. J. Michael DiMaio, MD, Chairman of the Board at Spectral AI. "The results of this U.S. Burn Pivotal Study will be used by our data science team and our panel of burn experts to complete years of work and bring this crucial advancement in burn wound assessment to patients and providers in 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. DeepView is a predictive device that offers clinicians an objective and immediate assessment of a 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, DeepView 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 DeepView, 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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